
**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): June 19, 2020

Inovio Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-14888
(Commission
File Number)

33-0969592
(IRS Employer
Identification No.)

660 W. Germantown Pike, Suite 110
Plymouth Meeting, PA 19462
(Address of principal executive offices, including zip code)

(267) 440-4200
(Registrant's telephone number, including area code)

N/A
(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, \$0.001 par value	INO	The Nasdaq Stock Market LLC

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 June 22, 2020, Inovio Pharmaceuticals, Inc. (the “**Company**”) entered into an Other Transaction Authority for Prototype Agreement (the “**OTA Agreement**”) with the U.S. Department of Defense (the “**DoD**”) to fund the Company’s efforts in developing its next-generation intradermal electroportation device, known as CELLECTRA® 3PSP, and associated arrays to be used for delivery of the Company’s vaccine candidate, INO-4800, as protection against COVID-19. Under the OTA Agreement, the Company intends to develop the CELLECTRA 3PSP device and arrays for use in the U.S. military population and the U.S. population as a whole, subject to approval of the device by the U.S. Food and Drug Administration (the “**FDA**”). The OTA Agreement is also expected to support large-scale manufacturing of the CELLECTRA 3PSP device, as well as large-scale DNA plasmid production for manufacture and supply of a specified number of doses of INO-4800 in support of FDA approval of the device. The total amount of funding being made available to the Company under the OTA Agreement is approximately \$54.5 million.

Under the OTA Agreement, the Company has agreed that, for a period of six years, it will not offer, sell or otherwise provide the production model of the CELLECTRA 3PSP prototype to any entity at a price lower than that offered to the DoD. In addition, if the Company develops a commercialized version or derivative of the production model of the prototype with similar capability and intended application, but at a lower unit price, the Company will be obligated to make the DoD aware of the similar product and the technical and price differences between the products, and no entity will be entitled to receive a lower price than the DoD for similar purchase quantities of such product.

The DoD may, among other things, suspend or terminate the OTA Agreement if the Company materially fails to comply with the provisions of the OTA Agreement after issuance of a cure notice and failure of the Company to cure the defect within a specified time. The DoD may also terminate the OTA Agreement in its discretion at any time upon at least 30 days’ prior written notice to the Company.

Additionally, on June 19, 2020, the Company was awarded a fixed-price contract (the “**Procurement Contract**”) from the DoD for the purchase of the Company’s intradermal CELLECTRA® 2000 device and accessories. The CELLECTRA 2000 devices will be used to inject INO-4800 in the Company’s planned later-stage clinical trials. The total purchase price under the Procurement Contract is approximately \$16.6 million.

The foregoing description of the material terms of the OTA Agreement and the Procurement Contract does not purport to be complete and is qualified in its entirety by reference to such agreements, which will be filed with the Securities and Exchange Commission as exhibits to the Company’s Quarterly Report on Form 10-Q for the quarter ending June 30, 2020.

Item 7.01 Regulation FD Disclosure.

On June 23, 2020, the Company issued a press release announcing the total funding of \$71 million being made available pursuant to the OTA Agreement and the Procurement Contract. The funding is being provided by the DoD’s Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (“**JPEO-CBRND**”) and JPEO-CBRND’s Joint Product Lead CBNRD Enabling Technologies. A copy of this press release is furnished herewith as Exhibit 99.1 to this report. The information contained in the press release furnished as Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), and is not incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01 Other Events.

On June 23, 2020, the Company established a new wholly-owned subsidiary, Inovio Asia LLC, established under the laws of South Korea, through which the Company intends to advance its corporate development projects and other functions in South Korea and other Asian countries.

