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| **Prospectus Supplement No. 3**  **To Prospectus dated March 23, 2021** | **Filed Pursuant to Rule 424(b)(3)**  **Registration Statement No. 333-239958** |

**GEOVAX LABS, INC.**

**Up to 1,819,966 Warrants to Purchase Common Stock**

We are supplementing the prospectus dated March 23, 2021 covering the sale of up to 1,819,966 shares of common stock, $0.001 par value, underlying warrants previously issued by us that are issuable at a price of $5.00 per share from time to time upon exercise of outstanding warrants issued to investors in our September 2020 public offering, the issuance of which was previously registered on a Registration Statement on Form S-1 (File No. 333- 239958).

This prospectus supplement supplements information contained in the prospectus dated March 23, 2021 and should be read in conjunction therewith, including any previous supplements and amendments thereto, which are to be delivered with this prospectus supplement.

This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the prospectus dated March 23, 2021, including any previous supplements and amendments thereto.

This prospectus supplement is being filed to update and supplement the information in the prospectus dated March 23, 2021 with information contained in our Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 11, 2021 (excluding the items therein that were furnished rather than filed), with information contained in our Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 20, 2021, with information contained in our Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 29, 2021 (excluding the items therein that were furnished rather than filed), with information contained in our Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 10, 2021 (excluding the items therein that were furnished rather than filed), and with information contained in our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2021, filed with the Securities and Exchange Commission on November 12, 2021.

Investing in our common stock involves certain risks. See “Risk Factors” beginning on page 6 of the prospectus dated March 23, 2021 for a discussion of these risks.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement in truthful or complete. Any representation to the contrary is a criminal offense.**

The date of this Prospectus Supplement is November 12, 2021.

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the**

**Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported):**  **August 11, 2021**

**GEOVAX LABS, INC.**

**(Exact name of registrant as specified in its charter)**

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| --- | --- | --- | --- | --- |
| **Delaware** |  | **001-39563** |  | **87-0455038** |
| **(State or other jurisdiction of**  **incorporation or organization)** |  | **(Commission File No.)** |  | **(IRS Employee Identification No.)** |

**1900 Lake Park Drive, Suite 380**

**Smyrna, Georgia 30080**

**(Address of principal executive offices) (Zip code)**

**(678) 384-7220**

**(Registrant**’**s telephone number, including area code)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions.

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐  Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR240.14a-12)

☐  Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

☐  Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13(e)-4(c))

Securities registered pursuant to Section 12(b) of the Act:

|  |  |  |
| --- | --- | --- |
| Title of each class | Trading  Symbol(s) | Name of each exchange on which registered |
| Common Stock, par value $0.001 per share | GOVX | The Nasdaq Capital Market |
| Warrants to Purchase Common Stock | GOVXW | The Nasdaq Capital Market |

Indicate by check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial reporting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

This Form 8-K and other reports filed by GeoVax Labs, Inc. (the “Registrant” or the “Company”) from time to time with the Securities and Exchange Commission (collectively the “Filings”) contain forward looking statements and information that are based upon beliefs of, and information currently available to, the Registrant’s management as well as estimates and assumptions made by the Registrant’s management. When used in the Filings the words “anticipate”, “believe”, “estimate”, “expect”, “future”, “intend”, “plan” or the negative of these terms and similar expressions as they relate to the Registrant or the Registrant’s management identify forward looking statements.  Such statements reflect the current view of the Registrant with respect to future events and are subject to risks, uncertainties, assumptions and other factors relating to the Registrant’s industry, operations and results of operations and any businesses that may be acquired by the Registrant. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned. Except as required by law, the Registrant does not undertake to update its forward-looking statements.

**Item 2.02      Results of Operations and Financial Condition.**

On August 11, 2021, we issued a press release reporting our results of operations for the quarter ended June 30, 2021. A copy of the press release is attached to this Current Report.

**Item 5.02**          **Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers**

As noted at Item 5.07 below, our Stockholders approved an increase in the number of shares subject to the GeoVax Labs, Inc. 2020 Stock Incentive Plan to 1,500,000 shares. Details of the increase were previously reported in our definitive proxy materials filed June 21, 2021.

**Item 5.07**          **Submission of Matters to a Vote of Security Holders.**

The Company held its annual meeting of stockholders on August 11, 2021. The Company received proxies totaling approximately 59.2% of its 6,327,702 issued and outstanding shares of common stock as of the record date of June 14, 2021. The stockholders voted on the following proposals and the results of the voting are presented below.

**Election of Directors**

Our stockholders voted to elect the slate of directors consisting of five members to hold office until the next annual meeting of stockholders or until their successors are duly elected and qualified. There were a total of 2,771,740 broker non-votes on this item.

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| --- | --- | --- |
| **Nominee** | **For** | **Withheld** |
| Randal D. Chase, Ph.D. | 870,381 | 104,140 |
| David A. Dodd | 866,353 | 108,168 |
| Dean G. Kollintzas | 871,611 | 102,910 |
| Robert T. McNally, Ph.D. | 860,197 | 114,324 |
| John N. Spencer, Jr. | 858,436 | 116,085 |

**Increase in Shares Reserved for Stock Incentive Plan**

Our stockholders approved the increase in the aggregate number of shares of common stock subject to the GeoVax Labs, Inc.2020 Stock Incentive Plan from 250,000 shares, as adjusted, to 1,500,000 shares. There were a total of 2,771,740 broker non-votes on this item.

|  |  |  |
| --- | --- | --- |
| **For** | **Against** | **Abstain** |
| 715,001 | 229,974 | 29,546 |

**Ratification of Independent Auditor**

Our stockholders approved the ratification of Wipfli LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2021.

|  |  |  |
| --- | --- | --- |
| **For** | **Against** | **Abstain** |
| 3,505,099 | 98,143 | 143,019 |

**Item 9.01    Financial Statements and Exhibits.**

(d)     Exhibits

|  |  |
| --- | --- |
| Exhibit No. | Description |
| 99.1 | Press release dated August 11, 2021 |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 11, 2021

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|  | GEOVAX LABS, INC. | |  |
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|  |  | |  |
|  | By: | /s/ Mark W. Reynolds |  |
|  |  | Mark W. Reynolds |  |
|  |  | Chief Financial Officer |  |

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the**

**Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported):**  **August 19, 2021**

**GEOVAX LABS, INC.**

**(Exact name of registrant as specified in its charter)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Delaware** |  | **001-39563** |  | **87-0455038** |
| **(State or other jurisdiction of**  **incorporation or organization)** |  | **(Commission File No.)** |  | **(IRS Employee Identification No.)** |

**1900 Lake Park Drive, Suite 380**

**Smyrna, Georgia 30080**

**(Address of principal executive offices) (Zip code)**

**(678) 384-7220**

**(Registrant**’**s telephone number, including area code)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions.

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13(e)-4(c))

Securities registered pursuant to Section 12(b) of the Act:

|  |  |  |
| --- | --- | --- |
| Title of each class | Trading  Symbol(s) | Name of each exchange on which registered |
| Common Stock, par value $0.001 per share | GOVX | The Nasdaq Capital Market |
| Warrants to Purchase Common Stock | GOVXW | The Nasdaq Capital Market |

Indicate by check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial reporting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

This Form 8-K and other reports filed by GeoVax Labs, Inc. (the “Registrant” or the “Company”) from time to time with the Securities and Exchange Commission (collectively the “Filings”) contain forward looking statements and information that are based upon beliefs of, and information currently available to, the Registrant’s management as well as estimates and assumptions made by the Registrant’s management. When used in the Filings the words “anticipate”, “believe”, “estimate”, “expect”, “future”, “intend”, “plan” or the negative of these terms and similar expressions as they relate to the Registrant or the Registrant’s management identify forward looking statements.  Such statements reflect the current view of the Registrant with respect to future events and are subject to risks, uncertainties, assumptions and other factors relating to the Registrant’s industry, operations and results of operations and any businesses that may be acquired by the Registrant. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned. Except as required by law, the Registrant does not undertake to update its forward-looking statements.

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| **Item 8.01** | **Other Events.** |

On August 19, 2021, we issued a press release reporting the presentation of data from ongoing studies of our preventive vaccine against COVID-19. The presentation titled, “Design of a Universal SARS-CoV-2 Vaccine Against Evolving Variants,” was delivered virtually by Mark J. Newman, Ph.D., GeoVax’s Chief Scientific Officer, during the European Society of Medicine (ESMED) General Assembly, being held August 19-21 in Berlin, Germany.

A copy of the press release is attached to this Current Report. Dr. Newman’s full presentation is available on GeoVax’s website at www.geovax.com/investors/events.

|  |  |
| --- | --- |
| **Item 9.01** | **Financial Statements and Exhibits.** |

(d)     Exhibits

|  |  |
| --- | --- |
| Exhibit No. | Description |
| 99.1 | Press release dated August 19, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 20, 2021

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| --- | --- | --- | --- |
|  | GEOVAX LABS, INC. | |  |
|  |  | |  |
|  |  | |  |
|  | By: | /s/ Mark W. Reynolds |  |
|  |  | Mark W. Reynolds |  |
|  |  | Chief Financial Officer |  |

**Exhibit 99.1**



**GeoVax Presents COVID-19 Vaccine Data at the European Society of Medicine (ESMED) General Assembly**

***GeoVax Vaccine Being Developed as a Universal Vaccine to***

***Address Evolving SARS-CoV-2 Variants***

**ATLANTA, GA, August 19, 2021** - GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company specializing in developing human vaccines and cancer immunotherapies, today presented data from ongoing studies of its preventive vaccine against COVID-19. The presentation titled, “Design of a Universal SARS-CoV-2 Vaccine Against Evolving Variants,” was delivered virtually by Mark J. Newman, Ph.D., GeoVax’s Chief Scientific Officer, during the European Society of Medicine (ESMED) General Assembly, being held August 19-21 in Berlin, Germany.

First-generation SARS-CoV-2 vaccines were rapidly developed and have proven highly efficacious in the human population and were designed to encode the prefusion stabilized Spike protein (S) with the goal of inducing high levels of neutralizing antibodies. However, potential limitations of narrowly focusing on S are becoming apparent with emerging variants that partially escape neutralization by vaccine induced antibodies. Thus, the effectiveness of these vaccines against new SARS-CoV-2 variants and future coronavirus spillover events remains in question.

Using its novel Modified Virus Ankara - Virus Like Particle (GV-MVA-VLPTM) platform, GeoVax has developed a design strategy for vaccines expected to induce broader immunity through inclusion of multiple structural and nonstructural proteins from the target pathogen. The GV-MVA-VLPTM platform is known to elicit a balanced humoral (antibody) and cellular response against a range of immunogens, possibly making immune escape against emerging variants less likely. Expression of the SARS-CoV-2 spike, membrane and envelope proteins by MVA supports the *in vivo* formation of virus like particles, or VLPs, which induce both antibody and T-cell responses. Incorporation of sequence-conserved nonstructural proteins can provide targets for T-cell responses to increase the breadth and function of vaccine-induced immune responses. This strategy provides the basis for generating a universal vaccine with augmented potential to alleviate the burden of disease caused by circulating coronaviruses.

In his talk, Dr. Newman discussed GeoVax’s vaccine design strategy for developing a universal SARS-CoV-2 vaccine and presented stability and protein expression data for the Company’s initial vaccine candidate, GEO-CM02, which encodes the Spike (S), Membrane (M) and Envelope (E) proteins. Dr. Newman also presented vaccine efficacy and immunogenicity data for GEO-CM02 from hamster and transgenic mice studies to date.

Dr. Newman’s presentation is available on GeoVax’s website at www.geovax.com/investors/events.

Dr. Newman commented, “Our studies to date support the use of MVA as a vector for the design and production of next-generation vaccines encoding multiple coronavirus proteins, using the S protein as the antibody target and the M and E proteins as T-cell targets. The combination of S, M and E protein expression supports VLP formation and optimal immunogenicity. In our studies, we observed the induction of functional antibodies and T-cell responses that mediate protection from infection and pathogenesis.”

David Dodd, GeoVax President and CEO, further commented, “The presentation of data from this study further validates our platform and approach to addressing COVID-19 and its variants. Our vaccines under development are intended to be used as either a primary vaccine or to boost other COVID-19 vaccines as part of vaccination strategies to provide immunity to a range of coronavirus variants. We believe a critical and significant opportunity exists for a pan-coronavirus vaccine with the attributes the GV-MVA-VLPTM technology can offer.”

**About GeoVax**

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing human vaccines against infectious diseases and cancer using a novel patented Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) based vaccine platform. On this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses proteins that assemble into VLP immunogens in the person receiving the vaccine. The production of VLPs in the person being vaccinated can mimic virus production in a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection. The MVA-VLP derived vaccines can elicit durable immune responses in the host similar to a live-attenuated virus, while providing the safety characteristics of a replication-defective vector.

GeoVax’s current development programs are focused on preventive vaccines against COVID-19, HIV, Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as therapeutic vaccines against multiple cancers. The Company has designed a preventive HIV vaccine candidate to fight against the subtype of HIV prevalent in the commercial markets of the Americas, Western Europe, Japan, and Australia; human clinical trials for this program are managed by the HIV Vaccine Trials Network (HVTN) with the support of the National Institutes of Health (NIH). GeoVax’s HIV vaccine is also part of a collaborative effort toward a functional cure for HIV.

***Forward-Looking Statements***

*This release contains forward-looking statements regarding GeoVax*’*s business plans. The words* “*believe,*”“*look forward to,*”“*may,*”“*estimate,*”“*continue,*”“*anticipate,*”“*intend,*”“*should,*”“*plan,*”“*could,*”“*target,*”“*potential,*”“*is likely,*”“*will,*”“*expect*” *and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Actual results may differ materially from those included in these statements due to a variety of factors, including whether: GeoVax is able to* *obtain acceptable results from additional tests of its preventive vaccine against SARS-CoV-2, GeoVax*’*s vaccines can provoke the desired immune responses, and those vaccines can be used effectively as a primary or booster to other vaccines, GeoVax*’*s viral vector technology adequately amplifies immune responses to cancer antigens, GeoVax can develop and manufacture its vaccines with the desired characteristics in a timely manner, GeoVax*’*s vaccines will be safe for human use, GeoVax*’*s vaccines will effectively prevent targeted infections in humans, GeoVax*’*s vaccines will receive regulatory approvals necessary to be licensed and marketed, GeoVax raises required capital to complete vaccine development, there is development of competitive products that may be more effective or easier to use than GeoVax*’*s products, GeoVax will be able to enter into favorable manufacturing and distribution agreements, and other factors, over which GeoVax has no control.*

*Further information on our risk factors is contained in our registration statement on Form S-1 and the periodic reports on Form 10-Q and Form 10-K that we have filed and will file with the SEC. Any forward-looking statement made by us herein speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by U.S. federal securities law.*

**Contact:**

GeoVax Labs, Inc.

investor@geovax.com

678-384-7220

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**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the**

**Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported):**  **September 28, 2021**

**GEOVAX LABS, INC.**

**(Exact name of registrant as specified in its charter)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Delaware** |  | **001-39563** |  | **87-0455038** |
| **(State or other jurisdiction of**  **incorporation or organization)** |  | **(Commission File No.)** |  | **(IRS Employee Identification No.)** |

**1900 Lake Park Drive, Suite 380**

**Smyrna, Georgia 30080**

**(Address of principal executive offices) (Zip code)**

**(678) 384-7220**

**(Registrant**’**s telephone number, including area code)**

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☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13(e)-4(c))

Securities registered pursuant to Section 12(b) of the Act:

|  |  |  |
| --- | --- | --- |
| Title of each class | Trading  Symbol(s) | Name of each exchange on which registered |
| Common Stock, par value $0.001 per share | GOVX | The Nasdaq Capital Market |
| Warrants to Purchase Common Stock | GOVXW | The Nasdaq Capital Market |

Indicate by check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial reporting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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| **Item 1.01** | **Entry into a Material Definitive Agreement** |

On September 28, 2021, GeoVax Labs, Inc. (the “Company”), through its wholly-owned subsidiary GeoVax, Inc., entered into an Assignment and License Agreement the (“License Agreement”) with PNP Therapeutics, Inc. (“PNP”) under which the Company obtained exclusive worldwide rights to key intellectual property, including Gedeptin® patents, know-how, regulatory filings, clinical materials, and trademarks. The Gedeptin® patent portfolio was originally licensed from the University of Alabama at Birmingham (“UAB”) and Southern Research Institute (“SRI”) by PNP. Under the terms of the License Agreement, the Company is the successor to PNP under the Exclusive License Agreement between UAB, SRI and PNP, and has acquired the exclusive rights to develop and commercialize Gedeptin®, a novel patented product for the treatment of solid tumors.

The terms of the License Agreement, include an (i) an upfront payment at closing, (ii) milestone payments due upon the achievement of selected development and regulatory events, and (iii) quarterly support payments for the lesser period of three years or the Company’s filing for FDA approval of its Biologics License Application on the use of Gedeptin® for the treatment of head and neck cancer in humans. The Company will also pay tiered percentage annual royalties in the low-to-mid teens on Net Sales (as defined in the License Agreement) of products covered under the License Agreement on a country-by-country and product-by-product basis, subject to specified reductions.

Under the License Agreement, the Company also issued a warrant (the “Warrant”) to PNP, exercisable at any time following March 28, 2022, and prior to September 28, 2026, for up to 100,000 shares of the Company’s common stock at an exercise price of $13.00 per share.

The License Agreement will remain in effect during the original term (the “Original Term”), which concludes upon FDA approval of a generic or biosimilar product, and then will automatically renew for 5-year additional terms following the expiration of the Original Term, subject to customary termination rights.

The foregoing summaries of the License Agreement and Warrant do not purport to be complete and are subject to, and qualified in their entirety by, the License Agreement and Warrant attached as Exhibit 10.1 and 4.1 to this Current Report on Form 8-K, respectively, which are incorporated herein by reference.

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| **Item 3.02** | **Unregistered Sales of Equity Securities** |

The information set forth under Item 1.01 of this Current Report on Form 8-K with respect to the Warrant issued in connection with the License Agreement is incorporated by reference to this Item 3.02. The Warrant was issued in reliance upon the exemption from the registration requirements of the of 1933, as amended (the “Securities Act”), set forth under Section 4(a)(2) of the Securities Act relating to sales by an issuer not involving any public offering and in reliance on similar exemptions under applicable state laws. PNP represented that it is an accredited investor and that it is acquiring the Warrant for investment purposes only and not with a view to any resale, distribution or other disposition of such security in violation of the United States federal securities laws. Neither this Current Report on Form 8-K, nor the exhibits attached hereto, is an offer to sell or the solicitation of an offer to buy the securities described herein.

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| **Item 7.01** | **Regulation FD Disclosure** |

On September 28, 2021, the Company issued a press release entitled “GeoVax Expands Immuno-Oncology Pipeline with Acquisition of Clinical-Stage Cancer Program.” A copy of the Company’s press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Forward-Looking Statements**

This Current Report on Form 8-K and other reports filed by the Company from time to time with the Securities and Exchange Commission (collectively the “Filings”) contain forward-looking statements and information that are based upon beliefs of, and information currently available to, the Company’s management as well as estimates and assumptions made by the Company’s management. When used in the Filings the words “anticipate”, “believe”, “estimate”, “expect”, “future”, “intend”, “plan” or the negative of these terms and similar expressions as they relate to the Company or the Company’s management identify forward looking statements.  Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions and other factors relating to the Company’s industry, operations and results of operations and any businesses that may be acquired by the Company. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned. Except as required by law, the Company does not undertake to update its forward-looking statements.

|  |  |
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| **Item 9.01** | **Financial Statements and Exhibits** |

(d)     Exhibits

|  |  |
| --- | --- |
| Exhibit No. | Description |
| 4.1 | Warrant issued to PNP Therapeutics, Inc., dated September 28, 2021 |
| 10.1 | Assignment and License Agreement, dated September 28, 2021, by and between GeoVax, Inc. and PNP Therapeutics, Inc. (1) |
| 99.1 | Press release dated September 28, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

(1) Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted as the Company has determined (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm to the Company if publicly disclosed.

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 29, 2021

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| --- | --- | --- | --- |
|  | GEOVAX LABS, INC. | |  |
|  |  | |  |
|  |  | |  |
|  | By: | /s/ Mark W. Reynolds |  |
|  |  | Mark W. Reynolds |  |
|  |  | Chief Financial Officer |  |

**Exhibit 4.1**

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES.

**COMMON STOCK PURCHASE WARRANT**

**GEOVAX LABS, INC.**

|  |  |
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| Warrant Shares: 100,000 (the “Warrant Shares”) | Original Issuance Date: September 28, 2021 (the “Original Issuance Date”) |

THIS COMMON STOCK PURCHASE WARRANT (this “Warrant”) certifies that, for value received, PNP Therapeutics, Inc. or its assigns (the “Holder”) is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time six months after the date hereof and on or prior to 5:00 p.m. (Atlanta time) on September 28, 2026 (the “Termination Date”) but not thereafter, to subscribe for and purchase from GeoVax Labs, Inc., a Delaware corporation (the “Company”), up to 100,000 shares (as subject to adjustment hereunder, the “Warrant Shares”) of common stock of the Company, par value $0.001 per share (“Common Stock”). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

“Affiliate” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

“Business Day” means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided that banks shall not be deemed to be authorized or obligated to be closed due to a “shelter in place,” “non-essential employee” or similar closure of physical branch locations at the direction of any governmental authority if such banks’ electronic funds transfer systems (including for wire transfers) are open for use by customers on such day.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock Equivalents” means any securities of the Company which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Trading Day” means a day on which the Common Stock is traded on a Trading Market.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“Transfer Agent” means American Stock Transfer & Trust Company, LLC, the current transfer agent of the Company, with a mailing address of 6201 15th Avenue, Brooklyn, NY 11219 and a facsimile number of 718-765-8717, and any successor transfer agent of the Company.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is traded on OTCQB or OTCQX, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the OTC Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Warrants” means this Warrant.

Section 2. Exercise.

a) Exercise of Warrant. Subject to the provisions of Section 2(e) herein, exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times beginning six months after the Original Issuance Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be $13.00, subject to adjustment hereunder (the “Exercise Price”).

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

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|  | (A) = | the last VWAP immediately preceding the time of delivery of the Notice of Exercise giving rise to the applicable “cashless exercise”, as set forth in the applicable Notice of Exercise (to clarify, the “last VWAP” will be the last VWAP as calculated over an entire Trading Day such that, in the event that this Warrant is exercised at a time that the Trading Market is open, the prior Trading Day’s VWAP shall be used in this calculation); |

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|  | (B) = | the Exercise Price of this Warrant, as adjusted hereunder; and |

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|  | (X) = | the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise. |

The Company agrees not to take any position contrary to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause a physical certificate for the Warrant Shares purchased hereunder to be delivered to the Holder, registered in the Company’s share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earlier of: (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, and (ii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise, all subject to receipt of any cash payments required by the Holder (such date, the “Warrant Share Delivery Date”). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. The Company agrees to use reasonable best efforts to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, “Standard Settlement Period” means the standard settlement period, expressed in a number of Trading Days, on the Company’s primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall round up or down, as applicable, to the nearest whole share.

v. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vi. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time after the issuance of this Warrant the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to all of the record holders of any class of shares of Common Stock (the “Purchase Rights”), then upon exercise of this Warrant the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon such exercise of this Warrant immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights.

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to all of the holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled upon exercise of this Warrant to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquired upon such exercise of this Warrant immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution.

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, issued by a third party or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a “Fundamental Transaction”), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the “Alternate Consideration”) receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction. For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the “Successor Entity”) to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(d) pursuant to written agreements prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction). Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the “Company” shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein. For the avoidance of doubt, if, at any time while this Warrant is outstanding, a Fundamental Transaction occurs, pursuant to the terms of this Section 3(d), the Holder shall not be entitled to receive more than one of (i) the consideration receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction, or (ii) the assumption by the Successor Entity of all of the obligations of the Company under this Warrant and the option to receive a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least twenty (20) calendar days prior to the applicable record or effective date hereinafter specified, a notice (unless such information is filed with the Commission, in which case a notice shall not be required) stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K if required by law. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. Subject to Section 4(d), this Warrant and all rights hereunder are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. In order to effectuate a transfer (in whole or in part) of this Warrant, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the “Warrant Register”), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

d) Transfer Restrictions. Prior to any proposed transfer of this Warrant or the Warrant Shares, unless there is in effect a registration statement under the Securities Act, covering the proposed transfer, the Holder thereof shall give written notice to the Company of such Holder’s intention to effect such transfer. Each such notice shall describe the manner and circumstances of the proposed transfer in sufficient detail, and shall, if the Company so requests, be accompanied (except in transactions in compliance with Rule 144) by either (i) a written opinion of legal counsel who shall be reasonably satisfactory to the Company addressed to the Company and reasonably satisfactory in form and substance to the Company’s counsel, to the effect that the proposed transfer of the Securities may be effected without registration under the Securities Act and any applicable state securities laws, or (ii) a “no action” letter from the Commission to the effect that the transfer of such Securities without registration will not result in a recommendation by the staff of the Commission that action be taken with respect thereto, whereupon the Holder of the Securities shall be entitled to transfer the Securities in accordance with the terms of the notice delivered by the Holder to the Company. Each certificate evidencing the Warrant should shall bear the appropriate restrictive legend set forth above, except that such certificate shall not bear such restrictive legend if in the opinion of counsel for the Company such legend is not required in order to establish compliance with any provisions of the Securities Act.

e) Representations by the Holder. The Holder, by the acceptance hereof, represents and warrants that Holder is aware the Warrant and Warrant Shares are “restricted securities” and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Warrant and Warrant Shares as principal for its own account and not with a view to or for distributing or reselling such Warrant and Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such securities in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such securities in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting such Holder’s right to sell the in compliance with applicable federal and state securities laws). Such Holder is acquiring the Warrant and Warrant Shares hereunder in the ordinary course of its business. The Holder is a sophisticated investor that is acquiring this Warrant for its own account for investment and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act and applicable state securities laws.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting the rights of a Holder to receive Warrant Shares on a “cashless exercise,” and to receive the cash payments contemplated pursuant to Sections 2(d)(i) and 2(d)(iv), In no event, including if the Company is for any reason unable to issue and deliver Warrant Shares upon exercise of this Warrant as required pursuant to the terms hereof, shall the Company be required to net cash settle an exercise of this Warrant or cash settle in any other form.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of Georgia, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the State of Georgia. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the State of Georgia for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys’ fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder’s rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys’ fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at 1900 Lake Park Drive, Suite 380, Smyrna, Georgia 30080, Attention: Mark W. Reynolds, E-mail: MReynolds@GeoVax.com, or such other facsimile number, email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number, e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (Atlanta, Georgia time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K if required by law.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

k) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder of this Warrant, provided that adjustments may be made to the Warrant terms and rights of this Warrant in accordance with Section 3 of this Warrant without the consent of any Holder or beneficial owner of the Warrants.

l) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

m) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

*(Signature Page Follows)*

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **GEOVAX LABS, INC.** | |  |
|  |  |  |  |
|  |  |  |  |
|  | By: |  |  |
|  |  | Name: |  |
|  |  | Title: |  |

**NOTICE OF EXERCISE**

TO: GEOVAX LABS, INC.

(1) The undersigned hereby elects to purchase \_\_\_\_\_\_\_\_ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The Warrant Shares shall be delivered to the following DWAC Account Number:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[SIGNATURE OF HOLDER]

|  |  |
| --- | --- |
| Name of Investing Entity: |  |

|  |  |
| --- | --- |
| *Signature of Authorized Signatory of Investing Entity*: |  |

|  |  |
| --- | --- |
| Name of Authorized Signatory: |  |
| Title of Authorized Signatory: |  |

|  |  |
| --- | --- |
| Date: |  |

**ASSIGNMENT FORM**

*(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)*

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

|  |  |
| --- | --- |
| Name: |  |
|  | (Please Print) |
| Address: |  |
| Phone Number:  Email Address: | (Please Print)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Dated: , |  |
| Holder’s Signature: |  |
| Holder’s Address: |  |

**Exhibit 10.1**

**THE SYMBOL** “**[\*\*\*]**” **DENOTES PLACES WHERE CERTAIN IDENTIFIED**

**INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)**

**NOT MATERIAL, AND (ii)** **WOULD LIKELY CAUSE COMPETITIVE HARM TO THE**

**COMPANY IF PUBLICLY DISCLOSED**

**ASSIGNMENT AND LICENSE AGREEMENT**

**by and between**

**PNP THERAPEUTICS, INC**

**and**

**GEOVAX, INC.**

**ASSIGNMENT AND LICENSE AGREEMENT**

THIS ASSIGNMENT AND LICENSE AGREEMENT (this “**Agreement**”), dated as of September 28, 2021 (the “**Effective Date**”), is made by and between PNP Therapeutics, Inc., a company organized and existing under the laws of the state of Delaware, with a principal place of business at 15 Richard Arrington Jr. Blvd, Birmingham, Alabama 35203 (“**PNP**”), and GeoVax, Inc. a company organized and existing under the laws of the state of Georgia, with a principal place of business at 1900 Lake Park Dr. SE, Smyrna, GA 30080 (“**GeoVax**”). PNP and GeoVax are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

**WHEREAS**, PNP owns certain regulatory assets, license and other agreements, trademarks, know-how, documents and other intellectual property rights covering Ad/PNP-F-araAMP Technology and Gedeptin® in particular;

**WHEREAS**, the Parties desire that GeoVax acquire or license, as described below, all rights held by PNP pertaining to Gedeptin®, and more generally, Ad/PNP-F-araAMP Technology, so that GeoVax may Develop and Commercialize Products that include Gedeptin® in the Territory for use in the Field;

**WHEREAS**, PNP has exclusively licensed patents, patent applications and know-how owned by the UAB Research Foundation (“UABRF”) and Southern Research Institute (“SR”) (together “PNP Licensor”) under an Exclusive License Agreement between UABRF (on behalf of itself and SR) and PNP, dated September 28, 2021, covering Ad/PNP-F-araAMP Technology and in particular Gedeptin® and its therapeutic uses (“PNP Gedeptin® Exclusive License Agreement”); and

**WHEREAS**, PNP Licensor has agreed in writing to allow PNP to fully assign all of its rights in the PNP Gedeptin® Exclusive License Agreement to GeoVax such that GeoVax will replace PNP as the exclusive licensee to further allow GeoVax to Develop and Commercialize Licensed Products in the Field in the Territory;

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency of which are hereby acknowledged, PNP and GeoVax hereby agree as follows:

**ARTICLE I  
DEFINITIONS**

As used in this Agreement, the following capitalized terms, whether used in the singular or plural, will have the respective meanings set forth below or as otherwise defined in this Agreement:

**1.01** “**Accounting Principles**” means, with respect to GeoVax, PNP or any other Person, United States Generally Accepted Accounting Principles, or International Financial Reporting Standards, in each case as used by the relevant Party in its books and records, and consistently applied.

**1.02** “**Ad/PNP-F-araAMP Technology**”means vector expressing a purine nucleoside phosphorylase gene (“Ad/PNP”) (including specifically, Gedeptin®, which is a vector expressing a tailed mutant purine nucleoside phosphorylase (PNP) as defined in 1.25) and its use in combination with a purine nucleoside cleaved by the PNP to release a tumor-toxic purine metabolite.

**1.03** “**Affiliate**” means, with respect to a Party, any other Person that directly or indirectly controls, is controlled by or is under common control with such Party. A Person will be deemed to control another Person if such Person possesses the power to direct or cause the direction of the management, business and policies of such Person, whether through the ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting securities of such Person, by contract or otherwise.

**1.04** “**Applicable Law**” means the laws of any jurisdiction that are applicable to the Parties or their respective Affiliates in carrying out activities hereunder or to which the Parties or their respective Affiliates carry out the activities hereunder is subject, and will include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, policies, directions, directives and orders of any statutory authority, tribunal, arbitral body, board, or court or any central, state, or provincial government or local authority or other governmental entity in such jurisdictions, including Good Laboratory Practices, Good Clinical Practices and Good Manufacturing Practices.

**1.05** “**Biologics License Application**” or (“**BLA**”) means a filing under 21 C.F.R. §§ 600-680 filed pursuant to the United States Food & Drug Act or any application or submission for Regulatory Approval of a biologic product filed with a Regulatory Authority that is the equivalent thereof.

**1.06** “**Business Day**” means any day (other than a Saturday or Sunday) when banks are open for business in Atlanta, Georgia.

**1.07** “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, for so long as this Agreement is in effect; provided, however, that (a) the first Calendar Quarter of the Term will extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term will end upon the expiration of this Agreement.

**1.08** “**Calendar Year**” means each successive period of twelve (12) months commencing on January 1 and ending on December 31, for so long as this Agreement is in effect; provided, however, that (a) the first Calendar Year of the Term will commence on the Effective Date and end on December 31, 2021 and (b) the last Calendar Year of the Term will commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

**1.09** “**Change of Control**” means, with respect to a Party: (a) the sale of all or substantially all of such Party’s assets or business relating to this Agreement; (b) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a Person, or group of Persons acting in concert, acquires more than fifty percent (50%) of the voting equity securities or management control of such Party, in each case, directly or indirectly.

**1.10** “**Clinical Trial**” means any clinical study or clinical trial of a Licensed Product, including a post-Regulatory Approval study.

**1.11** “**Commercialization**” or “**Commercialize**” means, with respect to a Licensed Product, any activities directed to the marketing, promotion, distribution, offering for sale and selling such product, importing and exporting such product for sale, including all post-launch regulatory activities and interactions with Regulatory Authorities regarding the foregoing.

**1.12** “**Commercially Reasonable Efforts**” means, with respect to the efforts to be expended by GeoVax with respect to any objective (including Development or Commercialization of a Compound or Product, as applicable), consistent with the reasonable best practices of companies of similar size and capitalization in the biopharmaceutical industry to accomplish such objective, including with respect to the Development or Commercialization (as applicable) of a Licensed Product, that is at a similar stage in its development or product life cycle as the Compound or Product.

**1.13** “**Confidential Information**” means, as applicable, all Know-How and all proprietary or non-public scientific, clinical, regulatory, marketing, financial, commercial or other information or data, whether communicated in writing, verbally, electronically or by other means, that is provided by or on behalf of one Party to the other Party in connection with this Agreement. The Parties hereby agree and acknowledge that any information disclosed under the Existing Confidentiality Agreement will be deemed disclosed under this Agreement.

**1.14** “**Control**”, “**Controls**” or “**Controlled by**” means, with respect to any asset, including Patents, Know-How or other intellectual property assets or rights, as applicable, the legal authority or right (whether by ownership or license or other right, other than pursuant to a license under this Agreement) of a Party to grant access to, or a license or sublicense of, such items or right, or otherwise disclose such proprietary or trade secret information to another Person without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense or misappropriating the proprietary or trade secret information of a Third Party.

**1.15** “**Cost of Goods**”means the price to manufacture and/or acquire the Licensed Product as determined in accordance with United States generally accepted accounting principles (GAAP).

**1.16** “**Development**” or “**Develop**” means all preclinical drug development activities and all clinical drug development activities, including test method development, stability testing, assay development, audit development, toxicology, formulation, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials (including any post-marketing studies), packaging development, regulatory affairs, and the preparation, filing, and prosecution of all regulatory filings and documentation as necessary to obtain Regulatory Approval to market or sell a product.

**1.17** “**Dollar**” and “**$**” means a U.S. dollar.

**1.18** “**Existing Confidentiality Agreement**” means the Confidentiality Agreement between the Parties with an effective date of August 12, 2019.

**1.19** “**European Union**” or “EU” means that political and economic union as named of countries as of the Effective Date of this Agreement or which may be amended from time to time by the EU itself.

**1.20** “**EMA**” means the European medicines agency which is the decentralized agency of the European Union responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.

**1.21** “**FDA**” means the United States Food and Drug Administration, or any successor entity thereto.

**1.22** “**Field**” means all therapeutic uses.

**1.23** “**First Commercial Sale**” means, with respect to a Licensed Product in a given country in the Territory, the first sale in the Field after the receipt of Regulatory Approval allowing such sale in such country. Sales for sampling and promotional use, or compassionate or experimental use, will not be considered to constitute a First Commercial Sale. For clarity, First Commercial Sale will be determined on a Licensed Product-by-Licensed Product and country-by-country basis.

**1.24** “**First Indication**”means the treatment of Head and Neck (H&N) cancer in a human.

**1.25** “**Gedeptin**®”means a vector expressing a tailed mutant purine nucleoside phosphorylase (PNP) with the sequence with a tail of between ten (10) and fifty (50) additional amino acid residues relative to the wild type purine nucleoside phosphorylase The amino acid sequence of Gedeptin® is provided in Schedule A.

**1.26** “**GeoVax Gedeptin**® **Exclusive License Agreement**”means that exclusive license agreement originally among UABRF/SR and PNP which is transferred by assignment from PNP to GeoVax as part of this Assignment and License Agreement.

**1.27** “**Good Clinical Practices**” means the current Good Clinical Practices as such term is defined from time to time by the FDA, or analogous set of regulations, guidelines or standards as defined by other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or Commercialization of Product in a particular jurisdiction of the Territory, as applicable.

**1.28** “**Good Laboratory Practices**” means the current Good Laboratory Practice regulations of the FDA as described in the United States Code of Federal Regulations and all applicable FDA rules, regulations, order, and guidances, or analogous set of regulations, guidelines or standards as defined by other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or Commercialization of Product in a particular jurisdiction of the Territory, as applicable.

**1.29** “**Good Manufacturing Practices**” means the current Good Manufacturing Practices as such term is defined from time to time by the FDA or analogous set of regulations, guidelines or standards as defined by other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or Commercialization of Product in a particular jurisdiction of the Territory, as applicable.

