## IN THE COURT OF COMMON PLEAS OF MONTGOMERY COUNTY, PENNSYLVANIA

INOVIO PHARMAECUTICALS INC

VS.

GENEONE LIFE SCIENCE INC

NO. 2020-06554

## NOTICE TO DEFEND - CIVIL

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

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Commencement of Action:  Complaint  Writ of Summer  Writ of Su	mons 🗖 1	Petition Declaration of Taking	·				
Lead Plaintiff's Name: Inovio Pharmaceuticals, Inc.		Lead Defendant's Name VGXI Inc.	:				
Are money damages requested?	☑ Yes   □ No	Dollar Amount Rec (check one)	quested:	within arbitration limits cutside arbitration limits			
Is this a Class Action Suit?	□ Yes    ■ No	Is this an MDJ	Appeal?	□ Yes   No			
Name of Plaintiff/Appellant's Attorney: Gibbons P.C John C. Romeo, Esq. and Stephen J. Finley, Esq  Check here if you have no attorney (are a Self-Represented [Pro Se] Litigant)							
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## **NOTICE**

## Pennsylvania Rule of Civil Procedure 205.5. (Cover Sheet) provides, in part:

#### Rule 205.5. Cover Sheet

- (a)(1) This rule shall apply to all actions governed by the rules of civil procedure except the following:
  - (i) actions pursuant to the Protection from Abuse Act, Rules 1901 et seq.
  - (ii) actions for support, Rules 1910.1 et seq.
  - (iii) actions for custody, partial custody and visitation of minor children, Rules1915.1 et seq.
    - (iv) actions for divorce or annulment of marriage, Rules 1920.1 et seq.
  - (v) actions in domestic relations generally, including paternity actions, Rules1930.1 et seq.
    - (vi) voluntary mediation in custody actions, Rules 1940.1 et seq.
- (2) At the commencement of any action, the party initiating the action shall complete the cover sheet set forth in subdivision (e) and file it with the prothonotary.
- (b) The prothonotary shall not accept a filing commencing an action without a completed cover sheet.
  - (c) The prothonotary shall assist a party appearing pro se in the completion of the form.
- (d) A judicial district which has implemented an electronic filing system pursuant to Rule 205.4 and has promulgated those procedures pursuant to Rule 239.9 shall be exempt from the provisions of this rule.
- (e) The Court Administrator of Pennsylvania, in conjunction with the Civil Procedural Rules Committee, shall design and publish the cover sheet. The latest version of the form shall be published on the website of the Administrative Office of Pennsylvania Courts at <a href="https://www.pacourts.us">www.pacourts.us</a>.

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LAWYER REFERENCE SERVICE MONTGOMERY BAR ASSOCIATION 100 West Airy Street (REAR) NORRISTOWN, PA 19401

(610) 279-9660, EXTENSION 201

SCIENCE, INC.,

Defendants.

## **GIBBONS P.C.** BY: John C. Romeo ID #77692 Stephen J. Finley ID #200890 One Logan Square 130 N. 18th Street, Suite 1210 Philadelphia, PA 19103 Telephone: 215-446-6261 Facsimile: 215-446-6325 sfinley@gibbonslaw.com jromeo@gibbonslaw.com **COOLEY LLP** Michael J. Klisch (Of Counsel) Joshua M. Siegel (Of Counsel) 1299 Pennsylvania Ave., NW, Suite 700 Washington, DC 20004-2400 Telephone: (202) 842-7800 Facsimile: (202) 842-7899 mklisch@cooley.com jsiegel@cooley.com Robert T. Cahill (Of Counsel) 11951 Freedom Drive Reston, Virginia 20190 Telephone: (703) 456-8044 Facsimile: (703) 456-8100 Attorneys for Plaintiff Inovio rcahill@cooley.com Pharmaceuticals, Inc. INOVIO PHARMACEUTICALS, INC., **COURT OF COMMON PLEAS** OF MONTGOMERY COUNTY Plaintiff, JUNE TERM, 2020 NO. 2020-06554 v. VGXI INC. and GENEONE LIFE

## **COMPLAINT IN EQUITY**

Plaintiff Inovio Pharmaceuticals, Inc. ("Inovio"), in support of its Verified Complaint against defendants VGXI, Inc. ("VGXI, Inc.") and GeneOne Life Science, Inc. ("GeneOne") (together, "VGXI"), states the following:<sup>1</sup>

#### NATURE OF THE CASE

- 1. This case, pure and simple, is about VGXI wrongfully blocking the path to the development of a COVID-19 vaccine, which is causing, and will cause, irreparable harm of the worst kind to Inovio and the global community.
- 2. Specifically, VGXI is breaching its explicit contractual obligation to transfer critical technology needed to manufacture Inovio's COVID-19 vaccine candidate, currently in Phase I clinical human trials and showing significant promise.
- 3. VGXI has no justifiable reason for its misconduct and seems to care nothing about the fact that a vaccine must be developed at warp speed to (a) stem the tide of the hugely catastrophic pandemic and (b) allow the world to start recovering from the global financial crisis that worsens every day because of the ripple effect caused by stay at home orders instituted around the globe to protect the public health.

## A. The Damage Caused by COVID-19 is Immeasurable.

4. In January 2020, the World Health Organization declared COVID-19, a disease caused by a novel coronavirus, SARS-CoV-2 ("Virus"), a Public Health Emergency of International Concern with global impact. Since then, the Virus has spread at an incredibly rapid rate to 188 countries, including the entire U.S. Declared a pandemic in March 2020, the Virus has been devastating populations and entire economies with the United States recording the

The contract at issue in this case refers to VGXI, Inc. and GeneOne (formerly known as VGX International, Inc.) together as "VGXI." To avoid confusion, this Complaint also refers to those entities together as VGXI.

highest number of cases and deaths to date. While the ultimate impact of this invisible killer on the world's health and economy is not yet entirely knowable or quantifiable, the known effects are, putting it mildly, staggering.

- 5. In just six months, the Virus has infected over 6 million people globally and killed more than 370,000. The U.S. has been hit particularly hard by the Virus, which has thus far killed 104,000+ people, more deaths than U.S. casualties in the Vietnam War, Korean War, Iraq War and September 11 terrorist attacks, combined. The U.S. death toll is projected to exceed 135,000 by August 2020. Left unabated, the Virus will continue to ravage the global population with estimated infection rates between 50-80%.
- 6. Montgomery County is one of the hardest hit suburban communities in the country, with over 6,000 confirmed cases and more than 600 deaths. Montgomery County is combatting an infection rate of nearly one percent.
- 7. COVID-19 has brought the world economy to its knees. People are facing food and product shortages, global trade has slowed dramatically, travel and tourism has effectively come to a standstill, business and schools have been closed for months, tens of millions of jobs have vanished almost immediately, and millions of people will continue to become unemployed on a daily basis. As of May 1, 2020, "estimates so far indicate the virus could trim global economic growth by as much as 2.0% per month if current conditions persist. Global trade could also fall by 13% to 32%, depending on the depth and extent of the global economic downturn." See <a href="https://fas.org/sgp/crs/row/R46270.pdf">https://fas.org/sgp/crs/row/R46270.pdf</a>. The International Monetary Fund projects negative 3% growth in global GDP for 2020. *Id*.
- 8. The U.S. is experiencing unemployment not seen since the Great Depression, as 40.7 million Americans have filed unemployment claims as a result of the stay at home orders

and the catastrophic havoc wreaked by the pandemic. The U.S. unemployment rate in April alone was 14.7%, and is projected to exceed 23% in June. COVID-19 is destroying lives and livelihoods, and will no doubt continue destroying both without a vaccine.

## B. Inovio is Developing a Vaccine That Appears Promising.

- 9. The worldwide health and medical community is doing everything necessary to develop a vaccine as expeditiously as possible. The U.S. federal government deployed "Operation Warp Speed," a public-private partnership to facilitate, at an unprecedented pace, the development of "substantial quantities of a safe and effective vaccine available for Americans by January 2021." <a href="https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html">https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html</a>.
- 10. A COVID-19 vaccine requires testing and manufacturing in parallel to streamline and keep aligned with the warp speed efforts to meet this urgent public health need.
- 11. Inovio is devoting significant resources to developing a vaccine, which it started developing in January 2020. Its vaccine candidate is the *only* one currently in human trials in the United States using an innovative DNA approach, and its progress has been promising. Its preclinical data, which has been published and peer-reviewed, shows that the vaccine demonstrated robust neutralizing antibody and immune responses against the Virus. It is in Phase I human clinical trials, which are expected to conclude this summer and, pending regulatory approval, will immediately move into Phase II and possibly Phase II/III human clinical trials.
- 12. Inovio has a straightforward written contract with VGXI that requires VGXI to transfer certain technology for the manufacture of Inovio's vaccine if VGXI turns down the opportunity to manufacture the vaccine itself. VGXI has repeatedly told Inovio, orally and in writing, that it cannot manufacture further batches of Inovio's vaccine at any time in 2020

because it does not have the manufacturing capacity to do so. VGXI had already recognized that its lack of manufacturing capacity and ability to manufacture for commercial supply was an issue before the COVID-19 pandemic occurred. As a result, it is building a new commercial scale manufacturing facility that *might* be available for some activity in early 2022. But, in this environment, that is at least a year or two way, and the world simply cannot wait for VGXI because every minute counts.

- 13. VGXI's inability to do the work is not egregious, but rather its refusal to honor its unequivocal contractual obligation to transfer the needed technology for the manufacture of the vaccine is the appalling breach.
- 14. VGXI's breach is causing irreparable harm, and will continue to do so because its failure to transfer the technology is delaying the scale-up, manufacture, and availability of the vaccine, as Inovio and others manufacturers will need to start over and develop an FDA-approved process to manufacture the vaccine. That work will take time the world does not have. The resulting delay in manufacturing a vaccine, caused by VGXI, irreparably harms the public and Inovio. If the vaccine is effective and is approved, Inovio will need hundreds of millions, or even billions, of doses. Like all parties seeking to develop a COVID-19 vaccine, Inovio cannot wait until it receives regulatory approval before starting manufacturing scale up. Rather, it must do that now so that it can begin to distribute the vaccine the instant it is approved. VGXI's breach significantly delays this process and will substantially reduce the number of available doses, which harms public health and the economy. VGXI is holding the vaccine and world health hostage, perhaps to squeeze more money from Inovio or because it is having buyer's remorse over its existing contract. Indeed, it offers no credible legal or factual reason for its

gross misconduct while the worldwide death toll continues to mount and the global financial crisis ruins lives everywhere, and continues unabated.

15. Among other things, this Court should order VGXI to comply with its contractual obligation to transfer its technology immediately to avoid further unimaginable and immeasurable irreparable harm to all of humanity, and award Inovio damages for VGXI's breaches of the parties' agreement.

#### THE PARTIES

- 16. Plaintiff Inovio is a Delaware corporation with its principal place of business located at 660 W. Germantown Pike, Suite 110, Plymouth Meeting, Pennsylvania. Inovio is a biotechnology company focused on rapidly bringing to market precisely-designed DNA medicines to protect and treat people from infectious diseases (such as COVID-19), cancer, and diseases associated with human papillomavirus.
- 17. Defendant VGXI, Inc. is a Delaware corporation with a principal place of business located at 2700 Research Forest Drive, The Woodlands, Texas. VGXI, Inc. is a contract manufacturer of DNA plasmids to be used in preclinical research and human clinical trials. The DNA plasmids VGXI, Inc. manufactures cannot be commercialized (*i.e.*, sold to the public) because VGXI does not have the required FDA manufacturing approvals to do so.
- 18. Defendant GeneOne, formerly known as VGX International, Inc., is a Korean corporation with its principal place of business located at The Pinnacle Gangnam, 10<sup>th</sup> Floor, 343 Hakdong-Ro, Gangnam-Gu, Seoul, Korea. GeneOne is the parent company of VGXI, Inc.

#### JURISDICTION AND VENUE

- 19. The Court has subject matter jurisdiction over this case pursuant to 42 Pa. C.S.A. § 931.
- 20. The Court has personal jurisdiction over VGXI because, among other things, they consented to the Court's jurisdiction over them.
- 21. Venue is proper in this Court pursuant to Pa. R.C.P. §§ 1006 and 2179(a), and because VGXI consented to venue in this Court.

## **FACTS**

## A. Inovio's Innovative DNA-Based Approach to Developing Vaccines.

- 22. Most conventional viral vaccines are made by using viruses that are either inactivated or dead. These viruses contain proteins called antigens. When the inactivated or dead virus is injected into the body, the body detects the antigens as a foreign substance. Our immune system reacts similarly to how it would if it were infected by a live form of the virus by making antibodies that destroy the inactivated (or dead) virus. The antibodies stay in the body and provide immunity from the live virus because, if a live virus infects a person, the body already has the antibodies needed to fight it. A flu vaccine is perhaps the most widely known example of how a typical viral vaccine works. But, Inovio's vaccine candidate is not typical.
- 23. Inovio develops *DNA* vaccines, an innovative approach to immunization that is fundamentally different than conventional vaccines. A DNA vaccine is not made from a dead or inactivated virus. Instead, it uses only the part of the virus's genetic code that encodes the antigens associated with the virus. When a DNA vaccine is administered to a subject, the machinery in the subject's cells use the DNA to produce the antigen, and the immune system then creates antibodies to fight the virus. No virus is ever introduced into the body.

