# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

# **FORM 10-Q**

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

For the quarterly period ended September 30, 2023

1 of the quarterly period chaca september 50, 2025
OR
$\hfill\Box$ Transition report pursuant to section 13 or 15(d) of the securities exchange act of 1934
For the transition period from to  Commission File Number: 001-38869
HOOKIPA PHARMA INC. (Exact Name of Registrant as Specified in its Charter)

**Delaware** (State or other jurisdiction of incorporation or organization)

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

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

10118 (Zip Code)

Registrant's telephone number, including area code: +43 1 890 63 60 Securities registered pursuant to Section 12(b) of the Act:

# 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 filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  $\ ^{\circ}$  Yes  $\ ^{\circ}$  No  $\ ^{\circ}$ 

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting

company, and emerging grow	un company in Rule 120-2 of the Exchange Act.		
Large accelerated filer Non-accelerated filer Emerging growth Company		Accelerated filer Smaller reporting company	
If an emerging growth compan	— y, indicate by check mark if the registrant has elected not to use the exised financial accounting standards provided pursuant to Section 13(a		
Indicate by check mark whether	er the registrant is a shell company (as defined in Rule 12b-2 of the Ad	et). Yes □ No ⊠	

As of November 2, 2023, the registrant had 81,550,590 shares of common stock and 2,399,517 shares of Class A common stock outstanding, each \$0.0001 par value per share.

#### FORWARD-LOOKING STATEMENTS

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

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

- our expectations about market trends; and
- our ability to comply with Nasdaq listing rules and our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended.

All of our forward-looking statements are as of the date of this 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/), Securities and Exchange Commission 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)

	Sep	tember 30, 2023	Dec	ecember 31, 2022	
Assets					
Current assets:					
Cash and cash equivalents	\$	107,676	\$	112,488	
Restricted cash		_		537	
Accounts receivable		675		6,533	
Receivable research incentives		22,375		15,479	
Prepaid expenses and other current assets		8,745		12,159	
Total current assets		139,471		147,196	
Non-current assets:					
Restricted cash		419		419	
Property, plant and equipment, net		20,167		17,970	
Operating lease right of use assets		2,862		4,006	
Other non-current assets	_	1,091		863	
Total non-current assets		24,539	_	23,258	
Total assets	\$	164,010	\$	170,454	
Liabilities and Stockholders' Equity					
Current liabilities					
Accounts payable	\$	8,929	\$	5,488	
Deferred revenues		16,054		15,684	
Operating lease liabilities, current		1,498		1,688	
Accrued expenses and other current liabilities		13,069		11,178	
Loans payable, current		1,026		1,594	
Total current liabilities		40,576		35,632	
Non-current liabilities					
Loans payable, non-current		_		911	
Operating lease liabilities, non-current		1,330		2,310	
Deferred revenues, non-current		23,719		25,664	
Other non-current liabilities		3,334		3,420	
Total non-current liabilities		28,383		32,305	
Total liabilities		68,959		67,937	
Commitments and contingencies (Note 12)					
Staglikaldow? aguittu					
Stockholders' equity: Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at September 30, 2023 and					
December 31, 2022, respectively; Series A convertible preferred stock, 2,978 shares designated, 370 and 1,697 shares outstanding at September 30, 2023 and December 31, 2022, respectively; Series A-1 convertible preferred stock, 15,800 shares designated, 10,800 and 15,800 shares outstanding at September 30, 2023 and					
December 31, 2022, respectively; Series A-2 convertible preferred stock, 15,268 shares and no shares		0		0	
designated, and 15,268 and no shares outstanding at September 30, 2023 and December 31, 2022, respectively Common stock, \$0.0001 par value; 200,000,000 shares authorized at September 30, 2023 and		U		U	
December 31, 2022, respectively; 81,550,590 shares and 52,317,138 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively		8		5	
Class A common stock, \$0.0001 par value; 3,900,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; 2,399,517 shares issued and outstanding at September 30, 2023 and					
December 31, 2022, respectively		0		0	
Additional paid-in capital		445,512		397,349	
Accumulated other comprehensive loss		(6,026)		(7,156	
Accumulated deficit		(344,443)		(287,681	
Total stockholders' equity		95,051		102,517	
Total liabilities and stockholders' equity	\$	164,010	\$	170,454	

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

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

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

	Thr	ee months end	led Se	<u>ptember 30,</u> 2022	Ni	ne months en 2023	ded September 30, 2022		
Revenue from collaboration and licensing	\$	6,867	\$	2,230	\$	12,722	\$	6,421	
Operating expenses:	•	0,00	-	_,	-	,	-	٠, ٠_ــ	
Research and development		(24,625)		(18,286)		(65,262)		(51,053)	
General and administrative		(4,912)		(4,937)		(14,259)		(14,935)	
Total operating expenses		(29,537)		(23,223)		(79,521)		(65,988)	
Loss from operations		(22,670)	_	(20,993)	-	(66,799)		(59,567)	
Other income (expense):									
Grant income	\$	2,916	\$	2,081	\$	7,486	\$	5,926	
Interest income		1,570		535		4,052		724	
Interest expense		(49)		(105)		(268)		(579)	
Other income and (expenses), net		(833)		202		(1,029)		893	
Total other income, net		3,604		2,713		10,241	_	6,964	
Net loss before tax		(19,066)		(18,280)		(56,558)		(52,603)	
Income tax expense		0	_	(0)		(204)	_	(1)	
Net loss		(19,066)		(18,280)		(56,762)		(52,604)	
		(-0,000)		(==,===)	_	(00,00)		(==,===)	
Other comprehensive (loss) income:									
Foreign currency translation gain (loss), net of tax		1,216		(1,367)		1,130		(2,855)	
Comprehensive loss	\$	(17,850)	\$	(19,647)	\$	(55,632)	\$	(55,459)	
Net loss per share — basic and diluted	\$	(0.17)	\$	(0.25)	\$	(0.64)	\$	(0.83)	

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

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

# (In thousands, except share amounts)

	Conv	ed Sto	ck	Common	Stock		mmon Stock	Additio	n	Accumulated Other Comprehensive	A	ccumulated	Sto	Total ockholders'
n. 1	Shares	Am	ount	Shares	Amoun	Shares	Amount	Capita	<u> 11                                  </u>	Loss		Deficit	_	Equity
Balances as of December 31, 2022	17,497	\$	0	52,317,138	\$ 5	2,399,517	\$ 0	\$ 397,3	49	\$ (7,156)	\$	(287,681)	\$	102,517
Issuance of common stock														
upon exercise of stock options	_		_	5,684	0		_		1	_		_		1
Foreign currency translation														
adjustment, net of tax	_		_	_	_	_	_		—	(17)		_		(17)
Stock-based compensation														
expense	_		_	_	_	_	_	$\epsilon$	558			_		658
Net loss			_						_			(19,680)		(19,680)
Balances as of	4= 40=			== === ===		2 200 =4=				<b>*</b> (= 4=0)		(20= 204)		00.450
March 31, 2023	17,497	\$	0	52,322,822	\$ 5	2,399,517	\$ 0	\$ 398,0	800	\$ (7,173)	\$	(307,361)	\$	83,479
Conversion of Series A														
convertible preferred stock to														
common stock	(1,327)		(0)	1,327,000	0	_	_		(0)	_		_		_
Conversion of Series A-1														
convertible preferred stock to														
common stock	(5,000)		(0)	5,000,000	1	_	_		(1)			_		_
Issuance of Series A-2 convertible preferred stock upon public offering at \$1,310 per share for cash, net of issuance costs of \$1.470	15,268		0					18,5	.21					18,531
Issuance of common stock	15,268		U	_	_	_	_	10,5	31	_		_		16,531
upon public offering at \$1.31 per share for cash, net of														
issuance costs of \$2,205	_		_	22,900,768	2	_	_	27,7				_		27,795
ATM costs	_		_	_	_	_	_	(	(86)	_		_		(86)
Foreign currency translation adjustment, net of tax	_		_	_	_	_	_		_	(69)		_		(69)
Stock-based compensation														606
expense	_		_	_	_	_	_	6	96	_				696
Net loss			_						_			(18,016)		(18,016)
Balances as of June 30, 2023	26,438	\$	0	81,550,590	\$ 8	2,399,517	\$ 0	\$ 444,9	41	\$ (7,242)	\$	(325,377)	\$	112,330
Issuance costs Series A-2 convertible preferred stock			_	_					(1)	_		_		(1)

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Issuance costs common stock										
upon public offering	_	_	_	_	_	_	(2)	_	_	(2)
Foreign currency translation										
adjustment, net of tax	_	_	_	_	_	_	_	1,216	_	1,216
Stock-based compensation										
expense	_	_	_	_	_	_	574	_	_	574
Net loss	_	_	_	_	_	_	_	_	(19,066)	(19,066)
Balances as of										
September 30, 2023	26,438	\$ 0	81,550,590	\$ 8	2,399,517	<u>\$</u>	\$ 445,512	\$ (6,026)	\$ (344,443)	\$ 95,051

							on Stock			Additional	Accumulated Other				Total
	Preferr			Common			Class A Cor			Paid-In	Comprehensive		Accumulated		ckholders'
- 1	Shares	Amo	ount	Shares	An	ount	Shares	Amo	unt	Capital	Income (Loss)		Deficit		Equity
Balances as of December 31, 2021	1,697	\$	0	27,383,483	\$	3	3,819,732	\$	0	\$ 317,135	\$ (4,78	n) (	\$ (222,766)	\$	89,592
Issuance of Series A-1	1,037	J.	U	27,303,403	Ф		3,013,732	J.		\$ 317,133	J (4,70	<u> </u>	(222,700)	Φ	03,332
convertible preferred stock upon public offering at \$2,000 per share for cash, net of	15,800		0							20.625					20.625
issuance costs of \$1,975	15,800		U			_			_	29,625		_			29,625
Issuance of common stock upon public offering at \$2.00 per share for cash, net of issuance costs of \$2,713	_		_	21,700,000		2	_		_	40,685	_	_	_		40,687
Issuance of common stock upon stock purchase agreement with Gilead at \$3.00 per share for cash, no										·					·
issuance costs	_		_	1,666,666		0	_		_	5,000	_	_	_		5,000
Issuance of common stock upon exercise of stock options	_		_	10,034		0	_		_	1	-	_	_		1
Vesting of equity grants			_	112,551		0			_	(0)		_			
ATM costs	_		_	_		_	_		_	(142)	-	-	_		(142)
Foreign currency translation adjustment, net of tax	_		_			_	_		_	_	(48	7)	_		(487)
Stock-based compensation										4.604					4.604
expense	_		_	_		_	_		_	1,621	-	-			1,621
Net loss			_					_					(17,968)		(17,968)
Balances as of March 31, 2022 Issuance of common stock	17,497	\$	0	50,872,734	\$	5	3,819,732	\$	0	\$ 393,925	\$ (5,26	7)	\$ (240,734)	\$	147,929
upon exercise of stock options Foreign currency translation	_		_	12,062		0	_		_	1	_	_	_		1
adjustment, net of tax Stock-based compensation	_		_	_		_	_		_	_	(1,00	1)	_		(1,001)
expense	_		_	_		_	_		_	1,381	_	_	_		1,381
Net loss	_		_	_		_	_		_	_	_	-	(16,356)		(16,356)
Balances as of June 30, 2022	17,497	\$	0	50,884,796	\$	5	3,819,732	\$	0	\$ 395,307	\$ (6,26	8) 3	\$ (257,090)	\$	131,954
Conversion of Class A common stock to common stock									(0)			≠ :		_	
				1,420,215		0	(1,420,215)		(0)	_	_	-	_		_
Issuance of common stock upon exercise of stock options	_		_	12,127		0	_		_	1	-	_	_		1

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Foreign currency translation								(1.207)		(1.267)
adjustment, net of tax	_	_	_	_	_	_	_	(1,367)	_	(1,367)
Stock-based compensation										
expense	_	_	_	_	_	_	1,040	_	_	1,040
Net loss	_	_	_	_	_	_	_	_	(18,280)	(18,280)
Balances as of										
September 30, 2022	17,497	\$ 0	52,317,138	\$ 5	2,399,517	\$ 0	\$ 396,348	\$ (7,635)	\$ (275,370)	\$ 113,348