**1.30** “**Improvement Patents**” means all Patents owned or Controlled by GeoVax claiming or covering any (i) use of Gedeptin® or its manufacture with a first priority date that is on or after the Effective Date, or (ii) a Know-How Improvement arising on or after the Effective Date that is not covered by (i) above.

**1.31** “**IND**” means an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to the FDA or other Regulatory Authority in conformance with the requirements of such Regulatory Authority.

**1.32** “**Know-How**” means all proprietary information and materials (whether patentable or not) including (a) ideas, discoveries, inventions, improvements, technology or trade secrets, (b) pharmaceutical, chemical and biological materials, products, components or compositions, (c) methods, procedures, formulas, processes, tests, assays, techniques, regulatory requirements and strategies, (d) biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical or safety data and information, (e) technical and non-technical data and other information related to the foregoing, and (f) drawings, plans, designs, diagrams, sketches, specifications or other documents containing or relating to such information or materials pertaining to Ad/PNP-F-araAMP Technology or Gedeptin®.

**1.33** “**Know-How Improvement**” means all Know-How (whether or not patentable) conceived, discovered, Developed or reduced to practice that is owned or Controlled by GeoVax or any of its Affiliates in the performance of activities under this Agreement (including the Development, Manufacture or Commercialization of Licensed Product) arising on or after the Effective Date of this Agreement.

**1.34** “**Licensed Product**”meansa pharmaceutical composition that includes Gedeptin® for use in the Field in the Territory for a First Indication or a Second Indication.

**1.35** “**Manufacture**” or “**Manufacturing**” means all activities related to the manufacturing of a biologic or pharmaceutical product, or any ingredient thereof, including test method development and stability testing, formulation, process development, manufacturing for use in non-clinical or clinical studies, manufacturing scale-up, quality assurance and quality control development, quality control testing (including in-process release and stability testing), packaging, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, and regulatory activities related to all of the foregoing.

**1.36** “**Marketing Authorization**” means a necessary approval from the FDA or other Regulatory Authority to market and sell a biologics or pharmaceutical product in any country or region, as applicable.

**1.37** “**Marketing Authorization Application**”means an application or submission for Marketing Authorization that is, or is the equivalent of, an NDA or BLA filed pursuant to the United States Food & Drug Act or other Regulatory Authority to obtain marketing approval for a pharmaceutical or biologics product in a given country or region, as applicable.

**1.38** “**NDA**” means a New Drug Application filed pursuant to the United States Food & Drug Act or any application or submission for Regulatory Approval of a pharmaceutical product filed with a Regulatory Authority that is the equivalent thereof.

**1.39** “**Net Sales**”means the gross amount set forth on the invoice relating to any Sale of a Licensed Product by the Licensee, or its Sublicensees, less (a) discounts actually allowed, (b) rebates, price reductions, rebates to social and welfare systems, charge backs, government mandated and similar rebates, (c) credits for claims, allowances, retroactive price reductions or returned goods, (d) prepaid freight and insurance, (e) customs duties, sales taxes or other governmental charges actually paid in connection with such Sale (but excluding income tax).

**1.40** “**Patent**” means (a) all patents and patent applications in any country or supranational jurisdiction worldwide, (b) any substitutions, divisionals, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents or patent applications, and (c) foreign counterparts of any of the foregoing.

**1.41** “**Person**” means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

**1.42** “**PNP Gedeptin**® **Exclusive License Agreement**” means that license agreement between UABRF and PNP, dated September 28, 2021, whereby UABRF on behalf of itself and SR licensed its patent rights and know-how to PNP in Ad/PNP-F-araAMP Technology, including Gedeptin®.

**1.43** “**Regulatory Approvals**” means any approvals, licenses, registrations or authorizations (excluding Price and Reimbursement Approvals, insurance and formulary approvals, licenses, registrations or authorizations) of any regional, national, state or local Regulatory Authority, or other regulatory agency, department, bureau or governmental entity, necessary for the marketing and sale of a Licensed Product or conduct of Clinical Studies in a regulatory jurisdiction.

**1.44** “**Regulatory Authority**” means: (a) the FDA; or (b) the EMA or (c) any and all governmental or supranational agencies, ministries, authorities or other bodies with similar regulatory authority with respect to approval or registration of pharmaceutical or biologic products in any other jurisdiction anywhere in the world.

**1.45** “**Second Indication**”means the treatment of an indication other than Head and Neck cancer, and includes all subsequent indications after the First Indication.

**1.46** “**Term**” means the Term as provided in ARTICLE XI.

**1.47** “**Territory**” means the world.

**1.48** “**Third Party**” means any Person other than (a) PNP and its Affiliates and (b) GeoVax and its Affiliates, which is independent of (a) and (b).

**1.49** “**UABRF/SR Patents**”are those patents and patent applications licensed to GeoVax by UABRF on behalf of itself and SR under the GeoVax Gedeptin® Exclusive License Agreement.

**1.50** “**Valid Claim**” means a claim of an issued and unexpired patent included within the UABRF/SR Patents licensed to GeoVax under the GeoVax Gedeptin® Exclusive License Agreement, that cover the composition of matter, use, manufacture or other aspect of the Licensed Product, and that has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer.

**ARTICLE II  
ASSIGNMENT AND LICENSE GRANTS**

**2.01 Grants of Assignment Rights from PNP to GeoVax**

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|  | **(a)** | PNP hereby fully and irrevocably assigns to GeoVax its full rights and interests to the PNP assets listed in Section 2.01 below. Simultaneous with and on the same day as the execution of this Assignment and License Agreement, PNP shall execute all necessary documents, and also any useful documents requested by GeoVax, to confirm the assignment transfer of the listed PNP assets to GeoVax and shall cooperate to provide any additional requested documents thereafter. It is acknowledged and agreed that the assignments from PNP are fully effective as of the execution of this Assignment and License Agreement, even if the individual subject matter confirmatory assignments described below in the Exhibits in Schedule 2.01 are not received, complete, accepted or valid. |

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|  | **(i)** | PNP Gedeptin® Exclusive License Agreement |

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|  | **1)** | PNP hereby fully assigns all of its rights and obligations in the PNP Gedeptin® Exclusive License Agreement between UABRF and PNP to GeoVax. PNP shall execute the confirmatory assignment in the form provided as Exhibit B in Schedule 2.01. |

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|  | **2)** | PNP provides a true copy of the written consent from UABRF on behalf of itself and SR to assign the PNP Exclusive License Agreement to GeoVax, which is appended to this Assignment and License Agreement as Exhibit C in Schedule 2.01. |

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|  | **3)** | PNP represents and warrants that (i) there are no outstanding obligations or payments due to PNP Licensor under the PNP Exclusive License Agreement as of the Effective Date of this Assignment and License Agreement, (ii) PNP is not in breach of any obligations under the PNP Exclusive License Agreement, and (iii) has received written confirmation of (i) and (ii) from PNP Licensor, which is provided as Exhibit D in Schedule 2.01. |

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|  | **4)** | Following the assignment of the PNP Exclusive License Agreement to GeoVax, PNP shall have no further rights or obligations under the PNP Exclusive License Agreement. |

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|  | **(ii)** | PNP owned or Controlled Trademarks on Gedeptin® |

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|  | **1)** | PNP represents and warrants that the list of trademarks provided as Exhibit E in Schedule 2.01 constitutes all trademarks owned or Controlled by PNP pertaining to Gedeptin® (“PNP Trademarks”). |

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| --- | --- | --- |
|  | **2)** | PNP hereby fully and irrevocably assigns all of its trademarks pertaining to Gedeptin® to GeoVax. PNP shall execute the confirmatory assignment of all PNP owned or Controlled trademarks on Gedeptin® to GeoVax using the trademark assignment form provided as Exhibit F in Schedule 2.01. |

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|  | **3)** | Following the assignment of the PNP trademarks to GeoVax, PNP shall have no further ownership rights in the PNP Trademarks. |

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|  | **(iii)** | Gedeptin® Regulatory Filings. |

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| --- | --- | --- |
|  | **1)** | PNP hereby fully and irrevocably assigns to GeoVax all INDs owned by PNP on Gedeptin® and its therapeutic use. PNP shall execute the confirmatory assignment provided in Exhibit G in Schedule 2.01 assigning the INDs to GeoVax. PNP represents that Exhibit G in Schedule 2.01 includes a complete list of all INDs for Gedeptin®. |

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|  | **2)** | PNP also fully and irrevocably assigns to GeoVax all written and electronic documents relating to the clinical studies carried out by or on behalf of PNP on Gedeptin® or its use, and shall execute such confirmatory assignment provided in Exhibit H in Schedule 2.01. |

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|  | **3)** | PNP further provides a full right of reference to GeoVax to use as necessary to access any files or documents held by the FDA pertaining to any clinical study of Gedeptin® in Exhibit I, including any PNP controlled Drug Master Files. |

|  |  |  |
| --- | --- | --- |
|  | **4)** | PNP assigns all communications with the FDA and other Regulatory Authorities pertaining to Gedeptin® to GeoVax. PNP represents and warrants that the list of regulatory communications with the FDA, and any other Regulatory Authorities on Gedeptin® provided as Exhibit J in Schedule 2.01 constitutes a complete list of all communications pertaining to the Development of Gedeptin®. |

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| --- | --- | --- |
|  | **5)** | PNP provides Exhibit K in Schedule 2.01 constitutes a list of all patient files pertaining to the clinical Development of Gedeptin®, and represents that it has provided these files to GeoVax or will do so within 10 Business Days of the execution of this Assignment and License Agreement. |

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|  | **6)** | PNP represents that Exhibit L in Schedule 2.01 lists all Drug Master Files including manufacturing information submitted to the FDA for the Gedeptin® clinical trials. |

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|  | **7)** | PNP also fully and irrevocably assigns to GeoVax the FDA Orphan Drug Designation for Gedeptin® granted by the FDA. PNP shall provide GeoVax with all written and electronic documents relating to the clinical studies carried out by or on behalf of PNP on Gedeptin® or its use, and shall execute such confirmatory assignment provided in Exhibit M in Schedule 2.01. PNP represents that Exhibit N in Schedule 2.01 lists all communications with the FDA pertaining to the grant of Orphan Drug Designation for Gedeptin®. |

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|  | **(iv)** | Gedeptin® Clinical Trial Agreements |

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|  | **1)** | PNP hereby assigns its full rights to all Gedeptin® Clinical Trial Agreements to GeoVax. PNP shall execute the confirmatory assignment provided in Exhibit O in Schedule 2.01. PNP represents that Exhibit P provides a full list of all Gedeptin® Clinical Trial Agreements that have ever been in effect, along with whether the Agreements are in still force or have been terminated. |

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|  | **2)** | PNP represents that each current third-party contractor to a Clinical Trial Agreement that is listed on Exhibit P in Schedule 2.01 has been notified about the assignment of the Clinical Trial Agreement, and that there is no provision in any Clinical Trial Agreement that prohibits the transfer by assignment, or for which a condition of the transfer has not been met. |

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|  | **3)** | PNP represents and warrants that it is not in breach, and has not been in breach, of any Clinical Trial Agreement listed in Exhibit P and does not owe any payments or further duties to any clinical trial sites, contract research organizations, healthcare facilities or other entities in connection with the Clinical Trial Agreements or Clinical Trials on Gedeptin® generally. |

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|  | **(v)** | Gedeptin® Manufacturing Protocols and Agreements |

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|  | **1)** | PNP has, or will within 10 Business Days of the Effective Date of this Assignment and License Agreement, provide GeoVax with all documents, within its Control, pertaining to the manufacture of Gedeptin®. |

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|  | **(vi)** | Gedeptin® Clinical Trial Material PNP warrants that Exhibit Q provides a comprehensive list of all Clinical Trial Material of Gedeptin® in its possession as of the Effective Date. All materials listed on Exhibit Q which will be provided to GeoVax within 10 Business Days of the Effective Date. |

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|  | **(vii)** | Gedeptin® Starting Materials and Intermediates PNP warrants that Exhibit R provides a comprehensive list of all starting materials and intermediates for the manufacture of Gedeptin® in its possession as of the Effective Date. |

**2.02 Exclusive Grant of PNP Know-How to GeoVax.** During the Term, PNP grants to GeoVax an exclusive royalty-bearing license, with the right to grant sublicenses as provided herein to all PNP Know-How to research, Develop, Manufacture, have Manufactured, use, import, export, sell, offer for sale, and otherwise Commercialize Licensed Product, and more generally Ad/PNP-F-araAMP Technology, in the Field in the Territory.

**2.03 Sublicenses.** Subject to the provisions of this Section, GeoVax may grant sublicenses in the Territory under the Know-How licenses granted to GeoVax in Section 2.02. For each such sublicense, GeoVax will enter into a written and enforceable sublicense agreement with the sublicensee that is consistent with the terms of this Agreement, including this Section 2.03 (each, a “**Sublicense Agreement**”). In each Sublicense Agreement, GeoVax will require that, in the event of a termination in which the provisions of Section 11.07 apply, the Sublicense Agreement will be assignable by GeoVax to PNP (at PNP’s written request). The Sublicense Agreement will require that the sublicensee comply with the applicable terms and conditions of this Agreement. The grant of any such sublicense will not relieve GeoVax of its obligations under this Agreement and GeoVax will be liable for the performance or non-performance of its sublicensee hereunder. GeoVax will promptly (but in all cases within ten (10) Business Days after entering into any Sublicense Agreement) provide PNP with a fully executed copy of each Sublicense Agreement.

**2.04 Third Party Contractors**. Subject to the provisions of this section, GeoVax will be entitled to engage the services of its Affiliates and Third Parties to perform the Development and Commercialization and other activities on behalf of GeoVax with respect to the Development and Commercialization of Licensed Product. For each such engagement, GeoVax will enter into a written and enforceable contract agreement with the Affiliates or Third Party that is consistent with the terms of this Agreement (each, a “Third Party Contract”). In each Third Party Contract, GeoVax will require that in the event of a termination in which the provisions of Section 11.07 apply, the Third Party Contract will be assignable by GeoVax to PNP (at PNP’s request). The contracting of any such activities will not relieve GeoVax of its obligations under this Agreement and GeoVax will be liable for the performance or non-performance of its Third Party Contractors hereunder.

**ARTICLE III**

**DEVELOPMENT, MANUFACTURE, AND COMMERCIALIZATION**

**3.01 Development, Manufacture, and Commercialization.**

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|  | **(a)** | **Overview.** During the Term,GeoVax will be solely responsible for the Development, Manufacture, and Commercialization, including all costs thereof, of Licensed Product in the Field in the Territory. |

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|  | **(b)** | **Diligence.** GeoVax will use Commercially Reasonable Efforts to Develop (including filing NDAs and obtaining Regulatory Approval) and Commercialize at least one Licensed Product in the Field in the Territory. If GeoVax determines, consistent with the foregoing diligence obligation, to cease Development and Commercialization of Licensed Product in the Field in the Territory because such Development and Commercialization is not progressing adequately in clinical trials, is not meeting a desired or necessary clinical endpoint, or otherwise would not be commercially or therapeutically reasonable to continue, GeoVax shall provide prompt written notice to PNP of such determination, which notice shall specifically reference this Section and shall also constitute notice of termination pursuant to ARTICLE XI of this Agreement. |

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|  | **(c)** | **Minimum Diligence**. Notwithstanding (b), GeoVax shall not cease the Development of Gedeptin® prior to the termination or completion of the Phase II Trial in Head and Neck Cancer, which shall constitute a requirement of Diligence. |

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|  | **(d)** | **Contract Research Organization (**“**CRO**”**).** GeoVax will assume sole responsibility for completion of the ongoing PNP sponsored, FDA funded Phase II trial in Head and Neck (H&N) cancer (the First Indication). |
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|  | **(i)** | GeoVax shall retain, at GEOVAX’s sole cost, an experienced cancer Clinical Research Organization (“CRO”) to accelerate completion of the ongoing Phase II trial for the use of Product in H&N cancer. GeoVax will retain the CRO within six (6) months of execution of the Agreement. |

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|  | **(ii)** | If GeoVax fails to retain a CRO within six months of execution of this Assignment and License Agreement, GeoVax will notify PNP in writing and will provide an explanation for the failure to engage a CRO within the six month timeframe and a summary of GeoVax’s strategy to resolve the issue. If a qualified CRO has not been retained by six (6) months following the execution of the Agreement, PNP shall be entitled to a one-time penalty fee in the amount of \*\*\* ($\*\*\*), payable immediately, and the right to conduct due diligence on possible CROs for presentation to GeoVax. GeoVax shall retain sole control over the selection ofa CRO. GeoVax will notify PNP when a CRO has been retained and will provide PNP with the name and contact information of the CRO. The CRO will be act under the sole direction of GeoVax. |

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|  | **(e)** | **Performance.** GeoVax will ensure that the Development of the Licensed Product will be undertaken in a professional manner and in compliance with Good Laboratory Practices, Good Clinical Practices, Good Manufacturing Practices and all other Applicable Laws. |

**3.02 Development Reports**. GeoVax will provide PNP with summarized written reports describing its progress with respect to its Development efforts (each, a “**Development Report**”). Such Development Reports will be furnished once a year, starting one year from the Effective Date of this Assignment and License Agreement, and continuing as long as Development of the Licensed Product continues.

**3.03 Regulatory Filings and Regulatory Approvals**. After the Effective Date of this Assignment and License Agreement, all regulatory filings and regulatory approvals will be filed in the name of and owned by GeoVax. GeoVax will own and solely Control all Regulatory Filings and Approvals for all Licensed Products throughout the Territory for use in the Field.

**3.04 Pharmacovigilance.**

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|  | **(a)** | **Adverse Events.** GeoVax will be solely responsible for the collection, review, assessment, tracking and filing of information related to adverse events associated with Licensed Product in the Field in the Territory, in accordance with all Applicable Laws, and will, upon request of PNP, provide PNP with a summary of any adverse event reports and information related thereto. |

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|  | **(b)** | **Global Safety Database.** From and after the Effective Date, GeoVax will assume responsibility for maintaining a global safety database for the Licensed Product consistent with industry practices. Within 10 Business Days of the Effective Date, PNP will provide GeoVax with any legacy Significant Adverse Event reports as applicable in the form of an electronic copy of the CIOMS I form. |

**3.05 Materials Transfer**.PNP shall transfer all Gedeptin® materials, including packaged vials and bulk materials, to GEOVAX within 10 Business Days of the Execution Date of this Assignment and License Agreement.

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|  | **(a)** | **Documentation and Transfer Process**. In connection with the transfer of Gedeptin®, the following shall apply: |

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|  | **(i)** | PNP will share with GeoVax any Material Safety Data Sheets requested by GeoVax and reasonably available to PNP. |

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|  | **(ii)** | GeoVax will be solely responsible for any testing associated with the transferred material prior to use. |

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|  | **(iii)** | GeoVax will be responsible for all documentation, licenses, costs, etc. that are needed for and related to the continuing storage, pick-up, transport, and subsequent delivery of the transferred material to the location designated by GeoVax. |

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|  | **(iv)** | GeoVax shall be solely responsible for the production and sourcing of all Development and Commercial materials for Licensed Product after the Effective Date of this Assignment and License Agreement. |

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|  | **(v)** | GeoVax shall use reasonable commercial efforts to supply sufficient Gedeptin® material, at no cost, in support of Dr. Eric Sorscher’s work, including specifically, sufficient material for a fifteen-person breast cancer trial. GeoVax will also provide regulatory oversight, as required by the IND, to support the fifteen-person breast cancer trial. |

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|  | **(vi)** | GeoVax will not object to Dr. Sorscher continuing scientific research pertaining to the Ad/PNP-F-araAMP Technology, submitting patent improvements pertaining to the Ad/PNP-F-araAMP Technology, writing and submitting grants concerning the Ad/PNP-F-araAMP Technology, and publishing articles concerning the Ad/PNP-F-araAMP Technology. |

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|  | **(vii)** | To the extent that PNP Controls any improvements pertaining to the Ad/PNP-F-araAMP Technology, GeoVax shall be granted, and is hereby granted, an exclusive, worldwide license, with the right to sublicense to such improvements. Such license under this Section 3.05(vii) shall be granted, and is hereby granted, subject to the terms of this Agreement, except that no additional upfront license fees shall be required. |

**3.06 Regulatory Matters and Governance**

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|  | **(a)** | GeoVax shall be responsible for maintaining complete and accurate files of all regulatory submission to and communications with Regulatory Authorities in the Territory. |

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|  | **(b)** | GeoVax shall solely own all regulatory approvals on Gedeptin® in the Territory and shall be solely responsible for all communications with all Regulatory Authorities. |

**ARTICLE IV**

**MARKETING**

**4.01** GeoVax will be responsible for, and have discretion over the marketing, strategy, pricing, promotion, physician targeting, reimbursement, branding and sale of the Product in the Territory. GeoVax shall request approval to use the name of PNP in marketing materials, if it desires to do so.

**ARTICLE V  
COMPLIANCE**

**5.01 Compliance with Legal and Ethical Requirements.** PNP certifies that it has conducted all activities to date, including all Development and Manufacturing of the Licensed Product, in compliance with all Applicable Laws and ethical business practices. GeoVax certifies that it will conduct all activities after the Effective Date of this Assignment and License Agreement, including all Development, Manufacturing and Commercialization of the Licensed Product, in compliance with all Applicable Law and ethical business practices.

**ARTICLE VI  
FINANCIAL PROVISIONS; REPORTS**

**6.01 License Fee Payments**.

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|  | **(a)** | In consideration of the assignments and licenses granted hereunder, GeoVax shall pay PNP $\*\*\* U.S. Dollars (\*\*\* U.S. Dollars) within 10 Business Days of the execution of this Assignment and License Agreement by wire transfer to the bank account designated by PNP in writing. |

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|  | **(b)** | GeoVax shall thereafter make a quarterly payment of $\*\*\* (T\*\*\* U.S. Dollars) to PNP, as ongoing consideration for the assignments and licenses granted hereunder, beginning on the last day of the first quarter of 2022, until the first of the following events occur: |

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|  | a) | GeoVax files for approval of its Biologics License Application on the use of Gedeptin® for the First Indication to the FDA; or |

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|  | b) | The total amount of such quarterly payments equals $\*\*\* (\*\*\* U.S. Dollars). |

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|  | **(c)** | In further consideration for the assignments and licenses hereunder, GeoVax shall issue to PNP a Common Stock Purchase Warrant for One Hundred Thousand (100,000) shares of GeoVax common stock with a 5-year term and a strike price of $13.00 U.S. dollars within 10 Business Days of the Effective Date of this Assignment and License Agreement. |

**6.02 Payments for Development Milestones.** As further consideration for the assignments and licenses granted hereunder, GeoVax shall pay PNP the following clinical trial milestone payments.

|  |  |
| --- | --- |
| **Development Milestones** | **Payment** |
| FDA BLA or NDA accepted for review for the First Indication using the Licensed Product | $\*\*\* |
| First FDA regulatory approval of the Licensed Product for the First Indication | $\*\*\* |
| First approval of the Licensed Product for the First Indication by a health authority within a member state of the European Union. | $\*\*\* |
| First human dosed with Licensed Product in a first Phase II trial for a Second Indication. | $\*\*\* |
| First Regulatory approval of the Licensed Product for a Second Indication by the U.S. FDA or a health authority of a European Union member | $\*\*\* |

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|  | **(i)** | For the avoidance of doubt, no payments shall be due for expansion of an existing Indication to a subset of that Indication. |

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|  | **(ii)** | Each Development Milestone Payment shall be payable only once for the First Indication and only once for the Second Indication, and after which no further Development Milestones shall be due. |

**6.03 Royalty Payments.** In consideration for the exclusive Know-How license granted under this Assignment and License Agreement, the following Royalty Payments shall be due on annual Licensed Product Net Sales on a country-by-country and Licensed Product-by-Licensed Product basis.

|  |  |
| --- | --- |
| **Portion of Annual Licensed Product Net Sales** | **Applicable**  **Rate On**  **Net Sales** |
| $0 to $\*\*\* U.S. Dollars | \*\*\*% |
| Above $\*\*\* U.S. Dollars to $\*\*\* | \*\*\*% |
| Above $\*\*\* U.S. Dollars | \*\*\*% |

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|  | **(i)** | Reductions in the Applicable Royalty Rate. The Applicable Royalty Rate shall be reduced on the occurrence of the following events. |

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| --- | --- | --- |
|  | **a)** | On loss of regulatory exclusivity on a Licensed-Product by Licensed Product and country-by-country basis, the royalty rate shall be reduced by a percentage equal to \*\*\*% of the above listed Royalty Rate as a Percentage of Net Sales. |

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| --- | --- | --- |
|  | **b)** | On the event of loss of patent protection under the GeoVax Gedeptin® Exclusive License Agreement, resulting in the loss of all licensed Valid Claims on a Licensed-Product by Licensed Product and country-by-country basis, the royalty rate shall be reduced by a percentage equal to \*\*\*% of the above listed Royalty Rate as a Percentage of Net Sales. |

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|  | **c)** | The royalty reductions in a) and b) are additive such that prior to the regulatory approval of a Third Party generic or biosimilar formulation of the Product, on a Licensed-Product by Licensed Product and country-by-country basis, the applicable royalty rate for the Licensed Product with no regulatory exclusivity and no patent protection under the GeoVax Gedeptin® Exclusive License Agreement, shall be \*\*\*% of those listed in the Royalty Rates as a Percentage of Net Sales. |

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|  | **d)** | Upon the regulatory approval of a Third Party generic or biosimilar formulation of on a Licensed-Product by Licensed Product and country-by-country basis, the applicable Royalty Rate will be reduced to \*\*\*% of Net Sales on all Net Sales. For the avoidance of doubt, this royalty rate reduction will not apply to the approval of an Authorized Generic (AG) or similar formulation of the Product. |

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|  | **(iii)** | **Royalty Anti-Stacking Protection** |

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|  | **1)** | In the event GeoVax reasonably concludes in its own sole discretion that it needs one or more Third Party licenses other than the GeoVax Gedeptin® Exclusive License Agreement to Commercialize a Licensed Product, the applicable royalty due to PNP shall be reduced by \*\*\*% of the royalty payable under the Third Party license. |

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|  | **2)** | Notwithstanding the reduction in royalties for Royalty Stacking provided in this Section 6.02 (ii) 1), in no event shall the royalty rate on Net Sales owed to PNP fall below \*\*\*% during the Term of this Assignment and License Agreement if there is patent or regulatory exclusivity, or \*\*\*% if there is no patent or regulatory exclusivity on a Licensed-Product by Licensed Product and country-by-country basis. |

**6.04 Report of Net Sales and Payment**

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|  | **(i)** | Following the first regulatory approval a Licensed Product, GeoVax shall provide a written report to PNP quarterly, within forty-five (45) calendar days after the first day of each of January, April, July, and October, during the life of this Assignment and License Agreement, stating in each such quarterly report the Net Sales calculation for all Licensed Products on a Licensed-Product by Licensed Product and country-by-country basis sold during the preceding three calendar months on which a royalty is payable. |

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|  | **(ii)** | Concurrent with the delivery of the Report of Net Sales, GeoVax shall pay to PNP all royalties due as indicated in the Report, which, unless otherwise agreed in writing, shall be provided by wire transfer to a bank account designated in writing in advance by PNP. |

**6.05 Auditing**

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|  | **(i)** | PNP may audit GeoVax, no more than once per calendar year, for the Term of this Agreement to confirm the numbers being reported in the quarterly reports provided to PNP by GEOVAX. PNP will notify GEOVAX of any intention to audit 30 (thirty) Business Days prior to the audit and the Parties shall agree to a date acceptable to both Parties. |

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|  | **(ii)** | No more than the prior 24 (twenty-four) months can be audited during any one audit. |

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|  | **(iii)** | PNP shall hire a Third Party auditor, acceptable to GeoVax, to perform these audits and will be responsible for all costs associated with the audit. |

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|  | **(iv)** | If the auditor finds an error in royalties paid that favors GeoVax by greater than 5% of the amount due, GeoVax shall pay a difference between the amount paid and the amount determined to be owed as well as the costs associated with the audit. |

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|  | **(v)** | Amounts paid that disfavor GeoVax and constitute an overpayment to PNP by greater than 5% of the amount due shall be credited by PNP toward future royalty payments by GeoVax. |

**6.06 Payments from Sublicensee to GEOVAX**

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|  | **(i)** | If GeoVax sublicenses a portion or all of the Know How license granted under this Assignment and License Agreement to a Third Party under Section 2.03, no separate payment is due to PNP for the fact of accomplishment of the sublicense. |

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|  | **(ii)** | GeoVax will not owe PNP for any milestone accomplished by, or royalties on Net Sales, which might be due under this Agreement if the milestone or Net Sales had been performed by GeoVax or its Affiliates, but instead GeoVax shall pay PNP for payments received by it from a Third Party for a sublicense during the Term according to the following: |

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| --- | --- |
| **Payment from Sublicensee** | **Percentage of Payment** |
| Upfront fees and milestone payments from sublicensee | \*\*\*% |
| Margin on Transfer Pricing\* | \*\*\*% |
| Royalty payments from Sublicensee | \*\*\*% |

\*Margin on Transfer Pricing shall mean (price paid to GeoVax by Sublicensee for Licensed Product) - (GeoVax’s Cost of Goods + 10% + outbound freight, shipment, and insurance costs + excise taxes, use taxes, tariffs, sales taxes, and customs duties, and other governmental charges imposed on the sale of such Licensed Product, which are not reimbursed by Sublicensee).

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|  | **(iii)** | The sublicense may but is not required, to include a license fee, one or more milestones or other non-royalty consideration. |

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|  | **(iv)** | No payments shall be due to PNP for any reimbursements by a sublicensee to GeoVax for any costs incurred by GeoVax, including but not limited to reimbursement of research or Development or Commercialization costs of Licensed Product, which are pass through costs, to which GeoVax may include up to a 10% surcharge to cover internal processing costs. |

**ARTICLE VII**

**INTELLECTUAL PROPERTY**

**7.01 Ownership and Licenses** GeoVax shall and does (i) exclusively license PNP Licensor patent rights on Gedeptin® in and according to the terms of the GeoVax Gedeptin® Exclusive License Agreement, (ii) exclusively license PNP Know-How on Gedeptin® through the license grants in and according to the terms of this Assignment and License Agreement, and (iii) solely own all Improvement Patents and Improvement Know-How arising on or after the Effective Date of this Assignment and License Agreement (“GeoVax Intellectual Property”). GeoVax, through its counsel, shall solely Control all prosecution, litigation and defense of all intellectual property related to GeoVax Intellectual Property to protect Licensed Product and its manufacture or use.

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| --- | --- | --- |
|  | **(a)** | The rights and responsibilities between PNP Licensor and GeoVax pertaining to the prosecution, litigation and defense of Patents exclusively licensed to GeoVax from PNP Licensor under the GeoVax Gedeptin® Exclusive License Agreement pertaining to Licensed Product are fully set out in that agreement and not restated here. |

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|  | **(b)** | The prosecution, litigation and defense of Gedeptin® trademarks assigned to GeoVax under this Assignment and License Agreement shall be solely Controlled by GeoVax as the sole owner of such trademarks by assignment. |

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|  | **(c)** | The prosecution, litigation and defense of PNP Know How exclusively licensed to GeoVax under this Assignment and License Agreement shall be solely Controlled by GeoVax as a first right. In the event GeoVax elects not to enforce PNP Know How, then PNP shall have the second right to enforce PNP Know How and bear all such costs. |

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|  | **(d)** | Each Party shall reasonably support the other in any of the above actions by making applicable personnel available, providing existing requested data/records, and executing documents, in each case at no charge to the other Party, except as otherwise provided herein. |

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|  | **1)** | If GEOVAX successfully enforces licensed PNP Know How, it shall first have the right to recoup 100% of its out-of-pocket expenses incurred from any recovery, and PNP shall then recover 100% of any costs incurred, and any remaining proceeds (including damages, settlement proceeds or sublicense proceeds) shall be considered Net Sales on which royalties are due paid 65% to GEOVAX, and 35% to PNP. |

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|  | **2)** | If PNP requests in writing to GeoVax that it enforces PNP Know How and GeoVax does not take appropriate steps to do so within 30 Business Days of the PNP notification, then PNP may exercise a second right of enforcement at its sole cost. PNP shall have the right to settle the matter and GEOVAX shall have the right to join any such action, and any recovery shall first be used to pay to PNP its expenses, then to GEOVAX to cover its expenses, and then paid 65% to PNP and 35% to GEOVAX. |

**7.02 Know How Due Care and Notice of Loss**

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|  | **(a)** | PNP shall use best efforts to protect confidential exclusively licensed PNP Know How by maintaining the confidentiality of trade secrets and preventing any form of publication or transfer of information, materials, data or other forms of Know How. |

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| --- | --- | --- |
|  | **(b)** | PNP shall provide GeoVax with prompt notice in writing of the loss of any PNP Know How by publication, loss of trade secret, or any other way that is exclusively licensed to GeoVax, and the Parties shall cooperate together to mitigate any damage. |

**ARTICLE VIII  
CONFIDENTIALITY AND PUBLICATION**

**8.01 Confidentiality.**

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|  | **(a)** | **Nondisclosure Obligation.** Each of PNP and GeoVax will use Confidential Information received by it from, or on behalf of, the other Party only in accordance with this Assignment and License Agreement and, except as otherwise set forth herein, will not disclose to any Third Party any such Confidential Information without the prior written consent of the other Party. The foregoing obligations will survive the expiration or termination of this Agreement for a period of seven (7) years. These obligations will not apply to Confidential Information that the receiving Party can reasonably demonstrate: |

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|  | **(i)** | is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party’s written records; |

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|  | **(ii)** | is at the time of disclosure, or thereafter becomes, published or otherwise part of the public domain without breach of this Agreement by the receiving Party; |

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|  | **(iii)** | is subsequently disclosed to the receiving Party by a Third Party who has the right to make such disclosure, as documented by the receiving Party’s written records; or |

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|  | **(iv)** | is independently developed by the receiving Party or its Affiliates and without the aid, use or application of any of the disclosing Party’s Confidential Information, and such independent development can be documented by the receiving Party’s written records. |

Any combination of features or disclosures will not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party, as applicable.

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|  | **(b)** | **Disclosure to Agents.** Notwithstanding the provisions of this Section 8 and subject to the other terms of this Agreement, GeoVax will have the right to disclose Confidential Information of PNP to its respective sublicensees, agents, consultants, Affiliates or other Third Parties (collectively “**Agents**”) directly involved in the Development, Manufacturing or Commercialization of the Licensed Product (or for such Agents to determine their interest in performing such activities) in accordance with this Agreement. A Party disclosing Confidential Information of the other Party to its Agents will ensure that such Agents are bound by confidentiality and non-use obligations no less restrictive than those contained in this Agreement and will be fully liable to the other Party for breach of such confidentiality and non-use obligations of its Agents. |

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|  | **(c)** | **Additional Permitted Disclosures.** Notwithstanding the provisions of this Section 8, the following disclosures of the other Party’s Confidential Information is permitted as follows: |

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|  | **(i)** | GeoVax may disclose Confidential Information of PNP to any Regulatory Authority to gain approval to conduct Clinical Trials for the Licensed Product or to market the Licensed Product, or other governmental authority in accordance with this Agreement; provided that such disclosure may be made only to the extent reasonably necessary to obtain such patents or authorizations; and provided, further, that notice of the intended disclosure is provided to PNP; |

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|  | **(ii)** | is deemed necessary by counsel to the receiving Party to be disclosed to such Party’s attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party, on the condition that such attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement or are otherwise bound by substantially similar confidentiality and non-use obligations under professional codes of conduct or the like; and |

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|  | **(iii)** | a Party may disclose such Confidential Information as is required to be disclosed by Applicable Law; provided that notice is promptly delivered to the other Party in order to provide an opportunity to seek a protective order or other similar order with respect to such Confidential Information and thereafter the receiving Party discloses to the requesting entity only the minimum information required to be disclosed in order to comply with the request, whether or not a protective order or other similar order is obtained by the other Party. |

**8.02 Breach of Confidentiality.** The Parties agree that the disclosure of the other Party’s Confidential Information in violation of this Agreement may cause such other Party irreparable harm and that any breach or threatened breach of this Agreement by the receiving Party entitles such other Party to seek injunctive relief, in addition to any other legal or equitable remedies available to it, in any court of competent jurisdiction.