- 24. DNA vaccines offer simple and effective means of inducing broad-based immunity, and offer a host of advantages over traditional vaccines.
- 25. First, DNA vaccines are faster to produce, meaning they can be made in a much shorter time span because it is easier to make and purify large amounts of a DNA sequence than it is to make large amounts of dead or inactivated virus. Speed is particularly important when making vaccines because strains of a bacteria or virus are constantly mutating and changing.
- 26. Second, DNA vaccines are easier to store and transport than conventional vaccines. DNA is very stable and does not need to be kept at frozen temperatures like many conventional vaccines.
- 27. *Third*, the foregoing advantages mean that DNA vaccines can be more cost effective than some traditional vaccines.
- 28. Fourth, DNA vaccines are safer than traditional viral vaccines. Many traditional vaccines require growing large amount of the live infectious virus during the manufacturing process, which poses a risk that those who are making the vaccine will become infected with an inactivated or attenuated virus. Because some traditional vaccines involve injecting the subject with a dead or inactivated virus, there is a risk of the virus reverting back to an active form once it is in the body, thereby infecting the subject with the disease. Since DNA vaccines do not require injecting the subject with the complete virus, but only part of its genetic code, there is no risk of the vaccine reverting back to a virulent form once inside the subject.
- 29. To Inovio's knowledge, its vaccine is the only COVID-19 vaccine in clinical development that is a DNA-based vaccine.

## B. The Supply Agreement and its Key Terms.

- 30. On June 25, 2008, Inovio and VGXI entered into a Supply Agreement, and in September 2013, they executed the First Amendment thereto ("First Amendment"). *Exhibit 1*. The Supply Agreement, as amended, is referred to as the "Agreement."
- 31. The Agreement sets forth the terms under which VGXI would manufacture and supply to Inovio certain DNA-based products for Inovio to use in preclinical studies, clinical trials, and/or future commercialization. VGXI is the primary manufacturer for Inovio's products.
- 32. VGXI owns certain proprietary information and methods used to manufacture Inovio's products (the "VGXI Technology"). The VGXI Technology includes data, manufacturing processes, and the technology and know how to build/operate a specialized piece of equipment.
- 33. Inovio's DNA-based products are designed to be manufactured using VGXI's Technology.
- 34. The Agreement *expressly permits the manufacture of* Inovio's products *using the VGXI Technology* if VGXI is unable, or refuses, to manufacture Inovio's products.
- 35. "Most Favored" Status. Section 2.8(b) of the Agreement provides that Inovio will initially treat VGXI as its "Most Favored Supplier to DNA plasmids and VGXI agrees to treat [Inovio] as its Most Favored Customer." The Agreement specifies the give and take of this "Most Favored" relationship.
- 36. Under certain circumstances, Inovio is obligated to engage VGXI to manufacture Inovio's products, meaning that in those circumstances, the Agreement effectively gives VGXI a right of first refusal on Inovio's manufacturing projects. *Exhibit 1*, §§ 2.1(a), 2.8(a).
- 37. If VGXI is unable, or refuses, to manufacture an Inovio product, as is the undisputed case here, it must transfer its manufacturing methods (including the VGXI

Technology) to locations of Inovio's choice:

In accordance to Section 2.8 (Most Favored Status), if VGXI is unable to manufacture or refuses a production project, VGXI *shall deliver* at no cost to Inovio, a transfer documentation package to enable Inovio to transfer the manufacturing process to a location of Inovio's choosing. The documentation package shall include the deliverables outlined in the exhibit II. VGXI will further provide a project plan and personnel required to facilitate transfer of the manufacturing methods to [Inovio's] selected location.

Exhibit 1, § 2.9(a)(iii) (emphasis added).

- 38. The transfer of the documentation package, and VGXI's provision of a project plan and personnel required to facilitate transfer of manufacturing methods, to another manufacturer is called a "Technology Transfer." This enables a manufacturer other than VGXI to manufacture Inovio's products using VGXI's Technology.
- 39. Section 2.9(a)(iii) is a material, indeed critical, term of the Agreement because it safeguards Inovio's ability to have its products manufactured using the VGXI Technology, around which Inovio designed its products.
- 40. When Inovio wants to manufacture its products, Section 2.9(a)(iii) requires VGXI to either (a) manufacture the product itself, in which case VGXI would use the VGXI Technology, or (b) permit the Technology Transfer, which would permit another manufacturer to use the VGXI Technology to manufacture Inovio's products. In either case, Section 2.9(a)(iii) ensures the VGXI Technology will be used to manufacture Inovio's products.
- 41. But, if VGXI refuses to permit the Technology Transfer, Inovio cannot manufacture the product promptly, safely, or perhaps at all. That is because other manufacturers would need to develop their own manufacturing process, which is often a time consuming and regulated process that would substantially delay the successful manufacture and distribution of Inovio's products.

- 42. Exhibit II to the Agreement specifies "the deliverables" to be included in the "documentation package" in the Technology Transfer. They include, among other things, information and documents such as "quality procedures," procedures for "instrumentation and equipment," procedures "to control raw materials and finished products," procedures "to control the manufacture of drugs and drug products," procedures "that control the packaging and labeling of drugs and drug products," and "measures and activities related to laboratory procedures, testing, analytical methods development and validation."
- 43. **Inovio's Ownership of Information Relating to its Products.** Section 2.9(a)(ii) provides:

[Inovio] shall own the PRODUCT manufactured as part of the Agreement. For avoidance of doubt, [Inovio's] right, title, and interest include[s]: . . . (ii) PRODUCT-specific process documents and protocols, Bill of Materials, copies of Batch Records, [Inovio's] approved QA/QC testing documents and protocols, Analytical testing documents and protocols, Research and Development documents and data generated pursuant to this Agreement.

- 44. Information described in Section 2.9(a)(ii) is within the scope of the information that the Agreement requires VGXI to provide as part of a Technology Transfer.
  - 45. **Duration of the Agreement**. Section 3.3 provides:

This Agreement shall remain in effect for ten (10) years ("INITIAL TERM") from the Effective Date. Unless sooner terminated as provided herein, this Agreement shall continue in effect after the INITIAL TERM unless and until either party provides at least one hundred eighty (180) days' written notice prior to the end of the INITIAL TERM or any time thereafter of the notifying party's determination not to continue this Agreement, which notice shall specify the effective date of the termination.

46. While the Initial Term of the Agreement has expired, the Agreement is still in effect because no party has provided the required written notice of a determination not to continue the Agreement.

## C. Inovio Learns of the Virus and Urgently Races to Develop a Vaccine Against it.

- 47. In late December 2019, Inovio learned about the Virus, which caused an outbreak of respiratory disease in Wuhan, China, now referred to as COVID-19. As detailed above, COVID-19 is a world-wide pandemic causing historic and unimaginable loss of life (and quality of life) and the largest economic disruption since the Great Depression.
- 48. Inovio immediately committed significant resources to urgently develop and get to market a vaccine in record time to protect against the Virus. As part of the CDC's Operation Warp Speed, U.S. regulatory authorities are taking steps to reduce significantly the time it takes to get regulatory approval for each step in the vaccine development process. Pending regulatory approval and funding, Inovio seeks to have 1 million doses of a vaccine manufactured by the end of 2020, and 50-100 million doses manufactured by the end of 2021, but only if VGXI honors its contractual obligation to transfer the deliverables immediately. Every minute counts.
- 49. On January 10, 2020, Chinese researchers shared the genetic sequence of the novel coronavirus that Inovio used to design a construct for a DNA vaccine candidate to protect against the Virus, which it calls INO-4800 ("Vaccine"). Inovio designed the Vaccine to precisely match the DNA sequence of the Virus.
- 50. Inovio has deep experience working with coronaviruses and is the only company with a Phase 2a vaccine for a related coronavirus that causes Middle East Respiratory Syndrome (MERS).
- 51. In mid-January, Inovio began preclinical testing on the Vaccine.<sup>2</sup> Its testing included Inovio developing large-scale manufacturing plans for testing the Vaccine. This

The preclinical stage tests the safety and efficacy of the vaccine in-vitro (e.g., cell culture) and in-vivo (animals). Phase I tests the safety of a vaccine on a small number of healthy human subjects (typically 20-80); Phase II tests efficacy on a larger group of healthy patients (typically a few dozen to 300); and Phase III tests both efficacy and safety in an even larger

planning was made more complicated by two factors unique to developing a COVID-19 vaccine: the high volume of doses needed and the warp speed at which the doses must be manufactured.

- D. VGXI Repeatedly and Clearly Informs Inovio that VGXI is Unable to Manufacture the Vaccine Because it Lacks the Capacity to do so.
- 52. It soon became obvious that, as a matter of basic mathematics, VGXI would not be able to manufacture anywhere close to 1 million doses of the Vaccine by the end of 2020, and that Inovio would have to, as permitted by the Agreement, find additional manufacturers to meet that need.
- 53. VGXI admittedly has limited large-scale clinical manufacturing capability, which consists of a single 400-liter fermenter. A 400-liter fermenter yields a batch (also called a "lot") of approximately 30,000 doses, a process that takes two weeks. VGXI is acutely aware of its capacity constraints, as it recently announced that it would *begin* construction on another commercial manufacturing facility (to become operational in 2022) to house a large-scale 1500-liter fermenter.
- 54. Since at least January 2020, VGXI repeatedly and clearly notified Inovio that it had no available large-scale manufacturing slots in 2020 because those slots already had been taken by VGXI's other customers or reserved for other Inovio DNA plasmids (only 2 slots).
- 55. On January 13, 2020, Robert Juba (Inovio's VP, Biological Manufacturing and Clinical Supply Management) asked Dorothy Peterson (VGXI's Chief Operating Officer) whether VGXI had any open large-scale manufacturing slots for the Vaccine. Ms. Peterson wrote that, other than the two large-scale slots Inovio previously had secured for the manufacture of another Inovio product (an HIV drug), "there are no other 400 L[itre] slots in 2020." This was

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group of healthy patients (typically a few hundred to 3,000). The FDA must approve the vaccine's progress through each phase before it can proceed to the next phase of testing.

consistent with VGXI's representations to Inovio concerning its 2020 limited large-scale manufacturing capacity, as VGXI stated in April 2019 that its large-scale manufacturing slots were booked for the next year.

- 56. Ultimately, after extensive negotiations (which required Inovio to get approval from the National Institutes of Health), Inovio gave up the two large-scale manufacturing slots it had reserved for other plasmids and substituted the Vaccine in their place. That enabled VGXI to manufacture two large-scale lots of the Vaccine (a total of 55,000 doses). VGXI delivered one lot (approximately 26,000 doses) to Inovio in April 2020, and is due to deliver another lot (approximately 29,000 doses) in late June 2020.
- 57. On March 24, 2020, in response to more discussions about VGXI's capacity for large-scale manufacturing, VGXI reiterated to Inovio that "[a]s we have discussed, our schedule for large scale is currently full for the remainder of 2020." VGXI did not offer Inovio any other large-scale manufacturing slots, or claim that it could fill 1 million doses by the end of 2020.
- 58. In short, VGXI admittedly cannot meet Inovio's need for 1 million doses of the Vaccine by the end of 2020, and VGXI repeatedly informed Inovio of that fact.

## E. Because VGXI was Unable to Manufacture the Vaccine, Inovio Engages Two Other Manufacturers.

- 59. Because VGXI was unable to manufacture the needed doses of the Vaccine, Section 2.9(a)(iii) protected Inovio's ability to ensure that another manufacturer could use the VGXI Technology to manufacture the Vaccine, as it required VGXI to provide a Technology Transfer (which included the VGXI Technology) to Inovio.
- 60. Ology Bioservices, Inc. ("Ology") is one of the manufacturers chosen by Inovio to manufacture the Vaccine.

- 61. On or about March 25, 2020, Inovio informed VGXI about Inovio's relationship with Ology and the subsequent need for VGXI to provide a Technology Transfer to Ology. Inovio also stated that because of the urgent pace of development, and in parallel with the Technology Transfer, Ology would attempt to manufacture the Vaccine using Ology's own process. It was not (and is not) known if Ology's process will be successful, as the Vaccine it manufactures must be "analytically comparable" to the Vaccine manufactured using the VGXI Technology, which is a strict standard.
- 62. On March 26, 2020, Inovio and Ology publicly announced that the Department of Defense ("DoD") awarded Ology with a contract valued at \$11.9 million to work with Inovio to manufacture the Vaccine. The aim of that program is to rapidly and efficiently deliver the Vaccine to the DoD for upcoming clinical trials.
- 63. Between late March and early May 2020, Inovio repeatedly asked VGXI about the required Technology Transfer to Ology, and VGXI slow-rolled the process and refused to commit to providing the Technology Transfer.
- 64. Another manufacturer chosen by Inovio to manufacture the Vaccine was Richter-Helm BioLogics, GmbH & Co. KG ("Richter-Helm").
- 65. On April 30, 2020, Inovio and Richter-Helm publicly announced they had entered into an agreement whereby Richter-Helm would manufacture the Vaccine. VGXI had provided a Technology Transfer to Richter-Helm in 2015 for another of Inovio's product candidates, so it had access to the VGXI Technology. Richter-Helm agreed it would be able to allocate five large-scale manufacturing slots which could potentially deliver 500,000 doses of the Vaccine by the end of 2020. VGXI was aware of this transaction before it was announced publicly.