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

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

# (In thousands)

	Nir	Nine months ended Septemb					
		2023		2022			
Operating activities:							
Net loss	\$	(56,762)	\$	(52,604)			
Adjustments to reconcile net loss to net cash used in operating activities:							
Stock-based compensation expense		1,928		4,042			
Depreciation and amortization expense		2,274		2,698			
Other non-cash items		4		(12)			
Changes in operating assets and liabilities:							
Accounts receivable		5,838		5,405			
Receivable research incentives		(7,227)		(5,383)			
Prepaid expenses and other current assets		3,507		1,743			
Other non-current assets		(242)		251			
Accounts payable		4,104		1,588			
Deferred revenues		(1,161)		10,323			
Operating lease liabilities		(819)		(1,223)			
Accrued expenses and other liabilities		2,052		(254)			
Other non-current liabilities		204		292			
Net cash used in operating activities		(46,300)		(33,134)			
Investing activities:		/a =a=:		(			
Purchases of property and equipment		(3,737)		(4,418)			
Net cash used in investing activities	<u></u>	(3,737)		(4,418)			
		(0,101)		(1,110)			
Financing activities:							
Payments related to finance leases		_		(24)			
Proceeds from issuance of convertible preferred stock, net of issuance costs		18,530		29,625			
Proceeds from issuance of common stock, net of issuance costs		27,794		45,691			
Payments for deferred offering costs		(149)		_			
Repayments of borrowings		(1,754)		(2,825)			
Not each provided by financing activities		44,421		72.467			
Net cash provided by financing activities	<u></u>	44,421	_	72,467			
Net (decrease) increase in cash, cash equivalents and restricted cash		(5,616)		34,915			
Cash, cash equivalents and restricted cash at beginning of period		113,444		66,912			
Effect of exchange rate changes on cash, cash equivalents and restricted cash		267		(1,151)			
Cash, cash equivalents and restricted cash at end of period	\$	108,095	\$	100,676			
Supplemental disclosure of cash flow information:		(40)		(0.1)			
Cash paid for interest	\$	(10)	\$	(21)			
Cash paid for income taxes	\$	(204)	\$	(1)			
Supplemental disclosure of non-cash financing activities:							
Property and equipment additions in accounts payable and accrued expenses	\$	(121)	\$	(239)			
Lease assets obtained in exchange for new operating lease liabilities	\$	19	\$	227			
Lease assets obtained in exchange for new operating lease liabilities	\$	19	\$	227			

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

## 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 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 consolidated balance sheet as of December 31, 2022 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying condensed consolidated balance sheet as of September 30, 2023, the condensed consolidated statements of operations, and comprehensive loss for the three and nine months ended September 30, 2023 and 2022, the condensed consolidated statement of convertible preferred stock and stockholders' equity for the three and nine months ended September 30, 2023 and 2022 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2023 and 2022 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, 2022 included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission ("SEC"). 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 September 30, 2023, the Company has funded its operations with proceeds from sales of common stock, sales of convertible preferred stock, sales of redeemable convertible preferred stock, collaboration and licensing agreements, grants and borrowings under various agreements with foreign public funding agencies. Since inception, the Company has incurred recurring losses, including net losses of \$56.8 million for the nine months ended September 30, 2023 and \$64.9 million for the year ended December 31, 2022. As of September 30, 2023, the Company had an accumulated deficit of \$344.4 million. The Company expects to continue to generate operating losses in the foreseeable future. As of November 9, 2023, 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 may 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 and general and administrative expenses, the present value of lease right of use assets and corresponding liabilities, the valuation of stock-based awards and the valuation of current and non-current loans payable. 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.

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.

# **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

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

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 condensed 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. For the three and nine months ended September 30, 2023 and September 30, 2022 the net proceeds from the Company's offerings have been deposited in interest-bearing bank accounts with two of the largest investment grade U.S. financial institutions and have been partially invested in money market funds. The money market funds, held in U.S. dollars, are primarily invested in U.S. and foreign short-term debt obligations. As of September 30, 2023 and December 31, 2022, the Company's cash and cash equivalents included smaller amounts of cash balances held in accounts with regional European banks at the Company's Austrian subsidiary, partially in euros. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

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

As of September 30, 2023 and December 31, 2022, Gilead Sciences, Inc. ("Gilead") and F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (together "Roche") accounted for the majority of the accounts receivable balance. For the three and nine months ended September 30, 2023 and the three and nine month ended September 30, 2022 Gilead and Roche accounted for the majority of the Company's revenues. Other customers accounted for less than 10.0% of accounts receivable or net sales. The Company monitors the financial performance of its customers so that it can appropriately respond to changes in their credit worthiness. To date, the Company has not experienced any significant losses with respect to collection of its accounts receivable.

# Cash equivalents

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. As of September 30, 2023 and December 31, 2022, cash equivalents consisted of money market funds and short-term deposits.

#### 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.

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

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to
determining the fair value of the assets or liabilities, including pricing models, discounted cash flow
methodologies and similar techniques.

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

#### Property and equipment

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

	Estimated useful life
	shorter of useful life or
Leasehold improvements	term of lease
Laboratory equipment	2 - 10 years
Furniture and fixtures	2 - 10 years
Computer equipment and software	2 - 4 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Expenditures for repairs and maintenance are charged to expense as incurred. When property and equipment is sold or otherwise disposed of, the cost and related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is reflected in the consolidated statements of operations.

#### Leases

The determination whether an arrangement qualifies as a lease is made at contract inception. A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset to the Company by the end of the lease term, (ii) the Company holds an option to purchase the leased asset that it is reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, or (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term. All other leases are recorded as operating leases and are included in right of use ("ROU") assets and lease liabilities in the consolidated balance sheets. For leases with an initial term of 12 months or less, the Company does not recognize a right of use asset or lease liability. These short-term leases are expensed on a straight-line basis over the lease term.

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

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

assets, in accrued expenses and other current liabilities and in other non-current operating lease liabilities in the consolidated balance sheets. The ROU asset is tested for impairment in accordance with Accounting Standards Codification ("ASC") 360.

#### **Capitalized Software Development Cost**

The Company capitalizes certain implementation costs for internal-use software incurred in a cloud computing agreement that is a service contract. Eligible costs associated with cloud computing arrangements, such as software business applications used in the normal course of business, are capitalized in accordance with ASC 350. These costs are recognized on a straight-line basis in the same line item in the statement of operations and comprehensive loss as the expense for fees for the associated cloud computing arrangement, over the term of the arrangement, plus reasonably certain renewals.

#### Revenue recognition from contracts with customers

The Company recognized revenue from collaboration and license agreements with Gilead and Roche.

Under the collaboration and license agreement with Gilead (as amended and restated, the "Gilead Collaboration Agreement"), the parties agreed to collaborate with respect to two preclinical research programs to evaluate potential vaccine products for the treatment, cure, diagnosis or prevention of the hepatitis B virus ("HBV") and the human immunodeficiency virus ("HIV"). In February 2022, the parties signed an amended and restated collaboration agreement (the "Restated Gilead Collaboration Agreement"), which revised the terms only for the HIV program, whereby the Company will take on development responsibilities for the HIV program candidate through a Phase 1b clinical trial. The Company's performance obligations under the terms of the original agreement include one combined performance obligation for each research program (HBV and HIV) comprised of the transfer of intellectual property rights (licenses) and providing research and development services. The terms of the Restated Gilead Collaboration Agreement added an additional performance obligation to perform research and development work for the HIV program. The licenses do not represent distinct performance obligations, because they cannot be used without the research and development services. Payments to the Company under the Restated Gilead Collaboration Agreement include a non-refundable up-front payment, payments for research and development activities, payments based upon the achievement of defined milestones, and if certain future conditions are met, payments for manufacturing services, commercial milestones and royalties on product sales.

Under the research collaboration and license agreement with Roche (the "Roche Collaboration Agreement"), the Company has agreed to conduct research and early clinical development through Phase 1b for HB-700, a novel investigational arenaviral immunotherapy for the treatment of KRAS-mutated cancers. The Roche Collaboration Agreement also includes an obligation of the Company to deliver a specified package of preclinical data and results with respect to a second program, targeting undisclosed cancer antigens (collectively "UCAs") and an option for Roche to license the UCA program. The Company's performance obligations under the terms of the Roche Collaboration Agreement include one combined performance obligation for the transfer of intellectual property rights (licenses) and providing research and development services for the HB-700 program, and a second, separate performance obligation to perform research and development services with respect to the UCA program. The UCA Option provides a right to license the program at the standalone selling price and therefore does not constitute a separate performance obligation. Payments to the Company under the Roche Collaboration Agreement include a non-refundable up-front payment, payments based upon the achievement of defined milestones, an additional payment if the option for the UCA program is exercised and royalties on product sales.

The Company evaluates its collaboration and licensing arrangements pursuant to ASC 606 Revenue from Contracts with Customers. To determine the recognition of revenue from arrangements that fall within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the

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

performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation.

Under ASC 606, the Company applies significant judgement to evaluate whether the promises under the collaboration and licensing arrangements, represent separate or one or more combined performance obligations, the allocation of the transaction price to identified performance obligations, the timing of revenue recognition, whether the UCA Option constitutes a material right, and the determination of when milestone payments are probable of being received.

Upfront payment and program initiation fee

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

The non-refundable program initiation payment received from Gilead upon signing of the Restated Collaboration Agreement was also initially recorded as deferred revenue and is recognized on a percent of completion basis using total estimated research and development costs (input method) for the performance of the obligations. The percent of completion basis using research and development costs was considered the best measure of progress in which control of the performance obligations transfers to the customer, due to the immediate benefit that it adds to the value of the customer's rights on the program, the short time intervals in which development results are shared and the nature of the work being performed.

The non-refundable upfront-payment received by the Company upon signing of the Roche Collaboration Agreement, was initially recorded as deferred revenue and allocated between the HB-700 program and the UCA program. Such amounts are recognized as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development costs (input method) for each of the obligations during the initial term of the contract. The percent of completion basis using research and development costs was considered the best measure of progress in which control of the performance obligations transfers to the customer.

# Reimbursement for services

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

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

Research and development milestones

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

Sales-based milestones and royalty payments

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

Cost to fulfill contracts

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

#### 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.

Recently Issued Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40). The ASU provides guidance that simplified the accounting for certain financial instruments with characteristics of liabilities and equity. The new guidance reduced the number of accounting models for convertible debt and convertible preferred stock instruments and made certain disclosure amendments intended to improve the information provided to users. The guidance also amended the derivative guidance for the "own stock" scope exception, which exempts qualifying instruments from being accounted for as derivatives if certain criteria are met. Finally, the standard changed the way certain convertible instruments are treated when calculating earnings per share. This guidance is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, with early adoption permitted. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

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

#### 3. Collaboration and Licensing Agreements

### Gilead Collaboration and License Agreement

In June 2018, the Company entered into the Gilead Collaboration Agreement whereby the Company and Gilead agreed to collaborate with respect to two preclinical research programs to evaluate potential vaccine products for the treatment, cure, diagnosis or prevention of HBV and HIV. In February 2022, the Company signed the Amended and Restated Collaboration Agreement, which altered key aspects of the collaboration pertaining to the HIV therapeutic. Most importantly, the Amended and Restated Collaboration Agreement allocated additional research and development responsibility to the Company with respect to the Company's HIV candidate and provided for additional funding by Gilead of such research and development activities as well as increased later stage development and commercial milestone payments.

Under the Gilead Collaboration Agreement, the Company granted Gilead an exclusive, royalty-bearing license to the Company's technology platforms. Upon entering into the agreement in June 2018, the Company received a non-refundable \$10.0 million upfront payment from Gilead and upon signing of the Restated Gilead Collaboration Agreement in February 2022, the Company received a program initiation fee of \$15.0 million. Gilead is also obligated to make additional payments to the Company upon the achievement of pre-clinical, development and commercial milestones. The development milestones amount to \$140.0 million for the HBV program, and up to \$172.5 million for the HIV program, inclusive of a \$10.0 million program completion fee, payable upon Gilead's exercise of the option to pursue further development activities post Phase 1b. The commercial milestones amount to a total of \$50.0 million for the HBV program, and \$65.0 million for the HIV program. Additionally, Gilead is obligated to pay royalties on net sales for each program. Payments from Gilead generally have a 60-day payment term.