**8.03 Publicity and Publications.**

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|  | **(a)** | Other than an initial press release that announces this Assignment and License Agreement, a Party may not use the name of the other Party in any publicity or advertising in connection with this Agreement or the activities hereunder, and may not issue a press release or otherwise publicize or disclose any information related to this Agreement or the terms or conditions herein or the activities hereunder, except (i) as consented to in advance by the other Party in writing or (ii) on the advice of its counsel as required by Applicable Law (*e.g.*, any Securities and Exchange Commission filings and disclosures) and provided the Party who will be disclosing such information has consulted with the other Party to the extent feasible prior to such disclosure with respect to the substance of the disclosure (and subject further to the provisions of this Section 8.03 with respect to disclosure of the terms and conditions of this Agreement). |

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|  | **(b)** | GeoVax (or its Affiliate or sublicensee) shall have the sole right in its discretion to make scientific presentations or otherwise publish clinical results on the Development of Licensed Product or Ad/PNP-F-araAMP Technology generally. |

**8.04 Terms of Agreement.** Neither Party nor its Affiliates will disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except as follows: a Party and its Affiliates may disclose the terms or conditions of this Agreement (but not any other Confidential Information, which may be disclosed only as described elsewhere in this ARTICLE III), (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary, provided that such advisors are subject to confidentiality with regard to such information under an agreement or ethical obligation; (b) to a Third Party in connection with (i) a merger, consolidation, sublicense or similar transaction by such Party or its Affiliates, (ii) the sale of all or substantially all of the assets of such Party or its Affiliates to which this Agreement relates, or (iii) with respect to disclosure by PNP, in connection with a sale of the royalties or other rights to payments contained herein, provided that, in each case, the disclosing Party will ensure that such Third Party is bound by confidentiality and non-use obligations with respect to Confidential Information of the other Party substantially no less restrictive than those contained in this Agreement and such disclosing Party will be fully liable to the other Party for breach of such confidentiality and non-use obligations by such Third Parties; (c) to the United States Securities and Exchange Commission or any other securities exchange or governmental authority, including as required to make an initial or subsequent public offering; or (d) as otherwise required by Applicable Law; provided, that in the case of (c) and (d), the disclosing Party will (x) if practicable, provide the other Party with reasonable advance notice of and an opportunity to comment on any such required disclosure, (y) if requested by such other Party, seek, or cooperate with such Party’s efforts to obtain, confidential treatment or a protective order with respect to any such disclosure to the extent available, and (z) use good faith efforts to incorporate the comments of such other Party in any such disclosure or request for confidential treatment or protective order. GeoVax agrees and understands that PNP may be required to disclose, on a non-confidential basis, both a general description and certain specific provisions of this Agreement in connection with its solicitation of shareholder approval of the transaction contemplated hereby.

**8.05 Existing Confidentiality Agreement**s. As of the Effective Date, the terms of this ARTICLE VIII will supersede the Existing Confidentiality Agreement, and will apply to any “Confidential Information” disclosed by a Party or any of its Affiliates or representatives thereunder.

**ARTICLE IX  
REPRESENTATIONS AND WARRANTIES; COVENANTS**

**9.01 Representations and Warranties of Each Party.** Each of PNP and GeoVax hereby represents and warrants to the other Party as of the Effective Date as follows:

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|  | **(a)** | it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation; |

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|  | **(b)** | the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action; |

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|  | **(c)** | it has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder; |

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|  | **(d)** | the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions herein does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) any loan agreement, guaranty, financing agreement, or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its corporate charter or other operative documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound; |

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|  | **(e)** | except for the Regulatory Approvals required to market the Product, the execution, delivery and performance of this Agreement by such Party do not require the consent, approval or authorization of, or notice, declaration, filing or registration with, any governmental authority or Regulatory Authority and the execution, delivery or performance of this Agreement will not violate any Applicable Law applicable to such Party; and |

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|  | **(f)** | this Agreement has been duly authorized, executed and delivered and constitutes such Party’s legal, valid and binding obligation enforceable against it in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors’ rights and to the availability of particular remedies under general equity principles. |

**9.02 Additional PNP Representations and Warranties.** PNP hereby represents and warrants to GeoVax, as of the Effective Date, as follows:

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|  | **(a)** | To the knowledge of PNP, there have been no violations of any Applicable Laws in the Development of Gedeptin® as of the Effective Date of this Assignment and License Agreement. |

**9.03 Additional GeoVax Representations and Warranties.** GeoVax hereby represents and warrants to PNP as follows:

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|  | **(a)** | GeoVax has the capacity and resources to Develop Compound and Product in accordance with this Agreement, including in accordance with the Development Plan, and to Commercialize Compound and Product in accordance with this Agreement, and it is qualified, experienced in, and competent to perform the activities contemplated by this Agreement. |

**ARTICLE X  
INDEMNIFICATION AND LIMITATION ON LIABILITY**

**10.01 Indemnification by GeoVax.** GeoVax will indemnify, defend and hold harmless PNP and its Affiliates, and each of its and their respective employees, officers, directors, agents, successors and assigns (each, a “**PNP Indemnified Party**”) from and against any and all liability, loss, damage, cost and expense (including reasonable attorneys’ fees) (collectively, a “**Liability**”) arising out of or related to claims, allegations, suits, actions or proceedings asserted by any Third Party (each, a “**Third Party Claim**”) arising out of or relating to (a) the Development, Manufacture, Commercialization or other use or disposition of Compound or Product by or on behalf of GeoVax, its Affiliates or sublicensees (including any Third Party Claims arising out of or relating to any Product withdrawals or recalls), (b) any breach by GeoVax of any of its representations, warranties or covenants under this Agreement, or (c) the negligence or willful misconduct of GeoVax, its Affiliates or sublicensees, or their respective employees, officers, directors or agents in performing any activities or obligations hereunder. Notwithstanding the foregoing, GeoVax will have no obligation under this Agreement to indemnify, defend or hold harmless any PNP Indemnified Party against any such Third Party Claim to the extent resulting from the gross negligence or willful misconduct of PNP or any other PNP Indemnified Party or to the extent resulting from PNP’s breach of its representations, warranties or covenants under this Agreement.

**10.02 Indemnification by PNP.** PNP will indemnify, defend and hold harmless GeoVax and its Affiliates, and each of its and their respective employees, officers, directors, agents, successors and assigns (each, an “**GeoVax Indemnified Party**”) from and against any Liability arising out of or related to a Third Party Claim arising out of or relating to (a) the Development, Manufacture, Commercialization or other use or disposition of Compound or Product by or on behalf of PNP or its Affiliates prior to the Effective Date; (b) any breach by PNP of any of its representations, warranties or covenants under this Agreement or (c) the negligence or willful misconduct of PNP or its Affiliates, or their respective employees, officers, directors or agents in performing any activities or obligations hereunder. Notwithstanding the foregoing, PNP will have no obligation under this Agreement to indemnify, defend or hold harmless any GeoVax Indemnified Party with respect to any such Third Party Claim to the extent resulting from the gross negligence or willful misconduct of GeoVax or any other GeoVax Indemnified Party or to the extent resulting from GeoVax’s breach of its representations, warranties or covenants under this Agreement.

**10.03 Process for Indemnification.** If either Party seeks indemnification (the “**Indemnified Party**”), it will inform the other Party (the “**Indemnifying Party**”) of the Third Party Claim giving rise to the obligation to indemnify pursuant to such Section as soon as reasonably practicable after receiving notice of the Third Party Claim (provided, however, that any delay or failure to provide such notice will not constitute a waiver or release of, or otherwise limit, the Indemnified Party’s rights to indemnification under, as applicable, except to the extent that such delay or failure actually and materially prejudices the Indemnifying Party’s ability to defend against the relevant Third Party Claim). The Indemnifying Party will have the right to assume the defense of any Third-Party Claim if it has assumed responsibility for the Third Party Claim in writing. The Indemnified Party will cooperate with the Indemnifying Party and the Indemnifying Party’s insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party’s cost and expense. The Indemnified Party will have the right to participate, at its own expense and with counsel of its choice, in the defense of any Third-Party Claim that has been assumed by the Indemnifying Party. The Indemnifying Party will not settle any Third-Party Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld. The Indemnified Party will not settle or compromise any indemnifiable Third-Party Claim without the prior written consent of the Indemnifying Party, not to be unreasonably withheld. Limitation of Liability.

**10.04 NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES (INCLUDING LOST PROFITS OR LOST REVENUES) ARISING FROM OR RELATING TO THIS AGREEMENT (INCLUDING BREACH OF THIS AGREEMENT) OR THE EXERCISE OF ITS RIGHTS HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION X IS INTENDED TO OR WILL LIMIT OR RESTRICT (a) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY WITH RESPECT TO LIABILITIES TO THIRD PARTIES UNDER THIRD PARTY CLAIMS UNDER SECTION X, OR (b) DAMAGES AVAILABLE FOR A PARTY**’**S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE X.**

**10.05 Insurance**. During the Term, GeoVax will, at its own expense, procure and maintain (and cause its Affiliates and sublicensees to procure and maintain) policies of insurance (including product liability insurance) in an amount and with terms which are consistent with normal business practices of prudent companies in the pharmaceutical industry, but in all cases, not less than two million Dollars ($2,000,000) per occurrence and two million Dollars ($2,000,000) in the aggregate, from an insurer with an A.M. Best rating of A- or better or Standard and Poor rating of A- or better, or otherwise acceptable to PNP. Such liability insurance will insure against any liability arising out of GeoVax’s (and its Affiliates’, sublicensees’ and contractors’) actions under this Agreement, including personal injury arising out of Product. All such policies will name PNP as an additional insured, and insurers will waive all rights of subrogation against PNP. Upon PNP’s request, GeoVax will promptly provide for itself and its sublicensees copies of certificates of insurance evidencing such coverages. GeoVax will notify PNP not less than thirty (30) Business Days in advance of any material change or cancellation of any policy. GeoVax will continue to maintain such insurance in effect after the expiration or termination of this Agreement during any period in which GeoVax or its Affiliates or sublicensees continue to Develop, Manufacture, or Commercialize Compound or Products. If any insurance is on a claims-made basis, GeoVax will maintain such insurance for a period of not less than five (5) years after it has ceased all Development, Manufacture, and Commercialization of any Compound or Product. It is understood that such insurance will not be construed to create a limit of GeoVax’s liability with respect to its indemnification obligations or otherwise.

**ARTICLE XI  
TERM AND TERMINATION**

**11.01 Term and Expiration**. The Know How licenses granted under this Assignment and License Agreement will be effective as of the Effective Date and, unless terminated earlier by mutual written agreement of the Parties or pursuant to this ARTICLE XI, will continue in effect as follows:

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|  | **(a)** | during the Original Term of this Agreement, which concludes upon FDA approval of a biosimilar or interchangeable under an ABLA or a generic under an ANDA or the equivalent by another Regulatory Authority, but excluding an Authorized Generic (AG) or the equivalent or a similar formulation of the Product, on a Licensed Product-by Licensed Product and country-by-country basis, and |

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|  | **(b)** | following expiration of the Original Term, the Know How license shall automatically renew for five-year Additional Terms, unless GeoVax notifies PNP (i) within 120 days following expiration of the Original Term of its intent not to renew, or (ii) prior to 120 days of the expiration of an Additional Term of its intent not to renew. |

**11.02 Termination At Will by GeoVax of First Indication on Phase II Termination or Completion**. GeoVax, at its sole discretion, can elect to discontinue Development of Gedeptin® no sooner than termination/completion of the Phase II trial, and only at that point under the conditions that GeoVax determines in its discretion that clinical development is not progressing adequately, is not meeting a desired or necessary clinical endpoint, or otherwise would not be commercially or therapeutically reasonable to continue.

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|  | **(a)** | If, GeoVax, under Section 11.02, at its sole discretion, decides not to out-license its license rights to an independent Third Party for Development of Gedeptin®, GeoVax shall notify PNP in writing of its intent to terminate the licenses granted under this Assignment and License Agreement prior to filing for Regulatory Approval by a Regulatory Authority on a Licensed Product-by Licensed Product and country-by-country basis. GeoVax shall terminate its Know How license from PNP, and promptly return all transferred Know How back to PNP. PNP shall thereafter have the right to enter into a sublicense of the GeoVax Gedeptin® Exclusive License Agreement from GeoVax, or can request that GeoVax assign its GeoVax Gedeptin® Exclusive License Agreement to PNP. The Parties shall agree on which route of transfer is preferred, and if they disagree, GeoVax shall transfer by sublicense on terms to be agreed |

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|  | **(b)** | On request by PNP, if GeoVax terminates the Gedeptin® Development under Section 11.02 and does not, in its sole discretion, after due diligence, transfer its ownership rights in the Licensed Product to a Third Party, it shall permit PNP to acquire such assets for \*\*\*% of Net Sales. Notwithstanding this residual permission, PNP shall have no conditional rights whatsoever in GeoVax solely owed Gedeptin® assets, including but not limited to Gedeptin® Regulatory Approvals, regulatory submissions, documents or materials, and shall have no rights of notice or review pertaining to such GeoVax owned assets. If PNP requests and obtains ownership of the Gedeptin® assets, GeoVax shall reasonably and promptly cooperate with PNP under Section 11.02 to transfer the assets. |

**11.03 Termination At Will by GeoVax of Second Indication after Initiation.** GeoVax may in its sole discretion notify PNP in writing of its intent to terminate the Development or Commercialization of any Second Indication, and if so, the terms of Section 11.02 shall not apply. GeoVax may sublicense its Know How license to a third Party for any such Second Indication, or may terminate its Know How license, in its discretion. GeoVax shall dispose of its Licensed Product owned assets in its sole discretion according to its business needs and opportunities.

**11.04 Expiration of Royalty Term.** Upon expiration of the Royalty Term with respect to a given Licensed Product, and provided that GeoVax has paid all Royalties due hereunder with respect to such Product, GeoVax’s license pursuant to Section 2.02 with respect to the Development, Manufacture, and Commercialization of such Product will become a fully paid-up, non-exclusive, irrevocable, perpetual license.

**11.05 Termination for Cause.**

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|  | **(a)** | **Termination for Cause.** This Agreement may be terminated upon written notice by either Party at any time during the Term: |

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|  | **(i)** | upon or after a material breach of this Agreement by the other Party if the breaching Party has not cured such breach within thirty (30) Business Days following receipt of written notice from the non-breaching Party requesting cure of the breach; provided, however, any right to terminate under this section will be stayed and the cure period tolled in the event that, during any cure period, the Party alleged to have been in material breach will have initiated dispute resolution in accordance with Section 12.05 respect to the alleged breach, which stay and tolling will last so long as the allegedly breaching Party diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings; or |

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|  | **(ii)** | upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings by or against the other Party, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party, or in the event a receiver or custodian is appointed for such other Party’s business, or if a substantial portion of such other Party’s business is subject to attachment or similar process; provided, however, that in the case of any involuntary bankruptcy proceeding, such right to terminate will only become effective if the proceeding is not dismissed within sixty (60) Business Days after the filing thereof. |

**11.06 Effect of Termination Generally.**

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|  | **(a)** | **Termination of Licenses.** Notwithstanding anything contained herein to the contrary, following any unconditional termination of this Agreement, all licenses granted to GeoVax hereunder will terminate and will revert back to PNP. |

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|  | **(b)** | **Return of Confidential Information.** Upon termination of this Agreement, GeoVax will return all Know How documents, and copies thereof, including those in the possession of GeoVax’s Agents, containing PNP’s Confidential Information, as well as all other physical embodiments of such Confidential Information. However, GeoVax may retain one (1) copy of such documents in a secure location for archival purposes. |

**11.07 Product Reversion.** Upon termination of this Agreement, the following provisions will apply:

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|  | **(a)** | Effective upon such termination, PNP shall have the right for ninety (90) calendar days to negotiate with GeoVax for an exclusive worldwide license, with the right to grant sublicenses (through multiple tiers), under the GeoVax Improvement Patents, and GeoVax Improvement Know How to Develop, Manufacture, use and Commercialize the Licensed Products in the Field in the Territory. |

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|  | **(b)** | Upon PNP’s written request, GeoVax will reasonably cooperate with PNP (or its designee(s)) to enable PNP (or its designee(s)) to assume responsibility for the Development, Manufacture and Commercialization of Compound and Product in the Field in the Territory. Such cooperation and assistance will be provided in a timely manner and at fully loaded cost paid by PNP to GeoVax for assets already assigned under Section 2.01 (resulting in a buy-back), and will include, without limitation, to the extent requested by PNP and agreed to by GeoVax subject to the written agreement of terms, the following: |

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|  | **(i)** | GeoVax will transfer and assign to PNP (or its designee) all BLAs, INDs, NDAs, Regulatory Approvals, and all supporting documentation for such filings and applications (including all data), made or obtained by or on behalf of GeoVax or any of its Affiliates or any of its sublicensee or subcontractors relating to Licensed Product. |

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|  | **(ii)** | GeoVax will transfer and assign to PNP (or its designee) all rights in any trademarks and trade dress, and will transfer and assign to PNP all rights in any domain names containing such trademarks, to the extent that such trademarks or trade dress, as applicable, have actually been or are planned to be used by GeoVax or any of its Affiliates or any of its sublicensees or subcontractors in connection with Compound or Product; provided, however, that for clarity, the foregoing trademarks and trade dress will exclude the corporate names, logos, trademarks and trade dress of GeoVax or any of its Affiliates, sublicensees or subcontractors. |

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|  | **(iii)** | GeoVax will transfer to PNP (or its designee), to the extent not previously provided, a copy of all GeoVax Know-How and Know-How Improvements, including all information contained in GeoVax’s regulatory or safety databases, in the format then currently maintained by GeoVax. |

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|  | **(iv)** | GeoVax will assign to PNP (or its designee) any Sublicense Agreements or Subcontract Agreements previously entered into by GeoVax (or any of its Affiliates) to the extent related to Licensed Product, or terminate such Sublicense Agreements or Subcontract Agreements to the extent related to Compound or Product, in each case, as and to the extent requested by PNP. |

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|  | **(v)** | If requested by PNP, GeoVax, its Affiliates and its sublicensees and subcontractors will after written agreement on cost and reimbursement, complete any Clinical Trials related to Product in the Field that (x) are being conducted under GeoVax’s (or its Affiliate’s or sublicensee’s or subcontractor’s) IND for Product and are ongoing as of the date this Agreement is terminated, and (y) for which it is not practicable to transfer responsibility for conducting such studies to PNP (as reasonably determined by PNP), in each case, as and to the extent requested by PNP; |

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|  | **(vi)** | If requested by PNP, GeoVax will transfer to PNP (or its designee), at GeoVax’s fully allocated manufacturing cost for the Product, any quantities of Licensed Compound in the possession of GeoVax or its Affiliates or sublicenses or subcontractors (including clinical trial supply and Product intended for commercial sale), as requested by PNP. |

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|  | **(vii)** | At PNP’s request, GeoVax shall promptly provide to PNP copies of all Clinical Trial, contract manufacturing, supply agreements or service agreements entered into by GeoVax or its Affiliates with respect to the Product(s). At PNP’s written request and after agreement on fully loaded cost, GeoVax shall promptly assign (or cause to be assigned), such agreements to PNP. In the event that such an assignment is not permitted under a particular clinical trial, contract manufacturing, supply agreement or service agreement, then GeoVax shall reasonably cooperate (at PNP's request and expense) to assist PNP in obtaining the benefits of such agreement, after reimbursement to GeoVax of its costs. |

Without limiting the foregoing, GeoVax will use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture and Commercialization of the Product from GeoVax to PNP (or its designee) in a prompt manner, as and to the extent requested by PNP, and will provide PNP (or its designee) with such other transition assistance as reasonably requested by PNP, including, if requested by PNP, entering into a transition services agreement at agreed fully loaded cost reimbursement to GeoVax.

**11.08 Survival.** Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination, and the provisions on Definitions (as necessary for the interpretation of other surviving provisions), Intellectual Property, Confidentiality, Representations and Warranties, Covenants, Indemnification and Limitation on Liability and Term and Termination will survive the expiration or termination of this Agreement. Any expiration or early termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including the obligation to pay Royalties and other amounts for Licensed Product sold prior to such expiration or termination. These provisions are in addition to any other relief and remedies available to either Party under this Agreement and under Applicable Law.

**ARTICLE XII  
MISCELLANEOUS**

**12.01 Force Majeure**. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement (except the obligation to make payments when due) to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including pandemics, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God. The affected Party will notify the other Party of such force majeure circumstances as soon as reasonably practicable and will promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

**12.02 Assignment.** This Agreement may be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, in each case, in whole or in part only as a result of a merger, transfer of going concern, sale of stock, sale of assets or other similar transaction (including by operation of law)) by either Party, and without the consent of the other Party. For clarity and by example, GeoVax may, without PNP’s consent, assign this Agreement in connection with a Change of Control of GeoVax, or sale of substantially all assets pertaining to the subject matter of this Assignment and License Agreement and the Development and/or Commercialization of Gedeptin®. PNP may, by example, without GeoVax’s consent, assign this Agreement or its rights and obligations hereunder in whole or in part to (i) an Affiliate of PNP or (ii) in connection with a Change of Control of PNP, and (c) PNP may, without GeoVax’s consent, assign to a Third Party its rights to receive royalties or other payments contained herein and any and all provisions related thereto (including audit rights and reporting rights). Any permitted assignee will assume all obligations of its assignor under this Agreement. This Agreement is binding upon the permitted successors and assigns of the Parties. Any attempted assignment not in accordance with this Section 12.02 will be void *ab initio*. Notice of assignment must be provided to the other Party within five (5) Business Days of the assignment, along with a copy of the assignment document.

**12.03 Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties will in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

**12.04 Notices**. All notices which are required or permitted hereunder will be in writing and sufficient if delivered personally, sent by e-mail (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

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| if to GeoVax, to: | Attention: Mr. David A. Dodd  GeoVax, Inc. |
|  | 1900 Lake Park Dr. SE  Smyrna, GA 30080  \*\*\* |

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| with a copy to: | Knowles Intellectual Property Strategies, LLC  400 Perimeter Center Terraces NE  Suite 200  Atlanta, GA 30346 |
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| if to PNP, to: | 15 Richard Arrington Jr. Blvd N.  Birmingham, AL 35203 |
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| with a copy to: | Steiner Law LLC  2100 First Avenue N., Suite 600  Birmingham, AL 35203 |

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) when delivered if personally delivered or sent by e-mail with receipt confirmed on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) Business Day following the date of mailing, if sent by registered or certified mail.

**12.05 Dispute Resolution; Choice of Law.**

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|  | **(a)** | **Informal Discussions.** Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this Agreement, or the rights or obligations of the Parties hereunder, the Parties will first try to settle their differences amicably between themselves. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within thirty (30) calendar days after such notice appropriate representatives of the Parties will meet for attempted resolution by good faith negotiations. If such representatives are unable to resolve promptly such disputed matter within the thirty (30) calendar days, either Party may refer the matter by written notice to the other to a designated PNP Executive and a designated GeoVax Executive for discussion and resolution. If the PNP Executive and the GeoVax Executive are unable to resolve such dispute within thirty (30) days of such written notice, either Party may commence an action in accordance with the provisions of this Section. |

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|  | **(b)** | **Governing Law**. This Agreement will be governed by and construed in accordance with the laws of the State of Delaware and the federal laws of the United States, without reference to any rules of conflict of laws. The Parties hereby agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement and are strictly excluded. |

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|  | **(c)** | **Venue; Waiver of Jury Trial**. If the Parties do not fully settle following the procedure described herein and a Party wishes to pursue the matter, each dispute, controversy or claim arising from or related to this Agreement or the breach thereof shall be brought in the federal court for the Northern District of Georgia, if federal jurisdiction is available, or, alternatively, in the state courts in Atlanta, Georgia. Each of the Parties hereby submits to the exclusive jurisdiction of such courts for the purpose of any such litigation; provided, that a final judgment in any such litigation shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. Each Party irrevocably and unconditionally agrees not to assert (i) any objection which it may ever have to the laying of venue of any such litigation in such courts, (ii) any claim that any such litigation brought in any such court has been brought in an inconvenient forum, or (iii) any claim that such court does not have jurisdiction with respect to such litigation. EACH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT TO A TRIAL BY JURY AND AGREES THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY LITIGATION. |

**12.06 Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America that may be imposed upon or related to PNP or GeoVax from time to time by the government of the United States of America. Furthermore, GeoVax agrees that it will not export, directly or indirectly, any technical information acquired from PNP under this Agreement or any products using such technical information to any country for which the United States government or any agency thereof at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the Department of Commerce or other agency of the United States government when required by an applicable statute or regulation.

**12.07 Entire Agreement.** This Assignment and License Agreement, together with the Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof (including the Existing Confidentiality Agreement) are superseded by the terms of this Agreement. The Exhibits to this Agreement are incorporated herein by reference and will be deemed a part of this Agreement.

**12.08 Amendments.** This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

**12.09 Independent Contractors.** It is expressly agreed that GeoVax and PNP are independent and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither GeoVax nor PNP will have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other Party, without the prior written consent of the other Party.

**12.10 Waiver.** The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, will not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

**12.11 Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

**12.12 Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

**12.13 Interpretation.** Unless the context of this Agreement otherwise requires, (a) words of any gender include all genders, (b) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular will include the plural, and vice versa, (d) whenever any provision of this Agreement uses the term “including” (or “includes” or words of similar import), such term will not be limiting and such term will be deemed to mean “including without limitation” (or “includes without limitation”), (e) the word “or” will not be construed as exclusive and shall have the meaning ordinarily ascribed to the phrase “and/or”, (f) references to any Articles or Sections include Sections and subsections that are part of the reference Article or section (e.g., a section numbered “Section 2.2(a)” would be part of “Section 2.2”, and references to “Article 2” or “Section 2.2” would refer to material contained in the subsection described as “Section 2.2(a)”), (g) references to “days” will mean calendar days unless otherwise indicated.

**12.14 Counterparts.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

**12.15 Further Actions**. Each Party will execute, acknowledge and deliver such further instruments, and to do all such other ministerial, administrative or similar acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**12.16 No Third-Party Rights**. The provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity will have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party.

**12.17 Expenses**. Except as otherwise specifically provided in this Agreement, each Party (and its Affiliates) will bear its own costs and expenses in connection with entering into this Agreement and the consummation of the transactions and performance of its obligations contemplated hereby.

**12.18 Extension to Affiliates.** Each Party will have the right to extend the rights, licenses, immunities and obligations granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement will apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to such Party. Each Party will remain fully liable for any acts or omissions of such Affiliates.

**This Assignment and License Agreement is Agreed To:**

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| **For PNP Therapeutics** | **For GeoVax, Inc.** |
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| **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
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Schedule 2.01

**Schedule 2.01**

**EXHIBITS**

|  |  |
| --- | --- |
| A | Protein Sequence of Gedeptin® |
| B | Confirmatory Assignment of PNP Gedeptin® Exclusive License Agreement To GeoVax |
| C | Copy of written consent by UABRF/SR to assign PNP Gedeptin® License Agreement to GeoVax |
| D | Letter from UABRF/SR confirming no outstanding obligations or payments owed by PNP |
| E | List of Trademarks owned or controlled by PNP on Gedeptin® |
| F | Confirmatory Assignment of Trademarks on Gedeptin® from PNP to GeoVax |
| G | Confirmatory Assignment of PNP Regulatory Filings on Gedeptin® and full list of BLAs and NDAs by number and country |
| H | Confirmatory Assignment of all written and electronic documents relating to Gedeptin® clinical trials |
| I | Right of Reference from PNP to all clinical trial files and documents held by FDA or another Regulating Authority |
| J | List of all regulatory communications with FDA or other Regulatory Authorities on Gedeptin® |
| K | List of all patient files pertaining to clinical development of Gedeptin® |
| L | List of all Drug Master Files including manufacturing information and CMC information submitted to FDA for Gedeptin® clinical trials |
| M | Confirmatory Assignment of FDA Orphan Drug Designation |
| N | Complete list of communications with FDA on Orphan Drug Designation for Gedeptin® |
| O | Confirmatory Assignment of all Gedeptin® Clinical Trial Agreements |
| P | List of all Gedeptin® Clinical Trial Agreements, whether in force or terminated |
| Q | Complete list of all Clinical Trial Materials and other Gedeptin® supplies |
| R | Complete list of all Clinical Trial Materials and other Gedeptin® starting materials and intermediates |

**Exhibit B**

**EXCLUSIVE LICENSE AGREEMENT CONFIRMATORY ASSIGNMENT**

WHEREAS, PNP Therapeutics, Inc., a privately held company incorporated under the laws of the state of Delaware and having its principal place of business at 15 Richard Arrington Jr Blvd N, Birmingham, AL 35203 (“PNP”) is the named licensee in the Exclusive License Agreement dated September 28, 2021 (attached hereto as Appendix B.1), by and between PNP Therapeutics, Inc., UAB Research Foundation (“UABRF”), and Southern Research Institute, Inc. (“SRI”) (the “PNP Gedeptin® Exclusive License Agreement”);

WHEREAS, GeoVax, Inc., a corporation duly organized and existing under the laws of the State of Georgia and having its principal place of business at 1900 Lake Park Dr SE, Smyrna, GA 30080 (“GeoVax”), by virtue of an Assignment and License Agreement dated September 28, 2021, by and between PNP and GeoVax, has been assigned by PNP, pursuant to Section 12.5 of the PNP Gedeptin® Exclusive License Agreement, all interests, rights, and obligations held by PNP pursuant to the PNP Gedeptin® Exclusive License Agreement, for which UABRF and SRI have consented to as evidence by notice and acknowledgement of assignment, a copy of which is attached as Exhibit C; and,

WHEREAS, GeoVax and PNP desire to confirm through this Confirmatory Assignment the assignment of all interests, rights, and obligation in and under the PNP Gedeptin® Exclusive License Agreement from PNP to GeoVax;

NOW, THEREFORE, for good and valuable consideration previously paid to PNP by GeoVax, the receipt and sufficiency of which is hereby acknowledged by PNP, PNP and GeoVax hereby confirm the following:

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| --- | --- | --- |
|  | 1. | PNP hereby confirms the conveyance and assignment to GeoVax, and GeoVax confirms the acceptance of such conveyance and assignment from PNP, of all of PNP’s rights, interests, and obligation in and under the PNP Gedeptin® Exclusive License Agreement. |

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|  | 2. | PNP confirms that: |

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|  | (i) | PNP has all authority necessary to assign the PNP Gedeptin® Exclusive License Agreement to GeoVax, and the execution and delivery of assignment of the UABRF-PNP License Agreement has been duly and validly authorized; |

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|  | (ii) | the PNP Gedeptin® Exclusive License Agreement is currently valid and subsisting and in full force and effect; |

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|  | (iii) | PNP has no current outstanding obligations or payments due under the PNP Gedeptin® Exclusive License Agreement , and UABRF has confirmed such as evidence by the executed letter attached as Exhibit D; |

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|  | (iv) | PNP has not assigned its interests and rights under the PNP Gedeptin® Exclusive License Agreement to any other person or entity or granted, either expressly or impliedly, any rights with respect to the PNP Gedeptin® Exclusive License Agreement to any other person or entity; |

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|  | (v) | there are no liens or security interests against the PNP Gedeptin® Exclusive License Agreement; and |

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|  | (vi) | execution of the assignment does not violate or conflict with any other agreement to which PNP is a party or provision of PNP’s Certificate of Incorporation or By-laws. |

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|  | 3. | GeoVax confirms that PNP shall not be liable for any obligations incurred by GeoVax pursuant to the PNP Gedeptin® Exclusive License Agreement as of the date of the Assignment and License Agreement. |

IN WITNESS WHEREOF, the parties hereto have caused the Confirmatory Assignment to be executed by their respective duly authorized representatives as of the day and year above written.

|  |  |
| --- | --- |
| Date: |  |
|  | **By:** **James F. Fuqua** |
|  | **Title: President**  **On Behalf of PNP THERAPEUTICS, INC.** |

STATE OF ALABAMA

Before me, a Notary Public in and for the State of ALABAMA, on this 28th day of September, 2021, personally appeared **JAMES F. FUQUA**, who, being duly sworn, signed and acknowledged the foregoing Assignment as his free act and deed.

NOTARY PUBLIC

(SEAL)

My Commission Expires:

|  |  |
| --- | --- |
| Date: |  |
|  | **By:** **David A. Dodd** |
|  | **Title: Chief Executive Officer**  **On Behalf of GeoVax, Inc** |

STATE OF GEORGIA

Before me, a Notary Public in and for the State of Georgia, on this 28th day of September, 2021, **DAVID A. DODD** personally appeared, who, being duly sworn, signed and acknowledged the foregoing Assignment as his/her free act and deed on behalf of and to bind **GEOVAX, INC**.

NOTARY PUBLIC

(SEAL)

My Commission Expires:

THE SYMBOL “[\*\*\*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED  
INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i)  
NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE  
COMPANY IF PUBLICLY DISCLOSED

**Appendix B.1**

**EXCLUSIVE LICENSE AGREEMENT**

This exclusive license agreement (this “Agreement”) is made and is effective as of September 28, 2021, (the “Effective Date”) among The UAB Research Foundation (“UABRF”), a non-profit 501(c)(3) corporation incorporated in the State of Alabama, Southern Research Institute, a not for profit 501(c)(3) corporation existing under the laws of the State of Alabama (SR) (UABRF and SR, hereinafter collectively referred to as “Licensor”) and PNP Therapeutics Inc, (the “Licensee”), a privately held company incorporated under the laws of the state of Delaware, with its principal places of operations as described in the signature block on the signature page below.

**RECITALS**

WHEREAS, UABRF and SR together own all right, title and interest in (i) the intellectual property described in UABRF intellectual property disclosures numbered U2007-0047 and U2011-0026, entitled “The Use of Trichomonas Vaginalis Purine Nucleoside Phosphorylase (PNP) to Activate Fludarabine in the Treatment of Cancer” and “Improvements in PNP based Cancer Therapy using External Beam Radiation and Intratumoral Prodrug”, respectively, which were jointly developed by the Inventors (defined below) while employed by UABRF’s affiliate, the University of Alabama at Birmingham (“UAB”), and Southern Research Institute, respectively, and (ii) the patent applications listed under Exhibit A which are part of the Licensed Patents which cover such intellectual property and associated Know-How;

WHEREAS, pursuant to that certain License Agreement, dated as of July 17, 2001 between the Parties (the "Original Agreement"), Licensor exclusively licensed to Licensee certain patents and patent applications in accordance with the terms and conditions of the Original Agreement;

WHEREAS, the Parties have subsequently either amended or amended and restated the Original

Agreement on April 18, 2007 (by executing that certain Amended and Restated License Agreement), on July 18, 2008 and June 30, 2013 (by executing those certain First and Second Amendments to Amended and Restated License Agreement, respectively), on January 1, 2015 (by executing that certain Second Amended and Restated License Agreement (the Second Amended and Restated License Agreement), and on July 23, 2018 (by executing that certain First Amendment to the Second Amended and Restated License Agreement); and

WHEREAS, the Parties now wish to terminate all agreements described above and replace them with this Agreement;

NOW, THEREFORE, in consideration of the premises described above and the mutual promises and agreements set forth in this Agreement, the Parties agree as set forth below.

**SECTION 1 DEFINITIONS**

The definitions used in this Agreement are set forth below.

1.1 “Ad/PNP-F-araAMP Technology” means an adenoviral vector expressing the E. Coli purine nucleoside phosphorylase gene (“Ad/PNP”), and its use in combination with a purine nucleoside phosphate to release a tumor-toxic purine metabolite, including specifically Ad/PNP-F-araAMP which is a nonreplicating adenoviral vector expressing a tailed mutant *E. coli* purine nucleoside phosphorylase (“PNP”). The amino acid sequence of PNP expressed by the adenoviral vector is provided in attached Exhibit D.

1.2 “Affiliate” means any Person that directly or indirectly controls, is controlled by, or is under common control with a Party. “Control” means (i) the beneficial ownership of at least fifty percent (50%) of the voting securities of a Person with voting equity, or (ii) the power to direct or cause the direction of the management or policies of a Person.

1.3 “Agreement” means this agreement, as amended from time to time in accordance with the terms and conditions set forth in this agreement.

1.4 “Cost of Goods” means the price to manufacture and/or acquire the Licensed Product as determined in accordance with United States generally accepted accounting principles (GAAP).

1.5 “First Commercial Sale” means the first Sale of a Licensed Product by the Licensee, its Affiliates or its Sublicensees to a Third Party, under an approved NDA by the U.S. Food and Drug Administration or the equivalent in another country.

1.6 “First Indication” means the treatment of Head and Neck (H&N) cancer in humans.

1.7 “For Value” means any consideration, remuneration or benefit of any kind, whether received directly or indirectly, including, but not limited to, cash, equity, debt, preferential treatment, including waiver, rebate, discount, etc.

1.8 “Inventions” means discoveries, designs, developments, methods, modifications, improvements, compositions of matter, methods of use, processes of preparation, formulae, techniques, and trade secrets based on the Ad/PNP-F-araAMP Technology, whether or not patentable.

1.9 “Inventors” means Dr. Eric J. Sorscher (UAB) and Dr. William B. Parker (SR).

1.10 “Know How” means any and all proprietary information which pertain to the Invention or Ad/PNP-F-araAMP Technology (whether patentable or not) including (a) ideas, discoveries, inventions, improvements, technology or trade secrets, (b) methods, procedures, formulas, processes, tests, assays, techniques, regulatory requirements and strategies, (c) biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical or safety data and information, (d) technical and nontechnical data and other information related to the foregoing, and (e) drawings, plans, designs, diagrams, sketches, specifications, laboratory notebooks, or other documents containing or relating to such information.

1.11 “Licensed Field of Use” means all therapeutic uses.

1.12 “Licensed Patents” means all existing patents and/or patent applications owned or controlled by Licensor, covering the Ad/PNP-F-araAMP Technology including (a) the patents and/or patent applications set forth on attached Exhibit A, (b) any foreign patent applications based thereon, (c) all patents proceeding from such domestic and foreign patent applications, (d) all divisionals, continuations, reissues, reexaminations and extensions of any patent or patent application described in (a) - (c) above.

1.13 “Licensed Product” means a product that includes the Ad/PNP-F-araAMP Technology, including its individual components, Ad/PNP and any product or part thereof, process or service, the development, manufacture, use, import, export, offer for sale or sale of which, but for the licenses granted hereunder, would infringe a Valid Patent Claim set forth in any Licensed Patent.

1.14 “Licensed Territory” means worldwide.