## F. VGXI Breaches the Agreement by Refusing to Provide the Technology Transfer and Purporting to Terminate the Agreement.

- 66. On May 6, 2020, despite its duty to do so, VGXI still had not committed to providing the Technology Transfer to Ology. Mr. Juba again sought to address the Technology Transfer with Ms. Peterson, who responded that she would "take a look at this today."
- 67. On May 7, 2020, VGXI purported to terminate the Agreement, and informed Inovio that VGXI would not permit the Technology Transfer to Ology. *Exhibit 2*.
- 68. This letter was based on a false premise (*i.e.*, that Inovio breached the Agreement because it "failed to provide VGXI the opportunity to manufacture Inovio's COVID-19 DNA vaccine as required under the Supply Agreement").
- 69. VGXI claimed that the Agreement expired under Section 3.3(a), and VGXI "will not extend the agreement beyond the Initial Term." Finally, it made a vague and unsubstantiated claim that Inovio "may have [] shared" VGXI's confidential information with Ology. It concluded with an offer "to negotiate a new master services agreement for future business . . . ."
- 70. VGXI's refusal to provide the Technology Transfer to Ology was and is a clear breach of Section 2.9(a)(ii) and (iii) of the Agreement, which imposed a duty on VGXI to provide the Technology Transfer.
- 71. VGXI's effort to terminate and purported termination of the Agreement is invalid, and is itself a flagrant breach of the Agreement, as the Agreement has not expired under Section 3.3(a), because under that provision the Agreement remains in effect after the Initial Term (which expired in 2018) unless otherwise terminated by one of the parties upon 180 days' notice, which never happened. In short, Inovio has not materially breached the Agreement, or otherwise done anything to warrant a lawful termination of the Agreement.

- 72. On May 7, 2020, VGXI sent a letter to Ology for the express purpose of interfering in the business relationship between Inovio and Ology. *Exhibit 3*. This letter too was based on a false premise: that "Inovio does not have any right to transfer VGXI's intellectual property" and VGXI has "not provided any authorization to Inovio to provide these rights to third parties."
- 73. Because VGXI cannot fulfill Inovio's manufacturing request, Section 2.9(a)(iii) of the Agreement imposed an absolute duty on VGXI to permit the Technology Transfer to Ology, which includes providing Ology with VGXI's Technology.
- 74. On May 11, 2020, Inovio responded to VGXI's May 7, 2020 letter. Exhibit 4. The May 11 letter notified VGXI that Inovio did not breach the Agreement, and that the Agreement did not expire under Section 3.3(a). It stated that Inovio "takes the protection of its intellectual property assets, as well as those of our partners, very seriously," and that Inovio "acted appropriately under the terms of the Agreement and did not inappropriately release confidential information to a third party." It concluded with an offer to discuss the matter with VGXI in an attempt to reach a resolution.
- 75. Between May 8 and 27, 2020, the parties' CEOs spoke in an attempt to resolve the dispute, but they reached an impasse and were unable to do so. Inovio offered a proposal to resolve the dispute, yet VGXI steadfastly refused to provide a substantive response.
- G. The Vaccine Currently is in Phase I Human Clinical Trials, and the Preliminary Data for the Vaccine is Encouraging.
- 76. The data from the Vaccine's preclinical study showed that the Vaccine demonstrated a robust neutralizing antibody and immune responses against the Virus. This data was published in a peer-reviewed journal.

- 77. As of June 2020 (the time of filing this Complaint), the Vaccine is in Phase I human clinical trials in the U.S. (Pennsylvania and Missouri), and Inovio plans to start Phase I trials in China and South Korea. The Phase I trials are anticipated to conclude in Summer 2020.
- 78. Provided Inovio obtains regulatory approval, Inovio anticipates conducting Phase II/Phase III human clinical trials as quickly as possible after the close of the Phase I trials.

## H. VGXI's Breach of the Agreement Causes Irreparable Harm.

- 79. VGXI's refusal to provide the Technology Transfer to Ology in breach of Defendants' contractual obligations, and its invalid purported termination of the Agreement, causes irreparable harm.
- 80. VGXI's breaches of the Agreement delay the scale-up, manufacturer, and availability of the Vaccine. VGXI is one of only a limited number of DNA plasmid manufacturers in the world. However, without a technology transfer of VGXI's manufacturing process to one of this small group of DNA manufacturers, as required under the Agreement, Inovio would be severely delayed, and thereby irreparably damaged, in its ability to provide the requisite number of Vaccine doses for the public benefit. But VGXI has no available capacity in the near term to manufacture any of Inovio's products and cannot manufacture products for commercial sale as it lacks the necessary approvals and facility.
- 81. That leaves only one company, Richter-Helm, with knowledge of the existing manufacturing process (which it learned through a 2015 Technology Transfer). Richter-Helm does not have the capacity or availability to manufacture the volume of DNA plasmids Inovio needs to develop, test, and potentially produce one million doses in 2020, over 100 million doses in 2021, and hundreds of millions of doses thereafter. Accordingly, VGXI's breaches of the Agreement will likely deprive the world of millions of Vaccine doses.

- 82. Because VGXI does not have FDA approval to manufacture vaccines for commercial sale, Inovio must hire other (FDA approved) manufacturers to manufacture doses for public use.
- 83. Because of the desire to develop and distribute an effective vaccine at warp speed, Inovio seeks to get multiple manufacturers on board now before final FDA approval so that it immediately can scale up manufacturing and begin distributing as many doses as possible the instant the Vaccine is approved.
- 84. These manufacturers could set up manufacturing quickly if, as the contract requires VGXI to do, VGXI provides the Technology Transfer.
- 85. But because VGXI refuses to provide the Technology Transfer, these other manufacturers must set up the manufacturing process from scratch, a process which can take months, or even years, with a DNA vaccine. This delay will cause a loss of time that could otherwise be used to make the Vaccine, which in turn results in delays getting it to patients around the world who desperately need it. There is also no guarantee that a new process will produce product that will meet the stringent criteria needed to demonstrate comparability with the existing vaccine in clinical testing.

## COUNT I (Breach of Contract)

- 86. Paragraphs 1-85 of this Complaint are incorporated herein as if set forth in their entirety.
  - 87. The Agreement is a valid and enforceable contract between Inovio and VGXI.
- 88. VGXI had a contractual duty to (a) perform the Technology Transfer and provide the information required by the Agreement, and (b) comply with the termination and expiration provisions of the Agreement.

- 89. VGXI materially breached its contractual duties by (a) refusing to perform the Technology Transfer and provide the information required by the Agreement, (b) purporting to terminate the Agreement in violation of its terms, and (c) treating the Agreement as expired contrary to its terms.
- 90. Inovio performed all of its contractual obligations or was otherwise excused for its non-performance.
- 91. As a result of VGXI's breaches of the Agreement, Inovio (a) has suffered money damages in excess of the Court's compulsory arbitration limits, together with prejudgment interest, (b) is entitled to VGXI's specific performance of the Agreement, (c) will suffer immediate, immeasurable, and irreparable harm, unless VGXI is enjoined from continuing to refuse to perform the Technology Transfer and provide the information required by the Agreement; (d) has no adequate remedy at law, and (e) is entitled to recover the expenses, attorney's fees and costs that it incurs arising out of VGXI's intentional breach of the Agreement.

## COUNT II (Declaratory Judgment)

- 92. Paragraphs 1-91 of this Complaint are incorporated herein as if set forth in their entirety.
- 93. There is a real case and controversy between Inovio and VGXI concerning whether (a) Inovio breached the Agreement by failing to provide VGXI the opportunity to manufacture the Vaccine, (b) VGXI must complete the Technology Transfer and provide the information required by the Agreement, (c) the Agreement expired, and (d) the Agreement is still in effect or VGXI properly terminated it.

- 94. This declaratory judgment action, brought under the Declaratory Judgments Act, 42 Pa.C.S.A. §§ 7531 et seq., is appropriate because there are antagonistic claims between the parties indicating imminent and inevitable litigation, and there is a clear manifestation that the declaration sought will be of practical help in ending the controversy.
- 95. This declaratory judgment action also is appropriate because it will address questions concerning the performance and expiration of the Agreement and will allow Inovio to obtain a declaration of its rights, status, and legal relations under the Agreement.
- 96. Inovio respectfully requests that the Court enter a declaratory judgment and declare that (a) Inovio did not breach the Agreement; (b) VGXI is required to complete the Technology Transfer and provide the information required by the Agreement; (c) the Agreement did not expire; (d) the Agreement is still in effect; and (e) VGXI's purported termination was ineffective.

#### PRAYER FOR RELIEF

WHEREFORE, Inovio requests this Court:

- 1. Enter judgment against Defendants, jointly and severally, on each Count set forth in this Complaint;
- 2. Award Inovio damages in an amount to be proven at trial, and that such award be imposed on Defendants jointly and severally;
- 3. Award Inovio monetary damages in excess of the Court's compulsory arbitration limits, together with interests and costs, and that such award be imposed on Defendants jointly and severally;
  - 4. Award Inovio specific performance of the Agreement by Defendants;
  - 5. Issue a preliminary and permanent injunction requiring that:

- a. No later than seven (7) days after the entry of the injunction, Defendants shall provide to Inovio the Technology Transfer, including a documentation package that shall include all deliverables required by Exhibit II to the Agreement and all information described in Section 2.9(a)(ii). The Technology Transfer will include all materials, documents, information, equipment, actions, audits, approvals, assessments, and training described in Section 2.9(a)(ii) and Exhibit II, including but not limited to a complete electronic set of the most recent revisions of all documents related to the manufacture, testing, and release of any Inovio product (which includes all information and procedures contained or referenced in any batch record for any Inovio product, and all information necessary to the construction, acquisition, assembly, implementation and maintenance of process-specific equipment).
- b. No later than thirty (30) days after the date the Technology Transfer is complete, Defendants shall provide Inovio with (a) a project plan and personnel required to facilitate transfer of the manufacturing methods at a location Inovio shall designate (see Agreement, § 2.9(a)(iii)), and (b) initial and continued training as stipulated in SOP 10002 (Personnel Training Program) (see Agreement, Exhibit II, Personnel).
- c. The information provided by VGXI pursuant to the injunction shall include, at a minimum, all information that VGXI provided to Richter-Helm as part of the previous Technology Transfer under the Agreement.

- d. Defendants shall deliver such further information, documents, materials,
   and reasonable cooperation as shall be necessary or reasonably appropriate
   to effectuate the purposes of the injunction;
- 6. Enter a declaratory judgment that (a) Inovio did not breach the Agreement, (b) the Agreement did not expire or terminate, (c) the Agreement is still in effect, and (d) VGXI's purported termination was ineffective;
- 7. Award Inovio its expenses, attorney's fees and costs, as permitted by law and the Agreement, and that such award be imposed on Defendants jointly and severally;
- 8. Awarding Inovio prejudgment and post-judgment interest, and that such award be imposed on Defendants jointly and severally; and
  - 9. Award Inovio such other and further relief as the Court may deem just and proper.

#### **JURY DEMAND**

Inovio demands a trial as to all claims and issues that may be tried to a jury.

## INOVIO PHARMACEUTICALS, INC.

Dated: June 3, 2020

#### s/John C. Romeo

John C. Romeo (ID #77692) Stephen J. Finley (ID #200890) GIBBONS P.C. One Logan Square 130 N. 18th Street, Suite 1210 Philadelphia, PA 19103 Telephone: 215-446-6261 Facsimile: 215-446-6325

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## **VERIFICATION**

I, Robert Juba, Vice President, Biological Manufacturing and Clinical Supply

Management of Inovio Pharmaceuticals, Inc. state that I am authorized to make this Verification
on behalf of Inovio Pharmaceuticals, Inc.; that the statements in the foregoing Complaint in

Equity are true and correct to the best of my knowledge, information and belief; and that this

Verification is made subject to the penalties of 18 Pa.C.S.A. §4904 relating to unsworn
falsification to authorities.

Robert Juba

Inovio Pharmaceuticals Inc.

V.P., Biological Manufacturing and Clinical Supply

Dated: June 3, 2020

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# Exhibit 1

## **SUPPLY AGREEMENT**

This **SUPPLY AGREEMENT** is made and entered into as of June 25, 2008 among VGXI, Inc., a Delaware corporation having an address of 2700 Research Forest Drive, The Woodlands, Texas 7738, VGX International, Inc. a Korean company having an address of Jung-Hun Building, #701, 944-1 Daechi 3-Dong, Gangnam-gu, Seoul, Korea, (collectively, "VGXI"), VGX Pharmaceuticals, Inc. a Delaware corporation having an address of 450 Sentry Parkway, BlueBell, PA 19422 ("VGXP").

