# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

	FORM 10-Q	
(Mark One)		
☑ QUARTERLY REPORT PURSUANT TO OF 1934	O SECTION 13 OR 15(	d) OF THE SECURITIES EXCHANGE ACT
For the	quarterly period ended Ju OR	ne 30, 2020
☐ TRANSITION REPORT PURSUANT TO OF 1934	_	d) OF THE SECURITIES EXCHANGE ACT
For the transition pe	riod from	to
Сол	mmission File Number: 00	1-38869
	KIPA PHARN ne of Registrant as Specifie	
Delaware (State or other jurisdiction of incorporation or organization)		81-5395687 (I.R.S. Employer Identification No.)
350 Fifth Avenue, 72nd Floor, Suite 7. New York, New York (Address of principal executive office		10118 (Zip Code)
	one number, including are gistered pursuant to Section	
Securities registered pursuant to Section 12(b) of	the Act:	
Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	HOOK	The Nasdaq Global Select Market
Indicate by check mark whether the registrant (1) has Exchange Act of 1934 during the preceding 12 mont and (2) has been subject to such filing requirements:	ths (or for such shorter perio	d that the registrant was required to file such reports),
•	apter) during the preceding 1	Interactive Data File required to be submitted pursuant 2 months (or for such shorter period that the registrant
Indicate by check mark whether the registrant is a late company, or an emerging growth company. See the company," and "emerging growth company" in Rule	definitions of "large accelera	
Large accelerated filer □  Non-accelerated filer ⊠  Emerging growth Company ⊠		Accelerated filer ☐ Small reporting company ☐
If an emerging growth company, indicate by check is complying with any new or revised financial accoun	ū	-
Indicate by check mark whether the registrant is a sl	hell company (as defined in	Rule 12b-2 of the Act). Yes $\square$ No $\boxtimes$
As of August 13, 2020, the registrant had 2 outstanding, each \$0.0001 par value per share.	21,834,692 shares of commo	on stock and 3,819,732 shares of Class A common stock

#### 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;
- potential impacts due to the coronavirus pandemic such as delays, interruptions or other adverse effects on clinical
  trials, delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare
  systems and disruption of the global economy, and the overall impact of the coronavirus pandemic on our
  business, financial condition and results of operations;
- our manufacturing, commercialization and marketing capabilities and strategy;
- the potential benefits of and our ability to maintain our collaboration with Gilead Sciences, Inc., and establish or maintain future collaborations or strategic relationships or obtain additional funding;
- the rate and degree of market acceptance and clinical utility of our current and future product candidates;
- our intellectual property position, including the scope of protection we are able to establish and maintain for
  intellectual property rights covering our VaxWave and TheraT technologies and the product candidates based on
  these technologies, the validity of intellectual property rights held by third parties, and our ability not to infringe,
  misappropriate or otherwise violate any third-party intellectual property rights;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- regulatory developments in the United States and foreign countries;
- competitive companies, technologies and our industry and the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;

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

All of our forward-looking statements are as of the date of this 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.

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

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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)

	J	June 30,		December 31,		
		2020		2019		
Assets	,					
Current assets:						
Cash and cash equivalents	\$	92,857	\$	113,151		
Accounts receivable		4,738		1,537		
Receivable research incentives		10,950		8,190		
Prepaid expenses and other current assets		9,348		5,139		
Total current assets	<u> </u>	117,893		128,017		
Non-current assets:						
Restricted cash		425		424		
Property and equipment, net		6,030		5,126		
Operating lease right of use assets		6,949		7,875		
Finance lease right of use assets		1,399		1,602		
Other non-current assets		572		701		
Total non-current assets		15,375		15,728		
Table server	\$	133,268	\$	143,745		
Total assets	Þ	133,200	<u> </u>	143,743		
Liabilities and Stockholders' Equity						
Current liabilities						
Accounts payable	\$	6.965	\$	944		
Deferred revenues	Ψ	4,365	Ψ	3,591		
Operating lease liabilities, current		1,841		1.814		
Accrued expenses and other current liabilities		5,400		8,406		
Total current liabilities		18,571	_	14,755		
Non-current liabilities		10,571		14,755		
Loans payable, non-current		3,818		3,495		
Operating lease liabilities, non-current		4,398		5,290		
Deferred revenues, non-current		760		72		
Other non-current liabilities		1,806		2,234		
Total non-current liabilities	_	10,782	_	11,091		
Total liabilities		29,353		25,846		
Total habilities		23,333	_	23,040		
Stockholders' equity:						
Common stock, \$0.0001 par value; 100,000,000 shares authorized at June 30, 2020 and December 31, 2019,						
respectively; 21,834,692 shares and 21,746,392 shares issued and outstanding at June 30, 2020 and						
December 31, 2019, respectively		3		3		
Class A common stock, \$0.0001 par value; 3,900,000 shares authorized at June 30, 2020 and						
December 31, 2019, respectively; 3,819,732 shares issued and outstanding at June 30, 2020 and						
December 31, 2019, respectively		0		0		
Additional paid-in capital		229,828		225,568		
Accumulated other comprehensive loss		(4,879)		(4,653)		
Accumulated deficit		(121,037)		(103,019)		
Total stockholders' equity		103,915		117,899		
Total liabilities, convertible preferred stock and stockholders' equity	\$	133,268	\$	143,745		
rotal natifices, convertible preferred stock and stockholders equity	Ψ	100,400	Ψ	140,740		

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

# (In thousands, except share and per share amounts)

	Three months ended June 30,					Six months er		
		2020		2019		2020		2019
Revenue from collaboration and licensing	\$	6,685	\$	4,051	\$	10,381	\$	6,286
Operating expenses:								
Research and development		(11,564)		(13,929)		(23,090)		(24,108)
General and administrative		(4,347)		(3,751)		(8,976)		(6,462)
Total operating expenses		(15,911)		(17,680)		(32,066)		(30,570)
Loss from operations		(9,226)		(13,629)		(21,685)		(24,284)
Other income (expense):								
Grant income	\$	1,595	\$	1,544	\$	3,067	\$	2,736
Interest income		59		511		371		575
Interest expense		(166)		(210)		(393)		(423)
Other income and expenses, net		646		(195)		622		88
Total other income, net		2,134		1,650		3,667		2,976
Net loss before tax		(7,092)		(11,979)		(18,018)		(21,308)
Income tax expense		(0)		(100)		(0)		(100)
Net loss		(7,092)		(12,079)		(18,018)		(21,408)
Other comprehensive loss:								
Foreign currency translation gain (loss), net of tax		(133)		300		(226)		(435)
Comprehensive loss	\$	(7,225)	\$	(11,779)	\$	(18,244)	\$	(21,843)
•						•		
Net loss per share — basic and diluted	\$	(0.28)	\$	(0.63)	\$	(0.70)	\$	(2.10)
The 1000 per onare outse and analed	Ė	(	÷	(1111)	Ė	(11 1)	÷	( ' ')
Weighted average common shares outstanding — basic								
and diluted	2!	5,647,819	1	9,240,977		25,638,913	1	0,174,157
una anarca		5,5 17,015	=	5,= 10,577				, ., ., ., .,

