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 10, 2021**

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 10, 2021, HOOKIPA Pharma Inc. (the "Company") announced Financial Results for the Third Quarter ended September 30, 2021. 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 10, 2021
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 10, 2021

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

HOOKIPA Pharma Reports Third Quarter 2021 Financial Results and Recent Highlights

- Clinical collaboration with Merck & Co., Inc., Kenilworth, NJ, USA, set to evaluate HB-201 in combination with pembrolizumab in 1st- and 2nd-line HNSCC patients

- Based on recent strong data updates, HOOKIPA advancing HB-201 to Phase 2, prioritizing immuno-oncology pipeline across numerous cancers

New York, US and Vienna, Austria, November 10, 2021 - 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 business highlights for the third quarter of 2021.

"Our team remains focused on optimizing the potential of our versatile arenaviral platform to redefine success in cancer immunotherapy by driving strong tumor-specific T cell responses. Third quarter highlights include our clinical collaboration with Merck & Co., Inc., Kenilworth, NJ, USA, on our HB-200 program in head and neck cancer and the publication of our pre-clinical data in melanoma in Nature Communications, both of which offered external validation of the promise of our technology," said Joern Aldag, Chief Executive Officer at HOOKIPA. "Given our recent HB-200 data update, we're even more energized about the start of our Phase 2 combination study of HB-201 with pembrolizumab as a 1st- or 2nd-line treatment in head and neck cancers, as well as progressing and expanding our oncology pipeline with candidates for prostate and KRAS-mutated cancers."

Quarter Highlights

- In August, pre-clinical data on HOOKIPA's arenaviral immunotherapeutic in melanoma was published in the peer-reviewed journal, *Nature Communications*. The data showed that HOOKIPA's replicating Lymphocytic choriomeningitis (LCMV)-based vector, designed to target melanoma, modulated the tumor micro-environment and induced potent, antigen-specific T cell responses, resulting in tumor regression and tumor eradication in the pre-clinical setting. The data reinforce the potential of HOOKIPA's arenaviral immunotherapeutic technology to activate and mobilize anti-tumor T cells for effective control and eradication of established tumors.

- In September, HOOKIPA announced a clinical collaboration and supply agreement with Merck & Co, Inc., Kenilworth, NJ, USA (known as MSD outside of the United States and Canada) to evaluate the combination of HB-200, a novel arenaviral immunotherapeutic, and KEYTRUDA® (pembrolizumab) as 1st-line treatment for patients with advanced head and neck cancer.

Business updates

On November 9, 2021 HOOKIPA provided a data update across its clinical development program. HOOKIPA announced it is advancing HB-201 to Phase 2, to be evaluated in combination with pembrolizumab as 1st- or 2nd-line treatment for Human Papillomavirus 16 Positive (HPV16+) squamous cell head and neck cancers (HNSCC). Interim Phase 1 data in heavily pre-treated patients continue to show HB-200 monotherapy (both HB-201 alone and HB-202/HB-201) is highly effective at expanding T cells, has a favorable tolerability profile and promising, early anti-tumor activity. As of November 1, 2021, among 28 patients dosed intravenously, HB-200 resulted in a 75 percent disease control rate and shrinkage of target lesions in 53 percent of patients. In these patients, HOOKIPA has observed three partial responses (including one confirmed and one unconfirmed in an ongoing patient) and one ongoing patient with a near partial response (29 percent tumor shrinkage). Based on the strength of the HB-200 data, HOOKIPA has prioritized its oncology portfolio, including HB-300 for prostate

cancer and HB-700 for KRAS-mutated cancers, and plans further development of its infectious disease programs to be done in partnership with other companies.

Upcoming Milestones

- Phase 1 HB-200 HPV16+ HNSCC additional data: mid-year 2022
- Phase 2 HB-201 + pembrolizumab HPV16+ HNSCC 1st-line initial data: second half of 2022
- Phase 2 HB-201 + pembrolizumab HPV16+ HNSCC 2nd-line initial data: second half of 2022
- Randomized Phase 2 HB-200 + pembrolizumab HPV16+ HNSCC 1st-line trial initiation: first half of 2023
- Investigational New Drug application for HB-300 in metastatic prostate cancer: third quarter 2022

Third Quarter 2021 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of September 30, 2021 was $82.7 million compared to $143.2 million as of December 31, 2020. The decrease was primarily attributable to cash used in operating activities.

