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, 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 Capital 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, 2024, HOOKIPA Pharma Inc. (the "Company") announced Financial Results for the Third Quarter 2024. 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, 2024
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, 2024

By:/s/ Malte Peters
Malte Peters
Chief Executive Officer
(Principal Executive Officer)

HOOKIPA Pharma Reports Third Quarter 2024 Financial Results and Provides Recent Business Updates

Enrollment of 68 patients completed Phase 2 study for eseba-vec + pembrolizumab in HPV+ HNSCC four months ahead of schedule

SITC 2024 late-breaking poster highlights Phase 2 eseba-vec data updates for increased number of patients reflecting ORR and durability in line with prior data

First patients dosed in Phase 2 investigator led study with MSKCC in new clinical setting as adjuvant therapy for head and neck cancer

Strength of HB-700 KRAS-inhibitor program highlighted by preclinical dataset presented at recent RAS Targeted Drug Development Summit

NEW YORK, NY and VIENNA, AUSTRIA November 14, 2024 - HOOKIPA Pharma Inc. (NASDAQ: HOOK, "HOOKIPA", the "Company"), a clinical-stage biopharmaceutical company developing next generation immunotherapeutics for the treatment of cancer and serious infectious disease, today reported financial results for the third quarter ended September 30, 2024 and provided recent business highlights, including an update on the progress of the lead clinical program, eseba-vec.

"HOOKIPA made excellent progress across each program in our pipeline in the third quarter," said Malte Peters, MD, Chief Executive Officer of HOOKIPA. *"We advanced the development of eseba-vec for HPV16+ head and neck squamous cell carcinoma (HNSCC), through the start of an investigator initiated study in the new clinical setting of adjuvant care, and presented continued positive, updated data from our Phase 2 study in first-line recurrent/metastatic disease as a late breaking abstract at SITC 2024. In parallel, we have made significant progress with our review of the business strategy and operations, having implemented a number of initiatives to optimize spending and ensure prioritization of resources."*

Recent Developments

Oncology
Eseba-vec: Pivotal-trial ready immunotherapy for human papilloma virus type 16 positive (HPV16+) cancers, including head and neck squamous cell carcinoma (HNSCC) and oropharyngeal squamous cell carcinoma (OPSCC). HOOKIPA owns all rights to this program

- **Enrollment completed in the Phase 2 H200-001 study** for eseba-vec in combination with pembrolizumab in HPV+ HNSCC with 68 patients enrolled as of October 2024.
- **First Patients Dosed in Phase 2 Adjuvant Therapy IIT with MSKCC:** On October 30, 2024, HOOKIPA announced that researchers at Memorial Sloan Kettering Cancer Center (MSKCC) dosed the first patients in an investigator initiated trial (IIT) evaluating eseba-vec in patients with minimal residual disease positive (MRD+) HPV-16+ driven, locally advanced HNSCC, following treatment for curative intent. The study could pave the way to broaden the eseba-vec HNSCC opportunity into adjuvant care.
- **Updated Phase 2 Data Presented as SITC 2024 Late-Breaker:** On November 9, 2024, HOOKIPA's clinical collaborator, Alan Ho, MD, PhD, Chief of the Head and Neck Oncology Service at MSKCC, presented a late-breaking poster at the 39th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2024). The presentation provided updated results, including data from additional patients enrolled in the Phase 2 trial evaluating

eseba-vec plus pembrolizumab as 1L treatment of recurring/metastatic HPV16+ HNSCC in patients with PD-L1 CPS levels of greater than or equal to 20. Eseba-vec treatment resulted in continued, durable clinical responses and antigen-specific T cell responses.

HB-700: The HB-700 program is a novel Phase 1-ready immunotherapy for KRAS-mutated cancers, including pancreatic, colorectal and lung cancer. The investigational therapy was designed to target the most prevalent KRAS mutations of these cancers in a single therapy. HOOKIPA owns all rights to this program and the Investigational New Drug Application (IND) received FDA clearance in April 2024.

