

UNITED STATES
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): **March 18, 2021**

ORAMED PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

DELAWARE (State or Other Jurisdiction of Incorporation)	001-35813 (Commission File Number)	98-0376008 (IRS Employer Identification No.)
1185 Avenue of the Americas, Third Floor, New York, New York (Address of Principal Executive Offices)		10036 (Zip Code)

844-967-2633
(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 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, par value \$0.012	ORMP	The Nasdaq Capital Market, Tel Aviv Stock Exchange

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

Emerging growth company ☐

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

Item 1.01. Entry into a Material Definitive Agreement.

On March 18, 2021, Oramed Pharmaceuticals Inc., or the Company, entered into the definitive agreements described below in connection with the formation of Oravax Medical Inc., a Delaware corporation in which the Company will hold a 63% equity interest, or Oravax. Oravax is focused on the development of novel oral COVID-19 vaccines based on Oramed's proprietary PODTM oral delivery technology and Premas Biotech Pvt. Ltd.'s, or Premas, novel vaccine technology that was previously owned by Cystron Biotech LLC, or Cystron, and later acquired by Akers Biosciences Inc., or Akers.

License Agreement

On March 18, 2021, the Company and Oramed Ltd., the Company's wholly-owned subsidiary, collectively Oramed, entered into a License Agreement, or the License Agreement, with Oravax, pursuant to which Oramed will grant to Oravax an exclusive, worldwide license under Oramed's rights in certain patents and related intellectual property, or the License, in which Oravax will receive certain rights relating to Oramed's proprietary oral delivery technology to further develop, manufacture and commercialize oral vaccines for COVID-19 and other novel coronaviruses based on Premas's proprietary vaccine technology involving a triple antigen virus like particle, or the Product.

In consideration for the grant of the License, the License Agreement provides that Oramed will receive (i) royalties equal to 7.5% on net sales, as defined in the License Agreement, of each product commercialized by Oravax, its affiliates and permitted sublicensees related to the License during the term specified in the License Agreement, (ii) sublicensing fees equal to 15% of any non-sales-based consideration received by Oravax from a permitted sublicensee and (iii) other payments ranging between \$25 million to \$100 million, based on certain sales milestones being achieved by Oravax. The parties further agreed to establish a development and steering committee, which will consist of three members, of which two members will be appointed by Oramed, that will oversee the ongoing research, development, clinical and regulatory activity with respect to the Product. In addition, Oramed agreed to buy and Oravax agreed to issue to the Company 1,890,000 shares of common stock of Oravax, representing 63% of the common stock of Oravax for the aggregate amount of \$1.5 million. Akers agreed to contribute to Oravax \$1.5 million in cash and substantially all of the assets of Cystron, including a license agreement to the Premas novel vaccine technology. Nadav Kidron, Oramed's President and Chief Executive Officer, was one of the former members of Cystron.

The description of the License Agreement is qualified in its entirety by the full text of the License Agreement, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K, or this Current Report, and is incorporated by reference herein.

Stockholders Agreement

Concurrently with the execution and delivery of the License Agreement, Oramed entered into a Stockholders Agreement, or the Stockholders Agreement, with Akers, Premas, Cutter Mill Capital LLC, or Cutter Mill, and Run Ridge LLC, or Run Ridge, entities controlled by Michael Vasinikovich and Craig Schwabe, former members of Cystron, and collectively with Akers, Premas, Cutter Mill and Run Ridge, the Stockholders Parties. Pursuant to the Stockholders Agreement, among other things, Oramed will have the right to appoint two out of the three members to the board of directors of Oravax, or the Oravax Board, one of which is the Company's Chief Executive Officer who will serve as the chairman of Oravax Board, conditioned upon Oramed maintaining certain ownership thresholds. Akers will have the right, until the third anniversary of the Stockholders Agreement effective date, to appoint one member to the Oravax Board. Oravax's common stock held by the Stockholders Parties will be subject to certain transfer restrictions. In addition, the Stockholders Parties will have certain rights of participation in future financings as well as rights of first refusal and co-sale related to future potential transactions.

The description of the Stockholders Agreement is qualified in its entirety by the full text of the Stockholders Agreement, a copy of which is filed as Exhibit 10.2 to this Current Report and is incorporated by reference herein.

Item 7.01. Regulation FD Disclosure.

On March 19, 2021, Oramed Pharmaceuticals Inc. posted to its website an investor presentation, a copy of which is attached hereto as Exhibit 99.1.

Item 8.01 Other Events.

In connection with the formation of Oravax, the Company announced that in a pilot study in pigs, within 42 days after a single oral administration, the oral COVID-19 vaccine being developed by Oravax promoted both systemic immunity through Immunoglobulin G (IgG), the most common antibody in blood and bodily fluids that protects against viral infections, and Immunoglobulin A (IgA). The Company also announced that Oravax anticipates commencing a clinical study in human subjects during the second quarter of 2021.

Forward-looking statements: This Current Report contains forward-looking statements. For example, the Company using forward-looking statements when the Company discusses the expected timing of a clinical study for the potential Oravax vaccine and its potential to protect against COVID-19. In addition, historic results of scientific research and clinical trials do not guarantee that the conclusions of future research or trials will suggest identical or even similar conclusions. These forward-looking statements are based on the current expectations of the management of the Company only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements, including the risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; difficulties or delays in obtaining regulatory approval or patent protection for the Company's product candidates; competition from other pharmaceutical or biotechnology companies; and the Company's ability to obtain additional funding required to conduct its research, development and commercialization activities. In addition, the following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; delays or obstacles in launching the Company's clinical trials; changes in legislation; inability to timely develop and introduce new technologies, products and applications; lack of validation of the Company's technology as it progresses further and lack of acceptance of the Company's methods by the scientific community; inability to retain or attract key employees whose knowledge is essential to the development of the Company's products; unforeseen scientific difficulties that may develop with the Company's process; greater cost of final product than anticipated; loss of market share and pressure on pricing resulting from competition; laboratory results that do not translate to equally good results in real settings; the Company's patents may not be sufficient; and finally that products may harm recipients, all of which could cause the actual results or performance of the Company to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, the Company undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting the Company, reference is made to Company's reports filed from time to time with the Securities and Exchange Commission.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

10.1 +	License Agreement, dated as of March 18, 2021, by and between Oramed Pharmaceuticals Inc., Oramed Ltd. and Oravax Medical Inc.
10.2	Stockholders Agreement, dated as of March 18, 2021, by and between Oramed Pharmaceuticals Inc., Akers Biosciences Inc., Premas Biotech PVT Ltd., Cutter Mill Capital LLC, and Run Ridge LLC.
99.1	Investor Presentation dated March 19, 2021. (Furnished herewith.)

- + Certain confidential portions of this exhibit were omitted because the identified confidential provisions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

ORAMED PHARMACEUTICALS INC.

By: /s/ Nadav Kidron
Name: Nadav Kidron
Title: President and CEO

March 19, 2021

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO ORAMED PHARMACEUTICALS INC. IF PUBLICLY DISCLOSED. OMISSIONS ARE DENOTED IN BRACKETS WITH ASTERISKS THROUGHOUT THIS EXHIBIT.

LICENSE AGREEMENT

This License Agreement (“**Agreement**”), effective as of March 18, 2021 (the “**Effective Date**”), is entered into by and among Oramed Pharmaceuticals Inc. and Oramed Ltd. (together, “**Oramed**”), and Oravax Inc. (“**Oravax**”).

RECITALS

WHEREAS, Oramed owns or otherwise controls certain Patent Rights, Know-How and Information (all as defined below) related to Oramed’s oral drug delivery technology as is more specifically set forth in Exhibit A hereto (the “**Licensed IP**”); and

WHEREAS, Oravax desires to obtain, and Oramed is willing to grant to Oravax, an exclusive worldwide license under Oramed’s rights in the Licensed IP to develop and otherwise commercialize Products in the Field based thereon (as such terms are defined below), on the terms and subject to the conditions set forth herein; and

WHEREAS, Oravax has obtained exclusive, perpetual, worldwide rights to the Oravax Technology (as defined below) by way of an Assignment and Contribution Agreement by and between Oravax and Akers Biosciences, Inc. executed as of March 18, 2021 (the “**Akers Agreement**”) pursuant to which inter alia the Amended & Restated License Agreement dated March 18, 2020 by and between Premas Biotech PVT, Ltd. and Cystron Biotech, LLC was assigned to Oravax (the “**Premas License Agreement**”);

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

ARTICLE 1

DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms shall have the respective meanings set forth below:

- 1.1. “**Act**” shall mean, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301 et seq., and/or the Public Health Service Act, 42 U.S.C. §§262 et seq., as such may be amended from time to time.
 - 1.2. “**Affiliate**” shall mean, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with such Person. A Person shall 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 50% or more of the voting securities of such Person, by contract or otherwise.
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- 1.3. **“Agreement”** shall mean this License Agreement, including all Schedules and Exhibits hereto, as it may be amended, supplemented or modified from time to time in accordance with its terms.
- 1.4. **“Applicable Laws”** shall mean the applicable laws and regulations of any jurisdiction, which are applicable to any of the Parties in carrying out activities hereunder or to which any of the Parties in carrying out the activities hereunder is subject, and shall include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, policies, directions, directives and orders of any statutory authority, tribunal, board, or court or any central or state government or local authority or other governmental entity in such jurisdictions.
- 1.5. **“Bankruptcy Laws”** shall have the meaning provided in Article 12.1.
- 1.6. **“BLA”** shall mean: (a) in the United States, a Biologics License Application (as more fully defined in 21 CFR 601.2, et seq.) filed with the FDA, or any successor application thereto; or (b) in any other country or group of countries, the equivalent application or submission for approval to market a biological product filed with the governing Regulatory Authority in such country or group of countries.
- 1.7. **“Claim”** shall have the meaning provided in Article 10.1.
- 1.8. **“Closing”** shall have the meaning provided in the Akers Agreement.
- 1.9. **“Combination Product”** means a product offering sold under a single price consisting of a Product in combination with, or supplied with, one or more other products, whether or not such other products are sold separately.
- 1.10. **“Commercially Reasonable Efforts”** shall mean, with respect to the efforts to be expended by a Party with respect to any objective, activity or decision under this Agreement, the level of reasonable, diligent, good faith efforts that similarly situated biopharmaceutical companies typically devote to products owned by them that are at a similar stage in their development or product life and are of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval, the profitability of the product, and other relevant factors. Commercially Reasonable Efforts shall be determined on a market-by-market and product-by-product basis, and it is anticipated that the level of effort will be different for different markets, and will change over time, reflecting changes in the status of the Product and the market(s) involved.
- 1.11. **“Competitive Infringement”** shall have the meaning provided in Article 8.4.
- 1.12. **“Confidential Information”** shall mean any and all non-public Information, whether communicated in writing or by any other method, which is provided by or on behalf of one Party to the other Party in connection with this Agreement.
- 1.13. **“Control”, “Controls” or “Controlled by”** shall mean, with respect to any Patent Rights, Information, Know-How or other intellectual property rights, the possession by a Person of the ability (whether by ownership, license or other right, *other than* pursuant to a license granted under this Agreement) to grant access to, or a license or sublicense of, such Patent Rights, Know-How, Information or other intellectual property rights without violating the terms of any agreement or other arrangement with any other Person.

- 1.14. **“Development Period”** means the period covered by the Development Plan.
- 1.15. **“Development Plan”** means the plan for the research and clinical development of Products in the Field in the Territory which shall be agreed to by the DSC following the Effective Date, and which may be amended by the DSC from time to time.
- 1.16. **“Developmental Milestone”** shall have the meaning provided in Article 4.1.
- 1.17. **“Dispute”** shall have the meaning provided in Article 11.1.
- 1.18. **“DSC”** shall have the meaning given to such term in Article 3.4(a).
- 1.19. **“Export Control Laws”** shall mean all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury, or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§1 et. seq., the Arms Export Control Act, 22 U.S.C. §§2778 and 2779, and the International Boycott Provisions of Article 999 of the U.S. Internal Revenue Code of 1986 (as amended).
- 1.20. **“Fair Market Value”** means the cash consideration which one would realize from an unaffiliated, unrelated buyer in an arm’s length sale of an identical item sold in the same quantity, under the same terms, and at the same time and place.
- 1.21. **“FCPA”** shall mean the U.S. Foreign Corrupt Practices Act (15 U.S.C. §§78dd-1, et. seq.) as amended.
- 1.22. **“FDA”** shall mean the U.S. Food and Drug Administration and any successor entity thereto.
- 1.23. **“Field”** shall encompass the vaccination against, and prevention, treatment, and management, of COVID-19 and any mutations thereof, and any other novel coronavirus and any mutations thereof after the Effective Date, and any symptoms related to the foregoing.
- 1.24. **“GCP”** shall mean the then current “good clinical practices” as such term is defined from time to time by the FDA or other Regulatory Authority of competent jurisdiction pursuant to its regulations, guidelines or otherwise, as applicable.
- 1.25. **“GLP”** shall mean the then current “good laboratory practices” as such term is defined from time to time by the FDA or other Regulatory Authority of competent jurisdiction pursuant to its regulations, guidelines or otherwise, as applicable.

- 1.26. **“GMP”** shall mean the then current “good manufacturing practices” as such term is defined from time to time by the FDA or other Regulatory Authority of competent jurisdiction pursuant to its regulations, guidelines or otherwise, as applicable.
- 1.27. **“Gross Sales”** means the cash consideration or Fair Market Value of any non-cash consideration actually received attributable to the sale, use, lease, transfer or other disposition of any Product(s).
- 1.28. **“IND”** shall mean 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 a Regulatory Authority in conformance with the requirements of such Regulatory Authority, including any such application filed with the FDA pursuant to 21 CFR Part 312.
- 1.29. **“Indemnified Party”** shall have the meaning provided in Article 10.3.
- 1.30. **“Indemnifying Party”** shall have the meaning provided in Article 10.3.
- 1.31. **“Information”** shall mean any and all proprietary data, information, materials and know-how (whether patentable or not) that are not in the public domain, 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, safety, manufacturing and quality control data and information related thereto, (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.
- 1.32. **“Infringe” or “Infringement”** means any infringement as determined by Applicable Law, including, without limitation, direct infringement, contributory infringement or any inducement to infringe.
- 1.33. **“Invention”** shall mean any invention, whether or not patentable, including, without limitation, those made in the course and as a result of the conduct of the activities contemplated by this Agreement.
- 1.34. **“Joint Invention”** shall have the meaning provided in Article 8.1.
- 1.35. **“Joint Patent Rights”** shall have the meaning provided in Article 8.1.
- 1.36. **“Know-How”** shall mean any and all Information not in the public domain held in any form (including without limitation that comprised in or derived from drawings, data formulae, patterns, specifications, notes, samples, chemical compounds, biological materials, computer software, component lists, instructions, manuals, brochures, catalogues and process descriptions and scientific approaches and methods).
- 1.37. **“Licensed IP”** shall have the meaning provided in the preamble.
- 1.38. **“Losses”** shall have the meaning provided in Article 10.1.

- 1.39. **“Marketing Approval”** shall mean all approvals from the relevant Regulatory Authority in a given country necessary to market and sell a pharmaceutical product in such country, including pricing and reimbursement approvals if required for marketing or sale of such product in such country.
- 1.40. **“Net Sales”** means the Gross Sales of the Product by or on behalf of the Oravax and/or any of its subsidiaries, to a third-party purchaser, less the following customary and commercially reasonable deductions (without duplication), determined in accordance with generally accepting accounting principles in the United States of America (“GAAP”) and actually taken, paid, accrued, allocated, or allowed based on good faith estimates:
- (i) trade, cash, or quantity discounts, allowances and credits;
 - (ii) excise taxes, use taxes, tariffs, sales taxes and customs duties, or other government charges imposed on the sale of the Product, specifically excluding, for clarity, any income taxes assessed against the income arising from such sale,
 - (iii) compulsory or negotiated payments and cash rebates or other expenditures to governmental authorities or agencies (or designated beneficiaries thereof) in the context of any national or local health insurance programs or similar programs, including pay-for-performance agreements, risk sharing agreements as well as government levied fees as a result of the Affordable Care Act and other similar legislation and foreign equivalents;
 - (iv) rebates, chargebacks, administrative fees, and discounts (or the equivalent thereof) to managed health care organizations, group purchasing organizations, insurers, pharmacy benefit managers (or the equivalent thereof), specialty pharmacy providers, governmental authorities, or their agencies or purchasers, reimbursers or trade customers, as well as amounts owed to patients through co-pay assistance cards or similar forms of rebate to the extent the latter are directly related to the prescribing of the Products;
 - (v) gross sales offsets provided to specialty pharmacies, warehousing chains or distributors for their services provided;
 - (vi) outbound freight, shipment, and insurance costs;
 - (vii) retroactive price reductions, credits, or allowances actually granted upon claims, rejections, or returns of Products, including for recalls or damaged or expired goods, billing errors and reserves for returns; and
 - (viii) any invoiced amounts that are not collected by the Company and/or any of its subsidiaries, including bad debts, despite the Company’s best commercial efforts to collect such amounts.

Net Sales will not include transfers or dispositions for: (i) clinical trial purposes; (ii) compassionate use or patient assistance programs; or (iii) similar uses in a limited number to support regulatory approvals or as required by any governmental authority or agency, such as test marketing programs or other similar programs or studies.

In the event that the Products are sold in the form of a Combination Product in a given country, then Net Sales for such Combination Product in such country will be determined as follows: (1) in the event that any Products is sold in the form of Combination Products, if the Products is sold separately and all other products in such Combination Product are sold separately, then Net Sales for the determination of royalties of Combination Products will be calculated by multiplying Net Sales of such Combination Product by the fraction $A/(A+B)$, where A is the average Net Sales price of the Products component contained in the Combination Product in the applicable country, and B is the sum of the average Net Sales prices of all other product components included in the Combination Product in the applicable country, (2) if the Products is sold separately, but not all other products in a Combination Product are sold separately, then Net Sales for the determination of royalties of Combination Products will be calculated by multiplying Net Sales of such Combination Product by the fraction A/C , where A is the average Net Sales price of the Products component in the Combination Product in the applicable country, and C is the average Net Sales price of the entire Combination Product in the applicable country, (3) if the Product is not sold separately, but all other products in a Combination Product are sold separately, then Net Sales for such Combination Product will be calculated by multiplying actual Net Sales of such Combination Product by the fraction $(C-B)/C$, where B is the sum of the average Net Sales prices of all other product components included in the Combination Product in the applicable country, and C is the average Net Sales Price of the entire Combination Product in the applicable country, and (4) if Net Sales of a Combination Product cannot be determined using the methods (1) through (3) above, then the parties hereto will negotiate in good faith, at the latest six (6) months before the expected launch of such Combination Product, an allocation of Net Sales of such Combination Product to the respective API components or product components thereof, as the case may be, based on the fair market value of such components for the purposes of determining a Products specific or licensed API specific allocated Net Sales, and if the Parties are unable to agree on such a reasonable allocation no later than three (3) months prior to the estimated launch date of such Combination Product, then Net Sales of such Combination Product will be calculated based on the Company's good faith estimate of the fair market value of the Products and each of the other product components included in such Combination Product when sold in such country. Royalty Payments related to such Combination Product will be calculated, due, and payable based only on such allocated Net Sales.

- 1.41. **"Non Sales-Based Sublicense Consideration"** means any cash or non-cash consideration received, including, but not limited to, sublicense initiation fees, sublicense annual fees, sublicense milestone payments, or other such non sale-based royalty consideration payable received by Oravax or any Sublicensee as consideration for or under a sublicense agreement. Non Sale-Based Sublicense Consideration does not include the Royalties set forth in Article 4.2 payable to Oramed by Oravax under this Agreement. Any non-cash consideration received by Oravax or any Sublicensee from such sublicense agreement shall be valued at its Fair Market Value as of the date of receipt.
- 1.42. **"Oramed Indemnitees"** shall have the meaning provided in Article 10.1.
- 1.43. **"Oramed Patent Rights"** shall have the meaning provided in Article 8.2(a).
- 1.44. **"Oravax Indemnitees"** shall have the meaning provided in Article 10.2.
- 1.45. **"Oravax Patent Rights"** shall have the meaning provided in Article 8.2(d).
- 1.46. **"Oravax Technology"** shall mean all Patent Rights and Know-How set forth in Exhibit B hereto.

