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): **January 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	**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 1.02 Termination of a Material Definitive Agreement.

On January 25, 2024, HOOKIPA Pharma Inc. ("HOOKIPA") received written notice (the "Notice") from F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (collectively referred to as "Roche") of their decision to terminate the Research Collaboration and License Agreement (the "Collaboration Agreement") among Roche and Hookipa Biotech GmbH ("HOOKIPA GmbH," and together with HOOKIPA, the "Company"), a wholly-owned subsidiary of HOOKIPA, dated October 18, 2022. Roche's decision to terminate the Collaboration Agreement was made according to Roche's right to terminate without cause, acknowledging that, to date, HOOKIPA met all go-forward criteria under the Collaboration Agreement.

The Collaboration Agreement was entered into to (i) grant Roche an exclusive license to research, develop, manufacture and commercialize the Company's pre-clinical HB-700 cancer program, an arenaviral immunotherapeutic for KRAS-mutated cancers, and (ii) grant Roche an option right to exclusively license for research, development manufacturing and commercialization, a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens.

Pursuant to the terms of the Collaboration Agreement and the Notice, the Collaboration Agreement will be terminated on April 25, 2024. The Company remains eligible for a final milestone payment associated with an IND submission. Effective April 25, 2024, the Company will regain full control of the associated intellectual property portfolio and will have full collaboration and licensing rights for the HB-700 program. After the termination of the Collaboration Agreement, and except as disclosed above, there is no other material relationship between the Company and Roche.

Item 2.02 Results of Operations and Financial Condition.

On January 29, 2024, HOOKIPA issued a press release which contained information regarding its preliminary, unaudited estimate of cash and cash equivalents and restricted cash of approximately $117.5 million as of December 31, 2023. This information is preliminary and unaudited. Accordingly, undue reliance should not be placed on such preliminary numbers. The Company expects to report its audited cash, cash equivalents and marketable securities, as well as other information necessary for a complete understanding of its financial position, in its Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

The information in this Item 2.02 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. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), if such subsequent filing specifically references the information furnished pursuant to Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On January 29, 2024, HOOKIPA announced its decision to prioritize clinical development of HB-200 for the treatment of HPV16+ head and neck cancers and Gilead-partnered programs in infectious disease and to pause development activities related to HB-300 and most of its preclinical research activities. In connection with this strategic refocus, on January 22, 2024, HOOKIPA's board of directors approved a plan to reduce the Company's workforce by 55 full-time employees, or approximately 30% of the Company's then-current employee base and to rebalance the Company's cost structure in alignment with the new prioritization of R&D programs (together, the "Reduction Plan"), and the Company notified affected employees on January 29, 2024. HOOKIPA expects to implement and substantially complete the Reduction Plan during the first quarter of 2024. In connection with the Reduction Plan, the affected employees will be provided severance benefits, including cash severance payments. Each affected employee's eligibility for these severance benefits is contingent upon such employee's entering into an effective separation agreement, which includes a general release of claims against the Company. The workforce reduction is expected to result in approximately $1.5 million in severance, restructuring and related costs. HOOKIPA expects a non-cash impairment of "assets under construction" between $10 million and $13 million from the discontinuation of the GMP facility project as part of the Reduction Plan. The Company expects to recognize deferred upfront and milestone payments under the Collaboration Agreement of approximately $20 million in connection with the termination by Roche.

The estimated charges that the Company expects to incur in connection with this Reduction Plan are subject to a number of assumptions, and actual results may differ materially from these estimates. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the Reduction Plan.

Item 2.06 Material Impairments.

To the extent applicable, the information contained in Item 2.05 above is incorporated into this Item 2.06 by reference.

Item 7.01 Regulation FD Disclosure.

On January 29, 2024, the Company issued a press release announcing updates on the Company's business priorities and oncology partnership programs. A copy of the press release is furnished hereto as Exhibit 99.1.

The information in this Item 7.01 and Exhibit 99.1 attached hereto is intended to be furnished and 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 set forth by specific reference in such filing.

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 HOOKIPA's expectation about any or all of the following: (i) the timing and consequences regarding the termination of the Collaboration Agreement, (ii) the extent, timing and plan of, and the costs and estimated cash expenditures from, the Reduction Plan, and (iii) expected cash and cash equivalents as of December 31, 2023. Forward-looking statements can be identified by terms such as "will," "intent," "expects," "plans," "potential," "would" or similar expressions and the negative of those terms. HOOKIPA 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 HOOKIPA 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 HOOKIPA'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 HOOKIPA's planned clinical trials and studies may not be favorable; that one or more of HOOKIPA'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 HOOKIPA's Form 10-Q for the quarter ended September 30, 2023 filed with the U.S. Securities and Exchange Commission, and in any other subsequent filings made by HOOKIPA 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. HOOKIPA 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. Exhibits.