The \$10.0 million upfront payment, the \$15.0 million initiation fee and \$8.0 million in milestone payments were initially recorded as deferred revenue in the consolidated balance sheet and are recognized as revenue when revenue recognition criteria are met. As of September 30, 2023, \$10.5 million of such payments were still recorded as a liability in deferred revenues, current and non-current. As of December 31, 2022, \$14.3 million of upfront, initiation and milestone payments were included as a liability in deferred revenues, current. Approximately 4% of deferred revenue is expected to be recognized as revenue in the remainder of 2023, 46% in 2024, 34% in 2025 and the remaining 16% in 2026.

In the three months ended September 30, 2023, the Company recognized \$1.2 million of the milestone and initiation payments that were originally recorded as deferred revenue. Furthermore, the Company recognized \$0.5 million revenue from cost reimbursements for research and development services. In the three months ended September 30, 2022, the Company recognized \$1.3 million of the upfront and milestone payments that were originally recorded as deferred revenue. Furthermore, the Company recognized \$0.9 million revenue from cost reimbursements for research and development services.

In the nine months ended September 30, 2023, the Company recognized \$3.8 million of the milestone and initiation payments that were originally recorded as deferred revenue. Furthermore, the Company recognized \$1.3 million revenue from cost reimbursements for research and development services. In the nine months ended September 30, 2022, the Company recognized \$2.9 million of the upfront and milestone payments that were originally recorded as deferred revenue. Furthermore, the Company recognized \$3.5 million revenue from cost reimbursements for research and development services.

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 September 30, 2023 and December 31, 2022, the contract asset relating to

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

the sublicense payment was \$0.2 million and \$0.2 million, respectively, and there was no liability relating to sublicense payment.

#### Roche Collaboration and License Agreement

In October 2022, the Company entered into the Roche Collaboration Agreement whereby the Company and Roche agreed to collaborate with respect to the development of novel arenaviral immunotherapies for KRAS-mutated cancers and, potentially, a second, novel arenaviral immunotherapeutic program targeting specific undisclosed cancer antigens.

Under the Roche Collaboration Agreement, the Company granted Roche an exclusive, royalty-bearing license to the Company's technology platforms. Upon signing the Roche Collaboration Agreement in October 2022, the Company received a non-refundable upfront payment of \$25.0 million and Roche will be obliged to pay an additional \$15.0 million payment if the option for the UCA program is exercised. The Company is also eligible for event-based milestone payments of up to an aggregate of \$335.0 million during the research and development phase of the HB-700 program for up to four oncology indications and up to an aggregate of \$250.0 million in payments related to the achievement of sales-based milestones. For the additional UCA program, subject to option-exercise, the Company is eligible for up to an aggregate of \$173.0 million in event-based milestone payments during research and development for up to four oncology indications as well as up to an aggregate of \$160.0 million in sales-based milestones. Upon commercialization, the Company is eligible to receive tiered royalties on the worldwide net sales of HB-700 and, subject to option exercise, the UCA program. The royalty payments are subject to reduction under specified conditions set forth in the Roche Collaboration Agreement. Payments from Roche generally have payment terms between 30 days and 60 days.

The \$25.0 million upfront payment, and a \$10.0 million milestone payment received in the three months ended March 31, 2023 were initially recorded as deferred revenue in the consolidated balance sheet and are recognized as revenue when revenue recognition criteria are met. As of September 30, 2023, \$29.3 million of such payments were still recorded as a liability in deferred revenues, current and non-current. The deferred revenues related to the \$25.0 million upfront payment and the \$10.0 million milestone payment are subject to foreign currency exchange rate fluctuations in future accounting periods. Approximately 24% of deferred revenue is expected to be recognized as revenue in the remainder of 2023, 23% in 2024, 21% in 2025, 20% in 2026 and the remaining 12% in 2027.

In the three months ended September 30, 2023, the Company recognized \$4.9 million of the upfront and milestone payments that were originally recorded as deferred revenue. Furthermore, the Company recognized \$0.3 million revenue from cost reimbursements for activities related to the preparation of a first in human trial.

In the nine months ended September 30, 2023, the Company recognized \$7.3 million of the upfront and milestone payments that were originally recorded as deferred revenue. Furthermore, the Company recognized \$0.3 million revenue from cost reimbursements for activities related to the preparation of a first in human trial.

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 September 30, 2023 the contract asset and the liability relating to the sublicense payment was \$2.2 million and \$2.5 million, respectively. As of December 31, 2022 the contract asset and the liability relating to the sublicense payment was \$1.5 million and \$1.2 million, respectively.

# 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 September 30, 2023 Using				
	Level 1	Level 2	Level 3	Total		
Cash equivalents:						
Money market funds	\$ 103,495	\$ —	\$ —	\$ 103,495		
Total	\$ 103,495	\$ —	\$ —	\$ 103,495		
	Fair Val Level 1	ue Measurement a Level 2	nt December 31, 2 Level 3	2022 Using Total		
Cash equivalents:						
Money market funds	Ф 05 404	ф	dr.			
wioney market rands	\$ 85,491	\$ —	<b>5</b> —	\$ 85,491		

During the nine months ended September 30, 2023, there were no transfers between Level 1, Level 2 and Level 3.

# 5. Property, plant and equipment, net

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

	September 30,		December 31,	
		2023		2022
Land	\$	1,938	\$	1,959
Leasehold improvements		3,147		3,164
Construction in progress		12,550		10,567
Laboratory equipment		8,335		7,403
Furniture and fixtures		626		622
Computer equipment and software		2,561		2,034
Property and equipment, gross		29,157	-	25,749
Less: Accumulated depreciation		(8,990)		(7,779)
Property and equipment, net	\$	20,167	\$	17,970

Construction-in-progress as of September 30, 2023 and December 31, 2022 mainly related to investments in connection with the Company's GMP manufacturing facility project.

#### 6. Receivable research incentive

The Company participates in a research incentive program provided by the Austrian government under which it is entitled to reimbursement of a percentage of qualifying research and development expenses and capital expenditures incurred in Austria. Submissions for reimbursement under the program are submitted annually. Incentive amounts are generally paid out during the calendar year that follows the year of the expenses but remain subject to subsequent examinations by the responsible authority. Reimbursements received in excess of the recognized receivable research incentive for a certain period are recorded within other long-term liabilities for potential repayment until such time that an audit has taken place, upon expiration of the potential reclaim period, or when it is no longer probable that a reclaim will happen. The years 2018 to present remain open to examination by the authorities.

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

As of September 30, 2023, the Company recognized receivables of \$22.4 million from the research incentive program, which are reported in receivable research incentive in the Company's condensed consolidated balance sheet. As of December 31, 2022, the receivables from the research incentive program were \$15.5 million.

During the three months ended September 30, 2023 and 2022, the Company recorded \$2.9 million and \$2.0 million, respectively, of income related to the incentive program within the Company's condensed consolidated statements of operations and comprehensive loss as part of the grant income. Research incentives depend on the eligible research and development expenses of the respective period.

During the nine months ended September 30, 2023 and 2022, the Company recorded \$7.2 million and \$5.4 million, respectively, of income related to the incentive program within the Company's condensed consolidated statements of operations and comprehensive loss as part of the grant income. Research incentives depend on the eligible research and development expenses of the respective period.

# 7. Accrued expenses and other current liabilities

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

	September 30,	December 31,
	2023	2022
Salaries and bonuses	5,345	4,481
Social security contributions	290	267
Unearned grant income (current)	96	300
Sublicense fees	2,461	1,220
Accrued external research and development expenses	3,790	3,458
Accrued external general and administration expenses	358	898
Income taxes	127	230
Other accruals and liabilities	602	324
	\$ 13,069	\$ 11,178

#### 8. Loans payable

As of September 30, 2023 and December 31, 2022, loans payable consisted of the following (in thousands):

Sept		Dec	cember 31,	
	2023		2022	
\$	1,122	\$	2,855	
	(96)		(350)	
\$	1,026	\$	2,505	
	¢	(96)	\$ 1,122 \$ (96)	

In connection with the funding agreements with the Austrian Research Promotion Agency, (*Österreichische Forschungsförderungsgesellschaft*, or "FFG"), the Company has received various loans ("FFG Loans"). The FFG Loans were made on a project-by-project basis. Amounts due under the FFG Loans bear interest at a rate of 0.75% per annum and mature in March 2024. Interest on amounts due under the loans is payable semi-annually in arrears, with all principal and remaining accrued interest due upon maturity.

The FFG Loans bear interest at rates that are below market rates of interest. The Company accounts for the imputed benefit arising from the difference between an estimated market rate of interest and the rate of interest charged by FFG as grant income from FFG. On the date that FFG loan proceeds are received, the Company recognizes the

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

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.

Principal repayments of \$1.8 million were made in the nine months ended September 30, 2023. A principal repayment of \$2.8 million was made in the nine months ended September 30, 2022.

As of September 30, 2023, the aggregate minimum future principal payments due in connection with the FFG Loans are summarized as follows (in thousands):

Payments Due by Calendar Year	Amount
2023 (remaining 3 months)	_
2024	1,122
2025	_
2026	_
2027	_
Thereafter	_
Total	\$ 1,122

#### 9. Common stock, Class A common stock and convertible preferred stock

The Company's capital structure consists of common stock, Class A common stock and preferred stock. As of September 30, 2023, the Company was authorized to issue 200,000,000 shares of common stock, 3,900,000 shares of Class A common stock and 10,000,000 shares of preferred stock. The Company has designated 2,978 of the 10,000,000 authorized shares of preferred stock as non-voting Series A convertible preferred stock, 15,800 of the 10,000,000 authorized shares of preferred stock as non-voting Series A-1 convertible preferred stock and 15,268 of the 10,000,000 authorized shares of preferred stock as non-voting Series A-2 convertible preferred stock. As of September 30, 2023, the Company had 81,550,590 shares of common stock, 2,399,517 shares of Class A common stock, 370 shares of Series A convertible preferred stock and 15,268 shares of Series A-2 convertible preferred stock outstanding and issued.

On June 5, 2023, the Company closed a public offering of 22,900,768 shares of its common stock and 15,268 shares of Series A-2 convertible preferred stock at a public offering price of \$1.31 and \$1,310.00 per share, respectively, for net proceeds of \$46.2 million after deducting underwriting discounts and commissions and offering expenses.

In July 2022 and August 2022 certain of the Company's stockholders elected to convert an aggregate of 1,420,215 shares (769,734 and 650,481 shares, respectively) of Class A common stock owned by such holders into an aggregate of 1,420,215 shares of the Company's common stock.

On February 15, 2022, the Company entered into a Stock Purchase Agreement (the "Stock Purchase Agreement") with Gilead, that requires Gilead, at the Company's option, to purchase up to \$35.0 million of the Company's common stock. On February 15, 2022, Gilead purchased an initial amount of 1,666,666 shares of the Company's common stock in exchange for \$5.0 million in cash at a purchase price per share equal to \$3.00. Pursuant to the terms of the Stock Purchase Agreement, the Company may require Gilead to purchase the balance of the \$30.0 million of common stock, at the discretion of the Company, in one or two subsequent purchases at a price equal to the volume weighted average purchase price preceding such purchase, as defined in the Stock Purchase Agreement, plus, for the first subsequent purchase, which can be up to the full \$30.0 million balance, a premium of 30%. The Company's right to sell shares of its common stock to Gilead is subject to specified limitations, including a limitation that prevents the Company from requesting purchases of shares of common stock by Gilead that would result in a beneficial ownership of more than 19.9% of the total number of outstanding shares of common stock by Gilead. At

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

September 30, 2023, this limitation would have prevented the Company from requesting that Gilead purchase the full remaining \$30.0 million balance of the investment commitment. The Company agreed to file a registration statement on Form S-3 to register for resale any additional shares of common stock issued to Gilead within four months from issuance.

On March 4, 2022, the Company closed a public offering of 21,700,000 shares of its common stock and 15,800 shares of Series A-1 convertible preferred stock at a public offering price of \$2.00 and \$2,000.00 per share, respectively, for net proceeds of \$70.2 million after deducting underwriting discounts and commissions and offering expenses.

The Company has three series of preferred stock authorized, issued and outstanding as of September 30, 2023: Series A convertible preferred stock, Series A-1 convertible preferred stock and Series A-2 convertible preferred stock. Shares of Series A, Series A-1 and Series A-2 convertible preferred stock may be independently converted into common stock. Holders of Series A, Series A-1 and Series A-2 convertible preferred stock have equal rights, powers and privileges.

Holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of Class A common stock and Series A, Series A-1 and Series A-2 convertible preferred stock are not entitled to vote, except as required by law. The holders of common stock and Class A common stock do not have any cumulative voting rights.

Each holder of Class A common stock has the right to convert each share of Class A common stock into one share of common stock at such holder's election. Each holder of Series A, Series A-1 and Series A-2 convertible preferred stock has the right to convert each share of Series A, Series A-1 and Series A-2 convertible preferred stock into 1,000 shares of common stock at any time at the holder's option, provided that the holder will be prohibited, subject to certain exceptions, from converting Series A, Series A-1 and Series A-2 preferred stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding.

Holders of common stock and Class A common stock are entitled to receive ratably any dividends declared by the board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Holders of Series A, Series A-1 and Series A-2 preferred stock will be entitled to receive dividends at a rate equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends actually paid on shares of the Company's common stock. Holders of common stock and Class A common stock have no preemptive rights, conversion rights, or other subscription rights or redemption or sinking fund provisions.

In the event of a liquidation, dissolution, or winding up of the Company, holders of our Series A, Series A-1 and Series A-2 preferred stock will receive a payment equal to \$0.001 per share of Series A, Series A-1 and Series A-2 preferred stock before any proceeds are distributed to the holders of common stock. Then, holders of common stock and Class A common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities.

There were 370 and 1,697 shares of Series A convertible preferred stock, 10,800 and 15,800 shares of Series A-1 convertible preferred stock and 15,268 and no shares of Series A-2 convertible preferred stock outstanding as of September 30, 2023 and December 31, 2022, respectively. In May 2023 certain of the Company's stockholders elected to convert an aggregate of 1,327 shares of Series A convertible preferred stock and an aggregate of 5,000 shares of Series A-1 convertibles preferred stock owned by such holders into an aggregate of 6,327,000 shares of the Company's common stock.

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

#### 10. Stock-based compensation

#### 2018 Stock Option and Grant Plan

In June 2018, the Board of Directors approved the 2018 Stock Option and Grant Plan. Options granted under the 2018 Stock Option and Grant Plan generally vest over four years, with 25% of the options vesting upon the first anniversary of the grant date and the remaining 75% of the options vesting in 12 equal quarterly installments following the first anniversary of the grant date, provided the option holder continues to have an employment or service relationship with the Company on each vesting date. The options expire on the 10<sup>th</sup> anniversary of the grant date. As of September 30, 2023, 782,176 options granted under the 2018 Stock Option and Grant Plan remained outstanding. Any authorization to issue new options under the 2018 Stock Option and Grant Plan was cancelled upon the effectiveness of the 2019 Stock Option and Incentive Plan and no further awards will be granted under the 2018 Plan.

#### 2019 Stock Option and Incentive Plan

On April 1, 2019, the Company's stockholders approved the 2019 Stock Option and Incentive Plan, which became effective as of the effective date of the registration statement in connection with the Company's IPO. The plan provides for the grant of shares of restricted stock, long term incentive awards, stock options or other equity-based awards. As of September 30, 2023, the maximum number of shares of the Company's common stock that may be issued under the Company's 2019 Stock Option and Incentive Plan was 8,067,480 shares which shall be cumulatively increased each year by up to 4.0% of the then outstanding number of shares of common stock and Class A common stock. Options granted under the 2019 Stock Option and Incentive Plan generally vest over four years, with 25% of the options vesting upon the first anniversary of the grant date and the remaining 75% of the options vesting in 12 equal quarterly installments following the first anniversary of the grant date, provided the option holder continues to have an employment or service relationship with the Company on each vesting date. Initial options granted to non-executive directors upon their election generally vest over a three-year term with 33% of the options vesting upon the first anniversary of the grant date and the remaining 67% of the options vesting in eight equal quarterly installments following the first anniversary of the grant date. Option re-grants to non-executive directors generally vest on the first anniversary of the grant date. The options expire on the 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.

In addition, there were 500,000 shares reserved for stock options issued as inducement grants to new employees granted outside of the Company's equity-based compensation plans under Rule 5635(c)(4) of the Nasdaq Listing Rules.

On August 7, 2023, the Company's board of directors approved a one-time offer to eligible non-executive, non-director employees to exchange certain outstanding stock options for new stock options with modified terms. Under the stock option exchange program (the "Offer"), the Company offered to exchange certain out-of-the-money stock options for new stock options at an exchange ratio of between 1.75 and 2.50 surrendered options for one new option exercisable for shares of common stock with a lower exercise price and extended vesting terms. Pursuant to the Offer, a total of 82 eligible participants tendered, and the Company accepted for cancellation, stock options to purchase an aggregate of 543,228 shares of the Company's common stock with exercise prices between \$6.90 and \$14.00. The eligible options that were accepted for cancellation represented approximately 86.6% of the total shares of common stock underlying all of the eligible options. In accordance with the terms and conditions of the Offer, on September 12, 2023, the Company issued new options to purchase an aggregate of 274,485 shares of common stock in exchange for the cancellation of the tendered eligible options. The exercise price per share of each new option granted in the Offer is \$1.00. New options issued for previously vested stock options vest over a three-year term in twelve equal quarterly installments. The stock option exchange offer resulted in incremental stock-based compensation expense of \$0.1 million, which will be recognized using the graded-vesting method over the remaining requisite service period of the new stock options.

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

The following table presents a summary of awards outstanding:

	As of September 30, 2023						
	2018 Plan	2019 Plan	Inducement Awards	Total			
Granted and outstanding awards:							
Stock options	782,176	7,352,196	230,000	8,364,372			
Total	782,176	7,352,196	230,000	8,364,372			

# Stock option valuation

The Company estimates the option's fair value on the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to expected term, volatility, the risk-free interest rate, the dividend and employee exercise behavior. Forfeitures are accounted for when they occur. Expected volatilities utilized in the Black-Scholes model are based on historical volatilities of a group of comparable companies. The group of representative companies have characteristics similar to the Company, including the stage of product development and focus on the life science industry. Management believes that this represents the most accurate basis for estimating expected future volatilities under the current conditions. The risk-free interest rate is derived from the yields for 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 months ended S	eptember 30,	Nine months ended September 30,			
	2023	2022	2023	2022		
Risk-free interest rate	4.48 %	— %	3.70 %	2.87 %		
Expected term (in years)	4.4	_	5.7	6.0		
Expected volatility	90.6 %	— %	93.5 %	84.9 %		
Expected dividends	— %	— %	— %	— %		

For the 2023 and 2022 grants, the Company used the simplified method in developing an estimate of the expected term due to a lack of historical exercise data.

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

### Stock option activity

The following table summarizes the Company's stock option activity since January 1, 2023 (in thousands, except share and per share amounts):

	Number of Shares	A E	eighted verage xercise Price	Weighted Average Remaining Contractual Term (in years)	In	gregate ntrinsic Value
Outstanding as of December 31, 2022	6,532,523	\$	6.19	7.7	\$	490
Granted	2,817,145		1.00			
Exercised	(5,684)		0.10			
Forfeited	(979,612)		8.11			
Outstanding as of September 30, 2023	8,364,372	\$	4.22	7.7	\$	353
Options exercisable as of September 30, 2023	3,894,079	\$	6.98	6.2	\$	353
Options unvested as of September 30, 2023	4,470,293	\$	1.81	8.9	\$	_

The aggregate intrinsic value of stock options was calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The fair value per common stock used for calculating the intrinsic values as of September 30, 2023 and December 31, 2022, was \$0.62 and \$0.81, respectively.

Cash received from stock option exercise under share-based payment arrangements for the nine months ended September 30, 2023 was \$1 thousand. Cash received from stock option exercise under share-based payment arrangements for the nine months ended September 30, 2022 was \$3 thousand.

#### Common Stock Awards

In the three months ended March 31, 2022 the Company issued unrestricted shares of common stock to its executive team. The Company's executive team agreed to convert a portion of their base salaries, for the six months ended June 30, 2022, for shares of the Company's fully vested common stock having a value equal to their foregone salary, determined based on a value of \$3.00 per share, resulting in the issuance of 112,551 shares of common stock in the three months ended March 31, 2022. The total fair value of common stock awards issued during the three months ended March 31, 2022 was \$0.2 million. The grant date fair value per share of common stock was \$1.50 and was measured at the closing price of the common stock on the date of grant. Expenses were recorded immediately and are included in stock-based compensation in the three months ended March 31, 2022. No unrestricted shares of common stock were issued in the three and nine months ended September 30, 2023.

# 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 September 30,			Nin	e months end	led September 30,		
		2023		2022		2023		2022
Research and development expenses	\$	216	\$	428	\$	764	\$	1,568
General and administrative expenses		358		612		1,164		2,474
	\$	574	\$	1,040	\$	1,928	\$	4,042

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

#### 11. Income taxes

Income tax expense during the nine months ended September 30, 2023 resulted from U.S. federal and state income tax as well as minimum tax obligations in Austria. Income tax expense during the nine months ended September 30, 2022 resulted from minimum tax obligations in Austria. During the three and nine months ended September 30, 2023 and 2022, the Company recorded no income tax benefits for the net operating losses incurred, due to its uncertainty of realizing a benefit from those items. The Company's losses before income taxes were generated in the United States and Austria. The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets resulting from its net operating loss carryforwards. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of September 30, 2023 and December 31, 2022. Management reevaluates the positive and negative evidence at each reporting period.

#### 12. 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 September 30, 2023.

As of September 30, 2023 and December 31, 2022, the Company's operating lease right-of-use assets were \$2.9 million and \$4.0 million, respectively, which are reported in operating lease right-of-use assets in the Company's condensed consolidated balance sheets. As of September 30, 2023, the Company had outstanding operating lease obligations of \$2.8 million, of which \$1.5 million is reported in operating lease liabilities, current portion and \$1.3 million is reported in operating lease liabilities, non-current portion in the Company's condensed consolidated balance sheets. As of December 31, 2022, the Company had outstanding operating lease obligations of \$4.0 million, of which \$1.7 million is reported in operating lease liabilities, current portion and \$2.3 million is reported in operating lease liabilities, non-current portion 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 1.2% and 2.1 years, respectively.

# 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 September 30, 2023, the Company's total non-cancellable obligations under contracts with CMOs were \$9.3 million, of which \$2.1 million relate to 2023 (remaining three months) deliverables, \$7.0 million relate to 2024 deliverables, and \$0.2 million relate to 2025 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 nine months ended September 30, 2023, the Company recorded \$0.6 million and \$1.1 million, respectively, in licensing fees related to intellectual property licenses as research and development expenses. The amount is mainly related to the upfront payment and milestone payments received by the Company under the Gilead Collaboration Agreement and the Roche Collaboration Agreement. The amount recognized as expenses has 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 September 30, 2023 or December 31, 2022.

#### Legal proceedings

At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company was recently a party to a patent proceeding opposing European Patent No. 3218504 (the "EP '504 Patent"), which was granted to the University of Geneva in July 2020 and is exclusively licensed to the Company. In a decision that has become final, the Opposition Division of the European Patent Office ("EPO") dismissed the opposition, and maintained the patent as granted. The Company expenses the costs related to this case and other such legal proceedings as incurred.