- 1.47. **“Party”** shall mean Oravax and Oramed, individually, and **“Parties”** shall mean Oravax and Oramed, collectively.
- 1.48. **“Patent Certification”** shall have the meaning provided in Article 8.4.
- 1.49. **“Patent Rights”** shall mean (i) patents and patent applications (which for the purposes of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention); (ii) any and all divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, patent term extensions, supplementary protection certificates and the like of any such patents and patent applications; and (iii) any and all foreign equivalents of the foregoing.
- 1.50. **“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.
- 1.51. **“Product”** shall mean any oral vaccines for COVID-19 and other novel coronaviruses utilizing the Oravax Technology for use in the Field that is integrated with or delivered by way of the Licensed IP under this Agreement.
- 1.52. **“Regulatory Authority”** shall mean any country, federal, regional, supranational, state or local regulatory agency, department, bureau or other governmental or regulatory authority having the administrative authority to regulate the development or marketing of pharmaceutical products in any country or other jurisdiction.
- 1.53. **“Regulatory Documentation”** shall mean all regulatory applications, registrations, licenses, authorizations and approvals (including all INDs, BLAs and Marketing Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), and all reports and documentation in connection with clinical studies and tests (including study reports and study protocols, and copies of all interim study analyses), and all data contained in any of the foregoing, including all INDs, BLAs, advertising and promotion documents, manufacturing data, drug master files, clinical data, adverse event files and complaint files, in each case related to a Product.
- 1.54. **“Relevant Oramed Patent Claims”** shall have the meaning provided in Article 8.3(a)(i).
- 1.55. **“Rules”** shall have the meaning provided in Article 11.2.
- 1.56. **“Sale Transaction”** shall have the meaning provided in Article 12.5(a).
- 1.57. **“Sublicense”** shall mean a Third-Party sublicense under the license granted by Oramed to Oravax pursuant to Article 2.1, whether such Third Party’s sublicense was granted to it directly by Oravax or indirectly through one or more tiers of sublicense.
- 1.58. **“Term”** shall have the meaning provided in Article 9.1.
- 1.59. **“Territory”** shall mean the entire world.
- 1.60. **“Third Party”** shall mean an entity other than Oravax and Oramed.

- 1.61. **“Third Party Acquirer”** shall have the meaning provided in Article 12.5(a).
- 1.62. **“Valid Patent Claim”** shall mean a claim of an issued and unexpired patent included within the Oramed Patent Rights, which claim has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction (which decision is not appealable or has not been appealed within the time allowed for appeal), and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.

ARTICLE 2

LICENSE GRANT

- 2.1. **License Grant.** Subject to the Closing, Oramed will grant to Oravax an exclusive (even as to Oramed except as necessary for Oramed to perform its obligation hereunder and under the Development Plan), worldwide license including the right to sublicense through multiple tiers of sublicensees under the Licensed IP, to discover, develop, make, have made, use, sell, have sold, offer for sale, market, export, import and otherwise commercialize and exploit Products in the Field in the Territory.
- 2.2. **Sublicensing.** Oravax may grant sublicenses under the license granted pursuant to Article 2.1 subject to the receipt of the prior written consent of Oramed, not to be unreasonably withheld. Oravax shall provide Oramed with a copy of any sublicense agreement entered into by Oravax within 30 days of its execution.

ARTICLE 3

DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION

- 3.1. **Responsibility.** Oravax (itself and/or with or through its Sublicensees) shall be solely responsible, at its own expense, for, and shall control all aspects of, worldwide development (including pre-clinical and clinical development), manufacture, registration and commercialization (including marketing, promoting, selling, distributing and determining pricing for) Products in the Territory. Oravax will ensure that all such activities will be carried out in accordance with this Agreement, the Development Plan, all Applicable Laws (including, to the extent applicable, as applicable, GLP, GCP and/or GMP) and the instructions of the DSC (as defined below). All Regulatory Documentation, including without limitation, INDs and BLAs will be filed in the name of, and owned by, Oravax. Oramed will reasonably assist Oravax with filings related to any such Regulatory Documentation as requested by Oravax. To the extent that Oramed has any responsibility for engaging in discussions with, and/or making filings with any Regulatory Authorities, Oramed shall ensure that Oravax has the opportunity to be present for any such discussions (to the extent permitted by Law) and the opportunity to review and provide comments to any such filings reasonably in advance of such discussion or any filing deadline.
- 3.2. **Diligence.** Oravax (itself and/or with or through its Sublicensee(s), and any subcontractors) shall use Commercially Reasonable Efforts to develop, seek Marketing Approval for, and commercialize one or more Products in at least one (1) country in the Territory during the Term.

- 3.3. **Records.** Oravax shall maintain, or cause to be maintained, complete and accurate records of all development work conducted by or on behalf of Oravax with respect to Products, including all results, data, inventions and developments made in the performance of such development work. All such records maintained shall be in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.
- 3.4. **Development and Steering Committee.**
- (a) Within ten (10) days after the Effective Date or such other date as agreed by the Parties, a Development and Steering Committee (“DSC”) shall be established with the responsibilities and authority set forth in this Article 3.4. The DSC shall consist of three (3) members, two (2) of which shall be appointed by Oramed. Each Party may, with notice to the other, substitute any of its members serving on the DSC. Oramed will have the right to appoint one of its members to be the chairperson of the DSC. The DSC will be in place until the earlier of (i) expiration and/or termination of the Development Period or (ii) there is a written agreement between the Parties to disband the DSC.
 - (b) The DSC shall have the responsibility and authority to: (i) provide a forum for exchange of information related to the development of Products in the Field in the Territory; (ii) review and discuss any proposed material amendments or updates to the Development Plan; (iii) oversee the implementation of the Development Plan; (iv) monitor the progress of the Development Plan against the metrics agreed to by the Parties (such as timeline and costs); and (iv) perform any other functions as the Parties may agree in writing.
 - (c) The DSC shall hold meetings as mutually agreed by the Parties, but in no event less than quarterly unless Oravax and Oramed mutually agree in writing, no later than 30 days in advance of any scheduled meeting of the DSC, that no new business has transpired that would require a meeting of the DSC. Meetings may be held in person, by telephone or video conference as agreed by the Parties.
 - (d) The quorum for DSC meetings shall be two (2) members provided that a representative of Oravax must be present. The members of the DSC shall act in good faith to cooperate with one another and to reach agreement with respect to issues to be decided by the DSC.
 - (e) Disagreements among the DSC will be resolved via good-faith discussions; provided, that in the event of a disagreement that cannot be resolved within 30 days after the date on which the disagreement arose, the matter shall be escalated to the CEOs of Oramed and Oravax for attempted resolution. In the event, the CEOs are not able to resolve the matter, the Oramed shall have the deciding vote. For clarity, Oramed shall not have final decision-making authority with respect to disputes about the interpretation or termination of this Agreement.
 - (f) At each DSC meeting, Oravax will keep the DSC informed regarding the progress and results of development activities with respect to Products in the Territory in the Field.
- 3.5. **Limitations on Authority.** Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in the DSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The DSC shall not have the power to amend, modify, or waive compliance with any provision of this Agreement, which may only be amended or modified as provided in Article 12.3 or compliance with which may only be waived as provided in Article 12.4.

- 3.6. **Development Plan.** After the Effective Date, the Parties shall meet to discuss in good faith the parameters of the Development Plan. The Parties shall use Commercially Reasonable Efforts to ensure that the Development Plan is in place within 90 days after the Effective Date, and the Development Plan shall then be attached to this Agreement as Exhibit C. Oravax will keep true, correct and complete records of all development activities that it performs (or that are performed on its behalf) during the Development Period. Oravax will make all such records available to Oramed at its request.
- 3.7. **Reports.** Within 30 days of the end of each calendar quarter of each year during the Development Period, Oravax shall deliver to Oramed a written progress report regarding, to the extent applicable, (i) the status of any Product in development, (ii) any Product-related regulatory submissions and approvals and (iii) the status of any Product related patent applications in each country in the Territory.
- 3.8. **Compliance with Applicable Laws.** After the expiration and/or termination of the Development Period, Oravax shall conduct and/or cause to be conducted, all development, regulatory, manufacturing and commercialization activities that it performs, and/or that are performed on its behalf, with respect to Products anywhere in the world in compliance with all Applicable Laws and, as applicable, GLP, GCP and/or GMP.

ARTICLE 4

CONSIDERATION AND CONTRIBUTION

- 4.1. **Sales Milestone Payments.** In partial consideration of the license granted herein, upon the first achievement of each of the milestone events set forth in the table below by Oravax or any Sublicensee, Oravax shall pay to Oramed the corresponding one-time milestone payment set forth below (each a “**Sales Milestone**”). Each such Sales Milestone payment shall be payable only once, in each case upon the first achievement of the applicable milestone, and no amounts shall be due for subsequent or repeated achievements of such milestone:

Cumulative Gross Sales attaining the following amounts		Payment
\$[**]		\$ 25,000,000
\$[**]		\$ 50,000,000
\$[**]		\$ 100,000,000

- 4.2. **Royalties.** In further consideration of the exclusive license granted herein, Oravax shall, on behalf of itself and all Sublicensees, pay to Oramed royalties (“**Royalties**”) calculated as 7.5% of Net Sales of Product attributable to Oravax and Sublicensees during the Term. Royalties shall be due within 60 days after the end of each calendar quarter and shall accompany the royalty report required under Article 4.4.

- 4.3. **Non-Sale Based Sublicense Consideration.** Oravax shall pay to Oramed 15% percent of all Non-Sale-Based Sublicense Consideration during the Term. Non-Sale-Based Sublicense Consideration owed to Oramed shall be due and payable within 30 days of its actual receipt by Oravax or a Sublicensee, as the case may be.
- 4.4. **Reports and Royalty Payments.** Oravax shall deliver to Oramed within 60 days after the end of each calendar quarter, any part of which is within the Term and as long as Products continue to be sold, a written report, certified by the chief executive officer of Oravax and setting forth in reasonable detail the calculation of the Royalties and Non-Sale-Based Sublicense Consideration due to Oramed for such calendar quarter per a template to be provided by Oramed. The report shall include the following information: (i) Number of Product(s) sold and cost per unit; (ii) Type of Product sold; (iii) countries in which Products were sold; (iv) Net Sales listed on a product-by-product basis, and a country-by-country basis, or an affirmative statement that no sales were made. The report shall also itemize the permitted deductions applied to the Gross Sales of Product and used to arrive at the resulting Net Sales; (v) if any consideration was received in currencies other than U.S. dollars, a description of the currency exchange calculations; and (vi) payments owed to Oramed, listed by category, including without limitation, Royalties Non Sale-Based Sublicense Consideration segregated on a sublicense agreement-by-sublicense agreement basis, or an affirmative statement that none was received.
- 4.5. **Records; Audits.**
- (a) Oravax will maintain and will include in all agreements with Sublicensees a provision that the Sublicensees shall maintain, complete and accurate books and records that enable the consideration payable hereunder to be verified. The records for each calendar quarter shall be maintained for five (5) years after the submission of each report under Article 4.4 hereof.
 - (b) Upon reasonable prior notice to Oravax or Sublicensees, Oramed or its appointed accountants, at Oramed's expense, shall have access to such books and records relating to Net Sales of Product as necessary to conduct a review or audit of Net Sales of Product for the purposes of verifying the accuracy of any reports and payments delivered under this Agreement. Such access shall be available to Oramed during normal business hours, not more than once each calendar year of the Term. Such audits may not (a) be conducted for any Calendar Quarter more than two (2) years after the end of such Calendar Quarter, (b) be conducted more than once in any twelve (12) month period (unless a previous audit during such twelve (12)-month period revealed an underpayment with respect to such period) or (c) be repeated for any Calendar Quarter. If any amounts due to Oramed have been underpaid; then Oravax shall within 30 days of the conclusion of the audit pay Oramed the amount of such underpayment plus interest from the due date until paid, at a rate equal to 1.5% per month (or the maximum allowed by law, if less). If an audit of Oravax's or any Sublicensee's records indicate that Oravax has underpaid royalties by 5% or more, Oravax will pay the costs and expenses incurred by Oramed and its accountants, if any, in connection with the review or audit. Any overpayments shall be either refunded to Oravax or applied against the next quarterly royalty payment.
 - (c) Whenever Oravax or Sublicensees have their books and records audited by an independent certified public accountant, Oravax shall (and shall make reasonable efforts to cause its Sublicensees to), within 30 days of the conclusion of such audit, provide Oramed with a copy of the audit report or that portion of the audit report that relates to Royalties and Non Sale-Based Sublicense Consideration.

- 4.6. **Oramed Contribution and Equity Grant.** Immediately following the Closing, Oramed will contribute an amount in cash equal to \$1,500,000 to Oravax and (ii) immediately upon receipt of such amount, Oravax will issue 1,890,000 shares of the capital stock of Oravax to Oramed, free and clear of all liens and encumbrances (other than transfer restrictions arising under applicable securities laws or as set forth in Oravax's Certificate of Incorporation and that certain Stockholders' Agreement dated as of March 18, 2021 entered into by and among Oravax, Oramed, Akers Biosciences Inc., Premas Biotech Pvt. Ltd., Cutter Miller Capital LLC, and Run Ridge LLC), representing 63% of the issued and outstanding share capital of Oravax, on a fully-diluted basis, as of the date of issuance.

ARTICLE 5

PAYMENT

- 5.1. **Exchange Rate; Manner and Place of Payment.** All payment amounts in this Agreement are expressed in U.S. dollars, and all payments hereunder shall be payable in U.S. dollars. When conversion of payments from any foreign currency is required, such conversion shall be calculated using an exchange rate equal to the average of the interbank rates of exchange for such currency as reported at OANDA.com, or should such rates cease to be published by OANDA, a successor or replacement agreed upon by the parties, on the last day of the calendar quarter for which payment is due. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to the bank and account of Oramed Pharmaceuticals Inc. designated in writing by Oramed.
- 5.2. **Income Tax Withholding.** If Oravax is advised in writing by its attorneys or accountant that Oravax is required to withhold any portion of any payment made to Oramed under this Agreement, Oravax shall (i) deduct such taxes from the payment made to Oramed, (ii) timely pay the taxes to the proper taxing authority, (iii) send proof of payment to Oramed and certify its receipt by the taxing authority within 30 days following such payment, (iv) reasonably cooperate with Oramed, if requested, to obtain available reductions, credits or refunds of such taxes and (v) provide Oramed a copy of such written advisement or instructions at least 30 days, or such shorter period as reasonably practicable given the timing of the subject advice or instructions received by Oravax, in advance of such withholding. Without limiting the generality of the foregoing, upon request by Oramed, Oravax shall provide Oramed such information in Oravax's possession as may be reasonably necessary for Oramed to obtain the benefit of any present or future treaty against double taxation which may apply to payments made to Oramed under this Agreement.

ARTICLE 6

CONFIDENTIALITY

- 6.1. **Confidential Information.** Except to the extent expressly authorized by this Agreement, each Party (in such capacity, the "**Receiving Party**") agrees that it shall keep confidential and shall not publish or otherwise disclose to any Third Party, and shall not use for any purpose other than as expressly provided for in this Agreement or any other written agreement between the Parties, any Confidential Information furnished or made available to it by or on behalf of the other Party (in such capacity, the "**Disclosing Party**"). The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than a commercially reasonable standard of care) to ensure that it, and its and its Affiliates', employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information. The Licensed IP shall be deemed the Confidential Information of Oravax notwithstanding the fact that it was furnished by Oramed to Oravax in the first instance. Subject to the foregoing, Oramed shall be entitled to issue press releases and make market and regulatory filings with respect to the transactions contemplated herein without the prior approval of Oravax. The Oravax Technology shall be deemed the Confidential Information of Oravax.

- 6.2. **Exceptions.** Confidential Information shall not include any information which the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available; (b) is known by the Receiving Party and/or any of its Affiliates at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the Receiving Party and/or any of its Affiliates by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party and/or any of its Affiliates, without the use of Confidential Information of the Disclosing Party. Any combination of features or disclosures shall not be deemed to fall within the exclusions set forth in the preceding clauses (a) and (b) 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.
- 6.3. **Authorized Disclosure.** Notwithstanding the provisions of Article 6.1, the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:
- (a) filing, prosecuting, or maintaining Patent Rights as permitted by this Agreement;
 - (b) enforcing such Party's rights under this Agreement (including registering the licenses granted hereunder with applicable authorities) and in performing its obligations under this Agreement.
 - (c) prosecuting or defending litigation as permitted by this Agreement;
 - (d) complying with applicable court orders, applicable laws, rules or regulations, or the listing rules of any exchange on which the Receiving Party's securities are traded;
 - (e) disclosure to Affiliates, actual and potential sublicensees, partners, employees, consultants or agents of the Receiving Party who have a need to know such information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, provided, in each case, that any such Affiliate, actual or potential sublicensee, employee, consultant or agent agrees to be bound by terms of confidentiality and non-use comparable in scope to those set forth in this Article 6; and
 - (f) disclosure to Third Parties in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third-Party investors or acquirers in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by reasonable obligations of confidentiality and non-use.

Notwithstanding the foregoing, in the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to Article 6.3(c) or 6.3(d), it will, except where legally impermissible, give reasonable advance notice to the Disclosing Party of such disclosure and use Commercially Reasonable Efforts to secure confidential treatment of such information at least as diligent as the Receiving Party would use to protect its own confidential information, but in no event less than commercially reasonable efforts. In any event, the Receiving Party agrees to take all reasonable action to avoid disclosure of Confidential Information hereunder.

- 6.4. **Filing of this Agreement.** The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with any securities authority or with any stock exchange on which securities issued by a Party are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each Party will ultimately retain control over what information to disclose to any securities authority or stock exchange, as the case may be, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party will be obligated to consult with or obtain approval from the other Party with respect to any filings to any securities authority or stock exchange. Oravax hereby consents to Oramed's use of its name in any filing with a Regulatory Authority as well as any private placement memorandum or other investment document related to Oramed or its securities; provided that, Oravax shall be afforded a reasonable opportunity to review any such filing of investment document and any comments provided by Oravax to Oramed with respect to the use of its name in such filing or investment document shall be considered in good faith by Oramed.

ARTICLE 7

REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS

- 7.1. **Mutual Representations and Warranties.** Each Party represents and warrants to the other that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action; (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and (d) neither Party nor any of their employees or agents is debarred or disqualified under the Act or comparable Applicable Laws outside the United States.

