



HOOKIPA Pharma Reports Second Quarter 2022 Financial Results and Corporate Updates

August 11, 2022

- HB-200 Phase 1 data presented at ASCO met all endpoints in heavily pre-treated head and neck cancer patients; Phase 2 study underway
- US Food and Drug Administration accepted HOOKIPA's Investigational New Drug Application for HB-300 for the treatment of metastatic castration-resistant prostate cancer; Drug Master File accepted to support future regulatory submissions

NEW YORK and VIENNA, Austria, Aug. 11, 2022 (GLOBE NEWSWIRE) -- HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapies based on its proprietary arenavirus platform, today reported financial results for the second quarter of 2022 and Company updates.

"We continued to observe validation of our novel arenaviral platform in the second quarter with key Phase 1 data presented at ASCO for HB-200 in head and neck cancer and our plans to move forward with the Phase 2 program," said Joern Aldag, Chief Executive Officer at HOOKIPA. "We have expanded our clinical portfolio with the concurrent FDA acceptance of our investigational new drug application for HB-300 in prostate cancer and our Drug Master File. The Drug Master File is significant as it supports the implementation of our platform approach, facilitating reduced cycle time between preclinical studies and clinical entry of our pipeline projects across various cancer types."

HOOKIPA Portfolio Highlights

- In July, HOOKIPA announced that the [US FDA accepted](#) HOOKIPA's Investigational New Drug Application for HB-300 for the treatment of metastatic castration-resistant prostate cancer. A Drug Master File was also accepted, facilitating reduced cycle time between completion of preclinical studies and clinical entry of HOOKIPA's pipeline projects.
- In June, HOOKIPA announced [positive Phase 1 data and Phase 2 plans 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. The Phase 2 trial will proceed with alternating 2-vector therapy alone and in combination with pembrolizumab, which will help inform the randomized Phase 2 trial planned to start in the first half of 2023.
- In June, HOOKIPA [presented preclinical data](#) on its novel arenaviral HIV therapeutic vaccines. The data were presented at the Keystone Symposium and highlighted robust and high-quality immune responses following administration of arenaviral therapeutic vaccines in a preclinical setting. Alternating 2-vector therapy induced greater immune response than single-vector therapy, translating to a significant reduction in viral load.
- In April, [new data were announced](#) at the American Association for Cancer Research (AACR) Annual Meeting showing HOOKIPA's arenaviral immunotherapies induced potent T cell responses in novel combinations and against tumor self-antigens. Preclinical data also expanded evidence on arenaviral immunotherapy targeting self-antigens, reinforcing the scientific approach for the HB-300 program in prostate cancer.

HOOKIPA Leadership Updates

- In May, HOOKIPA [announced the promotion](#) of Christine D. Baker to Chief Operating Officer. Baker was previously Chief Business Officer for HOOKIPA.
- In June, HOOKIPA [announced several executive leadership changes](#). Igor Matushansky, Chief Medical Officer and Global Head of Research and Development transitioned to Chair of HOOKIPA's Scientific Advisory Board. Katia Schlienger, Senior Vice President and Head of Immuno-oncology was promoted to Executive Vice President, Clinical Development. Roman Necina, Chief Technology Officer, was appointed to the newly created role of Chief Development Officer.

Upcoming Anticipated Milestones

- Phase 2 HB-200 data in combination with pembrolizumab in HPV16+ head and neck cancer:
 - First-line initial data expected in the second half of 2022
 - Second-line initial data expected in the second half of 2022

- Randomized Phase 2 HB-200 study in combination with pembrolizumab in first-line for HPV16+ HNSCC: First half of 2023 (Fast Track designation)
- Hepatitis B therapeutic IND: 2022 (Gilead-led)
- Prostate cancer First Patient Enrolled expected in first quarter of 2023

Second Quarter 2022 Financial Results

Cash Position: HOOKIPA's cash, cash equivalents and restricted cash as of June 30, 2022 was \$118.9 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.

Revenue was \$2.7 million for the three months ended June 30, 2022, compared to \$5.4 million for the three months ended June 30, 2021. The decrease was primarily due to lower cost reimbursements received under the Collaboration Agreement with Gilead. The \$4.0 million milestone payment and the \$15.0 million initiation fee received in the three months ended March 31, 2022 largely remained recorded as deferred revenue to be recognized in future accounting periods.

Research and Development Expenses: HOOKIPA's research and development expenses were \$16.1 million for the three months ended June 30, 2022, compared to \$19.6 million for the three months ended June 30, 2021. The decrease for the three months ended June 30, 2022 compared to the three months ended June 30, 2021 was primarily driven by lower manufacturing expenses for our HB-200 and Gilead partnered programs, a decrease in personnel-related expenses including stock-based compensation, and a decrease in laboratory consumables that was 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 for the three months ended June 30, 2022 were \$5.0 million, compared to \$5.1 million for the three months ended June 30, 2021. The decrease was primarily due to a decrease in personnel-related expenses and a decrease in other expenses that was partially offset by an increase in professional and consulting fees. The decrease in personnel-related expenses resulted from decreased stock compensation expenses and the conversion of a portion of the base salaries of the Company's executive team for the six months ended June 30, 2022 into common stock with a fair value below the conversion rate, 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 \$16.4 million for the three months ended June 30, 2022 compared to a net loss of \$17.2 million for the three months ended June 30, 2021. This decrease was primarily due to a decrease in research and development expenses.

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,	
	2022	2021	2022	2021
Revenue from collaboration and licensing	\$ 2,746	\$ 5,378	\$ 4,191	\$ 10,679
Operating expenses:				
Research and development	(16,147)	(19,572)	(32,767)	(39,736)
General and administrative	(5,026)	(5,095)	(9,998)	(9,404)
Total operating expenses	(21,173)	(24,667)	(42,765)	(49,140)
Loss from operations	(18,427)	(19,289)	(38,574)	(38,461)
Total interest, other income and taxes, net	2,071	2,136	4,250	4,070
Net loss	\$ (16,356)	\$ (17,153)	\$ (34,324)	\$ (34,391)
Net loss per share — basic and diluted	(0.23)	(0.52)	(0.58)	(1.05)

Condensed Balance Sheets (Unaudited) (In thousands)

	As of June 30, 2022	As of December 31, 2021
Cash, cash equivalents and restricted cash	\$ 118,859	\$ 66,912
Total assets	172,212	126,045
Total liabilities	40,258	36,453
Total stockholders' equity	131,954	89,592

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+ cell responses and pathogen-neutralizing antibodies. HOOKIPA's pipeline includes its wholly owned investigational arenaviral immunotherapies targeting HPV16+ cancers, prostate cancer, KRAS-mutated cancers (including colorectal, pancreatic and lung), and other undisclosed programs. In addition, HOOKIPA aims to develop functional cures for HBV and HIV in collaboration with Gilead.

Find out more about HOOKIPA online at www.hookipapharma.com.

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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 June 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.