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 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 May 12, 2021, HOOKIPA Pharma Inc. (the "Company") announced Financial Results for the First Quarter 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 May 12, 2021

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 12, 2021

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

HOOKIPA Pharma Reports First Quarter 2021 Financial Results and Recent Highlights

- Oncology programs advance with preliminary Phase 1 immunogenicity data showing robust antigen-specific CD8+ T cell response after one dose of HB-201 or HB-202; clinical results consistent with those observed in pre-clinical studies
- HOOKIPA on track to report additional HB-201 and HB-202 clinical data on T cell response and preliminary antitumor activity at ASCO and other upcoming conferences

New York, US and Vienna, Austria, May 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 first quarter of 2021.

"We had a strong start to the year as we drive our pipeline forward to deliver a new class of arenavirus-based immunotherapeutics. As we shared at AACR, one initial dose of our lead oncology candidates, HB-201 or HB-202, each induced a robust increase in antigen-specific T cells, including an increase of up to 8% of antigen-specific circulating CD8+ T cells, in people with advanced Human Papillomavirus 16-positive (HPV16+) cancers," said Joern Aldag, Chief Executive Officer at HOOKIPA. "We believe these data are impressive, and they are consistent with the pre-clinical data published in Cell Reports Medicine in March. Both data sets highlight the potential of our engineered arenavirus platform to redefine success in cancer immunotherapy. As our clinical programs progress, we're excited about the oral abstract presentation at ASCO (#2502) and other future data presentations at upcoming conferences."

Program Highlights

- In April 2021, HOOKIPA announced positive preliminary Phase 1 immunogenicity data for its lead oncology candidates, HB-201 and HB-202, for the treatment of advanced HPV16+ cancers, reinforcing the promising anti-tumor activity reported from the Phase 1/2 clinical trial in December 2020. The preliminary immunogenicity 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. The data were presented at a late-breaker poster session at the virtual American Association for Cancer Research (AACR) Annual Meeting.

- In March, Cell Reports Medicine published pre-clinical data on HOOKIPA's arenaviral therapeutics. The peer-reviewed article showed that intravenous HB-201 administration induced single digit percentage of antigen-specific CD8+ T cells, while alternating administration of HB-201 and HB-202 induced a potent CD8+ T cell response, exceeded 50% of the circulating T cell pool. The two-vector cancer therapeutic approach also resulted in tumor cures and long-term immunity in a pre-clinical setting.

- HOOKIPA's prophylactic Cytomegalovirus, or CMV, vaccine candidate, HB-101, continued to enroll patients awaiting kidney transplantation in a Phase 2 clinical trial. We expect to conclude trial enrollment in mid-2021 and to report additional safety, immunogenicity, and efficacy data from evaluable patients in the second half of 2021.

Upcoming Milestones

- Oral abstract presentation at ASCO (#2502 at 3:00pm EDT on June 7): First report of the safety/tolerability and preliminary antitumor activity of HB-201 and HB-202, an arenavirus-based cancer immunotherapy, in patients with HPV16+ cancers
- Initial HB-201/HB-202 Phase 1/2 efficacy data in HPV16+ cancers in mid-2021
- Additional HB-101 CMV Phase 2 efficacy data in H2 2021
- Advancing our HB-300 to IND for the treatment of metastatic prostate cancer
- HBV and HIV collaboration with Gilead Sciences advancing towards clinical studies

First Quarter 2021 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of March 31, 2021 was $128.1 million compared to $143.2 million as of December 31, 2020. The decrease was primarily attributable to cash used in operating activities.

Revenue was $5.3 million for the three months ended March 31, 2021, and $3.7 million for the three months ended March 31, 2020. The increase was primarily due to higher cost reimbursements received under the Collaboration Agreement with Gilead and the recognition of cost reimbursements initially recognized as deferred revenue.

Research and Development Expenses: HOOKIPA's research and development expenses were $20.2 million for the three months ended March 31, 2021, compared to $11.5 million for the three months ended March 31, 2020.

The primary drivers of the increase in direct research expenses were an increase in clinical trial expenses of $1.5 million and an increase in manufacturing and quality control expenses of $4.6 million.

The increase was mainly due to the progress in our HB-201 and HB-202 clinical trials, the increased patient recruitment in our HB-201 and HB-202 clinical trial, 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. This increase in HB-201/HB-202 and Gilead related direct expenses was partially offset by a decrease in direct costs related to our HB-101 program due to slower patient recruitment as a result of the COVID pandemic.

The increase in internal research and development expenses was mainly due to an increase of personnel-related research and development expenses, resulting primarily from a higher headcount, while stock-based compensation expenses included in personnel-related research and development expenses decreased. In addition, an increase in facility related costs and an increase in other internal costs contributed to the overall increase in internal research and development expenses.

General and Administrative Expenses: General and administrative expenses for the three months ended March 31, 2021 were $4.3 million, compared to $4.6 million for the three months ended March 31, 2020. The decrease was primarily due to a decrease in personnel-related expenses, partially offset by an increase in professional and consulting fees. The decrease in personnel-related expenses resulted from decreased stock compensation expenses, partially offset by increased salaries and a growth in headcount in our general and administrative functions.

Net Loss: HOOKIPA's net loss was $17.2 million for the three months ended March 31, 2021 compared to a net loss of $10.9 million for the three months ended March 31, 2020. This increase was due to an increase in research and development expenses, partially offset by an increase in revenues from collaboration and licensing, a decrease in general and administrative expenses, and an increase in grant income.

About HOOKIPA

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical-stage biopharmaceutical company developing a new class of immunotherapeutics based on its proprietary arenavirus platform that reprograms the body's immune system.

HOOKIPA's proprietary arenavirus-based technologies, non-replicating and replicating, induce robust antigen-specific CD8+ T cells and pathogen-neutralizing antibodies. HOOKIPA's 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 not used in combination, our replicating arenavirus technology has the potential to induce CD8+ T cell response levels previously not achieved by other immuno-therapy approaches.

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 in a Phase 1/2 clinical trial.

HOOKIPA's non-replicating prophylactic Cytomegalovirus vaccine candidate, HB-101, 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.

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 March 31, 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 March 31,	
	2021	**2020**
Revenue from collaboration and licensing	$ 5,301	$ 3,696
Operating expenses:		
Research and development	(20,164)	(11,526)
General and administrative	(4,309)	(4,629)
Total operating expenses	(24,473)	(16,155)
Loss from operations	(19,172)	(12,459)
Total interest, other income and taxes, net	1,934	1,533
Net loss	$ (17,238)	$ (10,926)
Net loss per share — basic and diluted	(0.53)	(0.43)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of March 31, 2021	**As of December 31, 2020**
Cash, cash equivalents and restricted cash	$ 128,145	$ 143,177
Total assets	169,941	187,817
Total liabilities	29,886	31,694
Total stockholders' equity	140,055	156,123

For further information, please contact:

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