- 7.2. **Oramed Representations and Warranties.** Oramed represents and warrants to Oravax that, as of the Effective Date of this Agreement: (i) Exhibit A attached hereto contains a true and complete list of the Licensed IP, in each case, as it exists on the Effective Date; (ii) it has the right to grant to Oravax the license granted under this Agreement; (iii) it will not transfer, assign, encumber, grant, sell, lease or otherwise dispose of the Licensed IP in any way which is inconsistent with the rights granted to Oravax under this Agreement; (iv) Oramed's ownership of the Licensed IP is free and clear of any encumbrance, lien, or claim of ownership by any Third Party in the Field; (v) to Oramed's knowledge, each of the Patents set forth on Exhibit A (the "Patents") properly identifies each and every inventor of the claims thereof as determined in accordance with the laws of the jurisdiction in which such Patent is issued or such application is pending; (vi) all such inventors have assigned their entire right, title, and interest in and to such inventions to Oramed and all such assignments have been duly recorded and are enforceable in accordance with Applicable Law, and there are no claims or assertions in writing received by Oramed regarding the inventorship of any Patent alleging that additional or alternative inventors should be listed; (vii) all filing, application and renewal fees with respect to the Patents have been duly paid, and Oramed has taken all material steps required for the maintenance and prosecution of the Patents in accordance with Applicable Law; (viii) Oramed has no knowledge, of any actual infringement or threatened infringement of any of the Patents by any Person; and (ix) Oramed has not received any written communication from, or written demand of, any claims or litigation that has been brought or threatened by any Person alleging that any Patent is invalid or unenforceable.
- 7.3. **Oravax Representations and Warranties.** Oravax represents and warrants to Oramed that, as of the Effective Date of this Agreement: (i) it will as of the Closing hold an exclusive, perpetual, worldwide license, including the right to sublicense through multiple tiers of sublicensees as well as the right to modify and amend such sublicenses in and to the Oravax Technology; (ii) the Premas License Agreement will be as of the Closing duly assigned to Oravax and will be in full force and effect, and Oravax undertakes not to exercise its right pursuant to Article 9.4 of the Premas License Agreement (At-Will Termination by Licensee) without the prior written consent of Oramed; (iii) the Oravax Technology is free and clear of any liens, claims, encumbrances, security interests and obligations – legal, financial or otherwise – other than as set forth in the Akers Agreement and the Premas License Agreement; and (iv) it has no actual knowledge as of the Effective Date hereof of any legal suit or proceeding by a Third Party contesting the ownership or validity of the Oravax Technology, or claiming that the practice of the Oravax Technology in the manner contemplated by Oravax would infringe the rights of such Third Party.
- 7.4. **DISCLAIMER OF WARRANTIES.** EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

7.5. **Mutual Covenants.** In addition to any covenants made by a Party elsewhere in this Agreement, each Party hereby covenants to the other as follows:

- (a) neither such Party will knowingly employ or use the services of any Person who is debarred or disqualified under United States law, including 21 U.S.C. §335a, or any foreign equivalent thereof, in connection with activities relating to any Product; and in the event that such Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any Person providing services to such Party with respect to any activities relating to any Product, such Party will immediately notify the other Party in writing and such Party will cease employing, contracting with, or retaining any such Person to perform any services relating to any Product;
- (b) neither such Party will, in connection with the exercise of its rights or performance of its obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a public official or entity or other Person for purpose of obtaining or retaining business for or with, or directing business to, any Person, including such Party, nor will such Party directly or indirectly promise, offer or provide any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a public official or entity or any other Person in connection with the exercise of such Party's rights or performance of such Party's obligations under this Agreement; and
- (c) neither such Party or any of its employees and contractors, in connection with the exercise of such Party's rights or performance of such Party's obligations under this Agreement, shall cause the other Party to be in violation of the FCPA or Export Control Laws.

7.6. **Performance by Sublicensees and Subcontractors.** The Parties recognize that each Party may perform some or all of its obligations or exercise some or all of its rights under this Agreement through one or more subcontractors, or, in the case of Oravax, Sublicensees; *provided, however*, that in each case (a) none of the other Party's rights hereunder are diminished or otherwise adversely affected as a result of such delegation or subcontracting, and (b) each such subcontractor or Sublicensee undertakes in writing obligations of confidentiality and non-use regarding Confidential Information and ownership of Inventions which are substantially the same as those undertaken by the Parties pursuant to Article 6 and Article 8.1; and *provided, further*, that such Party shall at all times be fully responsible for the performance and payment of such subcontractor or Sublicensee.

7.7. **Limitation of Liability.** EXCEPT FOR LIABILITY FOR BREACH OF ARTICLES 6 (CONFIDENTIALITY) OR 8 (INTELLECTUAL PROPERTY) OR IN THE CASE OF FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *provided, however*, that this Article 7.7 shall not be construed to limit either Party's indemnification obligations under Article 10.

ARTICLE 8

INTELLECTUAL PROPERTY

8.1. **Ownership.** As between the Parties, (i) Oramed is and shall at all times be the sole and exclusive owner of all right, title and interest in and to the Licensed IP, and to any Inventions developed, made, conceived or created by Oravax or Sublicensees as a result of the exercise of the licenses hereunder that relate directly to the Licensed IP and all intellectual property rights therein (all of the foregoing, “**New Developments**”). New Developments shall be deemed within the scope of the Licensed IP; (ii) Oravax is and shall at all times be the sole and exclusive owner of all right, title and interest in and to the Oravax Technology and Oravax shall at all times be the sole and exclusive owner of the Oravax Technology. The Parties shall jointly own rights in any other Invention that (i) does not fall within the Licensed IP, New Developments, or Oravax Technology; and (ii) that is made jointly by one or more employees or agents of each Party and/or other persons acting under its authority (“**Joint Inventions**”) and Patent Rights therein (“**Joint Patent Rights**”). For clarity, Inventions developed exclusively by one Party shall not be considered Joint Inventions, and Inventions that fall within the Licensed IP, New Developments, or Oravax Technology shall not be considered Joint Inventions, irrespective of which Party employs or pays the inventors. Subject to the limitations and limited rights and licenses granted under this Agreement, neither party may exploit, practice, use or encumber, any Joint Inventions and Joint Patent Rights without the other Party’s prior written consent. Each Party shall be liable with respect to its own employees for compliance with any applicable legislation and its own policies concerning employee inventions, including payment of employee invention awards (if any).

8.2. **Patent Prosecution and Maintenance.**

- (a) **Licensed IP Patent Rights.** Subject to Article 8.2(b) and the last sentence of this Article 8.2(a), Oramed shall have the right, but not the obligation, to control the preparation, filing, prosecution and maintenance of Patent Rights which underly the Licensed IP and the New Developments (“**Oramed Patent Rights**”) at Oramed’s sole expense and by counsel of its choice. Oramed shall keep Oravax reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of such Patent Rights including copies of all patent office communications filed or received that fall within the licenses granted in this Agreement, and Oramed or its counsel shall directly provide to Oravax copies of all material proposed patent office submissions at least 30 days before any deadline so that Oravax will have an opportunity to review and comment. Oramed agrees, and will instruct its counsel, to implement such Oravax comment and other input unless there is a good faith reason not to do so. In the event that Oramed desires to abandon or cease prosecution or maintenance of any such Patent Right in any country or jurisdiction (such country or jurisdiction, the “**Abandoned Territory**”), Oramed shall provide written notice to Oravax of such intention to abandon no later than 70 days prior to the next deadline for any action that must be taken with respect to such Patent Right in the relevant patent office. In such case, upon receipt of a written request by Oravax to assume responsibility for prosecution and maintenance and exclusive ownership of such Patent Right, Oramed shall allow Oravax at its sole cost and expense and by counsel of its own choice, delivered no later than 30 days after receipt of notice from Oravax to assume such responsibility and exclusive ownership.

- (b) **Oravax Right to Direct.** In the event that Oravax requests that Oramed file and maintain any Oramed Patent Right in a jurisdiction in which an application with respect to such Patent Right has not been filed as of the Effective Date, Oramed shall comply with Oravax's request; provided that the preparation, filing, prosecution and maintenance of such Patent Right in such jurisdiction shall be at Oravax's expense and otherwise in accordance with Article 8.2(a).
- (c) **Joint Patent Rights.** Oravax shall have the first right, but not the obligation, to prepare, file, prosecute and maintain all Joint Patent Rights, by counsel of Oravax's choice which counsel shall be reasonably acceptable to Oramed. Oramed will reimburse Oravax for half of the costs of such activities related to Joint Patent Rights within 30 days of being invoiced, unless Oramed notifies Oravax it wishes to assign its undivided half of any Joint Patent Right(s) to Oravax before such cost has been incurred by Oravax, and then Oramed effectuates such Assignment after which it will have no rights to such Joint Patent Right(s). Oravax shall keep Oramed reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of the Joint Patent Rights, and shall provide to Oramed copies of all material patent office submissions within a reasonable amount of time following submission thereof by Oravax and allow for Oramed to have reasonable input into the prosecution strategy for the Joint Patent Rights. In the event that Oravax desires to abandon or cease prosecution or maintenance of any Joint Patent Right, Oravax shall provide written notice to Oramed of such intention to abandon promptly after Oravax makes such determination, which notice shall be given no later than 70 days prior to the next deadline for any action that must be taken with respect to such Joint Patent Right in the relevant patent office. In such case, Oramed shall have the right, in its discretion, exercisable upon written notice to Oravax delivered no later than 30 days after receipt of notice from Oravax, to assume responsibility for prosecution and maintenance of such Joint Patent Right, at its sole cost and expense and by counsel of its own choice, and if Oramed exercises such right, then Oravax shall cease to have any ownership rights to such Joint Patent Right; provided that such Joint Patent Right shall be deemed thereafter to be Licensed IP and therefore subject to this Agreement.
- (d) **Oravax Technology Patent Rights.** Except as provided in Article 8.2(c), as between the Parties, Oravax shall have the sole right, but not the obligation, to control the preparation, filing, prosecution and maintenance of Patent Rights which underly the Oravax Technology ("**Oravax Patent Rights**"), at Oravax's sole expense and by counsel of its choice.
- (e) **Cooperation of the Parties.** Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of Patent Rights under this Agreement and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates and the like with respect to any Patent Right as well as in registering the licenses granted hereunder with the applicable authorities. Such cooperation includes, but is not limited to: (i) executing all papers and instruments, or requiring its employees or contractors to execute such papers and instruments, so as to effectuate the exclusive ownership or either Party of its respective Patent Rights, and to effectuate joint ownership of Joint Inventions and Joint Patent Rights, as set forth in Article 8.1; and to enable the other Party to apply for and to prosecute patent applications in any country in accordance with the foregoing provisions of this Article 8.2; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications including prompt disclosure of Inventions that will be owned by the other Party under this Article 8.

8.3. **Interference, Opposition, Invalidity, Reexamination, Reissue, and Other Post-Issuance Proceedings.**

(a) **Relevant Oramed Patent Claims.**

- (i) **Oramed First Right.** Oramed shall, within ten (10) days of learning of such event, inform Oravax of any request for, or filing or declaration of, any interference, opposition, invalidation, reissue, reexamination, *inter partes* review, or post grant review relating to claims of the Oramed Patent Rights that cover any Product in the Field or their use in the development or manufacture of any Product in the Field (the “**Relevant Oramed Patent Claims**”). With respect to any request for, or filing or declaration of, any interference, opposition, invalidation, reissue, reexamination, *inter partes* review, or post grant review relating to Relevant Oramed Patent Claims, Oramed shall have the first right (in its discretion) to initiate, prosecute and/or respond, to such action or proceeding, provided that Oramed shall consult with Oravax with respect to any such action or proceeding and shall consider Oravax’s position in good faith. In the event that Oramed elects to initiate, prosecute and/or respond to any interference, opposition, invalidation, reexamination, reissue, *inter partes* review, or post grant review proceeding relating to any Relevant Oramed Patent Claim, the expenses thereof shall be borne solely by Oramed. Oramed shall keep Oravax informed of developments in any such action or proceeding involving any Relevant Oramed Patent Claim. Further such Relevant Oramed Patent Claim shall thereafter be deemed to be Licensed IP and therefore subject to this Agreement.
- (ii) **Oravax Back-Up Right.** Oramed shall promptly inform Oravax in the event that Oramed elects not to initiate, prosecute and/or respond to any interference, opposition, invalidation, reissue, reexamination, *inter partes* review, or post grant review relating to any Relevant Oramed Patent Claim, and in such case, Oravax shall have the right to do so (in Oravax’s discretion), at its cost and expense within 90 days of receiving notice from Oramed of its election not to prosecute and/or respond. Oravax shall keep Oramed informed of developments in any such action or proceeding involving any Relevant Oramed Patent Claim.
- (b) **Joint Patent Rights.** Each Party shall, within ten (10) days of learning of such event, inform the other Party of any request for, or filing or declaration of, any interference, opposition, invalidation, reissue, reexamination, *inter partes* review, or post grant review relating to Joint Patent Rights (a “**Joint Patent Claim**”). The Parties shall mutually agree on a case-by-case basis which Party will have the right to handle any interference, opposition, invalidation, reissue, reexamination or post grant review proceeding relating to claims of the Joint Patent Rights and how the expenses of such action or proceeding will be allocated. Neither Party shall settle any interference, opposition, invalidation, reissue, reexamination, *inter partes* review, or post grant review action or proceeding relating to any Joint Patent Claim without the prior written consent of the other Party, which consent shall not be unreasonably withheld. The Party handling such action or proceeding shall keep the other Party informed of developments in any such action or proceeding involving any Joint Patent Claim.

(c) **Oravax Patent Rights.**

- (i) **Oravax First Right.** Oravax shall, within ten (10) days of learning of such event, inform Oramed of any request for, or filing or declaration of, any interference, opposition, invalidation, reissue, reexamination, *inter partes* review, or post grant review relating to claims of the Oravax Patent Rights that cover any Product in the Field or their use in the development or manufacture of any Product in the Field (the “**Relevant Oravax Patent Claims**”). With respect to any request for, or filing or declaration of, any interference, opposition, invalidation, reissue, reexamination, *inter partes* review, or post grant review relating to Relevant Oravax Patent Claims, Oravax shall have the first right (in its discretion) to initiate, prosecute and/or respond, to such action or proceeding, provided that Oravax shall consult with Oramed with respect to any such action or proceeding and shall consider Oramed’s position in good faith. In the event that Oravax elects to initiate, prosecute and/or respond to any interference, opposition, invalidation, reexamination, reissue, *inter partes* review, or post grant review proceeding relating to any Relevant Oramed Patent Claim, the expenses thereof shall be borne solely by Oravax. Oravax shall keep Oramed informed of developments in any such action or proceeding involving any Relevant Oravax Patent Claim.
- (ii) **Oramed Back-Up Right.** Oravax shall promptly inform Oramed in the event that Oravax elects not to initiate, prosecute and/or respond to any interference, opposition, invalidation, reissue, reexamination, *inter partes* review, or post grant review relating to any Relevant Oravax Patent Claim, and in such case, Oramed shall have the right to do so (in Oramed’s discretion), at its cost and expense within 90 days of receiving notice from Oravax of its election not to prosecute and/or respond. Oramed shall keep Oravax informed of developments in any such action or proceeding involving any Relevant Oravax Patent Claim.

8.4. **Enforcement and Defense of Patent Rights.** Each Party shall notify the other Party in writing within 10 Business Days (except as expressly set forth below) of becoming aware of any alleged or threatened infringement by a Third Party of any of the Oramed Patent Rights, Joint Patent Rights or Oravax Patent Rights (“**Infringement**”), including (x) any such alleged or threatened Infringement on account of a Third Party’s manufacture, use or sale of a Product in the Field, (y) submission of a BLA (a Biologics License Applications in the United States or a comparable application for Marketing Approval under Applicable Law in any country other than the United States) or other BLA for a Product in the Field (a “**Patent Certification**”), and (z) any declaratory judgment action filed by a Third Party that is developing, manufacturing or commercializing a Product in the Field alleging the invalidity, unenforceability or non-infringement of any of the Oramed Patent Rights, Joint Patent Rights or Oravax Patent Rights ((x)-(z), collectively, “**Competitive Infringement**”); *provided, however*, that each Party shall notify the other Party of any Patent Certification regarding any Oramed Patent Right, Oravax Patent Right or Joint Patent Right that it receives, and such Party shall provide the other Party with a copy of such Patent Certification, within five (5) days of receipt.

- (a) **Competitive Infringement.** Oravax shall have the first right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to Competitive Infringement of a Oramed Patent Right, Oravax Patent Right or a Joint Patent Right, in each case that covers a Product (collectively, the “**Relevant Patent Rights**”), at Oravax’s own expense and by counsel of its own choice. If Oravax fails to bring any such action or proceeding with respect to Competitive Infringement of any Relevant Patent Right within 90 days following the notice of alleged Competitive Infringement, Oramed shall have the right to bring (or defend) and control any such action at its own expense and by counsel of its own choice, and Oravax shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.
- (b) **Other Infringement.** The Parties shall mutually agree on a case-by-case basis (A) whether to bring (or defend) and control any action or proceeding with respect to Competitive Infringement of any Patent Right that is not a Relevant Patent Right, (B) which Party would bring (or defend) and control such action, and (C) how the expenses of, and any recovery from, any such action would be allocated.
- (c) **Cooperation.** In the event a Party brings (or defends) an Infringement action in accordance with this Article 8.4, or in the event a Party is entitled to bring (or defend) an infringement action in accordance with this Article 8.4 but lacks standing to do so, the other Party shall cooperate fully, including, if required to bring (or defend) such action, the furnishing of a power of attorney or being named as a party. Neither Party shall enter into any settlement or compromise of any action under this Article 8.4 which would in any manner alter, diminish, or be in derogation of the other Party’s rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.
- (d) **Recovery.** Except as otherwise agreed by the Parties in connection with a cost-sharing arrangement, any recovery realized by a Party as a result of any action or proceeding pursuant to this Article 8.4, whether by way of settlement or otherwise, shall be applied (i) to reimburse the documented out-of-pocket legal expenses of the Party that brought (or defended) and controlled such action or proceeding incurred in connection with such action or proceeding, (ii) to reimburse the documented out-of-pocket legal expenses of the other Party incurred in connection with such action or proceeding, and (iii) if Oravax is the prosecuting party then any remaining amount attributable to recovery for lost sales or profits shall be deemed “Net Sales” in the calendar quarter in which the money is actually received and Oravax shall pay the corresponding Royalties to Oramed in accordance with the terms of this Agreement and (iv) if Oramed is the prosecuting party then the remaining amount shall be shared equally (50%/50%) by the Parties (including any treble, punitive or other multiplier of damages and interest awarded with respect thereto).

- 8.5. **Patent Term Extensions.** The Parties shall mutually agree on a case-by-case basis the Oramed Patent Rights and/or the Joint Patent Rights for which applications will be made for extension of patent term in any country and/or region for any Product in the Field, which Party will make such application and how to allocate resulting costs equitably. Each Party shall provide all reasonable assistance to the other in connection with such filings. In the event that a Party desires to not apply for a patent extension for any Oramed Patent Rights and/or Joint Patent Rights for which there is a reasonable basis to file for such extension, such Party shall provide written notice of such intention to not file no later than 70 days' prior to the next deadline for any action that must be taken with respect to such Oramed Patent Right and/or Joint Patent Right in the relevant patent office and the other Party shall have the option to apply for, and to control, an extension at its cost and expense for such Oramed Patent Right and/or Joint Patent Rights.
- 8.6. **Infringement of Third-Party Rights.** Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either Party pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party. Neither Party shall have the right to settle any patent infringement litigation under this Article 8.6 in a manner that diminishes the rights or interests of the other Party without the written consent of such other Party (which shall not be unreasonably withheld).

ARTICLE 9

TERM AND TERMINATION

- 9.1. **Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated in accordance with this Article 9, continue for the longer of: (i) on a country-by-country basis until the expiration of the last-to-expire of all Valid Claims in the Oramed Patent Rights in all countries in the Territory; or (ii) for twenty years from the Effective Date of this Agreement (the "**Term**").
- 9.2. **Termination for Material Breach.** Each Party shall have the right to terminate this Agreement in its entirety upon written notice to the other Party if such other Party is in material breach of this Agreement and has not cured such breach within 90 days after notice from the terminating Party indicating the nature of such breach and the actions required to cure such breach if not apparent, or if such other Party is dissolved or liquidated or takes any corporate action for such purpose; makes a general assignment for the benefit of creditors; or has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business; or, in the case of termination by Oramed, if the Premas License Agreement has been terminated for any reason. Any such termination shall become effective at the end of such 90-day period unless the breaching Party has cured such breach prior to the end of such period.
- 9.3. **Termination for Patent Challenge.** Oramed shall have the right to terminate this Agreement immediately upon written notice to Oravax if Oravax directly, or through assistance granted to a Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of term or the grant of a supplementary protection certificate with respect to, any Oramed Patent Right.
- 9.4. **Voluntary Termination by Oravax.** Oravax shall have the right to terminate this Agreement in its entirety at any time prior to submission of an application by Oravax for the receipt of Marketing Approval with respect to a Product by providing sixty (60) days' prior written notice to Oramed, provided that Oravax's termination shall not be deemed to cure any breach existing as of the date of such termination.

