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 23, 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 May 23, 2024, HOOKIPA Pharma Inc. (the "Company") issued a press release entitled "HOOKIPA Pharma Announces Positive Clinical Data to be Presented at the American Society for Clinical Oncology 2024 Annual Meeting." 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 (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On May 23, 2024, the Company announced updated results from its Phase 1/2 clinical trial of HB-200 for the treatment of human papillomavirus 16 positive (HPV16+) head and neck cancers, clinical data from an investigator initiated trial of neoadjuvant HB-200 plus chemotherapy for the treatment of patients with non-metastatic HPV16+ oropharyngeal cancers, and preclinical data for HB-700 designed to treat KRAS-mutated lung, colorectal, pancreatic and other cancers.

HB-200 in combination with pembrolizumab:

Updated data as of January 12, 2024, included 42 first line patients with HPV16+, PD-L1 positive, recurrent or metastatic head and neck squamous cell carcinoma. Median follow-up time was 5.6 months.

HB-200 + pembrolizumab were generally well tolerated. Grade ≥3 treatment-related adverse events (TRAEs) were reported in 6 (14%) patients, serious TRAEs were reported in 3 (7%) patients, and TRAEs leading to treatment discontinuation were reported in 2 (5%) patients. No treatment-related death were reported.

Among 35 evaluable patients—those with ≥ 1 post-baseline tumor response assessment—3 confirmed complete responses, 9 confirmed partial responses, and 3 unconfirmed partial responses were observed. Notably, among patients with PD-L1 CPS ≥20 (N=17), objective response rate, based on confirmed responses, was 53%, complete response rate was 18%, and disease control rate was 82%.

HB-200 plus chemotherapy (neoadjuvant setting):

In an Investigator Initiated Trial (IIT), led by Dr. Ari Rosenberg of the University of Chicago Department of Medicine, of neoadjuvant HB-200 plus chemotherapy for the treatment of patients with non-metastatic HPV16+ oropharyngeal cancers, twenty-one patients with HPV16+ oropharyngeal cancers were enrolled and treated across multiple cohorts and dose levels. All patients completed neoadjuvant HB-200/chemotherapy and response-stratified locoregional treatment. Deep responses following HB-200/chemotherapy were observed in 17/21 (81%) patients, and in 14/15 (93%) patients treated with higher dose levels 1 or 2. All three patients who underwent transoral robotic surgery (TORS) had no viable tumor at time of surgery. Two patients (9%) had persistent disease following chemoradiotherapy and underwent salvage surgery with no evidence of disease at last follow-up.

HB-700 preclinical data:

A transgene cassette consisting of peptide stretches including KRAS mutations G12D, G12V, G12C, G12R and G13D was generated by in silico aided antigen design. KRAS mutation specific CD8+ T cell expansion was evaluated in HLA transgenic mice treated with HB-700 and functionality of induced CD8+ T cells was evaluated by assessing CD8+ T cell mediated killing of mutant KRAS peptide loaded target cells in vivo.

All treatment regimens were well tolerated, and no mortalities or major adverse events were observed. The results indicate efficient induction of KRAS mutation specific T cell responses in HLA transgenic mice. Expanded CD8+ T cells were capable of killing cells loaded with KRAS mutation specific peptides in vivo indicating functionality of the induced T cell responses. No specific cytotoxicity towards target cells pulsed with KRAS wild type peptides was observed in any of the groups.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated May 23, 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: May 23, 2024

HOOKIPA Pharma Inc.

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

Exhibit 99.1

HOOKIPA Pharma Announces Positive Clinical Data to be Presented at the American Society for Clinical Oncology 2024 Annual Meeting

- HOOKIPA to present an oral abstract at the American Society for Clinical Oncology (ASCO) 2024 Annual Meeting on June 4
- Updated data of HB-200 plus pembrolizumab demonstrate a favorable safety profile and promising clinical activity
- In a subset of patients with PD-L1 combined positive score (CPS) of 20 or higher, data showed confirmed objective response rate (ORR) of 53%, complete response (CR) rate of 18%, and disease control rate (DCR) of 82%
- Company will also present promising preliminary progression-free survival and overall survival data for patients with CPS ≥20 on June 4

NEW YORK and VIENNA, May 23, 2024 - HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced positive updated results from its Phase 1/2 clinical trial of HB-200 for the treatment of human papillomavirus 16 positive (HPV16+) head and neck cancers. The data were published in the Company's abstract for the ASCO 2024 Annual Meeting and support the Company's pivotal Phase 2/3 trial design for HB-200 in combination with pembrolizumab in the first line setting.

The abstract reported data as of January 12, 2024, and included 42 patients treated with HB-200 plus pembrolizumab. The treatment was generally well tolerated with a low rate of treatment-related discontinuation and no treatment-related deaths.

Among a subpopulation of 17 evaluable patients with CPS of 20 or higher, the updated data showed confirmed ORR of 53 percent, CR rate of 18 percent, and DCR of 82 percent. This subpopulation is representative of patients eligible for the Company's pivotal Phase 2/3 trial, which will begin enrolling patients in the fourth quarter of 2024.

