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

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **March 19, 2020**

**HOOKIPA PHARMA INC.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-38869**  
(Commission  
File Number)

**81-5395687**  
(IRS 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**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
Common stock, \$0.0001	HOOK	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

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

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**Item 2.02 Results of Operations and Financial Condition.**

On March 19, 2020, HOOKIPA Pharma Inc. (the “Company”) announced its financial results for the fourth quarter and year ended December 31, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Press release issued by HOOKIPA Pharma Inc. on March 19, 2020</a>

## 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: March 19, 2020

By: /s/ Joern Aldag

Joern Aldag  
Chief Executive Officer  
(Principal Executive Officer)



## **HOOKIPA Pharma Reports Fourth Quarter and Full Year 2019 Financial Results and Provides a Corporate Update**

**New York, US and Vienna, Austria**, March 19, 2020 - HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on its proprietary arenavirus platform, today reports its financial results and corporate update for the fourth quarter and full year 2019 .

“In 2019, HOOKIPA achieved its development progress and financial goals,” commented Joern Aldag, HOOKIPA’s Chief Executive Officer. “We dosed our first patient in HB-201, our first immuno-oncology clinical trial in Human Papillomavirus-positive cancers, continued enrolling our Cytomegalovirus prophylaxis trial HB-101, progressed our collaboration with Gilead for HBV and HIV, and executed our Series D and IPO early in the year to fund our clinical trials beyond proof of concept. Well prepared for an important, data-rich year 2020, we now have to assume that the coronavirus pandemic will very likely affect how we will operate in order to fully execute our 2020 strategic plan in order to remain on track for our previously announced clinical milestones. Focusing first on our people and then on business continuity, we have instituted a work from home policy for those who do not need the company infrastructure for their work. We maintain our labs for business critical projects and stay in close connection with manufacturers and clinical trial sites. Our people are remarkable in doing everything under our control to deliver in the context of this situation.”

### **R&D Pipeline Update and Clinical Progress**

#### **HB-101, lead product candidate in infectious diseases**

HOOKIPA’s VaxWave<sup>®</sup>-based prophylactic Cytomegalovirus (CMV) vaccine candidate, HB- 101, continues to enroll patients in a Phase 2 randomized, double-blinded clinical trial in CMV-negative patients awaiting kidney transplantation from CMV-positive donors. Based on HB-101’s tolerability profile in the target patient population dosed to date and to gain further insights that will inform the Phase 3 trial design, the Company added a new cohort of CMV-positive recipients awaiting kidney transplantation from CMV-positive or -negative donors to the trial protocol in early 2020. HOOKIPA expects to report safety and immunogenicity data in the first half of 2020 from approximately one-third of the total 150 patients to be enrolled, including placebo recipients. The immunogenicity data set will contain both CMV-specific antibody (gB) and CMV-specific CD8<sup>+</sup> T cell responses. Preliminary efficacy data is on track to follow late in the second half of 2020.

#### **HB-201 and HB-202, programs for the treatment of Human Papillomavirus-positive cancers**

HB-201 and HB-202, HOOKIPA’s TheraT<sup>®</sup>-based lead oncology product candidates, are in development for the treatment of Human Papillomavirus serotype 16-positive (HPV16<sup>+</sup>) cancers. HOOKIPA dosed the first patient in an open label, dose escalating Phase 1/2 clinical trial for HB-201 in December 2019, HOOKIPA’s first clinical trial in immuno-oncology. The Company expects preliminary results in late 2020 or early 2021. HOOKIPA’s second planned Phase 1/2 clinical trial will assess the safety and efficacy of the combination of HB-201 and HB-202 in HPV16<sup>+</sup> cancers, with or without an approved checkpoint inhibitor. HOOKIPA remains on track to file the HB-202 Initial New Drug submission with the U.S. Food and Drug Administration in the first half 2020. The planned HB-202/201 clinical trial is an open label, dose escalation Phase 1/2 trial with the primary endpoint to evaluate safety and tolerability. That trial is expected to commence later in 2020.

### **Strategic Collaborations**

#### **Gilead Sciences Collaboration for HIV and HBV Therapeutic Vaccines**

During 2019, HOOKIPA received \$6.0 million in milestone payments from Gilead for the delivery of research vectors and advancing the programs closer to clinical trials. Based on preclinical data generated to date, Gilead committed to preparations to advance the HBV and HIV vectors toward development, with the HBV development decision triggering a milestone payment of \$4.0 million, which the Company received in early 2020. To enable the development activities and expanded research programs, Gilead agreed to reserve manufacturing capacity and increase reimbursement budgeted for the Company’s expanded resources allocated to the Gilead collaboration.

