UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): March 8, 2023

OPKO Health, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-33528**	**75-2402409**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4400 Biscayne Blvd.	**Miami,**	**Florida**	**33137**
(Address of Principal Executive Offices)			(Zip Code)

Registrant's telephone number, including area code: (305) 575-4100

Not Applicable
Former name or former address, if changed since last report

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:

☐ 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 each exchange on which registered
Common Stock, par value $0.01 per share	OPK	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 1.01. **Entry into a Material Definitive Agreement.**

On March 8, 2023, ModeX Therapeutics, Inc. ("ModeX"), a wholly-owned subsidiary of OPKO Health, Inc. ("OPKO"), OPKO with respect to certain sections, and Merck Sharp & Dohme LLC ("Merck") entered into a License and Research Collaboration Agreement (the "Agreement") pursuant to which Merck obtained from ModeX a license to certain patent rights and know-how of ModeX.

Under the terms of the Agreement, ModeX granted to Merck an exclusive, sublicensable, royalty-bearing license under applicable intellectual property, to conduct research under a research program to be established by the parties, and to develop, manufacture, use and commercialize (i) a multivalent or monovalent vaccine assembled using the ModeX platform for Epstein-Barr Virus ("Vaccine"), and (ii) any pharmaceutical or biological preparation in final form containing a Vaccine for sale or for administration to human patients in a clinical trial for all uses ("Product"). ModeX will receive an initial payment of $50 million within thirty days of the signing of the Agreement. ModeX is also eligible to receive up to an additional $872.5 million upon the achievement of certain commercial and development milestones under several indications. ModeX is also eligible to receive tiered royalty payments ranging from high single digits to low double digits upon achievement of certain sales target of the Product. Certain of the rights subject to the license were obtained by ModeX from Sanofi pursuant to that certain License Agreement entered into as of July 1, 2021 ("Sanofi In-License Agreement") between ModeX and Sanofi, a French corporation ("Sanofi"), and a portion of the upfront payment, milestones and royalties received by ModeX under the Agreement may be payable to Sanofi under the terms of the Sanofi In-License Agreement.

As part of the strategic collaboration, ModeX and Merck will establish a research program for research and other development activities related to the development of a Vaccine or Product undertaken by the parties pursuant to a research plan. The parties will also establish a joint steering committee to facilitate the research program.

The Agreement will remain in effect until one or more Products receives marketing authorization, and thereafter, until expiration of all royalty obligations unless earlier terminated as permitted under the Agreement. In addition to termination rights for material breach and bankruptcy, Merck is permitted to terminate the Agreement in its entirety without cause after a specified notice period. If the Agreement is terminated by Merck for convenience or by ModeX for Merck's uncured material breach, ModeX may elect to receive a reversion license such that ModeX can continue its work with Vaccines and Products which have not been terminated due to a material safety issue.

A copy of the press release announcing the Agreement is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The foregoing description is a summary only and is qualified in its entirety by reference to the Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending March 31, 2023.

ITEM 9.01. **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company dated March 8, 2023.
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

Exhibit Index

Exhibit No.	Description
99.1	Press Release of the Company dated March 8, 2023.

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 hereunto duly authorized.

OPKO Health, Inc.

By: /s/ Steven D. Rubin

Date: March 8, 2023

Name: Steven D. Rubin

Title: Executive Vice President-Administration

OPKO Health's ModeX Therapeutics Enters into Exclusive Worldwide License and Collaboration Agreement with Merck to Develop Epstein-Barr Virus Vaccine Candidate

- *MDX-2201 leverages ModeX's innovative biologics platform to target multiple Epstein-Barr virus (EBV) proteins*
- *EBV is the leading cause of infectious mononucleosis and is also associated with some specific types of cancer*

MIAMI (March 8, 2023) - OPKO Health, Inc. (NASDAQ: OPK) today announced that ModeX Therapeutics, Inc., an OPKO Health company, entered into an exclusive worldwide license and collaboration agreement with Merck, known as MSD outside the United States and Canada, for the development of MDX-2201, ModeX's preclinical nanoparticle vaccine candidate targeting EBV.

"We are delighted to enter this collaboration with Merck to develop a vaccine against EBV, a virus that takes a profound toll on human health worldwide. Targeting four proteins used by EBV to infect cells, this vaccine candidate embodies the novel multitargeting approach developed by ModeX scientists," said Gary Nabel, M.D., Ph.D., President and Chief Executive Officer of ModeX and Chief Innovation Officer of OPKO.

