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): **August 13, 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 August 13, 2020, HOOKIPA Pharma Inc. (the "Company") announced its financial results for the second quarter ended June 30, 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 August 13, 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: August 13, 2020

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

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

New York, US and Vienna, Austria, August 13, 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 for the second quarter ended June 30, 2020 and provides a corporate update.

"In the second quarter, we released positive interim safety and immunogenicity results from our Phase 2 trial of HB-101 to prevent Cytomegalovirus (CMV) infections. HB-101 was observed to be well tolerated and immunogenic in patients with end-stage kidney disease. Antibody and T cell immunogenicity data confirm our Phase 1 results," commented Joern Aldag, HOOKIPA's Chief Executive Officer. "Furthermore, our immuno-oncology trial using HB-201 monotherapy for patients with HPV16+ tumors is progressing well and has recently completed enrollment at the second dose level in the intravenous group. The HB-202 Investigational New Drug (IND) was cleared by the U.S. Food and Drug Administration (FDA), allowing the alternating use of two vectors (HB-202 + HB-201) in this trial. We expect to begin treating HPV16+ patients with this new alternating, two-vector therapy in late 2020. We plan to report further data on the HB-101 program by the end of 2020 and initial data from the HB-201 monotherapy program by late 2020 or early 2021."

R&D Pipeline Update and Clinical Progress

HB-101, lead product candidate in infectious diseases
HOOKIPA's 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. In June 2020, HOOKIPA announced positive Phase 2 interim data on the trial's primary endpoints: safety, and B cell and T cell immunogenicity. The interim data demonstrated that HB-101 was well tolerated, with a lower rate of adverse events in patients with end-stage kidney disease than in the Phase 1 healthy volunteer trial. Patients who received the protocol recommended three doses of HB-101 showed comparable immunogenicity levels to those measured in the Phase 1 healthy volunteer trial. HOOKIPA continues to accrue patients, and plans to report preliminary efficacy and updated safety and immunogenicity data by the end of 2020.

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

In June 2020, HOOKIPA announced that the FDA cleared its IND Application for HB-202. With the IND clearance, HOOKIPA will be able to examine not only the safety and efficacy of HB-201 alone but also HB-201 in combination with HB-202 as an alternating, two-vector therapy. The planned clinical trial combining HB-202 with HB-201, 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.

In August 2020, the United States Patent and Trademark Office (USPTO) and the European Patent Office issued patents to the University of Geneva, licensed exclusively to HOOKIPA, that cover HOOKIPA´s proprietary replicating arenavirus technology (TheraT®), including HB-201 and HB-202. The USPTO also granted a patent specifically related to HB-201 and HB-202 product candidates.

Strategic Collaborations

Gilead Sciences Collaboration for HIV and HBV Therapeutic Vaccines: Since the start of the collaboration in 2018, HOOKIPA received $21.0 million in upfront and milestone payments from Gilead for the delivery of research vectors and for advancing the programs towards clinical trials, including a milestone payment of $4.0 million, which the Company received in early 2020. Based on preclinical data generated to date, Gilead committed to advancing the HBV and HIV vectors toward development. To enable the development activities and expanded research programs, Gilead agreed to reserve manufacturing capacity and increase reimbursement planned for the Company's expanded resources allocated to the Gilead collaboration. The HOOKIPA team has continued to meet all milestones agreed with Gilead on time despite the pandemic.

COVID-19
HOOKIPA continues to monitor the COVID-19 situation closely and to adapt to the COVID-19 measures and recommendations issued by the US and Austrian governments. For disclosures of risks and uncertainties resulting from the COVID-19 disease outbreak, including the impact on the enrollment of patients and timing of clinical results, see HOOKIPA's quarterly report on Form 10-Q for the quarter ended June 30, 2020.

Second Quarter 2020 Financial Results

Cash Position:
HOOKIPA's cash, cash equivalents and restricted cash as of June 30, 2020 was $93.3 million compared to $113.6 million as of December 31, 2019. The decrease was primarily attributable to cash used in operating activities.
Revenue was $6.7 million for the three months ended June 30, 2020 compared to $4.1 million for the three months ended June 30, 2019. The increase was primarily due to higher cost reimbursements received under the collaboration agreement with Gilead and the partial recognition of a milestone payment we received from Gilead in February 2020.

Research and Development Expenses:
HOOKIPA's research and development expenses were $11.6 million for the three months ended June 30, 2020 compared to $13.9 million for the three months ended June 30, 2019.
The primary drivers of the decrease compared to 2019 were a decrease in manufacturing and quality control expenses of $2.0 million along with a general decrease in other direct R&D expenses of $1.1 million.

General and Administrative Expenses: General and administrative expenses amounted to $4.3 million for the three months ended June 30, 2020 compared to $3.8 million for the three months ended June 30, 2019. The increase was primarily due to an increase in personnel-related expenses and in costs associated with ongoing business activities and operating as a public company, which was partially offset by a decrease in professional and consulting fees which resulted from the prior-year effect related to the closing of the Company's initial public offering in April 2019.

Net Loss: HOOKIPA's net loss was $7.1 million for the three months ended June 30, 2020 compared to a net loss of $12.1 million for the three months ended June 30, 2019.

– END –

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 reprograms the body's immune system.

HOOKIPA's proprietary arenavirus-based technologies, non-replicating (VaxWave®) and replicating (TheraT®), induce robust antigen-specific $CD8^+$ T cells and pathogen-neutralizing antibodies. HOOKIPA's "off-the-shelf" viral vectors target antigen presenting cells in vivo to activate the immune system. Both technologies enable repeat administration to augment and refresh immune responses. As a monotherapy, our replicating arenavirus technology has the potential to induce $CD8^+$ T cell response levels previously not achieved by other immuno-therapy approaches.

HOOKIPA's non-replicating prophylactic Cytomegalovirus (CMV) vaccine candidate is currently in a Phase 2 clinical trial for patients awaiting kidney transplantation. To expand its infectious disease portfolio, HOOKIPA entered into a collaboration

and licensing agreement with Gilead Sciences, Inc. to research arenavirus-based 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 lead replicating arenavirus 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 application was cleared by the FDA in June 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, the impact of COVID-19 on the enrollment of patients and timing of clinical results for HB-101 and other programs, 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 June 30, 2020 which is 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 June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Revenue from collaboration and licensing	$ 6,685	$ 4,051	$ 10,381	$ 6,286
Operating expenses:				
Research and development	(11,564)	(13,929)	(23,090)	(24,108)
General and administrative	(4,347)	(3,751)	(8,976)	(6,462)
Total operating expenses	(15,911)	(17,680)	(32,066)	(30,570)
Loss from operations	(9,226)	(13,629)	(21,685)	(24,284)
Total interest, other income and taxes, net	2,134	1,550	3,667	2,876
Net loss	$ (7,092)	$ (12,079)	$ (18,018)	$ (21,408)
Net loss per share — basic and diluted	(0.28)	(0.63)	(0.70)	(2.10)
Weighted average common shares outstanding — basic and diluted	25,647,819	19,240,977	25,638,913	10,174,157

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of June 30, 2020	As of December 31, 2019
Cash, cash equivalents and restricted cash	$ 93,282	$ 113,575
Total assets	133,268	143,745
Total liabilities	29,353	25,846
Total stockholders' equity	103,915	117,899

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