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 11, 2023**

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 11, 2023, HOOKIPA Pharma Inc. (the "Company") announced Financial Results for the First Quarter 2023. 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 8.01 Other Events.

In April, the Company presented preclinical data resulting from an exploratory, non-commercial research effort as an oral presentation at the American Association for Cancer Research Annual Meeting highlighting the potential of its arenaviral immunotherapy in combination with Roche's targeted PD1-IL2 variant (PD1-IL2v) as a potential promising next-generation immunotherapy. The data show that PD1-IL2v treatment subsequent to arenaviral immunotherapy further strengthens T cell responses, resulting in strong anti-tumor activity and high tumor cure rates. Similar results were seen for both tumor-associated oncoviral antigens and self-antigens, underscoring the potential of the combination for multiple tumor types.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by HOOKIPA Pharma Inc. on May 11, 2023
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 11, 2023

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

Exhibit 99.1

HOOKIPA Pharma Reports First Quarter 2023 Financial Results and Recent Business Highlights

- HOOKIPA on track to report Phase 2 data on HB-200 for head and neck cancer in combination with pembrolizumab in 2Q 2023
- Phase 1 clinical trials initiated for two programs (HB-300 for advanced prostate cancer and Gilead-partnered HB-400 for chronic hepatitis B)
- HB-700 for KRAS-mutated cancers achieved $10 million milestone payment in Roche collaboration

NEW YORK and VIENNA, May 11, 2023 - 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 2023.

"We are happy to report continued progress across our oncology and infectious disease portfolios, as our HB-300 program for advanced prostate cancer and Gilead-partnered HB-400 program for the treatment of chronic hepatitis B both entered the clinic. Further, our HB-700 program in collaboration with Roche achieved a success-based milestone payment associated with manufacturing for our clinical supplies," said Joern Aldag, Chief Executive Officer at HOOKIPA. "We are on track to report Phase 2 data from our lead program, HB-200 in combination with pembrolizumab, in the second quarter of 2023, which is an exciting step forward as we expect the results to inform our next, potentially registrational trial."

Quarter highlights

Oncology

- In February, HOOKIPA announced that it had achieved a $10 million milestone payment under its collaboration agreement with Roche to develop HB-700, a novel arenaviral immunotherapy for KRAS-mutated cancers. The success-based milestone payment reflects the start of the HB-700 manufacturing process to support a Phase 1 clinical trial.
- In April, HOOKIPA announced the acceptance of a trial-in-progress presentation at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting on its ongoing Phase 1/2 study of HB-300 for the treatment of advanced prostate cancer. Enrollment is ongoing and initial data are expected in the first half of 2024.

Infectious disease

- In January, HOOKIPA recieved a $5 million milestone payment under its collaboration agreement with Gilead Sciences for the completion of the regulatory support package for Gilead's Phase 1 clinical trial of HB-400, an alternating, 2-vector non-replicating arenaviral therapeutic vaccine for the treatment of chronic hepatitis B. The first participant was dosed in April 2023. Gilead is solely responsible for further development and commercialization of the hepatitis B product candidate.

Corporate

- In March, HOOKIPA announced the appointment of Terry Coelho to its Board of Directors, Audit Committee and Compensation Committee. Terry brings more than 35 years of experience in business strategy, broad financial transactions and business development of large pharmaceutical and smaller biotechnology companies.

Upcoming Milestones

- Phase 2 HB-200 in HPV16+ head and neck cancers
  - 1st-line initial data in combination with pembrolizumab: 2Q 2023
  - 2nd+-line initial data in combination with pembrolizumab: 2Q 2023
  - Post-standard of care monotherapy: additional data 2Q 2023
  - Randomized Phase 2 in 1st-line with pembrolizumab: study kick-off 2023 (Fast Track designation)
- HB-300 in prostate cancer: preliminary safety, tolerability and immunogenicity data expected 1H 2024
- HB-700 in KRAS-mutated cancers: submit IND 1H 2024
- HB-500 in HIV: submit IND 2023

First Quarter 2023 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of March 31, 2023 was $110.0 million compared to $113.4 million as of December 31, 2022. The decrease was primarily attributable to cash used in operating activities, partly offset by funds resulting from the Gilead and Roche collaborations.

Revenue: Revenue was $3.2 million for the three months ended March 31, 2023 compared to $1.4 million for the three months ended March 31, 2022. The increase was primarily due to higher recognition of upfront and milestone payments under the Gilead and Roche collaborations, partially offset by lower cost reimbursements received under the Gilead collaboration.

Research and Development Expenses: HOOKIPA's research and development expenses were $20.9 million for the three months ended March 31, 2023, compared to $16.6 million for the three months ended March 31, 2022. The primary drivers of the increase in research and development expenses by $4.3 million compared to the three months ended March 31, 2022 were higher clinical study expenses for our HB-200 program and higher expenses for research and development services for our HB-200 program, as well as increased spending for our Gilead and Roche partnered programs, partially offset by lower manufacturing expenses for our HB-200 and Gilead partnered programs.

General and Administrative Expenses: General and administrative expenses amounted to $4.9 million for the three months ended March 31, 2023, compared to $5.0 million for the three months ended March 31, 2022. The decrease compared to the three months ended March 31, 2022 was primarily due to a decrease in professional and consulting fees and in other expenses, partially offset by an increase in personnel-related expenses.

Net Loss: HOOKIPA's net loss was $19.7 million for the three months ended March 31, 2023, compared to a net loss of $18.0 million for the three months ended March 31, 2022. This increase was primarily due to an increase in research and development expenses, partially offset by an increase in revenues from collaboration and licensing, and an increase in grant income, and a decrease in general and administrative 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, which 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+ T cell responses and pathogen-neutralizing antibodies. HOOKIPA's pipeline includes its wholly owned investigational arenaviral immunotherapies targeting Human Papillomavirus 16-positive cancers, prostate cancers, and other undisclosed programs. HOOKIPA is collaborating with Roche on an arenaviral immunotherapeutic for KRAS-mutated cancers. 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.

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. 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, 2023, 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, (unaudited)	
	2023	2022
Revenue from collaboration and licensing	$ 3,176	$ 1,445
Operating expenses:		
Research and development	(20,931)	(16,620)
General and administrative	(4,902)	(4,972)
Total operating expenses	(25,833)	(21,592)
Loss from operations	(22,657)	(20,147)
Total interest, other income and taxes, net	2,977	2,179
Net loss	$ (19,680)	$ (17,968)
Net loss per share — basic and diluted	(0.27)	(0.40)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of March 31, 2023	As of December 31, 2022
Cash, cash equivalents and restricted cash	$ 110,021	$ 113,444
Total assets	163,088	170,454
Total liabilities	79,609	67,937
Total stockholders’ equity	83,479	102,517

For further information, please contact:

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