As previously announced, on June 3, 2020, the Company filed a complaint in the Court of Common Pleas of Montgomery County, Pennsylvania (the “**Court**”) seeking a preliminary injunction to compel VGXI, Inc. and GeneOne Life Science, Inc. (together, “**VGXI**”) to facilitate the transfer of manufacturing methods, using VGXI’s technology, under the parties’ existing supply agreement. On June 25, 2020, the Court denied the Company’s petition for the preliminary injunction. The Company is exploring its legal options, including a potential immediate appeal of the Court’s decision. In addition, the Company is taking the next steps, including continuing discussions with third-party manufacturers, necessary to support the rapid and large-scale manufacturing of INO-4800 to address the urgent global health need caused by the COVID-19 pandemic.

Forward-Looking Statements

This report contains certain forward-looking statements relating to the Company’s business that involve a number of risks and uncertainties, including statements related to expected development and manufacturing of its CELLECTRA 3PSP device and its vaccine candidate INO-4800 and planned corporate activities in Asia. These statements may be identified by introductory

words such as “may,” “expects,” “plan,” “believe,” “will,” “achieve,” “anticipate,” “would,” “should,” “subject to” or words of similar meaning, or by the fact that they do not relate strictly to historical or current facts. For such statements, the Company claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ from the expectations set forth herein as a result of a number of factors, including those discussed in the “Risk Factors” section of the Company’s most recently filed Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as well as other filings that the Company makes with the SEC from time to time. There can be no assurance that any of the forward-looking information provided herein will be proven accurate.

In addition, the forward-looking statements included in this report represent the Company’s views as of the date hereof. The Company anticipates that subsequent events and developments may cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the company specifically disclaims any obligation to do so, except as may be required by law. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this report.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99.1	Press Release, dated June 23, 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 hereunto duly authorized.

INOVIO PHARMACEUTICALS, INC.

Date: June 25, 2020

By: /s/ Peter Kies

Peter Kies

Chief Financial Officer



INOVIO Receives \$71 Million Contract From U.S. Department of Defense To Scale Up Manufacture of CELLECTRA® 3PSP Smart Device and Procurement of CELLECTRA® 2000 for COVID-19 DNA Vaccine

- U.S. Government will support the scale-up of INOVIO's proprietary intradermal DNA delivery device CELLECTRA® 3PSP to deliver INOVIO's COVID-19 vaccine
- INOVIO to report on interim US Phase 1 clinical trial results in late June
- INOVIO preparing for U.S. Phase 2/3 efficacy study to begin this summer

PLYMOUTH MEETING, PA – June 23, 2020 – INOVIO (NASDAQ:INO) today announced it has received \$71 million funding from the U.S. Department of Defense (DoD) to support the large-scale manufacture of the company's proprietary CELLECTRA® 3PSP smart device and the procurement of CELLECTRA® 2000 devices, which are used to deliver INO-4800 directly into the skin.

CELLECTRA® 3PSP is designed to deliver INO-4800 directly into the skin, where the vaccine prompts the body's immune system to drive a robust immune response. Interim results of U.S. Phase 1 clinical studies of INO-4800 will be available later this month. A Phase 2/3 efficacy trial is planned to begin this summer (July/August).

The DoD contract, from the JPEO-CRBND-EB through funding provided by the Defense Health Program, builds upon two separate prior \$5 million grants from the Bill & Melinda Gates Foundation and CEPI, to accelerate the testing of CELLECTRA® 3PSP. Initial development of this next generation CELLECTRA® 3PSP smart device began in 2019 with \$8.1 million in funding from the medical arm of the U.S. Defense Threat Reduction Agency's Medical CBRN Defense Consortium.

Dr. J. Joseph Kim, INOVIO's President and CEO, said, "INOVIO is very pleased to receive this significant funding from the U.S. Department of Defense to continue our rapid scale-up capacity for our breakthrough DNA medicines delivery device CELLECTRA®. We look forward to working closely with DoD, JPEO-CBRND and JPL-CBRND-EB to provide much needed protection to DoD

personnel and their families through development of a safe and effective vaccine against COVID-19. This next generation smart device leverages the efficacy delivery and safety track record of an earlier version that has received the CE mark certification and has been used in clinical trials to safely dose more than 2,000 patients in over 7,000 administrations of INOVIO's DNA medicines. The current DoD contract further supports INOVIO's large-scale production of devices and arrays to deliver potentially hundreds of millions of doses of INO-4800 next year to combat the global COVID-19 pandemic."