Under the terms of the agreement, OPKO will receive an upfront payment of $50 million and is eligible for milestone payments associated with progress in the development and commercialization of MDX-2201 of up to $872.5 million, as well as royalties on global sales.

ModeX and Merck will jointly advance MDX-2201 to an Investigational New Drug (IND) application filing, after which Merck will be responsible for clinical and regulatory activities, as well as product commercialization. Pre-IND filing activity will be guided by a joint steering committee comprised of representatives from both companies.

"We founded ModeX to develop innovative multispecific biologics for cancer and infectious diseases that target multifactorial pathways that cause illness," said Elias Zerhouni, M.D., President and Vice Chairman of OPKO. "This first collaboration leverages our scientific excellence and innovative platforms along with Merck's discovery and clinical development expertise with the goal of benefiting patients around the world."

"Through the acquisition of ModeX, we broadened our technology foundation and expanded our product pipeline into new therapeutic areas," said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "Merck represents the ideal partner to develop and commercialize a new vaccine candidate, and we are particularly proud to enter into this high-potential agreement so soon after completing the ModeX transaction last May."

"At Merck we have a proud legacy of developing vaccines including several that have the potential to help protect against certain types of cancer," said Tarit Mukhopadhyay, Ph.D., Vice President, Infectious Diseases and Vaccine Discovery, Merck Research Laboratories. "We look forward to working with the ModeX Therapeutics team to apply our experience and expertise to evaluate the potential of MDX-2201 to help protect against EBV infection and other, potentially related, conditions."

About MDX-2201
MDX-2201 is based on ModeX's ferritin nanoparticle vaccine platform, which can express as many as 24 copies of a recombinant antigen on its surface to enhance the presentation of key components of the virus and stimulate durable protective immunity. MDX-2201 presents antigens from four viral proteins involved in viral entry into host cells. These include a recombinant antigen designed from the proteins gH, gL and gp42, as well as an antigen derived from gp350. By using ModeX's multi-targeted approach,

this combination inhibits infection in two cell types, B cells and epithelial cells, which contrasts from efforts that previously focused on gp350 alone.

This EBV vaccine technology was the subject of preclinical data published in May 2022 in *Science Translational Medicine*. ModeX scientists previously worked at the Vaccine Research Center, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) and Sanofi in the early development of this vaccine candidate. This project also involved collaboration with scientists at the Laboratory of Infectious Diseases, NIAID.

About Epstein-Barr Virus
Epstein-Barr virus (EBV), a member of the herpes virus family, is one of the most common human viruses. Most people are infected with EBV at some point during their lives. EBV can cause infectious mononucleosis, also called mono, and is associated with other illnesses, including some specific types of cancer and multiple sclerosis. There are currently no FDA approved vaccines or treatments for EBV infection.

About ModeX Therapeutics
ModeX Therapeutics is a clinical-stage biopharmaceutical company developing innovative multispecific biologics for cancer and infectious disease. Its platforms unite the power of multiple biologics in a single molecule to create multispecific antibodies and vaccines with unprecedented versatility and potency in fighting complex disease. The ModeX pipeline includes candidates against both solid and hematologic tumors, as well as several of the world's most pressing viral threats. Its founding team includes globally recognized medical innovators with proven track records of delivering breakthroughs for patients. ModeX is an OPKO Health company based in Natick, Massachusetts. For more information, please visit www.modextx.com.

About OPKO Health, Inc.
OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development, and commercialization expertise and novel and proprietary technologies. For more information, visit www.opko.com.

Cautionary Statement Regarding Forward Looking Statements
This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding product development efforts, expected benefits of MDX-2201 and ModeX's ferritin nanoparticle vaccine platform, whether the collaboration with Merck will be successful, whether clinical trials for MDX-2201 will support marketing approval, whether MDX-2201 will be successfully developed or commercialized or meet expectations regarding its efficacy, safety and market potential, whether OPKO will receive milestone or royalty payments for development and commercialization of MDX-2201, expectations about the global EBV market, whether MDX-2201 has the potential to be first in class and will be approved by the FDA, as well as other non-historical statements, including statements about our expectations, products, beliefs or intentions regarding ModeX, projected future clinical developments, the potential for ModeX products and pipeline and any other statements regarding OPKO's and ModeX's future expectations, beliefs, plans, product candidates, objectives, financial conditions, assumptions or future events or performance. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and under the heading "Risk Factors" in our other filings with the Securities and Exchange Commission. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product

development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

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