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

# (In thousands, except share amounts)

	Conve	ertible		Comm	on Stock		Additional	Accumulated Other		Total
	Preferre	ed Stock	Commo	n Stock	Class A Co	mmon Stock	Paid-In	Comprehensive	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balances as of										
December 31, 2019	_	_	21,746,392	3	3,819,732	0	225,568	(4,653)	(103,019)	117,899
Issuance of common stock upon								( ) /	, , ,	
exercise of stock options	_	_	78,598	0	_	_	8	_	_	8
Foreign currency translation										
adjustment, net of tax	_	_	_	_	_	_	_	(93)	_	(93)
Stock-based compensation										
expense	_	_	_	_		_	2,094	_	_	2,094
Net loss									(10,926)	(10,926)
D.1 635 1.05 0000			24 02 4 000		2 040 =22		225.550	(4=40)	(440.04=)	400.000
Balances as of March 31, 2020	_	_	21,824,990	3	3,819,732	0	227,670	(4,746)	(113,945)	108,982
Issuance of common stock upon			9,702	0			7			7
exercise of stock options Foreign currency translation	_	_	9,702	U	_	_	/	_	_	/
adjustment (unaudited)								(133)		(133)
Stock-based compensation			_					(133)		(133)
expense	_	_	_	_	_	_	2.151	_	_	2,151
Net loss	_	_	_	_	_	_	2,151	_	(7,092)	(7,092)
1101									(7,002)	(7,002)
Balance as of June 30, 2020		<u>s                                    </u>	21,834,692	\$ 3	3,819,732	\$ 0	\$ 229,828	\$ (4,879)	\$ (121,037)	\$ 103,915
D. 1										
Balances as of	1 222 500	¢ 104 774	1 000 505	\$ 0		s –	d 2.22#	e (2.720)	¢ (50,000)	¢ (60.275)
December 31, 2018 Issuance of Series D preferred	1,323,506	\$ 104,774	1,006,595	\$ 0	_	s —	\$ 3,327	\$ (3,720)	\$ (59,982)	\$ (60,375)
stock, net of issuance costs of										
\$158	257,000	37,274								
Foreign currency translation	237,000	37,274	_							
adjustment, net of tax	_	_	_	_	_	_	_	(736)	_	(736)
Stock-based compensation	_	_	_	_	_	_	383	(750)	_	383
Net loss	_	_	_	_	_	_	_	_	(9,329)	(9,329)
Balances as of March 31, 2019	1,580,506	\$ 142,048	1,006,595	\$ 0		<u>s</u> —	\$ 3,710	\$ (4,456)	\$ (69,311)	\$ (70,057)
Issuance of common stock upon		<del>+</del>		<u> </u>		<u> </u>	,	* (3,000)	+ (00,000)	+ (10,001)
initial public offering at \$14.00										
per share for cash, net of issuance										
costs of \$9,386	_	_	6,000,000	1	_	_	74,614	_	_	74,615
Conversion of Series A, B, C and										
D preferred stock into common										
stock upon initial public offering	(1,580,506)	(142,048)	14,582,161	2	3,819,732	0	142,046	_	_	142,048
Foreign currency translation										
adjustment, net of tax	_	_	_	_	_	_	_	300	_	300
Stock-based compensation	_	_	_	_	_		1,206	_	_	1,206
Net loss									(12,079)	(12,079)
Balances as of June 30, 2019			24 -00 -5		2 040 =55		A 224			d 400.000
		<u> </u>	21,588,756	\$ 3	3,819,732	\$ 0	\$ 221,576	\$ (4,156)	\$ (81,390)	\$ 136,033

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

# (In thousands)

		Six months er 2020	ıded .	June 30, 2019
Operating activities:				
Net loss	\$	(18,018)	\$	(21,408)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense		4,245		1,589
Depreciation expense		887		670
Non-cash operating lease expense		987		735
Other non-cash items		(29)		51
Changes in operating assets and liabilities:				
Accounts receivable		(2,971)		1,892
Prepaid expenses and other current assets		(6,531)		(5,575)
Other non-current assets		127		204
Accounts payable		4,833		994
Deferred revenues		1,431		(2,265)
Operating lease liabilities		(927)		(1,698)
Accrued expenses and other liabilities		(1,668)		1,438
Other non-current liabilities		(39)		(80)
other non-current intomaces		(55)		(66)
Net cash used in operating activities		(17,673)	_	(23,453)
ivet cash used in operating activities		(17,073)		(23,433)
Investing activities:				
Purchases of property and equipment		(1,241)		(591)
Purchases of property and equipment		(1,241)		(391)
Not each used in investing activities		(1,241)		(591)
Net cash used in investing activities	_	(1,241)	_	(591)
Einanging activities				
Financing activities:		(GE)		(1.406)
Payments related to finance leases		(65)		(1,406)
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs				37,274
Proceeds from issuance of common stock, net of issuance costs		15		75,298
Payments for deferred offering costs		(128)		_
Repayments of borrowings		(1,256)		_
Net cash provided by (used in) financing activities		(1,434)		111,166
Net increase (decrease) in cash, cash equivalents and restricted cash		(20,348)		87,122
Cash, cash equivalents and restricted cash at beginning of period		113,575		48,580
Effect of exchange rate changes on cash, cash equivalents and restricted cash		55		(489)
Cash, cash equivalents and restricted cash at end of period	\$	93,282	\$	135,213
			_	
Supplemental disclosure of cash flow information:				
Cash paid for interest	\$	(47)	\$	(32)
Cash paid for income taxes	\$	(0)	\$	(100)
		(-)		( )
Supplemental disclosure of non-cash investing activities:				
Property and equipment additions in accounts payable and accrued expenses	\$	(368)		(191)
The state of the s	-	(300)		(101)

#### 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 common stock started trading on the Nasdaq Global Select Market under the ticker symbol "HOOK".

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

# 2. Summary of significant accounting policies

### Basis of presentation

The Company's 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 sheet as of June 30, 2020, the condensed consolidated statements of operations, and comprehensive loss for the three and six months ended June 30, 2020 and 2019, the condensed consolidated statement of redeemable convertible preferred stock and stockholders' deficit for the three and six months ended June 30, 2020 and 2019 and the condensed consolidated statements of cash flows for the six months ended June 30, 2020 and 2019 are unaudited.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements 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 audited financial statements for the year ended December 31, 2019 included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission. The results for any interim period are not necessarily indicative of results for any future period. Certain previous year amounts have been reclassified to conform to the current year presentation.

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

#### Going concern

Since inception, the Company's activities have consisted primarily of performing research and development to advance its technologies. The Company is still in the development phase and has not been marketing its technologies to date. Through June 30, 2020, the Company has funded its operations with proceeds from sales of common stock in its IPO, sales of redeemable convertible preferred stock, collaboration and licensing agreements, grants and borrowings under various agreements with foreign public funding agencies. Since inception, the Company has incurred recurring losses, including net losses of \$18.0 million for the six months ended June 30, 2020 and \$43.0 million for the year ended December 31, 2019. As of June 30, 2020, the Company had an accumulated deficit of \$121.0 million. The Company expects to continue to generate operating losses in the foreseeable future. As of August 13, 2020, the filing date of this Quarterly Report on Form 10-Q, the Company expects that its cash and cash equivalents will be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through at least 12 months from the issuance date of the 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 present value of lease right of use assets and corresponding liabilities, the valuation of common and preferred stock, the valuation of stockbased 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. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. The Company's accounting estimates and assumptions may change over time in response to COVID-19 and the change could be material in future periods. As of the date of issuance of these unaudited condensed consolidated financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update estimates, judgments or revise the carrying value of any assets or liabilities. Actual results may differ from those estimates or assumptions.

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

#### **Deferred offering costs**

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity as a reduction of the additional paid-in capital on a pro-rata basis generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss.

#### Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and short-term bank deposits held with banks in excess of publicly insured limits. The net proceeds from the Company's offerings have been deposited in interest-bearing bank accounts with investment grade US financial institutions and have been partially invested in a money market fund as of June 30, 2020. The money market fund, held in U.S. dollar, is primarily invested in U.S. and foreign short-term debt obligations. As of December 31, 2019 and June 30, 2020, the Company's cash and cash equivalents included smaller amounts of cash balances held in accounts with European banks at the Company's Austrian subsidiary, partially in euros. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

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

#### Cash equivalents

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. As of December 31, 2019 and June 30, 2020, cash equivalents consisted of money market funds

# Fair value measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

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

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

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above (see Note 4).

#### Property and equipment

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

	Estimated useful life
Leasehold improvements	5 years
Laboratory equipment	3 - 10 years
Furniture and fixtures	3 - 10 years
Computer equipment and software	3 - 4 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Expenditures for repairs and maintenance are charged to expense as incurred.

#### Leases

The determination whether an arrangement qualifies as a lease is made at contract inception. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the option will be exercised. The Company uses the implicit rate when readily determinable and uses its incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments. The incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease. The lease payments used to determine operating lease assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized as operating lease assets on the consolidated balance sheets. In addition, certain of the Company's arrangements contain lease and non-lease components. The Company generally separate lease payments from non-lease payments. Operating leases are reflected in operating lease assets, in accrued expenses and other current liabilities and in non-current operating lease liabilities in the consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. The right-of-use asset is tested for impairment in accordance with ASC 360.

# Revenue recognition from contracts with customers

The Company entered into a collaboration and license agreement (the "Gilead Agreement") with Gilead Sciences, Inc. ("Gilead") whereby the parties agreed to collaborate with respect to two preclinical research programs to evaluate potential vaccine products for the treatment, cure, diagnosis or prevention of the hepatitis B virus (HBV) and the human immunodeficiency virus (HIV). The Company's performance obligations under the terms of this agreement include one combined performance obligation for each research program (HBV and HIV) comprised of the transfer of intellectual property rights (licenses) and providing research and development services. The licenses do not represent distinct performance obligations, because they cannot be used without the research and development services. Payments to the Company under this agreement include a non-refundable up-front payment, payments for research and development activities, payments based upon the achievement of defined milestones, and if certain future conditions are met, payments for manufacturing services, commercial milestones and royalties on product sales.