## Recitals:

**WHEREAS**, VGXP owns certain proprietary DNA based product(s) to be identified from time to time ("PRODUCT");

WHEREAS, VGXP plans to develop such PRODUCTS and plans to file for approval of sale of PRODUCTs in countries throughout the world;

WHEREAS, VGXI has acquired VGXP's cGMP manufacturing facility in The Woodlands, TX for PRODUCTS via the asset purchase agreement ("APA"), entered into between VGXI, Inc. and VGX Pharmaceuticals, Inc. as of June 10, 2008:

WHEREAS, VGX International, Inc. and its branch office in the USA have the exclusive World-wide marketing and sales rights for the services of VGXI, Inc.;

WHEREAS, VGXI has obtained considerable and valuable proprietary knowledge pertaining to the manufacture and supply of PRODUCTS; and

WHEREAS, the parties desire to enter into this Agreement to set forth the terms and conditions under which VGXI shall manufacture and supply PRODUCT to VGXP for preclinical studies and/or clinical trials use and/or future commercialization;

**NOW, THEREFORE**, in consideration of the mutual covenants and consideration set forth herein, the parties hereto agree as follows:

#### **SECTION 1**

#### **DEFINITIONS**

**SECTION 1.1 <u>Definitions</u>**. As used herein, the following defined terms shall have the definitions set forth below:

(a) Intentionally Omitted

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- (b) "Affiliate" shall mean all corporations or business entities that, directly or indirectly, are controlled by, control or are under common control of a party, as the case may be. For this purpose, "control" shall mean the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person or entity, whether through the ownership of at least fifty percent (50%) of the voting shares or interest of such person or entity, by contract or otherwise.
- (c) "Applicable Law" shall mean all applicable provisions of federal or state statutes and regulations within the United States, including the Federal Food, Drug and Cosmetic Act (21 U.S.C. §301 et seq.), and similar laws or regulations of foreign jurisdictions and foreign regulatory agencies within the Territory, relating to the PRODUCT.
  - (d) Intentionally Omitted
  - (e) "Assignment" shall have the meaning ascribed in Section 4.6.
- (f) "Bankruptcy Event" shall have occurred when the entity in question becomes insolvent, or voluntary or involuntary proceedings by or against such entity are instituted in bankruptcy or under any insolvency law, or a receiver or custodian is appointed for such entity, or proceedings are instituted by or against such entity for corporate reorganization or the dissolution of such entity, which proceedings, if involuntary, shall have not been dismissed within one hundred and twenty (120) days after the date of filing, or such entity makes an assignment for the benefit or its creditors, or substantially all of the assets of such entity are seized or attached and not released within ninety (90) days thereafter.
  - (g) "Claims" shall have the meaning ascribed in Section 2.11.
- (h) "Designated Carrier" shall mean a carrier selected by VGXP to take possession of and transport PRODUCT from VGXI's Supply Facilities to destinations identified by VGXP.
  - (i) "Dispute" shall have the meaning ascribed in Section 4.15.
  - (j) "Forecast" shall have the meaning as described in 2.8
- (k) "Effective Date" shall mean the date on which VGXI and VGXP have both fully executed this AGREEMENT.
- (l) "Expiration Date" shall mean the expiration time period approved by the FDA (as hereinafter defined) or other regulatory agencies at the time of manufacture of the PRODUCT.
- (m) "FDA" shall mean the United States Food and Drug Administration or any successor entity performing similar functions.
- (n) "cGMP" shall mean current Good Manufacturing Practices as required by 21 CFR §§210.110-111, as such provisions may be amended from time to time.

- (o) "IND" shall mean an Investigational New Drug Application, as that term is contemplated by 21 C.F.R. part 312, filed with the FDA and similar applications filed with foreign regulatory agencies, including any amendments thereto.
  - (p) "Information" shall have the meaning ascribed in Section 4.1.
  - (q) "Initial Term" shall have the meaning ascribed in Section 3.3.
- (r) "Losses" shall mean collectively any and all claims, suits, proceedings, expenses, recoveries and damages, including court costs and reasonable attorneys' fees and expenses.
- (s) "NDA" shall mean, in the Territory, submissions to the FDA or other appropriate regulatory agency of an application to market a drug product under Section 505 of the Federal Food, Drug, and Cosmetic Act, as well as amendments, supplements, and postmarketing reports to the FDA or similar submissions to foreign regulatory agencies.
- (t) "Product" shall mean the specified DNA plasmids manufactured under this Agreement. "Grant Product" shall mean DNA plasmids to be manufactured for VGXP under a contract with the National Institutes of Allergy and Infectious Diseases (NIAID) or other such funding agencies, if awarded.
  - (u) "Product Liability Claim" shall have the meaning ascribed in Section 3.2(c).
- (v) "PROGRAM" shall mean the services to be performed for manufacturing of VGXP Products under this Agreement.
  - (w) "Purchase Price" shall have the meaning ascribed in Section 2.7.
  - (x) "Periodic Order" shall have the meaning ascribed in Section 2.8(a).
  - (y) Intentionally Omitted.
- (z) "Regulatory Approval" shall mean the first and any subsequent regulatory approval by the FDA, or any foreign regulatory agency, of an NDA or a supplement to it.
- (aa) "Regulatory Filings" shall mean all filings, submissions and related data and correspondence filed with or furnished to the FDA or any foreign regulatory agency relating in any respect to any Regulatory Approval.
  - (bb) "Shipment" shall have the meaning ascribed in Section 2.1(c).
  - (cc) "Specifications" shall have the meaning ascribed in Section 2.2.
- (dd) "Supply Facilities" shall mean the facilities of VGXI for the manufacture, production, supply or storage of PRODUCTS.
- (ee) "Territory" shall mean any country or territory where the PRODUCT has been approved by the appropriate government authority.

(ff) "Validation" shall mean satisfactory completion of test and validation runs to qualify VGXI Supply Facilities for cGMP operations.

#### **SECTION 2**

#### **SUPPLY AGREEMENT**

#### **SECTION 2.1 Supply.**

- (a) During the term of this Agreement, and subject to the other terms and conditions herein, VGXI shall supply and sell to VGXP, and VGXP shall purchase from VGXI certain quantities of PRODUCT ("PRODUCT QUANTITY"). PRODUCT QUANTITY shall be determined as outlined in Section 2.8.
- (b) The obligation of VGXP to purchase the PRODUCT QUANTITY from VGXI is contingent upon the ability of VGXI to supply such amount. Notwithstanding the first sentence of this Section 2.1, VGXP's obligation to purchase the PRODUCT QUANTITY from VGXI for the clinical use and/or sale is also contingent upon VGXP obtaining the appropriate Regulatory Approvals for the clinical use and/or sale of PRODUCT in the Territory.
- (c) During the term of this Agreement and provided that VGXP complies with its purchase obligations set forth herein, VGXI shall not, either directly or through any Affiliate, supply or sell PRODUCT to any other purchaser, whether in the Territory or outside the Territory.
- (d) VGXI shall supply PRODUCT to VGXP meeting the specifications (see Section 2.2, below) and manufactured in compliance with Applicable Law and cGMP when applicable. Each shipment of PRODUCT from VGXI to VGXP ("Shipment") shall be sampled and analyzed by VGXI to determine if the Shipment meets the specifications applicable at the time of delivery. VGXI shall deliver with each Shipment a certificate of analysis stating that the Shipment meets the applicable specifications when applicable. Upon delivery to the Designated Carrier or performance of certain events that both parties agree to and are clearly described in the purchase order such as completion of manufacturing of the Product to VGXP's satisfaction, title to the Product will pass from VGXI to VGXP.

#### **SECTION 2.2 Specifications.**

The specifications ("Specifications") for the PRODUCT will be provided by VGXP to VGXI at the time of the order placement, which shall provide at least the following details as provided in Exhibit I.

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## SECTION 2.3 Inspection of Manufacturing Facility.

- (a) VGXP or its representatives shall have the right, upon not less than thirty (30) days' advance notice and during regular business hours, to inspect, once each year during the term of this Agreement, the Supply Facilities, including all documentation related thereto. Such inspection shall be limited to those portions of the Supply Facilities as are involved in the production of the PRODUCT, and shall be conducted in a manner so as to minimize disruption of VGXI's and the inspected facilities' business operations.
- (b) After any such inspection, VGXP may provide VGXI with a written report of any requests and recommendations that, in VGXP's opinion, should be considered by VGXI. VGXI shall review the report and respond in writing within sixty (60) days. If VGXI agrees to implement any of VGXP's suggestions, VGXI will, at its option, provide VGXP an implementation timeline for those changes.
- (c) VGXI acknowledges that the provisions of this Section 2.3 granting VGXP certain inspection rights shall in no way relieve VGXI of any of its obligations under this Agreement, nor shall such provisions require VGXP to conduct any such inspections.

## SECTION 2.4 Notice of Inspection and Responses.

- (a) VGXI shall give VGXP immediate notice of any FDA or other regulatory inspection or audit of VGXI's Supply Facilities and shall provide VGXP with any notification provided to VGXI relating to such inspection or audit.
- (b) VGXI shall promptly provide to VGXP copies of any FDA or other regulatory inspection reports that VGXI or any Affiliate receives from the FDA or other governmental agency with jurisdiction over the Supply Facilities.
- (c) VGXI shall maintain sole responsibility and authority for any matter pertaining to governmental inspections, audits or related reports, including but not limited to preparation and submission of appropriate responses, regarding the Supply Facilities. If VGXI's responses to any regulatory inspection, audit or report are not satisfactory after VGXI has made reasonable efforts to provide satisfactory responses, VGXI shall promptly notify VGXP and include a VGXI summary of actions planned by VGXI to remedy the situation.

#### SECTION 2.5 Notice of Regulatory Action.

VGXI shall promptly notify VGXP of VGXI's receipt of any other substantive regulatory communications (other than discussed in Section 2.4 above) issued by the FDA or other governmental agency with jurisdiction over the Supply Facilities relating to the manufacture of PRODUCT for VGXP. VGXI shall maintain sole responsibility and authority for any matter pertaining to such regulatory communications, including but not limited to preparation and submission of responses, regarding the Supply Facilities.



## SECTION 2.6 Record Keeping.

VGXI shall keep and maintain complete and accurate production, batch, control, laboratory and other records in accordance with cGMP and all other Applicable Laws. VGXI shall provide copies of any of such records as shall be requested by VGXP from time to time, which records shall be delivered to VGXP by no later than three (3) weeks after notice of such request was received by VGXI.

#### SECTION 2.7 Orders, Prices and Terms.

- (a) The purchase price ("Purchase Price") for the PRODUCT purchased by VGXP from VGXI shall be determined mutually at the time of the order placement.
- (b) The purchase price for the Grant Product purchased by VGXP from VGXI shall be determined based on the contracted bid provided to the NIAID or other granting agency and subject to acceptance from the NIAID or other granting agency. VGXP as the prime contractor will continue to negotiate with the granting agency on behalf of VGXI to determine the final purchase price for the Grant Product, however VGXI will reserve the right to agree and accept the final purchase price of Grant Products.
- (c) Notwithstanding the foregoing, in the event that VGXP requests a change to the Specifications, VGXI shall notify VGXP within thirty (30) days of VGXI's receipt of such request whether the requested change will result in a material increase or decrease in the direct cost of manufacture of the PRODUCT and VGXI's estimate of the cost of implementing the change. If VGXP then confirms to VGXI that VGXP wants to have the change implemented, VGXP shall reimburse VGXI for the estimated costs of implementing the change and shall thereafter pay such increased or decreased price, as the case may be, for PRODUCT in an amount that enables VGXI to pass through its consequent direct cost increases or decreases.
- (d) VGXI will invoice VGXP at least thirty (30) days prior to each payment due date as specified in Section 2.8(d). VGXP shall pay VGXI for the Shipment within thirty (30) days of the date of the relevant invoice. All payments shall be made in U.S. Dollars without deduction of any kind, such as for withholding taxes.
- (e) VGXP will make a fifty (50) percent prepayment for all production prior to the scheduled and agreed commencement date for each Periodic Order. VGXP will make a final fifty (50) percent payment after the completion of work and the product has been released as finished goods, but prior to shipment or transfer of title.

## SECTION 2.8 Engagement of VGXI to Manufacture PRODUCT, Most Favored Status, Purchase Orders and Delivery.

(a) VGXP agrees to engage VGXI to manufacture PRODUCT periodically required by VGXP and to supply for VGXP PRODUCT QUANTITIES as shall be agreed upon from time to time by the Parties ("Periodic Order"), for VGXP's pre-clinical and clinical use, according to the terms and conditions set forth herein.



