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): **March 15, 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 2.02 Results of Operations and Financial Condition.

On March 15, 2023, HOOKIPA Pharma Inc. (the "Company") announced Financial Results for the Fourth Quarter and Full Year 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 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 Number	Description
99.1	Press release issued by HOOKIPA Pharma Inc. on March 15, 2023
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 thereunto duly authorized.

HOOKIPA Pharma Inc.

Date: March 15, 2023

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

HOOKIPA Reports Fourth Quarter and Full Year 2022 Financial Results and Provides 2023 Outlook

- Data from Phase 2 study of HB-200 in combination with pembrolizumab in head and neck cancers expected in 2Q 2023
- Phase 1 HB-300 trial in metastatic castration-resistant prostate cancer open for enrollment
- KRAS program (HB-700) achieved its first milestone payment in the Roche collaboration in February 2023; plan to submit IND in 1H 2024
- Strengthened cash position of $113.4 million at year-end; additional $15.0 million cash inflow from collaboration milestones in early 2023

NEW YORK and VIENNA, March 15, 2023 - HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics based on its proprietary arenavirus platform, today reported financial results and provided a corporate update for the fourth quarter and full year 2022, as well as the outlook for 2023.

"We made substantial progress in 2022 as we work to develop our novel arenaviral immunotherapies against a variety of cancers and infectious diseases. Our lead candidate, HB-200, advanced to Phase 2 in combination with pembrolizumab for head and neck cancers; our HB-300 program in prostate cancer advanced toward the clinic with IND acceptance; and we added a strategic collaboration with Roche to develop our HB-700 program for KRAS-mutated cancers," said Joern Aldag, Chief Executive Officer at HOOKIPA. *"We have started the year strongly with our HB-300 program now open for enrollment, and our HB-700 program achieving a key milestone as we move toward the clinic. We remain focused on driving our rich pipeline forward and generating clinical data that expands the evidence of our arenaviral platform technology to help address unmet needs in cancer."*

Oncology Portfolio
With a focus on its oncology portfolio, HOOKIPA advanced programs in each of the three pillars of its oncology strategy: targeting oncoviral antigens (HB-200); targeting self-antigens (HB-300); and targeting shared neoantigens (HB-700).

- **HB-200, a novel immunotherapy to treat head and neck cancers, advanced to Phase 2 in combination with pembrolizumab in 1st- and 2nd+-line settings and alone as post-standard of care treatment. Enrollment is on track, and HOOKIPA will provide a data update in 2Q 2023 via press release and an investor call**.
    - In January 2022, the first patient was dosed in the Phase 2 trial evaluating HB-200 in combination with pembrolizumab, as a potential treatment of 1st- and 2nd+-line advanced metastatic Human Papillomavirus 16 Positive (HPV16-positive) squamous cell head and neck cancers (HNSCC).
    - In June 2022, HOOKIPA announced positive Phase 1 monotherapy data for HB-200 for the treatment of advanced head and neck cancers at the American Society of Clinical Oncology (ASCO) Annual Meeting. Alternating 2-vector therapy showed superior antigen-specific T cell responses, more robust anti-tumor activity and similar tolerability vs. single-vector therapy
- **Novel prostate cancer immunotherapy, HB-300, achieved a regulatory milestone with Investigational New Drug Application (IND) acceptance.** In July 2022, HOOKIPA announced that the U.S. Food and Drug Administration (FDA) accepted HOOKIPA's IND for HB-300 for the treatment of metastatic castration-resistant prostate cancer.

- **HOOKIPA further expanded pipeline and strategic collaborations with the Roche/HB-700 agreement for KRAS-mutated cancers.** In October 2022, HOOKIPA announced a strategic collaboration and license agreement to develop HB-700 for KRAS-mutated cancers and a second undisclosed novel immunotherapy candidate. The Roche collaboration represents the first oncology license agreement for HOOKIPA. Under the terms of the agreement, HOOKIPA received $25 million in upfront cash, with an additional $15 million payment if Roche exercises the option to add an additional product candidate, and potential future milestone payments up to approximately $930 million for both programs, plus tiered royalties. In February 2023, HOOKIPA achieved a $10 million non-dilutive milestone payment, which reflected the start of the HB-700 manufacturing process to support a Phase 1 clinical trial.

- **Drug Master File (DMF) accepted to support future regulatory submissions in the US** in July 2022. The information contained in the DMF may be used to support additional INDs and other submissions. The DMF acceptance is HOOKIPA's biggest step to date toward a "plug & play" platform. The DMF shortens the future time interval between preclinical work and IND submission as HOOKIPA can forgo resubmission of the arenavirus backbone data with each new IND submission.