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

The Company evaluates its collaboration and licensing arrangements pursuant to Accounting Standards Codification (ASC) 606. To determine the recognition of revenue from arrangements that fall within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation.

Under ASC 606, the Company applies significant judgement to evaluate whether the obligations under the collaboration and licensing arrangement, represent separate or one or more combined performance obligations, the allocation of the transaction price to identified performance obligations, and the determination of when milestone payments are probable of being received.

#### Upfront payment

The non-refundable upfront-payment received by the Company under the Gilead agreement is recorded as deferred revenue and allocated between the two research program performance obligations. Such amounts are recognized as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development labor hours (input method) for each of the obligations. The percent of completion basis using labor hours was considered the best measure of progress in which control of the combined performance obligations transfers to the customer, due to the short time intervals in which research results are shared with the collaboration partner and the nature of the work being performed.

### Reimbursement for services

Under the Gilead Agreement, the Company incurs employee expenses as well as external costs for research and manufacturing activities presented as operating expenses or prepaid expenses. Based on the nature of the Company's responsibilities under the collaboration arrangement, reimbursement of those costs are presented as revenue and not deducted from expenses, as the Company controls the research activities. Amounts of consideration allocated to the performance of research or manufacturing services are recognized over the period in which services are performed. Reimbursements for external costs are recognized as revenues in the period in which the goods or services are received and external costs are recognized. Unpaid reimbursement amounts are presented as Accounts receivable.

#### Research and development milestones

The Gilead Agreement includes contingent milestone payments related to specified preclinical and clinical development milestones. These milestone payments represent variable consideration that are not initially recognized within the transaction price as they are fully constrained under the guidance in ASC 606, due to the scientific uncertainties and the required commitment from Gilead. The Company will continue to assess the probability of significant reversals for any amounts that become likely to be realized prior to recognizing the variable consideration associated with these payments within the transaction price.

# Sales-based milestones and royalty payments

The Gilead Agreement also includes certain sales-based milestone and royalty payments upon successful commercialization of a licensed product. In accordance with ASC 606-10-55-65, the Company recognizes revenues from sales-based milestone and royalty payments at the later of (i) the occurrence of the subsequent sale; or (ii) the performance obligation to which some or all of the sales-based milestone or royalty payments has been allocated has been satisfied. The Company anticipates recognizing these milestones and royalty payments if and when subsequent sales are generated from a licensed product by the collaboration partner.

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

Cost to fulfill contracts

The Company incurs costs for personnel, supplies and other costs related to its laboratory operations as well as fees from third parties and license expenses in connection with its research and development obligations under the collaboration and licensing agreement. These costs are recognized as research and development expenses over the period in which services are performed. Sublicense fees triggered by the receipt of payments are capitalized as an asset when the obligation to pay the fee arises. The capitalized asset is amortized over the period in which the revenue from the triggering payment is recognized.

#### Redeemable convertible preferred stock

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

#### 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 August 2018, the FASB issued ASU 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amendments in this update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this update. The standard became effective for the Company beginning on January 1, 2020. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses which was clarified and amended by the issuances of ASUs 2018-19, 2019-04, 2019-05 and 2019-11 in November 2018, April 2019, May 2019 and November 2019, respectively. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis are measured using an expected-loss model, replacing the current incurred-loss model, and recorded through an allowance for credit losses. The guidance also establishes a new impairment model for available-forsale debt securities. The Company adopted the new standard and the related amendments on January 1, 2020, on a modified retrospective basis, to the accounts receivable, contract asset balances and cash equivalents as of January 1, 2020. Under the current expected credit loss model, the Company adopted a provision matrix approach, utilizing historical loss rates based on the number of days past due, adjusted to reflect current economic conditions and

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

forecasts of future economic conditions. The Company has never experienced a credit loss on its accounts receivable, contract assets or on the principal or interest receivable of its cash equivalents. Accordingly, the effect of the adoption on the financial statement line items of accounts receivable, contract assets and cash equivalents was not material as of January 1, 2020. As a result of the adoption, the cumulative-effect adjustment to reflect the incremental estimated lifetime expected credit losses on the accounts receivable balance as of January 1, 2020 is immaterial. Therefore, the Company recognized no cumulative-effect adjustment within retained earnings on its condensed consolidated balance sheet as of January 1, 2020. The Company has not presented the amortized cost basis within each credit quality indicator by year of origination as all of its accounts receivable are due within one year or less.

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 adoption of this guidance on January 1, 2020 did not have a material impact on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, Clarifying the Interaction Between Topic 808 and 606, which clarifies when transactions between participants in a collaborative arrangement are within the scope of the FASB's revenue standard, Topic 606. The adoption of this guidance on January 1, 2020 did not have a material impact on the Company's consolidated financial statements.

#### Recently Issued Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12), which eliminates certain exceptions related to the general principles in ASC 740 and makes amendments to other areas with the intention of simplifying various aspects related to accounting for income taxes. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the potential impact of the adoption of these updates on its consolidated financial statements.

In March 2020, the FASB issued guidance which provides optional expedients and exceptions to address the impact of reference rate reform where contracts, hedging relationships and other transactions that reference the London Interbank Offered Rate ("LIBOR") or another reference rate need to be discontinued. This guidance was effective upon issuance and generally can be applied through December 31, 2022. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

In August 2018, the FASB issued guidance which modifies the disclosure requirements for defined benefit pension plans and other postretirement plans. The guidance removes disclosures that no longer are considered cost beneficial, clarifies the specific requirements of disclosures, and adds disclosure requirements identified as relevant. This guidance is effective for fiscal years ending after December 15, 2020. Early adoption is permitted. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements, however believes that the adoption of this guidance will not have a material impact on its consolidated financial statements.

#### 3. Collaboration and Licensing Agreements

#### Gilead Collaboration and License Agreement

In June 2018, the Company entered into the Gilead Agreement whereby the Company and Gilead agreed to collaborate with respect to two preclinical research programs to evaluate potential vaccine products for the treatment, cure, diagnosis or prevention of HBV and HIV.

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

Under the Gilead Agreement, the Company granted Gilead an exclusive, royalty-bearing license to the Company's technology platforms. Upon entering into the agreement, the Company received a non-refundable \$10.0 million upfront payment from Gilead. Gilead is also obligated to make additional payments to the Company upon the achievement of preclinical, 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.

The \$10.0 million upfront payment received in 2018 and a \$4.0 million milestone payment received in the six months ended June 30, 2020 were initially recorded as deferred revenue in the consolidated balance sheet and are recognized as revenue when revenue recognition criteria are met. As of June 30, 2020, \$4.1 million of upfront and milestone payments were included as a liability in deferred revenues, current and non-current. Approximately 56% of deferred revenue as of June 30, 2020 is expected to be recognized as revenue in the remainder of 2020, 38% in 2021 and the remaining 5% in 2022.

In the three months ended June 30, 2020, the Company recognized \$1.0 million of the upfront payment received in 2018 and \$0.6 million of the \$4.0 million milestone payment received earlier in 2020. In addition, the Company fully recognized a \$1.0 million milestone payment for a milestone achieved in the three months ended June 30, 2020 and \$4.1 million revenue from cost reimbursements for research and development services. For the three months ended June 30, 2019, revenue from reimbursement of research and development expenses was \$0.7 million, and revenue from partial recognition of the upfront payment was \$1.4 million. Additionally, the Company recognized a \$2.0 million milestone payment for a milestone achieved in the three months ended June 30, 2019.

In the six months ended June 30, 2020, the Company recognized \$1.4 million of the upfront payment received in 2018 and \$1.2 million of the \$4.0 million milestone payment received earlier in 2020. In addition, the Company fully recognized a \$1.0 million milestone payment for a milestone achieved in the six months ended June 30, 2020 and \$6.8 million revenue from cost reimbursements for research and development services. For the six months ended June 30, 2019, revenue from reimbursement of research and development expenses was \$2.0 million, and revenue from partial recognition of the upfront payment was \$2.3 million. Additionally, the Company recognized a \$2.0 million milestone payment for a milestone achieved in the six months ended June 30, 2019.

Sublicense fees payable to certain licensors of technologies upon the receipt of the deferred upfront and milestone payments, were capitalized as a contract asset and will be amortized over the period in which the revenue from the triggering payment is recognized. As of June 30, 2020 and December 31, 2019, the contract asset and the liability relating to the sublicense payment was \$0.2 million and \$0.3 million, respectively.