Revenue was $3.9 million for the three months ended September 30, 2021, and $4.0 million for the three months ended September 30, 2020. Revenues did not materially change compared to the three months ended September 30, 2020 though they included lower deferred revenues from upfront and milestone payments which were partially offset by higher cost reimbursements.

Research and Development Expenses: HOOKIPA's research and development expenses were $20.7 million for the three months ended September 30, 2021, compared to $16.0 million for the three months ended September 30, 2020.

The primary drivers of the increase in direct research and development expenses were an increase in manufacturing and quality control expenses of $2.1 million, along with a general increase in other direct research and development expenses and laboratory expenses of $1.6 million, partially offset by a decrease in expenses for clinical studies of $0.6 million. The increase in manufacturing and quality control expenses as well as other direct research and development expenses was mainly due to the progress in HOOKIPA's HB-201 and HB-202 clinical trial, in particular for monitoring and testing activities, and manufacturing and quality control work in preparation of a further extension of the trial. Clinical study expenses decreased primarily due to the completion of patient enrollment of the Phase 2 study for our CMV vaccine candidate HB-101.

Internal research and development expenses increased by $1.6 million, mainly due to HOOKIPA's increased research and development headcount.

General and Administrative Expenses: General and administrative expenses for the three months ended September 30, 2021 were $4.3 million, compared to $4.4 million for the three months ended September 30, 2020. The decrease was primarily due to a decrease in personnel-related expenses and a decrease in professional and consulting fees. The decrease in personnel-related expenses resulted from decreased stock compensation expenses, partially offset by a growth in headcount along with increased salaries in our general and administrative functions.

Net Loss: HOOKIPA's net loss was $20.0 million for the three months ended September 30, 2021, compared to a net loss of $13.6 million for the three months ended September 30, 2020. The increase was primarily due to an increase in HOOKIPA's research and development activities.

About HOOKIPA

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical-stage biopharmaceutical company focused on developing novel immunotherapies that mobilize and amplify targeted T cells to address unmet needs in cancer.

The company is leveraging its proprietary, versatile platform to engineer a broad pipeline of differentiated arenaviral therapeutics. These novel immunotherapies induce robust antigen-specific killer T cells to a broad range of self and non-self antigens, including viral antigens, tumor-associated antigens and neoantigens. HOOKIPA's platform technology uses replicating viral vectors based on the target cancer, with the potential to induce killer T cell response levels previously not achieved by other immunotherapy approaches.

HOOKIPA's pipeline includes wholly-owned investigational arenaviral immunotherapeutics targeting HPV16+ cancers, prostate cancer, KRAS-mutated cancers (including colorectal, pancreatic and lung), and other undisclosed projects. In addition, the company 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 for HB-101 and other programs, and other matters that could affect the sufficiency of existing cash to fund operations and HOOKIPA's ability to achieve the milestones under the agreement with Gilead. 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, 2021 which is available on the Securities 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,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenue from collaboration and licensing	$ 3,874	$ 4,040	$ 14,553	$ 14,421
Operating expenses:				
Research and development	(20,698)	(16,009)	(60,434)	(39,099)
General and administrative	(4,342)	(4,437)	(13,746)	(13,413)
Total operating expenses	(25,040)	(20,446)	(74,180)	(52,512)
Loss from operations	(21,166)	(16,406)	(59,627)	(38,091)
Total interest, other income and taxes, net	1,126	2,817	5,197	6,483
Net loss	$ (20,040)	$ (13,589)	$ (54,430)	$ (31,608)
Net loss per share — basic and diluted	(0.61)	(0.53)	(1.66)	(1.23)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of September 30, 2021	As of December 31, 2020
Cash, cash equivalents and restricted cash	$ 82,697	$ 143,177
Total assets	142,172	187,817
Total liabilities	34,086	31,694
Total stockholders' equity	108,086	156,123

For further information, please contact:

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