9.5. **Effect of Expiration or Termination.**

- (a) **Expiration.** Upon expiration (but not on earlier termination) of this Agreement, all licenses granted by Oramed to Oravax that were in effect immediately prior to such expiration shall survive on a non-exclusive, fully-paid up, royalty-free basis (*provided, however*, that the sales milestone payments pursuant to Article 4.1 shall remain in force).
- (b) **Any Termination.** Upon termination of this Agreement prior to its expiration, the license granted to Oravax pursuant to Article 2.1 shall automatically terminate and revert to Oramed, and all other rights and obligations of the Parties under this Agreement shall terminate, except as expressly provided in this Article 9. In the event of termination by Oramed under Article 9.2 or 9.3 or by Oravax under 9.4, all pre-clinical data, clinical data, INDs, all other Regulatory Documentation shall be transferred to Oramed together with such other information in possession of Oravax as requested or necessary to the continued development or commercialization of the Products.
- (c) **Accrued Obligations; Survival.** Neither expiration nor any termination of this Agreement shall relieve either Party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. In addition, the Parties' rights and obligations under Articles 6.1, 6.2, 6.3, 7.4, 7.7, 8.1, 8.2(c), 8.3(b), 8.5 (with respect to Joint Patents), 9.5 and Articles 5, 10, 11 and 12 of this Agreement shall survive expiration or any termination of this Agreement.
- (d) **Return of Confidential Information.** Within 30 days following the expiration or termination of this Agreement, except to the extent that a Party retains a license from the other Party as provided in this Article 9, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only subject to a continuing confidentiality obligations.
- (e) **Damages; Relief.** Termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to hereunder.

ARTICLE 10

INDEMNIFICATION

- 10.1. **Indemnification by Oravax.** Oravax hereby agrees to save, defend, indemnify and hold harmless Oramed, its officers, directors, agents, employees, successors and assigns (the **"Oramed Indemnitees"**) from and against any and all losses, damages, liabilities, expenses and costs, including reasonable and documented legal expense and attorneys' fees (**"Losses"**), to which any Oramed Indemnatee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a **"Claim"**) to the extent such Losses arise out of or relate to (a) the gross negligence or willful misconduct of any Oravax Indemnatee (defined below), (b) the breach by Oravax of any warranty, representation, covenant or agreement made by Oravax in this Agreement, or (c) the development, manufacture, use, sale, offer for sale or other disposition by or on behalf of Oravax and its Sublicensees of any Product; in each case, except to the extent such Losses result from (i) the gross negligence or willful misconduct of any Oramed Indemnatee or the breach by Oramed of any warranty, representation, covenant or agreement made by Oramed in this Agreement and (ii) any Claim for which Oramed is obligated to indemnify Oravax under Article 10.2.
- 10.2. **Indemnification by Oramed.** Oramed hereby agrees to save, defend, indemnify and hold harmless Oravax and its officers, directors, employees, consultants and agents (the **"Oravax Indemnitees"**) from and against any and all Losses to which any Oravax Indemnatee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of or relate to (a) the gross negligence or willful misconduct of any Oramed Indemnatee, (b) actual patent infringement or actual misappropriation of trade secrets arising out of the exercise of rights under the Licensed IP, or (c) the breach by Oramed of any warranty, representation, covenant or agreement made by Oramed in this Agreement; (i) the gross negligence or willful misconduct of any Oravax Indemnatee or the breach by Oravax of any warranty, representation, covenant or agreement made by Oravax in this Agreement and (ii) any Claim for which Oravax is obligated to indemnify Oramed under Article 10.1.
- 10.3. **Control of Defense.** In the event a Party (the **"Indemnified Party"**) seeks indemnification under Article 10.1 or 10.2, it shall inform the other Party (the **"Indemnifying Party"**) of a claim as soon as reasonably practicable after it receives notice of the claim (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a claim as provided in this Article 10.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice), shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration) using counsel reasonably satisfactory to the Indemnified Party, and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. If the Indemnifying Party does not assume control of such defense within 15 days after receiving notice of the claim from the Indemnified Party, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all costs, including reasonable and documented attorney fees, incurred by the Indemnified Party in defending itself within 30 days after receipt of any invoice therefor from the Indemnified Party. The Party not controlling such defense may participate therein at its own expense. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party without the prior written consent of the Indemnified Party. If the Parties cannot agree as to the application of Article 10.1 or 10.2 to any claim, pending resolution of the dispute pursuant to Article 11, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Article 10.1 or 10.2, as applicable, upon resolution of the underlying claim.

- 10.4. **Insurance.** Each Party shall procure and maintain adequate levels of insurance that are consistent with industry standards for similarly situated companies, including comprehensive or commercial general liability insurance (including contractual liability and product liability). Such insurance shall include commercially reasonable levels of insurance as may be customary in light of status of activities being conducted. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 10 or otherwise. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least 30 days prior to the cancellation, non-renewal or material change in such insurance which materially adversely affects the rights of the other Party hereunder.

ARTICLE 11

DISPUTE RESOLUTION

- 11.1. **Disputes.** Subject to Article 11.2, any claim, dispute, or controversy as to the breach, enforcement, interpretation or validity of, or otherwise related to or arising from, this Agreement (each, a **"Dispute"**) that cannot be resolved by the Parties within 30 days that a Party is notified of such Dispute, will be referred to the Chief Executive Officer of Oramed and the Chief Executive Officer of Oravax for attempted resolution, with each party exercising good faith in such attempt. In the event such executives are unable to resolve such Dispute within 30 days of such Dispute being referred to them, then, upon the written request of either Party to the other Party, as expressly set forth in Article 11.2.
- 11.2. **Court Actions; Jurisdiction.** Each of the Parties hereto: (i) consents to submit itself to the personal jurisdiction of any federal or state court located in the state of New York in the event any dispute arises out of or relates to this Agreement, including without limitation to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patent Rights or other intellectual property rights hereunder, (ii) agrees that it will not attempt to deny or defeat such personal jurisdiction by motion or other request for leave from any court, or to object to such courts as an inconvenient forum, (iii) agrees that it will not bring any action relating to this Agreement or any of the transactions contemplated hereby in any other court, and (iv) agrees that service of any process, summons, notice or document by express overnight (or 2-day) courier or by U.S. or international registered or certified mail to the Party at the address specified in Article 12.8 shall be effective service of process for any action, suit or proceeding brought against such Party in any such court.

ARTICLE 12

MISCELLANEOUS

- 12.1. **Rights Upon Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Article 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction outside the U.S. (collectively, the “**Bankruptcy Laws**”), licenses of rights to be “intellectual property” as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in- possession) and its successors and assigns (including a Title 11 trustee), shall promptly provide to the other Party copies of all Information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party’s written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.
- 12.2. **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding its conflicts of laws principles, except as to any issue which depends upon the validity, scope or enforceability of any Patent, which issue shall be determined in accordance with the laws of the country in which such patent was issued.
- 12.3. **Entire Agreement; Amendments.** This Agreement (including the Exhibits and Schedules hereto) is both a final expression of the Parties’ agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. The Exhibits and Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.
- 12.4. **Non-Waiver.** The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.
- 12.5. **Assignment.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); *provided, however*, that either Party may assign this Agreement and its rights and delegate its obligations hereunder without the other Party’s consent in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates to a Third Party (“**Third Party Acquirer**”), whether by merger, sale of stock, sale of assets or otherwise (each, a “**Sale Transaction**”). The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party’s successors and permitted assigns to the extent necessary to carry out the intent of this Article. Any assignment not in accordance with this Agreement shall be void. In the event of an assignment and assumption of rights and obligations under this Agreement to a Third Party in connection with a Sale Transaction, the assigning Party shall be relieved of all obligations to the non-assigning Party assumed by the applicable Third Party.

- 12.6. **Force Majeure.** Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control, including but not limited to Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, any strike or labor disturbance, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.
- 12.7. **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 shall 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 shall 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.
- 12.8. **Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile or electronic mail (in each case, if 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:

If to Oramed, to:

Oramed Pharmaceuticals Inc.
1185 Avenue of the Americas
New York, NY
Attention: Chief Operating & Business Officer
Fax: +972-2-566-0004
Email: josh@oramed.com

Oramed Ltd.
20 Mamilla Avenue, 3rd Floor
Jerusalem, Israel
9414904
Attention: Chief Operating & Business Officer
Fax: +972-2-566-0004
Email: josh@oramed.com

If to Oravax, to:

Oravax Medical Inc.
1185 Avenue of the Americas, 3rd Floor
New York, NY 10036
Attention: Joshua Silverman
Fax: N/A
E-mail: jsilverman@parkfieldfund.com

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 shall be deemed to have been given: (a) when delivered, if personally delivered or sent by facsimile or email 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 third business day following the date of mailing, if sent by mail.

- 12.9. **Interpretation.** The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. The term “including” or “includes” as used in this Agreement means including, without limiting the generality of any description preceding such term, and the word “or” has the inclusive meaning represented by the phrase “and/or.” Unless otherwise specified, references in this Agreement to any section shall include all subsections and paragraphs in such section and references in this Agreement to any subsection shall include all paragraphs in such subsection. All references to days in this Agreement shall mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.
- 12.10. **Relationship between the Parties.** The Parties’ relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party may assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.
- 12.11. **Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.
- 12.12. **No Third-Party Rights.** The provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity shall 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.

- 12.13. **Further Assurances.** Each Party agrees to do and perform all such further acts and things and will execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may deem advisable in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.
- 12.14. **Compliance with Securities Laws.** Oravax hereby acknowledges that it is aware, and Oravax shall advise its employees, agents, consultants and other representatives who are informed of the matters that are the subject of this Agreement, that United States securities laws place certain restrictions on any person who has material, non-public information concerning an issuer, with respect to purchasing or selling securities of such issuer or from communicating such information to any other person when it is reasonably foreseeable that such other person is likely to purchase or sell such securities. Oravax acknowledges its obligation to comply with all applicable securities laws in connection with the receipt of any Confidential Information of Oramed.
- 12.15. **Costs.** Except as specifically provided in this Agreement, each Party shall be solely responsible for all costs, fees and other expenses incurred in connection with this Agreement.
- 12.16. **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. This Agreement may be executed by facsimile or PDF signatures, which signatures shall have the same force and effect as original signatures.

[Remainder of this page intentionally left blank.]

IN WITNESS WHEREOF, the parties hereto have duly executed this License Agreement as of the Effective Date.

Oravax Medical Inc.

By: /s/ Josh Silverman
Name: Josh Silverman
Title: Chief Executive Officer

Oramed Pharmaceuticals Inc.

By: /s/ Nadav Kidron
Name: Nadav Kidron
Title: Chief Executive Officer

Oramed Ltd.

By: /s/ Nadav Kidron
Name: Nadav Kidron
Title: Chief Executive Officer

Exhibit A
Licensed IP

Exhibit C
Development Plan

STOCKHOLDERS AGREEMENT

THIS STOCKHOLDERS AGREEMENT (this “**Agreement**”), is made and entered into as of this 18th day of March, 2021, by and among Oravax Medical Inc., a Delaware corporation (the “**Company**”) and those certain stockholders of the Company listed on Schedule A (together with any subsequent stockholders or holders of options to acquire shares of the capital stock of the Company, or any transferees, who become parties hereto as “Stockholders” pursuant to Subsections 8.1 or 8.2 below, the “**Stockholders**”).

RECITALS

The parties desire to enter into this Agreement to set forth their agreements and understandings with respect to how shares of the Capital Stock of the Company held by them will be voted in connection with an acquisition of the Company or the election of directors to the board of directors of the Company (the “**Board**”) and certain other matters contemplated hereby.

AGREEMENT

NOW, THEREFORE, the Company and the Stockholders each hereby agree as follows:

1. Definitions. As used herein, the following terms shall have the following meanings:

1.1 “**Affiliate**” means, with respect to any Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including, without limitation, any general partner, officer, director, or managing member of such Person and any venture capital fund now or hereafter existing which is controlled by or under common control with one or more general partners or shares the same management company with such Person.

1.2 “**Akers**” means Akers Biosciences, Inc.

1.3 “**Capital Stock**” means (a) shares of common stock of the Company, par value \$0.001 per share (“**Common Stock**”) (whether now outstanding or hereafter issued in any context), (b) shares of preferred stock of the Company (whether now outstanding or hereafter issued in any context) and (c) and all other securities of the Company which may be exchangeable for, convertible into or issued in exchange for or in respect of shares of Common Stock (whether by way of stock split, stock dividends, combination, reclassification, reorganization or any other means).

1.4 “**Charter**” means that certain Certificate of Incorporation, filed with the Secretary of State of Delaware on March 10, 2021, as amended from time to time.

1.5 “**Company Notice**” means written notice from the Company notifying the Stockholders that the Company intends to exercise its Right of First Refusal as to some or all of the Transfer Stock with respect to any Proposed Stockholder Transfer.

1.6 “**Contribution Agreement**” means that certain Contribution and Assignment Agreement, dated as of the date hereof, by and among the Company, Akers and Cystron Biotech LLC (“**Cystron**”).

1.7 “**Deemed Liquidation Event**” means each of the following events, unless the Requisite Stockholders elect otherwise by written consent sent to the Company at least 10 days prior to the effective date of any such event: (a) a merger or consolidation in which (i) the Company is a constituent party, or (ii) a subsidiary of the Company is a constituent party and the Company issues shares of its Capital Stock pursuant to such merger, or consolidation, except, any such merger or consolidation involving the Company or a subsidiary in which the shares of Capital Stock outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of Capital Stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the Capital Stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation, or (b) (i) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company or any subsidiary of the Company of all or substantially all the assets of the Company and its subsidiaries taken as a whole, or (ii) the sale or disposition (whether by merger, consolidation or otherwise, and whether in a single transaction or a series of related transactions) of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except, in each case, where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Company.

1.8 “**Derivative Securities**” means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Common Stock, including options and warrants.

1.9 “**Going Public Event**” means (i) the IPO or (ii) any other listing of the Company’s shares on a national securities exchange (including, without limitation, a Spin Off).

1.10 “**IPO**” means the Company’s first underwritten public offering of its Common Stock under the Securities Act.

1.11 “**New Securities**” means, collectively, equity securities of the Company, whether or not currently authorized, as well as rights, options, or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.

1.12 “**Oramed**” means Oramed Pharmaceuticals, Inc. or one of its Affiliates.

1.13 “**Oramed License Agreement**” means that certain license agreement, dated as of the date hereof, by and among the Company, Oramed Pharmaceuticals, Inc. and one of its Affiliates for the development of an oral delivery system for that certain vaccine candidate described in the License Agreement (as such term is defined in the Contribution Agreement).

1.14 “**Person**” means any individual, corporation, partnership, trust, limited liability company, association or other entity.

1.15 “**Premas Parties**” means Premas Biotech PVT Ltd., Cutter Mill Capital LLC and Run Ridge LLC.

1.16 “**Proposed Stockholder Transfer**” means any assignment, sale, offer to sell, pledge, mortgage, hypothecation, encumbrance, disposition of or any other like transfer or encumbering of any Transfer Stock (or any interest therein) proposed by any of the Stockholder; provided, that a Proposed Stockholder Transfer shall not include any merger, consolidation or like transfer effected pursuant to a vote of the holders of Capital Stock of the Company.

1.17 “**Proposed Transfer Notice**” means written notice from a Stockholder setting forth the terms and conditions of a Proposed Stockholder Transfer.

1.18 “**Prospective Transferee**” means any person to whom a Stockholder proposes to make a Proposed Stockholder Transfer.

1.19 “**Qualified Financing**” has the meaning set forth in the Contribution Agreement.

1.20 “**Requisite Stockholders**” means the Stockholders holding at least a majority of the voting power of Common Stock, voting as a single class on an as-converted basis.

1.21 “**Right of Co-Sale**” means the right, but not an obligation, of a Stockholder to participate in a Proposed Stockholder Transfer on the terms and conditions specified in the Proposed Transfer Notice.

1.22 “**Right of First Refusal**” means the right, but not an obligation, of the Company, or its permitted transferees or assigns, to purchase some or all of the Transfer Stock with respect to a Proposed Stockholder Transfer on the terms and conditions specified in the Proposed Transfer Notice.

1.23 “**Shares**” means Capital Stock that is outstanding.

1.24 “**Secondary Notice**” means written notice from the Company notifying the Stockholders that the Company does not intend to exercise its Right of First Refusal as to all shares of any Transfer Stock with respect to a Proposed Stockholder Transfer on the terms and conditions specified in the Proposed Transfer Notice.

1.25 “**Secondary Refusal Right**” means the right, but not an obligation, of each Stockholder to purchase up to its pro rata portion (based upon the total number of shares of Capital Stock then held by all Stockholders) of any Transfer Stock not purchased pursuant to the Right of First Refusal, on the terms and conditions specified in the Proposed Transfer Notice.

1.26 “**Spin Off**” means the distribution of all or a portion of the shares of Common Stock owned by Akers to Akers’ stockholders on a pro rata basis and which results in the listing of the Common Stock on a national securities exchange.

1.27 “**Transfer Stock**” means shares of Capital Stock owned by a Stockholder or issued to a Stockholder after the date hereof (including, without limitation, in connection with any stock split, stock dividend, recapitalization, reorganization, or the like).

1.28 “**Undersubscription Notice**” means written notice from a Stockholder notifying the Company and the other Stockholders that such Stockholder intends to exercise its option to purchase all or any portion of the Transfer Stock not purchased pursuant to the Right of First Refusal or the Secondary Refusal Right.

1.29 “**Sale of the Company**” means either: (a) a transaction or series of related transactions in which a Person, or a group of related Persons, acquires shares of the Company from a Person other than the Company and, after such transaction or series of related transactions, holds more than fifty percent (50%) of the outstanding voting power of the Company; or (b) a transaction that qualifies or would qualify as a Deemed Liquidation Event.

1.30 “**Stockholder Notice**” means written notice from any Stockholder notifying the Company and the selling Stockholder(s) that such Stockholder intends to exercise its Secondary Refusal Right as to a portion of the Transfer Stock with respect to any Proposed Stockholder Transfer.

2. **Voting Provisions Regarding the Board and Other Matters.**

2.1 **Size of the Board.** Each Stockholder agrees to vote, or cause to be voted, all Shares now owned or hereafter acquired by such Stockholder, or over which such Stockholder has voting control, from time to time and at all times, in whatever manner as shall be necessary to ensure that the size of the Board shall be set and remain at three (3) directors. Each Stockholder agrees to attend, in person or by proxy, all meetings of stockholders called for the purpose of this Subsection 2.1 and to take all actions, including, but not limited to, the nomination of specified persons, the execution of written consents and the calling of a stockholder meeting for the purpose of this Subsection 2.1.

2.2 **Board Composition.** Each of the Stockholders hereby agrees to vote all of its Shares now owned or hereafter acquired by such Stockholder (and to attend, in person or by proxy, all meetings of stockholders called for the purpose of electing directors), and agrees to take all actions (including, but not limited, the nomination of specified persons, the execution of written consents and the calling of a stockholder meeting for the purpose of electing such specified persons), to elect and maintain the following persons as directors on the Board:

(a) Two (2) persons designated from time to time by Oramed, for so long as Oramed continues to beneficially own greater than 25% of the fully diluted capitalization of the Company; provided that one of such persons will be the then-existing chief executive officer of Oramed who shall serve as the chairman of the Board; and

(b) One (1) person designated from time to time by Akers (such director referred to as “**Akers Designee**”); provided, however, that, on or after the third (3rd) anniversary of the date hereof, Akers shall not have the right to designate the Akers Designee and each of the Stockholders shall be entitled to remove the Akers Designee pursuant to Subsection 2.4.

2.3 **Failure to Designate a Board Member.** In the absence of any designation from the applicable Stockholder(s), the director previously designated by them and then serving shall be reelected if still eligible and willing to serve as provided herein and otherwise, such Board seat shall remain vacant.

2.4 **Removal of Board Members.** Each Stockholder also agrees to vote, or cause to be voted, all of its Shares now owned or hereafter acquired by such Stockholder or over which such Stockholder has voting control, from time to time and at all times, in whatever manner as shall be necessary (and attend, in person or by proxy, all meetings of stockholders called for the purpose of electing directors), and agree to take all actions (including, but not limited to, the execution of written consents and the calling of a stockholder meeting) to ensure that:

(a) no director elected pursuant to Subsections 2.2 or 2.3 of this Agreement may be removed from office unless (i) such removal is directed or approved by the Requisite Stockholders; or (ii) the Stockholders originally entitled to designate or approve such director pursuant to Subsection 2.2 are no longer so entitled to designate or approve such director;

(b) any vacancies created by the resignation, removal or death of a director elected pursuant to Subsections 2.2 or 2.3 shall be filled pursuant to the provisions of this Section 2; and

(c) upon the request of the Requisite Stockholders to remove such director, such director shall be removed.

