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): April 25, 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 (Address of Principal Executive Offices)	**10118 (Zip Code)**

Registrant's telephone number, including area code: +43 1 890 63 60

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

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 each exchange on which registered
Common Stock, $0.0001 par value per share	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 7.01 Regulation FD Disclosure.

On April 25, 2024, HOOKIPA Pharma Inc. issued a press release entitled "HOOKIPA Pharma Announces Pivotal Phase 2/3 Trial Design for HB-200 in Combination with Pembrolizumab." A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference into this Item 7.01.

The information in this Item 7.01 and Exhibit 99.1 attached hereto is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("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, as amended, 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 No.	Description
99.1	Press Release, dated April 25, 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 hereunto duly authorized.

Date: April 25, 2024

HOOKIPA Pharma Inc.

By: /s/ Joern Aldag
Name: Joern Aldag
Title: Chief Executive Officer

Exhibit 99.1

HOOKIPA Pharma Announces Pivotal Phase 2/3 Trial Design for HB-200 in Combination with Pembrolizumab

- 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 aligned with FDA feedback
- HB-200 accepted for oral abstract presentation at ASCO 2024 Annual Meeting with data from approximately 40 patients treated with HB-200 in combination with pembrolizumab
- Two additional abstracts for HB-200 and HB-700 accepted for the ASCO 2024 Annual Meeting
- Company to host investor call at 8:00 a.m. ET on Thursday, April 25, 2024, to highlight path to potential registration; participant details below

NEW YORK and VIENNA, April 25, 2024 – HOOKIPA Pharma Inc. (NASDAQ: HOOK, HOOKIPA or the Company), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced its final pivotal Phase 2/3 trial design for HB-200 in combination with pembrolizumab. The Phase 2/3 trial design and protocol are based on alignment with the U.S. Food and Drug Administration (FDA) following the Company's Type C meeting with the FDA.

The seamless Phase 2/3 trial is for the investigational product HB-200 in combination with pembrolizumab for the treatment of patients with Human Papillomavirus 16-positive (HPV16+) recurrent/metastatic PD-L1 CPS $\geq$ 20 oropharyngeal squamous cell carcinoma (OPSCC) in the first line setting. The Company anticipates the first patient will be enrolled in the fourth quarter of 2024.

The Company also announced acceptance of its HB-200 study abstract as an oral presentation at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting in the head and neck cancer session to be held on June 4, 2024. The presentation will include data for approximately 40 head and neck cancer patients treated with HB-200 in combination with pembrolizumab.

"It has been a dream of mine—and my HOOKIPA colleagues—to translate our science into a product that will make an impact for patients and help them fight cancer and infectious diseases. I am happy to say that we are taking a very big step forward to making this dream a reality," said Joern Aldag, Chief Executive Officer of HOOKIPA. "We believe our data is best-in-class and puts us in the lead position for OPSCC in the first line setting. We have alignment with the FDA on our pivotal trial design and protocol, as well as PRIME designation for HB-200 in combination with pembrolizumab for the treatment of patients with OPSCC in the first line setting from the European Medicines Agency. We believe our trial design and alignment with our primary regulators can help us reach a potential registration more quickly. Further, we have been accepted for an oral abstract presentation at ASCO in June 2024 where we will present an update from our Phase 1/2 trial with approximately 40 patients treated with the combination of HB-200 and pembrolizumab."

HB-200 in combination with pembrolizumab pivotal Phase 2/3 trial design summary

- The trial will treat patients with HPV16+ recurrent/metastatic PD-L1 CPS ≥ 20 oropharyngeal squamous cell carcinoma in the first line setting.
- The trial is expected to enroll approximately 250 patients across the seamless Phase 2/3 design.
- Patients will be randomized one-to-one for HB-200 plus pembrolizumab or placebo plus pembrolizumab.
- The primary endpoints are objective response rate for the Phase 2 portion and overall survival for the Phase 3 portion.
- The Company may seek accelerated approval based on data from the Phase 2 portion of the trial, from approximately half of the Phase 2/3 study patients, if favorable.
- Phase 2 primary analysis expected in 2026 with potential subsequent filing for accelerated approval.