- **Presentation of Strong Preclinical Dataset:** On September 25, 2024, HOOKIPA presented the preclinical proof-of-concept dataset for HB-700 at the 6th Annual RAS-Targeted Drug Development Summit. The dataset demonstrated that HB-700 induced target-specific CD8+ T cells and target cell killing in several different animal and translational models.

Infectious Diseases
HOOKIPA is advancing two independent anti-viral programs (HB-400 for HBV and HB-500 for HIV-1) through a collaboration and license agreement with Gilead Sciences, Inc. (Gilead).

HB-400: An investigational therapeutic vaccine for the treatment of chronic hepatitis B (CHB).

- **Enrollment Completed in Phase 1a/1b Clinical Trial:** The vaccine is being evaluated in a Phase 1a/1b clinical trial (NCT05770895) in 83 subjects to assess the safety and immune response induced by HB400 in healthy participants and in participants with CHB on oral antiviral therapy

HB-500: An investigational therapeutic vaccine for the treatment of human immunodeficiency virus-1 (HIV-1).

- **Ongoing Phase 1b Clinical Trial:** The vaccine is being evaluated in a Phase 1b clinical trial (NCT06430905) to assess the safety and magnitude of cellular immune response against HIV-1 induced by HB-500 in people living with HIV who are taking anti-retroviral treatment. Under the collaboration agreement with Gilead, HOOKIPA received a $5 million milestone payment associated with dosing of the first subject in this trial in July 2024.

Corporate and Financial Updates

Corporate Highlights

- **Board of Director Changes:** On August 30, 2024, Director Julie O'Neill was appointed to be Non-Executive Chair of the Company's Board of Directors, succeeding Jan van de Winkel, who decided to step down from the Board due to increased time commitments from other executive responsibilities. Tim Reilly also stepped down from the Board to dedicate more time to his other professional responsibilities. HOOKIPA is grateful for the years of service each Director dedicated to the Company.

- **Leadership Changes:** On July 22, 2024, the Board of Directors appointed Malte Peters, MD, as Chief Executive Officer and Terry Coelho as Executive Vice President and Chief Financial Officer to lead the Company through its next phase of development and to realize the significant opportunity of HOOKIPA's pipeline.

- **Board Appointment:** On July 22, 2024, Sean Cassidy was appointed to the Board of Directors. Mr. Cassidy serves as the chair of the Audit Committee and as a member of the Compensation and the Nominating and Corporate Governance Committees.

- **Reverse Split:** On July 9, 2024, the Company effected a reverse stock split of the outstanding shares of its common stock on a one-for-ten (1:10) basis. The reverse stock split is part of the Company's plan to regain compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market.

Financial Highlights: Milestone Payments

- **Gilead:** In July, HOOKIPA received a $5.0 million milestone payment under its collaboration and license agreement with Gilead. The success-based milestone payment was achieved in connection with the dosing of the first subject in the Phase 1b clinical trial of HB-500 for the treatment of HIV-1, initiated on July 1, 2024.

Third Quarter 2024 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of September 30, 2024 was $60.0 million compared to $117.5 million as of December 31, 2023. The decrease was primarily attributable to cash used in operating activities, partially offset by cash received relating to milestone achievements under our collaboration agreements with Roche and Gilead.

Revenue: Revenue was $4.7 million for the three months ended September 30, 2024, compared to $6.9 million for the same period in 2023. The decrease was primarily due to lower partnering revenues as a result of the termination of the Roche collaboration agreement.

Research and Development Expenses: HOOKIPA's research and development expenses were $15.6 million for the three months ended September 30, 2024, compared to $24.6 million for the same period in 2023. The primary changes in research and development expenses were lower personnel-related and laboratory-related expenses, as well as lower manufacturing and research expenses, resulting from the pause in development activities related to HB-300 announced in January 2024, partially offset by higher clinical study expenses for the eseba-vec program.