(d) Exhibits

99.1	Press Release issued by HOOKIPA Pharma Inc. on January 29, 2024, furnished herewith.
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.

HOOKIPA Pharma Inc.

Date: January 29, 2024

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

Exhibit 99.1

HOOKIPA Pharma Provides Update on Business Priorities and Oncology Partnership Programs

- HOOKIPA to prioritize clinical development of HB-200 for the treatment of HPV16+ head and neck cancers and Gilead-partnered programs in infectious disease
- HOOKIPA will regain global development rights to HB-700 program for KRAS-mutated cancers from Roche; HOOKIPA remains eligible for milestone payment associated with submission of Investigational New Drug application
- HOOKIPA will implement cost saving initiatives, including a reduction of workforce by approximately 30 percent
- HOOKIPA maintains a strong cash position of $117.5 million as of December 31, 2023[1]

NEW YORK and VIENNA, January 29, 2024 – HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today announced that the Company will focus its resources in two strategic areas: (1) prioritize the clinical development of a randomized trial for its HB-200 program in human papillomavirus 16 positive (HPV16+) head and neck squamous cell carcinoma (HNSCC) and (2) its two Gilead-partnered infectious disease cure programs for hepatitis B and human immunodeficiency virus.

In the first-line setting HB-200, in combination with pembrolizumab, has demonstrated best-in-class antigen specific T cell activation and has doubled the historic objective response rates of standard of care treatment alone. The totality of the HB-200 data presents a clear opportunity for HOOKIPA to advance this program in a randomized trial starting in mid-2024.

"HOOKIPA has a tremendous opportunity to transform treatment of multiple disease areas using an entirely new class of medicines," said Joern Aldag, Chief Executive Officer at HOOKIPA. "As we move forward with our randomized trial for HB-200 in combination with pembrolizumab, we have made an important decision to focus our resources and pursue this opportunity in earnest. We will focus on clinical delivery and execution so that we can help address a significant unmet need for patients with advanced HPV16+ head and neck cancer."

The Company also announced that it has received notification from Roche of their decision to terminate the collaboration and licensing agreement for HOOKIPA's HB-700 program in KRAS mutated cancers. To date, HOOKIPA has met all go-forward criteria under the agreement and remains eligible for a final milestone payment associated with IND submission. Effective April 25, 2024, HOOKIPA will regain full control of the associated intellectual property portfolio and have full collaboration and licensing rights for this program. As part of its strategic refocus, HOOKIPA will pause development activities related to HB-300 and most of its preclinical research activities.

HOOKIPA will reduce its workforce by approximately 30 percent and rebalance its cost structure in alignment with the new prioritization of the Company's programs. HOOKIPA maintains a strong cash position of $117.5 million[1] as of December 31, 2023, and believes that the planned reductions will help to conserve resources and better align its organization in direct support of late stage clinical development efforts.

Pipeline Update and Upcoming Catalysts

The strategic priorities for HOOKIPA are to advance its clinical programs including HB-200 and its two Gilead-partnered infectious disease programs. The Company is planning to submit an IND for HB-700 in the first quarter of 2024 and will begin searching for a collaboration partner. At this time, the company will not pursue further preclinical programs into development and pause further development of its HB-300 to conserve capital and ensure pipeline success and operational efficiency.

Program	**Indication**	**Upcoming Catalysts**
Oncology Programs		
HB-200	HPV16+ HNSCC	· Additional first-line data for HB-200 in combination with pembrolizumab (1H 2024) · Initiation of randomized trial (mid-2024)
HB-700	KRAS	· IND submission (1Q 2024) · Publication of preclinical research (1H 2024) · Search for new collaboration partner

Infectious Disease Programs: Gilead-Partnered		
HB-400	HBV	· Gilead-led: Phase 1b actively enrolling · Next milestone: Phase 2 initiation (Timing TBD)
HB-500	HIV	· Initiation of Phase 1 trial · First patient dosed, milestone payment (1H 2024)

Paused Programs		
HB-300	Prostate Cancer	· Paused and utilize capital to support HB-200 development
Preclinical	Multiple targets	

[1] Cash position as of December 31, 2023, is unaudited

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.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements by HOOKIPA regarding: timing and consequences regarding the termination of the Roche Collaboration Agreement, the extent, timing and plan of and the costs and estimated cash expenditures from, the reduction of workforce, and expected cash and cash equivalents as of December 31, 2023. Forward-looking statements can be identified by terms such as "will," "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 public health crises, the impact of public health crises 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 annual report on Form 10-K for the period ended December 31, 2022, quarterly report on Form 10-Q for the quarter ended September 30, 2023 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 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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