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): **May 14, 2020**

HOOKIPA PHARMA INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38869**	**81-5395687**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

350 Fifth Avenue, 72nd Floor, Suite 7240 New York, New York	**10118**
(Address of principal executive offices)	(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:

Title of each class	**Trading Symbol(s)**	**Name of exchange on which registered**
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. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 14, 2020, HOOKIPA Pharma Inc. (the "Company") announced its financial results for the first quarter ended March 31, 2020. 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.

Exhibit Number	Description
99.1	Press release issued by HOOKIPA Pharma Inc. on May 14, 2020

SIGNATURES

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

HOOKIPA Pharma Inc.

Date: May 14, 2020

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

HOOKIPA Pharma Reports First Quarter 2020 Financial Results and Provides a Corporate Update

New York, US and Vienna, Austria, May 14, 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 first quarter ended March 31, 2020.

"The current unusually challenging times are impacting our industry significantly. HOOKIPA continues to progress well in areas which are under our control," commented Joern Aldag, HOOKIPA's Chief Executive Officer. "The HOOKIPA team is continuing to activate sites for our oncology candidate HB-201 and patients are accruing. We expect to submit the combined HB-202/201 IND to the U.S. Food and Drug Administration in the first half of 2020, as previously forecasted. For HB-101, although enrollment of kidney transplant patients is currently hampered by the impact of COVID-19, we expect to report preliminary safety and immunogenicity data in July 2020 and efficacy data by the end of 2020, roughly at the same time we expect to report preliminary safety and efficacy for HB-201. With approximately $105 million in cash and cash equivalents, we believe that we are well funded beyond multiple clinical data points across our programs. In addition, I am particularly proud of the remarkable contribution of the HOOKIPA team voluntarily accepting a significant reduction of their fixed salaries and thereby extending our cash runway."

R&D Pipeline Update and Clinical Progress

HB-101, lead product candidate in infectious diseases
HOOKIPA's VaxWave®-based prophylactic Cytomegalovirus (CMV) vaccine candidate, HB-101, is in a randomized, double-blinded Phase 2 clinical trial in patients awaiting kidney transplantation who are at risk for CMV-associated complications post-transplant. Due to the COVID-19 pandemic, nearly all ongoing Phase 2 trial sites have suspended patient enrollment, and it remains unclear when kidney organ transplants will resume at any of the trial sites.
By the end of July 2020, HOOKIPA expects to report safety data (on approximately one-third of the total 150 patients to be enrolled) as well as immunogenicity data (on approximately one-quarter of the total patients to be enrolled). The immunogenicity data will focus on CMV-neutralizing antibody responses. Analyses of cellular immune responses, including CD8+ T cells, have been limited to date due to the complexities of sample collection, transport, and analysis. HOOKIPA reiterates its guidance to deliver preliminary efficacy data by the end of 2020. Due to the COVID-19-impacted accrual, the timing of study completion will be delayed.

HB-201 and HB-202, programs for the treatment of Human Papillomavirus-positive cancers
HOOKIPA's lead oncology product candidates, HB-201 and HB-202, are in development for the treatment of Human Papillomavirus-positive (HPV+) cancers. In December 2019, HOOKIPA initiated the Phase 1/2 clinical trial for HB-201 and expects preliminary results in late 2020 or early 2021. The open label, dose escalating Phase 1/2 clinical trial is evaluating HB-201 in HPV16+ cancers, alone and in combination with an approved checkpoint inhibitor. HOOKIPA plans to enroll 100 patients in total with 20 patients in each dose escalation and expansion group, respectively. Enrollment of the first group of patients receiving the intravenously administered first dose level has been completed and the trial is accruing patients at the next higher dose level.

HOOKIPA remains on track to file the HB 202/201 Initial New Drug (IND) submission with the U.S. Food and Drug Administration in the first half of 2020. The planned clinical trial combining HB-202 with HB-201, also in patients with HPV16+ cancers, 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 for advancing the programs towards 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.

Other
At HOOKIPA's New York City headquarters, all employees will continue to work from home and are fully operational. The Austrian government has removed some of the previously mandated COVID-19 restrictions that it put in place during March 2020, and this has allowed HOOKIPA's Austrian site to ramp up its activities. The Company plans to increase its lab capacity to the extent safe and reasonable, and at the same time encourages all employees who can reasonably work from home to continue to do so.

First Quarter 2020 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of March 31, 2020 was $104.9 million compared to $113.6 million as of December 31, 2019. The decrease was primarily attributable to cash used in operating activities.
Revenue was $3.7 million for the three months ended March 31, 2020 compared to $2.2 million for the three months ended March 31, 2019. 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 $11.5 million for the three months ended March 31, 2020 compared to $10.2 million for the three months ended March 31, 2019.
The primary drivers of this increase were $1.3 million higher personnel expenses along with a general increase in internal research and development expenses, partially offset by an overall decrease in direct research and development expenses by $0.6 million. The latter reduction was a consequence of reduced activity around our earlier stage programs; in addition, preparation costs of clinical trials for our HB-201 and HB-202 programs were lower than in the same period last year. This decrease was partially offset by an increase in the direct costs related to our collaboration with Gilead due to an acceleration program and a modest increase in direct expenses for the HB-101 Phase 2 trial.

General and Administrative Expenses: General and administrative expenses amounted to $4.6 million for the three months ended March 31, 2020 compared to $2.7 million for the three months ended March 31, 2019. The increase was mainly due to personnel related expenses, an increase in professional and consulting fees, as well as costs related to being a public company, such as premiums for directors and officers liability insurance.
Net Loss: HOOKIPA's net loss was $10.9 million for the three months ended March 31, 2020 compared to a net loss of $9.3 million for the three months ended March 31, 2019. This increase was driven by higher research and development expenses, in particular for HOOKIPA's oncology programs, and an increase in general and administrative expenses following HOOKIPA's IPO.

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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 $CD8^+$ 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 $CD8^+$ 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.

In addition, HOOKIPA is building a proprietary immuno-oncology pipeline by targeting virally mediated cancer antigens, self-antigens and next-generation antigens. The TheraT® based lead oncology product candidates, HB-201 and HB-202, are in development for the treatment of Human Papilloma Virus 16-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.

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 quarterly report on Form 10-Q for the quarter ended March 31, 2020 which will be available on the Security and Exchange Commission’s website at www.sec.gov and HOOKIPA’s website at 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.

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

	Three months ended March 31,	
	2020	2019
Revenue from collaboration and licensing	$ 3,696	$ 2,235
Operating expenses:		
Research and development	(11,526)	(10,179)
General and administrative	(4,629)	(2,711)
Total operating expenses	(16,155)	(12,890)
Loss from operations	(12,459)	(10,655)
Total interest, other income and taxes, net	1,533	1,326
Net loss	$ (10,926)	$ (9,329)
Net loss per share — basic and diluted	(0.43)	(9.27)
Weighted average common shares outstanding — basic and diluted	25,630,007	1,006,595

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of March 31, 2020	As of December 31, 2019
Cash, cash equivalents and restricted cash	$ 104,877	$ 113,575
Total assets	135,967	143,745
Total liabilities	26,985	25,846
Total stockholders' equity	108,982	117,899

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