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 9, 2024**

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 Capital 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 9, 2024, HOOKIPA Pharma Inc. (the "Company") announced Financial Results for the First Quarter 2024. 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 March 9, 2024
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 9, 2024

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

HOOKIPA Pharma Reports First Quarter 2024 Financial Results and Recent Business Highlights

- Phase 2/3 pivotal trial design and protocol for HB-200 in combination with pembrolizumab for the first-line treatment of patients with HPV16+ recurrent or metastatic OPSCC aligns with U.S. Food and Drug Administration (FDA) feedback
- HB-200 program received Priority Medicines (PRIME) designation from the European Medicines Agency (EMA)
- Received FDA clearance for Investigational New Drug (IND) application for HB-700 for the treatment of KRAS mutated cancers

NEW YORK and VIENNA, May 9, 2024 - 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 recent business highlights for the first quarter of 2024.

"The first quarter was about focus at HOOKIPA. We are embarking on a pivotal trial for HB-200 in combination with pembrolizumab and made important decisions to align our organization for late-stage clinical trial execution. We also added to the depth of our executive team with a new Chief Development Officer, Mark Winderlich, who brings crucial experience to help us execute on our clinical development strategy," said Joern Aldag, Chief Executive Officer of HOOKIPA. *"We have made great progress and have an FDA-aligned pivotal Phase 2/3 trial design that is patient-centric and we believe has a high probability of success. Our path forward is clear, and the team is excited to take a major step on our path to deliver better outcomes for patients."*

Business Highlights and Recent Developments

Oncology

- HOOKIPA is preparing to start a seamless pivotal Phase 2/3 trial of HB-200 in combination with pembrolizumab for the treatment of patients with Human Papillomavirus 16-positive (HPV16+) recurrent/metastatic PD-L1 CPS ≥ 20 oropharyngeal squamous cell carcinoma (OPSCC) in the first line setting.
- The Phase 2/3 trial design and protocol are based on alignment with the FDA following the Company's Type C meeting.
- EMA granted PRIME designation to the investigational product HB-200 in combination with pembrolizumab. PRIME designation is intended to expedite development and review of drug candidates, alone or in combination with other drugs. Eligibility and approval are based on preliminary clinical evidence and indicate that the drug candidate may offer substantial improvement over existing therapies.
- The Company anticipates the first patient will be enrolled in the fourth quarter of 2024. HB-200 was accepted for an oral abstract presentation at the ASCO 2024 Annual Meeting with data from approximately 40 patients treated with HB-200 in combination with pembrolizumab.

- The HB-700 program is a novel arenaviral immunotherapy for KRAS-mutated cancers, including the five mutations that are the primary causes of lung, pancreatic and colon cancers. The Company received clearance from the U.S. Food and Drug Administration (FDA) for its Investigational New Drug (IND) application for HB-700 for the treatment of KRAS-mutated cancers. Effective April 25, 2024, HOOKIPA regained full control of the associated intellectual property portfolio and has full collaboration and licensing rights for this program.

Infectious Disease

- HB-400 is currently being evaluated in a Phase 1 trial and is one of two independent development programs in HOOKIPA's collaboration and license agreement with Gilead Sciences, Inc. (Gilead). Gilead is solely responsible for further development and commercialization of the HBV product candidate.

- HB-500 is an investigational therapeutic vaccine for the treatment of human immunodeficiency virus (HIV), also partnered with Gilead. HOOKIPA received FDA clearance of its IND application in the fourth quarter of 2023 and expects to initiate a Phase 1 clinical trial of HB-500 in people with HIV in the second quarter of 2024. Under the collaboration agreement with Gilead, HOOKIPA is eligible for a milestone payment upon dosing the first patient in this trial.

Corporate and Financial Updates

Corporate Highlights

- On January 29, 2024, HOOKIPA provided an update on its business priorities and oncology partnership programs. The Company announced that it will focus its resources in two strategic areas: (1) the clinical development of a randomized trial for its HB-200 program and (2) its two Gilead-partnered infectious disease cure programs for hepatitis B and HIV.

- Mark Winderlich, Ph.D., joined the Company on April 1, 2024, as Chief Development Officer to lead HOOKIPA's clinical research and development organization.

Financial Highlights

- HOOKIPA received a final $10.0 million milestone payment under its now-terminated HB-700 collaboration agreement with Roche. The success-based milestone payment was achieved in connection with HOOKIPA's submission of an IND application for HB-700 for the treatment of KRAS mutated tumors.

- Total revenues of $36.6 million, mainly driven by the recognition of previously received upfront and milestone payments under the now-terminated Roche collaboration, as well as the recent HB-700 milestone achievement, led to a profitable first quarter of 2024.