- (b) VGXP agrees to treat VGXI as its Most Favored Supplier for DNA plasmids and VGXI agrees to treat VGXP as its Most Favored Customer.
- (c) If VGXP manufactures, or has manufactured for it by a third party, PRODUCT utilized in studies for regulatory filings, without first obtaining from VGXI a refusal to manufacture the PRODUCT on substantially the same terms as manufactured by VGXP or the third party, VGXI may terminate this Agreement by written notice to VGXP.
- (d) In accordance with the Most Favored Status, if VGXI accepts engagement for Periodic Order, VGXI shall manufacture and supply for VGXP PRODUCT according to the Periodic Order and the terms and conditions set forth herein which shall be no less favorable to VGXP than the next best Periodic Order to customers other than VGXP.
- (e) In accordance with the Most Favored Status and to minimize the possibility that VGXI will not have the capacity or availability to produce VGXP products, VGXP will supply VGXI with a non binding two year forecast updated quarterly. Projects scheduled to commence within the subsequent six month period from any updated forecast shall be considered a binding commitment.
- (f) For each new PRODUCT that is to be produced by VGXI pursuant to the Periodic Order and Agreement, the Parties will prepare and sign new Exhibits to be attached hereto and upon such signing such new Exhibits shall become a part of this Agreement. Each such new set of Exhibits shall specifically reference this Agreement and be signed by both Parties hereto.
- (g) Each Shipment shall be delivered F.O.B., duty unpaid, by VGXI at Supply Facilities to a Designated Carrier. Each Shipment shall be shipped in accordance with the Specifications applicable at the time of delivery. The Designated Carrier selected by VGXP must be commercially reputable and able to track shipments. Title and risk of loss pass upon delivery by VGXI to the Designated Carrier at the Supply Facilities unless title and risk of loss pass upon otherwise clearly defined in Purchase Order.
- (h) Each Shipment shall be accompanied by a packing slip which states the purchase order number and describes the PRODUCT and a certificate of analysis when applicable. To the extent of any conflict or inconsistency between this Agreement and any purchase order, purchase order release, confirmation, acceptance or any similar documents, the terms of this Agreement shall govern.
- (i) VGXP shall notify VGXI of any short-shipment claims within ten (10) business days after receipt of a Shipment.

# SECTION 2.9 Inventions, Patents, Improvements and Rights.

a) VGXP Rights: VGXP shall own the PRODUCT manufactured as part of the Agreement.. For avoidance of doubt, VGXP's right, title and interest include:

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- (i) In-process goods and intermediates, finished PRODUCT, genetic constructs, cell stocks, Research Cell Banks and Master Cell Banks, Reagents developed to facilitate testing and characterization of in-process material and finished PRODUCT.
- (ii) PRODUCT-specific process documents and protocols, Bill of Materials, copies of Batch Records, VGXP's approved QA/QC testing documents and protocols, Analytical testing documents and protocols, Research and Development documents and data generated pursuant to this Agreement.
- (iii) In accordance to Section 2.8 (Most Favored Status), if VGXI is unable to manufacture PRODUCT, VGXI shall deliver at no cost to VGXP, a transfer documentation package to enable VGXP to transfer the manufacturing process to a location of VGXP's choosing. The documentation package shall include the deliverables outlined in the exhibit II. VGXI will further provide a project plan and personnel required to facilitate transfer of the manufacturing methods to VGXP selected location. A fee will be agreed between the Parties for this service and will be based upon industry standard fees for similar services.
- (iv) In the event that both Parties fulfill their obligations for notification, forecasting, and production under section 2.8, and VGXI refuses a production project, VGXI shall assist VGXP prevailing a royalty-bearing, world-wide license in perpetuity to intellectual property it owns, or has rights to practice thereunder, and is required for the performance of the refused PROGRAM and/or manufacture of the refused PRODUCT, provided VGXP uses this licensed intellectual property only for such performance and/or manufacture of the refused PRODUCT in a location of VGXP's choosing. For avoidance of doubt and in accordance to the Most Favored Status provision of Section 2.8, the terms of the license grant will be no less favorable than the next best license agreement with an entity other than VGXP.

# b) Grant-Back:

(i) At VGXP's request, VGXI will, at no cost, assign to VGXP any patentable PRODUCT improvement or use invention discovered by VGXI employees exclusively as a result of performing the PROGRAM under this Agreement ("PRODUCT INVENTION"); provided VGXP requests such assignment, in writing, within one year of notification of such PRODUCT INVENTION. For avoidance of doubt, PRODUCT INVENTION shall include, but not be limited to, PRODUCT sequence and Production Strain. Upon VGXP request, and at VGXP's expense, VGXI will execute any and all applications, assignments or other instruments and give testimony which shall be necessary to apply for and obtain Letters of Patent of the US or of any foreign country with respect to the PRODUCT INVENTION and VGXP shall compensate VGXI for the time devoted to such activities and reimburse it for expenses incurred. For PRODUCT INVENTIONs assigned pursuant to this section, VGXP shall

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- provide VGXI a royalty-free, non-exclusive license necessary solely to perform the PROGRAM for the term of this Agreement.
- VGXI shall retain all rights to any patentable invention relating to (ii) manufacturing and analytical methods and processes discovered in connection with the PROGRAM and any pre-existing know-how ("Process Invention"). For Process Inventions discovered in connection with the PROGRAM, VGXI will grant to VGXP a perpetual, world-wide, royalty-free, fully paid-up, non-exclusive license in perpetuity for VGXP to use such Process Inventions to manufacture PRODUCTs. Upon VGXI's request, and at VGXI's expense, VGXP will execute any and all applications, assignments or other instruments and give testimony which shall be necessary to apply for and obtain Letters of patent of the US or of any foreign country with respect to the Process Inventions and VGXI shall compensate VGXP for time devoted to such activities and reimburse it for expenses incurred. For avoidance of doubt, VGXP's rights hereof shall be restricted solely to Process Inventions discovered in connection with the PROGRAM for manufacturing of VGXP Products and VGXI's preexisting intellectual property rights shall not be impacted otherwise.
- c) VGXI reserves the right to use data during the course of the PROGRAM to support applications, assignments or other instruments necessary to apply for and obtain Letters of Patent of the U.S. or any foreign country with respect to Process Inventions so long as no information which VGXI is required to keep confidential under this Agreement is disclosed in any such application, assignment, or other instrument. VGXI shall notify VGXP ninety (90) days in advance of intent to file such application, assignment or other instrument.

# SECTION 2.10 Change of Control.

- (a) In the event of a "change in control" of VGXI, VGXI shall promptly notify VGXP of such change in control and VGXP shall be permitted to terminate this Agreement at its option with sixty days written notice. A "Change of Control" means a change in the direct or indirect power to direct or cause the direction of the management and policies of either Party, whether through ownership or voting securities, by contract, or otherwise.
- (b) In the event of termination of the Agreement due to a Change of Control (per Section 2.10(a)), the parties agree to uphold the rights and obligations provided in Section 2.9 (a) and (b) (VGXP Rights and Grant Back).

# **SECTION 2.11 PRODUCT Claims.**

(a) After delivery date or title has passed of a Shipment to VGXP, VGXP shall have thirty (30) days to examine the PRODUCT to determine if it conforms to the Specifications and,

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on the basis of such examination, to accept or reject such Shipment. Any claims for failure to so conform ("Claims") shall be made to VGXI in writing within that thirty (30)-day period indicating the nonconformance characteristics of the PRODUCT.

- (b) If VGXI agrees with such Claim, then as promptly as possible after the submission of a Claim by VGXP, VGXI shall, at VGXP's option, provide VGXP (i) with a credit against future billings equal to the full amount paid by VGXP for such Shipment or (ii) replacement of the Shipment free of charge. VGXI shall pay for all shipping costs of returning or destroying the Shipment that is the subject of such accepted Claims. VGXI shall bear the risk of loss for such returned Shipment, beginning at such time as it is taken from VGXP's premises for return delivery.
- (c) If VGXI does not agree with such Claim, then the parties shall submit the PRODUCT in question to a mutually appointed independent third party together with validated analytical methods of testing the PRODUCT to determine whether or not it complies with the Specifications applicable at the time of delivery. If the third party determines that the applicable Specifications were met, then VGXI will have no responsibility for any actions and/or costs described in Section 2.11(b), above, and VGXP shall pay the cost of the third party analysis. If the third party determines that the applicable Specifications were not met, then VGXI will be responsible for any actions and/or costs described in Section 2.11(b), above, as well as the cost of the third party analysis. In the event the parties cannot agree upon the appointment of such third party, or in the event it is not possible to acquire the services of such a third party, then such dispute shall be resolved pursuant to Section 4.15.

# SECTION 2.12 Additional Obligations of VGXI.

- (a) VGXI shall manufacture the PRODUCT in accordance with the Specifications for sale to VGXP taking care to adhere to cGMP, and all applicable FDA and other applicable laws, rules and regulations, including but not limited to the Food, Drug and Cosmetics Act and FDA Guides to Inspections of Bulk Pharmaceutical Chemicals.
  - (b) Intentionally omitted.
- (c) Neither VGXI nor its subcontractors shall initiate any contact with the FDA or any other regulatory agency in connection with the PRODUCTs without the prior written approval of VGXP. VGXI and/or such subcontractor shall inform VGXP, via same-day telephone and by receipt of written notice within one day thereafter, of any contacts of VGXI or such subcontractor by the FDA or any other regulatory agency in connection with the PRODUCT, and VGXI or such subcontractor shall prepare and submit to VGXP for its approval a written record of all such contacts. VGXP shall have the right to have a representative present at any time the FDA or other governmental authority shall elect to conduct an inspection of any site at which a manufacturing or other investigation of PRODUCT is being conducted. VGXI or such subcontractor shall forward to VGXP any notice relating to such inspection, immediately upon receipt thereof.
- (d) VGXI and/or its subcontractors shall forward to VGXP copies of any Regulatory Filings immediately upon submission thereof.

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(e) Any failure by VGXI to comply with any provision of this Section 2.12 in any respect shall be deemed a material breach of this Agreement.

# **SECTION 2.13 PRODUCT Complaints.**

- (a) VGXP shall notify VGXI as promptly as possible about complaints or information it receives concerning any incident that may cause the PRODUCT or its labeling to be mistaken for, or applied to, another article and information concerning bacteriological contamination or any significant chemical, physical, or other change or deterioration in the PRODUCT.
  - (b) The relevant contact person with respect to PRODUCT complaints shall be:

If to VGXI:

VGXI, Inc. 2700 Research Forest Drive, The Woodlands, Texas 7738 (Fax): 281.296.7333

If to VGXP:

VGX Pharmaceuticals, Inc. 450 Sentry Parkway Blue Bell, PA 19422 (Fax): 267.440.4242

# SECTION 2.14 Government Agency Recalls.

- (a) Each of the parties agrees to maintain or cause to be maintained such traceability records as are necessary to permit a recall, market withdrawal, stock recovery or similar action regarding PRODUCT.
- (b) In the event any governmental agency having applicable jurisdiction shall order any corrective action with respect to PRODUCT hereunder and the cause or basis of such corrective action is due to the actions or intentional and negligent inactions of VGXI under this Agreement, including the failure of the PRODUCT to meet the applicable Specifications, then:
  - (i) if VGXI agrees, VGXI shall be liable to VGXP to credit or replace such PRODUCT as required by Section 2.11(b); or
  - (ii) if VGXI does not agree, similar to the procedure in Section 2.11(c), the parties shall submit the details of the recall to an independent third party for analysis. If the third party determines that the applicable Specifications were met, then VGXI will have no responsibility for any actions and/or costs described in this Section 2.14 (b) and Section 2.11 (b) and VGXP shall pay the cost of the third party analysis. If the third party determines that the applicable Specifications

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were not met, then VGXI will be responsible for any actions and/or costs related to recalls as described in Section 2.11 (b) and VGXI shall pay the cost or the third party analysis.

# SECTION 2.15 Annual Review.

The parties agree to establish an annual business review process pursuant to which the parties will review (either in person, by telephone, videoconference or other mutually agreeable means) matters related to PRODUCT including the global PRODUCT demand as well as any possible PRODUCT shortage matters.

#### **SECTION 3**

# **GENERALLY APPLICABLE TERMS**

# SECTION 3.1 Representations, Warranties and Agreements.

- (a) VGXI represents and warrants to and agrees with VGXP that:
- (i) the PRODUCT supplied by VGXI will be manufactured by VGXI in compliance with Applicable Law and cGMP and shall meet the Specifications;
- (ii) the PRODUCT supplied by VGXI will be sold to VGXP free and clear of all liens, claims and encumbrances of any nature;
- (iii) to the best of its knowledge, the PRODUCT and its manufacture, import or sale by VGXI do not violate any valid patents, patent rights, copyrights, confidential information or trade secrets of any other person in the country where the PRODUCT is manufactured for supply to VGXP or is sold to or by VGXP;
- (iv) there are no pending or threatened suits, claims, or actions of any type whatsoever against VGXI with respect to the PRODUCT;
- (v) all necessary corporate authorizations, consents and approvals which are necessary or required for VGXI to enter into this Agreement have been duly obtained;
- (vi) to the best of its knowledge, the entering into of this Agreement by VGXI will not (i) violate any Applicable Law or any applicable ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other governmental body or (ii) conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute a default (or give rise to any right of termination, cancellation or acceleration) under, or result in the creation of any lien, security interest, charge or encumbrance upon any of the properties or assets of VGXI, under its organizational documents, as amended to date, or any material note, indenture, mortgage, lease, agreement, contract, purchase order or other instrument, document or agreement to which VGXI is a party or by which it or any of its properties or assets is bound or affected;

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- (vii) VGXI and its Affiliates, subcontractors, joint venture partners, and any other person or entity performing services under this Agreement shall comply with all Applicable Law related to their manufacture, import or sale of the PRODUCT by VGXI (this warranty does not and is not intended to address third party proprietary rights); and
- (viii) VGXI has not been debarred and VGXI has not and will not use in any capacity in connection with the performance of its obligations under this Agreement the services of any individual or person known by VGXI to be debarred in each case by the FDA or other applicable law or regulation.

