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): September 28, 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 7.01. **Regulation FD Disclosure.**

On September 28, 2023, ModeX Therapeutics, Inc. (the "Company"), a wholly-owned subsidiary of OPKO Health, Inc., announced that it had been awarded a contract from the Biomedical Advanced Research and Development Authority, part of the Administration for Strategic Preparedness and Response at the U.S. Department of Health and Human Services, to advance a platform and specific candidates designed to address a range of public health threats in viral infectious diseases. Under the terms of the contract, the Company will receive an initial $59 million for the development, manufacturing, and execution of a Phase 1 clinical trial for a next-generation MSTAR multispecific antibody with broad neutralizing activity against known variants of SARS-CoV-2. The Company is eligible to receive up to an additional $109 million, contingent on achieving certain milestones.

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

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, unless expressly stated otherwise.

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

(d) Exhibits

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

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company dated September 28, 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 September 28, 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
Name: Steven D. Rubin
Title: Executive Vice President-Administration

Date: September 28, 2023

ModeX Therapeutics Secures BARDA Contract to Develop Novel Multispecific Antibodies Against Viral Infectious Disease Threats

Provides Initial $59 Million and up to $168 Million Contingent on Milestones

NATICK, Mass. – **September 28, 2023** – ModeX Therapeutics Inc., an OPKO Health, Inc. company (NASDAQ: OPK), has been awarded a contract from the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response at the U.S. Department of Health and Human Services (HHS), to advance a platform and specific candidates designed to address a range of public health threats in viral infectious diseases.

The awarded funding will enable research, development and clinical evaluation of potent multispecific antibodies, based on ModeX proprietary MSTAR technology. MSTAR is a flexible plug-and-play platform able to incorporate four to six independent antibody binding sites into a single molecule, dramatically expanding their therapeutic potential while enabling rapid responses to emerging infections and their viral variants, including COVID-19, influenza, and other pathogens.

The SARS-CoV-2 program is supported by HHS' Project NextGen, which is dedicated to advancing a pipeline of innovative vaccines and therapeutics against COVID-19. The BARDA contract includes an initial $59 million for the development, manufacturing, and execution of a Phase 1 clinical trial for a next-generation MSTAR multispecific antibody with broad neutralizing activity against known variants of SARS-CoV-2. Such antibodies have the potential for both treatment and prevention of COVID-19.

This initiative builds on a collaboration between ModeX and the Vaccine Research Center of the National Institutes of Health (NIH) for the discovery and characterization of novel therapeutic antibodies against SARS-CoV-2. Additional funding of up to $109 million may be available from BARDA upon achieving particular milestones to develop multispecific antibodies targeting other viral pathogens such as influenza. As part of the research program, gene-based delivery methods for the multispecific antibodies will be developed using mRNA or DNA vectors to leverage the body's natural protein production processes.

"We are excited to partner with BARDA to advance the potential of our MSTAR multispecific antibody platform as a versatile solution to major viral threats," said Drs. Gary Nabel and Elias Zerhouni, Co-Founders of ModeX and, respectively, President, Chief Executive Officer of ModeX and President of OPKO. "This support allows ModeX to evaluate promising candidates in clinical trials to treat or prevent SARS-CoV-2 infection and explore the utility of the platform against diverse viruses. We eagerly anticipate working closely with BARDA to explore and further advance this innovative platform."

"This BARDA award represents the second major collaboration this year built on the strength of ModeX's research and development programs," added Dr. Phillip Frost, Chief Executive Officer of OPKO. "In March 2023, ModeX entered into an exclusive worldwide license and collaboration agreement with Merck to develop MDX2201, its nanoparticle vaccine candidate for Epstein-Barr virus. With BARDA's support, ModeX is poised to advance another exciting new technology with high potential to benefit patients."

This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number 75A50123C00056.

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. These statements concern, and these risks and uncertainties include, among others, product candidates being developed by ModeX and/or its collaborators or licensees and research and clinical programs now underway or planned, including without limitation ModeX's MSTAR technology, and its next-generation MSTAR multispecific antibody therapy intending to target known variants of SARS-CoV-2, as discussed in this press release, whether additional funding of up to $109 million will be granted to ModeX even if it were to achieve the specified milestones, the extent to which the results from the research and development programs conducted by ModeX and/or its collaborators may lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Modex's product candidates; uncertainty of the utilization, market acceptance, and commercial success of Modex's product candidates and the impact of studies (whether conducted by ModeX or others) on any of the foregoing or any potential regulatory approval of ModeX's product candidates; safety issues resulting from the administration of ModeX's product candidates in patients, including serious complications or side effects in connection with the use of ModeX's product candidates in clinical trials; determinations by regulatory and administrative governmental authorities which may delay or restrict ModeX's ability to continue to develop or commercialize its product candidates; competing drugs and product candidates that may be superior to, or more cost effective than, ModeX's product candidates; unanticipated expenses; the costs of developing products; the potential for any license or collaboration, (including ModeX's agreement with Merck) to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Modex's business; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, 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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