1.15 “Net Sales” means the gross amount set forth on the invoice relating to any Sale of a Licensed Product by the Licensee, its Affiliates or its Sublicensees, less (a) discounts actually allowed, (b) rebates, price reductions, rebates to social and welfare systems, charge backs, government mandated and similar rebates, (c) credits for claims, allowances, retroactive price reductions or returned goods, (d) prepaid freight and insurance, (e) customs duties, sales taxes or other governmental charges actually paid in connection with such Sale (but excluding income tax). Where a Licensed Product is not used, transferred or exchanged For Value, the Net Sales will be fair market cash value for such transaction to be agreed upon between the Parties. The following shall be excluded from Net Sales: Licensed Product for use in clinical trials or other scientific testing, clinical samples, charitable donations, promotional samples, and compassionate use and named patient samples, or other similar programs or studies.

1.16 “Parties” means Licensor and the Licensee, and each of them individually is a “Party”.

1.17 “Person” means an individual, corporation, partnership, trust, business trust, association or any other entity with a separate legal identity, including the Parties.

1.18 “Protection Activities” means taking all actions deemed necessary and desirable to protect the Licensed Patents, including, but not limited to, obtaining, filing for, securing, pursuing, prosecuting, and continuing or maintaining the Licensed Patents, but does not include litigation or inter-partes or adversarial activities.

1.19 “Protection Expenses” means all legal fees, costs and expenses reasonably incurred by Licensor in the performance of the Protection Activities, such fees, costs and expenses to be documented by written invoice.

1.20 “Representative(s)” means, with respect to each Party and their Affiliates, all directors, officers, employees, agents and advisors, and with respect to UABRF, the trustees of the University of Alabama System.

1.21 “Sale or Sales” means any use, transfer or exchange, For Value or otherwise, of a Licensed Product. Sales include all Sales by the Licensee, its Affiliates, and its Sublicensees and includes any transfer by the Licensee For Value to an Affiliate or a Sublicensee and by a Sublicensee to an Affiliate where there is no subsequent Sale (i.e., the Licensed Product is not further resold or transferred).

1.22 “Second Indication” means the treatment of an indication other than Head and Neck Cancer, and includes all subsequent indications after the First Indication.

1.23 “Sublicensee” means a Person, other than an Affiliate, who directly or indirectly has acquired rights to the Licensed Patents through an independent Third Party sublicensing arrangement pursuant to Section 2.5 of this Agreement.

1.24 “Third Party” means any Person other than the Parties and their Affiliates.

1.25 “United States” means the United States of America.

1.26 “Valid Patent Claim” means (i) a pending patent claim in an application included within the Licensed Patents, or (ii) an issued and unexpired patent claim included within the Licensed Patents which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, to which an appeal has not or cannot be taken within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

**SECTION 2 GRANT OF LICENSE**

2.1 Grant of License. Subject to the terms and upon the conditions set forth in this Agreement, Licensor hereby grants to the Licensee an exclusive, sublicensable right and license, subject to the terms and conditions of this Agreement, to (a) practice the Licensed Patents and Know-How, and (b) make, have made, develop, use, lease, offer to sell, sell, import and export Licensed Products, within the Licensed Field of Use in the Licensed Territory during the Term.

2.2 Rights of the United States Government. It is understood that if a United States governmental authority has funded research, during the course of or under which the Licensed Patent(s) was conceived or made, the United States government is entitled, as a right, under the provisions of 35 U.S.C. §§ 200-212 and applicable regulations of Chapter 37 of the Code of Federal Regulations, to a non-exclusive, non-transferable, paid-up license to practice or have practiced and use the affected Licensed Patents for governmental purposes. The Licensee acknowledges that the rights and license granted to it pursuant to this Agreement are subject to any and all rights of the United States government.

2.3 Reservation of Rights by Licensor and their Affiliates. Licensor reserves the right, for themselves and for their Affiliates to:

(a) practice and use, and to permit their Representatives to practice and use, the Licensed Patents within the Licensed Field of Use for non-commercial educational and research purposes and permit their respective Representatives to disseminate and publish scientific findings from research related to the Licensed Patents subject to thirty (30) day review by Licensee. If Licensee identifies patentable subject, matter during its review, Licensor shall delay such publication by an additional sixty (60) days to enable Licensee to protect such patentable subject matter; and

(b) grant to non-profit academic, educational or research institutions and governmental authorities, non-exclusive, royalty-free licenses to make and use the Licensed Patents within the Licensed Field of Use for non-commercial and non-clinical educational and research purposes and to permit their representatives to disseminate and publish scientific findings from such research related to the Licensed Patents subject to thirty (30) day review by Licensee. If Licensee identifies patentable subject, matter during its review, Licensor shall delay such publication by an additional sixty (60) days to enable Licensee to protect such patentable subject matter.

2.4 Title Remains with Licensor. All right, title and interest in and to the Licensed Patents remains with Licensor. Except as provided in this Agreement, no express or implied licenses with respect to the Licensed Patents or any other rights are transferred or granted to the Licensee by implication, estoppel, or otherwise.

2.5 Right to Grant Sublicenses. The Licensee has the right to grant sublicenses to any Person under this Agreement on the following terms and conditions:

(a) the execution of a sublicense shall not in any way diminish, reduce or eliminate any of the Licensee’s obligations under this Agreement, and the Licensee shall remain primarily liable for such obligations and any breach of any provision of this Agreement by a Sublicensee;

(b) the Licensee shall provide UABRF with a copy of any such sublicense granted by it under this Agreement within thirty (30) days of the execution of the sublicense;

(c) Licensor shall be third party beneficiary to each sublicense and each agreement evidencing a sublicensing arrangement shall include a statement and an acknowledgement by each Sublicensee to this effect;

(d) the Licensee may not sublicense the right to prosecute or protect the Licensed Patents to a Sublicensee;

(e) each Sublicensee shall obtain and maintain insurance coverage as described in Section 8.2;

(f) each Sublicensee shall be subject to indemnification obligations as described in Section 11.2; and

(g) in the event this Agreement is terminated or upon the expiration of the Term, (i) the Licensee shall notify each Sublicensee of the termination or expiration, (ii) each sublicense will terminate simultaneously with the termination or expiration of this Agreement, and (iii) each Sublicensee may enter into a license agreement with UABRF on substantially the same financial terms as the Sublicensee’s sublicense with the Licensee with UABRF’s approval (which approval shall be granted subject to such Sublicensee’s agreement to the terms as required in this Section).

**SECTION 3 DEVELOPMENT AND COMMERCIALIZATION**

3.1 Development and Commercialization Plan*.* During the Term, the Licensee shall use good faith, reasonable commercial efforts to develop, manufacture, commercialize and market Licensed Product through a diligent program designed to accomplish the commercial exploitation of the same and to make the Licensed Product covered by or embedded in the Licensed Patents available to the general public in accordance with the procedures and practices that are usual and customary for similar technologies and industries. The Parties acknowledge that the development and commercialization plan and milestones set forth below are reasonable. The Licensee shall use good faith, reasonable commercial efforts to achieve the milestones set forth below.

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| **#** | **Development and Commercialization Plan** | **Date** |
| 1 | Licensee retains a CRO within six (6) months of Effective Date. | As indicated |
| 2 | Licensee shall complete the Phase II trial for the First Indication within three (3) years of execution of this Agreement. |  |
| 3 | Licensee obtains first regulatory approval of the First Indication by the U.S. FDA or a health authority of a member state of the European Union within 8 years of execution of the Agreement. |  |
| 4 | Approval for initiation of first phase II trial for a second indication (non-  H&N) for Licensed Product within 7 years of execution of the Agreement. |  |

\* Should Licensee fail to retain a CRO within six (6) months of execution of the Agreement, Licensee will notify Licensor and will provide an explanation for the failure to engage a CRO within the 6-month timeframe and a summary of Licensee’s strategy to resolve the issue. If a qualified CRO has not been contracted by nine (9) months following the execution of this Agreement, Licensor shall be entitled to a one-time penalty fee in the amount of \*\*\*U.S. Dollars ($\*\*\*), payable immediately.

3.2 Development, Commercialization and Royalty Report. The Licensee shall provide UABRF, on each January 31 following the Effective Date, with written annual progress reports summarizing the activities of the Licensee relating to the development and commercialization plan. After the First Commercial Sale, the Licensee shall provide to UABRF written quarterly royalty reports, within forty-five (45) days after the first day of each of January, April, July, and October, setting forth all applicable information specified in Exhibit B. For example, if the First Commercial Sale happens on February 1, the first such quarterly report shall be due within 45 days after April 1st. Concurrently with the sending of such report to UABRF, the Licensee will pay UABRF all royalties dues under Section 5.4.

3.3 Patent Markings. The Licensee shall ensure that each Licensed Product manufactured and/or sold in the United States shall bear patent markings that meet all applicable requirements of 35 U.S.C. §287, as amended from time to time. All Licensed Products manufactured and/or sold outside of the United States shall be marked in such a manner as to conform to the applicable law of such country/jurisdiction.

3.4 Manufacturing in the United States. The Licensee acknowledges that, unless otherwise waived by the governmental authority that funded the development of the Licensed Patents, it is required to substantially manufacture in the United States any Licensed Products sold in the United States covered by the Licensed Patents.

**SECTION 4 PROTECTION OF THE LICENSED PATENTS; PATENT PROSECUTION**

4.1 Patent Protection Activities.

(a) *Licensee has Primary Responsibility.* Subject to the terms and conditions set forth in this Agreement, the Licensee shall be primarily responsible for undertaking all Protection Activities relating to the Licensed Patents.

(b) *Co-operation of the Licensor*. UABRF (as representative of the Licensor) shall cooperate fully with the Licensee and its designated legal counsel in connection with the Protection Activities.

(c) *Consultation with the Licensor.* The Licensee shall, and shall cause its designated legal counsel to, consult with UABRF (as representative of the Licensor) and provide to UABRF (as representative) all related documentation pertaining to substantive prosecutorial matters arising in connection with such Protection Activities, and UABRF (as representative) shall be given reasonable opportunity to discuss, advise and review issues with the Licensee and the Licensor’s designated legal counsel, which the Licensee will reasonably consider. The Licensee shall reimburse UABRF for all reasonable external expenses associated with such advise and review.

(d) *Foreign Protection Requested by the Licensee.* The Licensee must notify UABRF (as representative of the Licensor) in writing identifying foreign countries and jurisdictions, if any, the Licensee shall file foreign applications in and undertake Protection Activities in with respect to any Licensed Patents which have not yet entered the national stage of prosecution. The Parties acknowledge that the deadline has passed to enter any of current Licensed Patents in Exhibit A into additional foreign countries.

(e) *Foreign Patent Protection Not Requested by the Licensee.* Licensor may elect to undertake Protection Activities with respect to any Licensed Patents in any country or jurisdiction not so designated by the Licensee pursuant to Section 4.1(d) above. In such cases (i) the Licensor shall be responsible for all Protection Expenses incurred in connection therewith and the Licensee shall not be responsible for such expenses, (ii) the Licensed Patents so affected shall no longer be deemed to be licensed to the Licensee, (iii) the Licensee shall forfeit and shall no longer have any rights or obligations with respect thereto and (iv) Exhibit A shall be deemed to be amended accordingly to delete the affected Licensed Patents.

(f) *Terminated Licensed Patents.* The Licensee may, at any time during the Term, provide at least sixty (60) days written notice to UABRF (as representative of the Licensor) that it no longer wishes to be responsible for the Protection Expenses in connection with one or more Licensed Patents on a country-by-country basis. In such cases, (i) the Licensee shall continue to be responsible for all Protection Expenses incurred in connection therewith until the expiration of such sixty (60) day notice period and thereafter shall not be responsible for such expenses, and (ii) the Licensed Patent(s) so affected shall no longer be deemed to be licensed to the Licensee and Exhibit A shall deemed to be amended accordingly.

4.2 Patent Term Extensions.

(a) The Parties acknowledge that a Licensed Patent may be eligible for a patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, (the “Hatch-Waxman Act”) codified as 35 U.S.C. § 156, which permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. The Parties agree to cooperate to seek the benefit of a patent term extension of a Licensed Patent in the United States where possible which covers a Licensed Product. The Licensee shall have the sole responsibility to submit a Request for a Patent Term Extension at the U.S. Patent Office, and the Licensor shall fully cooperate with such submission, including providing and executing documents where necessary or useful that may include a Power of Attorney to act in the name of Licensor. Reasonable external expenses incurred by Licensor for providing such assistance shall be reimbursed by the Licensee.

(b) The Licensee shall also have the sole responsibility to file for any corresponding patent extensions in foreign countries, including Supplementary Protection Certificates in Europe, and the Licensor shall provide full cooperation, including by the prompt execution of any necessary or useful documents, that may include a Power of Attorney to act in the name of Licensor. Reasonable external expenses incurred by Licensor for providing such assistance shall be reimbursed by the Licensee.

**SECTION 5 FINANCIAL TERMS**

5.1 Patent Protection Expenses. During the Term and with respect to the Licensed Patent(s), the Licensee will be financially responsible for the payment of all Protection Expenses incurred after the Effective Date. The Licensee shall pay such amounts to UABRF (as representative of the Licensor) within thirty (30) days of receipt of an invoice for the same from UABRF.

5.2 Milestone Payments. During the Term, the Licensee shall pay to UABRF (as representative of the Licensor) the development and commercialization milestone payments as set forth below. Each such milestone payment is non-creditable and non-refundable and shall be due within thirty (30) days of achievement. The Licensee shall provide written notice to UABRF (as representative of the Licensor) to accompany the payment identifying the milestone that has been achieved.

|  |  |
| --- | --- |
| **Milestones** | **Payment** |
| FDA NDA/BLA accepted for review for the First Indication of a Licensed Product | $\*\*\* |
| First FDA regulatory approval of the Licensed Product for the First Indication. | $\*\*\* |
| First approval of the Licensed Product for the First Indication by a health authority within a member state of the European Union. | $\*\*\* |
| First human dosed with Licensed Product in a first Phase II trial for a Second Indication | $\*\*\* |
| First Regulatory approval of the Licensed Product for a Second Indication by the U.S. FDA or a health authority of a European Union member | $\*\*\* |

(i) For the avoidance of doubt, no payments shall be due for expansion of an existing Indication to a subset of that Indication.

(ii) Each Development Milestone Payment shall be payable only once for the First Indication and only once for the Second Indication, and after which no further Development Milestones shall be due.

5.3 Running Royalty Payments. During the Term and with respect to each country or jurisdiction within the Licensed Territory, the Licensee shall pay to UABRF, as the representative of Licensor, a continuing royalty of \*\*\*percent (\*\*\*%) on all Net Sales of Licensed Products, irrespective of whether such Sale was made by Licensee, its Affiliates or Sublicensees, arising in such country/jurisdiction until the expiration of the last Valid Patent Claim in that country/jurisdiction. All such amounts shall be paid concurrently with the royalty reports per Section 3.2.

5.4 Royalty Stacking. The royalty rate for Net Sales of Licensed Products (as described under

5.3) in the patented territory shall be reduced pro rata once the total royalty burden that the Licensee is obligated to pay to the Licensor and any third parties for a single product reaches an aggregate total of ten percent (10%), such that Licensee royalty burden does not exceed ten percent (10%). Notwithstanding the above, the running royalties owed to the Licensor hereunder shall never be below \*\*\*percent (\*\*\*%). Any foreign currency exchange shall be at the applicable rates published in the Wall Street Journal on the last day of the reporting period.

5.5 Sublicensing Income Payments. The Licensee, for payments received by it in exchange for granting a sublicense to a Sublicensee, excluding any Licensee’s Affiliates, during the Term, shall pay to UABRF the following:

|  |  |
| --- | --- |
| **Payment from Sublicensee** | **Percentage of Payment** |
| Upfront fees, maintenance fees, milestone payments, etc from Sublicensee. For clarity, any income received by Licensee outside of that captured in | \*\*\*% |
| section 5.3 shall be considered as due under this section 5.5. |  |
| Margin on Transfer Pricing\* | \*\*\*% |
| Royalty payments from Sublicensee | \*\*\*% |

\*Margin on Transfer Pricing shall mean (price paid to Licensee by Sublicensee for Licensed Product) (Licensee’s Cost of Goods + 10% administrative charge + outbound freight, shipment, and insurance costs + excise taxes, use taxes, tariffs, sales taxes, and customs duties, and other governmental charges imposed on the sale of such Licensed Product, which are not reimbursed by Sublicensee).

Further, such payments shall be accompanied by a written notification of the nature and origin of the payment and the identity of the payor. For clarity, no payments shall be due to UABRF for any reimbursements by a Sublicensee to Licensee for any costs incurred by Licensee, including but not limited to reimbursement of research or development costs of Licensed Product.

5.7 Royalty Payments based on Net Sales effected by its Affiliates and Sublicensees. The Licensee shall pay to UABRF an amount equal to that which the Licensee would have been required to pay to UABRF had the Licensee effected the Sales actually effected by its Affiliates and Sublicensees.

5.8 Address for Payments. Except as otherwise directed by UABRF, all amounts due to be paid by the Licensee to UABRF (as representative of the Licensor) pursuant to this Agreement shall be paid to UABRF at the address set forth below its signature on the signature page of this Agreement.

5.9 Late Payment Penalty. The balance of any undisputed amount which remains unpaid more than thirty (30) business days after it is due to UABRF (as representative of the Licensor) shall accrue interest until paid at the rate equal to the lesser of one percent (1%) per calendar month or the maximum amount allowed under applicable law. Disputed amounts shall be subject to the dispute resolution procedures of Section 12.8 and the Late Payment Penalty waived during the dispute period. If it is determined that the Licensee owes the disputed amount, then the Late Payment Penalty shall be due retroactively to the due date and during the dispute period. However, in no event shall this interest provision be construed as a grant of permission for payment delays.

5.10 Currency Conversion. All amounts due to be paid to UABRF (as representative of the Licensor) pursuant to this Agreement shall be made in United States dollars. Any and all amounts received by the Licensee or generated in foreign currency shall be converted into United States dollars at the official rate of exchange from such currency to United States dollars at the rate quoted in the Wall Street Journal (United States edition) for the last business day of the calendar quarter in which payment is due to UABRF (as representative of the Licensor) or on a business day no earlier than five (5) business days before payment is made to UABRF.

**SECTION 6 RECORDKEEPING AND AUDIT RIGHTS**

6.1 Books and Records. The Licensee shall keep complete and accurate books, accounts and other records and documentation necessary to ascertain all transactions and events pursuant to which payments due to the Licensor under this Agreement arise or are accrued. All such books, accounts and other records and documentation shall be kept at the Licensee’s principal place of business for a period of not less than six (6) years following the end of the calendar year to which they pertain.

6.2 Right to Audit. The Licensor shall have the right to have the Licensee’s books and records audited by an external, qualified, independent certified public accounting firm of their choosing, under appropriate confidentiality provisions such as those set forth in Section 8.3 of this Agreement, to ascertain the accuracy of the reports and payments due to the Licensor under this Agreement and compliance by the Licensee, its Affiliates and its Sublicensees with their obligations pursuant to this Agreement and any sublicense. Such audit shall be conducted on thirty (30) days advance notice during normal business hours but not more than once in any twelve (12) month period. No more than the prior thirty-six (36) months can be audited during an audit. If any such examination reveals that the Licensee has underpaid or underreported any amount due under this Agreement, the Licensee shall promptly pay to UABRF (as representative of the Licensor) the amount so underpaid or underreported. If such underpayment or underreporting exceeds five percent (5%) for any twelve (12) month period examined, the Licensee shall immediately reimburse UABRF (as representative of the Licensor) the full costs and expenses incurred by it with respect to the audit. If the examination reveals that the Licensee has overpaid the amounts due to the Licensee by greater than five percent (5%) of the amount due for any twelve (12) month period examined), an amount equal to such overpayment shall be credited by the Licensor towards future royalty payments by the Licensee.

**SECTION 7 INFRINGEMENT; ENFORCEMENT**

7.1 Biologics Price Competition and Innovation Act (BPCIA). The Parties acknowledge that Licensed Products are reviewed in the United States by the FDA Center for Biologics Evaluation and Research and regulated under the Biologics Price Competition and Innovation Act, which provides an abbreviated pathway for biosimilar or interchangeable products to be approved by the FDA. Under 42 U.S.C. 351(k), patents that may be infringed by a sponsor of a biosimilar or interchangeable product must be in the “List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability” (referred to as the “Purple Book”). The Licensor agrees to reasonably cooperate with the Licensee in assisting it in listing all appropriate Licensed Patents during a BPCIA biosimilar procedure, including by providing and executing documents. The Licensor further agrees to reasonably cooperate with the Licensee in any exchange of information with a sponsor of a biosimilar or interchangeable product as allowed under 42 U.S.C. 351(k). Reasonable external expenses incurred by Licensor for providing such assistance shall be reimbursed by the Licensee.

(a) The Licensor also agrees to assist the Licensee as necessary or useful to prepare and submit a list of Licensed Patents that may be infringed by a sponsor of a biosimilar or interchangeable product under any corresponding procedure in a foreign country, including in China under Art. 76 of the 4th Amendment to the 1984 Patent Act. Reasonable external expenses incurred by Licensor for providing such assistance shall be reimbursed by the Licensee.

7.2 Notification of Infringement. During the Term, each Party shall provide prompt written notice to the other Party of any actual infringement or suspected/potential infringement of the Licensed Patents of which such Party is or becomes aware and shall provide, to the extent reasonable and practicable, any available evidence of such infringement by a Third Party (an “Infringement Notice”).

7.3 Licensee Right to Pursue/Prosecute. During the Term, the Licensee shall have the first right to resolve, in the Licensed Field of Use and in the Licensed Territory, any suspected/potential infringement and, in those jurisdictions in which the Licensee may file suit without the requirement that the owners of the Licensed Patents are parties to the lawsuit/action, prosecute any infringement of any Licensed Patents, in its own name and at its own expense, provided the Licensee remains in compliance, in all material respects, with its obligations under this Agreement. In those jurisdictions in which the owner of the Licensed Patents must participate as parties to the lawsuit/action, the Licensee may name UABRF/SR as a party for standing purposes only, upon written approval of the Board of Trustees of the University of Alabama.

The Licensee agrees to use reasonable efforts to abate or terminate such infringement without resorting to litigation when appropriate, which may include negotiating and executing a sublicense agreement which complies with the terms of Section 2.5 of this Agreement. Before the Licensee commences any legal action with respect to any infringement or potential infringement, it shall give careful consideration to: a) the views of the Licensor; b) there being reasonable legal and economic bases for doing so and c) giving the Licensor twenty days’ notice before commencing such legal action, where possible. The Licensor shall use reasonable efforts to cooperate with the Licensee in connection with any remedial action undertaken by the Licensee, including if Licensee commences a lawsuit. The Licensee shall be responsible for the costs and expenses incurred by Licensor with respect to such cooperation.

7.4 Control of Suit; Joinder; Expenses.

(a) *Initiated by the Licensee.* If the Licensee wishes to commence a lawsuit, it will endeavor to do so within ninety (90) days following (i) the commercial marketing of the Licensed Product by the infringer based on a regulatory drug approval, (ii) statutory authorization to bring an infringement suit prior to commercial marketing based on a drug approval or (iii) if the infringement is not based on regulatory review and approval, then based on a date of notification of relevant infringement pursuant to Section 7.2, except where it is reasonably pursuing other action (including negotiation) to terminate such infringement.

(b) *Initiated by Licensor.* If the Licensee elects not to exercise its right to commence, or fails to commence, an action within ninety (90) days of regulatory approval and commercial marketing of an infringing product, the Licensor may do so at its own expense, and shall retain sole control over the direction of such lawsuit. The Licensee shall cooperate fully with the Licensor in connection with such lawsuit and shall be responsible for the costs and expenses incurred by it with respect to its own co-operation.

(c) *Joinder by the Licensor.* The Licensor, to the extent permitted by applicable law, may elect to join in as a party to any infringement lawsuit initiated by the Licensee, and pay their own costs of such participation, however, the Licensee shall remain in sole control of the litigation. If the Licensor are involuntarily joined as parties to a lawsuit initiated by the Licensee, the Licensee shall pay all reasonable legal fees, costs and expenses incurred by the Licensor arising out of such joinder and participation, including, but not limited to reasonable legal fees, costs and expenses reasonably incurred by legal counsel selected and retained by the Licensor to represent them in such lawsuit.

7.5 Settlement. The Licensee may settle, enter into a consent judgment or other voluntary final disposition of any lawsuit initiated by it or to which it is a party, as long as it does not admit the invalidity or unenforceability of a Licensor’s Licensed Patent. Neither Party may settle or otherwise dispose of any lawsuit to which it is a party, which admits liability on the part of the other Party or which requires the other Party to pay money damages nor issue a formal statement without such other Party’s prior written consent.

7.6 Recoveries.

(a) With respect to any lawsuit commenced by the Licensee in which the Licensor is not a party pursuant to Section 7.3(a) above, or in which the Licensor is joined as a party pursuant to Section 7.3(c) above, any recovery of damages shall first be applied in satisfaction of the costs and expenses incurred by the Parties in bringing and handling such lawsuit, including attorneys’ fees, provided they are reasonably incurred, and any balance shall be shared as 70% to Licensee and 30% to Licensor

(b) *Lawsuit initiated by Licensor.* With respect to any lawsuit commenced solely by the Licensor pursuant to Section 7.4(b) above, all recoveries of damages shall belong to the Licensor . Furthermore, the Licensee shall pay over to UABRF (as representative of the Licensor) any payments designated as “royalties” made by the alleged infringer to the Licensee under any existing or future sublicense authorizing Licensed Products.

**SECTION 8 OTHER COVENANTS AND AGREEMENTS**

8.1 Use of Names. No Party may, without the prior written consent of the other Party:

(i) use (a) the name of the other Party or its Affiliates, if applicable, (b) the name or image of any Representative of the other Party, or (c) any trade-name, trademark, trade device, service mark or symbol owned by the other Party in any press release, publication, marketing or advertising material; or

(ii) represent, either directly or indirectly, that any product or service of the other Party is a product or service of the representing Party or that it is made in accordance with or utilizes the information or documents of the other Party.

Notwithstanding the above, the Licensee may disclose that it has received a license to Licensed Patents owned by the Licensor in connection with any Licensed Product and the Licensor may disclose that they have granted a license to the Licensee, and either Party may use the name of the other Party to the extent such use is reasonably necessary for complying with applicable law.

8.2 Insurance Coverage. Upon the Effective Date of this Agreement and during the Term of this Agreement, the Licensee shall purchase and maintain insurance coverage in type and amounts that are sufficient to fulfill the Licensee’s contractual obligations under this Agreement including, but not limited to, its indemnification and warranty obligations. For clarification, the Licensee shall obtain and maintain product liability insurance in an amount that is customary for the stage of product development and, if applicable, prior to commencing a clinical trial shall obtain and maintain clinical trial coverage in an amount of at least $10 million per occurrence. All insurance coverage shall be primary to any coverage carried by UABRF, SR and their respective Affiliates, be placed with a reputable insurance company with an A.M Best rating of at least A-X, list UABRF, SR and their respective Affiliates as additional insureds and waive all rights of subrogation against any additional insureds. If such insurance coverage is written on a “claims made” basis, the Licensee agrees to provide such coverage for ten years after this Agreement expires or is terminated. Upon UABRF’s (as representative of the Licensor) prior written consent such insurance coverage may be maintained through a self-insurance program, provided it has an acceptable risk management. The Licensee shall provide certificates of insurance evidencing the Licensee’s insurance coverage to UABRF (as representative of the Licensor) upon UABRF’s (as representative) reasonable request and prior to, if applicable, commencing its first clinical trial and the First Commercial Sale of a Licensed Product. The Licensee shall provide UABRF (as representative) with at least thirty (30) days prior written notice of any change in the terms or cancellation of coverage.

8.3 Confidentiality.

(a) *Superseding of Prior CDAs.* The Confidentiality provisions of Section 8.3 shall supersede any previous confidentiality agreements between the Parties.

(b) *Exchange of Proprietary Information.* The Parties acknowledge that during the Term they are likely to share information with each other that they each consider to be confidential and proprietary (“Proprietary Information”). For the purposes of this Agreement, the Party that discloses Proprietary Information shall be referred to as the “Disclosing Party” and the Party receiving the Proprietary Information, the “Receiving Party.”

(c) *Nature of Proprietary Information.* The Parties agree that all information that is provided to the other Party shall be deemed to be Proprietary Information.

(d) *Restrictions.* With respect to all Proprietary Information disclosed to it, the Receiving Party (i) shall keep it confidential (other than as permitted by this Agreement), (ii) shall store and maintain it with the same diligence and care as its own proprietary information, but no less than reasonable diligence and care, (iii) may only use it for the purpose for which it was disclosed by the Disclosing Party, (iv) may not disclose it (other than as permitted by this Agreement), (v) may not deconstruct, modify or copy it (other than as permitted by this Agreement), and (vi) may not transfer or assign it to any Third Party.

(e) *Access to the Proprietary Information.* The Proprietary Information may be used by, and disclosed to, on an “as-needed” basis, the Receiving Party’s Representatives. The Licensee may disclose Proprietary Information relating to the Licensed Patents to investors, prospective investors, consultants, collaborators and other Third Parties in the chain of manufacturing and distribution, if and only if, the Licensee obtains from such recipient a written confidentiality agreement, the provisions of which are at least as protective of The Licensor’s Proprietary Information as these set forth in this Section 8.3. Each Party will promptly notify the other Party of any unauthorized use of or access to the Proprietary Information of which it becomes aware.

(f) *Exceptions to Confidentiality Obligation.* The restrictions of confidentiality described above shall not apply to Proprietary Information (i) which as of the Effective Date or subsequently becomes available to the public without breach of this Agreement, (ii) if it is lawfully obtained from a Third Party not bound by similar confidentiality and use restrictions and obligations, (iii) if it is known by the Receiving Party prior to disclosure as evidenced by contemporaneous records, or (iv) if it is at any time developed by the Receiving Party independently of any disclosure made pursuant to this Agreement. In addition, the confidentiality obligations shall not apply to the Receiving Party if the Receiving Party is legally required by applicable law, court order or governmental authority to disclose the Proprietary Information, provided the Receiving Party discloses only the minimum to comply and, makes commercially reasonable efforts to provide prior notice to the Disclosing Party to enable it to contest the requirement or to seek a protective order.

(g) *Termination or Expiration of this Agreement*. Upon the expiration of the Term, or the earlier termination of this Agreement, each Receiving Party shall, at the Disclosing Party’s option and upon written notice thereof to the Receiving Party, return all Proprietary Information, copies and other tangible expressions thereof, to the Disclosing Party or provide the Disclosing Party with written notice that the Proprietary Information in its possession, or in the possession of its Representatives, has been destroyed within thirty (30) days after receipt of the Disclosing Party’s written notice to the Receiving Party requiring the Receiving Party to destroy the Proprietary Information in its possession. The Receiving Party may retain one archival copy of the Proprietary Information for purposes of compliance of its obligations under this Agreement.

(h) *Continuing Obligations after Termination/Expiration.* The restrictions and obligations set forth in Section 8.3(c) above shall continue for five (5) years from the termination or expiration of this Agreement.

8.4 UABRF/SR Interinstitutional Agreement

(a) The Parties acknowledge that UABRF and SR entered into an Interinstitutional Agreement on September 27, 2021 that governs the rights and responsibilities between UABRF and SR pertaining to this Agreement, a Confidential copy of which has been provided to the Licensee.

(b) UABRF represents that the Institutional Agreement remains in force and has not been breached by either Party and will not be amended in a manner that adversely affects the Licensee’s rights or obligations without the written consent of the Licensee.

(c) Under the Interinstitutional Agreement, UABRF and SR have agreed that UABRF shall control all licensing activities that pertain to this Agreement, including notice and financial rights and obligations of the Parties.

(d) UABRF agrees that the Licensee may fully satisfy its obligations under this Agreement by providing notice only to UABRF and by remitting payment obligations only to UABRF. SR shall not have an independent right to object to any notice or payment provided to UABRF, even if there is a disagreement between UABRF and SR about payment terms or SR receipt of notice or payment.

**SECTION 9 TERM AND TERMINATION**

9.1 Term. This Agreement shall commence on the Effective Date and shall continue, on a country-by-country basis, until the date of expiration of the last to expire of any Valid Patent Claim (inclusive of any extensions, supplementary protection certificates or their equivalents) within the Licensed Patents, unless terminated sooner in accordance with the terms of this Agreement (the “Term”).

9.2 Termination by the Licensee. The Licensee may terminate this Agreement at any time, in its sole discretion, by giving not less than ninety (90) days prior written notice to UABRF (as representative of the Licensor). Upon the reasonable request of UABRF (as representative), the Licensee shall provide assistance, at its expense, to UABRF (as representative) to enable the Licensor to facilitate and effect the transfer of applicable information and documents regarding the Licensed Patents to a new licensee.

9.3 Termination by the Licensor. The Licensor, acting through UABRF as representative, shall have the right to immediately terminate this Agreement upon the occurrence of any one or more of the following events:

(a) if the Licensee is in material default of any provision of this Agreement or its obligations under this Agreement and such default has not been remedied within the cure period (which may not be less than forty five (45) days) specified in a notice to cure from UABRF (as representative of the Licensor);

(b) if the Licensee fails to make a payment due under this Agreement and fails to cure such non-payment within forty-five (45) days of receipt of a non-payment notice from UABRF (as representative of the Licensor), or the Licensee fails to cure nonpayment of a minimum annual payment, unless such payment is disputed and the dispute process of Section 12.8 is initiated by the Licensee, in which case termination shall be stayed during the dispute period;

(c) if the Licensee fails to meet the development and commercialization milestones according to the development and commercialization plan set forth in Section 3.1, and Licensee has not amended the development and commercialization plan pursuant to Section 3.1 within 90 business days in writing;

(d) if an examination by the Licensor pursuant to Section 6.2 shows an underreporting or underpayment by the Licensee in excess of fifteen percent (15%) of the total amount due to the Licensor under this Agreement in any twelve (12) month period and such underreporting and amount due are not paid to the Licensor within 20 business days of undisputed confirmation;

(e) if the Licensee is convicted of a felony within the United States or similar crime in a jurisdiction outside of the United States relating to the manufacture, use or sale of a Licensed Product;

(f) if the Licensee shall become insolvent, shall make an assignment for the benefit of its creditors, or shall have a petition in bankruptcy filed for or against it which is not resolved within 180 days thereof; or

(g) if the Licensee fails to provide UABRF (as representative of the Licensor) with at least thirty (30) days prior written notice of any change in the terms or cancellation of insurance coverage as described in Section 8.2.

9.4 Effect of Termination or Expiration. Any termination or expiration of this Agreement will not relieve either Party of any obligation or liability accrued prior to such termination or expiration. Upon termination of this Agreement for an uncured breach after the dispute process of Section 12.8 is concluded, the Licensee shall a) submit a final report as described in Section 3.2; b) suspend its manufacture, use and sale of Licensed Products if requested by the Licensor and is in the reasonable best interest of patients receiving the drug; c) provide UABRF (as representative of the Licensor) with all data and know-how developed by the Licensee in the course of developing the Licensed Products at cost and the Licensor shall have the right to use such data and know-how for any purpose whatsoever, including the right to transfer same to future licensees; and d) provide UABRF (as representative of the Licensor) copies of any regulatory information filed with any U.S. or foreign government agency with respect to Licensed Products at cost of preparation and turn-over.

**SECTION 10 REPRESENTATIONS AND WARRANTIES; LIMITATIONS ON THE LICENSOR**’**S OBLIGATIONS**

10.1 Both Parties. Each Party represents and warrants to the other Party that it is duly incorporated, validly existing and in good standing under the laws of the jurisdiction in which it was formed, it has all necessary corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby, that the execution, delivery and performance of this Agreement by it will not conflict with or result in a breach of, or entitle any party thereto to terminate, an agreement or instrument to which it is a party, or by which any of its assets or properties are bound, and that this Agreement has been duly authorized, executed and delivered by it and constitutes a legal, valid and binding agreement of such Party, enforceable against it in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, moratorium, reorganization or other similar laws affecting creditors’ rights generally.

10.2 The Licensee. The Licensee makes the following representations and warranties to the Licensor.

(a) The Licensee possesses the necessary expertise and skill in the technical areas pertaining to the Licensed Patents, to make Licensed Products, and to make and has made, its own evaluation of the capabilities, safety, utility and commercial application of the Licensed Patents.

(b) Any activity undertaken with the Licensed Patents and the Licensed Products will be conducted in compliance with all applicable laws.

10.3 The Licensor. The Licensor makes the following representations and warranties to the Licensee:

(a) The Licensor has the right to grant the license under this Agreement and it has not granted to a Third Party any rights relating to the commercial exploitation of the Licensed Patents.

(b) To the Licensor’s best knowledge and based upon information and representations and warranties made to it by it’s respective Inventor and the assignments signed by the Inventors, the Licensor owns all right, title and interest in the Licensed Patents and there have been no claims made against the Licensor asserting the invalidity or non-enforceability of, or with respect to the Licensed Patents, and the Licensor is not aware that any such claims exist.

(c) To the Licensor’s best knowledge, (i) no action alleging infringement of the intellectual property rights of any Third Party has been made or threatened against the Licensor with respect to the Ad/PNP-F-araAMP Technology or the Licensed Patents, (ii) there is no pending or threatened action or litigation relating to the Ad/PNP-F-araAMP Technology or the Licensed Patents, and (iii) there are no judgements or settlements against or owed by Licensor relating to the Ad/PNP-FaraAMP Technology or the Licensed Patents.

(d) To the best of Licensor’s knowledge, Exhibit A sets forth a true, correct and complete list of the Licensor’s Patents existing as of the Effective Date that the Licensee has practiced with respect to the Licensed Product and the Ad/PNP-FaraAMP Technology.

(e) To the best of the Licensor’s knowledge, the Licensor or its counsel have presented all references, documents, or information for which it or the Inventors (while they were employed by the Licensor) had a duty to disclose under Applicable Law, including 37 C.F.R. 1.56 or its foreign equivalent, to the relevant patent examiners at the relevant patent offices for each Licensed Patent.