- **Potential of arenaviral immunotherapies in novel combinations and against tumor self-antigens highlighted at AACR.** In April 2022, HOOKIPA presented positive data at the 2022 American Association for Cancer Research Annual Meeting showing HOOKIPA's arenaviral immunotherapies induced potent T cell responses in novel combinations (such as co-stimulatory 4-1BB agonists or adoptive cell transfer) and against tumor self-antigens. The results highlighted the potential of HOOKIPA's novel arenaviral platform as a backbone of potential combination therapies, as well as expanded evidence reinforcing the scientific approach for the HB-300 program in prostate cancer. Of note, compelling pre-clinical data on the novel combination of arenaviral immunotherapy and PD-1 targeted IL-2 variant against a tumor self-antigen will be presented as an oral presentation at the 2023 AACR meeting in April.

Infectious Disease Portfolio

- **Collaboration with Gilead Sciences continues to advance development of functional cures for Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV).**
    - In February 2022, HOOKIPA and Gilead announced an amended collaboration and license agreement to develop HB-500, a novel arenaviral immunotherapy as a component of a potential functional curative regimen for HIV. HOOKIPA assumed development responsibility for advancing the HIV program through the completion of a Phase 1b clinical trial. Financial terms included a $4 million preclinical milestone, a $15 million non-refundable initiation fee, a $5 million equity investment at a premium to the then-current market price, and up to an additional $30 million of equity financing that can be drawn at HOOKIPA's discretion by December 31, 2023.

    - HOOKIPA's HB-400 program, in collaboration with Gilead as a curative regimen for HBV, advanced towards the clinic with the submission of the clinical trial application (IND equivalent) and HOOKIPA's completion of the regulatory support package for Gilead's Phase 1 clinical trial. This milestone earned HOOKIPA a $5 million non-dilutive payment under its collaboration agreement in January 2023. Gilead is solely responsible for further development and commercialization of the HBV product candidate; the first participant in the Phase 1 clinical trial is expected to be dosed in 2023.

- **Final Phase 2 data on HB-101 for Cytomegalovirus (CMV) prevention in live donor kidney transplant recipients:** Results of the Phase 2 clinical trial (NCT03629080), a prophylactic CMV vaccine candidate, show that HB-101 was immunogenic after at least two doses, inducing similar antibody responses to those observed in Phase 1. All participants who received three doses of HB-101, and for whom immunogenicity data were available, demonstrated a CMV-specific T cell immune response. In the efficacy analysis, participants who received three doses of HB-101 had a lower incidence of CMV viremia compared to the matched placebo group. Two doses of HB-101 did not reduce incidence of CMV infection, CMV disease, or use of antiviral treatment post-transplant compared to the placebo group. HOOKIPA has decided not to further invest in the HB-101 program, based on its corporate strategy to focus on oncology.

Corporate Updates

- In March 2022, HOOKIPA completed a $75 million public offering of common stock and non-voting convertible preferred stock.

- The company added two new Board members: Tim Reilly, Ph.D., in April, and Malte Peters, M.D., appointed in December and effective January 1, 2023. In March 2023, the Company appointed Terry Coelho to the board, effective, April 3, 2023.

- Over the course of 2022, HOOKIPA announced several executive leadership changes. In March 2022, Klaus Orlinger, Ph.D. was promoted to Chief Scientific Officer. Christine D. Baker was promoted to Chief Operating Officer in May 2022. In June 2022, Roman Necina was appointed to the newly created role of Chief Development Officer. In December 2022, Katia Schlienger, M.D., Ph.D., was promoted to Chief Medical Officer, effective January 1, 2023.

Upcoming Milestones

- Phase 2 HB-200 in HPV16+ head and neck cancers
  - 1st-line initial data in combination with pembrolizumab: 2Q 2023
  - 2nd+-line initial data in combination with pembrolizumab: 2Q 2023
  - Post-standard of care monotherapy: 2Q 2023
  - Randomized Phase 2 in 1st-line with pembrolizumab: study kick-off 2023 (Fast Track designation)
- HB-300 in prostate cancer: initial data expected 1H 2024
- HB-700 in KRAS-mutated cancers: submit IND 2024
- HB-400 in hepatitis B: first participant dosed 2023 (Gilead-led)
- HB-500 in HIV: submit IND 2023

Fourth Quarter and Full Year 2022 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of December 31, 2022 was $113.4 million compared to $66.9 million as of December 31, 2021. The increase was primarily attributable to funds resulting from the amended and restated Gilead collaboration agreement, the strategic collaboration and licensing agreement with Roche and the follow-on financing in March 2022, partly offset by cash used in operating activities.

