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): **June 5, 2022**

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 June 5, 2022, HOOKIPA Pharma Inc. (the "Company") issued a press release announcing data from the Phase 1 clinical trial evaluating single-vector HB-201 and alternating 2-vector HB-202/HB-201 in advanced Human Papillomavirus 16-positive ("HPV16+") head and neck cancer patients, and the recommended Phase 2 dose for its alternating 2-vector HB-202/HB-201 program.

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 June 5, 2022, the Company issued a press release announcing data from the Phase 1 clinical trial evaluating single-vector HB-201 and alternating 2-vector HB-202/HB-201 in advanced HPV16+ head and neck cancer patients, and the recommended Phase 2 dose for its alternating 2-vector HB-202/HB-201 program.

HB-200 Phase 1 Results:

Sixty-eight patients with advanced HPV16+ cancers were treated in the Phase 1 trial as of March 31, 2022. Fifty-four patients had advanced HPV16+ head and neck cancers with a median of three prior therapies (range of 1-11), including a checkpoint inhibitor regimen in 50 of the 54. Of these sixty-eight patients, five were continuing on treatment as of the cut-off date.

- Safety Data:
  - HB-200 was generally well tolerated, with comparable safety between the single-vector HB-201 and alternating 2-vector HB-202/HB-201.
  - The most common treatment-related side effects were flu-like symptoms, with only 8.8 percent experiencing treatment-related side effects rated grade 3 or higher.
- Anti-Tumor Efficacy Data:
  - The poster presented at ASCO provided updated anti-tumor activity on 43 Phase 1 patients with HPV16+ HNSCC who received therapy intravenously every three weeks for the first five doses and every six weeks thereafter, which is the route and frequency selected for further evaluation in Phase 2 cohorts. The 43 patients were comprised of 20 persons who received single-vector HB-201 and 23 who received alternating 2-vector HB-202/HB-201.
  - Alternating 2-vector HB-202/HB-201 demonstrated superior tumor response with 56 percent of treated patients showing target lesion shrinkage compared to 38 percent of HB-201 recipients.
  - Alternating 2-vector HB-202/HB-201 demonstrated decreases in visceral lesions in 59 percent of patients compared to 18 percent of HB-201 recipients.
  - Alternating 2-vector HB-202/HB-201 at the recommended Phase 2 dose demonstrated an 80 percent disease control rate.
- T-Cell Data:
  - Both HB-201 and alternating 2-vector HB-202/HB-201 were highly immunogenic.
  - 32 percent of patients that received alternating 2-vector HB-202/HB-201 had tumor-specific T cell levels greater than 5 percent of the circulating T cell pool, compared to 7 percent of HB-201 recipients achieving this threshold.

The Company believes that these results compare favorably to historical disease control rates achieved by pembrolizumab in recurrent or metastatic HNSCC patients. Based on peer-reviewed published data, pembrolizumab had disease control rates of 35 percent (overall) and 40 percent (HPV+ subset) in the 2nd+ -line setting.

Phase 2 Plans for Alternating 2-Vector HB-202/HB-201:

The Phase 2 part of the trial is open-label with primary endpoints of safety, tolerability and preliminary efficacy, defined by RECIST 1.1, for overall survival, progression-free survival and duration of response. Phase 2 is ongoing, evaluating HB-202/HB-201 alone in the post standard of care setting and in combination with pembrolizumab in 1st line and 2nd plus line settings. HB-201 in combination with pembrolizumab is being assessed for safety only in a small cohort. Initial results of HB-202/HB-201 in combination with pembrolizumab are anticipated in the second half of 2022 and will help inform the randomized Phase 2 trial of HB-202/HB-201 in combination with pembrolizumab planned for the first half of 2023. Initial results of HB-202/HB-201 as a post-standard of care treatment are expected in the first half of 2023.