General and Administrative Expenses: General and administrative expenses amounted to $6.7 million for the three months ended September 30, 2024, compared to $4.9 million for the same period in 2023. The primary drivers of the increase in general and administrative expenses were an increase in personnel-related expenses and an increase in professional and consulting fees incurred in connection with management transitions during the third quarter of 2024.

Restructuring Expenses: Restructuring expenses amounted to $0.9 million for the three months ended September 30, 2024, and resulted from severance and other personnel costs as well as professional fees related to a reduction in workforce and related activities conducted in the third quarter of 2024.

Impairment Expenses: Impairment expenses amounted to $0.2 million for the three months ended September 30, 2024, and resulted from write-downs related to laboratory equipment.

Net Loss: HOOKIPA's net loss was $13.8 million for the three months ended September 30, 2024, compared to a net loss of $19.1 million for the same period in 2023.

About HOOKIPA
HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical-stage biopharmaceutical company focused on developing next generation immunotherapeutics based on its proprietary arenavirus platform. The company's product candidates are designed to induce specific, robust and durable CD8+ T cells and antibodies to eliminate cancers and serious infectious diseases. HOOKIPA's pipeline includes biological therapies for oncology, targeting human papillomavirus type 16-positive (HPV16+) cancers, KRAS mutated cancers, and other targets. In addition, HOOKIPA has partnered with Gilead Sciences, Inc. to develop therapies that are intended to provide functional cures for hepatitis B virus (HBV) and human immunodeficiency virus-1 (HIV-1).

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 "anticipates", "believes", "could", "expects", "plans", "potential", "will", "would" or similar expressions and the negative of those terms. Forward-looking statements in this press release include HOOKIPA's statements regarding the potential of its product candidates to improve the care of the patients it seeks to treat, the potential of its Phase 2 IIT to support the use of eseba-vec in adjuvant care, and other statements that are not historical fact. 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, plans and timelines for the preclinical and clinical development of its product candidates, including the therapeutic potential, clinical benefits and safety thereof, expectations regarding timing, success and data announcements of current ongoing preclinical studies and clinical trials, the ability to initiate new clinical programs, the risk that the results of current preclinical studies and clinical trials may not be predictive of future results in connection with current or future preclinical studies and clinical trials, including those for eseba-vec (also known as HB200), HB-700, HB-400 and HB-500, 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, and HOOKIPA's ability to continue as a going concern 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, 2023, as well as discussions of potential risks, uncertainties, and other important factors in HOOKIPA's subsequent filings with the U.S. Securities and Exchange Commission (SEC), which are available on the SEC's website at www.sec.gov and HOOKIPA's website at www.hookipapharma.com. All information in this press release is as of the date of the release, and HOOKIPA undertakes no duty to update this information unless required by law.

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 investors and the public about our company, 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 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, 2024	2023	Nine months ended September 30, 2024	2023
Revenue from collaboration and licensing	$ 4,703	$ 6,867	$ 42,592	$ 12,722
Operating expenses:				
Research and development	(15,565)	(24,625)	(55,482)	(65,262)
General and administrative	(6,732)	(4,912)	(14,733)	(14,259)
Restructuring	(878)	—	(2,201)	—
Impairment	(172)	—	(172)	—
Total operating expenses	(23,347)	(29,537)	(72,588)	(79,521)
Loss from operations	(18,644)	(22,670)	(29,996)	(66,799)
Total interest, other income and taxes, net	4,803	3,604	11,443	10,037
Net loss	$ (13,841)	$ (19,066)	$ (18,553)	$ (56,762)
Net loss per share — basic and diluted	(1.10)	(1.73)	(1.48)	(6.41)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of September 30, 2024	As of December 31, 2023
Cash, cash equivalents and restricted cash	$ 59,957	$ 117,521
Total assets	109,730	161,337
Total liabilities	37,928	71,480
Total stockholders' equity	71,802	89,857

For further information, please contact:

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