THE FOREGOING WARRANTIES SHALL NOT COVER AND VGXI MAKES NO WARRANTIES WITH RESPECT TO ANY PRODUCT THAT HAS BEEN SUBJECT TO: (I) ABUSE, MISUSE, MISAPLICATION, NEGLECT, ALTERATION OR ACCIDENT AFTER TRANSFER OF TITLE; (II) IMPROPER OR INCORRECT STORAGE AFTER TRANSFER OF TITLE; OR (III) ANY MATERIALS, PARTS, GOODS OR OTHER COMPONENTS NOT SUPPLIED BY VGXI WHICH ARE USED BY VGXP IN CONNECTION WITH THE PRODUCT.

# (b) VGXP represents and warrants to VGXI that:

- (i) all necessary corporate and other authorizations, consents, and approvals which are necessary or required for VGXP to enter into this Agreement have been duly obtained;
- (ii) to the best of the knowledge of VGXP, the entering into of this Agreement by VGXP will not (A) violate any Applicable Law or any applicable ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other governmental body or (B) conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute a default (or give rise to any right of termination, cancellation or acceleration) under, or result in the creation of any lien, security interest, charge or encumbrance upon any of the properties or assets of VGXP under its organizational documents, as amended to date, or any material note, indenture, mortgage, lease, agreement, contract, purchase order or other instrument, documents or agreement in which VGXP is a party or by which it or any of its properties or assets is bound or affected;
- (iii) VGXP shall not, during the course of marketing any PRODUCT or using or selling the PRODUCT, engage in any act which results in the PRODUCT being adulterated or misbranded within the meaning of Applicable Law;
- (iv) VGXP shall comply with all Applicable Law related to the importation, use or sale of the PRODUCT in the Territory;
- (v) VGXP has not been debarred and VGXP has not and will not use in any capacity in connection with the performance of its obligations under this Agreement the services of any individual or person known by VGXP to be debarred in each case by the FDA or other applicable law or regulation.



(c) THE WARRANTIES CONTAINED IN THIS SECTION 3.1 ARE THE EXCLUSIVE WARRANTIES MADE BY THE PARTIES IN RESPECT TO THE PRODUCT, AND ALL OTHER WARRANTIES RELATING THERETO, EXPRESSED, STATUTORY OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE AND MERCHANTABILITY ARE HEREBY WAIVED AND EXCLUDED.

# **SECTION 3.2 Indemnification and Insurance.**

In order to distribute between themselves the responsibility for claims arising out of this Agreement, and except as otherwise specifically provided for herein, the parties agree as follows:

- VGXI shall defend and indemnify and hold VGXP (and its Affiliates, and their (a) respective officers, directors and employees) harmless against any and all Losses, arising out of, relating to, based on, or caused by (A) the breach by VGXI of any representation or warranty contained in this Agreement, (B) a claim that the formulation or manufacture of the PRODUCT by VGXI for VGXP or other activities of VGXI under this Agreement infringe on the patent or other intellectual property rights of a third party, (C) any governmental or regulatory action arising out of VGXI's manufacture, packaging or supply of the PRODUCT, or (D) any negligence or intentional misconduct by VGXI in connection with performing its obligations under this Agreement, in each case except to the extent that such Losses arise from or are aggravated in any substantial respect by the negligent acts of or failure to act by VGXP or its Affiliates. VGXP will promptly notify VGXI of any such Losses which come to VGXP's attention, but failure to do so will not relieve VGXI of its indemnification obligations under this Section 3.2(a) except to the extent any such delay results in a material prejudice to VGXI. Notwithstanding anything to the contrary in this Agreement, VGXI shall not be liable for any Losses to the extent that the Losses suffered by VGXP (and its Affiliates, and their respective officers, directors and employees) are the result of or in consequence of any failure by the indemnified party to take reasonable and prudent action to mitigate any Losses.
- (b) VGXP shall defend and indemnify and hold VGXI (and its Affiliates, and their respective officers, directors and employees) harmless against any Losses, arising out of, relating to, based on, or caused by (A) the breach by VGXP of any representation or warranty contained in this Agreement or (B) any negligence or intentional misconduct by VGXP in connection with performing its obligations under this Agreement, in each case except to the extent that such Losses arise from or are aggravated by the negligent acts of or failure to act by VGXI or its Affiliates. VGXI will promptly notify VGXP of any such Losses which come to VGXI's attention, but failure to do so will not relieve VGXP of its indemnification obligations under this Section 3.2(b) except to the extent any such delay results in a material prejudice to VGXP. Notwithstanding anything to the contrary in this Agreement, VGXP shall not be liable for any Losses where the Losses suffered by VGXI (and its Affiliates, and their respective officers, directors and employees) are the result of or in consequence of any failure by the indemnified party to take reasonable and prudent action to mitigate any Losses.
- (c) In the event either party becomes aware of any claims from third parties (including, without limitation, any person who uses any of the PRODUCT which VGXI or any of its Affiliates supplies to VGXP under this Agreement in clinical trials, in commercial use or



otherwise) with respect to the PRODUCT (whether related to the safety or efficacy, or arising out of alleged defects in materials, design or workmanship) (hereinafter, a "Product Liability Claim"), it shall promptly notify the other of such matter, and provide copies of any notices, claims, letters or other information which such party has received or possesses in connection with such Product Liability Claim. Each party shall reasonably cooperate with the other with respect to the defense and resolution of any such Product Liability Claim. VGXP shall defend and indemnify and hold VGXI (and its Affiliates, and their respective officers, directors and employees) harmless against any Losses, arising out of, based on, or caused by any such Product Liability Claim and shall have responsibility for controlling any litigation, defense or settlement of any such Product Liability Claim, unless the Claim relates to the manufacture of the PRODUCT by VGXI, in which case VGXP agrees to consult with VGXI before taking any action with respect to such litigation, defense or settlement.

(d) During the term of this Agreement, each party shall maintain product liability, general liability and other insurance coverage in amounts generally considered to be acceptable within the industry and otherwise sufficient to satisfy any indemnification obligation it may incur.

# SECTION 3.3 Term.

- (a) This Agreement shall remain in effect for ten (10) years ("INITIAL TERM") from the Effective Date. Unless sooner terminated as provided herein, this Agreement shall continue in effect after the INITIAL TERM unless and until either party provides at least one hundred eighty (180) days' written notice prior to the end of the INITIAL TERM or any time thereafter of the notifying party's determination not to continue this Agreement, which notice shall specify the effective date of the termination.
- (b) Notwithstanding any other provision of this Agreement, either VGXP or VGXI may terminate this Agreement by notice in writing to the other upon the occurrence of any of the following events:
- (i) if the notified party shall materially breach or fail in the observance or performance of any representation, covenant or obligation under this Agreement that the notified party fails to remedy within forty-five (45) days after the day of receipt by the notifying party, provided the notice identifies the material breach or failure and requires its remedy. In the event that the material breach or failure is not cured within such forty-five (45)-day period, this Agreement shall thereupon terminate;
- (ii) any representation or warranty made herein by the notified party that is materially false as of the Effective Date; or
  - (iii) the occurrence of a Bankruptcy Event on the part of the notified party.
- (c) Either party may terminate this Agreement in accordance with the provisions of Section 4.10.
- (d) VGXP shall have the right to terminate the Agreement in accordance with Section 2.10, above.

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### **SECTION 3.4 Effect of Termination.**

- (a) If this Agreement is terminated for any reason other than VGXP's failure to make payment under this Agreement VGXI may, in its sole discretion, complete the manufacture of any binding purchase order for PRODUCT and ship such PRODUCT pursuant to the terms of this Agreement.
- (b) The termination or expiration of this Agreement will not release either party from the obligation to pay any such payment or amount that may be owing to the other party (whether then or thereafter due) to operate any liability or obligation that had been incurred by either Party prior to any such termination.
- (c) Termination by VGXP in accordance with Section 2.10, above, shall result in the rights and obligations set forth in section 2.10 (b), in addition to the effect of termination otherwise provided in this Section 3.4.

### **SECTION 4**

# **MISCELLANEOUS**

# SECTION 4.1 Confidentiality; Press Releases.

- (a) VGXP and VGXI will be exchanging confidential and proprietary information relating to the PRODUCT, and their respective businesses ("Information") at the inception of and from time to time during the term of this Agreement. The party receiving such Information will maintain the Information in confidence using the same standard of care it uses to maintain its own information in confidence. Such obligation of confidentiality shall not apply to Information which (i) is known to the receiving party prior to the disclosure and is not otherwise subject to a confidentiality obligation, (ii) is publicly known by use and/or publication as of the date of the disclosure, (iii) becomes publicly known by use and/or publication after the date of disclosure through no fault of the receiving party, (iv) is received from a third party with a valid right to disclose such Information and who has no obligation of confidentiality to the disclosing party or (v) is developed independently by or for the receiving party and which is not otherwise subject to a confidentiality obligation. Such obligation of confidentiality shall continue for a period of ten (10) years from the date of termination of this Agreement.
- (b) Notwithstanding the foregoing Section 4.1(a), VGXI understands that VGXP may need to disclose to its manufacturers, subcontractors, wholesalers, other direct VGXP subcontractors, investment bankers and/or financing sources Information relating to the PRODUCT and this Agreement in order to effectively develop clinically, market and distribute the PRODUCT or otherwise engage in a bona fide financing transaction. Likewise, VGXP understands that VGXI may need to disclose to its Affiliates, manufacturers, subcontractors, wholesalers, other direct VGXI subcontractors, investment bankers and/or financing sources Information relating to the PRODUCT to perform its obligations under this Agreement and to engage in bona fide financing transactions. Accordingly, after reasonable written notice to the other party as to the need to make such a disclosure and the circumstances related thereto, and subject to the sole discretion of the requested party, the requesting party may disclose that



Information specifically permitted by the requested party in writing to permitted entities, provided that such entities undertake the same confidentiality obligation in a written agreement as the requesting party has with respect to Information and the requested party is specifically made a third party beneficiary to such agreement. Notwithstanding anything to the contrary in this Agreement each party and its Affiliates may freely disclose the fact of the Agreement without the other party's prior approval.

- connection with a public offering of securities), neither party will originate any publicity, news release, or other public announcement, written or oral, whether to the public press or otherwise, relating to this Agreement, any amendment hereto or to performance hereunder, or the existence of an arrangement between the parties, without the prior written approval of the other party, which consent shall not be unreasonably withheld or delayed (it being understood that such obligation is not intended to restrict either party's ability to promote, market and sell the PRODUCT or its services in a commercially reasonable manner). In the event disclosure is required by Applicable Law, then the party required to so disclose such Information shall, to the extent possible, provide to the other party for its approval (such approval not to be unreasonably withheld) a written copy of such public announcement at least ten (10) business days prior to disclosure. In the absence of a communication approving or disapproving of the public announcement from the party with the right of approval by the end of such ten (10) business day period, such party shall be deemed to have approved the public announcement.
- **SECTION 4.2** Survival. The termination of this Agreement shall not relieve the parties of their liabilities hereunder. Any termination of this Agreement shall not affect obligations accrued prior to such termination or any provisions of this Agreement that, by their terms, are to be performed after or are otherwise contemplated to survive the termination of this Agreement.
- **SECTION 4.3** <u>Penalties</u>. If either party terminates this Agreement in accordance with the terms hereof, the terminating party shall owe no penalty to the terminated party on account of such termination.
- SECTION 4.4 <u>Independent Contractor Status</u>. Neither party shall have any authority to obligate the other in any respect nor hold itself out as having any such authority. All personnel of VGXI shall be solely employees or consultants of VGXI and/or its Affiliates and shall not represent themselves as employees of VGXP, and all personnel of VGXP shall be solely employees or consultants of VGXP and its Affiliates and shall not represent themselves as employees of VGXI.
- **SECTION 4.5** <u>Binding Effect; Benefits</u>. This Agreement shall endure to the benefit of and be binding upon the parties and their respective permitted successors and assigns. Nothing contained herein shall give to any other person any benefit or any legal or equitable right, remedy or claim.