All Stockholders agree to execute any written consents required to perform the obligations of this Section 2, and the Company agrees at the request of any Person or group entitled to designate directors to call a special meeting of stockholders for the purpose of electing directors.

2.5 No Liability for Election of Recommended Directors. No Stockholder, nor any Affiliate of any Stockholder, shall have any liability as a result of designating a person for election as a director for any act or omission by such designated person in his or her capacity as a director of the Company, nor shall any Stockholder have any liability as a result of voting for any such designee in accordance with the provisions of this Agreement.

2.6 Other Matters. In addition to the election of directors contemplated by this Section 2, each Stockholder also agrees to vote or cause to be voted all Shares owned by such Stockholder, or over which such Stockholder has voting control, from time to time and at all times, in whatever manner as shall be necessary, in the same manner and to the same extent as directed by the Requisite Stockholders.

3. “Bad Actor” Matters.

3.1 Definitions. For purposes of this Agreement:

(a) **“Company Covered Person”** means, with respect to the Company as an “issuer” for purposes of Rule 506 promulgated under the Securities Act, any Person listed in the first paragraph of Rule 506(d)(1).

(b) **“Disqualified Designee”** means any director designee to whom any Disqualification Event is applicable, except for a Disqualification Event as to which Rule 506(d)(2)(ii) or (iii) or (d)(3) is applicable.

(c) **“Disqualification Event”** means a “bad actor” disqualifying event described in Rule 506(d)(1)(i)-(viii) promulgated under the Securities Act.

(d) **“Rule 506(d) Related Party”** means, with respect to any Person, any other Person that is a beneficial owner of such first Person’s securities for purposes of Rule 506(d) under the Securities Act.

3.2 Representations. Each Person with the right to designate or participate in the designation of a director pursuant to this Agreement hereby represents that (a) such Person has exercised reasonable care to determine whether any Disqualification Event is applicable to such Person, any director designee designated by such Person pursuant to this Agreement or any of such Person’s Rule 506(d) Related Parties, except, if applicable, for a Disqualification Event as to which Rule 506(d)(2)(ii) or (iii) or (d)(3) is applicable and (b) no Disqualification Event is applicable to such Person, any Board member designated by such Person pursuant to this Agreement or any of such Person’s Rule 506(d) Related Parties, except, if applicable, for a Disqualification Event as to which Rule 506(d)(2)(ii) or (c) or (d)(3) is applicable. Notwithstanding anything to the contrary in this Agreement, each Stockholder makes no representation regarding any Person that may be deemed to be a beneficial owner of the Company’s voting equity securities held by such Stockholder solely by virtue of that Person being or becoming a party to (x) this Agreement, as may be subsequently amended, or (y) any other contract or written agreement to which the Company and such Stockholder are parties regarding (1) the voting power, which includes the power to vote or to direct the voting of, such security; and/or (2) the investment power, which includes the power to dispose, or to direct the disposition of, such security. The Company hereby represents and warrants to the Stockholders that no Disqualification Event is applicable to the Company or, to the Company’s knowledge, any Company Covered Person, except for a Disqualification Event as to which Rule 506(d)(2)(ii–iv) or (d)(3) is applicable.

3.3 Covenants. Each Person with the right to designate or participate in the designation of a director pursuant to this Agreement covenants and agrees (a) not to designate or participate in the designation of any director designee who, to such Person's knowledge, is a Disqualified Designee, (b) to exercise reasonable care to determine whether any director designee designated by such person is a Disqualified Designee, (c) that in the event such Person becomes aware that any individual previously designated by any such Person is or has become a Disqualified Designee, such Person shall as promptly as practicable take such actions as are necessary to remove such Disqualified Designee from the Board and designate a replacement designee who is not a Disqualified Designee, and (d) to notify the Company promptly in writing in the event a Disqualification Event becomes applicable to such Person or any of its Rule 506(d) Related Parties, or, to such Person's knowledge, to such Person's initial designee named in Section 2, except, if applicable, for a Disqualification Event as to which Rule 506(d)(2)(ii) or (iii) or (d)(3) is applicable.

4. Agreement Among the Company and the Stockholders.

4.1 Right of First Refusal.

(a) Grant. Subject to the terms of Subsections 4.2 and 4.4 below, each Stockholder hereby unconditionally and irrevocably grants to the Company a Right of First Refusal to purchase all or any portion of Transfer Stock that such Stockholder may propose to transfer in a Proposed Stockholder Transfer, at the same price and on the same terms and conditions as those offered to the Prospective Transferee.

(b) Notice. Each Stockholder proposing to make a Proposed Stockholder Transfer must deliver a Proposed Transfer Notice to the Company and each other Stockholder not later than forty-five (45) days prior to the consummation of such Proposed Stockholder Transfer. Such Proposed Transfer Notice shall contain the material terms and conditions (including price and form of consideration) of the Proposed Stockholder Transfer, the identity of the Prospective Transferee and the intended date of the Proposed Stockholder Transfer. To exercise its Right of First Refusal under this Subsection 4.1, the Company must deliver a Company Notice to the selling Stockholder and the other Stockholders within fifteen (15) days after delivery of the Proposed Transfer Notice specifying the number of shares of Transfer Stock to be purchased by the Company. In the event of a conflict between this Agreement and any other agreement that may have been entered into by a Stockholder with the Company that contains a preexisting right of first refusal, the Company and the Stockholder acknowledge and agree that the terms of this Agreement shall control and the preexisting right of first refusal shall be deemed satisfied by compliance with Subsection 4.1(a) and this Subsection 4.1(b). In the event of a conflict between this Agreement and the Company's Bylaws, as amended, containing a preexisting right of first refusal, the terms of the Bylaws, as amended, will control and compliance with the Bylaws, as amended, shall be deemed compliance with Subsection 4.1(a) and this Subsection 4.1(b).

(c) Grant of Secondary Refusal Right to the Stockholders. Subject to the terms of Section 4.4 below, each Stockholder hereby unconditionally and irrevocably grants to the other Stockholders a Secondary Refusal Right to purchase all or any portion of the Transfer Stock not purchased by the Company pursuant to the Right of First Refusal, as provided in this Subsection 4.1(c). If the Company does not provide the Company Notice exercising its Right of First Refusal with respect to all Transfer Stock subject to a Proposed Stockholder Transfer, the Company must deliver a Secondary Notice to the selling Stockholder and to each other Stockholder to that effect no later than fifteen (15) days after the selling Stockholder delivers the Proposed Transfer Notice to the Company. To exercise its Secondary Refusal Right, a Stockholder must deliver a Stockholder Notice to the selling Stockholder and the Company within ten (10) days after the Company's deadline for its delivery of the Secondary Notice as provided in the preceding sentence.

(d) Undersubscription of Transfer Stock. If options to purchase have been exercised by the Company and the other Stockholders pursuant to Subsections 4.1(b) and 4.1(c) with respect to some but not all of the Transfer Stock by the end of the ten (10) day period specified in the last sentence of Subsection 4.1(c) (the “**Stockholder Notice Period**”), then the Company shall, immediately after the expiration of the Stockholder Notice Period, send written notice (the “**Company Undersubscription Notice**”) to those Stockholders who fully exercised their Secondary Refusal Right within the Stockholder Notice Period (the “**Exercising Stockholders**”). Each Exercising Stockholder shall, subject to the provisions of this Subsection 4.1(d), have an additional option to purchase all or any part of the balance of any such remaining unsubscribed shares of Transfer Stock on the terms and conditions set forth in the Proposed Transfer Notice. To exercise such option, an Exercising Stockholder must deliver an Undersubscription Notice to the selling Stockholder and the Company within ten (10) days after the expiration of the Stockholder Notice Period. In the event there are two (2) or more such Exercising Stockholders that choose to exercise the last-mentioned option for a total number of remaining shares in excess of the number available, the remaining shares available for purchase under this Subsection 4.1(d), shall be allocated to such Exercising Stockholders pro rata based on the proportion that the Shares held by an Exercising Stockholder bears to the Shares held by all Exercising Stockholders who wish to purchase the remaining unsubscribed shares of Transfer Stock, provided that no Exercising Stockholders shall be obligated to purchase more than the number of shares initially subscribed for. If the options to purchase the remaining shares are exercised in full by the Exercising Stockholders, the Company shall immediately notify all of the Exercising Stockholders and the selling Stockholder of that fact.

(e) Consideration; Closing. If the consideration proposed to be paid for the Transfer Stock is in property, services or other non-cash consideration, the fair market value of the consideration shall be as determined in good faith by the Board and as set forth in the Company Notice. If the Company or any Stockholder cannot for any reason pay for the Transfer Stock in the same form of non-cash consideration, the Company or such Stockholder may pay the cash value equivalent thereof, as determined in good faith by the Board and as set forth in the Company Notice. The closing of the purchase of Transfer Stock by the Company and the Stockholders shall take place, and all payments from the Company and the Stockholders shall have been delivered to the selling Stockholder, by the later of (i) the date specified in the Proposed Transfer Notice as the intended date of the Proposed Stockholder Transfer; and (ii) forty-five (45) days after delivery of the Proposed Transfer Notice.

4.2 Right of Co-Sale.

(a) Exercise of Right. If any Transfer Stock subject to a Proposed Stockholder Transfer is not purchased pursuant to Subsection 4.1 above and thereafter is to be sold to a Prospective Transferee, each respective Stockholder may elect to exercise its Right of Co-Sale and participate on a pro rata basis in the Proposed Stockholder Transfer as set forth in Subsection 4.2(b) below and, subject to Subsection 4.2(d), otherwise on the same terms and conditions specified in the Proposed Transfer Notice. Each Stockholder who desires to exercise its Right of Co-Sale (each, a “**Participating Stockholder**”) must give the selling Stockholder written notice to that effect within fifteen (15) days after the deadline for delivery of the Secondary Notice described above, and upon giving such notice such Participating Stockholder shall be deemed to have effectively exercised the Right of Co-Sale.

(b) Shares Includable. Each Participating Stockholder may include in the Proposed Stockholder Transfer all or any part of such Participating Stockholder’s Capital Stock equal to the product obtained by multiplying (i) the aggregate number of shares of Transfer Stock subject to the Proposed Stockholder Transfer (excluding shares purchased by the Company or the Participating Stockholders pursuant to the Right of First Refusal or the Secondary Refusal Right) by (ii) a fraction, the numerator of which is the number of shares of Capital Stock owned by such Participating Stockholder immediately before consummation of the Proposed Stockholder Transfer (including any shares that such Participating Stockholder has agreed to purchase pursuant to the Secondary Refusal Right) and the denominator of which is the total number of shares of Capital Stock owned, in the aggregate, by all Participating Stockholders immediately prior to the consummation of the Proposed Stockholder Transfer (including any shares that all Participating Stockholders have collectively agreed to purchase pursuant to the Secondary Refusal Right), plus the number of shares of Transfer Stock held by the selling Stockholder.

(c) Purchase and Sale Agreement. The Participating Stockholders and the selling Stockholder agree that the terms and conditions of any Proposed Stockholder Transfer in accordance with this Subsection 4.2 will be memorialized in, and governed by, a written purchase and sale agreement with the Prospective Transferee (the “**Purchase and Sale Agreement**”) with customary terms and provisions for such a transaction, and the Participating Stockholders and the selling Stockholder further covenant and agree to enter into such Purchase and Sale Agreement as a condition precedent to any sale or other transfer in accordance with this Subsection 4.2.

(d) Allocation of Consideration.

(i) Subject to Subsection 4.2(d)(ii), the aggregate consideration payable to the Participating Stockholders and the selling Stockholder shall be allocated based on the number of shares of Capital Stock sold to the Prospective Transferee by each Participating Stockholder and the selling Stockholder as provided in Subsection 4.2(b), provided that if a Participating Stockholder wishes to sell preferred stock of the Company, if any, the price set forth in the Proposed Transfer Notice shall be appropriately adjusted based on the conversion ratio of the preferred stock into Common Stock.

(ii) In the event that the Proposed Stockholder Transfer constitutes a Change of Control, the terms of the Purchase and Sale Agreement shall provide that the aggregate consideration from such transfer shall be allocated to the Participating Stockholders and the selling Stockholder on a pro rata basis in accordance with their respective percentage ownership of the Capital Stock of the Company, on a fully diluted basis or as otherwise set forth in the Charter.

(e) Purchase by Selling Stockholder; Deliveries. Notwithstanding Subsection 4.2(c) above, if any Prospective Transferee or Transferees refuse(s) to purchase securities subject to the Right of Co-Sale from any Participating Stockholder or Stockholders or upon the failure to negotiate in good faith a Purchase and Sale Agreement reasonably satisfactory to the Participating Stockholders, no Stockholder may sell any Transfer Stock to such Prospective Transferee or Transferees unless and until, simultaneously with such sale, such Stockholder purchases all securities subject to the Right of Co-Sale from such Participating Stockholder or Stockholders on the same terms and conditions (including the proposed purchase price) as set forth in the Proposed Transfer Notice and as provided in Subsection 4.2(d)(i); provided, however, if such sale constitutes a Change of Control, the portion of the aggregate consideration paid by the selling Stockholder to such Participating Stockholder or Stockholders shall be made in accordance with the first sentence of Subsection 4.2(d)(ii). In connection with such purchase by the selling Stockholder, such Participating Stockholder or Stockholders shall deliver to the selling Stockholder any stock certificate or certificates, properly endorsed for transfer, representing the Capital Stock being purchased by the selling Stockholder (or request that the Company effect such transfer in the name of the selling Stockholder). Any such shares transferred to the selling Stockholder will be transferred to the Prospective Transferee against payment therefor in consummation of the sale of the Transfer Stock pursuant to the terms and conditions specified in the Proposed Transfer Notice, and the selling Stockholder shall concurrently therewith remit or direct payment to each such Participating Stockholder the portion of the aggregate consideration to which each such Participating Stockholder is entitled by reason of its participation in such sale as provided in this Subsection 4.2(e).

(f) Additional Compliance. If any Proposed Stockholder Transfer is not consummated within sixty (60) days after receipt of the Proposed Transfer Notice by the Company, the Stockholders proposing the Proposed Stockholder Transfer may not sell any Transfer Stock unless they first comply in full with each provision of this Subsection 4.2. The exercise or election not to exercise any right by any Stockholder hereunder shall not adversely affect its right to participate in any other sales of Transfer Stock subject to this Subsection 4.2.

4.3 Effect of Failure to Comply.

(g) Transfer Void; Equitable Relief. Any Proposed Stockholder Transfer not made in compliance with the requirements of this Agreement shall be null and void ab initio, shall not be recorded on the books of the Company or its transfer agent and shall not be recognized by the Company. Each party hereto acknowledges and agrees that any breach of this Agreement would result in substantial harm to the other parties hereto for which monetary damages alone could not adequately compensate. Therefore, the parties hereto unconditionally and irrevocably agree that any non-breaching party hereto shall be entitled to seek protective orders, injunctive relief and other remedies available at law or in equity (including, without limitation, seeking specific performance or the rescission of purchases, sales and other transfers of Transfer Stock not made in strict compliance with this Agreement).

(h) Violation of First Refusal Right. If any Stockholder becomes obligated to sell any Transfer Stock to the Company or any other Stockholder under this Agreement and fails to deliver such Transfer Stock in accordance with the terms of this Agreement, the Company and/or such other Stockholder may, at its option, in addition to all other remedies it may have, send to such selling Stockholder the purchase price for such Transfer Stock as is herein specified and transfer to the name of the Company or such other Stockholder (or request that the Company effect such transfer in the name of a Stockholder) on the Company's books any certificates, instruments, or book entry representing the Transfer Stock to be sold.

(i) Violation of Co-Sale Right. If any Stockholder purports to sell any Transfer Stock in contravention of the Right of Co-Sale (a "**Prohibited Transfer**"), each Participating Stockholder who desires to exercise its Right of Co-Sale under Subsection 4.2 may, in addition to such remedies as may be available by law, in equity or hereunder, require such Stockholder to purchase from such Participating Stockholder the type and number of shares of Capital Stock that such Participating Stockholder would have been entitled to sell to the Prospective Transferee had the Prohibited Transfer been effected in compliance with the terms of Subsection 4.2. The sale will be made on the same terms, including, without limitation, as provided in Subsection 4.2(d)(i) and the first sentence of Subsection 4.2(d)(ii), as applicable, and subject to the same conditions as would have applied had the Stockholder not made the Prohibited Transfer, except that the sale (including, without limitation, the delivery of the purchase price) must be made within ninety (90) days after the Participating Stockholder learns of the Prohibited Transfer, as opposed to the timeframe proscribed in Subsection 4.2. Such Stockholder shall also reimburse each Participating Stockholder for any and all reasonable and documented out-of-pocket fees and expenses, including reasonable legal fees and expenses, incurred pursuant to the exercise or the attempted exercise of the Participating Stockholder's rights under Subsection 4.2.

4.4 Exempt Transfers.

(j) Notwithstanding the foregoing or anything to the contrary herein, the provisions of Subsections 4.1 and 4.2 shall not apply (i) in the case of a Stockholder that is an entity, upon a transfer by such Stockholder to its stockholders, members, partners or other equity holders or to any Affiliates of such Stockholder, including, without limitation, any transfer relating to or in respect of the Spin Off (which Spin Off, for the avoidance of doubt, the parties hereto acknowledge and agree is an exempt transfer not subject to any of the provisions of Section 4), (ii) to a repurchase of Transfer Stock from a Stockholder by the Company, or (iii) in the case of a Stockholder that is a natural person, upon a transfer of Transfer Stock by such Stockholder made for bona fide estate planning purposes, either during his or her lifetime or on death by will or intestacy to his or her spouse, child (natural or adopted), or any other direct lineal descendant of such Stockholder (or his or her spouse) (all of the foregoing collectively referred to as “family members”), or any custodian or trustee of any trust, partnership or limited liability company for the benefit of, or the ownership interests of which are owned wholly by such Stockholder or any such family members; provided that in the case of clause(s) (i), (iii) or (iv), the Stockholder shall deliver prior written notice to the Company and the other Stockholders of such pledge, gift, sale, assignment or transfer and such shares of Transfer Stock shall at all times remain subject to the terms and restrictions set forth in this Agreement and such transferee shall, as a condition to such permitted transfer, deliver a counterpart signature page to this Agreement as confirmation that such transferee shall be bound by all the terms and conditions of this Agreement as a Stockholder (but only with respect to the securities so transferred to the transferee), including the obligations of a Holder with respect to Proposed Stockholder Transfers of such Transfer Stock pursuant to Section 4; and provided further in the case of any transfer pursuant to clause (i) or (iv) above, that such transfer is made pursuant to a transaction in which there is no consideration actually paid for such transfer.

(k) Notwithstanding the foregoing or anything to the contrary herein, the provisions of Subsections 4.1 and 4.2 shall not apply to the sale of any Transfer Stock (i) to the public in an offering pursuant to an effective registration statement under the Securities Act; or (ii) pursuant to a Deemed Liquidation Event.

(l) Notwithstanding the foregoing, no Stockholder shall transfer any Capital Stock to (i) any entity which, in the determination of the Board, in good faith and upon advice of external counsel, directly or indirectly competes with the Company; or (ii) any customer, distributor or supplier of the Company, if the Board should determine that such transfer would result in such customer, distributor or supplier receiving information that would place the Company at a competitive disadvantage with respect to such customer, distributor or supplier.

4.5 Rights to Future Stock Issuances.

(m) Subject to the terms and conditions of this Subsection 4.5(a) and applicable securities laws, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to each Stockholder that is an “accredited investor” (as defined in Rule 501(a) under the Securities Act). A Stockholder shall be entitled to apportion the right of first offer hereby granted to it in such proportions as it deems appropriate among (i) itself, and (ii) its Affiliates.