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

#### 4. Fair Value of Financial Assets

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicating the level of the fair value hierarchy utilized to determine such fair values (in thousands):

		Fair Value Measurement at June 30, 2020 Using						
	I	Level 1		Level 2		evel 3		Total
Cash equivalents:								
Money market funds	\$	35,384	\$		\$		\$	35,384
Total	\$	35,384	\$	_	\$		\$	35,384
Fair Value Measurement at December 31, 2019 Using Level 1 Level 2 Level 3 Total								
	ī						2019 U	
Cash equivalents:	<u>I</u>	Fair Valu Level 1					2019 U	Ising Total
Cash equivalents:  Money market funds	<u> </u>						2019 U \$	

During the six months ended June 30, 2020, there were no transfers between Level 1, Level 2 and Level 3.

# 5. Accrued expenses and other current liabilities

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

	<u>J</u>	June 30, 2020		ember 31, 2019
Consulting fees	\$	1,033	\$	724
Salaries and bonuses		2,154		2,640
Social security contributions		278		177
Unearned grant income (current)		735		725
Loans		_		1,224
Invoices not yet received		1,023		2,673
Finance lease liabilities		155		159
Other accruals and liabilities		22		84
	\$	5,400	\$	8,406

# 6. Loans payable

As of June 30, 2020 and December 31, 2019, loans payable consisted of the following (in thousands):

	<u>J</u>	June 30,		ember 31,	
		2020	2019		
Loans from FFG	\$	6,031	\$	7,305	
Unamortized debt discount		(2,213)		(2,586)	
Total Loans payable, net	\$	3,818	\$	4,719	

In connection with the funding agreements with the Austrian Research Promotion Agency, (*Österreichische Forschungsförderungsgesellschaft*, or "FFG"), the Company has received various loans ("FFG Loans"). The FFG Loans were made on a project-by-project basis. Amounts due under the FFG Loans bear interest at rates ranging from 0.75% to

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

1.0% per annum and mature at various dates between June 2022 and March 2024. Interest on amounts due under the loans is payable semi-annually in arrears, with all principal and remaining accrued interest due upon maturity.

The FFG Loans bear interest at rates that are below market rates of interest. The Company accounts for the imputed benefit arising from the difference between an estimated market rate of interest and the rate of interest charged by FFG as grant income from FFG. On the date that FFG loan proceeds are received, the Company recognizes the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income, which is recognized as grant income over the term of the funding agreement.

In November 2019, the Company agreed to an earlier repayment schedule for \$3.3 million of the outstanding loans with FFG. As a result of the change, the Company reduced the deferred income attributable to the imputed benefit from below market interest by \$0.3 million and increased the carrying value of the loans by the same amount.

No principal repayment was made in the three months ended June 30, 2020. A principal repayment of \$1.3 million was made in the six months ended June 30, 2020. There were no principal payments due or paid under the FFG Loans during the three and six months ended June 30, 2019.

#### 7. Redeemable convertible preferred stock

Redeemable convertible preferred stock

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

In 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.

Upon the closing of the Company's IPO, all 1,580,506 then outstanding shares of Preferred Stock converted into 14,582,161 shares of common stock and 3,819,732 shares of Class A common stock. The related book value of \$142.0 million was reclassified to common stock and additional paid-in capital.

As of June 30, 2020 and 2019, the Company had no shares of Preferred Stock outstanding. The Company is authorized to issue 10,000,000 shares of undesignated preferred stock.

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

#### 8. Common stock and Class A common stock

In June 2018, the Company became the reporting entity in a transaction between entities under common control. In the accompanying 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.

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

As of June 30, 2020, the Company was authorized to issue 100,000,000 shares of common stock and 3,900,000 shares of Class A common stock and had 21,834,692 shares of common stock and 3,819,732 shares of Class A common stock outstanding and issued.

Holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of Class A common stock are not entitled to vote, except as required by law. Each holder of Class A common stock has the right to convert each share of Class A common stock into one share of common stock at such holder's election.

The holders of common stock and Class A common stock do not have any cumulative voting rights. Subject to any preferential dividend rights of any outstanding preferred stock, holders of common stock and Class A common stock are entitled to receive ratably any dividends declared by the board of directors out of funds legally available for that purpose. Holders of common stock and Class A common stock have no preemptive rights, conversion rights, or other subscription rights or redemption or sinking fund provisions.

In the event of a liquidation, dissolution, or winding up of the Company, holders of common stock and Class A common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities, subject to the preferences that may be applicable to any outstanding shares of preferred stock.

#### 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.

The exercise price for options granted as a replacement of the 2016 Stock Option Plan is the U.S. dollar equivalent of  $\[ \in \]$ 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.

#### 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. The options expire on the 10<sup>th</sup> anniversary of the grant date. As of June 30, 2020, 1,265,839 options granted under the 2018 Stock Option and Grant Plan remained outstanding. Any authorization to issue new options under the 2018 Stock Option and Grant Plan was cancelled upon the effectiveness of the 2019 Stock Option and Incentive Plan and no further awards will be granted under the 2018 Plan.

#### 2019 Stock Option and Incentive Plan

On April 1, 2019, the Company's stockholders approved the 2019 Stock Option and Incentive Plan, which became effective as of the effective date of the registration statement in connection with the Company's IPO. The maximum number of shares of the Company's common stock that may be issued under the Company's 2019 Stock Option and Incentive Plan is 3,630,686, shares which shall be cumulatively increased each year by up to 4% of the then outstanding number of shares. Options granted under the 2019 Stock Option and Incentive Plan generally vest over four years, with 25% of the options vesting upon the first anniversary of the grant date and the remaining 75% of the options vesting in 12 equal quarterly installments following the first anniversary of the grant date, provided the option holder continues to have an employment or service relationship with the Company on each vesting date. Initial options granted to non-executive directors upon their election generally vest over a three-year term with 33% of the options vesting upon the first anniversary of the grant date and the remaining 67% of the options vesting in eight equal quarterly installments following the first anniversary of the grant date. Option re-grants to non-executive directors generally vest on the first anniversary of the grant date. The options expire on the 10<sup>th</sup> anniversary of the grant date. For each option, the beneficiary is entitled to receive one share of common stock upon the exercise of the option.

#### Stock option valuation

The Company estimates the option's fair value on the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to expected term, volatility, the risk-free interest rate, the dividend and employee exercise behavior. Forfeitures are accounted for when they occur. Expected volatilities utilized in the Black-Scholes model are based on historical volatilities of a group of comparable companies. The group of representative companies have characteristics similar to the Company, including the stage of product development and focus of the life science industry. Management believes that this represents the most accurate basis for estimating expected future volatilities under the current conditions. The risk-free interest rate is derived from the yields for U.S. Treasuries with a remaining term approximating the expected life of the options. The expected term represents the period of time that the options granted are expected to be outstanding.

The following table summarizes the assumptions used in the Black-Scholes option-pricing model for estimating the fair value of stock options granted during:

	Three and six months end	ded June 30,
	2020	2019
Risk-free interest rate	0.44 %	2.45 %
Expected term (in years)	6.0	6.1
Expected volatility	79.0 %	73.5 %
Expected dividends	— %	— %

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

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

Stock option activity

The following table summarizes the Company's stock option activity since January 1, 2020 (in thousands, except share and per share amounts):

Number of Shares	A E	verage xercise	Weighted Average Remaining Contractual Term (in years)		aggregate Intrinsic Value
2,999,284	\$	7.63	8.1	\$	15,840
739,928		8.34			
(88,300)		0.16			
(64,941)		9.40			
3,585,971	\$	7.93	8.1	\$	15,945
				-	
1,223,596	\$	4.30	6.6	\$	9,659
2,362,375	\$	9.80	8.9	\$	6,286
	2,999,284 739,928 (88,300) (64,941) 3,585,971 1,223,596	Number of Shares  2,999,284 \$ 739,928 (88,300) (64,941) 3,585,971 \$ \$ 1,223,596 \$	Shares         Price           2,999,284         \$ 7.63           739,928         8.34           (88,300)         0.16           (64,941)         9.40           3,585,971         \$ 7.93           1,223,596         \$ 4.30	Number of Shares         Weighted Average Exercise Price         Average Remaining Contractual Term (in years)           2,999,284         \$ 7.63         8.1           739,928         8.34           (88,300)         0.16           (64,941)         9.40           3,585,971         \$ 7.93         8.1           1,223,596         \$ 4.30         6.6	Number of Shares         Weighted Average Exercise Price         Average Remaining Contractual Term (in years)         Average Remaining Contractual Term (in years)           2,999,284         \$ 7.63         8.1         \$ 739,928           (88,300)         0.16         (64,941)         9.40           3,585,971         \$ 7.93         8.1         \$ 1,223,596           1,223,596         \$ 4.30         6.6         \$ 3

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 June 30, 2020 and December 31, 2019, was \$11.62 and \$12.23, respectively.