Forward Looking Statements

This Current Report on Form 8-K and other related materials may contain a number of "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding the Company's expectation about any or all of the following: (i) the success, cost and timing of the Company's product development activities and clinical trials; (ii) the timing, scope or likelihood of regulatory filings and approvals, including timing of Investigational New Drug Application and Biological Licensing Application filings for the Company's current and future product candidates, and final U.S. Food and Drug Administration, European Medicines Agency or other foreign regulatory authority approval of the Company's current and future product candidates; (iii) the Company's ability to develop and advance its current product candidates and programs into, and successfully complete, clinical studies and (iv) risks relating to business interruptions resulting from the coronavirus (COVID-19) disease outbreak or similar public health crises, geopolitical instabilities and other matters that could affect the sufficiency of existing cash to fund operations and the Company's ability to achieve the milestones under the agreement with Gilead. Forward-looking statements can be identified by terms such as "believes," "expects," "plans," "potential," "would" or similar expressions and the negative of those terms the Company has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that it believes may affect its business, financial condition and results of operations. Although the Company believes that such statements are based on reasonable assumptions, forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond the Company's control, you should not rely on these forward-looking statements as predictions of future events. These risks and uncertainties include, among others: outcomes of the Company's planned clinical trials and studies may not be favorable; that one or more of the Company's product candidate programs will not proceed as planned for technical, scientific or commercial reasons; availability and timing of results from preclinical studies and clinical trials; uncertainty about regulatory approval to conduct clinical trials or to market a products; uncertainties regarding intellection property protection; and those risk and uncertainties described under the heading "Risk Factors" in the Company's Form 10-Q for the quarter ended March 31, 2022 filed with the U.S. Securities and Exchange Commission, and in any other subsequent filings made by the Company with the U.S. Securities and Exchange Commission, which are available at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. The Company disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this Current Report on Form 8-K, other than to the extent required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by HOOKIPA Pharma Inc. on June 5, 2022.
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: June 6, 2022

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

Exhibit 99.1

HOOKIPA announces positive Phase 1 data and Phase 2 plans for HB-200 program for the treatment of advanced head and neck cancers at ASCO

- Alternating 2-vector therapy showed superior antigen-specific T cell responses, more robust anti-tumor activity and similar tolerability vs. single-vector therapy
- Phase 2 to proceed with alternating 2-vector therapy in combination with pembrolizumab, which will help inform the randomized Phase 2 trial with pembrolizumab planned to start in the first half of 2023
- Additional Phase 2 cohort will evaluate alternating 2-vector only therapy in post-standard of care setting

New York, US and Vienna, Austria, June 5, 2022 - HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced positive Phase 1 results from its HB-200 program evaluating single-vector HB-201 and alternating 2-vector HB-202/HB-201 in advanced Human Papillomavirus 16-positive (HPV16+) head and neck cancer patients. HB-200 was generally well tolerated, rapidly induced a high magnitude of tumor-specific T cells and showed early anti-tumor activity in these difficult-to-treat patients. The company also announced the recommended Phase 2 dose for alternating 2-vector HB-202/HB-201, which showed superior immune and tumor response compared to single-vector HB-201. The data were presented in a poster presentation (abstract #2517) at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting.

"We're pleased to report the positive Phase 1 data on our novel arenaviral immunotherapies for advanced head and neck cancers, which highlight the ability of our platform technology to induce a high magnitude of potent, tumor-specific T cell responses," said Joern Aldag, Chief Executive Officer at HOOKIPA. "We're encouraged by the superior immune response generated by alternating 2-vector immunotherapy, which resulted in an 80 percent disease control rate in patients who have failed several previous regimens. These results help focus our efforts as we move HB-202/HB-201 at the recommended Phase 2 dose into the Phase 2 portion of the trial. The findings on our alternating 2-vector technology also help inform our development plans across our oncology portfolio and especially for our HB-300 program in prostate cancer."

HB-200 Phase 1 results (NCT04180215)

Sixty-eight patients with advanced HPV16+ cancers were treated in the Phase 1 trial as of March 31, 2022. Fifty-four patients had advanced HPV16+ head and neck cancers with a median of three prior therapies (range of 1-11), including a checkpoint inhibitor regimen in 50 of the 54. Of these sixty-eight patients, five were continuing on treatment as of the cut-off date.

Safety

Phase 1 results showed HB-200 was generally well tolerated, with comparable safety between the single-vector HB-201 and alternating 2-vector HB-202/HB-201. The most common treatment-related side effects were flu-like symptoms, with only 8.8 percent of patients experiencing treatment-related side effects rated grade 3 or higher. This favorable tolerability profile in heavily pre-treated patients highlights the potential for combination with checkpoint inhibitors and other agents.

Anti-tumor activity

The poster presented at ASCO provided updated anti-tumor activity on 43 Phase 1 patients with HPV16+ HNSCC who received therapy intravenously every three weeks for the first five doses and every six weeks thereafter, which is the route and frequency selected for further evaluation in Phase 2 cohorts. The 43 patients were comprised of 20 persons who received single-vector HB-201 and 23 who received alternating 2-vector HB-202/HB-201.

