# 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): June 22, 2020**

# 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 (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:

| 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 7.01 Regulation FD Disclosure.**

On June 22, 2020, HOOKIPA Pharma Inc. (the "Company") announced positive Phase 2 interim safety and immunogenicity results for its cytomegalovirus, or CMV, vaccine candidate HB-101. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 7.01 of Form 8-K, including the accompanying Exhibit 99.1, 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 liability of such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

**Item 8.01 Other Events.**

On June 22, 2020, the Company announced positive interim results on its prophylactic CMV vaccine candidate HB-101. HB-101 is being investigated in a double-blind Phase 2 clinical trial to assess safety, immunogenicity and efficacy in patients receiving a kidney transplant from a live donor. The Company reported that HB-101 was observed to be well tolerated with fewer adverse events in patients with end-stage kidney disease than in the Company's previous Phase 1 clinical trial of HB-101 in healthy volunteers. Patients who received three doses of HB-101 showed comparable immunogenicity to healthy volunteers in the Company's Phase 1 clinical trial of HB-101. In addition, in available samples, patients who received three doses of HB-101 had a CMV-specific cellular immune response.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release issued by HOOKIPA Pharma Inc. on June 22, 2020 |

**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: June 22, 2020

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

**HOOKIPA Announces Positive Phase 2 Interim Safety and Immunogenicity Results for its CMV Vaccine Candidate HB-101**

- Interim data demonstrate that HB-101 is well tolerated
- HB-101 elicits T cell and B cell responses in the target population

**New York, US and Vienna, Austria,** June 22, 2020 - HOOKIPA Pharma Inc. (NASDAQ: HOOK, 'HOOKIPA'), a company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on its proprietary arenavirus platform, today announced positive interim results on its prophylactic Cytomegalovirus (CMV) vaccine candidate HB-101. HB-101 is being investigated in a double-blind Phase 2 clinical trial (NCT03629080) to assess safety, immunogenicity and efficacy in patients receiving a kidney transplant from a live donor. HOOKIPA reported interim data on the trial's primary endpoints, safety and B cell and T cell immunogenicity.

Trial participants were blinded and randomized 2:1 to receive either HB-101 or placebo. Patients received either 2 or 3 doses prior to transplantation, depending on the transplantation time schedule.

**Tolerability profile of HB-101**
Safety and tolerability were evaluated in 51 CMV-negative patients prior to kidney transplantation. Of the 51 patients, only eight patients (16%) across the combined, blinded HB-101 and placebo groups showed adverse events related to the administration. Most of these adverse events were of mild intensity, indicating that HB-101 is generally well tolerated in this patient population. Of note, this target patient population reported fewer adverse events than the 54 healthy volunteers in HOOKIPA's recently published Phase 1 trial results[1].

**CMV-neutralizing antibody response to HB-101**
For the interim analysis, CMV-neutralizing antibody titers on the day of transplantation were evaluated in all of the 30 CMV-negative patients who had been transplanted by the cutoff date and had valid results. Nineteen of the 30 patients received HB-101 and eleven received placebo. All five patients (100%) who received three doses of HB-101 mounted CMV-neutralizing antibodies. Three of the fourteen patients (21%) who received only two doses of HB-101 also mounted CMV-neutralizing antibodies. The antibody response of the kidney transplant recipients who completed the three-dose regimen was comparable to the antibody response observed in the Phase 1 trial.

**T cell responses to HB-101**
Cellular immune responses to CMV on the day of transplantation were evaluated in 25 CMV-negative patients who had been transplanted in time for this interim analysis. Technically valid results from T cell assays on the day of transplantation were available for seven recipients (as a consequence of sample logistics and assay performance). Two of the seven patients received placebo and five received HB-101. All three patients (100%) who received three doses of HB-101 and one of the two patients who received only two doses (50%) mounted a

[1] Schwendinger M, et al. J Infect Dis. 2020. pii: jiaa121. doi: 10.1093/infdis/jiaa121

CMV-specific cellular immune response.

**Conclusions**:
The interim data demonstrate that HB-101 is well tolerated with fewer adverse events in patients with end-stage kidney disease than in the previous healthy volunteer trial. Patients who received three doses of HB-101 show comparable immunogenicity to healthy volunteers in HOOKIPA's Phase 1 clinical trial of HB-101.

"The interim results demonstrate that the vaccine is well-tolerated and immunogenic in patients with end-stage kidney disease," said Joern Aldag, CEO. "We are excited that we are seeing strong antibody and T cell responses, in particular in patients who received three administrations. We continue patient accrual and plan to report preliminary efficacy data and updated safety and immunogenicity data by the end of 2020."

– END –

**About Cytomegalovirus**
Cytomegalovirus, or CMV, is a virus that is commonly transmitted in childhood and early adulthood. Approximately 60% of the U.S. population has been exposed and is latently infected. Worldwide data indicate that half the people in industrialized countries and up to 99% of people in developing countries, including China and India, have been infected. Infections typically result in lifelong latent persistence of the virus with few symptoms, if any. However, in unborn children, when infected in utero, CMV infection can lead to significant morbidity and mortality. In addition, in immunosuppressed patients, such as transplant recipients, primary CMV infection or reactivation of CMV causes significant morbidity, mortality and graft rejection.

**About HOOKIPA**
HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on its proprietary arenavirus platform that is designed to reprogram the body's immune system.

HOOKIPA's proprietary arenavirus-based technologies, VaxWave®, a replication-deficient viral vector, and TheraT®, a replication-attenuated viral vector, are designed to induce robust antigen specific $CD8^+$ T cells and pathogen-neutralizing antibodies. Both technologies are designed to allow for repeat administration to augment and refresh immune responses. TheraT® has the potential to induce $CD8^+$ T cell response levels previously not achieved by other immuno-therapy approaches. HOOKIPA's "off-the-shelf" viral vectors target dendritic cells in vivo to activate the immune system.

HOOKIPA's VaxWave®-based prophylactic Cytomegalovirus (CMV) vaccine candidate is currently in a Phase 2 clinical trial in CMV-negative patients awaiting kidney transplantation from living CMV-positive donors as well as CMV-positive patients awaiting kidney transplantation from CMV-positive or -negative donors. To expand its infectious disease portfolio, HOOKIPA has entered into a collaboration and licensing agreement with Gilead Sciences, Inc. to jointly research and develop functional cures for HIV and chronic Hepatitis B infections.

In addition, HOOKIPA is building a proprietary immuno-oncology pipeline by targeting virally mediated cancer antigens, self-antigens and next-generation antigens. The TheraT® based lead oncology product candidates, HB-201 and HB-202, are in development for the treatment

of Human Papilloma Virus 16-positive cancers. The Phase 1/2 clinical trial for HB-201 was initiated in December 2019. The HB-202 IND application was cleared by the FDA in June 2020.

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 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 March 31, 2020 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.

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