

**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): **November 12, 2019**

**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  x

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.  x

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

On November 12, 2019, HOOKIPA Pharma Inc. (the “Company”) announced Financial Results and Clinical Progress Highlights for the three and nine months ended September 30, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press release issued by HOOKIPA Pharma Inc. on November 12, 2019</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: November 12, 2019

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



## **HOOKIPA Pharma Reports Third Quarter 2019 Financial Results and Provides a Corporate Update**

**New York, US and Vienna, Austria**, November 12, 2019 - 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 for the third quarter ended September 30, 2019 and provides a corporate update.

“In the third quarter, HOOKIPA has made significant progress toward achieving its corporate objectives. Highlights include demonstrating the potential of our TheraT<sup>®</sup> technology with the presentation of robust preclinical data at the CICON cancer immunotherapy conference in Paris. We also welcome two new individuals to our Executive Team who have very strong manufacturing expertise and business development capabilities,” commented Joern Aldag, HOOKIPA’s Chief Executive Officer. “Looking ahead, we reaffirm our plan to initiate our first clinical program for TheraT<sup>®</sup> in oncology before the end of 2019 and hope that the preclinical results showcased at CICON translate into positive results for cancer patients.”

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

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

HOOKIPA’s VaxWave<sup>®</sup>-based prophylactic Cytomegalovirus vaccine candidate, HB-101, is currently in a Phase 2 randomized, double-blinded clinical trial in cytomegalovirus-negative patients awaiting kidney transplantation from Cytomegalovirus-positive donors. The majority of sites have been activated. HOOKIPA expects safety and immunogenicity data in the first half of 2020 from the first cohorts enrolled. Preliminary efficacy data scheduled 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 lead oncology product candidates, are in development for the treatment of Human Papillomavirus (HPV)-positive cancers. In July 2019, HOOKIPA announced that its Investigational New Drug (IND) Application for a Phase 1/2 clinical trial of HB-201, a TheraT<sup>®</sup>-based immunotherapy for the treatment of HPV-positive cancers was accepted by the U.S. Food and Drug Administration (FDA). HOOKIPA reaffirms its plan to initiate a Phase 1/2 clinical trial of HB-201 in patients with treatment-refractory HPV16+ cancers before the end of the year. This trial will be HOOKIPA’s first clinical trial in immuno-oncology.

The HB-202 IND filing with the FDA is planned for the first half of 2020. A Phase 1/2 trial combining HB-201 and HB-202, both with and without a checkpoint inhibitor, in patients with treatment-refractory HPV16+ cancers is expected to commence in late 2020.

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During the CICON Cancer Immunotherapy Conference in September in Paris, HOOKIPA presented four posters highlighting the robust preclinical data and broad therapeutic potential for TheraT<sup>®</sup>-based immunotherapies.

## **Strategic Collaborations**

### **Progress under Gilead collaboration for therapeutic hepatitis B virus (HBV) and human immunodeficiency virus (HIV)**

In May 2019, HOOKIPA achieved a \$2.0 million research milestone for HBV by designing and delivering 10 research-grade vectors to Gilead Sciences, Inc., along with the characterization of these vectors and delivery of a data package for the HBV program. These research vectors will be subject to further pre-clinical testing in order to validate a clinical candidate for novel combination therapies for the treatment of HBV. This follows the delivery of 14 research-grade vectors for the HIV program in January 2019.

## **Management Update**

### **Christine D. Baker and Roman Necina joined HOOKIPA's Executive Team**

In September 2019, HOOKIPA announced the hiring of Christine D. Baker as Chief Business Officer (CBO) and Roman Necina, PhD, as Chief Technology Officer (CTO).

Ms. Baker joined HOOKIPA from EpicentRx in August, where she was the CBO and previously Novartis Oncology, where she was a leader in oncology business development and M&A. At HOOKIPA, Ms. Baker will be responsible for the company's business development, alliance management, and commercial planning and is based in HOOKIPA's New York City office.

Dr. Necina joined HOOKIPA in November from Takeda, where he was a Senior Vice President for Technical Development and Chief Strategist. He is based in Vienna and will be responsible for HOOKIPA's manufacturing operations including analytical and process development.

## **Third Quarter 2019 Financial Results**

HOOKIPA's net loss for the three months ended September 30, 2019 was \$11.4 million, compared to a net loss of \$4.0 million for the three months ended September 30, 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.

Revenue was \$2.0 million for the three months ended September 30, 2019, compared to \$1.9 million for the three months ended September 30, 2018.

HOOKIPA's research and development expenses for the three months ended September 30, 2019, were \$11.0 million, compared to \$6.2 million for the three months ended September 30, 2018. The primary drivers of the increase were an increase in direct research and development expenses by \$3.6 million and an increase in personnel expenses by \$0.9 million. Direct research and development expenses increased primarily due to the expansion of earlier stage programs and the preparation costs of clinical trials for HOOKIPA's HB-201 and HB-202 programs. In addition, costs related to HOOKIPA's collaboration with Gilead contributed to the increase in direct expenses.

General and administrative expenses for the three months ended September 30, 2019 were \$4.6 million, compared to \$1.3 million for the three months ended September 30, 2018. The

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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.

HOOKIPA's cash, cash equivalents and restricted cash as of September 30, 2019 was \$124.0 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.

### Upcoming Investor Events

- Jefferies 2019 London Healthcare Conference, November 20 - 21, 2019
- Piper Jaffray 31st Annual Healthcare Conference NY, December 3 - 5, 2019

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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<sup>®\*</sup>, a replication-deficient viral vector, and TheraT<sup>®\*</sup>, 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<sup>®</sup> 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<sup>®</sup>-based prophylactic cytomegalovirus vaccine candidate is currently in a Phase 2 clinical trial in patients awaiting kidney transplantation from living cytomegalovirus-positive 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 Hepatitis B infections.

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 Papillomavirus-positive cancers. The Phase 1/2 clinical trial initiation for HB-201 is still planned in 2019. The HB-202 IND filing is intended for the first half of 2020.

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

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\*Registered in Europe; Pending in the US.

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## 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 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 quarterly report on Form 10-Q for the quarter ended September 30, 2019 which is 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.**  
**Condensed Consolidated Statements of Operations (Unaudited)**  
(In thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Revenue from collaboration and licensing	\$ 2,038	\$ 1,900	\$ 8,324	\$ 2,549
Operating expenses:				
Research and development	(11,025)	(6,170)	(35,133)	(17,350)
General and administrative	(4,589)	(1,282)	(11,051)	(4,175)
Total operating expenses	(15,614)	(7,452)	(46,184)	(21,525)
Loss from operations	(13,576)	(5,552)	(37,860)	(18,976)
Other income (expense):				
Grant income	1,258	1,762	3,994	5,217
Interest income	565	—	1,140	0
Interest expense	(227)	(194)	(650)	(578)
Other income and expenses, net	604	33	692	19
Total other income (expense), net	2,200	1,601	5,176	4,658
Net loss before tax	(11,376)	(3,951)	(32,684)	(14,318)
Income tax expense	(9)	(2)	(109)	(27)
Net loss	\$ (11,385)	\$ (3,953)	\$ (32,793)	\$ (14,345)

	As of September 30, 2019	As of December 31, 2018
Cash, cash equivalents and restricted cash	\$ 124,010	\$ 48,580
Total assets	152,037	68,251
Total liabilities	26,280	23,852
Redeemable convertible preferred stock	—	104,774
Total stockholders' equity	125,757	(60,375)

For further information, please contact:

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