
**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): **August 8, 2024**

HOOKIPA PHARMA INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38869
(Commission
File Number)

81-5395687
(IRS Employer
Identification No.)

**350 Fifth Avenue, 72nd Floor,
Suite 7240
New York, New York**
(Address of principal executive offices)

10118
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
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 August 8, 2024, HOOKIPA Pharma Inc. (the “Company”) announced Financial Results for the Second 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release issued by HOOKIPA Pharma Inc. on August 8, 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: August 8, 2024

By: /s/ Malte Peters

Malte Peters
Chief Executive Officer
(Principal Executive Officer)



**HOOKIPA Pharma Reports Second Quarter 2024 Financial Results
and Recent Business Highlights**

New Leadership Appointments; Positive Clinical and Regulatory Reports for the Lead Product Candidate, HB-200 (eseba-vec); On track to initiate the Phase 2/3 “AVALON-1” study with eseba-vec in Q4 2024

- **ASCO 2024 Presentation:** Reported best-in-class Phase 2 data for first-line HPV16+ head and neck cancer patients treated with eseba-vec (formerly HB-200) in combination with pembrolizumab during oral presentation at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting
- **Regulatory Progress:** Announced alignment with U.S. Food and Drug Administration (FDA) for the AVALON-1 Phase 2/3 pivotal trial design and protocol for eseba-vec, in combination with pembrolizumab for the first-line treatment of patients with HPV16+ recurrent or metastatic oropharyngeal squamous cell carcinoma (OPSCC)
- **PRIME Designation:** Announced that EMA has granted PRIME designation for the investigational product eseba-vec for the treatment of patients with HPV16+ recurrent or metastatic PD-L1 CPS \geq 20 OPSCC in the first line setting
- **New IND Clearance in Oncology:** Received FDA clearance for Investigational New Drug (IND) application for HB-700 for the treatment of KRAS mutated cancers
- **Initiation of HIV Study with Partner, Gilead:** Dosed first person in Phase 1b clinical trial of HB-500 for the treatment of human immunodeficiency virus (HIV); achieved \$5 million milestone payment under collaboration and license agreement with Gilead Sciences, Inc. (Gilead)

NEW YORK and VIENNA, August 8, 2024 - 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 recent business highlights for the second quarter of 2024.

“It is an honor to be appointed CEO of HOOKIPA at such an important time for the Company. I am optimistic about the Company’s prospects, based on the strength of the pipeline, early clinical data, and the experience and dedication of the accomplished team we have in place,” said Malte Peters, Chief Executive Officer of HOOKIPA. *“Our best-in-class Phase 2 data that were presented at ASCO has generated significant momentum among investigators and this has enhanced the pace of enrollment in our ongoing Phase 2 study. In the meantime, preparations are well underway for our AVALON-1 pivotal adaptive Phase 2/3 trial of eseba-vec, expected to be initiated in the fourth quarter of this year.”*

“We have important work ahead of us in the second half of this year,” added Terry Coelho, Executive Vice President and Chief Financial Officer of HOOKIPA. *“We are keenly focused on clinical execution and operational excellence, and I look forward to working closely with Malte to explore opportunities to ensure that we are sufficiently capitalized to reach these goals.”*



Anticipated Catalysts

Oncology

- **Eseba-vec (HPV16+ OPSCC):** AVALON-1 pivotal study start (Q4 2024)
- **HB-700 (KRAS):** Partnering and collaborations under evaluation

Infectious Disease: Partnered with Gilead

- **HB-400 (HBV):** Complete Phase 1b enrollment and initiate Phase 2 study (timing to be determined by Gilead)
- **HB-500 (HIV):** Actively enrolling Phase 1b trial

Business Highlights and Recent Developments

Oncology

- **Eseba-vec:** HOOKIPA is on track to start a seamless pivotal Phase 2/3 trial of eseba-vec in combination with pembrolizumab for the treatment of patients with Human Papillomavirus 16-positive (HPV16+) recurrent/metastatic PD-L1 CPS \geq 20 OPSCC in the first line setting.
 - The AVALON-1 Phase 2/3 trial design and protocol has been aligned with the FDA with a path to potential accelerated approval.
 - The Company anticipates the trial will start in the fourth quarter of 2024.
 - Updated data from a Phase 2 trial of eseba-vec in combination with pembrolizumab were reported at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting. The data strongly validate the Company's clinical development plan.
- **HB-700:** The HB-700 program is a novel arenaviral immunotherapy for KRAS-mutated cancers, including the five mutations that are the primary causes of lung, pancreatic and colon cancers. The Company received clearance from the FDA for its IND application for HB-700 for the treatment of KRAS-mutated cancers. Effective April 25, 2024, HOOKIPA regained full control of the associated intellectual property portfolio and has full collaboration and licensing rights for this program.
 - Preclinical data published at the ASCO 2024 Annual Meeting demonstrated that HB-700 was well tolerated and induced KRAS mutation specific T cell responses in HLA transgenic mice.

