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 12, 2021**

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 12, 2021, HOOKIPA Pharma Inc. (the "Company") announced Financial Results for the Second Quarter ended June 30, 2021. 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 12, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 12, 2021

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

HOOKIPA Pharma Reports Second Quarter 2021 Financial Results and Recent Highlights

- Phase 1 HB-200 data recognized at premier oncology meetings, highlighting potential of novel arenaviral platform to deliver a new class of immunotherapeutics

- HOOKIPA on track to report comprehensive data from oncology and infectious disease programs in the second half of 2021

New York, United States and Vienna, Austria, August 12, 2021 - HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today reported financial results and business highlights for the second quarter of 2021.

"During the second quarter, we gained considerable momentum in highlighting the promise of our novel arenaviral platform to redefine success in cancer immunotherapy. Our HB-200 program in advanced Human Papillomavirus 16-positive ('HPV16+') cancers was featured prominently at both AACR and ASCO, with compelling tumor antigen-specific T cell responses and tumor control that replicate pre-clinical results," said Joern Aldag, Chief Executive Officer at HOOKIPA. "We are focused on advancing our oncology and infectious disease programs through the second half of the year, as we aim to deliver first-in-class arenaviral immunotherapies that induce potent, targeted immune responses to fight or prevent serious disease."

Quarter Highlights

- At the virtual American Association for Cancer Research ('AACR') Annual Meeting in April 2021, HOOKIPA presented positive preliminary Phase 1 immunogenicity data for HB-200 for the treatment of advanced HPV16+ cancers. These data demonstrated a robust increase in HPV16+-specific T cells, including an increase of up to 8% of antigen-specific circulating CD8+ T cells, after one dose of HB-201 or HB-202. Early HB-201 monotherapy data also highlighted immune system activation of increasing interferon-gamma and other immune stimulatory cytokines with a single dose.

- In June, HOOKIPA reported positive Phase 1 data from the ongoing Phase 1/2 study of HB-200 for the treatment of advanced HPV16+ cancers. The clinical data, presented as an oral presentation at the American Society of Clinical Oncology ('ASCO') Annual Meeting, showed HB-200 is highly immunogenic, inducing unprecedented levels of activated, tumor antigen-specific CD8+ T cells (an average of 6 percent and up to 40 percent of the T cell pool). In addition, HB-201 monotherapy showed an 18 percent overall response rate and median progression-free survival of 3.45 months in heavily pre-treated head and neck cancer patients who progressed on standard of care, including checkpoint inhibitors.

- HOOKIPA completed enrollment in the Phase 2 clinical trial of its prophylactic Cytomegalovirus ('CMV'), vaccine candidate, HB-101; the last patient was enrolled in June 2021. We expect to report additional safety, immunogenicity, and efficacy data from evaluable patients in the second half of 2021, with final top-line data readout in the first half of 2023. The protocol requires a 12-month follow up after transplantation, which is typically two to three months after enrollment.

- Jean-Charles Soria resigned as a Non-Executive Director of HOOKIPA's Board of Directors to avoid any conflicts of interest following a decision to join Amgen as senior vice president and lead of the oncology therapeutic area.

Upcoming Milestones

- Additional HB-201/HB-202 Phase 1/2 data in HPV16+ cancers and recommended Phase 2 dose for the HB-200 program in the fourth quarter of 2021
- HB-101 CMV Phase 2 data in the second half of 2021
- Advancing our HB-300 program to IND for the treatment of metastatic prostate cancer
- HBV and HIV collaboration with Gilead Sciences advancing towards clinical studies

Second Quarter 2021 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of June 30, 2021 was $102.9 million compared to $143.2 million as of December 31, 2020. The decrease was primarily attributable to cash used in operating activities.

Revenue was $5.4 million for the three months ended June 30, 2021, and $6.7 million for the three months ended June 30, 2020. The decrease was primarily due to receipt of a $1.0 million milestone payment under the Gilead collaboration during this time period in 2020, but not in 2021.

Research and Development Expenses: HOOKIPA's research and development expenses were $19.6 million for the three months ended June 30, 2021, compared to $11.6 million for the three months ended June 30, 2020.

The primary drivers of the increase in direct research expenses were an increase in manufacturing and quality control expenses of $1.6 million, and an increase in clinical operations expenses of $1.4 million, along with a general increase in other direct research and development expenses and laboratory expenses of $2.4 million. These expenses were mainly due to the progress in our HB-201 and HB-202 clinical trial, in particular for monitoring and testing activities, and manufacturing and quality control work in preparation of a further extension of the trial. Manufacturing and quality control expenses were also driven by the progress towards clinical development in our Gilead-partnered programs.

Internal research and development expenses increased by $2.6 million, mainly due to our increased research and development headcount.

General and Administrative Expenses: General and administrative expenses for the three months ended June 30, 2021 were $5.1 million, compared to $4.3 million for the three months ended June 30, 2020. The increase was primarily due to an increase in personnel-related expenses, partially offset by a decrease in professional and consulting fees. The increase in personnel-related expenses resulted from a growth in headcount along with increased salaries in our general and administrative functions, and increased stock compensation expenses.

Net Loss: HOOKIPA's net loss was $17.2 million for the three months ended June 30, 2021, compared to a net loss of $7.1 million for the three months ended June 30, 2020. This increase was due to an increase in research and development expenses, an increase in general and administrative expenses, a decrease in revenues from collaboration and licensing and a decrease in other income, partially offset by an increase in grant income.

About HOOKIPA

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical-stage biopharmaceutical company focused on developing novel immunotherapies that mobilize and amplify targeted T cells and antibodies, the body's natural infection killers, to fight or prevent serious disease.

HOOKIPA is developing a broad pipeline of potential first-in-class arenaviral immunotherapies in oncology and infectious disease. We are leveraging our proprietary, versatile platform to engineer arenaviral therapeutics that induce robust antigen-specific CD8+ T cells and pathogen-neutralizing antibodies to a broad range of self and non-self antigens, including viral antigens, tumor-associated antigens and neoantigens. Our immunotherapies are designed to use either non-replicating or replicating viral vectors based on the target disease, with the potential to induce CD8+ T cell response levels previously not achieved by other immunotherapy approaches.

HOOKIPA's pipeline includes ongoing clinical trials in Human Papilloma Virus 16-positive cancers and Cytomegalovirus, as well as preclinical research in prostate cancer, HIV and Hepatitis B. The latter two are in collaboration with Gilead Sciences, Inc.

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 materially 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 annual report on Form 10-Q for the financial year ended June 30, 2021 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,	
	2021	2020	2021	2020
Revenue from collaboration and licensing	$ 5,378	$ 6,685	$ 10,679	$ 10,381
Operating expenses:				
Research and development	(19,572)	(11,564)	(39,736)	(23,090)
General and administrative	(5,095)	(4,347)	(9,404)	(8,976)
Total operating expenses	(24,667)	(15,911)	(49,140)	(32,066)
Loss from operations	(19,289)	(9,226)	(38,461)	(21,685)
Total interest, other income and taxes, net	2,136	2,134	4,070	3,667
Net loss	$ (17,153)	$ (7,092)	$ (34,391)	$ (18,018)
Net loss per share — basic and diluted	(0.52)	(0.28)	(1.05)	(0.70)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of June 30, 2021	As of December 31, 2020
Cash, cash equivalents and restricted cash	$ 102,953	$ 143,177
Total assets	166,156	187,817
Total liabilities	40,222	31,694
Total stockholders' equity	125,934	156,123

For further information, please contact:

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