
**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 16, 2022**

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

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 16, 2022, HOOKIPA Pharma Inc. (the “Company”) announced Financial Results for the First Quarter 2022. 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release issued by HOOKIPA Pharma Inc. on May 16, 2022
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: May 16, 2022

By: /s/ Joern Aldag

Joern Aldag
Chief Executive Officer
(Principal Executive Officer)



HOOKIPA Pharma Reports First Quarter 2022 Financial Results and Recent Highlights

- HB-200 program on track to report Phase 1 data mid-year, Phase 2 data in combination with pembrolizumab in second half of 2022
- Q1 capital raise and Gilead collaboration funding generated a strong cash position of \$142 million

New York, US and Vienna, Austria, May 16, 2022 - 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 2022.

"We observed strong external validation of our novel arenaviral platform in the first quarter with our collaboration agreement with Gilead and our capital raise, which drew funding from new and existing top-tier investors," said Joern Aldag, Chief Executive Officer at HOOKIPA. "On the heels of our AACR data presentations, which showcased T cell and tumor response with our technology alone and in novel combinations, we remain focused on advancing our portfolio across cancer types. We look forward to sharing Phase 1 data from our HB-200 program mid-year and early Phase 2 data on HB-200 in combination with pembrolizumab in late 2022, as well as progressing with IND preparations for our HB-300 program in prostate cancer."

Quarter Highlights

- In January 2022, the [first patient was dosed in the Phase 2 trial](#) to assess HB-200 in combination with pembrolizumab as 1st-line and 2nd-line treatment for advanced head and neck squamous cell carcinoma (HNSCC). Results from the ongoing Phase 1 study have highlighted the potential additive benefits of this combination to improve anti-tumor response. Preliminary data is anticipated in the second half of 2022.
 - In February 2022, [HOOKIPA and Gilead agreed to advance its partnered HIV program](#), triggering a \$54 million commitment from Gilead. HOOKIPA assumed development responsibility for the HB-500 program through the completion of a Phase 1b clinical trial; Gilead has the exclusive right for further development thereafter. Financial terms included a \$4 million preclinical milestone, a \$15 million non-refundable initiation fee and \$35 million equity commitment at a premium to market price. The \$35 million equity commitment includes a first tranche of \$5 million (purchased at a \$3 share price on February 15) and the remaining \$30 million can be drawn at a 30 percent premium in a second tranche or at market price in a third tranche. If Gilead pursues further development, HOOKIPA is entitled to potential development and sales milestone payments exceeding \$237 million, as well as royalties on net product sales.
 - [Klaus Orlinger, Ph.D. was named Chief Scientific Officer](#). He was promoted from his previous role as Executive Vice President, Research. Klaus has played a leading role in the development of novel arenaviral immunotherapies and advancing them to the clinic since he joined the company in 2012.
 - In March 2022, HOOKIPA announced the acceptance of four poster presentations on preclinical, translational and clinical biomarker data at the American Association for Cancer Research Annual Meeting in April. [The data provided further evidence](#) of the potential of the arenaviral platform in various cancers, either alone or with other modalities. Specifically, the data showed:
 - the combination of co-stimulatory 4-1BB agonists with arenaviral immunotherapy in a preclinical setting increased tumor control and resulted in a higher cure rate than arenaviral immunotherapy alone;
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- replicating immunotherapy sequentially combined with adoptively transferred TCR transgenic T cells resulted in tumor cures in a preclinical setting;
 - arenaviral immunotherapy was able to overcome immune tolerance, induce potent T cell responses against two different tumor self-antigens and reduce tumor growth in these cancers in a preclinical setting;
 - HB-200 induced robust antigen-specific T cells that were high quality, expanding on previously reported data in patients with Human Papillomavirus 16-positive (HPV16+) head and neck cancer. Additional Phase 1 data, including the recommended Phase 2 dose for HB-202/HB-201 was [recently accepted for presentation](#) at the American Society of Clinical Oncology in June.
- In April, HOOKIPA reported the addition of [Tim Reilly, Ph.D. to its Board of Directors](#). Tim brings extensive product development experience to the Board.