Infectious Disease

- **HB-400:** HB-400 is an investigational therapeutic vaccine for the treatment of chronic hepatitis B (HBV) and is currently being evaluated in a Phase 1 trial. HB-400 is one of two independent development programs in HOOKIPA's collaboration and license agreement with Gilead. Gilead is solely responsible for further development and commercialization of the HBV product candidate.
- **HB-500:** HB-500 is an investigational therapeutic vaccine for the treatment of HIV, also partnered with Gilead. On July 1, 2024, HOOKIPA dosed the first eligible person living with HIV in the Phase 1b clinical trial of HB-500.
 - Under the collaboration agreement with Gilead, HOOKIPA received a \$5 million milestone payment associated with the first dosing for this trial.
 - HOOKIPA and Gilead also published two peer-reviewed preclinical research papers on HB-500 during the quarter:
 - In articles published in the [Journal of Virology](#), and [Vaccines](#), research demonstrated robust immunogenicity in non-human primates driven by administration of HB-500. The research also demonstrated the potential of immunogenicity of HB-500 to be enhanced when combined with a Flt3L-Fc fusion protein.
 - These findings show the potential that HB-500 can be a critical component of a curative treatment for HIV.

Corporate and Financial Updates

Corporate Highlights

- **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.
 - **New Leadership Team:** On July 22, 2024, the Board of Directors appointed Malte Peters, M.D., 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 realize the significant opportunity eseba-vec represents.
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- **Board Appointment:** Sean A. Cassidy was appointed to the Board of Directors on July 22, 2024, and will serve as the chair of the Audit Committee and member of the Compensation Committee.

Financial Highlights

- **Roche:** In April, HOOKIPA received a final \$10.0 million milestone payment under its now-terminated HB-700 collaboration agreement with Roche. The success-based milestone payment was achieved in connection with HOOKIPA's submission of an IND application for HB-700 for the treatment of KRAS mutated tumors.
- **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 person in a Phase 1b clinical trial of HB-500 for the treatment of HIV.

Second Quarter 2024 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of June 30, 2024 was \$77.4 million compared to \$117.5 million as of December 31, 2023. The decrease was primarily attributable to cash used in operating activities.

Revenue: Revenue was \$1.3 million for the three months ended June 30, 2024, compared to \$2.7 million for the same period in 2023. The decrease was primarily due to lower partial recognition of the upfront and milestone payments under the Roche collaboration as a result of the termination of the collaboration agreement with Roche.

Research and Development Expenses: HOOKIPA's research and development expenses were \$19.7 million for the three months ended June 30, 2024 and June 30, 2023, respectively. The primary changes in research and development expenses were lower personnel-related and laboratory-related expenses as well as lower manufacturing expenses, offset by higher clinical study expenses for the eseba-vec program.

General and Administrative Expenses: General and administrative expenses amounted to \$3.9 million for the three months ended June 30, 2024, compared to \$4.4 million for the same period in 2023. The primary driver of the decrease in general and administrative expenses was a decrease in personnel-related expenses and in professional and consulting fees.

Restructuring Expenses: Restructuring expenses amounted to \$0.1 million for the three months ended June 30, 2024, and resulted from severance and other personnel costs as well as consulting costs associated with the Company's restructuring plan announced in January 2024. The restructuring plan was completed as of June 30, 2024.

Net Loss: HOOKIPA's net loss was \$19.1 million for the three months ended June 30, 2024, compared to a net loss of \$18.0 million for the same period in 2023. This increase was primarily due to lower revenues resulting from lower partial recognition of the upfront and milestone payments under the terminated Roche collaboration.

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 undisclosed programs. 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

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,” “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 positively impact quality of life and alter the course of disease in the patients it seeks to treat, HOOKIPA’s plans, strategies, expectations and anticipated milestones for its preclinical and clinical programs, including the timing of initiating clinical trials (including the Phase 2/3 trial of eseba-vec) and patient enrollment, the availability and timing of results from preclinical studies and clinical trials, the timing of regulatory filings, the expected safety profile of HOOKIPA’s product candidates, and the probability of successfully developing and receiving regulatory approval for its product candidates. 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 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 and clinical trials, including those for eseba-vec, 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, HOOKIPA’s ability to effectively transition the recent senior executive leadership changes 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 Securities and Exchange Commission, 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, 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 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 June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Revenue from collaboration and licensing	\$ 1,290	\$ 2,679	\$ 37,889	\$ 5,855
Operating expenses:				
Research and development	(19,749)	(19,706)	(39,917)	(40,637)
General and administrative	(3,945)	(4,445)	(8,001)	(9,347)
Restructuring	(54)	—	(1,323)	—
Total operating expenses	<u>(23,748)</u>	<u>(24,151)</u>	<u>(49,241)</u>	<u>(49,984)</u>
Loss from operations	(22,458)	(21,472)	(11,352)	(44,129)
Total interest, other income and taxes, net	3,363	3,456	6,640	6,433
Net loss	<u>\$ (19,095)</u>	<u>\$ (18,016)</u>	<u>\$ (4,712)</u>	<u>\$ (37,696)</u>
Net loss per share — basic and diluted	(1.52)	(2.18)	(0.38)	(4.86)

Condensed Balance Sheets (Unaudited)
(In thousands)

	As of June 30, 2024	As of December 31, 2023
Cash, cash equivalents and restricted cash	\$ 77,353	\$ 117,521
Total assets	125,046	161,337
Total liabilities	38,982	71,480
Total stockholders' equity	86,064	89,857

For further information, please contact:

Investors & Media

Michael Kaiser, Investor Relations

michael.kaiser@hookipapharma.com

+1 (917) 984-7537