Additional data will be presented in the Head and Neck Oral Abstract Session at the ASCO 2024 Annual Meeting on June 4, at 11:09 a.m. CDT. During the presentation, preliminary progression-free survival and overall survival data will be shared for the first time.

"We are happy to provide an update on our clinical data and showcase the meaningful outcomes we are helping to drive for patients," said Joern Aldag, Chief Executive Officer of HOOKIPA. "The data exhibit strong evidence that has helped inform our pivotal Phase 2/3 trial design, which will begin enrolling patients later this year. This update gives us conviction that we are on the right path to achieve our goals and help provide a new targeted therapeutic option for patients battling HPV16+ head and neck cancer."

Results:

HB-200 in combination with pembrolizumab:

The abstract presented data as of January 12, 2024, and included 42 first line patients with HPV16+, PD-L1 positive, recurrent or metastatic head and neck squamous cell carcinoma.

The updated data continue to demonstrate a favorable safety profile of HB-200 in combination with pembrolizumab and promising clinical activity as a first line treatment. Median follow-up time was 5.6 months.

HB-200 + pembrolizumab were generally well tolerated. Grade ≥3 treatment-related adverse events (TRAEs) were reported in 6 (14%) patients, serious TRAEs were reported in 3 (7%) patients, and TRAEs leading to treatment discontinuation were reported in 2 (5%) patients. No treatment-related deaths were reported.

Among 35 evaluable patients—those with ≥ 1 post-baseline tumor response assessment—3 confirmed complete responses, 9 confirmed partial responses, and 3 unconfirmed partial responses were observed. Notably, among patients with PD-L1 CPS ≥20 (N=17), ORR, based on confirmed responses, was 53%, CR rate was 18%, and DCR was 82%.

Additional Abstracts at ASCO 2024 Annual Meeting:

HB-200 plus chemotherapy (neoadjuvant setting):

In addition, data from an Investigator Initiated Trial (IIT), led by Dr. Ari Rosenberg of the University of Chicago Department of Medicine, will be presented on June 3, in the Head and Neck Rapid Oral Abstract Session. The study concluded that neoadjuvant HB-200 plus chemotherapy for the treatment of patients with non-metastatic HPV16+ oropharyngeal cancers (OPC) is safe and feasible, with early efficacy signal in this setting warranting further study.

Twenty-one patients with HPV16+ OPC were enrolled and treated across multiple cohorts and dose levels. All patients completed neoadjuvant HB-200/chemotherapy and response-stratified locoregional treatment. Deep responses following HB-200/chemotherapy were observed in 17/21 (81%) patients, and in 14/15 (93%) patients treated with higher dose levels 1 or 2. All three patients who underwent transoral robotic surgery (TORS) had no viable tumor at time of surgery. Two patients (9%) had persistent disease following chemoradiotherapy and underwent salvage surgery with no evidence of disease at last follow-up. ctHPV-DNA and HPV16-specific T-cell response data will be presented at the meeting.

Enrollment to the subsequent randomized phase II part is ongoing. Details of the rapid oral presentation are included below.

HB-700 preclinical data:

HB-700 is an investigational arenaviral immunotherapy designed to treat KRAS-mutated lung, colorectal, pancreatic and other cancers. HB-700 is a replicating 2-vector therapy that targets the most common KRAS mutations (G12D, G12V, G12R, G12C and G13D) and has the potential to benefit a broader patient population than single mutation inhibitors.

A transgene cassette consisting of peptide stretches including KRAS mutations G12D, G12V, G12C, G12R and G13D was generated by in silico aided antigen design. KRAS mutation specific CD8+ T cell expansion was evaluated in HLA transgenic mice treated with HB-700 and functionality of induced CD8+ T cells was evaluated by assessing CD8+ T cell mediated killing of mutant KRAS peptide loaded target cells in vivo.

All treatment regimens were well tolerated, and no mortalities or major adverse events were observed. The results indicate efficient induction of KRAS mutation specific T cell responses in HLA transgenic mice. Expanded CD8+ T cells were capable of killing cells loaded with KRAS mutation specific peptides in vivo indicating functionality of the induced T cell responses. No specific cytotoxicity towards target cells pulsed with KRAS wild type peptides was observed in any of the groups. HOOKIPA's HB-700 investigational product candidate differs from KRAS inhibitors and has a wide range of combinability options including with small-molecule inhibitors. Based on these results, initiation of a Phase I study for the treatment of KRAS mutated cancers is planned.

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

Investigator Initiated Trial:

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.

About HB-700

HB-700 is an investigational arenaviral immunotherapy designed to treat KRAS-mutated lung, colorectal, pancreatic and other cancers. HB-700 is a replicating 2-vector therapy that targets the most common KRAS mutations (G12D, G12V, G12R, G12C and G13D) and has the potential to benefit a broader patient population than single mutation inhibitors.

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 process, the timing of regulatory filings, the challenges associated with manufacturing drug products, HOOKIPA's ability to successfully establish, protect and defend its intellectual property, 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 https://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, www.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.

For further information, please contact:

Investors & Media

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