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): **November 14, 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 2.02 Results of Operations and Financial Condition.

On November 14, 2022, HOOKIPA Pharma Inc. (the "Company") announced Financial Results for the Third Quarter 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 November 14, 2022
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: November 14, 2022

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

HOOKIPA Pharma Announces Third Quarter 2022 Financial Results and Provides a Business Update

- Major oncology collaboration and license agreement secured with Roche to develop HB-700 for KRAS-mutated cancers and an additional undisclosed oncology candidate
- Investigational New Drug Application for HB-300 for the treatment of metastatic castration-resistant prostate cancer accepted by the FDA
- Enrollment in the Phase 2 study of HB-200 in combination with pembrolizumab is ongoing; next data update expected in the first half of 2023

NEW YORK and VIENNA, November 14, 2022 - HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapies based on its proprietary arenavirus platform, today reported business highlights and financial results for the third quarter of 2022.

"We're proud of our steady momentum and the external validation of our arenaviral technology over the past few months. Securing our Roche collaboration to develop HB-700 for KRAS-mutated cancers was a key recent achievement, and we're pleased to move our prostate cancer product candidate, HB-300, toward the clinic following FDA clearance," said Joern Aldag, Chief Executive Officer at HOOKIPA. "With our cash position and upfront cash proceeds from the Roche collaboration, we are positioned to fund multiple clinical readouts in 2023 and 2024, including from our Phase 2 HB-200 program in combination with pembrolizumab."

Business Highlights and Recent Developments

- In the Phase 2 study of HB-200 in combination with pembrolizumab for patients with HPV16+ metastatic/recurrent head and neck cancer in the first- and second-line settings, enrollment is ongoing.

  More than 20 patients have been dosed, including those in the safety run-in who received lower doses than the recommended Phase 2 dose. As of today, only a small number of patients have received the recommended Phase 2 dose of HB-200 with pembrolizumab. More time and additional imaging assessments are required to mature the dataset and inform the next phase of development. HOOKIPA will provide a comprehensive data update in the first half of 2023.

- In October, HOOKIPA announced a strategic collaboration and licensing agreement with Roche to develop HB-700 for KRAS-mutated cancers and a second undisclosed novel arenaviral immunotherapy candidate. The Roche collaboration represents the first oncology licensing 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 July, HOOKIPA announced that the U.S. Food and Drug Administration accepted HOOKIPA's investigational New Drug Application for HB-300 for the treatment of metastatic castration-resistant prostate cancer. A Drug Master File also was accepted, reducing cycle time between completion of preclinical studies and clinical entry of HOOKIPA's pipeline projects.

- Following the submission of the clinical trial application (IND equivalent) for HB-400, a Hepatitis B therapeutic, in 2022, HOOKIPA expects the first patient to be dosed in a Phase 1 clinical trial during 2023.

Upcoming Milestones

- First patient enrolled in HB-300 Phase 1 study (prostate cancer) expected in the first quarter of 2023
- Phase 2 HB-200 data in combination with pembrolizumab in the first- and second-line setting for HPV16+ head and neck cancer expected in the first half of 2023
- Randomized Phase 2 HB-200 study in combination with pembrolizumab in the first-line setting for HPV16+ head and neck cancer expected to launch in 2023 (Fast Track designation)
- Phase 2 HB-101 data for the prevention of Cytomegalovirus (CMV) in kidney transplant recipients expected in the first half of 2023
- HB-400 Hepatitis B therapeutic (Gilead-led): first patient dosed 2023

Third Quarter 2022 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of September 30, 2022 was $100.7 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 and the follow-on financing in March 2022, partly offset by cash used in operating activities.

HOOKIPA's cash position as of September 30, 2022 does not include a $25.0 million upfront payment that the Company is entitled to receive under the strategic collaboration and licensing agreement signed with Roche in October 2022 and up to $30.0 million from the issuance of common stock that Gilead is required to purchase at the discretion of the Company pursuant to the terms of a stock purchase agreement signed in February 2022

Revenue: Revenue was $2.2 million for the three months ended September 30, 2022, compared to $3.9 million for the three months ended September 30, 2021. The decrease was primarily due to lower cost reimbursements received under the Collaboration Agreement with Gilead as Hookipa neared completion of HBV program assets in preparation for Gilead to progress with a Phase 1 clinical trial. The main parts of the $4.0 million milestone payment and the $15.0 million initiation fee received in the three months ended March 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 $18.3 million for the three months ended September 30, 2022, compared to $20.7 million for the three months ended September 30, 2021. The decrease for the three months ended September 30, 2022, compared to the three months ended September 30, 2021, was primarily driven by lower manufacturing expenses for our HB-200 and Gilead partnered programs, a decrease in laboratory consumables, and a decrease in personnel-related expenses including stock-based compensation that was partially offset by an increase in training and recruitment expenses..

General and Administrative Expenses: General and administrative expenses for the three months ended September 30, 2022, were $4.9 million, compared to $4.3 million for the three months ended September 30, 2021. The increase was primarily due to an increase in professional and consulting fees and an increase in training and recruitment expenses that was partially offset by a decrease in personnel-related expenses and a decrease in other expenses. The decrease in personnel-related expenses resulted from decreased stock compensation expenses, that was partially offset by a growth in headcount along with increased salaries in our general and administrative functions.

Net Loss: HOOKIPA's net loss was $18.3 million for the three months ended September 30, 2022, compared to a net loss of $20.0 million for the three months ended September 30, 2021. This decrease was primarily due to a decrease in research and development expenses.

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.

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 quarterly report on Form 10-Q for the quarter ended September 30, 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 September 30, 2022	2021	Nine months ended September 30, 2022	2021
Revenue from collaboration and licensing	$ 2,230	$ 3,874	$ 6,421	$ 14,553
Operating expenses:				
Research and development	(18,286)	(20,698)	(51,053)	(60,434)
General and administrative	(4,937)	(4,342)	(14,935)	(13,746)
Total operating expenses	(23,223)	(25,040)	(65,988)	(74,180)
Loss from operations	(20,993)	(21,166)	(59,567)	(59,627)
Total interest, other income and taxes, net	2,713	1,126	6,963	5,197
Net loss	$ (18,280)	$ (20,040)	$ (52,604)	$ (54,430)
Net loss per share — basic and diluted	(0.25)	(0.61)	(0.83)	(1.66)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of September 30, 2022	As of December 31, 2021
Cash, cash equivalents and restricted cash	$ 100,676	$ 66,912
Total assets	151,526	126,045
Total liabilities	38,178	36,453
Total stockholders' equity	113,348	89,592

For further information, please contact:

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

Investors
Matt Beck
Executive Director - Investor Relations
matthew.beck@hookipapharma.com
+1 917 209 6886