CELLECTRA® 3PSP is a small, portable, hand-held, user-friendly device that runs on "AA" batteries. The device has been designed to function reliably in challenging environments and can be stockpiled in large quantities without maintenance, characteristics that are critical in a pandemic situation. INOVIO's San Diego device manufacturing facility has produced initial quantities of the device, while also showing that the design and scale-up of the manufacturing processes can be transferred to contract manufacturers in order to further increase supply.

About the JPEO-CBRND

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense is the Joint Service's lead for development, acquisition, fielding and life-cycle support of chemical, biological, radiological and nuclear defense equipment and medical countermeasures. As an effective acquisition program, we put capable and supportable systems in the hands of the service members and first responders, when and where it is needed, at an affordable price. Our vision is a resilient Joint Force enabled to fight and win unencumbered by a chemical, biological, radiological, or nuclear environment; championed by innovative and state-of-the-art solutions. JPL-CBRND Enabling Biotechnologies (EB) is an organization established for the purpose of providing medical solutions, during a crisis, against future threats.

About INO-4800

INO-4800 is INOVIO's DNA vaccine candidate being developed to protect against the novel coronavirus SARS-CoV-2, which causes COVID-19. INO-4800 was designed using INOVIO's proprietary DNA medicine platform rapidly after the publication of the genetic sequence of the coronavirus that causes COVID-19. INOVIO has extensive experience working with coronaviruses and is the only company with a vaccine in Phase 2 development for a related coronavirus that causes Middle East Respiratory Syndrome (MERS).

INO-4800 is the only nucleic-acid based vaccine that is stable at room temperature for more than a year and does not require to be frozen in transport or storage, which are important factors when implementing mass immunizations.

About INOVIO's DNA Medicines Platform

INOVIO has 15 DNA medicine clinical programs currently in development focused on HPV-associated diseases, cancer, and infectious diseases, including coronaviruses associated with MERS and COVID-19 diseases being developed under grants from the Coalition for Epidemic Preparedness Innovations (CEPI) and the DoD. DNA medicines are composed of optimized DNA plasmids, which are small circles of double-stranded DNA that are synthesized or reorganized by a computer sequencing technology and designed to produce a specific immune response in the body.

INOVIO's DNA medicines deliver optimized plasmids directly into cells intradermally or intramuscularly using INOVIO's proprietary hand-held smart device called CELLECTRA®. The CELLECTRA device uses a brief electrical pulse to reversibly open small pores in the cell to allow the plasmids to enter, overcoming a key limitation of other DNA and other nucleic acid approaches, such as mRNA. Once inside the cell, the DNA plasmids enable the cell to produce the targeted antigen. The antigen is processed naturally in the cell and triggers the desired T cell and antibody-mediated immune responses. Administration with the CELLECTRA device is designed to ensure that the DNA medicine is efficiently delivered directly into the body's cells, where it can go to work to drive an immune response. INOVIO's DNA medicines do not interfere with or change in any way an individual's own DNA. The advantages of INOVIO's DNA medicine platform are how fast DNA medicines can be designed and manufactured, the stability of the products which do not require freezing in storage and transport, and the robust immune response, safety profile, and tolerability that have been demonstrated in clinical trials.

With more than 2,000 patients receiving INOVIO investigational DNA medicines in more than 7,000 applications across a range of clinical trials, INOVIO has a strong track record of rapidly generating DNA medicine candidates with potential to meet urgent global health needs.