Cash received from option exercise under share-based payment arrangements for the six months ended June 30, 2020 was \$15 thousand. No cash from option exercise was received in the six months ended June 30, 2019.

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 June 30,					Six months e	nded June 30,	
	2020			2019		2020	2019	
Research and development expenses	\$	\$ 771		401	\$	1,448	\$	662
General and administrative expenses	1,380		805		2,797			927
	\$	2,151	\$	1,206	\$	4,245	\$	1,589

# 10. Income taxes

Income tax expense during the three and six months ended June 30, 2020 and 2019 resulted from minimum tax obligations. During the three and six months ended June 30, 2020 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

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

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 June 30, 2020 and December 31, 2019. Management reevaluates the positive and negative evidence at each reporting period.

#### 11. Commitments and contingencies

**Operating and Finance 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 is required to maintain a cash balance of \$0.4 million to secure letters of credit associated with real estate leases. This amount was classified as non-current restricted cash in the Company's condensed consolidated balance sheet as of June 30, 2020.

As of June 30, 2020 and December 31, 2019, the Company's operating lease right-of-use assets were \$6.9 million and \$7.9 million, respectively, which are reported in operating lease right-of-use assets in the Company's condensed consolidated balance sheets. As of June 30, 2020 and December 31, 2019, the Company's finance lease right-of-use assets were \$1.4 million and \$1.6 million, respectively, which are reported in finance lease right-of-use assets in the Company's condensed consolidated balance sheets. As of June 30, 2020, the Company had outstanding operating lease obligations of \$6.2 million, of which \$1.8 million is reported in operating lease liabilities, current portion and \$4.4 million is reported in operating lease liabilities, non-current portion in the Company's condensed consolidated balance sheets. As of June 30, 2020, the Company had outstanding finance lease obligations of \$0.5 million, of which \$0.2 million is reported in accrued expenses and other current liabilities and \$0.3 million is reported in other non-current liabilities in the Company's condensed consolidated balance sheets. As of December 31, 2019, the Company had outstanding operating lease obligations of \$7.1 million, of which \$1.8 million is reported in operating lease liabilities, current portion and \$5.3 million is reported in operating lease liabilities, non-current portion in the Company's condensed consolidated balance sheets. As of December 31, 2019, the Company had outstanding finance lease obligations of \$0.5 million, of which \$0.2 million is reported in accrued expenses and other current liabilities and \$0.3 million is reported in other non-current liabilities in the Company's condensed consolidated balance sheets. The Company's weighted average discount rate and weighted average lease term remaining on operating lease liabilities is approximately 2.3% and 3.6 years, respectively. The Company's weighted average discount rate and weighted average lease term remaining on finance lease liabilities is approximately 1.7% and 3.4 years, respectively.

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 0.7 years without an option to renew and has been qualified as an operating lease.

#### 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 June 30, 2020, the Company's total non-cancellable obligations under contracts with CMOs, excluding embedded lease liabilities, were \$7.7 million, of which \$4.8 million relate to 2020 (remaining six months) deliverables and \$2.9 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.

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

In the three and six months ended June 30, 2020, the Company recorded \$0.1 million and \$0.2 million, respectively, in licensing fees from intellectual property licenses as research and development expenses. These amounts mainly related to the upfront payment and milestone payments received by the Company under the Gilead Agreement. The amounts recognized as expenses have been agreed to by the licensors but calculation of sublicensing fees on future payments may be subject to interpretation and may change until agreed to by the receiving party.

#### Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of June 30, 2020 and December 31, 2019.

#### 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):

		Three months	end	ed June 30,		June 30,		
		2020	2019			2020		2019
Numerator:								
Net loss	\$	(7,092)	\$	(12,079)	\$	(18,018)	\$	(21,408)
Denominator:								
Weighted-average common shares outstanding, basic								
and diluted	2	25,647,819		19,240,977		25,638,913		10,174,157
Net loss per share, basic and diluted	\$	(0.28)	\$	(0.63)	\$	(0.70)	\$	(2.10)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common shares (Common Stock and Class A Common Stock) outstanding would have been anti-dilutive. Potentially dilutive securities as of June 30, 2020 that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

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

	Three and six months ended June 30,				
	2020	2019			
Options issued and outstanding	3,585,971	2,592,955			
Total	3,585,971	2,592,955			

#### 13. Related parties

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

The Company is party to research and service arrangements with the University of Basel. Daniel Pinschewer, formerly Chief Scientific Officer, and his spouse are employees of the University of Basel and both involved in providing the services under these arrangements. In the three months ended June 30, 2020, the Company recorded no related party transactions. In the three months ended June 30, 2019, the Company recorded less than \$0.1 million, in the six months ended June 30, 2020 and 2019, the Company recorded \$0.3 million and \$0.3 million, respectively, in research and development expenses for service fees paid to the University of Basel, which represented related party transactions. The University of Basel is also entitled to receive de minimis royalties on the net sales of any product that is based on a patent created by Daniel Pinschewer in the course of his consulting services to the Company. In the three and six months ended June 30, 2020 and 2019, no royalties were paid pursuant to the terms of this arrangement.

During the six months ended June 30, 2019, the Company issued 50,670 shares of Series D Preferred Stock for total gross proceeds of \$7.4 million and 1,303,750 shares of common stock as part of the Company's IPO for total gross proceeds of \$18.3 million to certain stockholders that were related parties.

#### 14. Subsequent events

#### Stock option grant

On July 20, 2020, the Company granted options to employees to purchase 79,104 shares of common stock. All options granted on July 20, 2020 vest over four years, with 25% of the options vesting on May 15, 2021 and the remaining 75% of the options vesting in 12 equal quarterly installments following the first anniversary of the vesting date, provided the option holder continues to have an employment relationship with the Company on each vesting date.

# Restricted stock units grant

On July 20, 2020, the Company granted 44,308 restricted stock units to certain executive officers and employees, vesting in four equal installments on March 20, 2021, May 15, 2021, August 15, 2021 and November 15, 2021.

#### 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, 2019 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q and the "Risk Factors" section of our Annual Report on Form 10-K for the year end December 31, 2019, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

#### Overview

We are a clinical-stage biopharmaceutical company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on our proprietary arenavirus platform that is designed to reprogram the body's immune system. We are using our "off-the-shelf" technologies, VaxWave and TheraT, to elicit directly within patients a powerful and durable response of antigen-specific killer T cells and antibodies, thereby activating essential immune defenses against infectious diseases and cancers. We believe that our technologies can meaningfully leverage 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 randomized, double-blinded Phase 2 clinical trial in patients awaiting kidney transplantation who are at risk for pathology associated with Cytomegalovirus, or CMV, infections. In June 2020, we announced positive Phase 2 interim data on the trial's primary endpoints, safety and B cell and T cell immunogenicity. In this trial, HB-101 was observed to be well tolerated with a lower rate of adverse events in patients with end-stage kidney disease than in the Phase 1 healthy volunteer study. Patients who received three doses of HB-101 showed comparable immunogenicity levels to those measured in the Phase 1 healthy volunteer trial. We continue to accrue patients, and plan to report preliminary efficacy data and updated safety and immunogenicity data by the end of 2020.

Our lead oncology product candidates, HB-201 and HB-202, are in development for the treatment of Human Papillomavirus 16-positive (or HPV16+) cancers. In December 2019, we initiated the Phase 1/2 clinical trial for HB-201. The open label, dose escalating Phase 1/2 clinical trial is evaluating HB-201 in HPV16+ cancers alone and in combination with an approved checkpoint inhibitor. We plan to enroll 100 patients in total with 20 patients in each dose escalation and expansion group, respectively. Enrollment of patients at the intravenously administered first and second dose levels has been completed. We expect to report preliminary safety and efficacy data in late 2020 or early 2021.

In June 2020, we announced that the FDA cleared our IND application for HB-202. With the IND clearance, we will be able to examine not only the safety and efficacy of HB-201 alone but also HB-201 in combination with HB-202 as an alternating, two-vector therapy. The planned clinical trial combining HB-202 with HB-201 in patients with HPV16+ cancers is an open label, dose escalation Phase 1/2 trial with the primary endpoint to evaluate safety and tolerability, which is expected to commence later in 2020.

We also have a strategic partnership with Gilead Sciences, Inc., or Gilead, to develop infectious disease product candidates intended to support functional cures for chronic Hepatitis B virus, or HBV, and human immunodeficiency virus, or HIV, infections. Since the start of the collaboration in 2018, we received \$21.0 million in upfront and milestone payments from Gilead for the delivery of research vectors and for advancing the programs towards clinical trials, including a milestone payment of \$4.0 million, that we received in early 2020. Based on preclinical data generated to date, Gilead committed to advancing the HBV and HIV vectors toward development. To enable the development activities and expanded research programs, Gilead has agreed to reimburse our expanded resources allocated to the Gilead collaboration and to reserve manufacturing capacity with clinical material manufacturers.