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

## 13. Net loss per share

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders (in thousands, except for per share amounts):

	Three months ended September 30, 2023 2022			Nine months ende			<u>september 30,</u> 2022	
Numerator:		2023	_	2022		2023	_	2022
Net loss	\$	(19,066)	\$	(18,280)	\$	(56,762)	\$	(52,604)
Denominator:								
Weighted-average common shares outstanding,								
basic and diluted	8	33,950,107		54,733,709	6	7,933,579		49,403,999
Weighted-average Series A convertible preferred								
shares outstanding, basic and diluted, presented as		250 000		4 605 000		000 400		4 607 000
if converted into common stock <sup>(1)</sup>		370,000		1,697,000		992,183		1,697,000
Weighted-average Series A-1 convertible preferred								
shares outstanding, basic and diluted, presented as								
if converted into common stock <sup>(1)</sup>	1	10,800,000		15,800,000	1	3,107,692		12,153,846
Weighted-average Series A-2 convertible preferred								
shares outstanding, basic and diluted, presented as								
if converted into common stock <sup>(1)</sup>	1	15,268,000				6,543,429		
Total number of shares used to calculate net loss per								
share, basic and diluted	11	10,388,107		72,230,709	8	8,576,883		63,254,845
Net loss per share, basic and diluted	\$	(0.17)	\$	(0.25)	\$	(0.64)	\$	(0.83)

<sup>(1)</sup> Class A common stock, Series A, Series A-1 and Series A-2 convertible preferred stock are participating securities that have substantially the same terms and features as the Company's common stock. The Class A common stock, Series A, Series A-1 and Series A-2 convertible preferred stock is therefore included in the weighted-average number of shares outstanding to calculate net loss per share, basic and diluted as if converted in common stock. Each share of Class A common stock, Series A, Series A-1 and Series A-2 convertible preferred stock is independently convertible into one and 1,000 shares of common stock, respectively. 2,399,517 shares of the Company's common stock are issuable upon conversion of the Class A common stock, 370,000 shares of the Company's common stock are issuable upon conversion of Series A convertible preferred stock, 10,800,000 shares of the Company's common stock are issuable upon conversion of Series A-1 convertible preferred stock and 15,268,000 shares of the Company's common stock are issuable upon conversion of Series A-2 convertible preferred stock (see Note 9).

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

	Three and nine months en	nded September 30,
	2023	2022
Options issued and outstanding	8,364,372	6,016,997
Unvested restricted stock units	_	_
Total	8,364,372	6,016,997

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

# 14. Related Parties

Effective September 15, 2023, Malte Peters, a member of the Company's board of directors, agreed to lead the Company's clinical activities ad interim as Senior Clinical Advisor. During the three and nine months ended September 30, 2023, the Company recorded expense of less than \$0.1 million related to a consulting agreement entered into with Dr. Peters, effective September 15, 2023.

# 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, 2022 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC"). As a result of many factors, including those factors set forth in the "Risk Factors" section of our Annual Report on Form 10-K for the year end December 31, 2022, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

#### Overview

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

We are building a proprietary immuno-oncology pipeline by targeting oncoviral cancer antigens, self-antigens and next-generation antigens. Our oncology portfolio includes three disclosed programs, HB-200, HB-300 and HB-700, all of which use our replicating technology. HB-200 is in clinical development for the treatment of Human Papillomavirus 16-positive ("HPV16+") cancers in an ongoing Phase 1/2 clinical trial. HB-300 is in clinical development for the treatment of prostate cancer in an ongoing Phase 1 clinical trial, which opened for enrollment of patients in the first quarter of 2023. HB-700, which has been partnered with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (collectively referred to as "Roche"), is in preclinical development for the treatment of KRAS mutated cancers, including, lung, colorectal and pancreatic cancers.

Our HB-200 program is comprised of potential therapeutic agents for people with cancers caused by the Human Papillomavirus ("HPV"), specifically HPV16+ and includes HB-201 single-vector therapy and HB-202/HB-201 dual-vector therapy. HB-200 is being evaluated in an ongoing Phase 1/2 clinical trial. In the second quarter of 2022, data presented at scientific conferences showed that HB-202/HB-201 alternating dual-vector candidate induced immune and clinical responses, as well as stable disease as a monotherapy in some HPV16+ advanced metastatic/recurrent head and neck cancer patients who failed prior standard of care therapy. We believe that these early-stage data established proof of concept for our replicating viral vector immunotherapy candidate in oncology.

Based on the observed tolerability profile, anti-tumor activity and T cell response data, we are evaluating HB-202/HB-201 in combination with pembrolizumab in 1st line and 2nd line patients with advanced/metastatic head and neck cancer. In October of 2023, at the European Society for Medical Oncology (ESMO) Congress 2023, we presented preliminary data from our Phase 2 clinical trial showing that HB-200 in combination with pembrolizumab in a 1st line setting demonstrated promising anti-tumor activity with a 42% objective response rate and disease control rate (DCR) of 74% among 19 evaluable CPI-naïve patients with recurrent/metastatic HPV16+ PD-L1+ head and neck cancer. These data represent a doubling of the 19% objective response rate reported with pembrolizumab alone. Furthermore, preliminary data on HB-200 in combination with pembrolizumab in the 2nd line plus setting are also trending positively but need further maturation.

While recruitment in this Phase 1/2 clinical trial is ongoing, we are preparing to start a separate randomized Phase 2 trial to evaluate the combination of HB-200 and Merck & Co., Inc's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) for which we entered into a clinic collaboration with Merck & Co., Inc and for which we have been granted fast track designation by the U.S. Food and Drug Administration ("FDA").

In October 2022, we entered into a Research Collaboration and License Agreement (the "Roche Collaboration Agreement"), with Roche to (i) grant Roche an exclusive license to research, develop, manufacture and commercialize our pre-clinical HB-700 cancer program, an arenaviral immunotherapeutic for KRAS-mutated cancers, and (ii) grant Roche an option right to exclusively license for research, development manufacturing and commercialization, a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens. Pursuant to the Roche Collaboration

Agreement, we received a non-refundable upfront payment of \$25.0 million and are eligible to receive up to approximately \$930 million in potential future success-based milestone payments for both programs, plus tiered royalties. In the first quarter of 2023, we reported the achievement of the first milestone event under the Roche agreement, triggering a milestone payment of \$10.0 million.

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

We are collaborating with Gilead Sciences, Inc. ("Gilead") to research arenavirus functional cures for chronic Hepatitis B and HIV infections under a Collaboration and License Agreement signed in 2018 (the "Gilead Collaboration Agreement"). Both programs have completed preclinical research, and in April 2023 the first participant in a Phase 1 clinical trial of the Hepatitis B product candidate being conducted by Gilead has been dosed. Gilead is solely responsible for further development and commercialization of the Hepatitis B product candidate and we are eligible for up to a further \$185.0 million in development and commercialization milestone payments, plus tiered royalties. According to the amendment to the Gilead Collaboration Agreement, signed in February 2022, we have taken on development responsibilities for the HIV program candidate through a Phase 1b clinical trial and Gilead will provide funding through a combination of an initiation payment of \$15.0 million, a milestone payment of \$5.0 million and equity contributions of up to \$35.0 million. Gilead retains the exclusive option right, to further develop and commercialize the HIV program, in which case we are eligible for up to a further \$232.5 million in developmental and commercialization milestone payments, inclusive of a \$10.0 million option exercise payment, plus tiered royalties.

We have funded our operations to date primarily from public offerings of common stock and convertible preferred stock, including our initial public offering, as well as private placements of our redeemable convertible preferred stock, grant funding and loans from an Austrian government agency, and upfront, milestone and initiation payments from Gilead and Roche in connection with our respective collaboration and license agreements.

On April 23, 2019, we completed an initial public offering of our common stock (the "IPO") in which we issued 6.0 million shares of our common stock, at \$14.00 per share, for gross proceeds of \$84.0 million, or net proceeds of \$74.6 million. On December 11, 2020, we completed a follow-on public offering in which we issued 3.9 million shares of our common stock, at \$11.75 per share, and 2,978 shares of our Series A convertible preferred stock, at \$11,750.00 per share, for net proceeds of \$75.0 million after deducting underwriting discounts and commissions and offering expenses. In addition, in February 2022, Gilead purchased 1.7 million shares of our common stock for \$5.0 million. On March 4, 2022, we completed a follow-on public offering in which we issued 21.7 million shares of our common stock, at \$2.00 per share, and 15,800 shares of our Series A-1 convertible preferred stock, at \$2,000.00 per share, for net proceeds of \$70.2 million after deducting underwriting discounts and commissions and offering expenses. On June 5, 2023, we completed a follow-on public offering in which we issued 22.9 million shares of our common stock, at \$1.31 per share, and 15,268 shares of our Series A-2 convertible preferred stock, at \$1,310.00 per share, for net proceeds of \$46.2 million after deducting underwriting discounts and commissions and offering expenses. As of September 30, 2023, the principal amount outstanding under loans from government agencies was \$1.1 million and we had cash, cash equivalents and restricted cash of \$108.1 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 oncology product candidate, HB-200, will require substantial additional development time and resources before we would be able to apply for and receive regulatory approvals and begin generating revenue from product sales. Before launching our first products, if approved, we plan to establish our own manufacturing facility to reduce or eliminate our reliance on contract manufacturing organizations ("CMOs") which will require substantial capital expenditures and cause additional operating expenses. We currently have no marketing and sales organization and have no experience in marketing products; accordingly, we will incur

significant expenses to develop a marketing organization and sales force in advance of generating any commercial product sales. As a result, we will need substantial additional capital to support our operating activities. In addition, we expect to continue to incur legal, accounting and other expenses in operating our business, including the costs associated with operating as a public company.

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

We have incurred net losses each year since our inception in 2011, including net losses of \$19.1 million and \$56.8 million for the three and nine months ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of \$344.4 million and we do not expect positive cash flows from operations in the foreseeable future, if ever. We expect to continue to incur net operating losses for at least the next several years as we advance our product candidates through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, continue our research and development efforts and invest to establish further commercial manufacturing capacity.

# **Impacts of Coronavirus and Market Conditions on Our Business**

We have been actively monitoring the coronavirus pandemic situation and its impact globally. We believe our financial results for the three and nine months ended September 30, 2023 and 2022 were not significantly impacted by any lingering effects of the recent coronavirus pandemic. Further, disruption of global financial markets and a recession or market correction, including as a result of any resurgence of the coronavirus pandemic, the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, any escalation of the conflict in Israel and the Gaza Strip, and other global macroeconomic factors, could reduce our ability to access capital, which could, in the future, negatively affect our business and the value of our common stock.

## **Effects of Inflation**

We do not believe that inflation has had a material impact on our business or operating results during the periods presented. However, inflation, has had, and may continue to have, an impact on the labor costs we incur to attract and retain qualified personnel, costs to conduct clinical trials and other operational costs. Inflationary costs could adversely affect our business, financial condition and results of operations. In addition, increased inflation has had, and may continue to have, an effect on interest rates. Increased interest rates may adversely affect our borrowing rate and our ability to obtain, or the terms under which we can obtain, any potential additional funding.

# **Components of Our Results of Operations**

#### Revenue from collaboration and licensing

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

# Gilead Collaboration Agreement

On June 4, 2018, we entered into the Gilead Collaboration Agreement to evaluate potential vaccine products using or incorporating our replicating technology and non-replicating technology for the treatment, cure, diagnosis or prevention of HBV and HIV.

Under the Gilead Collaboration Agreement, we granted Gilead an exclusive, royalty-bearing license to our technology platform for researching, developing, manufacturing and commercializing products for HIV or HBV. We

received a non-refundable \$10.0 million upfront payment upon entering the Gilead Collaboration Agreement. In February 2022, we signed an amended and restated collaboration agreement (the "Restated Gilead Collaboration Agreement") which revised the terms only for the HIV program, whereby we will take on development responsibilities for the HIV program candidate through a Phase 1b clinical trial. Pursuant to the Restated Gilead Collaboration Agreement, Gilead will retain an exclusive right, the Option, to take back the development responsibilities, thus keeping the rights for the HIV program, including further development and commercialization in return for an option exercise payment of \$10.0 million. Pursuant to the Restated Gilead Collaboration Agreement, we are eligible for up to \$140.0 million in developmental milestone payments for the HBV program and \$50.0 million in commercialization milestone payments, If Gilead exercises the Option, we are eligible for up to \$172.5 million in developmental milestone payments for the HIV program, inclusive of the \$10.0 million Option exercise payment, and \$65.0 million in commercialization milestone payments for the HIV program. Upon the commercialization of a product, we are eligible to receive tiered royalties of a high single-digit to mid-teens percentage on the worldwide net sales of each HBV product, and royalties of a mid-singledigit to 10% of worldwide net sales of each HIV product. Gilead is obligated to reimburse us for our costs, including all benefits, travel, overhead, and any other expenses, relating to performing research and development activities under the Restated Gilead Collaboration Agreement with respect to the HBV program, and if the Option is exercised, any manufacturing costs related to the HIV program. Through September 30, 2023, we have received a non-refundable upfront payment of \$10.0 million, a program initiation fee of \$15.0 million and \$21.2 million in milestone payments for the achievement of pre-clinical research milestones from Gilead. In addition, we have recognized \$42.1 million of cost reimbursements for research and development services performed under the original and Restated Gilead Collaboration Agreement.