While promising anti-tumor activity was shown in both groups, alternating 2-vector HB-202/HB-201 showed superior tumor response with 56 percent of treated patients showing target lesion shrinkage compared to 38 percent of HB-201 recipients. In addition, decreases in visceral lesions were predominantly seen in patients who received 2-vector therapy: 59 percent of patients on HB-202/HB-201 compared to 18 percent on HB-201. Further, HB-202/HB-201 demonstrated an 80 percent disease control rate, which compares favorably to historical disease control rates achieved by pembrolizumab in recurrent/metastatic HNSCC patients, specifically 35 percent overall and 40 percent in the HPV+ subset, based on peer-reviewed published data.[1]

T cell data

While both HB-201 and alternating 2-vector HB-202/HB-201 were highly immunogenic, HB-202/HB-201 induced superior immune response with 32 percent of recipients achieving tumor-specific T cell levels greater than 5 percent of the circulating T cell pool (7 percent of HB-201 recipients achieved this threshold). Tumor specific T cells are essential in eradicating cancer cells.

“Patients with advanced head and neck cancers have limited options,” said Siqing Fu, M.D., Ph.D., professor of Investigational Cancer Therapeutics and principal investigator at The University of Texas MD Anderson Cancer Center, who presented the data at the ASCO meeting. “It’s encouraging to see a novel arenaviral immunotherapy demonstrate strong T cell response and anti-tumor activity in this difficult-to-treat population. I look forward to seeing future results from the Phase 2 portion in HPV16+ head and neck cancers, as well as in other types of cancer.”

About HB-202/HB-201

HB-201 and HB-202/HB-201 are HOOKIPA’s lead oncology candidates engineered with the company’s proprietary replicating arenaviral vector platform. HB-201 is a single-vector compound that uses Lymphocytic Choriomeningitis Virus as its arenaviral backbone. HB-202 is a single-vector compound that uses Pichinde Virus as its arenaviral backbone. Both express the same antigen, an E7E6 fusion protein derived from HPV16. HB-202/HB-201 is an alternating 2-vector immunotherapy designed to further focus the immune response against the target antigen. In pre-clinical studies, alternating administration of HB-201 and HB-202 resulted in a ten-fold increase in immune response and better disease control than either compound alone. Both novel immunotherapy candidates, in combination with pembrolizumab, received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of 1st-line advanced/metastatic HPV16+ head and neck cancers.

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[1] Mehra R et al. Efficacy and safety of pembrolizumab in recurrent/metastatic head and neck squamous cell carcinoma: pooled analysis after long-term follow up in KEYNOTE-012. *British J of Cancer.* 2018; 119:153-159.

About the HB-200 trial (NCT04180215)

This Phase 1/2 clinical trial is an open-label trial evaluating single-vector HB-201 and alternating 2-vector HB-202/HB-201 for the treatment of advanced HPV16+ cancers who progressed on standard of care, including checkpoint inhibitors. The primary endpoint of Phase 1 was a recommended Phase 2 dose.

In Phase 1, HB-201 was evaluated at three dose levels, with two dosing schedules and two administration routes in 40 patients. HB-202/HB-201 was evaluated at four dose levels and two administration routes in 28 patients. Based on safety, anti-tumor activity and T cell response data, HB-202/HB-201 has been advanced for further development in Phase 2.

The Phase 2 part of the trial is open-label with primary endpoints of safety, tolerability and preliminary efficacy, defined by RECIST 1.1, for overall survival, progression-free survival and duration of response. Phase 2 is ongoing, evaluating HB-202/HB-201 alone in the post standard of care setting and in combination with pembrolizumab in 1st line and 2nd plus line settings. HB-201 in combination with pembrolizumab is being assessed for safety only in a small cohort. Initial results of HB-202/HB-201 in combination with pembrolizumab are anticipated in the second half of 2022 and will help inform the randomized Phase 2 trial of HB-202/HB-201 in combination with pembrolizumab planned for the first half of 2023. Initial results of HB-202/HB-201 as a post-standard of care treatment are expected in the first half of 2023.

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+ cell responses and pathogen-neutralizing antibodies. HOOKIPA's pipeline includes its wholly-owned investigational arenaviral immunotherapeutics targeting HPV16+ cancers, prostate cancer, KRAS-mutated cancers (including colorectal, pancreatic and lung), 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.

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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, 2022, which is available on the Security and Exchange Commission's website at www.sec.gov and HOOKIPA's website at www.hookipapharma.com.