We have funded our operations to date primarily from private placements of our redeemable convertible preferred stock, with aggregate gross proceeds of approximately \$142.5 million, grant funding and loans from an Austrian government agency, and \$21 million in upfront and milestone payments from Gilead in connection with a research collaboration and license agreement. On April 23, 2019, we completed an initial public offering of our common stock, or IPO, in which we issued 6.0 million shares of our common stock, at \$14.00 per share, for gross proceeds of \$84.0 million, or net proceeds of \$74.6 million.

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

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

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

We have incurred net losses each year since our inception in 2011, including net losses of \$7.1 million and \$18.0 million for the three and six months ended June 30, 2020. As of June 30, 2020, we had an accumulated deficit of \$121.0 million and we do not expect positive cash flows from operations in the foreseeable future, if ever. We expect to continue to incur net operating losses for at least the next several years as we advance our product candidates through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, continue our research and development efforts and invest to establish a commercial manufacturing facility.

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

In March 2020, we announced initial potential business impacts related to the outbreak of a novel strain of virus named SARS-CoV-2 (severe acute respiratory syndrome 2), or coronavirus, which causes coronavirus disease, or COVID-19. As a result of the COVID-19 pandemic, we have experienced, and may further experience, disruptions that have and could further adversely impact our business operations as well as our preclinical studies and clinical trials. Specifically, nearly all of the Phase 2 trial sites we utilize for our HB-101 Phase 2 trial had temporarily suspended enrollment of patients and while many of them have recently resumed patient enrollment, it is unclear when all of the trial sites will be fully reactivated.

In addition, certain aspects of our supply chain had been temporarily impacted as certain of our third party suppliers and manufacturers have paused their operations in response to the COVID-19 pandemic or have otherwise encountered delays in providing their services. The uncertainties resulting from the COVID-19 pandemic have led us to focus on our core programs, HB-101, HB-201 and HB-202 as well as research and development activities under our collaboration with Gilead. Certain earlier stage programs, including HB-300, have been temporarily de-prioritized and were only allocated the ressources that could be made available without impacting our core programs. We continue to evaluate the extent to which these pauses and delays will impact our ability to manufacture our product candidates for

our clinical trials and conduct other research and development operations and maintain applicable timelines. The ultimate impact of the coronavirus pandemic on our business operations as well as our preclinical studies and clinical trials remains uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. We will continue to monitor the situation closely.

Furthermore, in order to preserve resources and liquidity, all of our officers have waived at least 25% of their cash salaries for the three months ended June 30, 2020, and the vast majority of our employees agreed to a temporary salary reduction of 20% for the three months ended June 30, 2020. We compensated our officers and employees for the forgone cash salaries by issuing restricted stock units in July 2020. Our directors have also accepted to receive equity instead of cash for their accrued board fees.

# **Components of Our Results of Operations**

#### Revenue from collaboration and licensing

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

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

Under the Collaboration Agreement, we granted Gilead an exclusive, royalty-bearing license to our technology platform for researching, developing, manufacturing and commercializing products for HIV or HBV. We received a non-refundable \$10.0 million upfront payment upon entering the Collaboration Agreement. 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 and \$11.0 million in milestone payments for the achievement of pre-clinical research milestones. In addition, we have recognized \$13.2 million of cost reimbursements for research and development services performed under the Collaboration Agreement.

#### **Operating Expenses**

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

#### Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities, including establishing our arenavirus platform, conducting preclinical studies, developing a manufacturing process, conducting a Phase 1 clinical trial and the ongoing Phase 2 clinical trial for HB-101 as well as initiating a Phase 1/2 trial

for HB-201 and preparing an IND for HB-202. Research and development activities account for a significant portion of our operating expenses. Research and development costs are expensed as incurred. These costs include:

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

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

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

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

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

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

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

#### General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs in our executive, finance and investor relations, business development and administrative functions. Other general and administrative expenses include consulting fees and professional service fees for auditing, tax and legal services, lease expenses related to our offices, premiums for directors and officers liability insurance, depreciation and other costs. We expect our general and administrative expenses to continue to increase in the future as we expand our operating activities and prepare for potential commercialization of our current and future product candidates, increase our headcount and investor relations activities and maintain compliance with requirements of the Nasdaq Global Select Market and the SEC.

#### **Grant Income**

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

# 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 we will likely not realize the benefits of the deferred tax asset, and accordingly, established a full valuation allowance as of June 30, 2020.

# **Results of Operations**

#### Comparison of Three and Six Months Ended June 30, 2020 and 2019

The following table summarizes our results of operations for the three and six months ended June 30, 2020 and 2019:

	Three months ended June 30,					Six months ended Jun			
		2020		2019		2020		2019	
Revenue from collaboration and licensing	\$	6,685	\$	4,051	\$ 1	10,381	\$	6,286	
Operating expenses:					-				
Research and development	(	11,564)		(13,929)	(2	23,090)		(24,108)	
General and administrative		(4,347)	4,347) (3,751)			(8,976)		(6,462)	
Total operating expenses	(	15,911)		(17,680)	(3	32,066)		(30,570)	
Loss from operations		(9,226)	(9,226) (13,629)		226) (13,629) (21,685		21,685)		(24,284)
Other income (expense):									
Grant income		1,595		1,544		3,067		2,736	
Interest income		59		511		371		575	
Interest expense		(166)		(166) (210)		.0) (393)		(423	
Other income and expenses, net		646		(195)		622		88	
Total other income (expense), net		2,134		1,650		3,667		2,976	
Net loss before tax		(7,092)		(11,979)	(2	18,018)		(21,308)	
Income tax expense		(0)		(100)		(0)		(100)	
Net loss	\$	(7,092)	\$	(12,079)	\$ (	18,018)	\$	(21,408)	

#### Revenue from Collaboration and Licensing

Revenue was \$6.7 million and \$10.4 million for the three and six months ended June 30, 2020, respectively, and \$4.1 million and \$6.3 million for the three and six months ended June 30, 2019, respectively.

The increase of \$2.6 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 was primarily due to higher cost reimbursements received under the Collaboration Agreement with Gilead and the partial recognition of a milestone payment we received from Gilead in February 2020. For the three months ended June 30, 2020, revenue included \$4.1 million from reimbursement of research and development expenses, \$1.6 million from partial recognition of revenue related to the upfront payment of \$10.0 million that we received in June 2018 and a milestone payment of \$4.0 million that we received in February 2020, as well as \$1.0 million of revenue that was recognized upon the achievement of a research milestone in June 2020. For the three months ended June 30, 2019, revenue from reimbursement of research and development expenses was \$0.7 million, revenue from partial recognition of the upfront payment was \$1.4 million and \$2.0 million of revenue was recognized upon the achievement of a research milestone in May 2019.

The increase of \$4.1 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily due to higher cost reimbursements received under the Collaboration Agreement with Gilead and the partial recognition of a milestone payment we received from Gilead in February 2020. For the six months ended June 30, 2020, revenue included \$6.8 million from reimbursement of research and development expenses, \$2.6 million from partial recognition of revenue related to the upfront payment of \$10.0 million that we received in June 2018 and a milestone payment of \$4.0 million that we received in February 2020, as well as \$1.0 million of revenue that was

recognized upon the achievement of a research milestone in June 2020. For the six months ended June 30, 2019, revenue from reimbursement of research and development expenses was \$2.0 million, revenue from partial recognition of the upfront payment was \$2.3 million and \$2.0 million of revenue was recognized upon the achievement of a research milestone in May 2019.

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

For the three and six months ended June 30, 2020, our research and development expenses were \$11.6 million and \$23.1 million, respectively, compared to \$13.9 million and \$24.1 million for the three and six months ended June 30, 2019.

The primary drivers of the decrease of \$2.3 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 were a decrease in manufacturing and quality control expenses of \$2.0 million along with a general decrease in other direct R&D expenses of \$1.1 million and a decrease in clinical operations expenses of \$0.6 million, partially offset by an increase in personnel expenses and stock based compensation by \$1.1 million and an overall increase of other R&D expenses. Manufacturing, quality control expenses and other direct R&D expenses decreased primarily due to the high level of expenses in the prior year period due to the preparation costs of clinical trials for our HB-201 and HB-202 programs and the expansion of earlier stage programs. Clinical operations expenses decreased due to the slow-down of recruitment in our clinical trials due to the COVID-19 pandemic. Personnel-related research and development expenses increased by \$1.1 million, primarily resulting from our increased research and development headcount and an increase in stock compensation expenses. In addition, an increase in facility related costs of \$0.2 million and in other internal costs of \$0.1 million contributed to the overall increase in internal research and development expenses of \$1.4 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019.

