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 31, 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 7.01 Regulation FD Disclosure.

On May 31, 2023, HOOKIPA Pharma Inc. (the "Company") issued a press release announcing preliminary data from the Phase 2 clinical trial evaluating HB-200 in Combination with Pembrolizumab in Patients with HPV16+ Head and Neck Cancers. The Company will host a live webcast on June 1, 2023 at 8:00 a.m. EDT. Joern Aldag, Chief Executive Officer, Katia Schlienger M.D., Ph.D., Chief Medical Officer, and Klaus Orlinger, Ph.D., Chief Scientific Officer will provide an overview of the HB-200 data and future plans for the Company's oncology program. Alan Ho, M.D., Ph.D., a study investigator, will also offer commentary on the unmet medical need for patients with head and neck cancer. The dial-in number for the conference call is 646-876-9923 for U.S. participants and +44 (0) 20808-06591 for international participants. A live webcast of the call can be accessed on the Company's website at www.hookipapharma.com/events. An archived webcast will be available for 30 days on the Events webpage.

The information contained in Item 7.01 of this Current Report (including Exhibit 99.1 attached hereto) shall not be deemed "filed" for purposes of Section 18 of 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 or the Exchange Act, except as expressly provided by specific reference in such a filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Item 8.01 Other Events.

On May 31, 2023, the Company announced preliminary data from the Phase 2 clinical trial evaluating HB-200 in Combination with Pembrolizumab in Patients with HPV16+ Head and Neck Cancers.

HB-200 results

As of March 31, 2023, 35 patients with HPV16+ recurrent/metastatic head and neck cancers received HB-200 in combination with pembrolizumab as part of the Phase 2 study: 20 patients were treated with HB-200 and pembrolizumab in the 1st-line setting and 15 in the 2nd-line setting. All received HB-200 intravenously every three weeks for the first five doses and every six weeks thereafter. HB-200 means 2-vector therapy with alternating application of HB-201 (LCMV), HB-202 (PICV) vectors, encoding HPV16 E6/E7 antigens.

1st-line combination data

HB-200 in combination with pembrolizumab demonstrated promising anti-tumor activity with a 43 percent objective response rate (6 of 14 patients with confirmed responses by investigator assessment under RECIST 1.1) among CPI-naïve patients with recurrent/metastatic HPV16+ PD-L1+ head and neck cancer. These data represent a doubling of the 19 percent objective response rate reported with pembrolizumab alone. As of March 31, 2023, 14 patients with at least two imaging assessments were included in the interim efficacy analysis. Six patients responded (one with confirmed complete response and five with confirmed partial responses), with a 71 percent disease control rate (10 of 14 patients), meaning stable disease or a complete or partial response. While recruitment is ongoing, based on these data, the Company is preparing to start a pivotal trial of HB-200 in combination with pembrolizumab as 1st-line treatment of recurrent/metastatic HPV16+ PD-L1+ head and neck cancers in 2024.

2nd-line plus combination data

Data on HB-200 in combination with pembrolizumab in the 2nd-line plus setting are trending positively in this small initial cohort, but they are preliminary and need further maturation. As of March 31, 2023, five patients with at least two imaging assessments were included in the interim efficacy analysis based on RECIST 1.1. Preliminary results show one confirmed partial response and three patients with stable disease. Preliminary median progression-free survival in this small cohort was 5.3 months. Enrollment is ongoing, and a decision on a potential path forward in the 2nd-line plus setting will be made in 2024.

Monotherapy data

Given the limited options for heavily pre-treated patients with recurrent/metastatic HPV16+ head and neck cancers, the Company continues to evaluate HB-200 as monotherapy among these patients in the ongoing Phase 1/2 trial. Follow-up data show HB-200 monotherapy demonstrated a preliminary median overall survival of 14.2 months in the intent-to-treat population, indicating potential for prolonged clinical benefit in this heavily pre-treated population. These data are based on 11 patients who received HB-200 as monotherapy at the same dose being evaluated in combination with pembrolizumab, with a median follow-up period of 12.8 months. Additional patients are also being followed to continue to assess median overall survival in a larger cohort.

Immunogenicity
Importantly, new follow-up data from heavily pre-treated patients show an association between the induction of unprecedented levels of functional T cells after treatment with HB-200 monotherapy and clinical benefit. T cell increases were rapid and sustained for at least 8 months, as of data cut-off. Patients who achieved disease control after treatment with HB-200 monotherapy generally had greater CD8+ T cell infiltration in tumors compared to patients whose disease progressed, suggesting an association of HB-200-induced T cells and clinical benefit.

Safety and tolerability profile

Results from the Phase 1/2 study showed that HB-200 was generally well tolerated among 132 patients treated. The safety profile was similar for patients who received HB-200 monotherapy or HB-200 in combination with pembrolizumab. This favorable tolerability profile highlights the potential of HB-200 – and arenaviral immunotherapies in general – to be combined with other immunotherapies where tumor antigen-specific T cells are needed. Only seven percent of patients showed serious adverse events related to the treatment with HB-200. Only two percent of patients discontinued due to such events.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by HOOKIPA Pharma Inc. on May 31, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL).