We determined that our performance obligations under the terms of the original Gilead Collaboration Agreement included one combined performance obligation for each of the HBV and HIV research programs, comprised of the transfer of intellectual property rights and providing research and development services. Accordingly, we recognized these amounts as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development labor hours for each of the performance obligations. The terms of the Restated Gilead Collaboration Agreement added an additional performance obligation to us to perform research and development work for the HIV program. We recognize the amounts of revenue allocated to the performance obligation resulting from the Restated Gilead Collaboration Agreement on a percent of completion basis over the performance period, using total estimated research and development costs as the measure of progress.

## **Roche Collaboration Agreement**

On October 18, 2022, we entered into the Roche Collaboration Agreement to (i) grant Roche an exclusive license to research, develop, manufacture and commercialize our pre-clinical HB-700 cancer program, an arenaviral immunotherapeutic for KRAS-mutated cancers, and (ii) grant Roche an exclusive option right to exclusively license for research, development manufacturing and commercialization, a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens.

Under the Roche Collaboration Agreement, we granted Roche an exclusive, royalty-bearing license to our technology platforms. Upon signing the Roche Collaboration Agreement in October 2022, we received a non-refundable upfront payment of \$25.0 million and Roche will be obliged to pay an additional \$15.0 million payment if the option (the "UCA Option") for the program targeting undisclosed cancer antigens (the "UCA Program") is exercised. We are also eligible for event-based milestone payments of up to an aggregate of \$335.0 million during the research and development phase of the HB-700 program for up to four oncology indications and up to an aggregate of \$250.0 million in payments related to the achievement of sales-based milestones. For the additional UCA Program, subject to UCA Option-exercise, we are eligible for up to an aggregate of \$173.0 million in event-based milestone payments during research and development for up to four oncology indications as well as up to an aggregate of \$160.0 million in sales-based milestones. Upon commercialization, we are eligible to receive tiered royalties on the worldwide net sales of HB-700 and, subject to UCA Option exercise, the UCA Program. The royalty payments are subject to reduction under specified conditions set forth in the Roche Collaboration Agreement. Through September 30, 2023, we have received from Roche the non-refundable upfront payment of \$25.0 million and \$10.0 million in milestone payments for the achievement of a GMP manufacturing milestone under the HB-700 program. In addition, we have recognized \$0.3 million of cost reimbursements for research and development activities related to a first human trial.

We determined that our performance obligations under the terms of the Roche Collaboration Agreement included one combined performance obligation for the transfer of intellectual property rights (licenses) and providing research and development services for the HB-700 program, and a second, separate performance obligation during the UCA Option period to perform research and development services with respect to the UCA Program. Accordingly, we allocated the non-refundable upfront payment of \$25.0 million between the two performance obligations. Milestone payments that are contingent on future events will be added to the transaction price when the triggering event has become probable. The consideration allocated to a performance obligation will be recognized as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development costs for each of the performance obligations. Milestone payments, or parts thereof, that relate to completed services will be reflected via a cumulative catch up for past performance.

# **Operating Expenses**

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

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

Since our inception, we have focused significant resources on our research and development activities, including establishing our arenavirus platform, conducting preclinical studies, developing a manufacturing process, conducting Phase 1 and Phase 2 clinical trials for HB-101 as well as the ongoing HB-200 Phase 1/2 study, and an investigational new drug ("IND") application for HB-300. Research and development activities account for a significant portion of our operating expenses. Research and development costs are expensed as incurred. These costs include:

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

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

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

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any product candidates that we develop from our programs. We are

also unable to predict when, if ever, material net cash inflows will commence from sales of product candidates we develop, if at all. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

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

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

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

	Three months ended September 30,			Nine months ended September 30,				
	2023		2022		2023		2022	
HB-200 program	\$	10,862	\$	7,305	\$	31,310	\$	20,761
HB-300 program		2,312		2,873		7,649		7,553
Gilead partnered programs		3,234		3,793		10,889		9,159
Roche partnered programs		6,689		_		10,014		
Other and earlier-stage programs		1,122		3,809		4,215		11,885
Other unallocated research and development expenses		406		506		1,185		1,695
Total research and development expenses	\$	24,625	\$	18,286	\$	65,262	\$	51,053

Other unallocated research and development expenses include stock-based compensation expense, certain lease expenses and other operating expenses that we do not track on a program-by-program basis, since our research and development employees and infrastructure resources are utilized across our programs.

#### General and Administrative Expenses

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

#### **Grant Income**

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

We participate in a research incentive program provided by the Austrian government under which we are entitled to reimbursement of a percentage of qualifying research and development expenses and capital expenditures incurred in Austria. Submissions for reimbursement under the program are submitted annually. Incentive amounts are generally paid out during the calendar year that follows the year of the expenses but remain subject to subsequent examinations by the responsible authority.

#### Interest Income

Interest income results of interest earned on our cash, cash equivalents, and restricted cash.

# Interest Expense

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

#### **Income Taxes**

Income tax expense results from U.S. federal and state income tax as well as foreign minimum income tax and profit on a legal entity basis. The losses that we have incurred since inception result primary from the losses of our Austrian subsidiary. We have considered that, at this point in time, it is uncertain whether we will ever be able to realize the benefits of the deferred tax asset, and accordingly, have established a full valuation allowance as of September 30, 2023.

## **Results of Operations**

#### Comparison of Three and Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three months ended September 30,			Nir		ed Sep	d September 30,		
	_	2023		2022		2023		2022	
Revenue from collaboration and licensing	\$	6,867	\$	2,230	\$	12,722	\$	6,421	
Operating expenses:									
Research and development		(24,625)		(18,286)		(65,262)		(51,053)	
General and administrative		(4,912)		(4,937)		(14,259)		(14,935)	
Total operating expenses		(29,537)		(23,223)		(79,521)		(65,988)	
Loss from operations		(22,670)		(20,993)		(66,799)		(59,567)	
Other income (expense):									
Grant income		2,916		2,081		7,486		5,926	
Interest income		1,570		535		4,052		724	
Interest expense		(49)		(105)		(268)		(579)	
Other income and expenses, net		(833)		202		(1,029)		893	
Total other income (expense), net		3,604		2,713		10,241		6,964	
Net loss before tax		(19,066)		(18,280)		(56,558)		(52,603)	
Income tax expense		0		(0)		(204)		(1)	
Net loss	\$	(19,066)	\$	(18,280)	\$	(56,762)	\$	(52,604)	

## Revenue from Collaboration and Licensing

Revenue was \$6.9 million and \$12.7 million for the three and nine months ended September 30, 2023, respectively compared to \$2.2 million and \$6.4 million for the three and nine months ended September 30, 2022, respectively.

During the three months ended September 30, 2023 revenue increased by \$4.7 million compared to the three months ended September 30, 2022. This increase was primarily due to higher partial recognition of the upfront and milestone payments under the Gilead and Roche collaborations, cost reimbursements under the Roche collaboration, partially offset by lower cost reimbursements received under the Restated Gilead Collaboration Agreement.

For the three months ended September 30, 2023 and 2022, revenue included \$0.8 million and \$0.9 million, respectively, from reimbursement of research and development expenses, and \$6.1 million and \$1.3 million, respectively, from partial recognition of upfront, milestone and initiation payments that were initially recorded as deferred revenue.

For the three months ended September 30, 2023, revenue included \$1.7 million related to the Restated Gilead Collaboration Agreement, of which \$0.5 million resulted from reimbursement of research and development expenses, and \$1.2 million from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue. In addition, revenue included \$5.2 million related to the Roche Collaboration Agreement, of which \$0.3 million

resulted from reimbursement of expenses, and \$4.9 million from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue.

For the three months ended September 30, 2022, revenue included \$2.2 million related to the Restated Gilead Collaboration Agreement, of which \$0.9 million resulted from reimbursement of research and development expenses, and \$1.3 million from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue.

During the nine months ended September 30, 2023 revenue increased by \$6.3 million compared to the nine months ended September 30, 2022. This increase was primarily due to higher partial recognition of the upfront and milestone payments under the Gilead and Roche collaborations, cost reimbursements under the Roche collaboration, partially offset by lower cost reimbursements received under the Restated Gilead Collaboration Agreement.

For the nine months ended September 30, 2023 and 2022, revenue included \$1.6 million and \$3.5 million, respectively, from reimbursement of research and development expenses, and \$11.1 million and \$2.9 million, respectively, from partial recognition of upfront, milestone and initiation payments that were initially recorded as deferred revenue.

For the nine months ended September 30, 2023, revenue included \$5.1 million related to the Restated Gilead Collaboration Agreement, of which \$1.3 million resulted from reimbursement of research and development expenses, and \$3.8 million from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue. In addition, revenue included \$7.6 million related to the Roche Collaboration Agreement, of which \$0.3 million resulted from reimbursement of expenses, and \$7.3 million from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue.

For the nine months ended September 30, 2022, revenue included \$6.4 million related to the Restated Gilead Collaboration Agreement, of which \$3.5 million resulted from reimbursement of research and development expenses, and \$2.9 million from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue.

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

For the three and nine months ended September 30, 2023, our research and development expenses were \$24.6 million and \$65.3 million, respectively, compared to \$18.3 million and \$51.1 million for the three and nine months ended September 30, 2022, respectively.

The increase of \$6.3 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was attributable to an increase in direct research and development expenses of \$5.1 million, and an increase in indirect research and development expenses of \$1.2 million. The increase in direct research and development expenses was primarily driven by higher clinical study expenses for our HB-200 program, as well as increased spending for our Roche partnered programs. Indirect research and development expenses increased mainly because of personnel related expenses, partially offset by lower expenses for consulting and professional services.

The increase of \$14.2 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was attributable to an increase in direct research and development expenses of \$9.8 million, and an increase in indirect research and development expenses of \$4.4 million. The increase in direct research and development expenses was primarily driven by higher clinical study expenses for our HB-200 program, as well as increased spending for our Gilead and Roche partnered programs, partially offset by lower manufacturing expenses for our HB-200 and HB-300 programs. Indirect research and development expenses increased mainly because of personnel related expenses, partially offset by lower expenses for consulting and professional services.

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

General and administrative expenses for the three and nine months ended September 30, 2023 were \$4.9 million and \$14.9 million for the three and nine months ended September 30, 2022, respectively.

General and administrative expenses for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 remained constant.

The decrease of \$0.6 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily due to a decrease in other expenses of \$1.4 million, partially offset by an increase in personnel-related expenses of \$0.5 million, and an increase in professional and consulting fees of \$0.2 million. The increase in personnel-related expenses resulted from a growth in headcount along with increased salaries in our general and administrative functions as well as expenses for contractors, partially offset by decreased stock compensation expenses.

#### **Grant Income**

In the three months ended September 30, 2023, we recorded grant income of \$2.9 million, compared to \$2.1 million in the three months ended September 30, 2022. Income from grants mainly included research incentives and imputed benefits from below market interest rates on loans from governmental agencies. The increase of \$0.8 million was primarily due to higher income from Austrian research and development incentives as a result of higher eligible research and development expenses.

In the nine months ended September 30, 2023, we recorded grant income of \$7.5 million, compared to \$5.9 million in the nine months ended September 30, 2022. Income from grants mainly included research incentives and imputed benefits from below market interest rates on loans from governmental agencies. The increase of \$1.6 million was primarily due to higher income from Austrian research and development incentives as a result of higher eligible research and development expenses.

## **Interest Income and Expense**

Interest income was \$1.6 million and \$4.1 million for the three and nine months ended September 30, 2023, respectively, compared to interest income of \$0.5 million and \$0.7 million for the three and nine months ended September 30, 2022, respectively. The increase in interest income for the three and nine months ended September 30, 2023 was a result of the rising U.S. dollar and euro interest rates. Interest income represents interest from cash and cash equivalents held in U.S. dollars and euros resulting from the proceeds from the issuance of common and preferred stock as well as payments received under our Gilead and Roche collaborations. During the three and nine months ended September 30, 2023 our cash, cash equivalents and restricted cash were mainly held in dollars at U.S. investment grade financial institutions or in money market funds. In addition, smaller amounts were held in euros and dollars at our Austrian subsidiary.