The primary drivers of the decrease of \$1.0 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 were a decrease in manufacturing and quality control expenses of \$2.7 million along with a general decrease in other direct R&D expenses of \$0.9 million, a decrease in clinical operations expenses of \$0.7 million and a decrease in R&D services of \$0.3 million, partially offset by an increase in personnel expenses and stock based compensation by \$2.6 million and an overall increase of other R&D expenses. Manufacturing, quality control expenses and other direct R&D expenses primarily decreased due to the high level of expenses in the prior year period due to the preparation costs of clinical trials for our HB-201 and HB-202 programs and the expansion of earlier stage programs. Clinical operations expenses decreased due to the slow-down of recruitment in our clinical trials in the second quarter of 2020 due to the COVID-19 pandemic. Personnel-related research and development expenses increased by \$2.6 million, primarily resulting from our increased research and development headcount and an increase in stock compensation expenses. In addition, an increase in facility related costs of \$0.3 million and in other internal costs of \$0.5 million contributed to the overall increase in internal research and development expenses of \$3.4 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019.

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

	 Three months	ended	Six months	d June 30,		
	2020		2019	2020		2019
Direct research and development expenses by program:						
HB-101	\$ 904	\$	1,274	\$ 2,249	\$	2,474
HB-201/202	2,134		3,681	4,088		6,746
Gilead partnered programs <sup>(1)</sup>	1,833		898	3,498		1,655
Other and earlier-stage programs	2,143		4,883	4,053		7,382
Sub-total direct expenses	7,014		10,736	13,888		18,257
Internal research and development expenses:						
Personnel related (including stock-based compensation)	3,208		2,128	6,578		3,979
Facility related	537		382	1,046		729
Other internal costs	805		683	1,578		1,143
Sub-total internal expenses	 4,550		3,193	9,202		5,851
Total research and development expenses	\$ 11,564	\$	13,929	\$ 23,090	\$	24,108

<sup>(1)</sup> 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 June 30, 2020 were \$4.3 million, compared to \$3.8 million for the three months ended June 30, 2019. The increase of \$0.5 million was primarily due to an increase in personnel-related expenses, which increased mainly due to an increase in stock compensation expenses, an increase in salaries and the growth in headcount in our general and administrative functions.

General and administrative expenses for the six months ended June 30, 2020 were \$9.0 million, compared to \$6.5 million for the six months ended June 30, 2019. The increase of \$2.5 million was primarily due to an increase in personnel-related expenses of \$1.8 million, and an increase in other general administrative expenses of \$1.1 million, partially offset by a decrease in professional and consulting fees of \$0.4 million. The increase in personnel-related expenses resulted from increased stock compensation expenses, increased salaries and a growth in headcount in our general and administrative functions. The decrease in professional and consulting fees resulted from the prior-year effect related to our IPO closing in April 2019 partially offset by an increase in costs associated with ongoing business activities and costs to operate as a public company.

#### **Grant Income**

In the three months ended June 30, 2020 we recorded grant income of \$1.6 million, compared to \$1.5 million in the three months ended June 30, 2019 from grants, research incentives and imputed benefits from below market interest rates on loans from governmental agencies. The increase of \$0.1 million was primarily due to higher income from Austrian research and development incentives, which was partially offset by the expiry of two grants from the Austrian Research Promotion Agency, or FFG.

In the six months ended June 30, 2020, we recorded grant income of \$3.1 million, compared to \$2.7 million in the six months ended June 30, 2019. The increase of \$0.4 million was primarily due to higher income from Austrian research and development incentives, which was partially offset by the expiry of two grants from the Austrian Research Promotion Agency.

# Interest Income and Expense

Interest income was \$0.1 million and \$0.4 million for the three and six months ended June 30, 2020, respectively, compared to interest income of \$0.5 million and \$0.6 million for the three and six months ended

June 30, 2019, respectively. The decrease in the six month ended June 30, 2020 was due to the drop in interest rates in the US. Interest income represents interest from cash and cash equivalents held in US dollars resulting from the proceeds from the issuance of Series D Preferred Stock, our IPO, and payments received under our collaboration with Gilead. During the three and six months ended June 30, 2020 our cash, cash equivalents and restricted cash were mainly held in dollars at US investment grade financial institutions or in money market funds. In addition smaller amounts were held in euros at our Austrian subsidiary which produced no material interest income due the low or zero interest rate policy in the European Monetary Union.

Interest expenses for loans from government agencies were \$0.2 million for both the three months ended June 30, 2020 and 2019 and \$0.4 million for both the six months ended June 30, 2020 and 2019. Interest expense was recorded at the market rate of interest, which exceeded the contractual interest.

#### **Other Income and Expenses**

In April 2020, we applied for support under the Corona Short-term Work Program in Austria to mitigate the financial impact of the COVID 19 pandemic. In the three months ended June 30, 2020, we recognized \$0.2 million in other operating income from non-refundable subsidies under this support program.

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

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

We have raised gross proceeds of approximately \$142.5 million from the issuance of our convertible preferred stock and \$21.0 million from non-refundable upfront and milestone payments pursuant to the Collaboration Agreement with Gilead. On April 23, 2019, we completed our IPO by issuing 6.0 million shares of our common stock, at \$14.00 per share, for gross proceeds of \$84.0 million, or net proceeds of \$74.6 million. As of June 30, 2020, the principal amount outstanding under loans from government agencies was \$6.0 million and we had cash, cash equivalents and restricted cash of \$93.3 million.

We have 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 June 30, 2020, the unamortized debt discount related to FFG Loans was \$2.2 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 June 30, 2020, we had an accumulated deficit of \$121.0 million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

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

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

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

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

ownership interest of our shareholders will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain additional funding on favorable terms when needed, we may have to delay, reduce the scope of or terminate one or more of our research and development programs or clinical trials.

#### Cash Flows

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

	Six months ended June 30,			
	2020			2019
Net cash used in operating activities	\$ (1	7,673)	\$	(23,453)
Net cash used in investing activities	(	(1,241)		(591)
Net cash provided by (used in) financing activities	(	(1,434)		111,166
Net increase (decrease) in cash and cash equivalents	(2	(0,348)		87,122

#### Cash Used in Operating Activities

During the six months ended June 30, 2020, cash used in operating activities was \$17.7 million, which consisted of a net loss of \$18.0 million, adjusted by non-cash charges of \$6.1 million and cash used due to changes in our operating assets and liabilities of \$5.8 million. The non-cash charges consisted primarily of stock-based compensation of \$4.2 million, depreciation and amortization expense of \$0.9 million and operating lease expenses of \$1.0 million. The change in our operating assets and liabilities was primarily due an increase in prepaid expenses and other current assets of \$6.4 million, a decrease in operating lease liabilities of \$0.9 million, a decrease of accrued expenses and other current liabilities of \$1.7 million and an increase in accounts receivable of \$3.0 million partially offset by an increase in deferred revenues of \$1.4 million and an increase in accounts payable of \$4.8 million.

During the six months ended June 30, 2019, cash used in operating activities was \$23.5 million, which consisted of a net loss of \$21.4 million, adjusted by non-cash charges of \$3.0 million and cash used due to changes in our operating assets and liabilities of \$5.1 million. The non-cash charges consisted primarily of depreciation and amortization expense of \$0.7 million, operating lease expenses of \$0.7 million and stock-based compensation of \$1.6 million. The change in our operating assets and liabilities was primarily due to an increase of \$5.6 million in prepaid expenses and other current assets, a decrease in deferred revenues of \$2.3 million, a decrease in operating lease liabilities of \$1.7 million, partially offset by a decrease in accounts receivable of \$1.9 million, a decrease in other non-current assets of \$0.2 million, an increase in accounts payable of \$1.0 million, and an increase in accrued expenses and current and non-current liabilities of \$1.4 million.

#### Cash Used in Investing Activities

During the six months ended June 30, 2020, cash used in investing activities was \$1.2 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 six months ended June 30, 2019, cash used in investing activities was \$0.6 million and resulted from capital expenditures in connection with an expansion of our laboratory and office space and purchase of property and equipment.

#### Cash Used in or Provided by Financing Activities

During the six months ended June 30, 2020, cash used for financing activities was \$1.4 million and resulted primarily from the repayment of a loan and payments associated with our shelf registration statement and our ATM-facility.