# SECTION 4.6 Assignment.

- (a) Neither party may assign this Agreement or any of its rights hereunder or delegate or subcontract the performance of any of its obligations hereunder, except in accordance with this Section 4.6.
- (b) Either party may assign or delegate any of its rights or obligations under this Agreement to an Affiliate upon prior written notice to the other party; provided that the assigning party shall remain liable for all obligations and liabilities under this Agreement (including, without limitation, any liabilities arising out of, relating to or based on any breach of, this Agreement) following such assignment or delegation.
- (c) VGXP may assign this Agreement and its rights and obligations hereunder (an "Assignment") to any person or entity (the "Assignee") that acquires:
  - (i) all or substantially all of VGXP's assets and business, whether by sale of assets, merger, consolidation or other business combination with or into VGXP, or
  - (ii) except in a transaction described in clause (i) above, any material portion of VGXP's assets, rights under patents, INDs or NDAs, or know-how primarily relating to the PRODUCT or primarily used in connection with VGXP's performance under this Agreement.

In connection with an Assignment pursuant to subsection (c) above, VGXP shall be released from its obligations and liabilities to the extent arising under this Agreement after such Assignment; it being understood that VGXP shall remain liable for its obligations and liabilities under this Agreement (including liabilities arising out of, relating to or based on, any breach of this Agreement) arising on or prior to such Assignment.

- (d) The (i) conversion from a limited liability company to a corporation and/or (ii) issuance by either party of securities in connection with any financing transaction or public offering shall not be deemed an assignment and shall be permitted without notice to or consent from the other party or its Affiliates, if (x) the assets and business of the party immediately after giving effect to such transaction include all or substantially all of the assets and business of the party immediately prior to such transaction and (y) the party's obligations and liabilities under this Agreement are not released or otherwise impaired as a result of such transaction.
- (e) Any attempted assignment, delegation or Assignment in violation of this Section 4.6 shall be deemed a material breach of this Agreement.
- SECTION 4.7 Entire Agreement: Amendments. The parties acknowledge that this Agreement sets forth the entire agreement and understanding of the parties as to the subject matter of this Agreement, and supersedes any prior verbal, written or other understandings of the parties with respect to the subject matter of this Agreement. This Agreement shall not be subject to any change or modification except by the execution of a written instrument subscribed to by the parties. To the extent of any conflict or inconsistency between this Agreement and any purchase



order, purchase order release, confirmation, acceptance or any similar document, the terms of this Agreement shall govern.

**SECTION 4.8** Severability. In the event that any provision of this Agreement would be held in any jurisdiction to be invalid, prohibited or unenforceable for any reason, such provision, as to such jurisdiction, shall be ineffective, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction. Notwithstanding the foregoing, if such provision could be more narrowly drawn so as not to be invalid, prohibited or unenforceable in such jurisdiction, it shall, as to such jurisdiction, be so narrowly drawn, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction.

**SECTION 4.9** Remedies, Etc. Unless otherwise expressly provided, all remedies hereunder are cumulative, are in addition to any other remedies provided for by law and may, to the extent permitted by law, be exercised concurrently or separately, and the exercise of any one remedy shall not be deemed to be an election of such remedy or to preclude the exercise of any other remedy.

SECTION 4.10 Force Majeure. Neither party shall be responsible nor liable to the other party for any failure to perform any of its obligations hereunder, if such failure results from wars, strikes, lockouts, riots, epidemic, disease, an act of god, civil commotion, fire, earthquake, storm, failure of public utilities, common carriers or suppliers, lack of insurance cover capacity or any other circumstances beyond the control of such party, whether or not similar to the above causes and whether or not foreseeable. An affiliated party shall use its best efforts to avoid or remove any such cause and shall resume performance under this Agreement as soon as feasible whenever such cause is removed; provided, however, that the foregoing shall not be construed to require either party to settle any dispute with any third party, to commence, continue or settle any litigation, or to incur any unusual or extraordinary expenses; provided further, however, that if such cause continues for more than ninety (90) days, either party may terminate this Agreement upon written notice to the other party without any further remedies.

SECTION 4.11 Notices. Any notice, request, consent or communication (collectively, a "Notice") under this Agreement shall be effective if it is in writing and (i) personally delivered, (ii) sent by certified or registered mail, postage prepaid, return receipt requested, (iii) sent by an internationally recognized overnight delivery service, with delivery confirmed, or (iv) telexed or facsimile, with receipt confirmed, addressed as set forth in this Section or to such address as shall be furnished by either party hereto to the other party hereto. A Notice shall be deemed to have been given as of (i) the date when personally delivered, (ii) five (5) business days after being deposited with the United States Postal Service, certified or registered mail, properly addressed, return receipt requested, postage prepared, (iii) one business days after being delivered to said overnight delivery service properly addressed, or (iv) confirmation of receipt of the e-mail, telex or facsimile, as the case may be. All Notices shall specifically state: (i) the provision (or provisions) of this Agreement with respect to which such Notice is given, and (ii) the relevant time period, if any, in which the party receiving the Notice must respond.

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If to VGXI:

VGXI, Inc. 2700 Research Forest Drive, The Woodlands, Texas 7738 (Fax): 281.296.7333

VGX International, Inc. Jung-Hun Building, #701, 944-1 Daechi3-dong, Kang-Nam Gu, Seoul, Korea

If to VGXP:

VGX Pharmaceuticals, Inc. 450 Sentry Parkway
Blue Bell, PA 19422
(Fax): 267.440.4242
Attention: President

**SECTION 4.12 <u>Waivers</u>**. The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party.

**SECTION 4.13** Counterparts. This Agreement may be executed in any number of counterparts, and execution by each of the parties of any one of such counterparts will constitute due execution of this Agreement. Each such counterpart shall be deemed to be an original instrument, and all such counterparts together shall constitute but one agreement.

**SECTION 4.14 <u>Headings</u>**. The article and section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

### SECTION 4.15 Governing Law; Dispute Resolution; Venue.

(a) The appropriate designated individuals representing both parties shall meet and attempt in good faith to settle any dispute, claim or controversy arising out of or relating to the interpretation or breach of this Agreement (the "Dispute"). However, if the designated individuals fail to resolve the Dispute within ten (10) business days, then such Dispute shall be referred for resolution to a designated senior executive of each party who has the authority to settle the Dispute but who is not directly involved in the Dispute provided that such a person exists. Otherwise, a party shall be entitled to appoint any senior executive as it sees fit. At the conclusion of the initial ten (10) business days period, the disputing party invoking this dispute resolution procedure shall give written notice to the other party and the receiving party shall, within (10) business days, submit a written response. The notice and response shall include: (i)



a statement of that party's position and a summary of evidence and arguments supporting its position; and (ii) the name and title of the senior executive who shall represent the party. The designated senior executive of each party shall attempt in good faith to settle such Dispute within thirty (30) days from the date the disputing party receives the above written response. If the dispute cannot be resolved within such thirty (30)-day period, either party shall be free to commence proceedings to resolve the dispute.

- (b) This Agreement shall be construed, governed, interpreted and applied in accordance with the laws of the Commonwealth of Pennsylvania without regard to the conflict of law principles thereof, and the United Nations Convention on Contracts for the International Sale of Goods is expressly disclaimed.
- (c) Any Dispute not resolved by the methods defined in Section 4.15(a) shall be governed by, and construed and enforced in accordance with, the laws of the Commonwealth of Pennsylvania.
- (d) With respect to any claim arising out of this Agreement the parties each irrevocably submits to the exclusive jurisdiction of the courts of Montgomery County, Pennsylvania and the United States District Court for the Eastern District of Pennsylvania, USA. The parties each irrevocably waive any objection that it may have at any time to the laying of venue of any suit, action, or proceeding arising out of or relating to this Agreement brought in any such court set forth in the previous sentence and irrevocably waives any claims that any such suit, action, or proceeding brought in any such court has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such suit, action, or proceeding, brought in any such court, that such court does not have jurisdiction over such party. Both parties agree that service of process upon either party in any such suit, action, or proceeding shall be deemed in every respect effective service or process if given as provided in Section 4.11 of this Agreement.

**SECTION 4.16** Further Assurance. At the request of any party hereto, the other party hereto shall execute and deliver from time to time such further instruments and shall provide reasonable cooperation in such proceedings or actions as shall be necessary or reasonably appropriate to effectuate the purposes of this Agreement. The executions, deliveries and cooperation of each party under this Section 4.16 shall be without further consideration and at such party's expense.

IN WITNESS WHEREOF, duly authorized representatives of the parties hereto have duly executed this Agreement as of the date first above written.

VGX Pharmaceuticals, Inc.

By Atrivera

Name: NIRANJAN Y, SARDESA

Title: SR. VP, RES & DEV

VGXI, Inc.

By:\_

Name:

Title:

VGX International, Inc.

Name: Title:

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# Exhibits:

I: Sample PRODUCT Specifications

II: Transfer Documentation Package



Exhibit I to Supply Agreement between VGXI and VGXP Dated 25 June 2008

# Minimum specifications for all GMP bulk plasmid DNA batches intended for human clinical use:

Evaluation	Specification
Nucleic Acid Concentration by A <sub>260</sub> , mg/mL	Report
Purity by A <sub>260/280</sub>	1.8 – 2.0
Identity by Restriction Analysis	стѕ
Structural Integrity by Percent Circular Forms Analysis by Gel Electrophoresis, (Total Circular Forms) %	Report
Structural Integrity by Percent Circular Forms Analysis by Gel Electrophoresis, (Total Supercoil Forms) %	Report
Percent Host-Cell RNA, %	≤ 2
Percent Host-Cell Protein, %	≤2
Percent Host-Cell DNA,%	≤ 2
Endotoxin, EU/mg	≤ 10
Osmolality, mOsm/kg H₂O	Report
рН	Report
Арреагапсе	Clear, colorless solution w/ no visible particulates
Total Aerobic Microbial Count	< 10 CFU/mL
Total Combined Molds and Yeast Count	< 10 CFU/mL
Test for Staphylococcus aureus	Absent / 10mL
Test for Pseudomonas aeruginosa	Absent / 10mL
Test for Salmonella species	Absent / 10mL
Test for Escherichia coli	Absent / 10mL

Page 1 of 2

**REVISION 1** 

Exhibit I to Supply Agreement between VGXI and VGXP Dated 25 June 2008

# Minimum specifications for all GMP vialed product DNA batches intended for human clinical use:

Evaluation	Specification
Nucleic Acid Concentration by A <sub>280</sub> , mg/mL	Product specific
Purity by A <sub>260/280</sub>	1.8 - 2.0
Identity by Restriction Analysis	CTS
Structural Integrity by Percent Circular Forms Analysis by Gel Electrophoresis, (Total Circular Forms) %	Report
Structural Integrity by Percent Circular Forms Analysis by Gel Electrophoresis, (Total Supercoil Forms) %	Report
Endotoxin, EU/mg	≤5
Osmolality, mOsm/kg H <sub>2</sub> O	Report
pH	Report
Appearance	Clear, coloriess solution w/ no visible particulates
Sterility	No Microbial Growth Observed

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Exhibit II to Supply Agreement between VGXI and VGXP Dated 25 June 2008

### **Technology Transfer Document list:**

VGXP will be provided a complete electronic set of the most recent revision of all the following documents related to the manufacture, testing, and release of the PRODUCT. An exact list of documents can not be supplied in advance, as it is expected that the documentation system of VGXI will continue to expand and evolve over time. The expected documents required can be categorized into the primary functions required to produce cGMP materials:

### **Management**

The Head of Quality Assurance has final approval for release of API and final drug product for commercial and/or clinical use, and for release to client, which is documented on a Product Disposition Form (10013.002). The head of QA and QC will sign the certificate of analysis and the Head of Quality Assurance will sign form 10013.002 indicating the release/rejection of product and its intended use/disposition.

#### **Personnel**

Initial and continued training will be performed as stipulated in SOP 10002 (Personnel Training Program).

Records of training and/or certification are maintained as stipulated in SOP 10002 (Personnel Training Program).

### The Quality System

The Quality System includes the review and approval duties (e.g., change control, batch release, annual record review, qualification protocols and reports, internal auditing, etc.). It includes all product defect evaluations and evaluation of returned and recailed drug products. VGX quality procedures are numbered in the 10000 category. Refer to the current SOP log which is updated as SOPs become effective and are revised.

#### **Facilities and Equipment System**

VGX general Facilities and Equipment Procedures typically are categorized as the 11000 series (instrumentation and equipment), 12000 (facilities) and 14000 (manufacturing procedures). Refer to the current SOP log for all relevant SOPs.

### **Materials System**

This system includes the procedures and processes followed to control raw materials and finished products including containers and closures, drug storage, distribution controls, and records. VGX general materials procedures are categorized as the 18000 series (general receiving and raw materials control). The 16000 and 17000 series (Clinical Operations) of procedures will apply to all VGX sites. Refer to the current SOP log for all relevant SOPs.