(n) The Company shall give notice (the “**Offer Notice**”) to each Stockholder, stating (i) its bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Securities.

(o) By notification to the Company within twenty (20) days after the Offer Notice is given, each Stockholder may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities which equals the proportion that the Common Stock then held by such Stockholder (including all shares of Common Stock then issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of any Derivative Securities then held by such Stockholder) bears to the total Common Stock of the Company then issued and outstanding (assuming full conversion and/or exercise, as applicable, of any Derivative Securities then outstanding). At the expiration of such twenty (20) day period, the Company shall promptly notify each Stockholder that elects to purchase or acquire all the shares available to it (each, a “**Fully Exercising Investor**”) of any other Stockholder’s failure to do likewise. During the ten (10) day period commencing after the Company has given such notice, each Fully Exercising Investor may, by giving notice to the Company, elect to purchase or acquire, in addition to the number of shares specified above, up to that portion of the New Securities for which Stockholders were entitled to subscribe but that were not subscribed for by the Stockholders which is equal to the proportion that the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of any Derivative Securities then held, by such Fully Exercising Investor bears to the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of any Derivative Securities then held, by all Fully Exercising Investors who wish to purchase such unsubscribed shares. The closing of any sale pursuant to this Subsection 4.5(b) shall occur within the later of ninety (90) days of the date that the Offer Notice is given and the date of initial sale of New Securities pursuant to Subsection 4.5(d).

(p) If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in Subsection 4.5(c), the Company may, during the ninety (90) day period following the expiration of the periods provided in Subsection 4.5(c), offer and sell the remaining unsubscribed portion of such New Securities to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, or if such agreement is not consummated within thirty (30) days of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Stockholders in accordance with this Subsection 4.5.

(q) The right of first offer in this Subsection 4.5 shall not be applicable to (i) shares of Common Stock issued in the IPO, and (ii) any New Securities as to which the rights of the Stockholders under this Subsection 4.5 have been waived by the affirmative vote (including by written consent) of the Requisite Stockholders.

4.6 Other Stockholder Rights/Obligations.

(r) The Company shall permit each Stockholder, at such Stockholder’s expense, to visit and inspect the Company’s properties; examine its books of account and records; and discuss the Company’s affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by the Stockholder; provided, however, that the Company shall not be obligated pursuant to this Subsection 4.6 to provide access to any information that the Board, upon advice of counsel, reasonably and in good faith considers to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

(s) The Company shall deliver to each Stockholder: (i) as soon as practicable, but in any event within ninety (90) days after the end of each fiscal year of the Company (A) an audited balance sheet as of the end of such year, (B) audited statements of income and of cash flows for such year, and (C) an audited statement of stockholders' equity as of the end of such year; (ii) as soon as practicable, but in any event within forty-five (45) days after the end of each of the first three (3) quarters of each fiscal year of the Company, unaudited statements of income and cash flows for such fiscal quarter, and an unaudited balance sheet and a statement of stockholders' equity as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements may (A) be subject to normal year-end audit adjustments; and (B) not contain all notes thereto that may be required in accordance with GAAP); (iii) as soon as practicable, but in any event within thirty (30) days of the end of each month, an unaudited income statement and statement of cash flows for such month, and an unaudited balance sheet and statement of stockholders' equity as of the end of such month, all prepared in accordance with GAAP (except that such financial statements may (A) be subject to normal year-end audit adjustments, and (B) not contain all notes thereto that may be required in accordance with GAAP); (iv) as soon as practicable, but in any event thirty (30) days before the end of each fiscal year, a budget and business plan for the next fiscal year (collectively, the "**Budget**"), approved by the Board, promptly after prepared, any other budgets or revised budgets prepared by the Company; and (v) such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as any Stockholder may from time to time reasonably request.; provided, however, that the Company shall not be obligated under this Subsection 4.6(b) to provide information (A) that the Company reasonably determines in good faith to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in a form acceptable to the Company); or (B) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel. If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries. Notwithstanding anything else in this Subsection 4.6(b) to the contrary, the Company may cease providing the information set forth in this Subsection 4.6(b) during the period starting with the date thirty (30) days before the Company's good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; provided that the Company's covenants under this Subsection 4.6(b) shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective.

(t) Each of the Premas Parties shall comply, and Akers shall comply and shall cause Cystron to comply with its obligations, covenants and agreements in the Contribution Agreement, including, without limitation: (i) the obligations, covenants and agreements set forth in Section 3 thereof in respect of any Royalty Payments (as defined therein), and (ii) the obligations, covenants and agreements set forth in Section 5 thereof, including, without limitation, in respect of the consummation of the Qualified Financing as soon as practicable, but no later than 3 months, following the effective date of the Contribution Agreement.

(u) Oramed shall comply with its obligations, covenants and agreements in the Oramed License Agreement, and its commitment to a Qualified Financing as soon as practicable, but no later than the time specified in the Oramed License Agreement.

(v) Confidentiality. Each Stockholder agrees that such Stockholder will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor or make decisions with respect to its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement, unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this Section 4.6(e) by such Stockholder); (b) is or has been independently developed or conceived by such Stockholder without use of the Company's confidential information, or (c) is or has been made known or disclosed to such Stockholder by a third party without a breach of any obligation of confidentiality such third party may have to the Company; provided, however, that an Stockholder may disclose confidential information (i) to its attorneys, accountants, consultants, and other professionals to the extent reasonably necessary to obtain their services in connection with monitoring its investment in the Company; (ii) to any prospective purchaser of any Capital Stock from such Stockholder, if such prospective purchaser agrees to be bound by the provisions of this Section 4.6(e), and provided that in no event shall such information be disclosed to a competitor of the Company, as determined by the Board; (iii) to any Affiliate, partner, member, stockholder, or wholly owned subsidiary of such Stockholder in the ordinary course of business, provided that such Stockholder informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information; or (iv) as may otherwise be required by law, regulation, rule, court order or subpoena, provided that such Stockholder promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure. Without derogating from the foregoing it is clarified that the aforesaid shall not prevent any Stockholder from (A) entering into any business, entering into any agreement with a third party, or investing in or engaging in investment discussions with any other company (whether or not competitive with the Company), provided, that, except as expressly permitted under the terms of this Section 4.6(d), such Stockholder does not and shall not, in any way whatsoever, disclose or otherwise make use of or reference to any proprietary or confidential information of the Company in connection with such activities; or (B) making any disclosures required by law, rule, regulation or court or other governmental order.

5. Spin Off. If requested by Akers, and if approved by the Board of the Company, the Company will cooperate with Akers in effecting the Spin Off, including, without limitation, by making such applications to the Nasdaq Stock Market or other national securities exchange for the listing of the Common Stock thereon and taking other commercially reasonable actions reasonably necessary or appropriate for the consummation of the Spin Off.

6. Matters Requiring Minority Stockholder Approval. For so long as any Stockholder holds at least 10% of the Company's issued and outstanding share capital, the Company hereby covenants and agrees with each of the Stockholders that the Company shall not, without approval of such Stockholder:

(a) change the principal business of the Company or exit the current line of business;

(b) sell, assign, license, pledge, or encumber all or substantially all of the intellectual property of the Company;

(c) liquidate, dissolve or wind-up the business and affairs of the Company or effect any Deemed Liquidation Event; or

(d) otherwise enter into or be a party to any transaction with any director, officer or employee of the Company or any "associate" (as defined in Rule 12b-2 promulgated under the Exchange Act) of any such Person, including without limitation any "management bonus" or similar plan providing payments to employees in connection with a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation, except for transactions made in the ordinary course of business and pursuant to reasonable requirements of the Company's business.

In addition, the Company shall not amend the initial Budget established pursuant to Section 6(b) of the Contribution Agreement without the prior written agreement of Akers during a period of six (6) months from the date of this Agreement.

7. Term. This Agreement shall be effective as of the date hereof and shall continue in effect until and shall terminate upon the earliest to occur of (a) a Going Public Event; (b) the consummation of a Sale of the Company and distribution of proceeds to or escrow for the benefit of the Stockholders in accordance with the Charter; (c) a Deemed Liquidation Event; and (d) termination of this Agreement in accordance with Subsection 8.8 below.

8. Miscellaneous.

8.1 Additional Parties. Notwithstanding anything to the contrary contained herein, if the Company issues additional shares of Capital Stock after the date hereof, following which any Person shall hold Shares constituting one percent (1%) or more of the Company's then outstanding Capital Stock (treating for this purpose all shares of Common Stock issuable upon exercise of or conversion of outstanding options, warrants or convertible securities, as if exercised and/or converted or exchanged), then, the Company shall cause such Person, as a condition precedent to entering into such agreement, to become a party to this Agreement by executing an Adoption Agreement in the form attached hereto as Exhibit A, agreeing to be bound by and subject to the terms of this Agreement as a Stockholder and thereafter such Person shall be deemed a Stockholder for all purposes under this Agreement. In addition, the Company may cause any other Person who acquired Capital Stock to become a party to this Agreement by executing an Adoption Agreement in the form attached hereto as Exhibit A.

8.2 Transfers. Each transferee or assignee of any Shares subject to this Agreement shall be subject to the terms hereof, and, as a condition precedent to the Company's recognition of such transfer, each transferee or assignee shall agree in writing to be bound by and subject to each of the terms of this Agreement by executing and delivering an Adoption Agreement substantially in the form attached hereto as Exhibit A. Upon the execution and delivery of an Adoption Agreement by any transferee, such transferee shall be deemed to be a party hereto as if such transferee were the transferor and such transferee's signature appeared on the signature pages of this Agreement and shall be deemed to be a Stockholder. By execution and delivery of a counterpart signature page to this Agreement, each of the parties appoint the Company as its attorney-in-fact for the purpose of executing any Adoption Agreement that may be required to be delivered under the terms of this Agreement. The Company shall not permit the transfer of the Shares subject to this Agreement on its books or issue a new certificate representing any such Shares unless and until such transferee shall have complied with the terms of this Subsection 8.2. Each certificate instrument, or book entry representing the Shares subject to this Agreement if issued on or after the date of this Agreement shall be notated by the Company with the legend set forth in Subsection 8.12.

8.3 Successors and Assigns. The terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. The rights of the Stockholders hereunder are not assignable without the Company's written consent (which shall not be unreasonably withheld, delayed or conditioned), except (a) by a Stockholder to any Affiliate, (b) by a Stockholder to any of its stockholders in connection with the Spin-Off, or (c) by a Stockholder to another Stockholder, it being acknowledged and agreed that any such assignment, including an assignment contemplated by the preceding clauses (a) through (c), shall be subject to and conditioned upon any such assignee's delivery to the Company and the other Stockholders of a counterpart signature page hereto pursuant to which such assignee shall confirm their agreement to be subject to and bound by all of the provisions set forth in this Agreement that were applicable to the assignor of such assignee. Except in connection with an assignment by the Company by operation of law to the acquirer of the Company, the rights and obligations of the Company under this Agreement may not be assigned under any circumstances; provided, that the Company's Right of First Refusal may be transferred or assigned with the approval of the Requisite Stockholders.

8.4 Governing Law. This Agreement and any controversy arising out of or relating to this Agreement shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware, without regard to conflict of law principles that would result in the application of any law other than the law of the State of Delaware.

8.5 Counterparts; Delivery. This Agreement may be (a) executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument; and (b) executed by electronic signature which shall be deemed an original signature. Any signatures, counterparts or otherwise may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

8.6 Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

8.7 Notices.

(a) All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or (a) personal delivery to the party to be notified, (b) when sent, if sent by electronic mail or facsimile during normal business hours of the recipient, and if not sent during normal business hours, then on the recipient's next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) business day after the business day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next business day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their address as set forth on Schedule A hereto, or to such email address, facsimile number or address as subsequently modified by written notice given in accordance with this Subsection 8.7.

(b) Consent to Electronic Notice. Each Stockholder consents to the delivery of any stockholder notice pursuant to the Delaware General Corporation Law (the "DGCL"), as amended or superseded from time to time, by electronic transmission pursuant to Section 232 of the DGCL (or any successor thereto) at the electronic mail address or the facsimile number set forth below such Stockholder's name on the Schedule hereto, as updated from time to time by notice to the Company, or as on the books of the Company. To the extent that any notice given by means of electronic transmission is returned or undeliverable for any reason, the foregoing consent shall be deemed to have been revoked until a new or corrected electronic mail address has been provided, and such attempted Electronic Notice shall be ineffective and deemed to not have been given. Each Stockholder agrees to promptly notify the Company of any change in its electronic mail address, and that failure to do so shall not affect the foregoing.

8.8 Consent Required to Amend, Terminate or Waive. This Agreement may be amended or terminated (other than pursuant to Section 8) and the observance of any term hereof may be waived (either generally or in a particular instance and either retroactively or prospectively) only by a written instrument executed by (a) the Company; and (b) Requisite Stockholders, *provided, however*, that if, at such time, there are no more than 5 Stockholders then such instrument shall be executed by the Stockholders representing at least 90% of the voting power of the Common Stock, voting as a single class on an as converted basis. Notwithstanding the foregoing:

(a) this Agreement may not be amended, modified or terminated and the observance of any term of this Agreement may not be waived with respect to any Stockholder without the written consent of such Stockholder unless such amendment, modification, termination or waiver applies to all Stockholders in the same fashion;

(b) Schedule A hereto may be amended by the Company from time to time to add Stockholders pursuant to Subsection 8.1 and information regarding additional Stockholders made parties hereto pursuant to Subsection 8.2 and permitted transferees and assignees of Stockholders without the consent of the other parties hereto; and

(c) any provision hereof may be waived by the waiving party on such party's own behalf, without the consent of any other party.

The Company shall give prompt written notice of any amendment, modification, termination, or waiver hereunder to any party that did not consent in writing thereto. Any amendment, modification, termination, or waiver effected in accordance with this Subsection 8.8 shall be binding on each party and all of such party's successors and permitted assigns, whether or not any such party, successor or assignee entered into or approved such amendment, modification, termination or waiver. No waivers of or exceptions to any item, condition or provision of this Agreement, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such term, condition or provision.

8.9 Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power or remedy of such non-breaching or non-defaulting party nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of or in any similar breach or default thereafter occurring; nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default previously or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any party of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

8.10 Severability. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision and such invalid or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

8.11 Entire Agreement. This Agreement (including the Exhibits hereto) and the Charter constitute the full and entire understanding and agreement between the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof (including, without limitation, any Board designation or nomination rights) existing between the parties is expressly canceled.

8.12 Share Certificate Legend. To the extent any Shares are issued after the date hereof to a Stockholder, each certificate, instrument, or book entry representing any such Shares shall be notated by the Company with legends reading substantially as follows:

“THE SHARES REPRESENTED HEREBY ARE SUBJECT TO A STOCKHOLDERS AGREEMENT, AS MAY BE AMENDED FROM TIME TO TIME, (A COPY OF WHICH MAY BE OBTAINED UPON WRITTEN REQUEST FROM THE COMPANY), AND BY ACCEPTING ANY INTEREST IN SUCH SHARES THE PERSON ACCEPTING SUCH INTEREST SHALL BE DEEMED TO AGREE TO AND SHALL BECOME BOUND BY ALL THE PROVISIONS OF THAT STOCKHOLDERS AGREEMENT, INCLUDING CERTAIN RESTRICTIONS ON TRANSFER AND OWNERSHIP SET FORTH THEREIN.”

The Company, by its execution of this Agreement, agrees that it will cause the certificates instruments, or book entry evidencing the Shares issued after the date hereof to a Stockholder to bear the legend required by this Subsection 8.12 of this Agreement, and it shall supply, free of charge, a copy of this Agreement to any holder of such Shares upon written request from such holder to the Company at its principal office. The parties to this Agreement do hereby agree that the failure to cause the certificates, instruments, or book entry evidencing the Shares to bear the legend required by this Subsection 8.12 herein and/or the failure of the Company to supply, free of charge, a copy of this Agreement as provided hereunder shall not affect the validity or enforcement of this Agreement.

8.13 Stock Splits, Stock Dividends, etc. In the event of any issuance of Shares of the voting securities of the Company hereafter to any of the Stockholders (including, without limitation, in connection with any stock split, stock dividend, recapitalization, reorganization, or the like), such Shares shall become subject to this Agreement and shall be notated with the legend set forth in Subsection 8.12.

8.14 Manner of Voting. The voting of Shares pursuant to this Agreement may be effected in person, by proxy, by written consent or in any other manner permitted by applicable law. For the avoidance of doubt, voting of the Shares pursuant to the Agreement need not make explicit reference to the terms of this Agreement.

8.15 Further Assurances. At any time or from time to time after the date hereof, the parties agree to cooperate with each other, and at the request of any other party, to execute and deliver any further instruments or documents and to take all such further action as the other party may reasonably request in order to evidence or effectuate the consummation of the transactions contemplated hereby and to otherwise carry out the intent of the parties hereunder.

8.16 Dispute Resolution The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of Delaware and to the jurisdiction of the United States District Court for the District of Wilmington for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of Delaware or the United States District Court for the District of Wilmington, and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

WAIVER OF JURY TRIAL: EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

8.17 Costs of Enforcement. If any party to this Agreement seeks to enforce its rights under this Agreement by legal proceedings, the non-prevailing party shall pay all reasonable costs and expenses incurred by the prevailing party, including, without limitation, all reasonable attorneys' fees, including on appeal.

8.18 Aggregation of Stock. All Shares held or acquired by a Stockholder and/or its Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement, and such Affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Stockholders Agreement as of the date first written above.

COMPANY:

ORAVAX MEDICAL, INC.

By: /s/ Josh Silverman
Name: Josh Silverman
Title: Chief Executive Officer

STOCKHOLDERS:

AKERS BIOSCIENCES INC.

By: /s/ Christopher Schreiber
Name: Christopher Schreiber
Title: Chief Executive Officer

CUTTER MILL CAPITAL LLC

By: /s/ Michael Vasinkevich
Name: Michael Vasinkevich
Title: Authorized Signatory

ORAMED PHARMACEUTICALS, INC.

By: /s/ Nadav Kidron
Name: Nadav Kidron
Title: Chief Executive Officer

PREMAS BIOTECH PVT LTD.

By: /s/ Prabuddha Kundu
Name: Prabuddha Kundu
Title: Managing Director

RUN RIDGE LLC

By: /s/ Craig M. Schwabe
Name: Craig M. Schwabe
Title: Authorized Signatory

Signature Page to Stockholders Agreement

SCHEDULE A

STOCKHOLDERS

Name and Address	Number of Shares Held
Oramed Pharmaceuticals, Inc. 1185 AVENUE OF THE AMERICAS, 3RD FLOOR, NEW YORK, NY, 10036	1,890,000
Akers Biosciences Inc. 1185 AVENUE OF THE AMERICAS, 3RD FLOOR, NEW YORK, NY, 10036	390,000
Run Ridge LLC 430 Park Avenue, 3rd Floor NewYork, NY 10022	18,000
Premas Biotech PVT Ltd. prabuddha.kundu@premasbiotech.com	360,000
Cutter Mill Capital LLC 430 Park Avenue, 3rd Floor NewYork, NY 10022	342,000

Schedule A

EXHIBIT A

ADOPTION AGREEMENT

This Adoption Agreement (“**Adoption Agreement**”) is executed on _____, 20__, by the undersigned (the “**Holder**”) pursuant to the terms of that certain Stockholders Agreement dated as of March 18, 2021 (the “**Agreement**”), by and among the Company and certain of its Stockholders, as such Agreement may be amended or amended and restated hereafter. Capitalized terms used but not defined in this Adoption Agreement shall have the respective meanings ascribed to such terms in the Agreement. By the execution of this Adoption Agreement, the Holder agrees as follows.

1.1 Acknowledgement. Holder acknowledges that Holder is acquiring certain shares of the capital stock of the Company (the “**Stock**”) or options, warrants, units or other rights to purchase such Stock (the “**Options**”), for one of the following reasons (Check the correct box):

- ☐ As a transferee of Shares from a party in such party’s capacity as a “Stockholder” bound by the Agreement, and after such transfer, Holder shall be considered a “Stockholder” for all purposes of the Agreement.
- ☐ As a new Stockholder in accordance with Subsection 8.1 of the Agreement, in which case Holder will be a “Stockholder” for all purposes of the Agreement.