About INOVIO

INOVIO is a biotechnology company focused on rapidly bringing to market precisely designed DNA medicines to treat and protect people from infectious diseases, cancer, and diseases associated with HPV. INOVIO is the first and only company to have clinically demonstrated that a DNA medicine can be delivered directly into cells in the body via a proprietary smart device to produce a robust and tolerable immune response. Specifically, INOVIO's lead candidate VGX-3100, currently in Phase 3 trials for precancerous cervical dysplasia, destroyed and cleared high-risk HPV 16 and 18 in a Phase 2b clinical trial. High-risk HPV is responsible for 70% of cervical cancer, 91% of anal cancer, and 69% of vulvar cancer. Also in development are programs targeting HPV-related cancers and a rare HPV-related disease, recurrent respiratory papillomatosis (RRP); non-HPV-related cancers glioblastoma multiforme (GBM) and prostate cancer; as well as externally funded infectious disease DNA vaccine development programs in Zika, Lassa fever, Ebola, HIV, and coronaviruses associated with MERS and COVID-19 diseases. Partners and collaborators include Advaccine, ApolloBio Corporation, AstraZeneca, The Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations (CEPI), Defense Advanced Research Projects Agency (DARPA)/Department of Defense (DOD), GeneOne Life Science/VGXI, HIV Vaccines Trial Network, International Vaccine Institute (IVI), Medical CBRN Defense Consortium (MCDC), National Cancer Institute, National Institutes of Health, National Institute of Allergy and Infectious Diseases, Ology Bioservices, the Parker Institute for Cancer Immunotherapy, Plumblin Life Sciences, Regeneron, Richter-Helm BioLogics, Roche/Genentech, University of Pennsylvania, Walter Reed Army Institute of Research, and The Wistar Institute. INOVIO also is a proud recipient of 2020 Women on Boards "W" designation recognizing companies with more than 20% women on their board of directors. For more information, visit www.inovio.com.

CONTACTS:

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Investors: Ben Matone, 484-362-0076, ben.matone@inovio.com

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This press release contains certain forward-looking statements relating to our business, including our plans to develop DNA medicines, our expectations regarding our research and development programs, including the availability and timing of data from the company's ongoing Phase 1 clinical trial of INO-4800 and the company's plans and ability to outsource manufacturing of its delivery devices to contract manufacturers. Actual events or results may differ from the expectations set forth herein as a result of a number of factors, including uncertainties inherent in pre-clinical studies, clinical trials, product development programs and commercialization activities and outcomes, the availability of funding to support continuing research and studies in an effort to prove safety and efficacy of electroporation technology as a delivery mechanism or develop viable DNA medicines, our ability to support our pipeline of DNA medicine products, the ability of our collaborators to attain development and commercial milestones for products we license and product sales that will enable us to receive future payments and royalties, our ability to secure adequate third-party manufacturing resources for the production of our product candidates, including the transfer of necessary processes, the adequacy of our capital resources, the availability or potential availability of alternative therapies or treatments for the conditions targeted by us or our collaborators, including alternatives that may be more efficacious or cost effective than any therapy or treatment that we and our collaborators hope to develop, issues involving product liability, issues involving patents and whether they or licenses to them will provide us with meaningful protection from others using the covered technologies, whether such proprietary rights are enforceable or defensible or infringe or allegedly infringe on rights of others or can withstand claims of invalidity and whether we can finance or devote other significant resources that may be necessary to prosecute, protect or defend them, the level of corporate expenditures, assessments of our technology by potential corporate or other partners or collaborators, capital market conditions, the impact of government healthcare proposals and other factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2019, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 and other filings we make from time to time with the Securities and Exchange Commission. There can be no assurance that any product candidate in our pipeline will be successfully developed, manufactured or commercialized, that final results of clinical trials will be supportive of regulatory approvals required to market products, or that any of the forward-looking information provided herein will be proven accurate. Forward-looking statements speak only as of the date of this release, and we undertake no obligation to update or revise these statements, except as may be required by law.