Anticipated Catalysts & Milestones

Program	Indication	Upcoming Anticipated Catalysts
Oncology Programs		
HB-200	HPV16+ HNSCC	● Additional Phase 2 first-line data for HB-200 in combination with pembrolizumab (ASCO 2024) ● Pivotal study start (4Q 2024)
HB-700	KRAS	● Publication of preclinical data (ASCO 2024)
Infectious Disease Programs: Gilead-Partnered		
HB-400	HBV	● Gilead-led: Phase 1b actively enrolling ● Next milestone: Initiation of Phase 2 (timing determined by Gilead)
HB-500	HIV	● Initiation of Phase 1 trial; first patient dosed and associated milestone payment (2Q 2024)

First Quarter 2024 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of March 31, 2024 was $93.0 million compared to $117.5 million as of December 31, 2023. The decrease was primarily attributable to cash used in operating activities.

Revenue: Revenue was $36.6 million for the three months ended March 31, 2024, compared to $3.2 million for the same period in 2023. The increase was primarily due to higher partial revenue recognition under the Roche collaboration as a result of the termination of the agreement, leading to accelerated recognition of the upfront and milestone payments that were initially recorded as deferred revenue.

Research and Development Expenses: HOOKIPA's research and development expenses were $20.2 million for the three months ended March 31, 2024, compared to $20.9 million for the same period in 2023. The primary drivers of the decrease in research and development expenses were lower personnel-related and laboratory-related expenses, partially offset by higher clinical study expenses for the HB-200 program.

General and Administrative Expenses: General and administrative expenses amounted to $4.1 million for the three months ended March 31, 2024, compared to $4.9 million for the same period in 2023. The primary driver of the decrease in general and administrative expenses was a decrease in personnel-related expenses.

Restructuring Expenses: Restructuring expenses amounted to $1.3 million for the three months ended March 31, 2024, and resulted from severance and other personnel costs as well as consulting costs associated with the Company's restructuring plan announced in January 2024.

Net Income (Loss): HOOKIPA's net income was $14.4 million for the three months ended March 31, 2024, compared to a net loss of $19.7 million for the same period in 2023. This increase was primarily due to the accelerated recognition of upfront and milestone payments under the Roche collaboration.

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, KRAS-mutated cancers, 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.

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 “anticipates”, “believes,” “expects,” “plans,” “potential,” “will,” “would” or similar expressions and the negative of those terms. Forward-looking statements in this press release include HOOKIPA’s statements regarding the potential of its product candidates to positively impact quality of life and alter the course of disease in the patients it seeks to treat, HOOKIPA’s plans, strategies, expectations and anticipated milestones for its preclinical and clinical programs, including the timing of initiating clinical trials and patient enrollment, the availability and timing of results from preclinical studies and clinical trials, the timing of regulatory filings, the expected safety profile of HOOKIPA’s product candidates, and the probability of successfully developing and receiving regulatory approval for its product candidates. 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, plans and timelines for the preclinical and clinical development of its product candidates, including the therapeutic potential, clinical benefits and safety thereof, expectations regarding timing, success and data announcements of current ongoing preclinical and clinical trials, the ability to initiate new clinical programs, the risk that the results of current preclinical studies and clinical trials may not be predictive of future results in connection with current or future preclinical and clinical trials, including those for HB-200, HB-700, HB-400 and HB-500, 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 public health crises, the impact of public health crises on the enrollment of patients and timing of clinical results, HOOKIPA’s ability to achieve the expected benefits of its strategic reprioritization. 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 Annual Report on Form 10-K for the year ended December 31, 2023, as well as discussions of potential risks, uncertainties, and other important factors in HOOKIPA’s subsequent filings with the Securities and Exchange Commission, which are available on the SEC’s website at www.sec.gov and HOOKIPA’s website at www.hookipapharma.com. All information in this press release is as of the date of the release, and HOOKIPA undertakes no duty to update this information unless required by law.

Availability of Other Information About HOOKIPA
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 investors 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 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, 2024	2023
Revenue from collaboration and licensing	$ 36,599	$ 3,176
Operating expenses:		
Research and development	(20,168)	(20,931)
General and administrative	(4,056)	(4,902)
Restructuring	(1,269)	—
Total operating expenses	(25,493)	(25,833)
Income (loss) from operations	11,106	(22,657)
Total interest, other income and taxes, net	3,277	2,977
Net income (loss)	$ 14,383	$ (19,680)
Net income (loss) per share:		
Basic	$ 0.11	$ (0.27)
Diluted	$ 0.11	$ (0.27)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of March 31, 2024	As of December 31, 2023
Cash, cash equivalents and restricted cash	$ 92,955	$ 117,521
Total assets	145,871	161,337
Total liabilities	41,349	71,480
Total stockholders' equity	104,522	89,857

For further information, please contact:

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