1.2 Agreement. Holder hereby (a) agrees that the [Stock][Options], and any other shares of capital stock or securities required by the Agreement to be bound thereby, shall be bound by and subject to the terms of the Agreement and (b) adopts the Agreement with the same force and effect as if Holder were originally a party thereto.

1.3 Notice. Any notice required or permitted by the Agreement shall be given to Holder at the address or facsimile number listed below Holder’s signature hereto.

HOLDER: _____

ACCEPTED AND AGREED:

By: _____
Name and Title of Signatory

ORAVAX MEDICAL INC.

Address: _____

By: _____

Title: _____

Facsimile Number: _____

Exhibit A



Addressing the Multibillion-Dollar Injectable Drug Markets with Oral Formulations

March 2021



Safe Harbor

Certain statements contained in this material are forward-looking statements. These forward-looking statements are based on the current expectations of the management of Oramed only, including with respect to clinical trials, milestones and the potential benefits of Oramed's products, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements, including the risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; difficulties or delays in obtaining regulatory approval or patent protection for our product candidates; competition from other pharmaceutical or biotechnology companies; and our ability to obtain additional funding required to conduct our research, development and commercialization activities, and others, all of which could cause the actual results or performance of Oramed to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Oramed undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Oramed, reference is made to Oramed's reports filed from time to time with the Securities and Exchange Commission, which involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Please refer to the company's filings with the Securities and Exchange Commission for a comprehensive list of risk factors that could cause actual results, performance or achievements of the company to differ materially from those expressed or implied in such forward-looking statements. Oramed undertakes no obligation to update or revise any forward-looking statements.

Oramed Snapshot

- **Proprietary oral protein delivery platform**
- **Diabetes first** - initially targeting the lucrative insulin market
- **Robust pipeline** leveraging IP portfolio for additional significant market opportunities
- **Strong financial position** over \$56M in cash and investments, no debt¹
- **Experienced management** team backed by world-class scientific experts
- **Multiple value-creation events** for 2021
- **NASDAQ/TASE:** ORMP



¹ As of February 28, 2021

Proprietary Technology for Oral Drug Delivery

Proteins and Peptides do Not Survive the Digestive System

Harsh pH

Stomach acidity cleaves and shreds protein

Protease attack

Proteases attack and break down proteins

Absorption barrier

Therapeutic proteins fail to be absorbed via the intestinal wall (barrier)



Oramed Technology Protects Drug Integrity and Increases Absorption

pH shield

Sensitive enteric coating protects capsule contents before entering small intestine

Protease protection

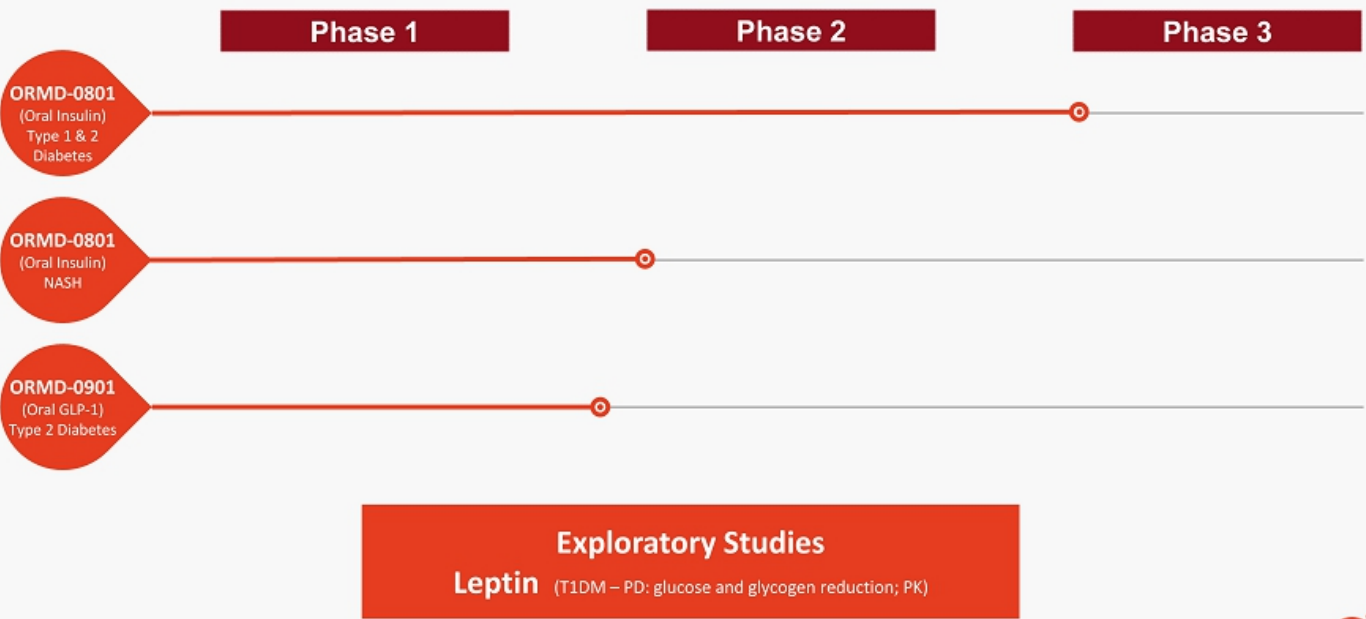
Protease inhibitors protect the active agent

Absorption enhancement

Assists the permeation of proteins/peptides across intestinal membrane and into bloodstream



Multiple Clinical-Stage Programs





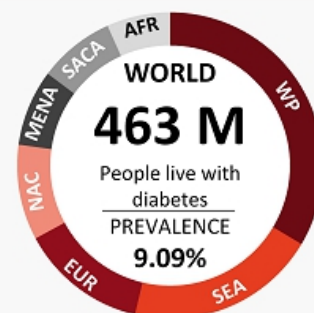
Diabetes:
Millions of diabetics
inject insulin today
and wish for oral dosage



1 in 11 Adults on the Planet Have Diabetes

10% healthcare
spent on diabetes

In 2019 diabetes
expenditure reached
US \$ 760 billion



2019




expected increase:

+237
MILLION

2045



<https://www.idf.org/e-library/epidemiology-research/diabetes-atlas/159-idf-diabetes-atlas-ninth-edition-2019.html>



ORMD-0801: Oral Insulin



ORMD-0801 - Flagship Product for Oral Treatment of Diabetes

>900

study subjects



>10,000

human doses



**No Serious
Drug-Related
Adverse
Events**



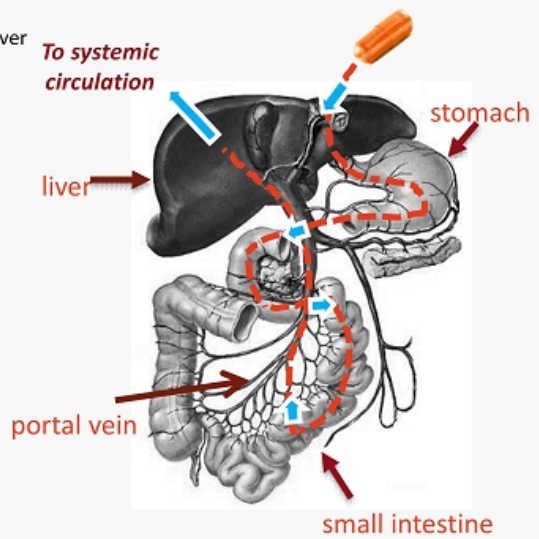
The Drawbacks of Injected Insulin vs. the Advantages of Oral Insulin

ENDOGENOUS INSULIN produced by the pancreas and delivered to the body via the liver

Injected Insulin introduced directly to the bloodstream, with only a fraction of it reaching the liver. This can cause excess sugar to be stored in fat and muscle which often results in weight gain and may also cause hypoglycemia.

Oral insulin, like natural insulin, is delivered first to the liver, resulting in:

- ✓ Better blood glucose control
 - ✓ Reduced hypoglycemia
 - ✓ Reduced hyperglycemia
- ✓ No weight gain



ORMD-0801 for Type 1 & Type 2 Diabetes



Diabetes inhibits the production of sufficient insulin and causes elevated levels of glucose in the blood

TYPE 1 Diabetes

- **T1DM is autoimmune:** The body destroys its own insulin-producing (beta) cells, leaving patients completely dependent on external insulin sources
- **10% of diabetics have T1DM:** Up to 37 million people worldwide have T1DM
- **Projected Market:** \$13 billion by 2023

TYPE 2 Diabetes

- **T2DM is metabolic:** The body becomes insulin resistant. Injections may be used to make up for the pancreas's inability to create sufficient insulin to keep blood sugar at normal levels
- **371 million people worldwide need treatment**
- **Projected Market:** \$59 billion by 2025

ORMD-0801 for Type 1 Diabetes (T1DM)

Potentially eliminating the need for insulin before each meal



T1DM patients are treated with various types of insulin replacement therapy

- Long-acting insulin (basal) helps maintain stable insulin levels during fasting periods
- Rapid-acting insulin (bolus) prior to each meal to stabilize blood sugar
- Administration is via injection or pump



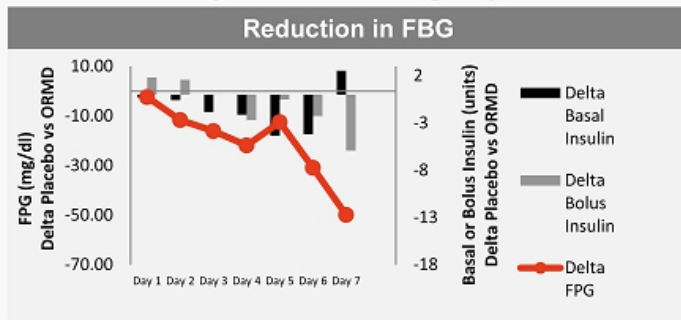
Oramed oral insulin

- Easier use and reduced systemic exposure
- Potentially reducing multiple daily injections
- Tighter regulation and control of blood sugar levels by directly targeting liver glucose (TiR), due to portal administration

Phase 2a T1DM Study

Consistent and Accumulative Effect of ORMD-0801 for Treating Type 1 Diabetes

Blood glucose levels lower day and night compared to control group



25

T1DM patients

7

days of treatment

3

times a day (at mealtime)

Primary Endpoint:

Evaluate change in exogenous insulin requirements in T1DM patients

Oral Insulin Reduces Exogenous Insulin Requirements



Decreased

- ✓ use of rapid-acting insulin
- ✓ levels of post-meal glucose
- ✓ levels of daytime glucose

Safe and Well Tolerated

Completed: 180 Patient Phase 2 Study for Type 2 Diabetes



33

US sites

180

patients

28

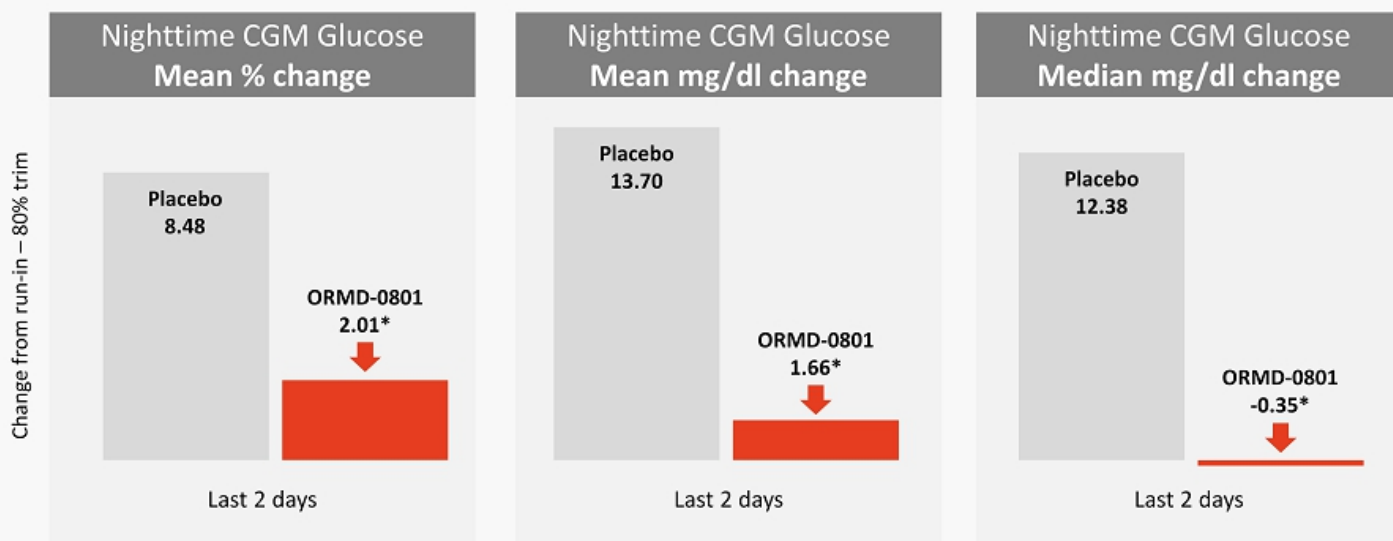
day treatment

1

Dose (nightly)

FDA Phase 2 Study

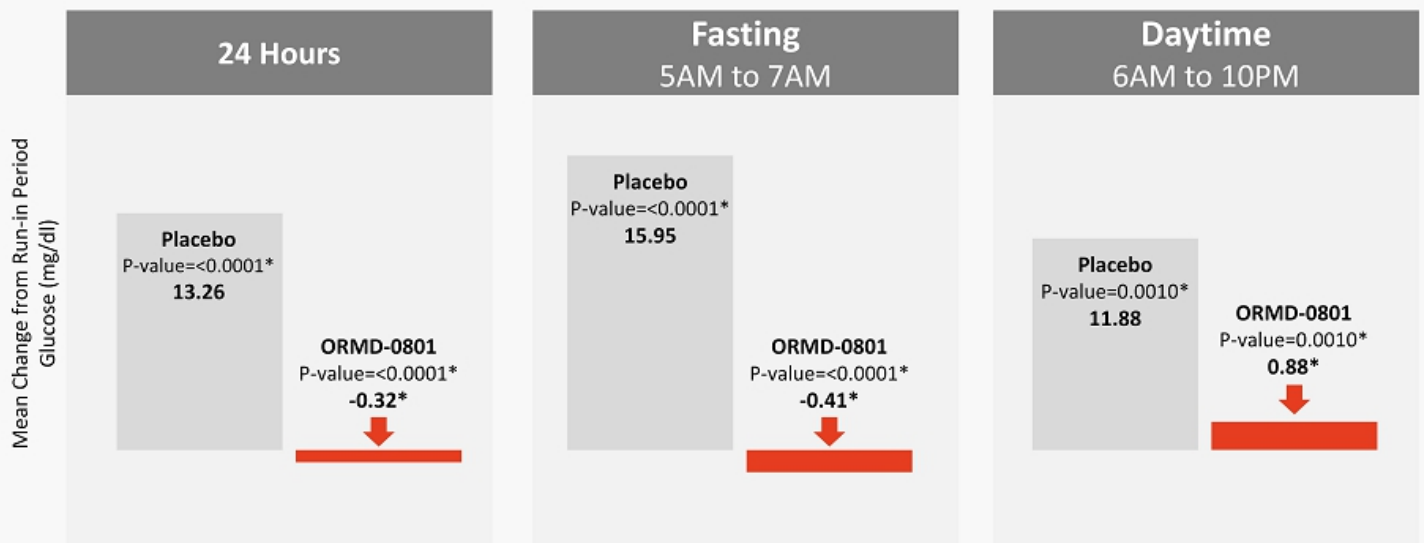
Achieved Every Primary Endpoint with No Drug Related Serious Adverse Events



* Indicates Statistically Significant Difference versus Placebo (p-Value<0.05)

FDA Phase 2 Study

Exploratory Endpoints: CGM Parameters



Completed: 298 Patient Phase 2b Trial



34 US sites*

298 Patients*

90 Day treatment

7 Doses

* 36 Sites: 2 sites (49 subjects) were excluded due to significant treatment by center interaction

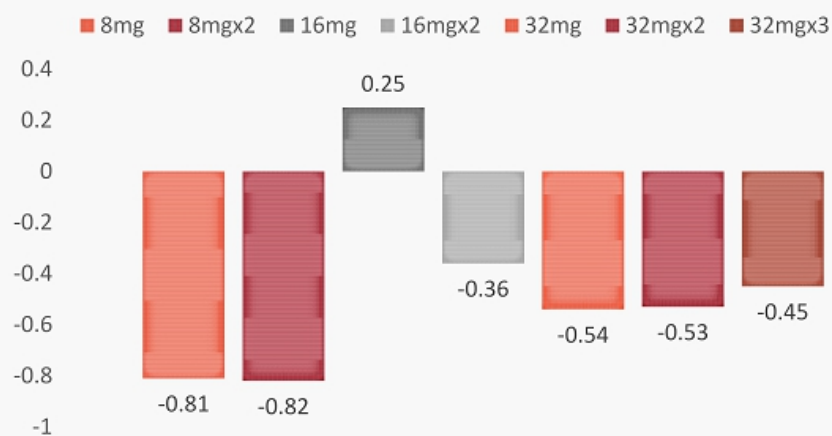
- 347 subjects received primary treatment and had baseline A1c (included in ITT)
- **298** subjects included in primary analysis
- **266** included in final analysis (Week 12 A1C results)

Endpoints

01	Primary Endpoint	<ul style="list-style-type: none">▪ Mean change in HbA1c from baseline to Week 12
02	Secondary Endpoints	<ul style="list-style-type: none">▪ Safety (AEs, hypoglycemic)▪ Fasting Plasma Glucose (FPG) + CGM▪ Weight
	Dose Finding	<ul style="list-style-type: none">▪ 96 mg/day (32 mg X 3/day)▪ 32 mg/day (32 mg X 1/day)▪ 32 mg/day (16 mg X 2/day)▪ 64 mg/day (32 mg X 2/day)▪ 16 mg/day (8 mg x 2/day)▪ 16 mg/day (16 mg X 1/day)▪ 8 mg/day (8 mg X 1/day)

Phase 2b: Primary Endpoint Successfully Met

HbA1c (%) Placebo Adjusted Change from Baseline



8 mg - 1/day

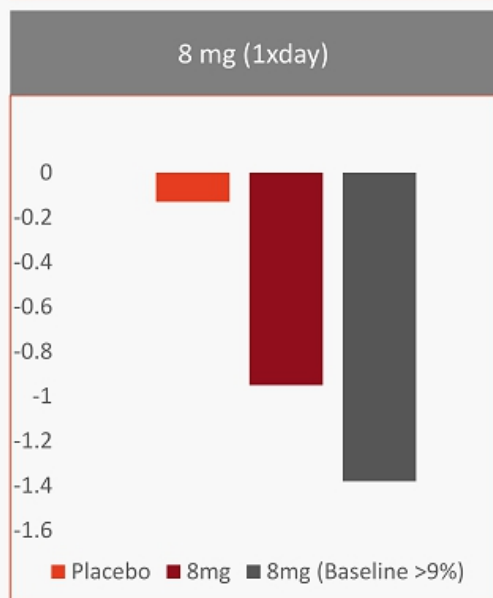
-0.95 (-0.81 placebo adjusted)

60-70% of the randomized patients were on 2 or more glucose lowering drugs

All Patients were on Metformin

Glucose lowering agents taken in addition to Metformin included:
Glibenclamide, Glipizide, Empagliflozin, Pioglitazone, Glimepiride, Dapagliflozin, Sitagliptin, Glibomet, Ertugliflozin

Phase 2b: 8 mg 1/day – HbA1c Change from Baseline at Week 12



- **0.95 (0.81 placebo adjusted) reduction**
 - **p-value: 0.0276**
 - [1.29 A1C reduction (Observed Means)]
- **1.26 placebo adjusted reduction (Baseline >9%)**

FDA Phase 2b Trial Results - Primary Endpoint Successfully Met



Safe and well tolerated

FDA BLA Pathway:

- Confirmatory Phase 3 Study
- Submission to FDA

Gain **12-year marketing** exclusivity upon FDA approval



Significant HbA1c lowering with 1X/daily treatment:

- ✓ No increase in Adverse Events compared to Placebo
- ✓ No increase in Hypoglycemic Events compared to Placebo
- ✓ No weight gain compared to Placebo

Pivotal Phase 3

Factors considered by the FDA in a pivotal Phase 3 program

1. **Efficacy:** The study is powered, based on previous Phase 2 data, to include sufficient patients that will provide statistical significance for primary endpoint provided that the drug performs at least equally well in the Phase 3 study as it did in the Phase 2 study.
2. **Safety:** The study has sufficient patients, as determined by the FDA, to demonstrate that the drug is safe in diabetic patients.
3. **Exposure:** The study must show that the drug remains safe in patients exposed to the drug over a period of 6 and 12 months
4. **Geographic variation:** USA, Israel and EU countries

Pivotal Phase 3: Two Protocols

ORA-D-013-1

A Double-Blinded, Placebo-Controlled, Double Dummy, Multi-Center Randomized, Phase 3 Study to Evaluate the Efficacy and Safety of ORMD-0801 in Subjects with Type 2 Diabetes Mellitus with Inadequate Glycemic Control on **Two or Three Oral Glucose-Lowering Agents**

ORA-D-013-2

A Double-Blinded, Placebo-Controlled, Multi-Center Randomized, Phase 3 Study to Evaluate the Efficacy and Safety of ORMD-0801 in Subjects with Type 2 Diabetes Mellitus with Inadequate Glycemic Control on **Diet Control Alone or on Diet Control and Metformin Monotherapy**

Pivotal Phase 3: Dosing (Selected from P2b study data)

▪ **ORA-D-013-01**

- Double Blind, Double Dummy
- 1:1:1 randomization
 - **8mg once-daily** at **night** and placebo 45 mins before breakfast
 - **8mg twice-daily** at **night** and 45 mins before **breakfast**
 - **Placebo twice-daily** at **night** and 45 mins before **breakfast**

▪ **ORA-D-013-02**

- Double Blind
- 1:1 randomization
 - **8mg at night**
 - **Placebo at night**

Pivotal Phase 3: Sample Size

	ORA-D-013-1	ORA-D-013-2
Sample size	675 adult male and female subjects	450 adult male and female subjects
Territory	US-based	US, Eastern and Western European and Israel-based
Number of Sites	75 US sites	28 US sites, 25 ex-US sites

ORA-D-013-1: Primary and Secondary Objectives

Primary Objective

- To compare the efficacy of ORMD-0801 to placebo in improving glycemic control as assessed by A1c in inadequately controlled T2DM subjects on two or three oral glucose-lowering agents.