## Fourth Quarter and Full Year 2019 Financial Results

**Cash Position:** HOOKIPA's cash, cash equivalents and restricted cash as of December 31, 2019 was \$113.6 million compared to \$48.6 million as of December 31, 2018. The increase was primarily attributable to \$37.3 million in net proceeds received from the issuance of shares of Series D convertible preferred stock in February 2019, and \$74.6 million in net proceeds received from HOOKIPA's initial public offering in April 2019, offset by cash used in operating and investing activities. On April 23, 2019, HOOKIPA completed an initial public offering of its common stock by issuing 6.0 million shares of its common stock, at \$14.00 per share.

Revenue was \$3.6 million for the three months ended December 31, 2019, and \$11.9 million for the full year ended December 31, 2019 compared to \$5.1 million for the three months ended December 31, 2018 and \$7.6 million for the full year ended December 31, 2018. Revenue was driven by the recognition of milestone payments and partial recognition of the upfront payment as well as cost reimbursements received under the Collaboration Agreement with Gilead.

**Research and Development Expenses:** HOOKIPA's research and development expenses were \$11.2 million for the three months ended December 31, 2019, and \$46.3 million for the full year ended December 31, 2019 compared to \$4.6 million for the three months ended December 31, 2018 and \$22.0 million for the full year ended December 31, 2018.

The primary drivers of the increase for 2019 were an increase in direct research and development expenses by \$19.9 million, and an increase in personnel expenses by \$3.1 million. Direct research and development expenses increased primarily due to the costs for conducting a Phase 2 clinical trial for the Company's HB-101 program the preparation costs of clinical trials for HOOKIPA's HB-201 and HB-202 programs, expansion of earlier stage programs and costs in connection with securing manufacturing capacity for production of clinical trial material. In addition, costs related to HOOKIPA's collaboration with Gilead contributed to the increase in direct expenses.

**General and Administrative Expenses:** General and administrative expenses were \$5.7 million for the three months ended December 31, 2019, and \$16.7 million for the full year ended December 31, 2019, compared to \$2.7 million for the three months ended December 31, 2018 and \$6.8 million for the full year ended December 31, 2018. The increase was mainly due to the growth in personnel related expenses, an increase in professional and consulting fees as well as costs associated with ongoing business activities and costs to operate as a public company.

**Net Loss:** HOOKIPA's net loss was \$10.2 million for the three months ended December 31, 2019 and \$43.0 million for the full year ended December 31, 2019, compared to a net loss of \$1.9 million for the three months ended December 31, 2018 and \$16.2 million for the full year ended December 31, 2018. This increase was due to an increase in research and development expenses, mainly driven by the progression of HOOKIPA's oncology programs, and an increase in general and administrative expenses following HOOKIPA's IPO.

### Conference Call

To access the live conference call, please dial +1 631 510 7495 (from the US) or +44 207 192 8000 (international) and refer to conference ID 1769733. A live audio webcast of the event will also be available within the Investors & Media section of HOOKIPA's website at <https://ir.hookipapharma.com/events>. An archived replay will be accessible for 30 days following the event.

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### About HOOKIPA

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

HOOKIPA's proprietary arenavirus-based technologies, VaxWave®, a replication-deficient viral vector, and TheraT®, a replication-attenuated viral vector, are designed to induce robust antigen specific CD8<sup>+</sup> T cells and pathogen-neutralizing antibodies. Both technologies are designed to allow for repeat administration to augment and refresh immune responses. TheraT® has the potential to induce CD8<sup>+</sup> T cell response levels previously not achieved by other immuno-therapy approaches. HOOKIPA's "off-the-shelf" viral vectors target dendritic cells in vivo to activate the immune system.

HOOKIPA's VaxWave®-based prophylactic Cytomegalovirus (CMV) vaccine candidate is currently in a Phase 2 clinical trial in CMV-negative patients awaiting kidney transplantation from living CMV-positive donors as well as CMV-positive patients awaiting kidney transplantation from CMV-positive or -negative donors. To expand its infectious disease portfolio, HOOKIPA has entered into a collaboration and licensing agreement with Gilead Sciences, Inc. to jointly research and develop functional cures for HIV and chronic Hepatitis B infections.

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In addition, HOOKIPA is building a proprietary immuno-oncology pipeline by targeting virally mediated cancer antigens, self-antigens and next-generation antigens. The TheraT<sup>®</sup> based lead oncology product candidates, HB-201 and HB-202, are in development for the treatment of Human Papilloma Virus16-positive cancers. The Phase 1/2 clinical trial for HB-201 was initiated in December 2019. The HB-202 IND submission is intended for the first half of 2020.