10.4 Limitations on the Licensor’s Representations and Warranties. EXCEPT AS SET FORTH IN THIS AGREEMENT, THE LICENSOR MAKES NO OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND. IN PARTICULAR, THE LICENSOR MAKES NO EXPRESS OR IMPLIED WARRANTIES REGARDING MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, VALIDITY AND SCOPE OF ANY LICENSED PATENTS, THE CAPABILITY, SAFETY, EFFICACY, UTILITY OR COMMERCIAL APPLICATION OR USEFULNESS FOR ANY PURPOSE OF ANY LICENSED PATENTS, OR THAT IT WILL NOT GRANT LICENSES TO ONE OR MORE THIRD PARTIES TO MAKE, USE OR SELL PRODUCTS OR PERFORM PROCESSES THAT MAY BE SIMILAR TO AND/OR COMPETE WITH ANY LICENSED PRODUCT.

**SECTION 11 LIABILITY AND INDEMNIFICATION**

11.1 No Liability of the Licensor. The Licensor, none of their respective Affiliates, or any their respective Representatives have any liability whatsoever to the Licensee, its Affiliates or any Sublicensee or any Person for or on account of any injury, loss or damage of any kind or nature, sustained by, assessed or asserted against, or any other liability incurred by or imposed upon the Licensee, its Affiliates or any Sublicensee or any Person, arising out of or in connection with or resulting from:

(a) the use of the Licensed Patents during the Term by the Licensee, its Affiliates and/or its Sublicensees unless there is a breach of a representation or warranty of Licensor including a violation of a duty of disclosure to the U.S. Patent Office or another patent office, provided such omission, breach or violation was not the responsibility of the Licensee to obtain or convey to the U.S. Patent Office or another patent office after licensee assumes control of patent prosecution;

(b) the production, use, practice, lease, or sale of any Licensed Product by the Licensee, its Affiliates and/or its Sublicensees;

(c) any advertising or other promotional activities undertaken by the Licensee, its Affiliates and/or its Sublicensees with respect to (a) and/or (b) above; or

(d) the Licensee’s compliance with, and performance of the Licensee’s representations and warranties given under, and the Licensee’s obligations pursuant to, this Agreement.

11.2 Indemnification by the Licensee. The Licensee agrees to defend, indemnify and hold the Licensor, each of their respective Affiliates, and all of their respective Representatives (collectively, “Indemnitees”) harmless from and against any and all Third Party claims, demands, losses, costs, expenses, deficiencies, liabilities or causes of action of any kind or nature (including, without limitation, reasonable attorneys’ fees and other costs and expenses of defense) (collectively, “Claims”) based upon, arising out of or otherwise relating to:

(a) the use of the Licensed Patents during the Term by the Licensee, its Affiliates and/or its Sublicensees unless there is a breach of a representation or warranty of Licensor including a violation of a duty of disclosure to the U.S. Patent Office or another patent office, provided such omission, breach or violation was not the responsibility of the Licensee to convey to the U.S. Patent Office or another patent office after licensee assumes control of patent prosecution;

(b) the production, use, practice, lease, or sale of any Licensed Product by the Licensee, its Affiliates and/or its Sublicensees;

(c) any advertising or other promotional activities undertaken by the Licensee, its Affiliates and/or its Sublicensees with respect to (a) and/or (b) above; or

(d) the Licensee’s compliance with, and performance of the Licensee’s representations and warranties given under, and the Licensee’s obligations pursuant to, this Agreement.

11.3 Procedures. The Indemnitees agree to provide the Licensee with prompt written notice of any Claim for which indemnification is sought under this Agreement. The Licensee shall, at its own expense, provide attorneys reasonably acceptable to the Licensor (as applicable) to defend against any such Claim. The Indemnitees shall cooperate fully with the Licensee in such defense and will permit the Licensee to conduct and control such defense and the disposition of such Claim (including all decisions relative to litigation, appeal, and settlement, subject to the qualifications set forth in this Section 11.3). The Licensee agrees to keep UABRF (as representative of the Licensor) informed of the progress in the defense and disposition of such Claim and to consult with UABRF (as representative of the Licensor) with regard to any proposed settlement. Neither the Licensee nor the Licensor shall settle any Claim without the prior written consent of the other, which consent shall not be unreasonably withheld.

11.4 Limitation of Liability. Except with respect to (a) breaches of confidentiality obligations under Section 8.3, (b) breaches of the representations and warranties; or (c) matters for which the Licensee is obligated to indemnify the Indemnitees under Section 11.2, neither Party, its Affiliates nor any of their respective Representatives will be liable to the other with respect to any subject matter of this Agreement under any contract, negligence, strict liability or other legal or equitable theory for (a) any indirect, incidental, consequential or punitive damages or lost profits or (b) cost of procurement of substitute goods, technology or services. Nothing in this Section shall relieve either Party from ordinary or direct damages to the other resulting directly from breach of its obligations under this Agreement. The Licensor’s aggregate liability for all damages of any kind arising out of or relating to this Agreement or its subject matter under any contract, negligence, strict liability or other legal or equitable theory shall not exceed the amounts paid to the Licensor under this Agreement.

**SECTION 12 MISCELLANEOUS**

12.1 Entire Agreement. This Agreement is the sole and entire agreement by and between the Parties regarding the subject matter set forth in this Agreement and supersedes all prior agreements. All previous negotiations, statements and preliminary instruments by the Parties with respect to the subject matter hereof are merged in this Agreement.

12.2 No Inducement. No Party has been induced, persuaded or motivated by any promise or representation made by the other Party to enter into this Agreement.

12.3 Independent Contractors. Independent Contractors. The Parties are independent contractors. No Party has the authority to bind or act on behalf of the other Party. The Parties do not intend to create an employer/employee relationship, joint venture or agency relationship.

12.4 No Third Party Beneficiaries. This Agreement is for the exclusive benefit of the Parties and their successors and permitted assignees. No other person or entity shall have any rights under this Agreement, unless and only to the extent permitted by applicable law.

12.5 Assignment. Neither Party shall sell, assign, transfer or otherwise dispose of this Agreement to a Third Party without the prior written consent of the other, which consent shall not be unreasonably withheld, conditioned or delayed except that either Party, without the consent of the other Party, may transfer or assign its rights and obligations hereunder to any of its Affiliates or to a successor to all or substantially all of its business that concerns this Agreement (whether by sale of equity or assets, merger, consolidation or otherwise). The Licensee shall notify UABRF (as representative of the Licensor) of such assignment within thirty (30) days by completing and mailing Exhibit C to UABRF at the address below the signature block of UABRF. Any attempted assignment of this Agreement not in compliance with the terms of this Section 12.5 will be null and void. No assignment will relieve any Party of the performance of any accrued obligation that such Party may then have pursuant to this Agreement.

12.6 Amendments. Any and all modifications to this Agreement shall only be effective and binding if in writing and signed by a duly authorized representative of each Party.

12.7 Notices. Any notice, request, approval or consent required to be given under this Agreement will be in writing and deemed sufficiently given when received, (i) if delivered to a Party in person, (ii) if transmitted by facsimile, when receipt is electronically confirmed; and (iii) if sent by recognized overnight courier or mailed in such Party’s national postal service, certified or registered mail, return receipt requested, postage prepaid to the address appearing below such Party’s signature on the last page of this Agreement, or at such other address as each Party subsequently notifies in accordance with this Section 12.7.

12.8 Disputes.

(a) *Equitable Relief.* Either Party may seek equitable and legal relief in the event of a breach or threatened breach by the other Party of its obligations under this Agreement, without the requirement to post a bond.

(b) *Internal Resolution.* In the event of any dispute arising out of or relating to this Agreement, the Parties shall try to settle such conflicts amicably between themselves in good faith as soon as practicable.

(c) *Mediation.* In the event the Parties are still unable to resolve the dispute by negotiation, the dispute may then be submitted by a Party to a mediator, mutually agreed to by the Parties, for nonbinding mediation. The Parties shall cooperate with the mediator in an effort to resolve such dispute.

(d) *Litigation.* If the dispute is not resolved within sixty (60) days of its submission to the mediator, either Party may resort to litigation.

(e) *Statute of Limitations.* The Parties agree that all applicable statutes of limitation and time-based defenses (including, but not limited to, laches and estoppel) shall

be tolled while the procedures set forth in Section 12.8(c) are pending. The Parties shall cooperate in taking any actions necessary to achieve this result.

12.9 Rights and Remedies. The rights and remedies provided by this Agreement are cumulative and the use of any one right or remedy by any Party shall not preclude or waive the right to use any or all other remedies. Such rights and remedies are given in addition to any other rights the Parties may have by law, statute, ordinance or otherwise.

12.10 Waiver. No term of this Agreement can be waived except by the written consent of the Party waiving compliance. No waiver of a provision, breach or default shall apply to any other provision or subsequent breach or default or be deemed continuous, nor will any single or partial exercise of a right or power preclude any other further exercise of any rights or remedies provided by law or equity.

12.11 Severability. In the event that any covenant, condition, or other provision contained in this Agreement is determined to be invalid, void or illegal, such covenant, condition or other provision shall be deemed deleted from the Agreement and shall not affect the validity of the remaining provisions of this Agreement.

12.12 Force Majeure. No Party shall be liable for any failure to perform its obligations under this Agreement to the extent such failure to perform is due to circumstances or events reasonably beyond such Party’s control; provided that the affected Party uses reasonable efforts to overcome or avoid the effects of such cause and continues to perform its obligations to the extent possible. In such circumstances the time for performance shall be extended by (at least) a period equivalent to the period during which performance of the obligation has been delayed or failed to be performed.

12.13 Survivability. All rights and obligations of the Parties which by intent or meaning have validity beyond or by their nature apply or are to be performed or exercised after the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement for the period so specified, if any, or for perpetuity.

12.14 Governing Law. This Agreement, and the application or interpretation hereof, shall be governed exclusively by its terms and by the laws of the State of Delaware.

12.15 Jurisdiction. The Licensee consents to the personal jurisdiction of the federal and state courts located in the State of Alabama with respect to all claims or other causes of action arising out of this Agreement.

12.16 Interpretation. Whenever used in this Agreement and when required by the context, the singular number shall include the plural and the plural the singular. Pronouns of one gender shall include all genders, masculine, feminine and neuter.

12.17 Captions. The captions as to contents of particular sections or paragraphs contained in this Agreement are inserted for convenience and are in no way to be construed as part of this Agreement or as a limitation on the scope of the particular sections or paragraphs to which they refer.

12.18 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which shall constitute one and the same instrument. Transmission by facsimile or e-mail of an executed counterpart of this Agreement shall be deemed to constitute due and sufficient delivery of such counterpart. If by e-mail, the executed Agreement must be delivered in a .pdf format.

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**IN WITNESS WHEREOF**, the Licensee and the Licensor have each caused its duly authorized representative to execute this Agreement, effective as of the Effective Date.

|  |  |
| --- | --- |
| **UABRF:** | **THE LICENSEE:** |
| **The UAB Research Foundation** | **PNP Therapeutics, Inc.** |
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|  |  |
| By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |
| Name: Karthik Gopalakrishnan, Ph.D. | Name: |
|  |  |
| Title: Director of Licensing and New Ventures | Title: |

|  |  |
| --- | --- |
| *Addresses For Notices and Payments:* | *Address For Notices:* |
| *For Delivery by Courier Service*:  The UAB Research Foundation  Attention: Executive Director  710 13th Street South  CSB 120  Birmingham, AL 35233  *For Delivery by U.S. Postal Service*:  The UAB Research Foundation  Attention: Executive Director  1720 2nd Avenue South  CSB 120  Birmingham, AL 35294  By email:  Innovation@uab.edu | PNP Therapeutics, Inc.  15 Richard Arrington Jr. Blvd  Birmingham, Alabama 35203 |

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the**

**Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported):  November 9, 2021**

**GEOVAX LABS, INC.**

**(Exact name of registrant as specified in its charter)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Delaware** |  | **001-39563** |  | **87-0455038** |
| **(State or other jurisdiction of**  **incorporation or organization)** |  | **(Commission File No.)** |  | **(IRS Employee Identification No.)** |

**1900 Lake Park Drive, Suite 380**

**Smyrna, Georgia 30080**

**(Address of principal executive offices) (Zip code)**

**(678) 384-7220**

**(Registrant’s telephone number, including area code)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions.

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13(e)-4(c))

Securities registered pursuant to Section 12(b) of the Act:

|  |  |  |
| --- | --- | --- |
| Title of each class | Trading  Symbol(s) | Name of each exchange on which registered |
| Common Stock, par value $0.001 per share | GOVX | The Nasdaq Capital Market |
| Warrants to Purchase Common Stock | GOVXW | The Nasdaq Capital Market |

Indicate by check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial reporting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

|  |  |
| --- | --- |
| **Item 1.01** | **Entry into a Material Definitive Agreement.** |

On November 9, 2021, GeoVax Labs, Inc. (“GeoVax” or the “Company”), through its wholly owned subsidiary GeoVax, Inc., entered into an Exclusive License Agreement the (“License Agreement”) with City of Hope (“COH”), a California nonprofit public benefit corporation, under which the Company obtained exclusive worldwide rights to further develop and commercialize COH04S1, a multi-antigenic SARS-CoV-2 vaccine currently undergoing Phase 2 human clinical trials. The License Agreement grants GeoVax rights to key patents, know-how, regulatory filings and clinical materials related to COH04S1.

The terms of the License Agreement, include an upfront fee consisting of an initial payment to COH of $5,000,000 within 30 days of the effective date of the License Agreement, and additional payments of $3,000,000 and $2,000,000 on the first and second anniversaries, respectively, of the effective date of the License Agreement. The terms also include milestone payments due upon the achievement of selected development, regulatory and sales events. The Company will also pay COH an annual royalty on net sales of products covered by the patents licensed from COH on a country-by-country and licensed product-by-licensed product basis, subject to specified reductions.

The foregoing summary of the License Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the License Agreement attached as Exhibit 10.1 to this Current Report on Form 8-K, which is incorporated herein by reference.

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| --- | --- |
| **Item 7.01** | **Regulation FD Disclosure.** |

On November 9, 2021, the Company and COH issued a joint press release discussing the License Agreement. A copy of the joint press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Forward-Looking Statements**

This Current Report on Form 8-K and other reports filed by the Company from time to time with the Securities and Exchange Commission (collectively the “Filings”) contain forward-looking statements and information that are based upon beliefs of, and information currently available to, the Company’s management as well as estimates and assumptions made by the Company’s management. When used in the Filings the words “anticipate”, “believe”, “estimate”, “expect”, “future”, “intend”, “plan” or the negative of these terms and similar expressions as they relate to the Company or the Company’s management identify forward looking statements.  Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions and other factors relating to the Company’s industry, operations and results of operations and any businesses that may be acquired by the Company. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned. Except as required by law, the Company does not undertake to update its forward-looking statements.

|  |  |
| --- | --- |
| **Item 9.01** | **Financial Statements and Exhibits.** |

(d)     Exhibits

|  |  |
| --- | --- |
| Exhibit No. | Description |
| 10.1 | Exclusive License Agreement, dated November 9, 2021, by and between GeoVax, Inc. and City of Hope (1) |
| 99.1 | Press release dated November 9, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

(1) Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted as (i) the Company has determined the omitted information is not material and (ii) the Company customarily and actually treats the omitted information as private or confidential.

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 10, 2021

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| --- | --- | --- | --- |
|  | GEOVAX LABS, INC. | |  |
|  |  | |  |
|  |  | |  |
|  | By: | /s/ Mark W. Reynolds |  |
|  |  | Mark W. Reynolds |  |
|  |  | Chief Financial Officer |  |
|  |  |  |  |

**Exhibit 10.1**

**THE SYMBOL “[\*\*\*]” DENOTES PLACES WHERE CERTAIN IDENTIFIEDINFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE**

**(i) THE COMPANY HAS DETERMINED THE OMITTED INFORMATION IS NOT MATERIAL, AND   
(ii) THE COMPANY CUSTOMARILY AND ACTUALLY TREATS THE OMITTED INFORMATION AS PRIVATE OR CONFIDENTIAL**

**exclusive LICENSE AGREEMENT**

**THIS EXCLUSIVE LICENSE AGREEMENT** (the “**Agreement**”) is made and entered into as of the 9th day of November, 2021 (the “**Effective Date**”) by and between GeoVax, Inc., a Georgia corporation with a principal place of business at 1900 Lake Park Drive, Suite 380, Smyrna, GA 30080 (“**Licensee**”), and City of Hope, a California nonprofit public benefit corporation located at 1500 East Duarte Road, Duarte, California 91010 (“**City of Hope**” or “**COH**”). Licensee and COH are each sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

**WHEREAS:**

A. COH operates an academic research and medical center that encourages the use of its inventions, discoveries and intellectual property for the benefit of the public and COH owns or Controls (as defined below) certain Patent Rights (as defined below) and Materials (as defined below) useful in the Field (as defined below);

B. The Inventions disclosed in the Patent Rights being licensed under this Agreement are owned by COH;

C. Certain clinical research relating to the Patent Rights and Materials was sponsored in part by a grant from the Carol Moss Foundation.

D. COH has obtained an active Investigational New Drug (IND) from the US Food and Drug Administration and has performed and/or sponsored certain clinical studies related to Patent Rights and Materials, which have generated data;

E. Licensee is a company dedicated to the commercial development and exploitation in the Field of products and services that incorporate one or more of the technologies described in the Patent Rights and therefore Licensee desires to obtain from COH a worldwide, exclusive license under the Patent Rights in the Field and also a worldwide, non-exclusive license to use the Materials in the Field, on the terms and subject to the conditions set forth herein;

F. Licensee is a wholly owned subsidiary of GeoVax Labs, Inc., a Delaware corporation having its principal place of business at 1900 Lake Park Drive, Suite 380, Smyrna, GA 30080.

**NOW, THEREFORE**, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and legal sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

**: DEFINITIONS**

“**Affiliate**” of a Party means a Person that, directly or indirectly (through one or more intermediaries) controls, is controlled by, or is under common control with such Party. For purposes of this Section 1.1, “control” means (i) the direct or indirect ownership of two-thirds or more of the voting stock or other voting interests or interests in profits, or (ii) the ability, acting in its sole discretion, to otherwise control or direct the decisions of the management, the board of directors, or equivalent governing body thereof. For the avoidance of doubt, any Person that is not an Affiliate as of the Effective Date, but later becomes an Affiliate through any transaction or series of related transactions will be deemed to be an Affiliate for purposes of this Agreement.

“**Business Day**” means any day, other than a Saturday, Sunday or day on which commercial banks located in Los Angeles, California or Atlanta, GA, are authorized or required by law or regulation to be closed for business.

“**Commercially Reasonable Efforts**” means the exercise of such efforts and commitment of such resources by Licensee, directly or through one or more Sublicensees, in a diligent manner consistent with organizations in the pharmaceutical industry for a comparable development or commercialization program at a similar stage of development or commercialization in each case taking into account on a jurisdiction by jurisdiction basis, issues of safety and efficacy, product profile, the proprietary position, the then current competitive environment for such product and the likely timing of such product’s entry into the market, the pricing and launching strategy for the respective product, the regulatory environment and status of such product, and other relevant scientific, technical and commercial factors. In the event that Licensee or a Sublicensee with respect to a given Licensed Product, has a program or product that competes with the programs contemplated by this Agreement, including but not limited to as an example, for a similar indication or a similar patient population with respect to such Licensed Product , then “Commercially Reasonable Efforts” shall also mean efforts at least comparable to those efforts and resources expended by Licensee or its Sublicensee on the competing program and/or product or service.

“**COH Confidential Information**” means Confidential Information disclosed or provided by, or on behalf of, COH to Licensee or its designees. COH Confidential Information includes Materials.

“**Combination Product**” means a Licensed Product consisting of (i) one or more products or technology covered by a Valid Claim packaged or related to, incorporates, or is manufactured using the Materials and (ii) one or more other pharmaceutically active components that are not covered by a Valid Claim and are not related to, incorporating, or manufactured using the Materials. All references to Licensed Products in this Agreement will be deemed to include Combination Products.

“**Confidential Information**” means: (i) all information and materials (of whatever kind and in whatever form or medium) disclosed by or on behalf of a Party to the other Party (or its designee) in connection with this Agreement, whether prior to or during the Term of this Agreement and whether provided orally, electronically, visually, or in writing; provided, that, all such information and materials initially disclosed in writing or electronically shall be clearly marked as “CONFIDENTIAL” and all such materials and information initially disclosed orally shall be reduced to writing and marked as “CONFIDENTIAL” within ten (10) days following the date of initial oral disclosure; (ii) all copies of the information and materials described in (i) above; and (iii) the existence and each of the terms and conditions of this Agreement; provided, further, that Confidential Information shall not include information and materials to the extent a Party can demonstrate through its contemporaneous written records that such information and materials are or have been:

known to the receiving Party, or in the public domain, at the time of its receipt by a Party, or which thereafter becomes part of the public domain other than by virtue of a breach of this Agreement or the obligations of confidentiality under this Agreement;

received without an obligation of confidentiality from a Third Party having the right to disclose without restrictions such information;

independently developed by the receiving Party without use of or reference to Confidential Information disclosed by the other Party; or

released from the restrictions set forth in this Agreement by the express prior written consent of the disclosing Party.

“**Control(s)**” or “**Controlled**” means the possession by a Party, as of the Effective Date, of rights sufficient to effect the grant of rights set forth in this Agreement without violating the terms of any agreement with any Third Party.

“**Covers**” or “**Covered by**” means, with reference to a particular Licensed Product, that the manufacture, use, sale, offering for sale, or importation of such Licensed Product would, but for ownership of, or a license granted under this Agreement to, the relevant Patent Right, infringe a Valid Claim anywhere in the Territory.

“**COVID-19**” means the illness or disease caused by a SARS-CoV-2 virus.

“**Dispute**” means any controversy, claim or legal proceeding arising out of or relating to this Agreement, or the interpretation, breach, termination, or invalidity thereof.

“**Europe**” means (i) the United Kingdom and (ii) the countries of the European Union, as it is constituted as of the date of the Development Milestone Event set forth in Section 4.3.

**“COVID-19 Patent Rights**” means: (i) United States Patent Application No. [\*\*\*], filed on [\*\*\*], and Patent Application No. [\*\*\*], filed on [\*\*\*]; (ii) patents, patent applications, continuations, divisional applications, and foreign equivalents that claim the same invention(s) and priority date as the foregoing; (iii) continuation-in-part applications that repeat a substantial portion of any of the foregoing applications; (iv) letters patent or the equivalent issued on any of the foregoing applications throughout the world; and (v) amendments, extensions, renewals, reissues, and re-examinations of any of the foregoing. Notwithstanding the foregoing, COVID-19 Patent Rights shall only include any continuation-in-part application to the extent that claims in such continuation-in-part application are supported in the specification of the parent application, unless otherwise mutually agreed to in writing by the Parties to this Agreement. Except as may otherwise be agreed in a separate writing, COVID-19 Patent Rights explicitly exclude any and all patents or patent applications based on research conducted by COH or its Affiliates after the Effective Date.

“**Field**” means the field of vaccine products targeted for prevention, reduction, amelioration or treatment against COVID-19.

“**First Commercial Sale**” means, with respect to a particular Licensed Product in a given country, the first arm’s-length commercial sale of such Licensed Product for value following Marketing Approval in such country by or under authority of Licensee or any Sublicensee to a Third Party who is not a Sublicensee.

“**GAAP**” means generally accepted accounting principles, consistently applied, as promulgated from time to time by the Financial Accounting Standards Board.

“**Generic or Biosimilar Product**” means, with respect to any Licensed Product in the United States, any product that is eligible for submission and approved for marketing by the FDA as a therapeutic biologic product under Section 351(k) of the Public Health Service Act (and not eligible for submission for marketing approval to the FDA under Section 505(b)(2) or Section 505(j) of the Federal Food, Drug and Cosmetic Act), including an expression construct used in the manufacture of the therapeutic biologic product, where such product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. With respect to Licensed Product in any country in the Territory other than the United States, a “Generic or Biosimilar Product” means any biologic product that is eligible for submission for approval under a law of a foreign jurisdiction, which is either similar to or a counterpart of the Public Health Service Act (and not eligible for submission for approval under a law of a foreign jurisdiction, which is either similar to or a counterpart of the Federal Food, Drug and Cosmetic Act), including an expression construct used in the manufacture of the therapeutic biologic product, requiring the biologic product to be similar to the reference medicine and not having any meaningful differences from the reference medicine in terms of quality, safety or efficacy.

“**Improvement**” means any modification of or improvement or enhancement to the technology that is the subject of the Patent Rights.

“**IND” or “Investigational New Drug Application**” means an Investigational New Drug application accepted by the United States Food and Drug Administration.

“**Invention**” means the inventions disclosed in the Patent Rights.

“**License Year**” means each calendar year during the Term of this Agreement; except that the first License Year shall commence on the Effective Date and end on December 31 of the calendar year in which the Effective Date occurs.

“**Licensed Product**” means a product (including kits, component sets or components thereof, regardless of concentration or formulation) that (i) is Covered by a Valid Claim, (ii) is manufactured by a process or used in a method Covered by a Valid Claim, (iii) is based on, related to, incorporates, or is manufactured using the Materials, or (iv) contains, as an active ingredient, any substance the manufacture, use, offer for sale or sale of which is Covered by a Valid Claim. By way of clarification, “Licensed Product” shall include a product manufactured in a country in which such manufacture is Covered by a Valid Claim and thereafter exported to and sold in a country in which no Valid Claim exists or vice versa.

“**Licensee Confidential Information**” means Confidential Information disclosed or provided by, or on behalf of, Licensee to COH or its designees.

“**Marketing Approval**” means all approvals, licenses, registrations or authorizations of any federal, state or local Regulatory Authority, department, bureau or other governmental entity, including, without limitation, pricing and reimbursement approvals, necessary for the manufacturing, use, storage, import, transport, distribution, marketing and sale of the applicable Licensed Products in a country or regulatory jurisdiction. Marketing Approval includes emergency use authorizations or similar authorizations in a country or regulatory jurisdiction.

“**Materials**” means (a) the biological materials specifically identified on Exhibit B, as well as tangible copies of technical information associated with such biological materials and (b) tangible copies of the technical information and data identified on Exhibit B.

“**Net Sales**” means the total gross amount invoiced by Licensee, its Affiliates and its Sublicensees (regardless of whether and when such invoices are actually paid) on the sale, lease, provision, or other disposition of the applicable Licensed Products to Third Parties (including, without limitation, the provision of any product or service by Licensee, its Affiliates or any of its Sublicensees that incorporates a Licensed Product but for clarity excluding documented research and/or development activities, valued at the actual expenditures), less the following items, as determined from the books and records of Licensee, its Affiliates or its Sublicensees:

insurance, handling, and transportation charges actually invoiced;

amounts repaid, credited or allowed for rejection, return or recall, retroactive price reductions, billing corrections or allowances, and invoiced amounts written-off as uncollectible (in accordance with the Licensee’s then current practices) (provided that Licensee uses reasonable efforts to collect all invoiced amounts);

sales, tariff duties, or other excise taxes or other governmental charges levied on or measured by the invoiced amount (including, without limitation, value added taxes);

brokerage, customs and import duties or charges;

distribution fees and sales commissions paid to Third Parties; and

normal and customary trade and quantity discounts (including chargebacks and allowances) and rebates which relate to the Licensed Products.

* + 1. Sales of Licensed Products between or among Licensee, its Affiliates or its Sublicensees shall be excluded from the computation of Net Sales, except in those instances in which the purchaser is also the end-user of the Licensed Product sold. Further, transfers of reasonable quantities of Licensed Product by Licensee, any of its Affiliates or of its Sublicensee to a Third Party that is not a Sublicensee for use in the development of such Licensed Product (and not for resale) and transfers of industry standard quantities of Licensed Product for samples or promotional purposes shall not be deemed a sale of such Licensed Product that gives rise to Net Sales for purposes of this Section 1.25.
    2. In the event that any Licensed Product is sold in the form of a Combination Product containing one or more other products, where all products in such Combination Product are sold separately, Net Sales for such Combination Products will be calculated by multiplying actual Net Sales of such Combination Products by the fraction A/(A+B) where A is the invoice price of the Licensed Product if sold separately, and B is the total invoice price of any other product or products in the combination if sold separately. To the extent that one or more of the Licensed Products, including the Licensed Product, in any Combination Product are not sold separately, the following provisions shall apply:

1. If the Licensed Product contained in the Combination Product is sold separately, but none of the other products included in such Combination Product are sold separately, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product as determined under the foregoing paragraph of this Section, by the fraction A/C, where A is the net invoice price of such Licensed Product component as sold separately in such country, and C is the net invoice price of the Combination Product in such country.
2. If the Licensed Product component of the Combination Product is not sold separately, but the other product(s) included in the Combination Product are sold separately in such country, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product in such country as determined under the foregoing paragraph of this Section, by the fraction (C-D)/C, where C is the net invoice price of the Combination Product, and D is the sum of the net invoice prices charged for the other product(s) in the Combination Product.
3. If none of the Licensed Product(s) included in the Combination Product, including the Licensed Product, are sold separately, Net Sales for the purpose of determining royalties due hereunder for the Combination Product shall be determined by mutual agreement of the Parties in good faith taking into account the perceived relative value contributions of the Licensed Product portion of the Combination Product and the other product(s) in the Combination Product. In case of disagreement, an independent expert agreed upon by both Parties or, failing such agreement, designated by the dispute resolution process in Article XII, shall determine such relative value contributions and such determination shall be final and binding upon the Parties.

**“Platform Patent Rights**” means: (i) Patent Application No [\*\*\*] filed on [\*\*\*]; (ii) patents, patent applications, continuations, divisional applications, and foreign equivalents that claim the same invention(s) and priority date as the foregoing; (iii) continuation-in-part applications that repeat a substantial portion of any of the foregoing applications; (iv) letters patent or the equivalent issued on any of the foregoing applications throughout the world; and (v) amendments, extensions, renewals, reissues, and re-examinations of any of the foregoing. Notwithstanding the foregoing, Platform Patent Rights shall only include any continuation-in-part application to the extent that claims in such continuation-in-part application are supported in the specification of the parent application, unless otherwise mutually agreed to in writing by the parties to this Agreement. Except as may otherwise be agreed in a separate writing, Platform Patent Rights explicitly exclude any and all patents or patent applications based on research conducted by COH or its Affiliates after the Effective Date.

“**Patent Rights**” means the COVID-19 Patent Rights and the Platform Patent Rights.

“**Person**” means any person or entity, including any individual, trustee, corporation, partnership, trust, unincorporated organization, limited liability company, business association, firm, joint venture or governmental agency or authority.

“**Phase** **1 Clinical Trial**” means, as to a specific Licensed Product, a clinical study in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects in patients as described in 21 C.F.R. § 312.21(a); or a similar clinical study in a country other than the United States.

“**Phase** **2 Clinical Trial**” means, as to a specific Licensed Product, a clinical study in humans designed with the principal purpose of determining initial efficacy and dosing of such Licensed Product in patients for the indication(s) being studied as described in 21 C.F.R. § 312.21(b); or a similar clinical study in a country other than the United States. Without limiting the foregoing, if (i) a protocol for a Phase 1 Clinical Trial includes the enrollment of a cohort of patients (“**Phase 2 Cohort**”) that would satisfy the foregoing definition of Phase 2 Clinical Trial, or (ii) a protocol for a Phase 1 Clinical Trial is amended to include the enrollment of a Phase 2 Cohort, then, in each case ((i)-(ii)), such Phase 1 Clinical Trial shall be deemed a Phase 2 Clinical Trial on and after the date of the first dosing of the first human subject in such Phase 2 Cohort.

“**Phase** **3 Clinical Trial**” means, as to a specific Licensed Product , a clinical study in humans of the efficacy and safety of such Licensed Product, which is prospectively designed to demonstrate statistically whether such Licensed Product is effective and safe for use in a particular indication in a manner sufficient to file an application to obtain Marketing Approval to market and sell that Licensed Product in the United States or another country for the indication being investigated by the study, as described in 21 C.F.R. § 312.21(c), or which is actually used to file an application to obtain Marketing Approval for such Licensed Product; or similar clinical study in a country other than the United States. Without limiting the foregoing, if (i) a protocol for a Phase 2 Clinical Trial includes the enrollment of a cohort of patients (“**Phase 3 Cohort**”) that would satisfy the foregoing definition of Phase 3 Clinical Trial, or (ii) a protocol for a Phase 2 Clinical Trial is amended to include the enrollment of a Phase 3 Cohort, then, in each case ((i)-(ii)), such Phase 2 Clinical Trial shall be deemed a Phase 3 Clinical Trial on and after the date of the first dosing of the first human subject in such Phase 3 Cohort.

“**Regulatory Authority**” means, with respect to any country or jurisdiction, any court, agency, department, authority or other instrumentality of any international, multinational or supra-national, national, regional, province, state, county, city or other political subdivision having responsibility for granting Marketing Approvals in such country or jurisdiction, including the Federal Food and Drug Administration in the United States, the European Medicines Agency in the European Union, the Ministry of Health, Labour and Welfare in Japan, and the National Medical Products Administration in China.

“**SARS-CoV-2**” means the severe acute respiratory syndrome coronavirus 2, as defined by the *Coronaviridae* Study Group of the International Committee on Taxonomy of Viruses (Nat Microbiol. 2020; 5(4): 536–544), including any variant thereof.

“**Sublicensee**” means a Third Party which enters into an agreement with Licensee or an Affiliate of Licensee, involving the grant to such Third Party of any rights under the license granted to Licensee or Affiliates of Licensee pursuant to this Agreement.

“**Sublicense Revenues**” means all consideration, in whatever form, due to Licensee or an Affiliate of Licensee from a Sublicensee in return for the grant of a sublicense of any of Licensee’s rights hereunder, excluding consideration in the form of: (i) royalties or other per-unit consideration received by Licensee or an Affiliate of Licensee and calculated wholly as a function of sales of Licensed Products (provided, that such sales are recognized as Net Sales under this Agreement for which a royalty is payable to COH), (ii) payments or reimbursement for documented research and/or development activities, valued at the actual expenditures, (iii) payments or reimbursement of reasonable patent expenses actually incurred or paid by Licensee or an Affiliate of Licensee and not otherwise reimbursed, or payment of patent expenses required to by paid by Licensee hereunder, (iv) payments for the purchase of equity in Licensee at the fair market value of such equity, and (v) payments recognized as Net Sales under this Agreement for which a royalty is payable to COH.

“**Territory**” means worldwide.

“**Third Party**” means a Person that is neither a Party to this Agreement nor an Affiliate of a Party.

“**Valid Claim**” means a claim of an issued and unexpired patent included in the Patent Rights in a particular jurisdiction, which claim has not, in such jurisdiction been finally rejected or been declared invalid or cancelled by the patent office or a court or other governmental agency of competent jurisdiction in a decision that is no longer subject to appeal as a matter of right; or (b) a claim of a pending patent application within Patent Rights that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling, provided that a Valid Claim shall exclude any such pending claim in an application that has not been granted within the later of three (3) years after the Effective Date or seven (7) years following the earliest priority filing date for such application.

**: DEVELOPMENT AND COMMERCIALIZATION EFFORTS**

**Development and Commercialization Responsibilities**. Licensee shall have the sole right and responsibility for, and control over, all of its development, manufacturing and commercialization activities (including all regulatory activities) with respect to Licensed Products in the Field.

**Transfer of Materials**. COH shall, promptly following the Effective Date, use reasonable efforts to provide Licensee with, and transfer to Licensee, the Materials, including the cGMP Standard Operating Procedures (SOPs) associated with the biological materials listed on Exhibit B.

**Transfer of Pre-Clinical Study Data.** COH shall provide the data and information listed on Exhibit B related to the preclinical (GLP and non-GLP) studies that were conducted during the development of the synthetic MVA-based SARS-CoV-2 vaccine in support of IND [\*\*\*] and clinical evaluation for the clinical trials listed in Exhibit A. In addition, upon the reasonable request from Licensee regarding any additional information with regards to such preclinical studies, COH shall use all reasonable efforts to provide such additional information to Licensee (to the extent such additional information is available to COH).

**Transfer of All Sponsor Obligations for IND Application(s)**.

(a) On or after the Effective Date, COH shall provide Licensee with a copy of all of the Materials in a manner mutually acceptable to the Parties. Simultaneous with the execution of this Agreement, COH and Licensee will execute the letters to the FDA materially consistent with the letter templates in Exhibit D, providing the FDA with a notice of transfer to Licensee of all COH sponsor obligations, including as set forth in 21 CFR §312.50, in accordance with 21 CFR §312.52 for IND [\*\*\*] and for the clinical trials described on Exhibit A. After such transfer, (i) Licensee shall use Commercially Reasonable Efforts to continue and complete the clinical trials listed on Exhibit A, (ii) COH shall continue to perform activities as contemplated pursuant to the protocols relating to the clinical trials listed on Exhibit A, and (iii) COH shall periodically invoice Licensee for the costs and services related to such activities, and Licensee shall reimburse COH for such costs and services within thirty (30) days of Licensee’s receipt of an invoice for such costs and services; provided, that the invoices for such costs and services listed on Exhibit A shall not exceed those set forth on Exhibit A through COH’s 2024 fiscal year.

(b) COH will provide digital copies of the meeting minutes, all meeting request packages, and any additional information or correspondence that was shared with the FDA and other global regulatory authorities regarding the clinical trials listed on Exhibit A. To the extent applicable, COH will provide the complete IND dossier that was submitted to the FDA in non-eCTD electronic format, or any other global regulatory authority, for the clinical trials listed on Exhibit A.