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 31, 2023

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

Exhibit 99.1

HOOKIPA Pharma Announces Positive Preliminary Phase 2 Data on HB-200 in Combination with Pembrolizumab in Patients with HPV16+ Head and Neck Cancers

- HB-200 in combination with pembrolizumab doubled the objective response rate of 1st-line pembrolizumab for patients with recurrent/metastatic head and neck cancer
- HOOKIPA is preparing to start a pivotal trial of HB-200 in combination with pembrolizumab as 1st-line treatment of recurrent/metastatic HPV16+ head and neck cancer in 2024
- Initial cohort of heavily pre-treated patients who received HB-200 monotherapy showed preliminary median overall survival of 14.2 months in the intent-to-treat population

NEW YORK and VIENNA, May 31st , 2023 - HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced positive preliminary data from its ongoing Phase 2 study of HB-200 in combination with pembrolizumab in patients with recurrent/metastatic Human Papillomavirus 16-positive (HPV16+) head and neck cancer. New data show a 43 percent objective response rate (ORR) with HB-200 in combination with pembrolizumab in checkpoint inhibitor (CPI)-naïve patients, doubling the 19 percent response rate for pembrolizumab alone. HOOKIPA plans to share the full data at a medical conference later this year and is preparing to start a pivotal trial of HB-200 in combination with pembrolizumab in the 1st-line setting in 2024. The company will host a webcast call June 1st at 8:00 a.m. EDT.

"Given the unmet medical need for patients with recurrent/metastatic HPV16+ head and neck cancers, we are thrilled to share the preliminary data on HB-200 in combination with pembrolizumab as they show a robust improvement in objective response rate and prolonged tumor control compared to pembrolizumab alone," said Joern Aldag, Chief Executive Officer at HOOKIPA. "Efficacy, immunogenicity and safety data observed in our HB-200 program to-date support our decision to progress to a pivotal trial of HB-200 in combination with pembrolizumab as 1st-line treatment for these patients. The data also underscore the scalability of our arenaviral platform across a range of cancers."

HB-200 results (NCT04180215)

As of March 31, 2023, 35 patients with HPV16+ recurrent/metastatic head and neck cancers received HB-200 in combination with pembrolizumab as part of the Phase 2 study: 20 patients were treated with HB-200 and pembrolizumab in the 1st-line setting and 15 in the 2nd-line setting. All received HB-200 intravenously every three weeks for the first five doses and every six weeks thereafter. HB-200 means 2-vector therapy with alternating application of HB-201 (LCMV), HB-202 (PICV) vectors, encoding HPV16 E6/E7 antigens.

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[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.

Webcast: HOOKIPA will host a live webcast on June 1, 2023 at 8:00 a.m. EDT. Joern Aldag, Chief Executive Officer, Katia Schlienger M.D., Ph.D., Chief Medical Officer, and Klaus Orlinger, Ph.D., Chief Scientific Officer will provide an overview of the HB-200 data and future plans for HOOKIPA's oncology program. Alan Ho, M.D., Ph.D., a study investigator, will also offer commentary on the unmet medical need for patients with head and neck cancer.

Dial In:	+1 646 876 9923
UK Dial In:	+44 208 080 6591
Austria Dial In:	+43 72 011 5988
Webinar ID:	899 3030 4628
Webcast:	Link

The webcast and the presentation will be available within the Investors & Media section of HOOKIPA's website at https://ir.hookipapharma.com/events. An archived replay will be accessible for 30 days following the event.

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 and pichinde virus. 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 for the treatment of 1st-line recurrent/metastatic HPV16+ head and neck cancers.

About the HB-200 trial (NCT04180215)
This Phase 1/2 clinical trial is an open-label trial evaluating HB-200 for the treatment of advanced HPV16+ cancers. Phase 1 assessed various dose levels, regimen, and modes of administration in a post-standard of care setting. Based on safety and tolerability, initial anti-tumor activity and T cell response data, HB-200 advanced for further development in Phase 2.

The Phase 2 part of the trial is open-label with primary endpoints of efficacy based on objective response and disease control rate as defined by RECIST 1.1 and iRECIST. The trial is evaluating HB-200 in combination with pembrolizumab in the 1st-line and 2nd-line plus settings, as well as HB-200 alone in the post-standard of care setting. HOOKIPA anticipates sharing an additional data update at an upcoming medical conference.

About Human Papillomavirus-driven Cancers
Human Papillomavirus, or HPV, is a common viral infection estimated to cause about 5 percent of the worldwide cancer burden. This includes up to 60 percent of head and neck, 89 percent of cervical, 78 percent of vaginal, 88 percent of anal, 67 percent of vulvar and 50 percent of penile cancers.

While there are numerous HPV types associated with cancer, HPV16 is the most common cause of cancer. Most HPV infections are cleared from the body with no lasting consequences. However, in some cases, HPV DNA becomes integrated into chromosomal DNA. When host cells take up this DNA, they express the HPV E6 and E7 proteins. This uptake can potentially lead to cancer since expression of these proteins leads to alterations in cell cycle control, which in turn predisposes these cells to become cancerous.

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.

For further information, please contact:

Media
Instinctif Partners

hookipa@instinctif.com
+44 (0) 7457 2020

Investors
Reinhard Kandera
Chief Financial Officer
IR@hookipapharma.com