Interest expenses for loans from government agencies were less than \$0.1 million for the three months ended September 30, 2023, compared to \$0.1 million for the three months ended September 30, 2022. Interest expenses for loans from government agencies were \$0.3 million for the nine months ended September 30, 2023, compared to \$0.6 million for the nine months ended September 30, 2022. Interest expense was recorded at the market rate of interest, which exceeded the contractual interest.

# Other Income and Expenses

Other expenses were \$0.8 million for the three months ended September 30, 2023, compared to other income of \$0.2 million for the three months ended September 30, 2022. The change in the three months ended September 30, 2023 resulted primarily from exchange rate differences and foreign currency remeasurements.

Other expenses were \$1.0 million for the nine months ended September 30, 2023, compared to other income of \$0.9 million for the nine months ended September 30, 2022. The change in the nine months ended September 30, 2023 resulted primarily from exchange rate differences and foreign currency remeasurements.

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

Since our inception in 2011, we have funded our operations primarily from public offerings and private placements of common stock and convertible preferred stock, including our initial public offering, as well as private placements of our redeemable convertible preferred stock, grant funding and loans from an Austrian government agency, and upfront, milestone and initiation payments from Gilead and Roche in connection with research collaboration agreements.

Prior to our IPO, we raised gross proceeds of approximately \$142.5 million from the issuance of our redeemable convertible preferred stock. In April 2019, we completed our IPO in which we issued and sold 6,000,000 shares of our common stock, at \$14.00 per share, for gross proceeds of \$84.0 million, or net proceeds of \$74.6 million. On December 11, 2020, we completed a follow-on public offering in which we issued 3,910,000 shares of our common stock, at \$11.75 per share, and 2,978 shares of our Series A convertible preferred stock, at \$11,750.00 per share, for net proceeds of \$75.0 million after deducting underwriting discounts and commissions and offering expenses. In addition, in February 2022, Gilead purchased 1,666,666 shares of our common stock for \$5.0 million, at a purchase price of \$3.00 per share and committed to purchase an additional \$30.0 million of common stock at our discretion subject to specified limitations (see "Note 9. Common stock, Class A common stock and convertible preferred stock"). On March 4, 2022, we completed a follow-on public offering in which we issued 21,700,000 shares of our common stock, at \$2.00 per share, and 15,800 shares of our Series A-1 convertible preferred stock, at \$2,000.00 per share, for net proceeds of \$70.2 million after deducting underwriting discounts and commissions and offering expenses. On June 5, 2023, we completed a follow-on public offering in which we issued 22,900,768 shares of our common stock, at \$1.31 per share, and 15,268 shares of our Series A-2 convertible preferred stock, at \$1,310.00 per share, for net proceeds of \$46.2 million after deducting underwriting discounts and commissions and offering expenses. We also received \$46.2 million from non-refundable upfront, milestone and initiation payments pursuant to the Restated Gilead Collaboration Agreement and \$35.0 million from non-refundable upfront and milestone payments related to the Roche Collaboration Agreement. As of September 30, 2023, we had cash, cash equivalents and restricted cash of \$108.1 million.

On July 12, 2022, we filed a registration statement on Form S-3, or the Registration Statement, with the SEC, which was declared effective on July 21, 2022. The Registration Statement registers the offering, issuance and sale of an unspecified amount of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into a Sales Agreement with SVB Securities LLC, as sales agent, to provide for the issuance and sale by us of up to \$50.0 million of common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus filed with the Registration Statement, or the ATM Program. As of September 30, 2023, no sales had been made pursuant to the ATM Program.

We entered into various funding agreements with the Austrian Research Promotion Agency (Österreichische Forschungsförderungsgesellschaft, or "FFG"). The loans by FFG (the "FFG Loans") were made on a project-by-project basis and bear interest at a rate of 0.75% per annum. In the event that the underlying program research results in a scientific or technical failure, the principal then outstanding under any loan may be forgiven by FFG and converted to non-repayable grant funding on a project-by-project basis. The FFG Loans contain no financial covenants and are not secured by any of our assets. The remaining debt obligation under the FFG loan is \$1.1 million, which is due for repayment upon final maturity in 2024.

Because the FFG Loans bear interest at below market rates we account for the imputed benefit arising from the difference between an estimated market rate of interest and the contractual interest rate as grant funding from FFG, which is included in grant income. On the date that FFG Loan proceeds are received, we recognize the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income. As of September 30, 2023, the unamortized debt discount related to FFG Loans was \$0.1 million.

We entered into arrangements with contract manufacturing organizations. As of September 30, 2023, we had total non-cancellable obligations under such contracts of \$9.3 million.

We do not expect positive cash flows from operations in the foreseeable future, if at all. Historically, we have incurred operating losses as a result of ongoing efforts to develop our arenavirus technology platform and our product candidates, including conducting ongoing research and development, preclinical studies, clinical trials, providing general and administrative support for these operations and developing our intellectual property portfolio. We expect to continue to incur net operating losses for at least the next several years as we progress clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization of our most advanced oncology product candidate HB-200, continue our research and development efforts relating to our other and future product candidates, and invest in our manufacturing capabilities and our own manufacturing facility.

#### **Future Funding Requirements**

We have no products approved for commercial sale. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of our product candidates. As a result, we are not profitable and have incurred losses in each period since our inception in 2011. As of September 30, 2023, we had an accumulated deficit of \$344.4 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 ongoing costs associated with operating as a public company.

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

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

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

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current and future product candidates and programs, and of conducting preclinical studies and clinical trials;
- the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the stability, scale and yields of our future manufacturing process as we scale-up production and formulation of our product candidates for later stages of development and commercialization;
- the timing of, and the costs involved in, obtaining regulatory and marketing approvals and developing our ability to establish sales and marketing capabilities, if any, for our current and future product candidates we develop if clinical trials are successful;
- the success of our collaboration with Gilead and Roche;
- 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, including the funds received under the Restated Gilead Collaboration Agreement, and the funds received under the Roche Collaboration Agreement, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. These estimates are based on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

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

#### Cash Flows

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

	Ni	Nine months ended September 30,		
		2023		2022
Net cash used in operating activities	\$	(46,300)	\$	(33,134)
Net cash used in investing activities		(3,737)		(4,418)
Net cash provided by financing activities		44,421		72,467
Net (decrease) increase in cash and cash equivalents		(5,616)		34,915

## Cash Used in Operating Activities

During the nine months ended September 30, 2023, cash used in operating activities was \$46.3 million, which consisted of a net loss of \$56.8 million, adjusted by non-cash charges of \$4.2 million and cash provided due to changes in our operating assets and liabilities of \$6.3 million. The non-cash charges consisted primarily of depreciation and amortization expense of \$2.3 million and stock-based compensation of \$1.9 million. The change in our operating assets and liabilities was primarily due to a decrease in accounts receivable of \$5.8 million, primarily resulting from the collection of a \$5.0 million milestone payment and cost reimbursements from Gilead, an increase in accounts payable of \$4.1 million, a decrease in prepaid expenses and other current assets of \$3.5 million, an increase in accrued expenses and other current liabilities of \$2.1 million, and an increase in other non-current liabilities of \$0.2 million, partially offset by an increase in receivable research incentives of \$7.2 million, a decrease in deferred revenues of \$1.2 million, a decrease in operating lease liabilities of \$0.8 million, and an increase in other non-current assets of \$0.2 million.

During the nine months ended September 30, 2022, cash used in operating activities was \$33.1 million, which consisted of a net loss of \$52.6 million, adjusted by non-cash charges of \$6.7 million and cash provided due to changes in our operating assets and liabilities of \$12.7 million. The non-cash charges consisted primarily of stock-based compensation of \$4.0 million and depreciation and amortization expense of \$2.7 million. The change in our operating assets and liabilities was primarily due an increase in deferred revenues of \$10.3 million, resulting from the receipt of the \$15.0 million program initiation payment from Gilead, a decrease in accounts receivable of \$5.4 million, primarily resulting from the collection of cost reimbursements from Gilead, a decrease in prepaid expenses and other current assets of \$1.7 million, an increase in accounts payable of \$1.6 million, an increase in other non-current liabilities of \$0.3 million, and a decrease in other non-current liabilities of \$0.3 million, and a decrease in operating lease liabilities of \$1.2 million, and a decrease in accrued expenses and other current liabilities of \$0.3 million.

#### Cash Used in Investing Activities

During the nine months ended September 30, 2023, cash used in investing activities was \$3.7 million. The decrease of \$0.7 million compared to the nine months ended September 30, 2022 resulted from lower capital expenditures in connection with our GMP manufacturing facility project and lower expenditures for purchase of equipment.

During the nine months ended September 30, 2022, cash used in investing activities was \$4.4 million and resulted primarily from capital expenditures in connection with our GMP manufacturing facility project as well as expenditures for laboratory and office space extension and purchase of equipment.

#### Cash Provided by Financing Activities

During the nine months ended September 30, 2023, cash provided by financing activities was \$44.4 million and consisted mainly of net proceeds of \$46.3 million from our follow-on public offering in June 2023, partially offset by principal repayments of loans of \$1.8 million.

During the nine months ended September 30, 2022, cash provided by financing activities was \$72.5 million and consisted mainly of net proceeds of \$70.2 million from our follow-on public offering in March 2022 and of net proceeds of \$5.0 million from Gilead's purchase of 1,666,666 shares of our common stock in February 2022.

## **Critical Accounting Policies and Estimates**

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 ("GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies and the methodologies and assumptions we apply under them have not materially changed, 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, 2022 filed with the Securities and Exchange Commission ("SEC") on March 15, 2023.

## **Recently Issued Accounting Pronouncements**

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

## **Emerging Growth Company Status 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 September 30, 2023 included small amounts of cash balances held by Hookipa Biotech GmbH in euro. Assets and liabilities of Hookipa Biotech GmbH are translated into U.S. dollars at the exchange rate in effect on the balance sheet date. Income items and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the condensed consolidated Statements of Convertible Preferred Stock and Stockholders' Equity as a component of accumulated other comprehensive loss. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other income and expenses, net in the condensed consolidated Statements of Operations and Comprehensive Loss as incurred.

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and restricted cash of \$108.1 million as of September 30, 2023, which included account balances with foreign banks. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, we do not believe that we have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates.

#### 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 September 30, 2023, management, with the participation of our Principal Executive Officer and Principal Financial and Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in

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

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Principal Executive Officer and Principal Financial and Accounting Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2023.

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

There were no changes in our internal control over financial reporting (as defined in Rules 13a 15(f) and 15d 15(f) under the Exchange Act) identified that occurred during the three months ended September 30, 2023 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.

In April 2021, a third party opposed European Patent No. 3218504 (the "EP '504 Patent") which was granted to the University of Geneva in July 2020 and is exclusively licensed to us. The patent is directed to our replicating arenavirus platform technology and is part of our strategy to protect current product candidates based on this platform technology, including our lead oncology product candidates HB-201 and HB-202. In a decision that has become final, the Opposition Division of the European Patent Office ("EPO") dismissed the opposition, and maintained the patent as granted.

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.

There have been no material changes to the Company's risk factors as disclosed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2022. Careful consideration should be given to these risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the SEC, in evaluating our company and our business. Investing in our common shares involves a high degree of risk. If any of these risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

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

None.

## Item 3. Defaults upon Senior Securities.

None.

#### Item 4. Mine Safety Disclosures.

Not applicable.

#### Item 5. Other Information.

During the three months ended September 30, 2023, none of the Company's directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934) adopted, terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

#### 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
3.1	Amended and Restated Certificate of Incorporation of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 1, 2022 (File No. 001-38869) and incorporated herein by reference)
3.1.1	Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 11, 2020 (File No. 001-38869) and incorporated herein by reference)
3.1.2	Certificate of Designation of Preferences, Rights and Limitations of the Series A-1 Preferred Stock of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 3, 2022 (File No. 001-38869) and incorporated herein by reference)
3.1.3	<u>Certificate of Designation of Preferences, Rights and Limitations of the Series A-2 Preferred Stock of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 2, 2023 (File No. 001-38869) and incorporated herein by reference)</u>
3.2	Amended and Restated Bylaws of the Company (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on April 23, 2019 (File No. 001-38869) and incorporated herein by reference)
10.1*#	Consultancy Service Agreement between Hookipa Biotech GmbH and Malte Peters, effective September 15, 2023
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*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

<sup>\*</sup> Filed herewith.

<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.