### **Production and Process Controls**

1This system includes procedures and processes followed to control the manufacture of drugs and drug products including batch records, in-process sampling and testing, and process validation. It also includes establishing, following, and documenting performance of approved manufacturing procedures. VGX general production procedures (this list is not all-inclusive)

9000 Receiving, Tracking and Storage of cGMP Samples
10010 Issuing Manufacturing Production Records and Analytical Test Records
14000(s) and 15000(s) SOPs include written manufacturing procedures

Exhibit II to Supply Agreement between VGXI and VGXP Dated 25 June 2008

### **Development Reports**

### **Packaging and Labeling Controls**

This system includes procedures and processes that control the packaging and labeling of drugs and drug products. It includes written procedures, label examination and usage, label storage and issuance, packaging and labeling operations controls, and validation of these operations. VGX general packaging and labeling procedures (this list is not all-inclusive:

- 10008 Generation and Control of Product Labels
- 10011 Lot Number Assignment
- 14036 Randomizing and Labeling of Drug Product and Placebo
- 14056 General Formulation and Filling of VGX Products using FP50 Filling Machine
- XXXX Client-specific formulation and fill SOPs

### **Laboratory Control System**

This system includes measures and activities related to laboratory procedures, testing, analytical methods development and validation or verification, raw materials control, tracking and release, and the stability program. QC works with QA to ensure the quality system functions appropriately and (in addition to the above functions) is responsible for:

Review and approval of all testing records
Review and approval of all raw material and product specifications;
Signing the certificate of analysis of API and final Product.

VGX general laboratory control procedures (this list is not all-inclusive):

9003 Initiation and Management of Stability Studies 13000(s) SOPs include written QC testing procedures 18000(s) General/Raw Materials receiving and control 30000(s) Raw Material Specifications Development Reports

#### **Management Review**

Senior management must review and assess the suitability and effectiveness of the quality system according to SOP 10017, Management Review.

Internal auditing of all systems, operations and documentation described above are performed as stipulated in SOP 10003 Internal Audit Procedure.

A.

### FIRST AMENDMENT TO THE SUPPLY AGREEMENT

This First Amendment to the Supply Agreement ("First Amendment") is made by and between VGXI, Inc., a Delaware corporation having an address of 2700 Research Forest Drive, The Woodlands, Texas 77381 VGX International, Inc. a Korean company having an address of Keungil Tower, #1903, 677-25 Yeoksam-Dong, Gangnam-Gu, Seoul, Korea, (collectively, "VGXI"), and Inovio Pharmaceuticals, Inc. (formerly doing business as VGX Pharmaceuticals) a Delaware corporation having an address of 1787 Sentry Parkway West, Blue Bell, PA 19422 ("Inovio"). The First Amendment shall be effective upon the date of the last signature, below ("First Amendment Effective Date"). VGXI and Inovio are individually referred to as "Party" and collectively as "Parties."

#### Recitals

WHEREAS, the Parties entered into a Supply Agreement effective on June 25, 2008; and

WHEREAS, the Parties wish to continue their relationship under the Supply Agreement with certain amendments provide herein:

NOW, THEREFORE, in consideration of the mutual covenants and considerations set forth herein, the Parties hereto agree as follows:

- 1. VGX Pharmaceuticals and Inovio Pharmaceuticals shall be referred to herein as "Inovio," and the defined term "VGXP" shall be replaced by "Inovio." Unless provided otherwise in this First Amendment, all other defined terms shall remain.
- 2. Section 1.1 (y) shall be replaced with the following:
  - (y) "Product Transfer" shall mean inovio transfers some or all of its rights to a Product to a third party ("Transferee") by the way of a sale, assignment, collaboration agreement or exclusive-license.
- 3. Section 1.1 (gg) shall be added to section 1.1 as follows:
  - 1.1 (gg) "Process Technology" shall mean any and all patented technology, trade-secrets, and know-how covering VGXI's proprietary manufacturing process used to manufacture and supply PRODUCTS. Patented technology shall include: US Patent No. 7,238,522 and US Patent Publication No. US2009-0004716, and any continuation, continuation-in-part, divisional and reissue applications thereof; and any foreign counterparts and extensions of any of the aforementioned.
- 4. Section 2.9 a) (iii) shall be amended such that the first sentence is replaced by the following sentence:

"In accordance to Section 2.8 (Most Favored Status), if VGXI is unable to manufacture or refuses a production project, VGXI shall deliver at no cost to Inovio, a transfer documentation package to enable Inovio to transfer the manufacturing process to a location of inovio's choosing."

- 5. Section 2.9 a) (iv) shall be removed in its entirety and remain blank.
- 6. Section 2.9 d) shall be added to the end of section 2.9 as follows:

### 2.9 d) Transfer of Process Technology

Notwithstanding anything to contrary in this agreement, VGXI agrees that upon receipt of a written notice from Inovio that it has made a Product Transfer of a Product to a Transferee, VGXI shall within thirty (30) days of such notice grant to the Transferee in writing a nonexclusive, royalty free, worldwide, perpetual license under Process Technology to research, have researched, develop, have developed, register, have registered, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell and have sold the PRODUCT. In addition, VGXI agrees that after receipt of a notice of Product Transfer and a written request by Transferee for a process transfer, it shall deliver to Transferee within sixty (60) days of the request a transfer package containing all documents, information and cell lines required by Transferee to implement VGXI's manufacturing process for the Product at a location of Transferee's choosing. The transfer package shall include the deliverables outlined in the exhibit II. Within the same sixty (60) day period, VGXI will also provide Transferee a project plan and personnel requirements to facilitate transfer of the manufacturing process to Transferee or Transferee's selected vendor, upon Transferee's choice. VGXI further agrees that at Transferee's request, it will provide free of charge up to thirty (30) man days of technical support to assist Transferee or Transferee's vendor with the implementation of VGXI's manufacturing process for the Product. The free support shall be available only during the six (6) month period after VGXI's receipt of the transfer request. After that period any technical support by VGXI will be at its discretion and paid for by Transferee at standard commercial rate applicable at that time.

Inovio agrees to reimburse VGXI for reasonable costs it incurred carrying out the aforementioned transfer activities and to pay VGXI one percent (1%) of any royalties collected by Inovio from Transferee from their SALES of PRODUCT(S) manufactured using the Process Technology.

"SALE" means any bona fide transaction for which consideration is received or promised for the sale, use, lease, transfer or other disposition of a PRODUCT to a third party that is not Transferee. A SALE of PRODUCT(S) shall be deemed completed at the time Transferee invoices, ships or receives payment for such PRODUCT(S), whichever occurs first.

VGXI, Inc.

**IN WITNESS WHEREOF**, the Parties hereby execute this First Amendment and acknowledge that they are authorized to execute same.

Sign:	Sign: Marcesai.
Name: Young 1c. Park	Name: NIRANJAN .Y. SARDESAL, Ph.i
Title:	Title:
Date: 9/4/2-13	Date: 4 September 2013

Inovio Pharmaceuticals, Inc.

# Exhibit 2



May 7, 2020

Inovio Pharmaceuticals
660 W Germantown Pike, Ste. 110
Plymouth Meeting, PA 19462
VIA FEDEX OVERNIGHT MAIL WITH PROOF OF RECEIPT AND EMAIL

Re: Supply Agreement with Effective Date June 25, 2008

Dear Joseph,

I write to you in response to recent public announcements by Inovio related to the manufacture of its DNA products, including the March 24, 2020 press release regarding its partner Ology Bioservices. Additionally, I have had repeated requests from Rob Juba, Vice President, Biological Manufacturing & Clinical Supplies Management, concerning providing technology transfer information to Ology Bioservices. Inovio does not have a right to request such transfer. This information is disheartening. As you are well aware, VGXI has spent decades developing its proprietary manufacturing technology, and VGXI and Inovio have operated under the Supply Agreement to establish a most-favored status with one another.

Regarding the manufacturing partnership with Ology, Inovio has failed to provide VGXI the opportunity to manufacture Inovio's COVID-19 DNA vaccine as required under the Supply Agreement. Also, confidential information regarding VGXI's proprietary manufacturing technology may have been shared by Inovio to one or more of its partners, including Ology, without authorization by VGXI. Please be aware that these are material breaches under the Supply Agreement.

This letter hereby serves as written notice that the Supply Agreement has expired per Section 3.3(a) and VGXI will not extend the agreement beyond the Initial Term. In addition, Inovio breached the Supply Agreement. Thus, the Supply Agreement is hereby terminated. As provided by the Supply Agreement, we will honor the executed Purchase Orders.

We appreciate our long standing business relationship. While it is unfortunate that there have been actions by Inovio in violation of the Supply Agreement; we are willing to negotiate a new master services agreement for future business, provided remedying and discontinuing any misappropriation of VGXI's intellectual property, including identification of recipients of unauthorized disclosure, and written confirmation of the return of all disclosed information and the destruction of all copies possessed by third parties. Through a new agreement, our respective parties can agree to terms and conditions that best fit each other's business model, and formalize the way we do business.

Regards,

Dorothy Peterson

Digitally signed by Dorothy Peterson Reason: I agree to the terms defined by the placement of my signature on this document

Date: 2020.05.07 11:14:26 -05'00'

Dorothy Peterson Chief Operating Officer, VGXI, Inc.

# Exhibit 3



May 7, 2020

Ology Bioservices 13200 NW Nano Court Alachua, FL 32615 +1 (386) 462-9663 Attn: Legal

Re: Manufacturing business with Inovio Pharmaceuticals

To Whom It May Concern,

We are aware of the press release made on March 24, 2020 related to your partnership with Inovio Pharmaceuticals ("Inovio") to manufacture Inovio's COVID-19 product. Additionally, we have received communication from Inovio that they wish to transfer VGXI's manufacturing process technology to your company.

VGXI has spent decades developing and perfecting a DNA manufacturing process that includes technology represented in US Patent No. 7,238,522, US Patent publication no 2020-0017819 A1, and proprietary know-how. We have been a long time most-favored vendor to Inovio; however, Inovio does not have any right to transfer VGXI's intellectual property. Additionally, we have not provided any authorization to Inovio to provide these rights to third parties.

I know you appreciate the value of intellectual property rights, and the need to zealously protect the same. Please let us know if any confidential material on the VGXI manufacturing technology has been shared, and forward any such material to us. Also, please cease any use of the materials and process related to the VGXI technology. Please advise us by May 17, 2020 that you have destroyed all of the information relating to VGXI's technology and that you will not be using VGXI's technology without explicit written authorization from VGXI. I appreciate your help in this matter.

Regards,

Dorothy Peterson

Digitally signed by Dorothy Peterson Reason: I agree to the terms defined by the placement of my signature on this document Date: 2020.05.07 11:11:06 -05'00'

Dorothy Peterson Chief Operating Officer VGXI, Inc.

# Exhibit 4



660 W. Germantown Pike, Suite 110, Plymouth Meeting, PA 19462

Phone: 267-440-4200

Fax: 267-440-4242

www.inovio.com

<u>VIA EMAIL</u> (ypark@vgxii.com) (dpeterson@vgxii.com)

May 11, 2020

VGXI, Inc. 2700 Research Forest Drive, Suite 180 The Woodlands, TX 77381 Attn: Young Park / Dorothy Peterson

Re: Supply Agreement with Effective Date June 25, 2008 (the "Agreement"), as amended by the First Amendment to the Supply Agreement Dated September 4, 2013 (the "First Amendment")

Dr. Mr. Park and Ms. Peterson:

This communication is in response to your letter dated May 7, 2020 (the "Letter") regarding the Agreement and the assertions made thereon. As you know, Inovio's work around COVID-19 is a crucial development program within the company, and therefore, also very important for many of our partners such as VGXI. Inovio understands the value of intellectual property and other proprietary information and takes the protection of its intellectual property assets, as well as those of our partners, very seriously.

Inovio believes that it acted appropriately under the terms of the Agreement and did not inappropriately release confidential information to a third party. In addition, on several occasions, Inovio reached out to VGXI with respect to using VGXI as the manufacturer of choice for INO-4800 and COVID-19-related projects, but was informed that VGXI did not have any large scale available manufacturing slots. An example of which may be found in the email from Ms. Peterson dated March 24, 2020, indicating that VGXI's schedule for large scale manufacturing is full for the remainder of 2020.

In any event, Inovio does not believe that the Agreement expired under Section 3.3 as the term continues in effect after such Initial Term unless otherwise terminated by one of the parties. In addition, to the extent VGXI wishes to terminate the Agreement pursuant to an alleged material breach as described in Section 3.3, an immediate termination is not available, but rather the notified party shall receive written notice of such asserted breach and the notified party has forty five (45) days after receipt of the notice to cure the alleged breach. As a result, Inovio believes that, to the extent the Letter is able to serve as such notice, the forty five (45) day period has been initiated. However, Inovio believes that the path forward is defined under Section 4.15 of the Agreement,



where the dispute resolution procedures are set forth. As a result, Inovio would be happy to meet and discuss the issue at hand so that both parties may come to an expeditious, reasonable and amicable resolution.

Sincerely,

Docusigned by:

024322F8FE6D4D1...

J. Joseph Kim

Chief Executive Officer

Inovio Pharmaceuticals, Inc.