Upcoming Milestones

- Phase 1 HB-200 data in HPV16+ head and neck cancer: Mid-2022
- Phase 2 HB-200 data in combination with pembrolizumab in HPV16+ head and neck cancer:
 - 1st-line initial data: 2H 2022
 - 2nd-line initial data: 2H 2022
- Randomized Phase 2 HB-200 study in combination with pembrolizumab in 1st line for HPV16+ HNSCC: 1H 2023 (Fast Track designation)
- Prostate cancer IND: 3Q 2022
- Hepatitis B therapeutic IND: 2022 (Gilead-led)

First Quarter 2022 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of March 31, 2022 was \$141.8 million compared to \$66.9 million as of December 31, 2021. The increase was primarily attributable to funds resulting from the amended and restated Gilead collaboration agreement, and the follow-on financing in March 2022, partly offset by cash used in operating activities.

Revenue was \$1.4 million for the three months ended March 31, 2022, and \$5.3 million for the three months ended March 31, 2021. The decrease was primarily due to lower cost reimbursements received under the Collaboration Agreement with Gilead and the fact that the \$4.0 million milestone payment and the \$15.0 million initiation fee received in the three months ended March 31, 2022 were mostly recorded as deferred revenue to be recognized in future accounting periods.

Research and Development Expenses: HOOKIPA's research and development expenses were \$16.6 million for the three months ended March 31, 2022, compared to \$20.2 million for the three months ended March 31, 2021.

The decrease for the three months ended March 31, 2022 compared to the three months ended March 31, 2021 was attributable to a decrease in direct research and development expenses, partially offset by an increase in indirect research and development expenses.

The decrease in direct research and development expenses was primarily driven by lower manufacturing expenses for our HB-200 and Gilead partnered programs and lower clinical study expenses due to the completion of patient enrollment of the Phase 2 study for our HB-101 program. Indirect research and development expenses increased slightly because of an increase in professional and consulting fees, partially offset by a decrease in personnel related costs.

General and Administrative Expenses: General and administrative expenses for the three months ended March 31, 2022 were \$5.0 million, compared to \$4.3 million for the three months ended March 31, 2021. The increase was primarily due to an increase in professional and consulting fees, and an increase in personnel-related expenses, partially offset by a decrease in other expenses. The increase in personnel-related expenses resulted from increased stock compensation expenses, a growth in headcount along with increased salaries in our general and administrative functions. The increase in professional and consulting fees was primarily attributable to intellectual property costs incurred in connection with filing and prosecuting patent applications as well as third-party license fees.

Net Loss: HOOKIPA's net loss was \$18.0 million for the three months ended March 31, 2022 compared to a net loss of \$17.2 million for the three months ended March 31, 2021. This increase was due to a decrease in revenues from collaboration and licensing, a decrease in grant income, an increase in general and administrative expenses, partially offset by a decrease in research and development expenses.

About HOOKIPA

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical-stage biopharmaceutical company focused on developing novel immunotherapies, based on its proprietary arenavirus platform, that are designed to mobilize and amplify targeted T cells and thereby fight or prevent serious disease. HOOKIPA's replicating and non-replicating technologies are engineered to induce robust and durable antigen-specific CD8+ cell responses and pathogen-neutralizing antibodies. HOOKIPA's pipeline includes its wholly-owned investigational arenaviral immunotherapeutics targeting HPV16+ cancers, prostate cancer, KRAS-mutated cancers (including colorectal, pancreatic and lung), and other undisclosed programs. In addition, HOOKIPA aims to develop functional cures of HBV and HIV in collaboration with Gilead.

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, 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, 2022 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,	
	2022	2021
Revenue from collaboration and licensing	\$ 1,445	\$ 5,301
Operating expenses:		
Research and development	(16,620)	(20,164)
General and administrative	(4,972)	(4,309)
Total operating expenses	<u>(21,592)</u>	<u>(24,473)</u>
Loss from operations	(20,147)	(19,172)
Total interest, other income and taxes, net	2,179	1,934
Net loss	<u>\$ (17,968)</u>	<u>\$ (17,238)</u>
Net loss per share — basic and diluted	(0.40)	(0.53)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of March 31, 2022	As of December 31, 2021
Cash, cash equivalents and restricted cash	\$ 141,803	\$ 66,912
Total assets	195,711	126,045
Total liabilities	47,782	36,453
Total stockholders' equity	147,929	89,592

For further information, please contact:

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