(c) Upon request from Licensee regarding any additional information with regards to the information collected pursuant to the protocols relating to clinical trials listed on Exhibit A, COH shall use all reasonable efforts to provide such additional information to Licensee (to the extent such additional information is available to COH).

(d) Licensee acknowledges and agrees that the transfer of COH’s sponsor obligations under this Section 2.4, and Licensee’s right to conduct clinical trials for which such sponsor obligations have been transferred, are subject to (i) any obligations owed by COH to third parties as of the Effective Date and as disclosed to Licensee, (ii) COH’s retained rights under Section 3.1.3, (iii) the Field limitation of the license grants in Sections 3.1.1-3.1.3, and (iv) the restrictions set forth in Section 3.1.5. COH expressly reserves the right to use all Materials, subject to the limitations in this Agreement. Licensee hereby grants COH a right of reference with respect to IND [\*\*\*] and the clinical trials listed on Exhibit A, including the right to reference all regulatory dossiers relating to Marketing Approvals for Licensed Products.

**Carol Moss Foundation Grant and Licensee Disclosure of Research Results**. Licensee hereby acknowledges that clinical trial [\*\*\*] as listed on Exhibit A was funded in part by a research grant from the Carol Moss Foundation, and hereby agrees to acknowledge such research grant in all public disclosures of research results relating to such clinical trial. Licensee shall provide COH with fourteen (14) days’ advanced written notice and a copy of any public disclosure of research results arising out of the clinical trials listed on Exhibit A prior to such disclosure. Licensee shall give reasonable consideration to comments that it receives from COH during such fourteen (14) day period, provided that, subject to the terms of this Agreement, Licensee shall have final discretion as to the public disclosure of such research results.

**Licensee Diligence**. Licensee shall use Commercially Reasonable Efforts to develop and commercialize Licensed Products in the Field, directly or through one or more Affiliates or Sublicensees. Without limiting the foregoing, if Licensee, directly or through one or more of its Affiliates or Sublicensees, fails to accomplish any one of the following “**Diligence Milestones**” set forth in this Section 2.6 by the date specified (each a “**Deadline Date**”) corresponding to such Diligence Milestone, COH shall have the right, at COH’s sole discretion and upon a 60-day advance notice to Licensee, to terminate this Agreement.

| “**Deadline Date**” | “**Diligence Milestone**” |
| --- | --- |
| [\*\*\*] from the Effective Date | Dose the first patient in a Phase 3 Clinical Trial of a Licensed Product within the Field anywhere in the Territory. |
| [\*\*\*] from the Effective Date | Obtain Marketing Approval of a Licensed Product within the Field anywhere in the Territory. |

The foregoing Diligence Milestones and Deadline Dates may only be modified through a written mutual agreement between the Parties.

**Governance**. COH and Licensee shall each designate one individual to serve as the main point of contact for communications related to development and commercialization of Licensed Products under this Agreement (each a “**Designated Representative**”). The initial Designated Representative of COH shall be George Megaw and the initial Designated Representative of Licensee shall be John W. Sharkey. Each Party may replace its Designated Representative at any time upon prior notice to the other Party. Licensee shall keep COH reasonably informed as to progress in the development and commercialization of Licensed Products. Without limiting the foregoing, on or before July 15 of each License Year during the Term of this Agreement and until the First Commercial Sale, Licensee shall provide to COH a written report setting forth, in reasonable detail, its activities and achievements with respect to the development and commercialization of Licensed Products during the preceding twelve months, including activities relating to the achievement of Diligence Milestones (the “**Annual Report**”). Each Annual Report shall also include the COH reference number, OTL 21-588. The Designated Representatives shall meet, either in person or via video, as needed but no less often than once each License Year to present and discuss the current status of the program. Each Party shall be responsible for all expenses incurred by its Designated Representative in the participation in such meetings, including the annual meetings. A copy of each Annual Report shall be provided, in addition to the persons set forth in Section 14.7 to: The Office of Technology Licensing, email: [licensing@coh.org](mailto:licensing@coh.org).

**: LICENSE GRANTS**

**Grant of Rights**.

**License to COVID-19 Patent Rights.** Subject to the terms and conditions of this Agreement, COH hereby grants to Licensee an exclusive royalty-bearing right and license under the COVID-19 Patent Rights to make, have made, use, offer for sale, sell, perform, and import Licensed Products, in the Field, in the Territory.

**License to Platform Patent Rights**. Subject to the terms and conditions of this Agreement, COH hereby grants to Licensee an exclusive royalty-bearing right and license under the Platform Patent Rights to make, have made, use, offer for sale, sell, perform, and import Licensed Products, in the Field, in the Territory.

**License to Materials.** COH hereby grants to Licensee a non-exclusive royalty-bearing right and license to use the Materials to make, have made, use, have used, offer for sale, sell, import, export, and otherwise dispose of, develop, commercialize, and exploit in any manner Licensed Products, in the Field, in the Territory.

**Reservation of Rights**. The foregoing grants of rights shall be subject to:  (i) the retained rights of the U.S. Government, if and to the extent applicable, in the Patent Rights pursuant to 35 U.S.C. §§ 200-212 and applicable U.S. government regulations; (ii) the royalty-free right of COH and its Affiliates to practice the Patent Rights for educational and research purposes; (iii) the right of COH and its Affiliates to publicly disclose research results, subject to the remainder of this Section 3.1.4; and (iv) the right of COH and its Affiliates to allow other collaborators to use the Patent Rights for the same purposes as (ii) and (iii). COH will provide Licensee with fourteen (14) days’ advanced written notice and a copy of any public disclosure of research results under this Section 3.1.4(iii) relating to the Patent Rights or Materials in the Field listing Don J. Diamond, Ph.D., as an author prior to such disclosure. COH shall give reasonable consideration to comments that it receives from Licensee during such fourteen (14) day period, provided that, subject to the terms of this Agreement, COH shall have final discretion as to the public disclosure of such research results. For clarity, this Section 3.1.4 does not permit COH, its Affiliates, or their collaborators to exploit the Patent Rights for commercialization purposes.

**Indications Other than COVID-19**. The rights and licenses granted to Licensee under this Agreement do not include the right or license (i) under the Patent Rights to make, have made, use, offer for sale, sell, perform, and import products or services outside the Field, such as the use of the Patent Rights for another indication (e.g., seasonal flu or RSV), or (ii) to use the Materials to make, have made, use, have used, offer for sale, sell, import, export, and otherwise dispose of, develop, commercialize, and exploit in any manner products or services outside the Field, such as the use of Materials for another indication (e.g., seasonal flu or RSV). Nothing in the foregoing prohibits Licensee from developing or commercializing a Combination Product targeting other indications (e.g., seasonal flu or RSV); provided, that such other pharmaceutically active components for the other indication (e.g., seasonal flu or RSV) in the Combination Product are not covered by a Valid Claim and are not related to, incorporating, or manufactured using the Materials.

**No Implied Licenses**. Licensee acknowledges that the licenses granted in this Agreement are limited to the scope expressly granted and that, subject to the terms and conditions of this Agreement, all other rights under all Patent Rights and the Materials, and other intellectual property rights Controlled by COH are expressly reserved to COH.

**Sublicensing**. Licensee shall have the right to grant sublicenses to Affiliates or Third Parties, effective upon notice to COH; provided, that the terms and conditions of any sublicense of Licensee’s rights shall (i) be consistent with this Agreement, (ii) be in writing, (iii) contain terms that do not exceed the scope of rights granted under this Agreement. Licensee shall be liable for any of its Sublicensee’s acts or omissions that would constitute a breach of this Agreement if such action or inaction were that of Licensee. A true and complete copy of each sublicense of Licensee’s rights hereunder, as well as any amendments thereto, shall be delivered to COH promptly following the effective date of each such sublicense or amendment. In the event this Agreement is terminated or upon the expiration of the Term, (i) the Licensee shall notify each Sublicensee of the termination or expiration, and (ii) each Sublicensee may enter into a license agreement with COH on such terms as mutually agreed to by the parties.

**No Grant-Backs**. All right, title, and interest in any Improvement conceived, made, or reduced to practice by Licensee that do not list a COH Personnel (as such term is defined in Exhibit C) as an inventor, and all of Licensee’s patents and patent applications claiming any such Improvements, will (i) as between the Parties, remain the sole and exclusive property of Licensee; and (ii) not be licensed to COH, unless the Parties otherwise specifically agree in writing.

**: PAYMENTS**

**Up-Front Payment**. In consideration for rights granted hereunder, Licensee shall pay to COH a one-time, non-refundable, upfront license fee of ten million dollars ($10,000,000), which, solely for the convenience of the Parties, shall be paid by Licensee as follows:

(a) Five million dollars ($5,000,000) within thirty (30) days following the Effective Date;

(b) Three million dollars ($3,000,000) no later than the first anniversary of the Effective Date; and

(c) Two million dollars ($2,000,000) no later than the second anniversary of the Effective Date.

For clarity, the above payment schedule is solely for the convenience of the Parties, and the entire amount of $10,000,000 is due to COH upon the Effective Date.

[\*\*\*]

(a) [\*\*\*]

(b) [\*\*\*]

**Development Milestone Payments**. Within thirty (30) days after the occurrence of each “**Development Milestone Event**” set forth below with respect to each of the first two Licensed Products in the Field, Licensee shall pay COH or its designee the amount indicated below:

| **Development Milestone Event** | **Amount Due** |
| --- | --- |
| #1. The first to occur of:  (a) Dosing of the first patient in a Phase 3 Clinical Trial; and  (b) The decision by the United States Food and Drug Administration that a Phase 2 Clinical Trial is sufficient for Marketing Approval. | $[\*\*\*] |
| #2. Upon first Marketing Approval in the United States. | $[\*\*\*] |
| #3. Upon first Marketing Approval in any country in Europe. There will be no payments due to COH under this Section upon the Marketing Approval in any subsequent country in Europe. | $[\*\*\*] |
| #4. Upon first Marketing Approval in any one of China or Japan. There will be no payments due to COH under this Section upon the Marketing Approval in the other country. | $[\*\*\*] |
| #5. Upon first Marketing Approval in one of Brazil, Australia, India, or Russia. There will be no payments due to COH under this Section upon the Marketing Approval in any subsequent country. | $[\*\*\*] |

For clarity, each payment for each Development Milestone Event #1 - #5 will be due twice: once when the applicable Development Milestone Event is met with respect to the first Licensed Product, and once when the applicable Development Milestone Event is met with respect to the second Licensed Product. The Parties agree that a second Licensed Product will be a Licensed Product directed to a different COVID-19 variant than the first Licensed Product, which would necessitate a new Marketing Approval by the applicable Regulatory Authority. A second Licensed Product shall not include any use of a Licensed Product that has been the subject of a Development Milestone Payment above, including but not limited to the following: (i) a Combination Product with such first Licensed Product directed to another indication (e.g., seasonal flu or RSV), (ii) an expanded use to treat any symptom, sequela, or other medical condition associated with COVID-19 with such first Licensed Product, (iii) an expanded use to treat a new set of patients or a sub-population of patients with such first Licensed Product, when such first Licensed Product has already been approved in a different patient population or sub-population of patients with respect to COVID-19.

**Sales Milestone Payments**. Within thirty (30) days after the occurrence of each “**Sales** **Milestone Event**” set forth below, Licensee shall pay COH or its designee the amount indicated below:

| **Sales Milestone Event** | **Amount Due** |
| --- | --- |
| #1. Upon Net Sales of Licensed Products first totaling $500 million in a License Year. | $[\*\*\*] |
| #2. Upon Net Sales of Licensed Products first totaling $1 billion in a License Year. | $[\*\*\*] |
| #3. Upon Net Sales of Licensed Products first totaling $2 billion in a License Year. | $[\*\*\*] |

**Royalties**.

**Base Royalties**. Subject to Subsections 4.5.2 and 4.6 below, Licensee shall pay to COH or its designee royalties in an amount equal to [\*\*\*] percent of Net Sales of Licensed Products.

**Royalty Reduction Upon Loss of Patent Coverage or Loss of Regulatory Exclusivity**. On a country-by-country and Licensed Product-by-Licensed Product- basis, the royalty rate payable under Section 4.5.1 on Net Sales of such Licensed Product in such country shall be reduced by [\*\*\*] during any period when (a) a particular Licensed Product is not Covered by a Valid Claim of the Patent Rights in a country in which such Licensed Product is manufactured, used, performed or sold, or (b) when a Generic or Biosimilar Product corresponding to a Licensed Product is launched in a country.

**Royalty Offsets**. If, in Licensee’s reasonable business judgment it is necessary to pay to a Third Party, other than a Sublicensee, consideration (whether in the form of a royalty or otherwise) for the right to make, have made, use, sell, offer for sale or import a specific Licensed Product in a given jurisdiction, and if the aggregate royalty rates of any and all royalties payable to such Third Party licensors when combined with the royalty rate payable to COH exceeds [\*\*\*] in the case of Net Sales of the applicable Licensed Product, then Licensee shall have the right with respect to any period for which royalties are due (i.e., a License Year) to set off up to [\*\*\*] of the aggregate royalties with respect to the applicable Licensed Product payable with respect to such period and such jurisdiction and to such Third Party licensors against royalties that would otherwise be due to COH hereunder with respect to such period and jurisdiction; provided, however, that only the royalties payable to those Third Party licensors that themselves agree to be subject to a third party royalty offset; and provided, further, however, that under no circumstances shall (a) the royalty offsets permitted in this Section 4.6 result in the reduction of the effective adjusted royalty rate and the royalty amount otherwise due to COH in any period for which payment is due and in any jurisdiction pursuant to Section 4.5, above, by more than [\*\*\*] (e.g., with respect to Licensed Products, the minimum effective adjusted royalty rate for Licensed Products shall be [\*\*\*] percent); and (b) the royalty offsets permitted in this Section 4.6 when combined with the royalty offsets applicable to Third Party licensors result in aggregate royalty rates payable to such Third Party licensors when combined with the royalty rate payable to COH that are less than [\*\*\*] of the Net Sales of the applicable Licensed Product.

**Sublicense Revenues**.

Licensee shall pay to COH the applicable percentage of all Sublicense Revenues under Section 4.7.2 within thirty (30) days after the Sublicense Revenue is received from the relevant Sublicensee. If Sublicense Revenues are not in cash or cash equivalents, the percentage share payable to COH pursuant to this Section 4.7 shall be due, in COH’s sole discretion, either in kind or in its cash equivalent.

(a) If the sublicense grant to the Sublicensee occurs prior to the earlier of (i) the dosing of the first patient in a Phase 3 Clinical Trial relating to the applicable Licensed Product in the Field, and (ii) the decision by the United States Food and Drug Administration that a Phase 2 Clinical Trial relating to the applicable Licensed Product in the Field is sufficient for Marketing Approval, then Licensee shall pay to COH [\*\*\*] of all Sublicense Revenues.

(b) If the sublicense grant to the Sublicensee occurs after the earlier of (i) the dosing of the first patient in a Phase 3 Clinical Trial relating to the applicable Licensed Product in the Field, and (ii) the decision by the United States Food and Drug Administration that a Phase 2 Clinical Trial relating to the applicable Licensed Product in the Field is sufficient for Marketing Approval, but prior to Marketing Approval of the applicable Licensed Product in the United States or any country in Europe in the Field, then Licensee shall pay to COH [\*\*\*] of all Sublicense Revenues.

(c) If the sublicense grant to the Sublicensee occurs after Marketing Approval of the applicable Licensed Product in the United States or any country in Europe in the Field, then Licensee shall pay to COH [\*\*\*] of all Sublicense Revenues.

The timing of the sublicense grant under Section 4.7.2 shall be determined on a Licensed Product-by-Licensed Product basis based on the development status of the Licensed Product in the sublicense on the date that the sublicense is granted. In a sublicense with multiple candidates, the development status of the most advanced candidate or product in the sublicense determines the applicable timing of the sublicense grant under Section 4.7.2.

**Timing of Royalty Payments**. Royalty payments due under Section 4.5, above, shall be paid annually within sixty (60) days following the end of each License Year until the first License Year in which annual Net Sales reach $[\*\*\*]. Thereafter, all royalty payments due under Section 4.5 shall be paid in quarterly installments, within sixty (60) days following the end of each calendar quarter.

**No Deductions from Payments**. Licensee is solely responsible for payment of any fee, royalty or other payment due to any Third Party in connection with the research, development, manufacture, distribution, use, sale, import or export of a Licensed Product and, except as set forth in Section 4.6 and Section 5.2.3, Licensee shall not have the right to set off any amounts paid to such a Third Party, including fee, royalty or other payment, against any amount payable to COH hereunder.

**Single Royalty**. Only a single royalty payment shall be due and payable on Net Sales of a Licensed Product, regardless if such Licensed Product is Covered by more than one Valid Claim.

**: REPORTS, AUDITS AND FINANCIAL TERMS**

**Royalty Reports**. Within sixty (60) days after the end of each calendar quarter in which a royalty payment under ARTICLE 4 is required to be made, Licensee shall send to COH a report of Net Sales of the Licensed Products for which a royalty is due, which report sets forth for such calendar quarter the following information, on a Licensed Product-by-Licensed Product and country-by-country basis: (i) total Net Sales, (ii) total gross sales of Licensed Products , (iii) the quantity of each Licensed Products sold performed, (iv) the exchange rate used to convert Net Sales from the currency in which they are earned to United States dollars; and (v) the total royalty payments due. All royalty reports shall also include the COH reference number, OTL 21-588. A copy of each royalty report shall be provided, in addition to the persons set forth in Section 14.7, to: The Office of Technology Licensing, email: otl-royalties@coh.org.

**Additional Financial Terms**.

**Currency**. All payments to be made under this Agreement shall be made in United States dollars, unless expressly specified to the contrary herein. Net Sales outside of the United States shall be first determined in the currency in which they are earned and shall then be converted into an amount in United States dollars. All currency conversions shall use the conversion rate reported by Reuters, Ltd. on the last Business Day of the calendar quarter for which such payment is being determined.

**Payment Method**. Amounts due under this Agreement shall be paid in immediately available funds, by means of wire transfer to an account identified by COH.

**Withholding of Taxes**. All payments hereunder shall be made free and clear of and without deduction or deferment in respect of any demand, set-off, counterclaim or other dispute and so far as is legally possible such payment shall be made free and clear of any taxes imposed by or under the authority of government or any public authority. If Licensee is required by law to withhold taxes in connection with any sums payable to COH under this Agreement, Licensee may deduct that amount from the payment it otherwise would have made to Licensor under this Agreement and shall include in the royalty report required pursuant to Section 5.1 the amount due before such withholding, the amount of the withholding under this Section 5.2.3, and the actual amount paid. The Parties may also require each Party to assist the other Party's legal efforts to minimize any applicable withholding tax and to provide the other Party with information and documents that may be required to recover the withholding tax or reduce it to a legal minimum.

**Late Payments**. Any amounts not paid on or before the date due under this Agreement are subject to interest from the date due through and including the date upon which payment is received. Interest is calculated, over the period between the date due and the date paid, at a rate equal to one and one-half percentage point (1.5%) over the “bank prime loan” rate, as such rate is published in the U.S. Federal Reserve Bulletin H.15 or successor thereto on the last Business Day of the applicable calendar quarter prior to the date on which such payment is due.

**Accounts and Audit**.

**Records**. Licensee shall keep, and shall require that each Sublicensee keep, full, true and accurate books of account containing the particulars of its Net Sales and the calculation of royalties. Licensee and its Sublicensees shall each keep such books of account and the supporting data and other records at its principal place of business. Such books and records must be maintained available for examination in accordance with this Section 5.3.1 for three (3) calendar year after the end of the License Year to which they pertain, and otherwise as reasonably required to comply with GAAP.

**Appointment of Auditor**. COH may appoint an internationally- recognized independent accounting firm to be agreed to by the Parties, which agreement shall not be unreasonably withheld or delayed, to inspect the relevant books of account of Licensee and its Sublicensees solely to verify any reports or statements provided, or amounts paid or invoiced (as appropriate), by Licensee or its Sublicensees.

**Procedures for Audit**. COH may exercise its right to have Licensee’s and its Sublicensees’ relevant records examined only during the three (3) year period during which Licensee is required to maintain records, no more than once in any twelve (12) – month period. Licensee and its Sublicensees are required to make records available for inspection only during regular business hours, only at such place or places where such records are customarily kept, and only upon receipt of at least fifteen (15) days advance notice from COH.

**Audit Report**. The independent accountant will be instructed to provide to COH an audit report containing only its conclusions and methodology regarding the audit, and specifying whether the amounts paid were correct and, if incorrect, the amount of any underpayment or overpayment. All information and materials made available to or otherwise obtained or prepared by or for the independent accountant in connection with such audit will be deemed Licensee’s Confidential Information and will be subject to the independent accountant’s entry, prior to conducting the audit, into a written confidentiality agreement with Licensee consistent with this Agreement.

**Underpayment and Overpayment**. After review of the auditor’s report: (i) if there is an uncontested underpayment by Licensee for all of the periods covered by such auditor’s report, then Licensee shall pay to COH the full amount of that uncontested underpayment, and (ii) if there is an uncontested overpayment for such periods, then COH shall provide to Licensee a credit against future payments (such credit equal to the full amount of that overpayment), or, if Licensee is not obligated to make any future payments, then COH shall pay to Licensee the full amount of that overpayment. Contested amounts are subject to dispute resolution under ARTICLE 12. If the total amount of any such underpayment (as agreed to by Licensee or as determined under ARTICLE 12) exceeds five percent (5%) of the amount previously paid by Licensee for the period subject to audit, then Licensee shall pay the reasonable costs for the audit. Otherwise, all costs of the audit shall be paid by COH.

**: LICENSEE COVENANTS**

Licensee covenants and agrees that:

in conducting activities contemplated under this Agreement, Licensee shall comply in all material respects with all applicable laws and regulations including, without limitation, those related to the manufacture, use, labeling importation and marketing of Licensed Products;

without limiting the foregoing and notwithstanding any other provision in this Agreement, Licensee acknowledges and agrees that it is an exclusive Licensee under this Agreement and agrees (i) to be subject to all laws and other obligations applicable to grants for research funding as they apply to an exclusive Licensee, including diligence, reporting, access and pricing requirements, and (ii) to reasonably assist COH as reasonably necessary to ensure COH remains in compliance with any laws and other obligations applicable to grants for research funding;

in the event that individuals employed by or otherwise affiliated with City of Hope or its Affiliates collaborate with, consult for, or otherwise provide consulting or other services to Licensee, its Affiliates or Sublicensees in such individuals’ personal capacity, the terms and conditions of Exhibit C shall apply; and

Licensee has not been convicted of a criminal offense related to health care, is not currently debarred, excluded or otherwise ineligible for participation in federally funded health care programs and has not arranged or contracted (by employment or otherwise) with any employee, contractor, or agent that it knew or should have known are excluded from participation in any federal health care program, and will not knowingly arrange or contract with any such individuals or entities during the Term of this Agreement. Licensee agrees to: (i) notify COH in writing immediately of any threatened, proposed or actual conviction relating to health care, of any threatened, proposed or actual debarment or exclusion from participation in federally funded programs, of Licensee or any officer or director of Licensee, and (ii) refrain from knowingly employing or contracting with individuals or entities excluded from participation in a federally funded health care program. Any breach of this Section 6.1.4 by Licensee shall be grounds for termination of this Agreement by COH in accordance with Section 8.2.

**: INTELLECTUAL PROPERTY; PATENT PROSECUTION, MAINTENANCE AND ENFORCEMENT.**

**Patent Prosecution, Maintenance and Enforcement**.

COH shall be responsible for the preparation, filing, prosecution, and maintenance of all Patent Rights, using counsel of its choice. COH will timely provide Licensee with copies of all relevant documentation relating to such prosecution and Licensee shall keep such information confidential. COH’s counsel shall take instructions only from COH. In addition, COH shall instruct the patent counsel prosecuting Patent Rights to (i) copy Licensee on patent prosecution documents that are received from or filed with the United States Patent and Trademark Office and foreign equivalent, as applicable; (ii) provide Licensee with copies of draft submissions to the USPTO prior to filing; and (iii) give reasonable consideration to the comments and requests of Licensee or its patent counsel, provided, that, (a) COH reserves the sole right to make all final decisions with respect to the preparation, filing, prosecution and maintenance of such patent applications and patents; and (b) the patent counsel remains counsel to COH (and shall not jointly represent Licensee unless requested by Licensee and approved by COH, and an appropriate engagement letter and conflict waiver are in effect). All patents and patent applications in Patent Rights, to the extent assignable in whole or in part to COH, shall be assigned to COH.

COH will not unreasonably refuse to amend any patent application in Patent Rights to include claims reasonably requested by Licensee to protect the products contemplated to be sold by Licensee under this Agreement. If Licensee informs COH of other countries or jurisdictions in which it wishes to obtain patent protection with respect to the Patent Rights, COH shall prepare, file, prosecute and maintain patent applications in such countries and any patents resulting therefrom (and, for the avoidance of doubt, such patent applications and patents shall be deemed included in the Patent Rights). On a country-by-country and patent-by-patent basis, Licensee may elect to surrender any patent or patent application in Patent Rights in any country upon sixty (60) days advance written notice to COH. Such notice shall relieve Licensee from the obligation to pay for future patent costs but shall not relieve Licensee from responsibility to pay patent costs incurred prior to the expiration of the sixty (60) day notice period. Such U.S. or foreign patent application or patent shall thereupon cease to be a Patent Right hereunder, Licensee shall have no further rights therein and COH shall be free to license its rights to that particular U.S. or foreign patent application or patent to any other party on any terms.

Each Party shall promptly provide written notice to the other in the event it becomes aware of any actual or probable infringement of any of the Patent Rights in or relevant to the Field or of any Third Party claim regarding the enforceability or validity of any Patent Rights (“**Infringement Notice**”). Licensee shall, in cooperation with COH, use reasonable efforts to terminate infringement without litigation.

If infringing activity has not been abated within ninety (90) days following the date the Infringement Notice takes effect, then Licensee may, following consultation with COH, in its sole discretion and at its sole expense, take action against any alleged infringer or in defense of such any claim with respect to any COVID-19 Patent Rights for which Licensee has exclusive rights under this Agreement. In the event Licensee undertakes the enforcement or defense of any Patent Rights in accordance with Section 7.1.4, COH shall use reasonable efforts to provide all reasonable cooperation and assistance, at Licensee’s expense, including providing access to relevant documents and other evidence, making its employees available at reasonable business hours, and being joined as a party to such action as necessary to maintain standing. Any recovery obtained by Licensee as the result of legal proceedings initiated and paid for by Licensee pursuant to this Section 7.1.4, after deduction of Licensee’s reasonable costs and expenses incurred in securing such recovery, shall be deemed to be Net Sales of Licensed Products in the calendar quarter in which such recovery was received and royalties shall be due and payable thereon accordingly.

If COH is involuntarily joined in a suit initiated by Licensee, then Licensee will pay any costs incurred by COH arising out of such suit, including but not limited to, reasonable legal fees of counsel that COH selects and retains to represent it in the suit.

In the event that Licensee declines either to cause such infringement to cease (e.g. by settlement or injunction) or to initiate and thereafter diligently maintain legal proceedings against the infringer other than as part of a mutually agreed upon bona fide strategy, developed with the guidance of outside patent counsel, to preserve the COVID-19 Patent Rights, COH may, in its sole discretion and at its sole expense, take action against such alleged infringer or in defense of any such Third Party claim. Any recovery obtained by COH as the result of any such legal proceedings shall be for the benefit of COH only. COH may settle any such suit, action, or other proceeding, whether by consent order, settlement, or other voluntary final disposition, without the prior written approval of Licensee, provided that COH shall not settle any such suit, action, or other proceeding in a manner that adversely affects the rights of Licensee concerning the COVID-19 Patent Rights without Licensee’s prior written consent, which consent shall not be unreasonably withheld or delayed.

**Trademarks**. Licensee shall be responsible for the selection, registration, maintenance, and defense of all trademarks for use in connection with the sale or marketing of Licensed Products in the Field in the Territory (the “**Marks**”), as well as all expenses associated therewith. All uses of the Marks by Licensee or a Sublicensee shall comply in all material respects with all applicable laws and regulations (including those laws and regulations particularly applying to the proper use and designation of trademarks in the applicable countries). Licensee shall not, without COH’s prior written consent, use any trademarks or house marks of COH or its Affiliates (including the COH corporate name), or marks confusingly similar thereto, in connection with Licensee’s commercialization of Licensed Products under this Agreement in any promotional materials or applications or in any manner implying an endorsement by COH of Licensee or the Licensed Products. Licensee shall own all Marks.

**Challenge to the Patent Rights by Licensee.**

7.3.1 COH may terminate this Agreement and all Sublicenses issued hereunder, upon written notice to Licensee in the event that Licensee or any of its Affiliates or Sublicensees directly or indirectly asserts a Patent Challenge. “**Patent Challenge**” means any challenge in a legal or administrative proceeding to the patentability, validity or enforceability of any of the Patent Rights (or any claim thereof), including by: (i) filing or pursuing a declaratory judgment action in which any of the Patent Rights is alleged to be invalid or unenforceable; (ii) citing prior art against any of the Patent Rights, filing a request for or pursuing a re-examination of any of the Patent Rights (other than with COH’s written agreement), or becoming a party to or pursuing an interference; or (iii) filing or pursuing any re-examination, opposition, cancellation, nullity or other like proceedings against any of the Patent Rights; but excluding any challenge raised as a defense against a claim, action or proceeding asserted by COH against Licensee, its Affiliates or Sublicensees. In lieu of exercising its rights to terminate under this Section 7.3.1, COH may elect upon written notice to increase the payments due under all of ARTICLE 4 by [\*\*\*], which election will be effective retroactively to the date of the commencement of the Patent Challenge. Licensee acknowledges and agrees that this Section 7.3.1 is reasonable, valid and necessary for the adequate protection of COH’s interest in and to the Patent Rights, and that COH would not have granted to Licensee the licenses under those Patent Rights, without this Section 7.3.1. COH will have right at any time in its sole discretion to strike this Section 7.3.1 (or any portion thereof) from this Agreement, and COH will have no liability whatsoever as a result of the presence or absence of this Section 7.3.1 (or any struck portion thereof).

7.3.2 If COH obtains a final non-appealable judgment upholding the validity and enforceability of the challenged Patent Rights and finding at least one claim of such Patent Rights to be infringed by Licensee or any one of its Affiliates or Sublicensees in the absence of this Agreement, Licensee shall reimburse COH all of its attorneys’ fees and expenses expended in connection with defending such lawsuit or other proceeding.

7.3.3 COH or its Affiliates, or any of the inventors listed on the patent applications comprising the Patent Rights, either individually or jointly, shall not directly or indirectly (i) dispute, challenge, or assist in the challenge of the validity, scope, construction, enforceability or the Patent Rights or any claims thereof, or (ii) participate in the re-examination, opposition, cancellation, nullity or other like proceedings against any of the Patent Rights, either in a court of law, before the U.S. Patent and Trademark Office, or other agency or tribunal, other than the defense of the foregoing initiated by a Person other than COH or its Affiliates. COH acknowledges and agrees that this Section 7.3.3 is reasonable, valid and necessary for the adequate protection of Licensee’s access to the Patent Rights, and that Licensee would not have entered into this Agreement, without this Section 7.3.3. Licensee will have right at any time in its sole discretion to strike this Section 7.3.3 (or any portion thereof) from this Agreement, and Licensee will have no liability whatsoever as a result of the presence or absence of this Section 7.3.3 (or any struck portion thereof).

**Payment of COH Patent Expenses**.

The Parties acknowledge that, prior to the Effective Date, COH incurred historic expenses with respect to the drafting, prosecution and maintenance of the Patent Rights. In consideration of such historic expenditures by COH, Licensee shall reimburse COH fifty-four thousand dollars ($54,000) in full reimbursement for such expenses. Licensee shall pay such invoices within thirty (30) days of receipt of each such invoice.

After the Effective Date, COH shall provide to Licensee an annual invoice and reasonably detailed documentation with respect to COH’s out-of-pocket expenses incurred with respect to such prosecution and maintenance of the COVID-19 Patent Rights and Platform Patent Rights for the prior License Year (“**Annual Patent Expenses**”). Licensee shall reimburse COH for one-hundred percent (100%) of such Annual Patent Expenses within thirty (30) days after receipt of such invoice and documentation; provided, however, that for each License Year during which COH is licensing the Platform Patent Rights to one or more licensees other than Licensee, Licensee shall only be required to reimburse COH for a percentage of the Annual Patent Expenses relating to the Platform Patent Rights for such License Year, as follows:

(Annual Patent Expenses) \* 1 / (1 + L) , where L is the number of licensees of the Platform Patent Rights other than Licensee.

COH shall use reasonable efforts to request such additional licensees of the Platform Patent Rights to reimburse a comparable portion of the past patent expenses attributed to the Platform Patent Rights that were paid exclusively by Licensee before the additional license.

**Marking**. Licensee and its Sublicensees shall mark all Licensed Products in such a matter as to conform with the patent laws of the country to which such Licensed Products are shipped or in which such products are sold.

**: TERM AND TERMINATION**

**Term**. The term of this Agreement (the “**Term**”) shall commence on the Effective Date and, notwithstanding any other provision of this Agreement, shall continue unless terminated in accordance with Section 2.6, Section 7.3.1, or Section 8.2 of this Agreement.

**Termination**.

**Material Breach**. Either Party may terminate this Agreement for any material breach by the other Party, provided, that, the Party seeking to terminate shall have first given the breaching Party notice of such material breach (“**Breach Notice**”) with reasonable particulars of the material breach, and the Party receiving the Breach Notice failed to cure that material breach within thirty (30) days after the date of receipt of the Breach Notice; provided, that, if the breaching Party responds to the Breach Notice by providing a Dispute Notice pursuant to ARTICLE 12 to the Party seeking to terminate within ten (10) days after the date of receipt of the Breach Notice, the Party alleging the material breach may not terminate this Agreement until completion of the Resolution Period pursuant to ARTICLE 12.

**Bankruptcy**. COH shall have the right to terminate this Agreement upon notice to Licensee, in the event that: (i) Licensee seeks protection of any bankruptcy or insolvency law other than with the prior consent of COH, or (ii) a proceeding in bankruptcy or insolvency is filed by or against Licensee and not withdrawn, removed or vacated within 120 days of such filing, or there is adjudication by a court of competent jurisdiction that Licensee is bankrupt or insolvent.

**Termination at Will by Licensee**. Licensee shall have the right to terminate this Agreement upon notice to COH without cause, effective no fewer than ninety (90) days following the date of such notice.

**Effect of Termination**.

Upon any termination of this Agreement pursuant to Section 2.6, Section 7.3.1, or Section 8.2, all rights and licenses granted to Licensee under ARTICLE 3 shall immediately terminate on and as of the effective date of termination as provided in Section 2.6, Section 7.3.1, or Section 8.2, except that Licensee shall have the right to continue to sell Licensed Products manufactured prior to the effective date of such termination until the exhaustion of Licensee’s inventory of Licensed Products.

Upon termination of this Agreement pursuant to Section 2.6, Section 7.3.1, or Section 8.2:

Each Party shall promptly return to the other Party all relevant records and materials in its possession or control containing or comprising the other Party’s Confidential Information and to which the Party does not retain rights hereunder.

Licensee shall discontinue making any representation regarding its status as a licensee of COH for Licensed Products. Subject to Section 8.3.1, above, Licensee shall cease conducting any activities with respect to the marketing, promotion, sale or distribution of Licensed Products and cease all use of the Materials or COH Confidential Information.

Termination of this Agreement through any means and for any reason pursuant to Section 2.6, Section 7.3.1, or Section 8.2, shall not relieve the Parties of any obligation accruing prior thereto, including the payment of all sums due and payable, and shall be without prejudice to the rights and remedies of either Party with respect to any antecedent breach of any of the provisions of this Agreement.

**Survival**. Sections 4.1, 4.4, 4.5, 4.8, 5.1, 5.2 (each of Sections 4.4, 4.5, 4.8, 5.1, and 5.2 to the extent these obligations arise under Section 8.3.1), 5.3, 7.5, 8.3, 8.4, ARTICLE 10, ARTICLE 11, ARTICLE 12, 14.2, 14.4, 14.6, 14.7, 14.10, 14.12, and 14.13 shall survive termination of this Agreement for any reason pursuant to Section 2.6, Section 7.3.1, or Section 8.2.

**: REPRESENTATIONS AND WARRANTIES**

**Mutual Representations and Warranties**. COH and Licensee each represents and warrants as follows:

It has the right and authority to enter into this Agreement and all action required to be taken on its behalf, its officers, directors, partners and stockholders necessary for the authorization, execution, and delivery of this Agreement and, the performance of all of its obligations hereunder, and this Agreement, when executed and delivered, will constitute valid and legally binding obligations of such Party, enforceable in accordance with its terms, subject to: (i) laws limiting the availability of specific performance, injunctive relief, and other equitable remedies; and (ii) bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance or other similar laws now or hereafter in effect generally relating to or affecting creditors’ rights generally;

It has read this Agreement, with assistance from its counsel of choice. It understands all of this Agreement’s terms. It has been given a reasonable amount of time to consider the contents of this Agreement before each Party executed it. It agrees that it is executing this Agreement voluntarily with full knowledge of this Agreement’s legal significance; and

It has made such investigation of all matters pertaining to this Agreement that it deems necessary, and does not rely on any statement, promise, or representation, whether oral or written, with respect to such matters other than those expressly set forth herein. It agrees that it is not relying in any manner on any statement, promise, representation or understanding, whether oral, written or implied, made by any Party, not specifically set forth in this Agreement. It acknowledges that, after the Effective Date, it may discover facts different from or in addition to those which it now knows or believes to be true. Nevertheless, it agrees that this Agreement shall be and remain in full force and effect in all respects, notwithstanding such different or additional facts.