HOOKIPA's cash position as of December 31, 2022 does not include a $5 million milestone payment that the Company received under the amended and restated Gilead collaboration agreement and a $10 million milestone payment that HOOKIPA received under the strategic collaboration and licensing agreement with Roche.

HOOKIPA does not hold cash deposits or securities at Silicon Valley Bank.

Revenue: Revenue was $7.8 million for the three months ended December 31, 2022, and $14.2 million for the year ended December 31, 2022 compared to $3.9 million for the three months ended December 31, 2021 and $18.4 million for the year ended December 31, 2021. The decrease in the full year revenues was primarily due to lower cost reimbursements received under the collaboration agreement with Gilead. This decrease was partially offset by the recognition of a milestone payment for supporting Gilead to progress with a Phase 1 clinical trial for the HBV program. A substantial part of the $4.0 million milestone payment and the $15.0 million initiation fee that were received for the HIV program under the restated Gilead collaboration agreement in the three months ended March 31, 2022, and the main part of the $25.0 million upfront payment that was received under the strategic collaboration and licensing agreement with Roche in the three months ended December 31, 2022, remained recorded as deferred revenue to be recognized in future accounting periods.

Research and Development Expenses: HOOKIPA's research and development expenses were $17.6 million for the three months ended December 31, 2022, and $68.6 million for the year ended December 31, 2022 compared to $22.4 million for the three months ended December 31, 2021, and $82.9 million for the year ended December 31, 2021. The primary drivers of the decrease in research and development expenses by $14.3 million compared to the year ended December 31, 2021 were lower manufacturing expenses for our HB-200, HB-300 and Gilead partnered programs and lower clinical study expenses due to the completion of patient enrollment of the Phase 2 trial for our HB-101 program, a decrease in personnel related expenses including stock based compensation, and a decrease in laboratory consumables, partially offset by an increase in professional and consulting fees and an increase in training and recruitment expenses.

General and Administrative Expenses: General and administrative expenses amounted to $3.8 million for the three months ended December 31, 2022 and $18.8 million for the year ended December 31, 2022 compared to $3.5 million for the three months ended December 31, 2021, and $17.3 million for the year ended December 31, 2021. The increase was primarily due to an increase in professional and consulting fees and an increase in training and recruitment expenses, partially offset by a decrease in personnel-related expenses and a decrease in other expenses.

Net Loss: HOOKIPA's net loss was $12.3 million for the three months ended December 31, 2022 and $64.9 million for the year ended December 31, 2022 compared to a net loss of $21.2 million for the three months ended December 31, 2021 and $75.7 million for the year ended December 31, 2021. This decrease was primarily due to a decrease in research and development expenses.

Conference call: HOOKIPA will host a conference call and live webcast at 8:30 am EDT today to discuss its financial results and provide a corporate update.

Dial In:	+1 800-715-9871
UK Dial In:	0800 260-6466
Austria Dial In:	+43 800 070441
Conference ID:	7669853
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 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 oncology 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.

HOOKIPA 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 annual report on Form 10-K for the year ended December 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.

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.

HOOKIPA Pharma Inc.
Consolidated Statements of Operations (Unaudited)
(In thousands, except share and per share data)

	Three months ended December 31, (unaudited)		Year ended December 31,	
	2022	2021	2022	2021
Revenue from collaboration and licensing	$ 7,828	$ 3,895	$ 14,249	$ 18,448
Operating expenses:				
Research and development	(17,592)	(22,419)	(68,645)	(82,853)
General and administrative	(3,824)	(3,523)	(18,759)	(17,269)
Total operating expenses	(21,416)	(25,942)	(87,404)	(100,122)
Loss from operations	(13,588)	(22,047)	(73,155)	(81,674)
Total interest, other income and taxes, net	1,277	812	8,240	6,009
Net loss	$ (12,311)	$ (21,235)	$ (64,915)	$ (75,665)
Net loss per share — basic and diluted	(0.17)	(0.65)	(0.99)	(2.30)

Condensed Balance Sheets
(In thousands)

	As of December 31, 2022	As of December 31, 2021
Cash, cash equivalents and restricted cash	$ 113,444	$ 66,912
Total assets	170,454	126,045
Total liabilities	67,937	36,453
Total stockholders' equity	102,517	89,592

For further information, please contact:

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