During the six months ended June 30, 2019, cash provided by financing activities was \$111.2 million, which consisted of net proceeds of \$37.3 million from the issuance of shares of our Series D convertible preferred stock in February 2019, and net proceeds of \$75.3 million from our IPO closing in April 2019, partially offset by an upfront payment for embedded finance lease assets.

#### **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 June 30, 2020 (in thousands):

	Payments Due by Calendar Year																																																					
	Total		Total		Total		Total		Less Than 1 Year				Less Than 1 Year																																1 - 3 Years							4 - 5 Years		re than Years
Lease commitments	\$	6,961	\$	1,985	\$	3,911	\$	1,065	\$	_																																												
CMO commitments		7,675		4,787		2,888		_		_																																												
Debt obligations		6,031		_		4,840		1,191		_																																												
Total	\$	20,667	\$	6,772	\$	11,639	\$	2,256	\$	_																																												

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.

There have been no material changes in our critical accounting policies during the six months ended June 30, 2020, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and

Results of Operations - Critical Accounting Policies" in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 19, 2020.

#### **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-O.

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

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

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during our most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. For so long as we remain a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure and other requirements that are applicable to other public companies that are not smaller reporting companies.

#### Item 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, cash equivalents and restricted cash as of June 30, 2020 included small amounts of cash balances held by Hookipa Biotech GmbH in euro. We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and restricted cash of \$93.3 million as of June 30, 2020, which included account balances with foreign banks. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, we do not believe that we have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates.

### Item 4. Controls and Procedures

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

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

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

As of June 30, 2020, management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934). Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of June 30, 2020.

#### **Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rules 13a 15(f) and 15d 15(f) under the Exchange Act) indentified that occurred during the three months ended June 30, 2020 that have materially affected, or are 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

In light of the rapid spread of SARS-CoV-2, which causes coronavirus disease 2019, or COVID-19, in the United States and globally, we are updating and supplementing our risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 19, 2020 to add the following new risk factor:

#### Our business may be adversely affected by the ongoing coronavirus pandemic

Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business activities and could cause significant disruption in the operations of third party manufacturers and CROs upon whom we rely. For example, beginning in late 2019, the outbreak of a novel strain of virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID-19, has evolved into a global pandemic. As of late March 2020, the coronavirus had spread to most regions of the world

As a result of the COVID-19 pandemic, we have experienced and may further experience disruptions that have and could further impact our business, preclinical studies and clinical trials, including:

- We believe that the COVID-19 pandemic has had, and will likely continue to have, an impact on various aspects of our clinical trials. For example, nearly all the Phase 2 trial sites we utilize in our HB-101 Phase 2 trial had temporarily suspended enrollment of patients and while many of them have recently resumed patient enrollment, it is unclear when all of the trial sites will be fully reactivated. And, for example, with clinical trials, investigators may not want to take the risk of exposing patients to COVID-19 since the dosing of patients is conducted within an in-patient setting. Other potential impacts of the coronavirus pandemic on our various clinical trials include patient dosing and study monitoring, which may be paused or delayed due to changes in policies at various clinical sites, federal, state, local or foreign laws, rules and regulations, including quarantines or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trials, interruption or delays in the operations of the U.S. Food and Drug Administration, or the FDA, or other reasons related to the coronavirus pandemic. If the coronavirus pandemic continues, other aspects of our clinical trials may be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, availability of clinical trial materials, and data analysis. Some patients and clinical investigators may not be able to comply with clinical trial protocols and patients may choose to withdraw from our studies or we may have to pause enrollment or we may choose to or be required to pause enrollment and or patient dosing in our ongoing clinical trials in order to preserve health resources and protect trial participants. It is unknown how long these pauses or disruptions could continue.
- We currently rely on third parties to, among other things, manufacture raw materials, manufacture our product candidates for our clinical trials, handle shipping of investigational drugs and clinical trial samples, perform quality testing and supply other goods and services to run our business. Certain of our third party manufacturers and suppliers have paused their operations in response to the coronavirus pandemic or have otherwise encountered delays in providing their services. As a result, we may not be able to manufacture our product candidates for our clinical trials and conduct other research and development operations and maintain current clinical and pre-clinical timelines. In addition, if

additional third parties in our supply chain for materials are adversely impacted by restrictions resulting from the coronavirus pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted in other ways, further limiting our ability to manufacture our product candidates for our clinical trials and conduct our research and development operations.

- We have recommended that all of our administrative employees work remotely, restricted on-site staff to only those personnel and contractors performing activities that must be completed on-site and limited the number of staff in any given research and development laboratory. In addition, all of our officers have waived at least 25% of their cash salaries for the three months ended June 30, 2020, and the vast majority of our employees agreed to a temporary salary reduction of 20%. We compensated our officers and employees for the forgone cash salaries by issuing restricted stock units in July 2020. Our directors have also accepted to receive equity instead of cash for their accrued board fees. Nevertheless, our increased reliance on personnel working from home, coupled with temporary salary reductions, may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, the remote access of employees could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors.
- Access to our laboratories by our employees and contractors conducting research and development activities may be limited for an extended period of time as a result of the social distancing requirements and the possibility that governmental authorities further modify current restrictions now, or in the future, if additional waves of coronavirus infections were to occur. As a result, this could delay timely completion of preclinical activities, including completing Investigational New Drug-enabling studies or our ability to select future development candidates, and initiation of additional clinical trials for other of our development programs. In addition, we could encounter delays in connection with implementing precautionary measures to mitigate the risk of exposing our facilities and employees to the coronavirus (for example, implementing screening procedures or procuring appropriate non-medical personal protective equipment for use while in our facilities) or otherwise in connection with addressing an actual or potential exposure to the coronavirus (for example, temporarily closing all or a portion of a facility or disinfecting all or a portion of a facility that may have been exposed to the coronavirus).
- Health regulatory agencies globally may experience disruptions in their operations as a result of the coronavirus pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection, and other timelines may be materially delayed. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. For example, regulatory authorities may require that we not distribute a product candidate lot until the relevant agency authorizes its release. Such release authorization may be delayed as a result of the coronavirus pandemic and could result in delays to our clinical trials.
- The trading prices for shares of our common stock and other biopharmaceutical companies have been
  highly volatile as a result of the coronavirus pandemic. As a result, we may face difficulties raising
  capital through sales of shares of our common stock or such sales may be on unfavorable terms. In
  addition, a recession, depression or other sustained adverse market event resulting from the spread of the
  coronavirus could materially and adversely affect our business and the value of our shares of common
  stock

In our key business locations in New York and Vienna, Austria, temporary restrictions imposed by the governments, states or local authorities have helped to slow down the further spread of COVID-19 and have led to a

reduction in infection rates. However, the coronavirus pandemic continues to rapidly evolve in other regions of the United States and the world. The ultimate impact of the coronavirus pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, additional or modified government actions, new information that will emerge concerning the severity and impact of coronavirus and the actions taken to contain coronavirus or address its impact in the short and long term, among others. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy. In addition, to the extent that the COVID-19 pandemic adversely affects our business, net assets, financial condition and results of operations, it may also have the effect of heightening many of the other risks described in this report and under "Risk Factors" in our 2019 Form 10-K. We will continue to monitor the situation closely.

There have been no other material changes from the risk factors disclosed in our Annual Report on Form 10-K filed with the SEC on March 19, 2020. Please refer to the complete Part I, Item 1A of our Annual Report for additional risks and uncertainties we are facing that may have a material adverse effect on our business prospects, financial condition and results of operations.

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

There were no unregistered sales of equity securities by us during the six months ended June 30, 2020.

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

The net proceeds from the offering have been partially invested in a money market fund and partially deposited in an interest-bearing bank account with an investment grade financial institution. There has been no material change in our planned use of the net proceeds from the offering as described in our Prospectus 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.

Exhibit Number	Description
31.1	Certificate of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certificate of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certificate of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

<sup>\*</sup> 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: August 13, 2020 By:/s/ Joern Aldag

Joern Aldag

Chief Executive Officer (Principal Executive Officer)

By:/s/ Reinhard Kandera

Reinhard Kandera

Chief Financial Officer (Principal Financial Officer)

# 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: August 13, 2020 /s/ Joern Aldag

Joern Aldag Chief Executive Officer (Principal Executive Officer)

# 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 Kandera, 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: August 13, 2020 /s/ Reinhard Kandera

Reinhard Kandera Chief Financial Officer (Principal Financial Officer)

# 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 June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Joern Aldag and Reinhard Kandera, 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: August 13, 2020 /s/ Joern Aldag

Joern Aldag

Chief Executive Officer (Principal Executive Officer)

Dated: August 13, 2020 /s/ Reinhard Kandera

Reinhard Kandera Chief Financial Officer (Principal Financial Officer)