Find out more about HOOKIPA online at [www.hookipapharma.com](http://www.hookipapharma.com).

### **HOOKIPA Forward Looking Statements**

Certain statements set forth in this press release constitute “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements can be identified by terms such as “believes,” “expects,” “plans,” “potential,” “would” or similar expressions and the negative of those terms. Such forward-looking statements involve substantial risks and uncertainties that could cause HOOKIPA’s research and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including HOOKIPA’s programs’ early stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, HOOKIPA’s ability to successfully establish, protect and defend its intellectual property, risks relating to business interruptions resulting from the coronavirus (COVID-19) disease outbreak or similar public health crises and other matters that could affect the sufficiency of existing cash to fund operations and HOOKIPA’s ability to achieve the milestones under the agreement with Gilead. HOOKIPA undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see HOOKIPA’s annual report on Form 10-K for the full year ended December 31, 2019 which will be available on the Security and Exchange Commission’s website at [www.sec.gov](http://www.sec.gov) and HOOKIPA’s website at [www.hookipapharma.com](http://www.hookipapharma.com).

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

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**HOOKIPA Pharma Inc.**  
**Consolidated Statements of Operations (Unaudited)**  
(In thousands, except share and per share data)

	Three months ended		Year ended December 31,	
	December 31, 2019	December 31, 2018	2019	2018
Revenue from collaboration and licensing	\$ 3,618	\$ 5,080	\$ 11,942	\$ 7,629
Operating expenses:				
Research and development	(11,179)	(4,615)	(46,312)	(21,965)
General and administrative	(5,664)	(2,669)	(16,715)	(6,844)
Total operating expenses	(16,843)	(7,284)	(63,027)	(28,809)
Loss from operations	(13,225)	(2,204)	(51,085)	(21,180)
Total interest, other income and taxes, net	2,981	312	8,048	4,943
Net loss	\$ (10,244)	\$ (1,892)	\$ (43,037)	\$ (16,237)
Net loss per share — basic and diluted	(0.40)	(2.05)	(2.41)	(17.76)
Weighted average common shares outstanding — basic and diluted	25,432,314	922,083	17,859,935	914,375

**Condensed Balance Sheets (Unaudited)**  
(In thousands)

	As of December 31, 2019	As of December 31, 2018
<b>Assets</b>		
<b>Current assets</b>		
Cash, cash equivalents	\$ 113,151	\$ 48,580
Accounts receivable	1,537	4,919
Receivable research incentives	8,190	2,329
Prepaid expenses and other current assets	5,139	6,483
<b>Total current assets</b>	<b>128,017</b>	<b>62,311</b>
<b>Non-current assets:</b>		
Restricted cash	424	—
Property and equipment, net	5,126	4,337
Operating lease right of use assets	7,875	—
Finance lease right of use assets	1,602	—
Other non-current assets	701	1,603
<b>Total non-current assets</b>	<b>15,728</b>	<b>5,940</b>
<b>Total assets</b>	<b>\$ 143,745</b>	<b>\$ 68,251</b>
<b>Liabilities, convertible preferred stock and stockholders' equity (deficit)</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 944	\$ 3,656
Deferred revenues	3,591	6,619
Operating lease liabilities, current	1,814	—
Accrued expenses and other current liabilities	8,406	4,420
<b>Total current liabilities</b>	<b>14,755</b>	<b>14,695</b>
<b>Non-current liabilities</b>		
Loans payable, non-current	3,495	4,392
Operating lease liabilities, non-current	5,290	—
Deferred revenues, non-current	72	1,663
Other non-current liabilities	2,234	3,102
<b>Total non-current liabilities</b>	<b>11,091</b>	<b>9,157</b>
<b>Total liabilities</b>	<b>25,846</b>	<b>23,852</b>
<b>Commitments and contingencies</b>	<b>—</b>	<b>104,774</b>
<b>Stockholders' equity (deficit):</b>		
Common stock	3	0
Class A common stock	0	—
Additional paid-in capital	225,568	3,327
Accumulated other comprehensive loss	(4,653)	(3,720)

Accumulated deficit	(103,019)	(59,982)
Total stockholders' equity (deficit)	117,899	(60,375)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 143,745	\$ 68,251

For further information, please contact:

**Media**

Nina Waibel  
Senior Director - Communications  
nina.waibel@hookipapharma.com

**Investors**

Matt Beck  
Executive Director - Investor Relations  
matthew.beck@hookipapharma.com

**Media enquiries**

Ashley Tapp  
Instinctif Partners  
hookipa@instinctif.com  
+44 (0)20 7457 2020