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

#### **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: November 9, 2023 By:/s/ Joern Aldag

Joern Aldag

Chief Executive Officer (Principal Executive Officer)

By:/s/ Reinhard Kandera

Reinhard Kandera Chief Financial Officer (Principal Financial and Accounting Officer)

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#### CONSULTANCY SERVICE AGREEMENT

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

1. HOOKIPA Biotech GmbH, FN 491551w, Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria ("Company")

and

2. Malte Peters, M.D., \*, \*, \* ("Consultant"),

each of them being also designated as a "Party" and together the "Parties".

## **Preamble**

## **WHEREAS**

- A. The Company is active in the biotechnological / pharmaceutical industry and in vaccine and immunotherapy development;
- B. The Consultant is an expert in the field of medical research and drug development;
- C. The Company intends to hire the Consultant to perform certain consultancy services as defined in Section 1 below.

NOW, THEREFORE, in consideration of the mutual promises and other good and valuable consideration, the Parties hereto agree as follows:

## 1. Services

The Consultant agrees to perform the consultancy services agreed in the Schedules of Work attached hereto as Exhibit A (the "Services"), within the Consulting Service Term of this Agreement, as stipulated in Section 12. The Company agrees that the Consultant shall have reasonable access to the Company's representatives as necessary and on a timely manner to perform the Services as per this Agreement. The Consultant commits to be available on average three (3) half-days per week (flexibly between eight (8) to sixteen (16) hours per week, however, not to exceed eighty (80) hours per month). Any deviation from this maximum needs to be preapproved by the Company in writing.

#### 2. Payment for Services

As consideration for the performance of the Services defined in Exhibit A, the Company agrees to pay the Consultant, as follows:

2.1 **Fees.** It is agreed between the Parties that the Services hereunder will be provided personally by the Consultant. The Company and Consultant shall mutually agree the amount of days anticipated for Services. As consideration for the performance of the Services, the Company undertakes to pay the Consultant an hourly rate of six-hundred Euros (600 €). In case the performance of the Services requires travelling by the Consultant, a rate of one half (1/2) of the normal billable hourly rate will be charged for travel time to and from the Consultants place of business and the location where the Services will be performed, and the billable travel hours will not exceed eight (8) hours per day. The monthly fees are limited to forty-eight thousand Euros (48,000 €). Any deviation from this limit needs to be pre-approved by the Company in writing and will be subject to the review and approval of HOOKIPA Pharma Inc´s Audit Committee.

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- 2.2 **Reimbursable Expenses.** In addition, the Consultant shall be reimbursed for all reasonable and necessary travel expenses (including transportation, lodging and meals) incurred in the performance of the Services provided herein upon prior written consent of the Company and proper receipts of such costs. For clarity, first class flights can be necessary in case Services need to be performed in the United States of America or any other overseas location requested by Company that requires more than 7 hours of air travel from Consultant's domicile.
- 2.3 **Payment Terms**. The Consultant shall send invoices for the Services rendered and for reimbursable expenses in accordance with this Agreement on a monthly basis. These invoices shall include all applicable taxes. The Company agrees that all invoiced fees and expenses payable under this Agreement shall be paid to the Consultant within thirty (30) business days of receipt of said invoice. Payments shall be made in Euro by wire transfer to the Consultant's designated bank account. Invoices shall be submitted electronically to accounting@hookipapharma.com.

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

#### 3. Reporting

The Consultant shall give to the Company such information regarding the performance and results of the Services as required by the Company. The Consultant shall perform the Services in a professional, competent and timely manner and in accordance with industry standards and all legal and regulatory requirements applicable to the performance of the Services. Company shall not direct the manner in which Services are performed by the Consultant. The Company shall, however, be entitled to more closely specify the scope of work of the Consultant and to suspend or terminate the Consultant Services.

#### 4. Confidentiality

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

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

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

- (i) at the time of the disclosure, is rightfully in the public domain;
- (ii) subsequently becomes available to the public other than by a breach of this Agreement;
- (iii) is rightfully in the possession of the Consultant at the time such information is disclosed by the Company, without any limitation on use or disclosure prior to its receipt from the Company, as shown by documents or other tangible evidence in the Consultant's possession;
- (iv) has been fully received by the Consultant from a third party, who did not obtain the same from the Company, directly or indirectly, as evidenced by written records of the Consultant;
- (v) has been independently developed by the Consultant without assistance, application or use of the Information, as evidenced by written records of the Consultant; or
- (vi) has been approved for release by a written authorization of the Company.

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

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

The Information will be disclosed to the Consultant with the express understanding that neither the Consultant nor the Company will be obligated to enter into any further agreement relating to the Information.

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

This Article shall apply for the full term of this Agreement and for five (5) years after termination of this Agreement.

## 5. Property Rights & Intellectual Property

- 5.1 **Definition of Property**. All materials provided by Company for use by Consultant during the course of this Agreement shall remain the property of Company, along with all intellectual property rights therein ("Property"). Such Property shall include, but not be limited to Information, any documentation, technology, tools, products, program source code, or business or technical information. Modifications made by Consultant to such Property, along with any other inventions conceived, made or reduced to practice by Consultant that incorporate or rely upon any Company Property or Information ("Inventions") shall be disclosed promptly by Consultant to, and remain the property of, Company. Consultant shall have no rights, express or implied, to use Company Property or Inventions for any purpose outside the scope of this Agreement. All Company Property will either be delivered to or in the hands of Company upon termination of the Services being provided.
- 5.2 **Ownership of Proprietary Information; Assignment**. All Property, Information and Inventions including all title, patents, patent rights, copyrights, trade secret rights, database rights and other intellectual or industrial property rights of any sort anywhere in the world in connection with such Property, Information and Inventions (collectively "Rights") shall be the sole property of Company. Consultant hereby assigns to Company any Rights that Consultant may have or acquire in such proprietary Information.
- 5.3 **Ownership of Work Product**. The work product developed by Consultant during the course of this Agreement shall be the property of:
  - Company, for all work products that consists of Company specific designs and programs, such as proprietary algorithms and expressions of trade secrets and other Company proprietary and/or confidential information;
  - b. Consultant, for all work product that consists of designs and programs of a general or non- proprietary nature, including but not limited to concepts, designs, methodologies, processes, tools, technologies, training, utilities and programs that do not incorporate Company's Property, Information or Inventions.
- 5.4 **Modifications to Work Product.** Company shall have the right to use and/or modify all work

product developed by Consultant under this Agreement, whether or not such work product is Company property as defined in Section 5.3a.

5.5. **Intellectual Property.** Any Rights related to the subject matter of this Agreement that are learned or discovered by Consultant during the term of this Agreement shall at all times be and remain the sole property of the Company. The Consultant agrees to execute any and all documents appropriate to verify or transfer ownership of such Rights to the Company. The Company is entitled to transfer the intellectual property rights in full or in part to any third party. With regard to intellectual property that cannot be entirely transferred to the Company, in particular intellectual property under the Austrian Copyright Act (*Urheberrechtsgesetz*) the Consultant shall transfer, upon the Company's request, any and all rights that can be derived from such intellectual property rights (in particular rights to use the intellectual property / *Werknutzungsrechte*) to the Company.

## 6. Vacation

The Consultant is not entitled to any paid vacation.

## 7. Non-Competition and Non-Solicitation Undertaking

The Consultant agrees, during the term of this Agreement not to act as a consultant for any direct competitor of the Company that develops recombinant arenavirus vectors. Furthermore, the Consultant shall not employ, solicit or endeavor or entice away from the Company any person who is or was an employee of the Company during the year immediately preceding termination of this Agreement.

### 8. Capacity and Approval

The Consultant represents and warrants that it is permitted to enter into this Agreement and perform the obligations contemplated thereby and that this Agreement and the terms and obligations thereof are not inconsistent with or in violation of his present employment or any other obligations of the Consultant. Should the Consultant be obliged under applicable laws and regulations or employment contracts to pay any portion of the remuneration under this Agreement to his employer or any other third party, the Consultant shall be solely responsible for such payments.

# 9. Independent Contractors

It is the express intention of the Parties that Consultant is an independent contractor, and is classified by the Company as such for all tax and employee benefit purposes, and is not an employee, agent, or partner of the Company.

Consultant acknowledges and agrees that Consultant is obligated to report as income all compensation received by Consultant pursuant to this Agreement and that Consultant is solely responsible for all taxes, withholdings, and other similar statutory obligations including, but not limited to, self-employment tax and social security. In the event that Consultant employs assistants or subcontractors to aid in the performance of the Services, the Parties agree that such assistants or subcontractors are employed or retained solely by Consultant, and that Consultant alone is responsible for providing workers' compensation insurance for, paying the compensation, salaries and wages of, and ensuring that all required tax withholdings are made for such assistants or subcontractors. Should any tax or social security authority hold the Company liable for any taxes or social security contributions in connection with this Agreement, the Consultant shall fully reimburse the Company such taxes or social security contributions.

Consultant acknowledges and agrees that Consultant will be solely responsible for any insurance including without limitation the medical, accident and other liability insurances for himself for performing the Services during the term of this Agreement. Consultant agrees to hold harmless the

Company and its directors, officers and employees from any claims, costs, damages or losses that may arise from medical conditions and/or accidents to Consultant during his performance of the Services.

#### 10. Entire Agreement

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

# 11. Applicable Law and competent jurisdiction

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

#### 12. Term and Termination

- 12.1 Upon signature by both Parties, but subject to HOOKIPA Pharma Inc´s Audit Committee´s approval of the terms of this Agreement, this Agreement shall become effective on September 15, 2023 ("Effective Date") and shall remain in force for six months ("Consulting Service Term"). The Agreement shall be automatically extended on a monthly basis, unless terminated by either Party in writing. Should HOOKIPA Pharma Inc´s Audit Committee not approve the terms of this Agreement within two weeks of the Effective Date, this Agreement shall immediately terminate.
- 12.2 This Agreement may be terminated by either Party at any time on cause (*aus wichtigem Grund*) with immediate effect as well as without cause upon a thirty (30) day written notice delivered to the other Party. In the event a notice of termination is issued, the Company shall promptly pay to the Consultant any monies due and owing to the Consultant in relation to any Services performed by the Consultant prior to the date of such termination and the Consultant will promptly return to the Company all tangible materials containing or embodying the Information. The requirements of Section 4, 5, 7, 9, 11 and 14 shall survive and remain in effect upon the expiration or termination of this Agreement.

#### 13. Professional Standards

Consultant represents and warrants that the Service shall be performed and completed in accordance with the appropriate professional standards and guidelines and all applicable laws, regulations and policies.

# 14. Severability

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

# 15. Notices

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

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

# 16. Assignment

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

# 17. Miscellaneous

This Agreement may be executed in one or more counterparts and by the different Parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one valid and binding Agreement. A facsimile copy or portable document format (PDF) copy of an executed counterpart signature page will be as valid as an originally executed counterpart for purposes of signing this Agreement.

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

HOOKIPA BIOTECH GMBH	CONSULTANT
Ву:	Ву:
Name:Joern Aldag	Name: Malte Peters, M.D.
Title: CEO	Date: September 12, 2023
Date: September 12, 2023	

# **EXHIBIT A**

# **Schedules of Work**

# Scope of the Services:

- Serve as "Senior Clinical Advisor" to Company and its affiliate HOOKIPA Pharma Inc. Support hand-over of clinical programs from current CMO
- Oversee clinical programs of Company and its affiliate HOOKIPA Pharma Inc.
- Provide guidance to Company and its affiliate HOOKIPA Pharma Inc. on further developments of HOOKIPA's clinical programs
- Functional lead of the clinical development function (including therapeutic areas), directly interacting with subject matter experts and staff at Company and its affiliate HOOKIPA Pharma Inc.
- Cooperation with COO to transition clinical operations and regulatory affairs from COO to one Global Research & Development function

•	Hand-over and onboarding of new Global Head of R&D function
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# 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 THE 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report), that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 9, 2023 /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 THE 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report), that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 9, 2023 /s/ Reinhard Kandera

Reinhard Kandera Chief Financial Officer (Principal Financial and Accounting 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 of HOOKIPA Pharma Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of their knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 9, 2023 /s/ Joern Aldag

Joern Aldag

Chief Executive Officer (Principal Executive Officer)

Dated: November 9, 2023 /s/ Reinhard Kandera

Reinhard Kandera Chief Financial Officer

(Principal Financial and Accounting Officer)