**Representations and Warranties of COH**. COH represents and warrants that, as of the Effective Date, to the actual knowledge of the Vice President, Business Innovation of its Office of Technology Licensing without independent inquiry, COH has not received any notice of (i) any litigation or similar proceedings involving the Patent Rights and the Materials, including any claim of inventorship or ownership; (ii) any allegation of an infringement or misappropriation of trade secrets, copyright, proprietary information or any other intellectual property rights of any Third Parties with respect to the Patent Rights; or (iii) any non-compliance of the Materials with respect to the applicable laws, rules, regulations and guidelines, including those that govern the confidentiality and privacy of individually identifiable health information including, without limitation, the Health Insurance Portability and Accountability Act of 1996.

**Representations and Warranties of Licensee and GeoVax Labs, Inc**.

Licensee represents and warrants that Licensee has not, prior to the Effective Date, entered into any agreements pursuant to which the Patent Rights have been sublicensed.

GeoVax Labs, Inc., a Delaware corporation having its principal place of business at 1900 Lake Park Drive, Suite 380, Smyrna, GA 30080 (“**Parent**”), represents and warrants that Licensee is and, except in the event of an assignment or transfer permitted under Section 14.1 of this Agreement, at all times during the Term of this Agreement will remain, under the control of Parent. Parent shall cause Licensee to comply in all respects with each of its representations, warranties, covenants, obligations, agreements and undertakings pursuant to or otherwise in connection with this Agreement. As a material condition to COH’s willingness to enter into this Agreement and perform its obligations hereunder, Parent hereby ensures performance and payments due by Licensee of each of its covenants, obligations and undertakings pursuant to or otherwise in connection with this Agreement and hereby represents, acknowledges and agrees that any breach of, or other failure to perform, any such representation, warranty, covenant, obligation, agreement or undertaking of Licensee shall also be deemed to be a breach or failure to perform by Parent, and COH shall have the right, exercisable in its sole discretion, to pursue any and all available remedies it may have arising out of any such breach or nonperformance directly against either or both of Parent or Licensee in the first instance.

**Exclusions**. Nothing in this Agreement is or shall be construed as:

A warranty or representation by COH as to the validity or scope of any claim or patent or patent application within the Patent Rights;

A warranty or representation by COH that anything made, used, sold, or otherwise disposed of under any license granted in this Agreement is or will be free from infringement of any patent rights or other intellectual property right of any Third Party;

A grant by COH, whether by implication, estoppel, or otherwise, of any licenses or rights under any patents other than Patent Rights and Materials as defined herein, regardless of whether such patents are dominant or subordinate to Patent Rights;

An obligation on COH to bring or prosecute any suit or action against a third party for infringement of any of the Patent Rights or Materials;

An obligation to furnish any Materials outside of the materials specifically identified in Exhibit C; or

A representation or warranty of the ownership of the Patent Rights and Materials other than as set forth in Section 9.2, above.

**DISCLAIMER. EXCEPT AS EXPLICITLY SET FORTH IN SECTION 9.2, NO WARRANTY IS GIVEN WITH RESPECT TO THE PATENT RIGHTS OR MATERIALS, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND THE PARTIES SPECIFICALLY DISCLAIM ANY EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, SUCH AS ANY USE, SAFETY, EFFICACY, APPROVABILITY BY REGULATORY AUTHORITIES, TIME AND COST OF DEVELOPMENT OR BREADTH OF SUBJECT MATTER OF THIS AGREEMENT, VALIDITY OF THE PATENT RIGHTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY OR OTHER RIGHTS OF ANY THIRD PARTY. THE MATERIALS ARE PROVIDED “AS IS”. THE WARRANTIES SET FORTH IN SECTIONS 9.1 AND 9.2, ABOVE, ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, NON-INFRINGEMENT AND ALL SUCH OTHER WARRANTIES ARE HEREBY EXPRESSLY DISCLAIMED.**

**: INDEMNIFICATION**

**Indemnification by Licensee**. Licensee shall defend, indemnify and hold harmless COH, its Affiliates, and their respective officers, directors, shareholders, employees, representatives, and agents (“**COH Indemnitees**”) from and against any and all Third Party liabilities, claims, suits, and expenses, including reasonable attorneys’ fees (collectively, “**Losses**”), arising out of or are in any way attributable to: (i) the material breach of any representation or warranty made by Licensee under this Agreement, (ii) the research, development, marketing, approval, manufacture, packaging, labeling, handling, storage, transportation, use, distribution, promotion, marketing or sale of Licensed Products or use or handling of the Materials by or on behalf of Licensee, any of its Affiliates or a Sublicensee or any other exercise of rights under this Agreement or pursuant to any sublicense, or (iii) the gross negligence, willful misconduct or failure to materially comply with applicable law by a Licensee, an Affiliate of Licensee, or a Sublicensee. Notwithstanding the foregoing, Licensee shall have no indemnification obligations under this Section 10.1 for any Losses arising due to (a) the material breach by COH of any representation or warranty made by COH or any COH Indemnitee’s obligation under this Agreement or (b) COH’s gross negligence, willful misconduct or failure to materially comply with applicable law by a COH Indemnitee.

**Procedure**. The indemnities set forth in this ARTICLE 10 are subject to the condition that the Party seeking the indemnity shall forthwith notify the indemnifying Party on being notified or otherwise made aware of a liability, claim, suit, action or expense and that the indemnifying Party defend and control any proceedings with the other Party being permitted to participate at its own expense (unless there shall be a conflict of interest which would prevent representation by joint counsel, in which event the indemnifying Party shall pay for the other Party’s counsel); provided, that, the indemnifying Party may not settle the liability, claim, suit, action or expense, or otherwise admit fault of the other Party or consent to any judgment, without the written consent of the other Party (such consent not to be unreasonably withheld). Notwithstanding the foregoing, no delay in the notification of the existence of any claim of Loss shall cause a failure to comply with this Section 10.2 as long as such delay shall not have materially impaired the rights of the indemnifying Party.

**Insurance**.

* + 1. Within thirty (30) days following the Effective Date, Licensee shall, at its own cost, procure and continue in effect during the Term of this Agreement and for five (5) years thereafter: (i) comprehensive general liability insurance with limits of not less than one million dollars ($1,000,000)  dollars per occurrence with an annual aggregate of three million dollars ($3,000,000)  dollars, including umbrella/excess liability at a one million dollar ($1,000,000) limit,  and (ii) product liability coverage, with limits of not less than five million dollars ($5,000,000) dollars per occurrence.  Licensee shall also, at its own cost, procure and continue in effect from commencement of any clinical trial and thereafter through the Term of this Agreement and for five (5) years thereafter, clinical trial insurance with limits of not less than five million dollars ($5,000,000) dollars per occurrence for death or bodily injury.

General Liability coverage shall name the COH Indemnitees and their respective successors as additional insureds. The COH Indemnitees shall be notified in writing by Licensee not less than thirty (30) days prior to any modification, cancellation or non-renewal of such policy. Licensee’s insurance must include a provision that the coverages will be primary and non-contributing over any and all insurance that may be maintained by COH, and will not participate with nor will be excess over any valid and collective insurance or program of self-insurance carried or maintained by the COH Indemnitees. Such insurance coverage shall be maintained with an insurance company or companies having an A.M. Best’s rating (or its equivalent) of A-XII or better.

* + 1. Licensee expressly understands that the coverage limits in Section 10.3.1 do not in any way limit Licensee’s liability.

**LIMITATION ON DAMAGES. NOTWITHSTANDING ANYTHING CONTAINED IN THIS AGREEMENT TO THE CONTRARY, EXCEPT IN RELATION TO LICENSEE’S INDEMNIFICATION OBLIGATIONS UNDER SECTION 10.1 AND ANY BREACH BY LICENSEE OR COH OF ARTICLE 11, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, EXEMPLARY, ENHANCED, PUNITIVE, CONSEQUENTIAL, INDIRECT, OR INCIDENTAL DAMAGES (INCLUDING LOSS OF GOODWILL, REPUTATION, BUSINESS PRODUCTION, REVENUES, PROFITS,** **ANTICIPATED PROFITS, CONTRACTS, OR OPPORTUNITIES, COSTS OF PROCURING SUBSTITUTE GOODS, LOST BUSINESS OR ENHANCED DAMAGES FOR INTELLECTUAL PROPERTY INFRINGEMENT) WHETHER BASED UPON BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, STRICT LIABILITY IN TORT OR ANY OTHER LEGAL THEORY** **(INCLUDING THE ENTRY INTO, PERFORMANCE, OR BREACH OF THIS AGREEMENT), REGARDLESS OF WHETHER SUCH LOSS OR DAMAGE WAS FORESEEABLE AND THE PARTY AGAINST WHOM LIABILITY IS CLAIMED HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED REMEDY OF ITS ESSENTIAL PURPOSE. IN NO EVENT SHALL COH BE LIABLE TO LICENSEE FOR AN AGGREGATE AMOUNT IN EXCESS OF THE TOTAL CONSIDERATION PAID TO COH HEREUNDER.**

**: CONFIDENTIALITY**

**Confidential Information**. During the Term of this Agreement and for five (5) years thereafter without regard to the means of termination: (i) COH shall not use, for any purpose other than the purpose contemplated by this Agreement, or reveal or disclose to any Third Party Licensee Confidential Information; and (ii) Licensee shall not use, for any purpose other than the purpose contemplated by this Agreement, or transfer, reveal or disclose COH Confidential Information to any Third Party. The Parties shall take reasonable measures to assure that no unauthorized use or disclosure is made by others to whom access to such information is granted.

**Exceptions**. Notwithstanding the foregoing, a Party may use and disclose Confidential Information of the other Party as follows:

if required by applicable law, rule, regulation, government requirement and/or court order, and/or the rules of any stock exchange; provided, that, the disclosing Party promptly notifies the other Party of its notice of any such requirement and provides the other Party a reasonable opportunity to seek confidential treatment, a protective order or other appropriate remedy and/or to comment on the disclosure and/or waive compliance with the provisions of this Agreement (for clarity, the foregoing includes the disclosing Party’s obligation to use all reasonable efforts to ensure confidential treatment is maintained and/or renewed for the maximum allowable time period);

to the extent such use and disclosure occurs in the filing or publication of any patent application or patent on Inventions;

as necessary or desirable for securing any regulatory approvals, including pricing approvals, for any Licensed Products; provided, that, the disclosing Party shall take all reasonable steps to limit disclosure of the Confidential Information outside such regulatory agency and to otherwise maintain the confidentiality of the Confidential Information;

to take any lawful action that it deems necessary to protect its interest under, or to enforce compliance with the terms and conditions of, this Agreement;

to the extent necessary, to its Affiliates, directors, officers, employees, consultants, vendors and clinicians under written agreements of confidentiality at least as restrictive as those set forth in this Agreement, who have a need to know such information in connection with such Party performing its obligations or exercising its rights under this Agreement; and

to actual and potential investors, providers of research funding, licensees, Sublicensees, consultants, vendors and suppliers, academic and commercial collaborators, and joint owners of the Inventions and/or the Patent Rights, under written agreements of confidentiality at least as restrictive as those set forth in this Agreement.

**Certain Obligations**. During the Term and for a period of five (5) years thereafter, Licensee, with respect to COH Confidential Information, and COH, with respect to Licensee Confidential Information, agree:

to use such Confidential Information only for the purposes contemplated under this Agreement,

to treat such Confidential Information as it would its own proprietary information which in no event shall be less than a reasonable standard of care,

to take reasonable precautions to prevent the disclosure of such Confidential Information to a Third Party without written consent of the other Party, and

to only disclose such Confidential Information to those employees, agents and Third Parties who have a need to know such Confidential Information for the purposes set forth herein and who are subject to obligations of confidentiality no less restrictive than those set forth herein.

**Termination**. Upon termination of this Agreement pursuant to Sections 2.6, or 8.2, and upon the request of the disclosing Party, the receiving Party shall promptly return to the disclosing Party or destroy all copies of Confidential Information received from such Party, and shall return or destroy, and document the destruction of, all summaries, abstracts, extracts, or other documents which contain any Confidential Information of the other Party in any form, except that each Party shall be permitted to retain a copy (or copies, as necessary) of such Confidential Information for archival purposes or to enforce or verify compliance with this Agreement, or as required by any applicable law or regulation.

**: DISPUTE RESOLUTION**

All Disputes shall be first referred to the Vice President, Business Innovation of COH and Chief Executive Officer of Licensee for resolution, prior to proceeding under the other provisions of this ARTICLE 12. A Dispute shall be referred to such executives upon one Party (the “**Initiating Party**”) providing the other Party (the “**Responding Party**”) with notice that such Dispute exists (“**Dispute Notice**”), together with a written statement describing the Dispute with reasonable specificity and proposing a resolution to such Dispute that the Initiating Party is willing to accept, if any. Within ten (10) Business Days after having received such statement and proposed resolution, if any, the Responding Party shall respond with a written statement that provides additional information, if any, regarding such Dispute, and proposes a resolution to such Dispute that the Responding Party is willing to accept, if any. If not otherwise resolved, the Parties shall engage in good faith efforts to negotiate a resolution to resolve the Dispute for the following fifteen (15) Business Days (the “**Resolution Period**”). In the event that such Dispute is not resolved during the Resolution Period, either Party may bring and thereafter maintain suit against the other with respect to such Dispute; provided, however, that the exclusive jurisdiction of any such suit shall be the state and federal courts located in New Castle County, Delaware, and the Parties hereby consent to the exclusive jurisdiction and venue of such courts. The Parties agree that a final judgment in any such claim is conclusive and may be enforced in any other jurisdiction by suit on the judgment or in any other manner provided by law.

**: GOVERNMENTAL MATTERS**

**Governmental Approval or Registration**. If this Agreement or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, Licensee shall assume all legal obligations to do so. Licensee shall notify COH if it becomes aware that this Agreement is subject to a U.S. or foreign government reporting or approval requirement. Licensee shall make all necessary filings and pay all costs including fees, penalties and all other out-of-pocket costs associated with such reporting or approval process.

**Export Control Laws**. Licensee acknowledges that the subject matter of this Agreement is subject to U.S. export control jurisdiction. Licensee shall observe all applicable U.S. and foreign laws with respect to its activities pursuant to this Agreement, including the transfer of Licensed Products and related technical data to foreign countries, including, without limitation, the International Traffic in Arms Regulations and the Export Administration Regulations, as well as end-user, end-use, and destination restrictions applied by the United States.

**Preference for United States Industry**. If Licensee sells a Licensed Product in the U.S., Licensee shall manufacture said product substantially in the United States, if and to the extent required under applicable U.S. laws and regulations.

**: MISCELLANEOUS**

**Assignment and Delegation**. Except as expressly provided in this Section 14.1, neither this Agreement nor any right or obligation hereunder shall be assignable in whole or in part, whether by operation of law, or otherwise by Licensee without the prior written consent of COH. Notwithstanding the foregoing, Licensee may (i) freely assign or otherwise transfer all or any of its rights, or delegate or otherwise transfer all or any of its obligations or performance, to Parent or an Affiliate, or (ii) assign or transfer its rights and obligations under this Agreement to a Person that succeeds to all or substantially all of Licensee’s business or assets, whether by sale, merger, operation of law or otherwise; provided, that, such Person agrees, in form and substance reasonably acceptable to COH, to be bound as a direct party to this Agreement in lieu of or in addition to Licensee. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the Parties hereto and their respective successors and permitted assignees. Any transfer or assignment of this Agreement in violation of this Section 14.1 shall be null and void.

**Entire Agreement**. This Agreement contains the entire agreement between the Parties relating to the subject matter hereof, and all prior understandings, representations and warranties between the Parties, including the Confidentiality Agreement between the Parties dated July 6, 2021, are superseded by this Agreement.

**Amendments**. Changes and additional provisions to this Agreement shall be binding on the Parties only if agreed upon in writing and signed by the Parties.

**Applicable Law**. This Agreement shall be construed and interpreted in accordance with the laws of the State of Delaware and all rights and remedies shall be governed by such laws without regard to principles of conflicts of law that would result in the application of the law of another jurisdiction.

**Force Majeure**. If the performance of this Agreement or any obligations hereunder is prevented, restricted or interfered with by reason of earthquake, fire, flood or other casualty or due to strikes, riot, storms, explosions, acts of God, war, terrorism, malicious acts of Third Parties, or a similar occurrence or condition beyond the reasonable control of the Parties, the Party so affected shall, upon giving prompt written notice to the other Parties, be excused from such performance during such prevention, restriction or interference, and any failure or delay resulting therefrom shall not be considered a breach of this Agreement. Notwithstanding anything in this Agreement or at law or in equity to the contrary, in no event shall an event of force majeure excuse, extend or delay a Party’s obligation to pay any amounts otherwise required to be paid by such Party pursuant to this Agreement. The Parties agree the effects of the SARS-CoV-2 pandemic and the measures adopted by competent governmental authorities in response to it as of the Effective Date may not be invoked as a force majeure for the purposes of this Agreement.

**Severability**. The Parties do not intend to violate any public policy or statutory common law. However, if any sentence, paragraph, clause or combination of this Agreement is in violation of any law or is found to be invalid, illegal, or otherwise unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability will not affect any other term or provision of this Agreement or invalidate or render unenforceable such sentence, paragraph, clause or combination in any other jurisdiction. Upon a determination that a sentence, paragraph, clause or combination is invalid, illegal, or unenforceable, the Parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

**Notices**. All notices, requests, demands, and other communications relating to this Agreement shall be in writing in the English language and shall be delivered in person or by delivery service or international courier with package tracing capability. Notices shall be sent via a service which provides traceability of packages and signature confirmation and shall be deemed to have been given on the date actually received. Except as provided in Section 14.12, notices shall be sent as follows:

|  |  |
| --- | --- |
| Notices to COH:  Office of Technology Licensing  City of Hope  1500 East Duarte Road  Duarte, CA 91010  Attn: Vice President, Business Innovation, Office of Technology Licensing  Fax 626-256-8651 | with a copy to:  Office of General Counsel  City of Hope  1500 East Duarte Road  Duarte, CA 91010  Attn: General Counsel  Fax 1 626-218-8663  Fax 2 626-256-8651 |
| Notices to Licensee:  David Dodd, CEO  GeoVax, Inc.  1900 Lake Park Drive  Suite 380  Smyrna, GA 30080  Fax: 678-384-7281 |  |

Either Party may change its address for notices or facsimile number at any time by sending notice to the other Party.

**Independent Contractor**. Nothing herein shall create any association, partnership, joint venture, fiduciary duty or the relation of principal and agent between the Parties hereto, it being understood that each Party is acting as an independent contractor, and neither Party shall have the authority to bind the other or the other’s representatives in any way.

**Waiver**. No delay on the part of either Party hereto in exercising any power or right hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any power or right hereunder preclude other or further exercise thereof or the exercise of any other power or right. No waiver of this Agreement or any provision hereof shall be enforceable against any Party hereto unless in writing, signed by the Party against whom such waiver is claimed, and shall be limited solely to the one event.

**Interpretation**. This Agreement has been prepared jointly and no rule of strict construction shall be applied against either Party. In this Agreement, the singular shall include the plural and vice versa and the word “including” shall be deemed to be followed by the phrase “without limitation.” The section headings contained in this Agreement are inserted for convenience only and shall not affect in any way the meaning or interpretation of this Agreement.

**Counterparts**. This Agreement may be executed in counterparts, each of which together shall constitute one and the same Agreement. For purposes of executing this agreement, a facsimile copy or an emailed PDF of this Agreement, including the signature pages, will be deemed an original.

**Publicity**. Subject to Section 11.2.1, neither Party may issue a press release (unless the information in such release or the release itself is filed to meet Licensee’s or Parent’s obligations under federal securities laws or the rules and regulations of any stock exchange or trading market) without the prior written consent of the other Party; provided, however, that once the existence or any terms or conditions of this Agreement has been publicly disclosed in a manner mutually and reasonably agreed-to by the Parties, either Party may republish the facts previously disclosed, using the exact language as previously disclosed, without the prior consent of the other Party; provided, further, that if the language being re-disclosed is a quotation from COH personnel, Licensee shall provide prior written notification to COH. In addition, COH may disclose the overall potential value of the Agreement to COH so long as the detailed and specific terms and conditions of this Agreement are not disclosed; provided that COH will provide Licensee at least three (3) Business Days’ notice prior to the first such public disclosure along with a copy of such proposed disclosure. If a Third Party inquires whether a license is available, COH may disclose the existence of the Agreement and the extent of its grant in Section 3.1 to such Third Party, but will not disclose the name of Licensee, except where COH is required to release information under either the California Public Records Act or other applicable law. Licensee may not reference COH in a press release, any other media release, or promotional material including websites or other electronic media without prior written consent from COH. Notwithstanding Section 14.7, with respect to COH, all notifications and requests for consents under this Section 14.12 should be directed to COH’s Media Department ([media@coh.org](mailto:media@coh.org)).

**No Third Party Beneficiaries**. Except for the rights of the COH Indemnitees and Licensee Indemnitees pursuant to ARTICLE 10 and Parent being a third-party beneficiary to this Agreement who is entitled to the rights and benefits hereunder and may enforce the provisions hereof as if it were a party hereto, nothing in this Agreement, either express or implied, is intended to or shall confer upon any Third Party any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

[*Signature page to follow*]

**IN WITNESS WHEREOF**, the Parties have executed this Agreement by their duly authorized representatives as of the Effective Date.

|  |  |  |  |
| --- | --- | --- | --- |
| GEOVAX, INC. | | CITY OF HOPE | |
| By: |  | By: |  |
| Name | David A. Dodd | Name: | Robert Stone |
| Title: | President and CEO | Title: | President and CEO |

|  |  |
| --- | --- |
| GEOVAX LABS, INC.  (solely with respect to Section 9.3.2) | |
| By: |  |
| Name | David A. Dodd |
| Title: | Chairman, President and CEO |

**List of Exhibits**

**EXHIBIT A – Clinical Trials**

**EXHIBIT B – Materials List**

**EXHIBIT C – Collaboration Terms**

**EXHIBIT D - Notices to FDA of Transfer of Sponsor Obligations**

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

#### FORM 10-Q

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2021

OR

**Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from to

**Commission File Number: 001-39563**

**GEOVAX LABS, INC.**

*(Exact name of registrant as specified in its charter)*

##### **Delaware** **87-0455038**

*(State or other jurisdiction (IRS Employer Identification No.)*

*of incorporation or organization)*

##### **1900 Lake Park Drive, Suite 380**

##### **Smyrna, Georgia 30080**

*(Address of principal executive offices) (Zip Code)*

##### **(678) 384-7220**

##### *(Registrant’s telephone number, including area code****)***

Securities registered pursuant to Section 12(b) of the Act:

|  |  |  |
| --- | --- | --- |
| Title of each Class | Trading Symbol | Name of each Exchange on which Registered |
| Common Stock $0.001 par value | GOVX | The Nasdaq Capital Market |
| Warrants to Purchase Common Stock | GOVXW | The Nasdaq Capital Market |

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non‑accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer

Non-accelerated filer  Emerging growth company

Smaller reporting company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):

Yes  No

As of November 11, 2021, 6,381,541 shares of the Registrant’s common stock, $.001 par value, were issued and outstanding.

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# Part I -- FINANCIAL INFORMATION

## Item 1 Financial Statements

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| GEOVAX LABS, INC. | | | | | | |
| CONDENSED CONSOLIDATED BALANCE SHEETS | | | | | | |
|  |  |  |  |  | | |
|  |  |  |  | September 30, |  | December 31, |
|  |  |  |  | 2021 |  | 2020 |
|  | | |  | (unaudited) |  |  |
| ASSETS | | |  |  |  |  |
| Current assets: | | |  |  |  |  |
|  | Cash and cash equivalents | |  | $ 18,107,019 |  | $ 9,883,796 |
|  | Grant funds and other receivables | |  | - |  | 182,663 |
|  | Prepaid expenses and other current assets | |  | 52,818 |  | 168,689 |
| Total current assets | | |  | 18,159,837 |  | 10,235,148 |
| Property and equipment, net | | |  | 168,653 |  | 147,741 |
| Deposits | | |  | 11,010 |  | 11,010 |
|  |  |  |  |  |  |  |
| Total assets | | |  | $ 18,339,500 |  | $ 10,393,899 |
|  |  |  |  |  |  |  |
| LIABILITIES AND STOCKHOLDERS’ EQUITY | | |  |  |  |  |
| Current liabilities: | | |  |  |  |  |
|  | Accounts payable | |  | $ 289,438 |  | $ 267,702 |
|  | Accrued expenses | |  | 46,212 |  | 359,281 |
|  | Current portion of notes payable | |  | - |  | 183,326 |
| Total current liabilities | | |  | 335,650 |  | 810,309 |
| Note payable, net of current portion | | |  | - |  | 14,738 |
| Total liabilities | | |  | 335,650 |  | 825,047 |
|  |  |  |  |  |  |  |
| Commitments (Note 8) | | |  |  |  |  |
|  |  |  |  |  |  |  |
| Stockholders’ equity: | | |  |  |  |  |
|  | Preferred Stock, $.01 par value: | |  |  |  |  |
|  |  | Authorized shares – 10,000,000 |  |  |  |  |
|  |  | Series B convertible preferred stock, $1,000 stated value; |  |  |  |  |
|  |  | -0- and 100 shares issued and outstanding at |  |  |  |  |
|  |  | September 30, 2021 and December 31, 2020, respectively |  | - |  | 76,095 |
|  | Common stock, $.001 par value: | |  |  |  |  |
|  |  | Authorized shares – 600,000,000 |  |  |  |  |
|  |  | Issued and outstanding shares – 6,381,541 and 3,834,095 at |  |  |  |  |
|  |  | September 30, 2021 and December 31, 2020, respectively |  | 6,382 |  | 3,834 |
|  | Additional paid-in capital | |  | 68,630,363 |  | 55,294,504 |
|  | Accumulated deficit | |  | (50,632,895) |  | (45,805,581) |
| Total stockholders’ equity | | |  | 18,003,850 |  | 9,568,852 |
|  |  |  |  |  |  |  |
| Total liabilities and stockholders’ equity | | |  | $ 18,339,500 |  | $ 10,393,899 |
|  |  |  |  |  |  |  |

See accompanying notes to condensed consolidated financial statements.

**GEOVAX LABS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

**(Unaudited)**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Three Months Ended September 30, | | |  | Nine Months Ended September 30, | | |
|  |  |  |  | 2021 |  | 2020 |  | 2021 |  | 2020 |
| Grant and collaboration revenue | | | | $ 30,414 |  | $ 415,458 |  | $ 220,539 |  | $ 1,572,037 |
|  |  |  |  |  |  |  |  |  |  |  |
| Operating expenses: | | | |  |  |  |  |  |  |  |
|  | Research and development | | | 1,224,362 |  | 416,756 |  | 2,659,980 |  | 1,687,113 |
|  | General and administrative | | | 757,432 |  | 435,013 |  | 2,562,641 |  | 1,364,650 |
| Total operating expenses | | | | 1,981,794 |  | 851,769 |  | 5,222,621 |  | 3,051,763 |
|  |  |  |  |  |  |  |  |  |  |  |
| Loss from operations | | | | (1,951,380) |  | (436,311) |  | (5,002,082) |  | (1,479,726) |
|  |  |  |  |  |  |  |  |  |  |  |
| Other income (expense): | | | |  |  |  |  |  |  |  |
|  | Interest income | | | 877 |  | 90 |  | 3,998 |  | 902 |
|  | Interest expense | | | - |  | (134,427) |  | (1,286) |  | (142,722) |
|  | Gain on debt extinguishment | | | - |  | - |  | 172,056 |  | - |
| Total other income (expense) | | | | 877 |  | (134,337) |  | 174,768 |  | (141,820) |
|  |  |  |  |  |  |  |  |  |  |  |
| Net loss | | | | $ (1,950,503) |  | $ (570,648) |  | $ (4,827,314) |  | $ (1,621,546) |
|  |  |  |  |  |  |  |  |  |  |  |
| Basic and diluted: | | | |  |  |  |  |  |  |  |
| Net loss per common share | | | | $ (0.31) |  | $ (0.73) |  | $ (0.80) |  | $ (2.85) |
| Weighted average shares outstanding | | | | 6,349,297 |  | 782,978 |  | 6,005,032 |  | 569,955 |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

See accompanying notes to condensed consolidated financial statements.

**GEOVAX LABS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS’ EQUITY (DEFICIENCY)**

**(Unaudited)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Three-Month and Nine-Month Periods Ended September 30, 2021 | | | | | | |
|  |  | |  |  |  |  | Total |
|  | Preferred Stock | | Common Stock | | Additional | Accumulated | Stockholders’ |
|  | Shares | Amount | Shares | Amount | Paid-in Capital | Deficit | Equity |
| Balance at December 31, 2020 | 100 | $ 76,095 | 3,834,095 | $ 3,834 | $ 55,294,504 | $(45,805,581) | $ 9,568,852 |
| Sale of common stock for cash | - | - | 1,644,000 | 1,644 | 9,407,276 | - | 9,408,920 |
| Issuance of common stock upon warrant exercise | - | - | 835,900 | 836 | 3,173,320 | - | 3,174,156 |
| Issuance of common stock for services | - | - | 1,472 | 1 | 5,999 | - | 6,000 |
| Stock option expense | - | - | - | - | 56,190 |  | 56,190 |
| Net loss for the three months ended March 31, 2021 | - | - | - | - | - | (1,562,778) | (1,562,778) |
| Balance at March 31, 2021 | 100 | 76,095 | 6,315,467 | 6,315 | 67,937,289 | (47,368,359) | 20,651,340 |
| Repurchase of preferred stock | (100) | (76,095) | - | - | 75,095 | - | (1,000) |
| Issuance of common stock for services | - | - | 12,235 | 13 | 65,828 | - | 65,841 |
| Stock option expense | - | - | - | - | 56,190 |  | 56,190 |
| Net loss for the three months ended June 30, 2021 | - | - | - | - | - | (1,314,033) | (1,314,033) |
| Balance at June 30, 2021 | - | - | 6,327,702 | 6,328 | 68,134,402 | (48,682,392) | 19,458,338 |
| Issuance of common stock upon warrant exercise | - | - | 53,839 | 54 | 229,946 | - | 230,000 |
| Stock option expense | - | - | - | - | 56,190 | - | 56,190 |
| Issuance of warrant for technology license | - | - | - | - | 209,825 | - | 209,825 |
| Net loss for the three months ended |  |  |  |  |  |  |  |
| September 30, 2021 | - | - | - | - | - | (1,950,503) | (1,950,503) |
| Balance at September 30, 2021 | - | $ - | 6,381,541 | $ 6,382 | $ 68,630,363 | $ (50,632,895) | $ 18,003,850 |

**GEOVAX LABS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS’ EQUITY (DEFICIENCY)**

**(Unaudited)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Three-Month and Nine-Month Periods Ended September 30, 2020 | | | | | | |
|  |  | |  |  |  |  | Total | |
|  | Preferred Stock | | Common Stock | | Additional | Accumulated | Stockholders’ | |
|  | Shares | Amount | Shares | Amount | Paid-in Capital | Deficit | Equity (Deficiency) | |
| Balance at December 31, 2019 | 2,486 | $ 1,932,433 | 14,992 | $ 15 | $ 39,340,509 | $(42,847,513) | $ (1,574,556) | |
| Sale of convertible preferred stock for cash | 300 | 300,000 | - | - | - | - | 300,000 | |
| Conversion of preferred stock to common stock | (2,386) | (1,856,338) | 674,067 | 674 | 1,855,664 | - | - | |
| Common stock issued for services | - | - | 521 | 1 | 5,999 | - | 6,000 | |
| Net loss for the three months ended March 31, 2020 | - | - | - | - | - | (595,694) | (595,694) | |
| Balance at March 31, 2020 | 400 | 376,095 | 689,580 | 690 | 41,202,172 | (43,443,207) | (1,864,250) | |
| Common stock issued for services | - | - | 2,124 | 2 | 11,998 | - | 12,000 | |
| Warrants issued in bridge financing | - | - | - | - | 457,833 |  | 457,833 | |
| Net loss for the three months ended June 30, 2020 | - | - | - | - | - | (455,204) | (455,204) | |
| Balance at June 30, 2020 | 400 | 376,095 | 691,704 | 692 | 41,672,003 | (43,898,411) | (1,849,621) | |
| Conversion of preferred stock to common stock | (300) | (300,000) | 42,723 | 43 | 299,957 | - | - | |
| Warrants exercised for common stock | - | - | 36,902 | 37 | (37) | - | - | |
| Common stock issued upon debenture conversion | - | - | 177,626 | 177 | 569,340 | - | 569,517 | |
| Common stock issued upon cancellation  of accrued compensation | - | - | 300,001 | 300 | 1,499,700 | - | 1,500,000 | |
| Sale of common stock for cash | - | - | 2,310,000 | 2,310 | 11,156,186 | - | 11,158,496 | |
| Common stock issued for services | - | - | 517 | - | 6,000 | - | 6,000 | |
| Net loss for the three months ended |  |  |  |  |  |  |  | |
| September 30, 2020 | - | - | - | - | - | (570,648) | (570,648) | |
| Balance at September 30, 2020 | 100 | $ 76,095 | 3,559,473 | $ 3,559 | $ 55,203,149 | $ (44,469,059) | $ 10,813,744 | |

See accompanying notes to consolidated financial statements.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **GEOVAX LABS, INC.**  **CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  **(Unaudited)** | | | | | | | | | | |
|  | | | | | | |  |  |  |  |
|  | | | | | | |  |  |  |  |
|  | | | | | | |  | Nine Months Ended September 30, | | |
|  | | | | | | |  | 2021 |  | 2020 |
| Cash flows from operating activities: | | | | | | |  |  |  |  |
|  | Net loss | | | | | |  | $ (4,827,314) |  | $ (1,621,546) |
|  | Adjustments to reconcile net loss to net cash | | | | | |  |  |  |  |
|  | used in operating activities: | | | | | |  |  |  |  |
|  |  | Depreciation and amortization | | | | |  | 26,806 |  | 2,983 |
|  |  | Stock-based compensation for employees and directors | | | | | | 168,570 |  | - |
|  |  | Stock-based compensation for consultants | | | | | | 80,733 |  | 24,000 |
|  |  | Warrant issued for technology license fee | | | | | | 209,825 |  | - |
|  |  | Gain on debt extinguishment | | | | | | (172,056) |  | - |
|  |  | Changes in assets and liabilities: | | | | |  |  |  |  |
|  |  |  | | Grant funds and other receivables | | | | 182,663 |  | (72,551) |
|  |  |  | | Prepaid expenses and other current assets | | | | 106,979 |  | 82,274 |
|  |  |  | | Amortization of debt discount | | | | - |  | 124,185 |
|  |  |  | | Accounts payable and accrued expenses | | | | (289,477) |  | 252,036 |
|  |  |  | | Total adjustments | | |  | 314,043 |  | 412,927 |
|  | Net cash used in operating activities | | | | | |  | (4,513,271) |  | (1,208,619) |
|  |  |  | | |  |  |  |  |  |  |
| Cash flows from investing activities | | | | | | |  |  |  |  |
|  | Purchase of property and equipment | | | | | |  | (47,718) |  | (2,470) |
|  | Net cash used in investing activities | | | | | |  | (47,718) |  | (2,470) |
|  |  | | | | | |  |  |  |  |
| Cash flows from financing activities: | | | | | | |  |  |  |  |
|  | Net proceeds from sale of common stock and warrants | | | | | | | 9,408,920 |  | 11,158,496 |
|  | Net proceeds from sale of preferred stock | | | | | |  | - |  | 300,000 |
|  | Net proceeds from warrant exercises | | | | | |  | 3,404,156 |  | - |
|  | Net proceeds from bridge financing | | | | | |  | - |  | 888,500 |
|  | Net proceeds from issuance of note payable | | | | | |  | - |  | 170,200 |
|  | Repurchase of preferred stock | | | | | |  | (1,000) |  | - |
|  | Principal repayment of note payable | | | | | |  | (27,864) |  | (8,854) |
|  | Net cash provided by financing activities | | | | | |  | 12,784,212 |  | 12,508,342 |
|  |  |  | | |  |  |  |  |  |  |
| Net increase in cash and cash equivalents | | | | | | | | 8,223,223 |  | 11,297,253 |
| Cash and cash equivalents at beginning of period | | | | | | | | 9,883,796 |  | 283,341 |
|  |  | |  | |  |  |  |  |  |  |
| Cash and cash equivalents at end of period | | | | | | | | $ 18,107,019 |  | $ 11,580,594 |
|  |  | |  | |  |  |  |  |  |  |

Supplemental disclosure of non-cash financing activities:

During the nine months ended September 30, 2021:

* 149,705 shares of common stock were issued upon the cashless exercise of stock purchase warrants
* $172,056 of principal and accrued interest related to a note payable was extinguished upon the loan’s forgiveness

During the nine months ended September 30, 2020:

* 716,790 shares of common stock were issued upon conversion of convertible preferred stock
* 36,902 shares of common stock were issued upon the cashless exercise of stock purchase warrants
* 300,001 shares of common stock and 300,001 stock purchase warrants were issued in exchange for cancellation of $1,500,000 owed to current and former employees and directors
* 177,626 shares of common stock, 126,042 pre-funded stock purchase warrants and 303,668 stock purchase warrants were issued upon conversion of $1,200,000 convertible debentures and $14,667 of related accrued interest

See accompanying notes to condensed consolidated financial statements.