The Company will host a conference call today where HOOKIPA's Executive Team will discuss the full details of the trial design, and the Company's clinical development strategy for oncology.

Call Details:

HOOKIPA HB-200 Phase 2/3 Clinical Trial Update
Thursday, April 25, 2024, 8:00 a.m. ET
Webcast Registration
Dial-in Registration

Abstract details: ASCO 2024 Annual Meeting

HB-200:
Title: HB-200 arenavirus-based immunotherapy plus pembrolizumab as first-line treatment of patients with recurrent/metastatic HPV16-positive head and neck cancer: Updated results
Presenter: Dr. Alan L. Ho, Head and Neck Oncologist at Memorial Sloan Kettering Cancer Center and a trial investigator
Abstract Type: Oral abstract
Session Name: Head and Neck Cancer
Session Date and Time: June 4, 2024; 9:45 AM-12:45 PM CDT
Abstract Number: 6005

Title: Neoadjuvant HPV16-specific arenavirus-based immunotherapy HB-200 plus chemotherapy followed by response-stratified de-intensification in HPV16+ oropharyngeal cancer: TARGET-HPV
Presenter: Dr. Ari Rosenberg, Principal Investigator, TARGET-HPV Trial, University of Chicago Medicine
Abstract Type: Rapid oral abstract
Session Name: Head and Neck Cancer
Session Date and Time: June 3, 2024; 8:00 AM-9:30 AM CDT
Abstract Number: 6017

Trial Sponsor: UChicago Medicine

HB-700
Title: Development of an arenavirus-based immunotherapy for treatment of KRAS mutant cancer
Abstract Type: Abstract only
Session Date: May 23, 2024
Abstract Number: e14672

About HB-200

HB-200 is HOOKIPA's lead oncology candidate engineered with the company's proprietary replicating arenaviral vector platform. It comprises two single-vector compounds with arenaviral backbones based on lymphocytic choriomeningitis virus (LCMV) and pichinde virus (PICV). Both express the same transgene encoding an E7E6 fusion protein derived from HPV16. HB-200 is an alternating 2-vector immunotherapy designed to further focus the immune response against the encoded antigen.

HB-200 in combination with pembrolizumab received Fast Track Designation from the U.S. Food and Drug Administration and PRIME designation from the European Medicines Agency for the treatment of first-line HPV16+ recurrent/metastatic oropharyngeal squamous cell carcinoma. These designations are supported by preliminary clinical evidence from the Phase 1/2, open-label, clinical trial (NCT04180215) evaluating safety, T cell response, and efficacy based on objective response rate (ORR) and disease control rate (DCR) as defined by RECIST 1.1. and iRECIST. As presented at the European Society for Medical Oncology Annual Congress 2023, HB-200 in combination with pembrolizumab showed a 42 percent confirmed ORR and disease control rate DCR of 74 percent across 19 evaluable patients, doubling the 19 percent ORR for pembrolizumab alone.[1]

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 unnamed indications. 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.

[1] Harrington et al. Pembrolizumab with or Without Chemotherapy in Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma: Updated Results of the Phase III KEYNOTE-048 Study. *Journal of Clinical Oncology.* 2023;41(4);790-802.

Forward Looking Statements

This press release contains 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," "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 expectations regarding the design and protocol of the Company's upcoming pivotal Phase 2/3 clinical trial of HB-200 in combination with pembrolizumab, the timing of patient enrollment in clinical trials and the availability of data therefrom, and the timing o submissions concerning regulatory approval, and other statements that are not historical fact. 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 risk that results of preclinical studies and clinical trials may not be predictive of future results in preclinical studies or 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 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 https://sec.gov and HOOKIPA's website at http://hookipapharma.com/. In addition, any forward-looking statements represent HOOKIPA's views only as of today and should not be relied upon as representing its views as of any subsequent date. HOOKIPA explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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 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.

For further information, please contact:

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