**GEOVAX LABS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2021**

**(unaudited)**

1. Description of Business

GeoVax Labs, Inc. (“GeoVax” or the “Company”), is a clinical-stage biotechnology company developing immunotherapies and vaccines against infectious diseases and cancers using novel vector vaccine platforms. GeoVax’s Modified Vaccinia Ankara-Virus-Like Particle (MVA-VLP) based platform utilizes MVA, a large virus capable of carrying several vaccine antigens, to express proteins that assemble into highly effective virus-like particle (VLP) immunogens in the person receiving the vaccine. The production of VLPs in the person being vaccinated can mimic virus production in a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection. The MVA-VLP derived vaccines can elicit durable immune responses in the host similar to a live-attenuated virus, while providing the safety characteristics of a replication-defective vector.

GeoVax’s MVA-VLP development programs are focused primarily on preventive vaccines against the SARS-CoV-2 virus (COVID-19) and immunotherapies for solid tumor cancers. Other development programs include preventive vaccines against Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, Lassa), Human Immunodeficiency Virus (HIV), and malaria. Certain of our vaccine development activities have been, and continue to be, financially supported by the U.S. Government. This support has been both in the form of research grants and contracts awarded directly to us, as well as indirect support for the conduct of preclinical animal studies and human clinical trials.

On September 28, 2021, GeoVax entered into an Assignment and License Agreement with PNP Therapeutics, Inc., whereby GeoVax expanded its immuno-oncology pipeline and added a new technology platform through the acquisition of exclusive rights to Gedeptin®, a novel patented product for the treatment of solid tumors through a gene therapy strategy known as GDEPT (Gene-Directed Enzyme Prodrug Therapy). In GDEPT, a vector is used to selectively transduce tumor cells with a nonhuman gene, which expresses an enzyme that can convert a nontoxic prodrug into a potent antitumor compound. A Phase 1/2 clinical trial is currently enrolling to evaluate the safety and efficacy of repeat cycles of Gedeptin therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC), with tumors accessible for injection and no curable treatment options. The FDA has granted Gedeptin Orphan Drug status for the treatment of HNSCC and the initial stage of the ongoing clinical trial is being funded by the FDA pursuant to its Orphan Products Clinical Trials Grants Program. GeoVax’s license to Gedeptin includes rights to expand its use to all human diseases and/or conditions including, but not limited to, cancers.

GeoVax is incorporated under the laws of the State of Delaware and our principal offices are located in the metropolitan Atlanta, Georgia area.

2. Basis of Presentation

The accompanying condensed consolidated financial statements at September 30, 2021 and for the three-month and nine-month periods ended September 30, 2021 and 2020 are unaudited, but include all adjustments, consisting of normal recurring entries, which we believe to be necessary for a fair presentation of the dates and periods presented. Interim results are not necessarily indicative of results for a full year. The financial statements should be read in conjunction with our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020. We expect our operating results to fluctuate for the foreseeable future; therefore, period-to-period comparisons should not be relied upon as predictive of the results in future periods.

We enacted reverse stock splits of our common stock on September 25, 2020 (1-for-20) and on January 21, 2020 (1-for-2,000). The accompanying financial statements, and all share and per share information contained herein, have been retroactively restated to reflect the reverse stock splits.

Our financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business for at least the twelve-month period following the issue date of these consolidated financial statements. We are devoting substantially all of our present efforts to research and development of our vaccine and immunotherapy candidates. We have funded our activities to date from sales of our equity securities, government grants and clinical trial assistance, and corporate and academic collaborations. We expect to incur future net losses and require substantial funds as we continue our research and development activities. Our transition to profitability will be dependent upon, among other things, the successful development and commercialization of our product candidates. We may never achieve profitability or positive cash flows, and unless and until we do, we will continue to need to raise additional funding. We intend to fund future operations through additional private and/or public offerings of debt or equity securities. In addition, we may seek additional capital through arrangements with strategic partners or from other sources. There can be no assurance that we will be able to raise additional funds or achieve or sustain profitability or positive cash flows from operations.

3. Significant Accounting Policies and Recent Accounting Pronouncements

We disclosed in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020 those accounting policies that we consider significant in determining our results of operations and financial position. During the nine months ended September 30, 2021, there have been no material changes to, or in the application of, the accounting policies previously identified and described in the Form 10-K, and there have been no other recent accounting pronouncements or changes in accounting pronouncements which we expect to have a material impact on our financial statements.

4. Basic and Diluted Loss Per Common Share

Basic and diluted loss per common share are computed based on the weighted average number of common shares outstanding. Common share equivalents consist of common shares issuable upon conversion of convertible preferred stock, and upon exercise of stock options and stock purchase warrants. All common share equivalents are excluded from the computation of diluted loss per share since the effect would be anti-dilutive. The weighted average number of common share equivalents which were excluded from the computation of diluted loss per share totaled 2,965,451 and 2,550,184 shares for the three-month and nine-month periods ended September 30, 2021, respectively, as compared to 204,553 and 78,754 shares for the three-month and nine-month periods ended September 30, 2020, respectively.

5. Property and Equipment

Property and equipment as shown on the accompanying Condensed Consolidated Balance Sheets is composed of the following as of September 30, 2021 and December 31, 2020:

|  |  |  |
| --- | --- | --- |
|  | September 30, 2021 | December 31, 2020 |
| Equipment and furnishings | $ 591,554 | $ 543,836 |
| Leasehold improvements | 115,605 | 115,605 |
| Total property and equipment | 707,159 | 659,441 |
| Accumulated depreciation and amortization | (538,506) | (511,700) |
| Property and equipment, net | $ 168,653 | $ 147,741 |

6. Accrued Expenses

Accrued expenses as shown on the accompanying Condensed Consolidated Balance Sheets are composed of the following as of September 30, 2021 and December 31, 2020:

|  |  |  |
| --- | --- | --- |
|  | September 30, 2021 | December 31, 2020 |
| Accrued salaries | $ 11,212 | $ 279,696 |
| Other accrued expenses | 35,000 | 79,585 |
| Total accrued expenses | $ 46,212 | $ 359,281 |

7. Notes Payable

*GRA Note* – On February 28, 2018, we entered into a Senior Note Purchase Agreement with Georgia Research Alliance, Inc. (GRA) pursuant to which we issued a five-year Senior Promissory Note (the “GRA Note”) to GRA in exchange for $50,000. The GRA Note bore an annual interest rate of five percent. Interest expense related to the GRA Note for the three-month and nine-month periods ended September 30, 2021 was $-0- and $633, respectively, as compared to $411 and $1,344, respectively, for the same periods of 2020. During May 2021, we repaid the remaining principal balance of $22,737 and retired the GRA Note.

*CARES Act Paycheck Protection Program Loan –* On April 17, 2020, we received a $170,200 bank loan backed by the United States Small Business Administration (SBA) pursuant to the Paycheck Protection Program (PPP) provisions of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The loan bore an annual interest rate of one percent. We recorded accrued interest expense related to the PPP Loan of $-0- and $653 for the three-month and nine-month periods ended September 30, 2021, respectively, as compared to $429 and $774, respectively, for the same periods of 2020. During May 2021, upon receiving payment from the SBA, the lender forgave the full principal balance of $170,200 together with $1,856 of accrued interest and extinguished the PPP Loan.

8. Commitments

*Lease Agreement*

We lease approximately 8,400 square feet of office and laboratory space pursuant to an operating lease which expires on December 31, 2022. Rent expense for the three-month and nine-month periods ended September 30, 2021 was $42,803 and $128,410, respectively, as compared to $41,539 and $124,617, respectively, for the same periods of 2020. Future minimum lease payments total $42,803 for the remainder of 2021 and $176,356 in 2022, although the lease may be terminated at any time by either party with ninety days’ written notice.

*Other Commitments*

In the normal course of business, we enter into various firm purchase commitments related to production and testing of our vaccine, conduct of research studies, and other activities. As of September 30, 2021, there are approximately $607,000 of unrecorded outstanding purchase commitments to our vendors and subcontractors, all of which we expect will be due in 2021.

9. Stockholders’ Equity

*Preferred Stock –* On June 7, 2021, we repurchased the remaining 100 shares of our Series B Convertible Preferred Stock for a total price of $1,000. As of September 30, 2021, there are no shares of our preferred stock outstanding.

*Public Offering –* On February 11, 2021, we closed an underwritten public offering of 1,644,000 shares of our common stock, including 204,000 shares sold pursuant to the full exercise of the underwriter’s option to purchase additional shares, at a price to the public of $6.25 per share. Net proceeds after deducting underwriting discounts and commissions and other offering expenses were approximately $9.4 million. Additionally, we issued to the underwriter, as a portion of the underwriting compensation, warrants to purchase 72,000 shares of our common stock at an exercise price of $6.875 per share.

*Stock Options –* We have a stock-based incentive plan (the “2020 Plan”) pursuant to which our Board of Directors may grant stock options and other stock-based awards to our employees, directors and consultants. A total of 1,500,000 shares of our common stock are reserved for issuance pursuant to the 2020 Plan. During the nine months ended September 30, 2021, there were no stock option transactions related to the 2020 Plan. As of September 30, 2021, there were 602,000 stock options outstanding, with a weighted-average exercise price of $2.79 per share and a weighted-average remaining term of 9.2 years.

*Stock Purchase Warrants –* During January and February 2021, 188,688 stock purchase warrants were exercised on a cashless basis, resulting in the issuance of 145,866 shares of our common stock, and 690,034 stock purchase warrants were exercised for cash, resulting in the issuance of 690,034 shares of our common stock for net proceeds to us of $3,174,156.

During August 2021, 27,004 stock purchase warrants were exercised on a cashless basis, resulting in the issuance of 3,839 shares of our common stock, and 50,000 stock purchase warrants were exercised for cash, resulting in the issuance of 50,000 shares of our common stock for net proceeds to us of $230,000.

On September 28, 2021, in connection with our entering into an Assignment and License Agreement with PNP Therapeutics, Inc. (PNP) we issued a five-year stock purchase warrant to PNP for 100,000 shares of our common stock at an exercise price of $13.00 per share.

As of September 30, 2021, there are 2,816,631 stock purchase warrants outstanding, with a weighted-average exercise price of $5.35 per share and a weighted-average remaining term of 3.9 years.

*Other Common Stock Transactions* – During the nine months ended September 30, 2021, we issued 13,707 shares of our common stock pursuant to consulting agreements.

**10. Stock-Based Expense**

Stock-based compensation expense related to employee and director stock options was $56,190 and $168,570 during the three-month and nine-month periods ended September 30, 2021, respectively; there was no stock-based compensation expense related to employee stock options during the comparable periods of 2020. Stock-based compensation expense related to stock options is recognized on a straight-line basis over the requisite service period for the award and is allocated to research and development expense or general and administrative expense based upon the related employee classification. As of September 30, 2021, there is $486,940 of unrecognized compensation expense that we expect to recognize over a weighted-average period of 2.2 years.

During the three-month and nine-month periods ended September 30, 2021, we recorded stock-based compensation expense of $29,560 and $80,733, respectively, associated with common stock issued for consulting services, as compared to $6,000 and $24,000, respectively, during the comparable periods of 2020. As of September 30, 2021, there is $39,773 recorded as a prepaid expense for these arrangements, which will be recognized as expense over the remaining terms of the related agreements.

During September 2021, we recorded $209,825 of expense associated with the issuance of a stock purchase warrant to PNP in connection with our entering into a technology licensing agreement; such amount was recorded as research and development expense.

11. Income Taxes

Because of our historically significant net operating losses, we have not paid income taxes since inception. We maintain deferred tax assets that reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. These deferred tax assets are comprised primarily of net operating loss carryforwards and also include amounts relating to nonqualified stock options and research and development credits. The net deferred tax asset has been fully offset by a valuation allowance because of the uncertainty of our future profitability and our ability to utilize the deferred tax assets. Utilization of operating losses and credits will be subject to substantial annual limitations due to ownership change provisions of Section 382 of the Internal Revenue Code. The annual limitation may result in the expiration of net operating losses and credits before utilization.

12. Grants and Collaboration Revenue

We receive payments from government entities under our grants from the National Institute of Allergy and Infectious Diseases (NIAID) and from the U.S. Department of Defense in support of our vaccine research and development efforts. We record revenue associated with government grants as the reimbursable costs are incurred. During the three-month and nine-month periods ended September 30, 2021, we recorded $30,414 and $220,539, respectively, of revenues associated with these grants, as compared to $231,330 and $1,186,844, respectively, for the comparable periods of 2020. During the three-month and nine-month periods ended September 30, 2020, we also recorded $184,128 and $385,193, respectively, of revenues associated with research collaboration agreements with third parties. As of September 30, 2021, there is an aggregate of $244,888 in approved grant funds available for use through mid-2022.

13. Subsequent Event

On November 9, 2021, we entered into an Exclusive License Agreement the (“License Agreement”) with City of Hope (“COH”) under which we obtained exclusive worldwide rights to key patents, know-how, regulatory filings and clinical materials related to COH’s COVID-19 vaccine program, currently undergoing human clinical trials. We will pay an upfront fee to COH of $5,000,000 within 30 days of the effective date of the License Agreement and are obligated to pay additional fees of $3,000,000 and $2,000,000 on the first and second anniversaries, respectively, of the effective date of the License Agreement. We will also pay COH milestone fees based on achievement of success-based development and regulatory milestones, and annual royalties on net sales of products covered by the License Agreement.

## Item 2 Management’s Discussion and Analysis of Financial Condition and Results of Operations

*The following Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”) is intended to help the reader understand our results of operations and financial condition. This MD&A is provided as a supplement to, and should be read in conjunction with, our condensed consolidated financial statements and the accompanying notes thereto and other disclosures included in this Quarterly Report on Form 10-Q (this “Report”), and our audited financial statements and the accompanying notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the Securities and Exchange Commission on March 23, 2021.*

**Forward-Looking Statements**

Information included in this Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Forward-looking statements are not statements of historical facts, but rather reflect our current expectations concerning future events and results. We generally use the words “believes,” “expects,” “intends,” “plans,” “anticipates,” “likely,” “will” and similar expressions to identify forward-looking statements. All statements in this Report, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations and objectives could be forward-looking statements. Such forward-looking statements, including those concerning our expectations, involve risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and factors include, but are not limited to, those factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020. We operate in a highly competitive, highly regulated and rapidly changing environment and our business is constantly evolving. Therefore, it is likely that new risks will emerge, and that the nature and elements of existing risks will change, over time. It is not possible for management to predict all such risk factors or changes therein, or to assess either the impact of all such risk factors on our business. We assume no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this Report.

**Overview**

GeoVax is a clinical-stage biotechnology company developing immunotherapies and vaccines against infectious diseases and cancers using novel vector vaccine platforms. GeoVax’s Modified Vaccinia Ankara-Virus-Like Particle (MVA-VLP) based platform utilizes MVA, a large virus capable of carrying several vaccine antigens, to express proteins that assemble into highly effective virus-like particle (VLP) immunogens in the person receiving the vaccine. The production of VLPs in the person being vaccinated can mimic virus production in a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection. The MVA-VLP derived vaccines can elicit durable immune responses in the host similar to a live-attenuated virus, while providing the safety characteristics of a replication-defective vector.

GeoVax’s MVA-VLP development programs are focused primarily on preventive vaccines against the SARS-CoV-2 virus (COVID-19) and immunotherapies for solid tumor cancers. Other development programs include preventive vaccines against Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, Lassa), Human Immunodeficiency Virus (HIV), and malaria. Certain of our vaccine development activities have been, and continue to be, financially supported by the U.S. Government. This support has been both in the form of research grants and contracts awarded directly to us, as well as indirect support for the conduct of preclinical animal studies and human clinical trials.

On September 28, 2021, we entered into an Assignment and License Agreement with PNP Therapeutics, Inc., whereby we expanded our immuno-oncology pipeline and added a new technology platform through the acquisition of exclusive worldwide rights to Gedeptin®, a novel patented product for the treatment of solid tumors through a gene therapy strategy known as GDEPT (Gene-Directed Enzyme Prodrug Therapy). In GDEPT, a vector is used to selectively transduce tumor cells with a nonhuman gene, which expresses an enzyme that can convert a nontoxic prodrug into a potent antitumor compound. GeoVax’s license to Gedeptin includes rights to expand its use to all human diseases and/or conditions including, but not limited to, cancers.

On November 9, 2021, we entered into an Exclusive License Agreement with City of Hope, whereby we obtained exclusive worldwide rights to develop and commercialize COH04S1, a multi-antigenic COVID-19 vaccine currently undergoing Phase 2 human clinical trials. This program is supplemental to, and synergistic with, our existing pan coronavirus vaccine (GEO-CM02), currently in preclinical testing.

Our programs are in various stages of development:

* COH04S1 is currently undergoing a Phase 2 clinical trial, evaluating its safety and efficacy as a preventive COVID-19 vaccine in blood cancer patients who have receive a bone marrow transplant or chimeric antigen receptor therapy (CAR T). The trial is also the first to compare an investigational COVID-19 vaccine to the current FDA-approved vaccine from Pfizer in people who are immunocompromised and receiving immunosuppressive therapy.
* Gedeptin® is currently undergoing a Phase 1/2 clinical trial for treatment of patients with advanced head and neck cancer, which is being conducted with funding support from the U.S. Food & Drug Administration (FDA) pursuant to its Orphan Products Grants Program.
* Our preventive HIV vaccine is focused on prevention of the subtype of HIV prevalent in the regions of the Americas, Western Europe, Japan and Australia, and which we expect will be included in an upcoming clinical trial (HVTN 132) managed by the HIV Vaccine Clinical Trials Network (HVTN) with support from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH).
* A consortium led by researchers at the University of California, San Francisco (UCSF) is conducting a clinical trial using our HIV vaccine as part of a combinational therapy to induce remission in HIV-positive individuals.
* Our pan coronavirus vaccine (GEO-CM02) is progressing in preclinical studies with support from a Small Business Innovative Research (SBIR) grant from NIAID.
* Our Lassa Fever vaccine program is undergoing preclinical studies with grant support from the U.S. Department of Defense.
* Development of our Sudan ebolavirus and Marburg virus vaccine candidates is being supported, in part, through a collaboration with researchers at the University of Texas Medical Branch (UTMB) and Battelle Memorial Institute utilizing the suite of preclinical services from NIAID.

Our corporate strategy is to advance, protect and exploit our differentiated vaccine/immunotherapy platform leading to the successful development of preventive and therapeutic vaccines against infectious diseases and various cancers. With our design and development capabilities, we are progressing and validating an array of cancer and infectious disease immunotherapy and vaccine product candidates. Our goal is to advance products successfully through human clinical testing and registration, while considering partnership or licensing arrangements for achieving regulatory approval and commercialization. We also leverage third-party resources through collaborations and partnerships for preclinical and clinical testing, and manufacturing with multiple government, academic and corporate entities.

We have not generated any revenues from the sale of the products we are developing, and we do not expect to generate any such revenues for at least the next several years. Our product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that we advance to clinical testing will require regulatory approval prior to commercial use and will require significant costs for commercialization. We may not be successful in our research and development efforts, and we may never generate sufficient product revenue to be profitable.

**Results of Operations**

The following tables summarize our results of operations for the three-month and nine-month periods ended September 30, 2021 and 2020:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | Three Months Ended September 30, | |  |
|  |  |  |  |  | 2021 | 2020 | Change |
| Grant and collaboration revenue | | | |  | $ 30,414 | $ 415,458 | $ (385,044) |
| Operating expenses: | | | |  |  |  |  |
|  | Research and development | | |  | 1,224,362 | 416,756 | 807,606 |
|  | General and administrative | | |  | 757,432 | 435,013 | 322,419 |
| Total operating expenses | | | |  | 1,981,794 | 851,769 | 1,130,025 |
| Loss from operations | | | |  | (1,951,380) | (436,311) | (1,515,069) |
| Total other income (expense) | | | |  | 877 | (134,337) | 135,214 |
| Net loss | | | |  | $ (1,950,503) | $ (570,648) | $ (1,379,855) |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | Nine Months Ended September 30, | |  |
|  |  |  |  |  | 2021 | 2020 | Change |
| Grant and collaboration revenue | | | |  | $ 220,539 | $ 1,572,037 | $ (1,351,498) |
| Operating expenses: | | | |  |  |  |  |
|  | Research and development | | |  | 2,659,980 | 1,687,113 | 972,867 |
|  | General and administrative | | |  | 2,562,641 | 1,364,650 | 1,197,991 |
| Total operating expenses | | | |  | 5,222,621 | 3,051,763 | 2,170,858 |
| Loss from operations | | | |  | (5,002,082) | (1,479,726) | (3,522,356) |
| Total other income (expense) | | | |  | 174,768 | (141,820) | 316,588 |
| Net loss | | | |  | $ (4,827,314) | $ (1,621,546) | $ (3,205,768) |

*Grant and Collaboration Revenues*

Our grant and collaboration revenues relate to grants and contracts from agencies of the U.S. government and collaborative arrangements with other third parties in support of our vaccine development activities. Detail concerning our grant and collaboration revenues and the remaining funds available for use as of September 30, 2021 is presented in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Revenues Recorded During the Periods: | | | | Unused Funds |
|  | Three Months Ended September 30, | | Nine Months Ended September 30, | | Available at  September 30, |
|  | 2021 | 2020 | 2021 | 2020 | 2021 |
| Lassa Fever – U.S. Army Grant | $ - | $ 231,330 | $ - | $ 1,186,844 | $ 165,500 |
| Covid-19 – NIH SBIR Grant | 30,414 | - | 220,539 | - | 79,388 |
| Malaria – Collaboration Revenue | - | 184,128 | - | 385,193 | - |
| Total | $ 30,414 | $ 415,458 | $ 220,539 | $ 1,572,037 | $ 244,888 |

Grant and collaboration revenues decreased by $385,044 (93%) for the three-month period ended September 30, 2021 compared to the three-month period ended September 30, 2020, and by $1,351,498 (86%) for the nine-month period ended September 30, 2021 compared to the nine-month period ended September 30, 2020, attributable to the differing mix of active grants and collaborations as shown in the table above, as well as the timing of expenditures related to such grants and collaborations.

*Research and Development Expenses*

Our research and development expenses can fluctuate considerably on a period-to-period basis, depending on the timing of expenditures related to our government grants and other research projects, and other factors. We do not disclose our research and development expenses by project, since our employees’ time is spread across multiple programs and our laboratory facility is used for multiple vaccine candidates. We track the direct cost of research and development expenses related to government grant revenue by the percentage of assigned employees’ time spent on each grant and other direct costs associated with each grant. Indirect costs associated with grants are not tracked separately but are applied based on a contracted overhead rate negotiated with the NIH. Therefore, the recorded revenues associated with government grants approximate the costs incurred.

For the three-month and nine-month periods ended September 30, 2021, research and development expenses increased by $807,606 (194%) and $972,867 (58%), respectively, versus the 2020 periods. Of these increases, $459,825 during each period relates to upfront license fees (inclusive of $209,825 of stock-based expense) associated with our in-license of Gedeptin in September 2021. Research and development expense for the three-month and nine-month periods ended September 30, 2021 includes stock-based compensation expense of $21,468 and $64,404, respectively associated with employee stock options; no stock-based compensation expense was allocated to research and development expense for the comparable periods of 2020 (see discussion under “Stock-Based Compensation Expense” below). The remaining increases of $326,313 and $448,638 for the three-month and nine-month periods ended September 30, 2021, respectively, relate primarily due to expenditures related to our COVID-19 vaccine program, manufacturing process development, and a generally higher level of activity, offset in part by lower external expenditures related to our government grants.

*General and Administrative Expenses*

For the three-month and nine-month periods ended September 30, 2021, general and administrative expenses increased by $322,419 (74%) and $1,197,991 (88%), respectively. General and administrative expense for the three-month and nine-month periods ended September 30, 2021 included stock-based compensation expense of $64,282 and $184,899, respectively; as compared to $6,000 and $24,000, respectively, for the comparable periods of 2020 (see discussion under “Stock-Based Compensation Expense” below). A significant portion of the increase during each period is attributable to higher Delaware franchise taxes, with the remainder primarily due to higher legal, accounting and patent costs; insurance costs; consulting fees; Nasdaq listing fees; investor relations costs; and personnel costs.

*Stock-Based Compensation Expense*

The table below shows the components of stock-based compensation expense for the three-month and nine-month periods ended September 30, 2021 and 2020. In general, stock-based compensation expense is allocated to research and development expense or general and administrative expense according to the classification of cash compensation paid to the employee, consultant or director to whom the stock compensation was granted.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|  | 2021 | 2020 | 2021 | 2020 |
| Stock option expense | $ 56,190 | $ - | $ 168,570 | $ - |
| Stock issued for consulting services | 29,560 | 6,000 | 80,733 | 24,000 |
| Total stock-based compensation expense | $ 85,750 | $ 6,000 | $ 249,303 | $ 24,000 |

As a result of the reverse stock splits enacted in April 2019 and in January 2020, we made adjustments and retroactive restatements to all of our outstanding stock options such that the balances in January 2020 were negligible. We therefore recorded no stock-based compensation expense related to our stock option plan for the majority of 2020. We re-initiated employee stock option grants in December 2020.

*Other Income (Expense)*

Interest income for the three-month and nine-month periods ended September 30, 2021 was $877 and $3,998, respectively, as compared to $90 and $902, respectively, for comparable periods of 2020. The variances between periods are primarily attributable to cash available for investment and interest rate fluctuations.

Interest expense for the three-month and nine-month periods ended September 30, 2021 was $-0- and $1,286, respectively, as compared to $134,427 and $142,772, respectively, for comparable periods of 2020. Interest expense for the 2021 periods relates to the GRA Note and PPP Loan, and for the 2020 periods relates to the GRA Note, PPP loan, financing costs associated with insurance premiums, and convertible debentures which were retired during 2020.

During the nine-month period ended September 30, 2021, we recorded a $172,056 gain on debt extinguishment associated with the forgiveness of the PPP loan principal and accrued interest.

**Critical Accounting Policies and Estimates**

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates and adjusts the estimates as necessary. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our financial statements, refer to Item 7 in Management’s Discussion and Analysis of Financial Condition and Results of Operations and Note 2 to our Consolidated Financial Statements contained in our Annual Report on Form 10-K for the year ended December 31, 2020. There have been no significant changes to our critical accounting policies from those disclosed in our 2020 Annual Report.

*Recent Accounting Pronouncements* **–** Information regarding recent accounting pronouncements is contained in Note 3 to the condensed consolidated financial statements, included in this Quarterly Report.

**Liquidity and Capital Resources**

From inception through September 30, 2021, we have accumulated net losses of approximately $50.6 million and we expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. We have funded our operations to date primarily from sales of our equity securities and from government grants and clinical trial assistance.

The following tables summarize our liquidity and capital resources as of September 30, 2021 and December 31, 2020, and our cash flows for the nine-month periods ended September 30, 2021 and 2020:

|  |  |  |  |
| --- | --- | --- | --- |
| Liquidity and Capital Resources |  | September 30, 2021 | December 31, 2020 |
| Cash and cash equivalents |  | $ 18,107,019 | $ 9,883,796 |
| Working capital |  | 17,824,187 | 9,424,839 |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Nine Months Ended September 30, | |
| Cash Flow Data |  | 2021 | 2020 |
| Net cash provided by (used in): |  |  |  |
| Operating activities |  | $ (4,513,271) | $ (1,208,619) |
| Investing activities |  | (47,718) | (2,470) |
| Financing activities |  | 12,784,212 | 12,508,342 |
| Net increase in cash and cash equivalents |  | $ 8,223,223 | $ 11,297,253 |

*Operating Activities* – Net cash used in operating activities of $4,513,271 for the nine months ended September 30, 2021, was primarily due to our net loss of $4,827,314, offset by non-cash items such as depreciation expense, stock-based compensation expense and the gain recognized on extinguishment of our PPP loan, and by changes in our working capital accounts. Net cash used in operating activities of $1,208,619 for the nine months ended September 30, 2020, was primarily due to our net loss of $1,621,546, offset by non-cash charges such as depreciation and stock-based compensation expense, and by changes in our working capital accounts.

*Investing Activities* – Net cash used in investing activities was $47,718 and $2,470 for the nine-month periods ended September 30, 2021 and 2020, respectively, and relates to purchases of property and equipment.

*Financing Activities* – Net cash provided by financing activities was $12,784,212 for the nine-month period ended September 30, 2021, consisting primarily of (i) net proceeds of $9,408,920 from a public offering of our common stock, (ii) $3,404,156 of net proceeds from the exercise of warrants, (iii) $1,000 expended for the repurchase of outstanding convertible preferred stock, and (iv) $27,864 in principal repayments toward a note payable to the Georgia Research Alliance, Inc. (the “GRA Note”); the GRA Note has now been fully repaid. Additionally, during May 2021, our PPP loan of $170,200, together with $1,856 of accrued interest, was forgiven by the lender and extinguished.

Net cash provided by financing activities was $12,508,342 for the nine-month period ended September 30, 2020, consisting of (i) net proceeds of $11,158,496 from a public offering of our common stock and warrants, (ii) net proceeds of $300,000 from the sale of our convertible preferred stock, (iii) $170,200 of PPP loan proceeds, (iv) $888,500 of net proceeds from issuance of a note payable, and (v) $8,854 in principal repayments toward the GRA Note.

**Funding Requirements and Sources of Capital**

Our primary uses of capital are for salaries and related expenses for personnel, manufacturing costs for preclinical and clinical materials, third-party research services, laboratory and related supplies, legal and other regulatory expenses, and general overhead costs. We expect these costs will continue to be the primary operating capital requirements for the near future.

We believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements through mid-2022. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties and is based on assumptions that may prove to be wrong; actual results could vary materially. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the progress of our research activities; the number and scope of our research programs; the progress and success of our pre-clinical and clinical development activities; the progress of the development efforts of parties with whom we have entered into research and development agreements; the costs of manufacturing our product candidates, and the progress of efforts with parties with whom we may enter into commercial manufacturing agreements; our ability to maintain current research and development programs and to establish new research and development and licensing arrangements; the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; the impact of any natural disasters or public health crises, such as the COVID-19 pandemic; the costs associated with any products or technologies that we may in-license or acquire; and the costs and timing of regulatory approvals.

We will need to continue to raise additional capital to support our future operating activities, including progression of our development programs, preparation for commercialization, and other operating costs. Financing strategies we may pursue include, but are not limited to, the public or private sale of equity, debt financings or funds from other capital sources, such as government funding, collaborations, strategic alliances or licensing arrangements with third parties. There can be no assurances additional capital will be available to secure additional financing, or if available, that it will be sufficient to meet our needs on favorable terms. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development of one or more of our product candidates.

We expect our research and development costs to increase as we continue development of our various programs and as we move toward later stages of development, especially with regard to clinical trials. Our expenditures during 2022 and beyond will increase significantly as a result of the license fees and development costs we assumed related to the Gedeptin and COH04S1 clinical programs. We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with biotechnology research and development. Due to these uncertainties, our future expenditures are likely to be highly volatile in future periods depending on the outcomes of the trials and studies. As we obtain data from pre-clinical studies and clinical trials, we may elect to discontinue or delay certain development programs to focus our resources on more promising product candidates. Completion of preclinical studies and human clinical trials may take several years or more, but the length of time can vary substantially depending upon several factors. The duration and the cost of future clinical trials may vary significantly over the life of the project because of differences arising during development of the human clinical trial protocols, including the length of time required to enroll suitable patient subjects, the number of patients that ultimately participate in the clinical trial, the duration of patient follow-up, and the number of clinical sites included in the clinical trials.

We expect, for the remainder of 2021, our general and administrative expenses to remain reasonably consistent with that of the third quarter of 2021. We expect that our general and administrative costs will increase during 2022 in support of expanded research and development activities and other general corporate activities.

*Grant Funding* – We have ongoing government support for our COVID-19 vaccine program through a Small Business Innovative Research (SBIR) grant from NIAID and for our Lassa Fever vaccine program via a grant from the U.S. Department of Defense. As of September 30, 2021, there is $244,888 in approved grant funds remaining and available for use through mid-2022. Additionally, our Sudan ebolavirus and Marburg virus vaccine candidates are being developed in collaboration with researchers at the University of Texas Medical Branch (UTMB) and Battelle Memorial Institute utilizing the suite of preclinical services from NIAID. We are currently seeking sources of capital through additional government and quasi-government grant programs and clinical trial support, although there can be no assurance any such funds will be obtained.

*Clinical Trial Support* – NIAID has funded the costs of conducting all of our human clinical trials (Phase 1 and Phase 2a) to date for our preventive HIV vaccines, with GeoVax incurring certain costs associated with manufacturing the clinical vaccine supplies and other study support. We expect that NIAID will also fund the cost of the planned Phase 1 trial (HVTN 132) to further evaluate the safety and immunogenicity of adding “protein boost” components to our vaccine, GOVX-B11. The start of HVTN 132 has been delayed due to COVID-19, and we await further information from NIAID and HVTN on when the trial may commence. Additionally, we are party to a collaboration with a consortium led by researchers at the University of California, San Francisco (UCSF), using our vaccine as part of a combinational therapy to induce remission in HIV-positive individuals; this program is currently undergoing clinical trials. Similar to HVTN 132, this trial has been affected by the pandemic, so we await further information regarding the status of patient enrollment and trial results. Our prior collaboration with American Gene Technologies International, Inc. (AGT) was recently discontinued due to AGT’s remodeling of their clinical trial plans. Gedeptin is in a Phase 1/2 trial, being conducted at Stanford University in collaboration with Emory University; the initial stage of the study (10 patients) is being funded by the FDA pursuant to its Orphan Products Clinical Trials Grants Program.

*Equity Funding* – During February 2021, we closed an underwritten public offering of our common stock for net proceeds of $9,408,920. During January, February and August 2021, certain of our outstanding stock purchase warrants were exercised, resulting in net proceeds to us of $3,404,156. As of September 30, 2021, there are 2,816,631 stock purchase warrants outstanding, including 1,819,966 publicly-traded warrants (Nasdaq: GOVXW) exercisable for cash at $5.00 per share and expiring on September 29, 2025. Should these warrants be exercised in full, we would receive approximately $9.1 million in gross proceeds.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements that are likely or reasonably likely to have a material effect on our financial condition or results of operations.

## Item 3 Quantitative and Qualitative Disclosures About Market Risk

Not applicable to smaller reporting companies.

## Item 4 Controls and Procedures

Evaluation of disclosure controls and procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that the information required to be disclosed in reports filed or submitted under the Securities Exchange Act of 1934, as amended (Exchange Act), is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to management, including the Chief Executive Officer and Principal Financial and Accounting Officer, as appropriate to allow timely decisions regarding required disclosure.

Our management has carried out an evaluation, under the supervision and with the participation of our Principal Executive Officer and our Principal Financial and Accounting Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rules 13a-15 and 15d-15 as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms.

Changes in internal control over financial reporting

Although we have modified certain of our internal control procedures as a result of the COVID-19 pandemic, there were no significant changes in our internal control over financial reporting that occurred during the three months ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*Limitations on controls*

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

# PART II -- OTHER INFORMATION

## Legal Proceedings

None.

### Risk Factors

For information regarding factors that could affect our results of operations, financial condition or liquidity, see the risk factors discussed under “Risk Factors” in Item 1A of our most recent Annual Report on Form 10-K. See also “Forward-Looking Statements,” included in Item 2 of this Quarterly Report on Form 10-Q. There have been no material changes from the risk factors previously disclosed in our most recent Annual Report on Form 10-K.

## Unregistered Sales of Equity Securities and Use of Proceeds

There were no sales of unregistered securities during the period covered by this report that have not previously been reported on Form 8-K.

## Defaults Upon Senior Securities

None.

## Mine Safety Disclosures

Not applicable

## Other Information

During the period covered by this report, there was no information required to be disclosed by us in a Current Report on Form 8-K that was not so reported, nor were there any material changes to the procedures by which our security holders may recommend nominees to our board of directors.

## Item 6 Exhibits

Exhibit

Number Description

4.1 Common Stock Purchase Warrant issued to PNP Therapeutics, Inc., dated September 28, 2021 (2)

10.1 Assignment and License Agreement, dated September 28, 2021, by and between GeoVax, Inc. and PNP Therapeutics, Inc. (2)

10.2 Exclusive License Agreement, dated November 9, 2021, by and between GeoVax, Inc. and City of Hope (3)

10.3\*,\*\* GeoVax Labs, Inc. 2020 Stock Incentive Plan, as amended and restated August 11, 2021

31.1\* Certification pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934

31.2\* Certification pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934

32.1\* Certification pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002

32.2\* Certification pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002

101.INS Inline XBRL Instance Document (the Instance Document does not appear in the Interactive Data Files because its XBRL tags are embedded with the Inline XBRL Document) (1)

101.SCH Inline XBRL Taxonomy Extension Schema Document (1)

101.CAL Inline XBRL Taxonomy Extension Calculation Linkbase Document (1)

101.DEF Inline XBRL Taxonomy Extension Definition Linkbase Document (1)

101.LAB Inline XBRL Taxonomy Extension Label Linkbase Document (1)

101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase Document (1)

104 Inline XBRL for the cover page of this Quarterly Report on Form 10-Q and included in the Exhibit 101 Inline XBRL Document Set (1)

\* Filed herewith

\*\* Indicates a management contract or compensatory plan or arrangement

(1) These interactive data files shall not be deemed filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, or Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under these sections.

(2) Incorporated by reference from the Registrant’s Current Report on Form 8-K filed September 29, 2021.

(3) Incorporated by reference from the Registrant’s Current Report on Form 8-K filed November 10, 2021.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this quarterly report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

GEOVAX LABS, INC.

(Registrant)

Date: November 12, 2021 By: /s/ Mark W. Reynolds

Mark W. Reynolds

Chief Financial Officer

(duly authorized officer and principal  
financial officer)