Secondary Objective

- To assess the safety of repeat administration of ORMD-0801 in inadequately controlled T2DM subjects on two or three oral glucose-lowering agents.

ORA-D-013-2: Primary and Secondary Objectives

Primary Objectives

■ Active vs Placebo:

- To evaluate the efficacy of ORMD-0801 compared to placebo in improving glycemic control as assessed by A1c in inadequately controlled T2DM subjects on diet control alone or on diet control and metformin monotherapy over a 26-week treatment period.

Secondary Objectives

■ Active vs Placebo:

- To evaluate the efficacy of ORMD-0801 compared to placebo in maintaining glycemic control over a 52-week treatment period.

Pivotal Phase 3: Key Inclusion Criteria

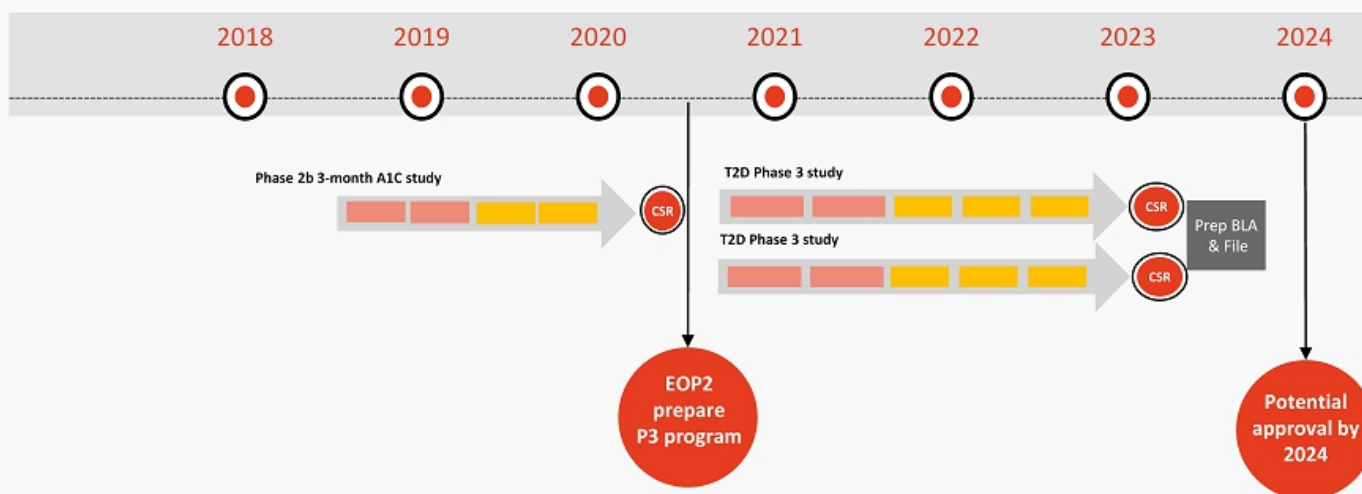
ORA-D-013-1

- HbA1c $\geq 7.5\%$ but $\leq 11.0\%$ at Screening.
- On a stable dose two or three of the following oral glucose-lowering agents for a 3-month period prior to Screening:
 - Metformin
 - DPP-4 inhibitor
 - SGLT-2 inhibitor
 - Thiazolidinedione
 - Sulfonylurea

ORA-D-013-2

- HbA1c $\geq 7.5\%$ but $\leq 11.0\%$ at Screening.
- Subjects should be on:
 - Diet and exercise alone for a period of at least 3 months prior to Screening; OR
 - Diet and exercise with a stable dose of metformin only (≥ 1500 mg or MTD) for a period of at least 3 months prior to Screening.

Pivotal Phase 3: Anticipated Clinical Development Timelines





China License Deal: 500M patient potential

- **License: Exclusive right to ORMD-0801 in Greater China**

- **Licensee: Hefei Tianhui ("HTIT")**

Owens with Sinopharm a state-of-the-art GMP API insulin manufacturing facility

- HTIT clinical trials of ORMD-0801 underway

- **\$50M Payments + Royalties:**

- \$12M in restricted stock (at premium)
- \$38M milestone payments
 - \$33M received to date
 - \$17M expected over the next 2-3 years
- Up to 10% royalties on net sales

Chinese diabetes market*

114M

diabetic
(10.9% of adult population)

~388M

prediabetic
(35.7% of adult population)



* [Journal of the American Medical Association](#)

Project Background



Seagrove Partners completed focus groups with 94 total participants including HCPs, Patients & Payers in July 2020.

Six Key Project Objectives:

1. Understand the Therapeutic Unmet Needs for PWD (Type 1 and Type 2)
2. Determine Total Addressable Market for Oral Insulin
3. Test Oral Insulin Target Product Profile with Payers, HCPs & Patients
4. Determine Preferred Patient Segments for Maximum Product Uptake
5. Understand Recommended Product Positioning
6. Gather Video Outtakes Highlighting Key Respondent

Key Findings

- Prescribers value ancillary benefits of existing diabetes medications. In addition to the solid A1C lowering impact, HCPs place a high value on weight loss, cardiovascular and renal benefits that existing medications provide.
- Positive response with some uncertainty on positioning. The initial response was a combination of excitement and skepticism (this good to be true?) for an oral insulin with no hypoglycemia. The majority of HCPs advocated upon before the introduction of LAI and insulin some disappointment in the A1C lowering capability, the overall health scores were high with HCPs in total stating they would "strongly recommend oral insulin" for 33% of T2 patients who are insulin candidates.
- Primary care physicians are attractive target. Most T2 patients are in later stages of the progression of diabetes and are on high TDD of insulin when they are an endo. The value proposition of ORMD-0801 must be highest when prescribed earlier in the treatment protocol to introduce insulin without the need for training etc. on injectable insulin.
- Oral insulin concept and physiologic MOA concept were positively received by Payers. Payers were enthusiastic about the clinical potential of oral insulin for T2 patients. Many commented on the physiologic MOA and ability to improve compliance at a lower cost alternative in the use for T1 patients - 75% (A1C) of payers can see success in using for DPP-4, SGLT-2, GLP-1, and LAI candidates.
- 80% of payers would be "very likely" or "likely" to recommend formulary coverage for T2D members in combination with the oral agents Metformin, SGLT-2s or GLP-1s.
- Positioning oral insulin as a new class has benefits. Positioning ORMD-0801 as a new class of medication (vs. being lumped in with insulin) allows more control over rebate levels and less (more liability) competitive for preferred coverage.
- Phase III design can bolster support for coverage. It was clear from the FG discussion that the Payers will rely on outcome data when determining coverage and rebate levels. The polling revealed that A1C improvement is still the gold standard and from the most group of important measure in reduction in hypoglycemia, increased TIR and evidence of beta cell preservation.

Patient Segmentation



First Line After Metformin (before GLP-1s/SGLT-2s)

This will likely require showing comparable A1C improvement with Metformin to the GLP-1/SGLT-2 classes, improved TIR and long-term evidence of beta cell preservation (which would delay the need for injectable insulin). This assumes there is still no weight gain or increase in hypo risk. Key requirement: better A1C improvement than DPP-4s.

Second OR Third Line for Select Patient Segments

Identify segments where clinical improvement is the highest. 1) Patients who cannot take GLP-1s or SGLT-2s 2) Patients who are hypo unaware (particularly for overnight control with decreased hypo) 3) Patients who cannot/will not take injections. This may end up becoming the product sweet spot and may be easiest to brand and promote. This would include current DPP-4 users.

Third Line in Combination with GLP-1s/SGLT-2s

Given the ancillary CV, renal and weight gain benefits of the GLP-1/SGLT-2 classes, oral insulin will require strong A1C, additional clinical data (e.g. improved TIR or enhanced combo effect with another class) as well as evidence that oral insulin delays the need for injectable insulin to be broadly recommended. Keep in mind this will be viewed as added cost to the system.

4th Line Post GLP-1s/SGLT-2s

With similar (but longer-term) clinical results to today, ORMD-0801 can be positioned as a precursor or "training insulin" particularly in primary care. The value proposition can be strengthened by showing a delay to injectable insulin.

Possible Positioning and SWOT

Ancillary "Upside" Package

- QID Dosing
- No Hypos
- Weight Neutral
- Durable Beta Cell Preservation
- Much Better TIR
- Much Better Deviations
- Better Post Prandial Control
- Data Supporting MOA

Ancillary "Base" Package

- QID Dosing
- No Hypos
- Weight Neutral
- Trend Towards Beta Cell Preservation
- Better TIR
- Much Better Deviations
- No Change on Post Prandial Control
- Data Supporting MOA

- Oral administration allows easier treatment with insulin by relieving glucose to exogenous replacement insulin use
- Physiologic treatment supports sleep apnea and healthy profile
- Clinical publications in positive impact of using insulin in the treatment of pathways
- A1C & response time reductions
- Once daily simplification

- DTC and PCP education generative, acceptable
- Patients who can't tolerate GLP-1s & SGLT-2s
- Development of new categories for formulary coverage
- Phase III to increase TIR and reduce STD, beta cell preservation
- Update ADA treatment guidelines to include oral insulin
- Adjunctive to LAI for T2DM to increase TIR and reduce TDD
- Potential treatment for NASH (per FDA approved Tx options)

A1C	Patient Segmentation
<1.3	Frontline Therapy with Metformin
1.0-1.2	Frontline Therapy with Metformin
0.8-1.0	Replacement for 2 nd Line Agents
0.6-0.8	Replacement for DPP4s
<0.4	3 rd Line Therapy for Those Who Can't Tolerate GLP-1s/SGLT-2s

A1C	Patient Segmentation
<1.3	Frontline Therapy with Metformin
1.0-1.2	Replacement for 2 nd Line Agents
0.8-1.0	Replacement for DPP4s
0.6-0.8	Replacement for DPP4s
0.6	3 rd Line Therapy for Those Who Can't Tolerate GLP-1s/SGLT-2s

31

Leveraging Oral Insulin for Nonalcoholic Fatty Liver Disease

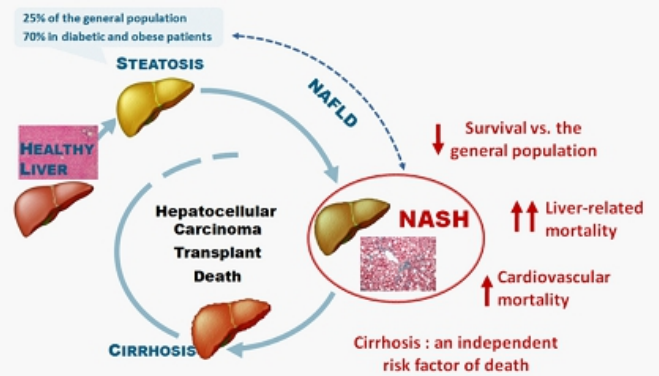
- Chronic liver disease caused by excessive fat in liver (MoA not fully known)
- Leads to fibrosis, cirrhosis and liver failure (death)
- 25% of adults in the U.S. have NAFLD
- 5% of adults in the U.S. have NASH
 - 37% among patients with T2DM


25% of the general population
70% in diabetic and obese patients

STEATOSIS

- Data from initial 8 patients presented at ADA 2020 :

- Safety:
 - 12-week, once-daily treatment had no SAEs
- Efficacy:
 - 30% relative reduction measured by MRI-PDFF
 - 6.9±6.8% mean reduction in liver fat content (p value: 0.035)
- Initiation of 10 additional patients in EU (ongoing)
- Initiation of Double-Blind Placebo-Controlled Study (n=30)





ORMD-0901: Oral GLP-1 Analog



GLP-1 Analog: ORMD-0901 for Oral GLP-1 (TD2M)



GLP-1 Analog

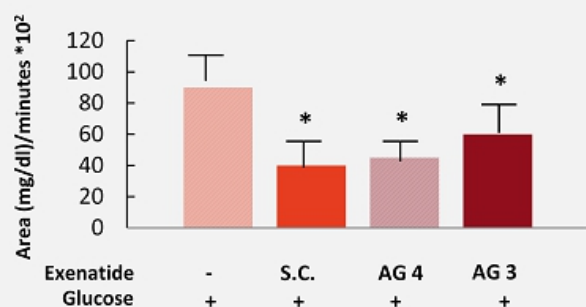
- T2DM medication
- Mimics the natural hormone in the body
- Compelling safety profile
- Decreases blood glucose levels
- Effectively reduces HbA1c
- Preserves beta cell function
- Promotes weight loss

ORMD-0901 Clinical Status

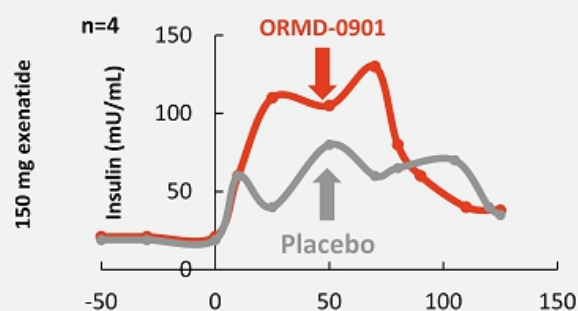
- IND
- Bioavailability study

Oral GLP-1 - ORMD-0901

Preclinical: Oral exenatide delivery amounted to a >50% reduction in mean glucose (similar to SC)



Human (4 healthy volunteers)



**ORMD-0901
formulations**

Preserved the biological activity of orally delivered exenatide. ORMD-0901 successfully curbed blood sugar excursions following glucose challenge



oravax – Novel Oral Covid-19 Company



x



■ JV:

- 63% Oravax's common stock
- Right to appoint the majority of BoD

■ License:

- Royalties: 7.5% of net sales
- Sublicensing: 15%
- Sales milestone: \$25M - \$100M

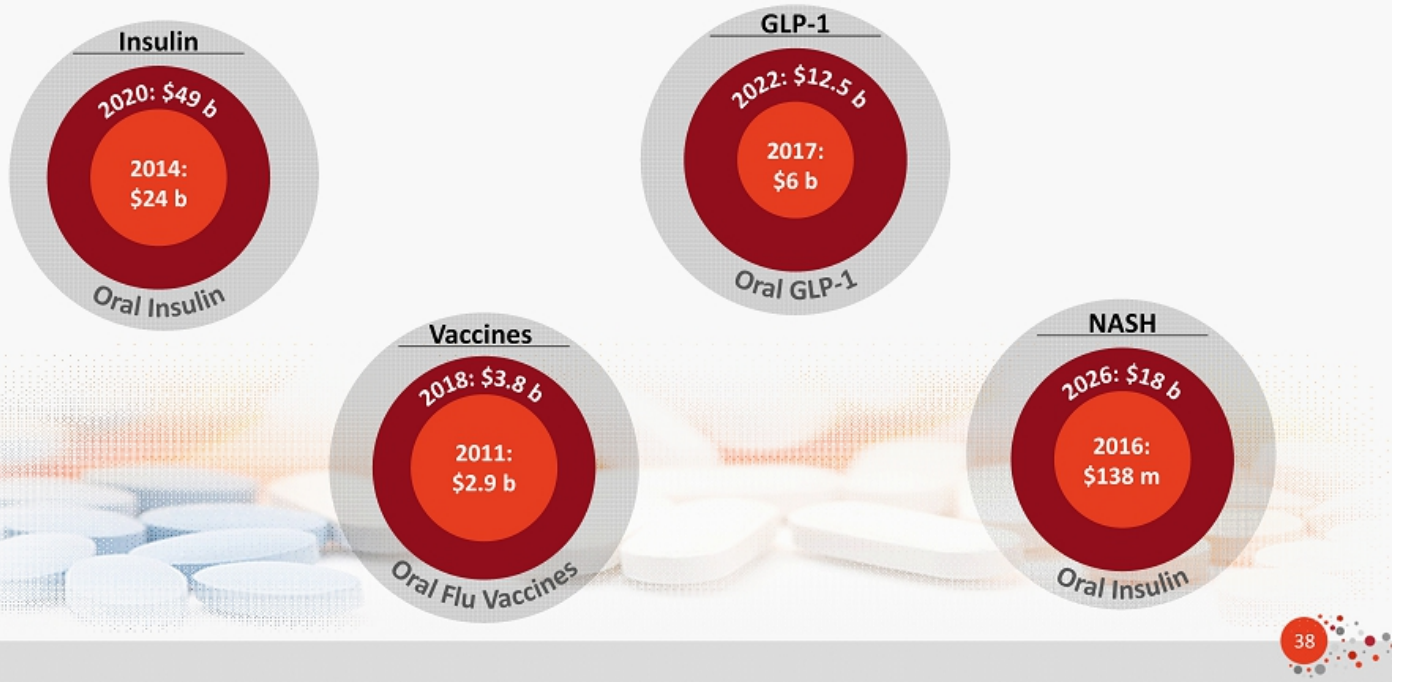
- **Universal COVID vaccine**
 - Triple antigen vaccine expected to be effective against COVID variants
- **Manufacturing advantages**
 - Ease of scale up
 - Straight-forward tech transfer
 - Manufacturing and COGs optimization
 - Consistent process
- **Safe, non-toxic, and efficacious in preclinical and GLP Tox studies in animals:**
 - No temperature rise, or body weight loss/gain, no adverse events noted in any animal
 - Significant antibody response, as well as cellular immune response
 - Showed desired immunological parameters and efficacy
 - Long term retention of the antibody response in animals, post 150 days
- **Oral format**
 - No needles
 - Easy to administer at home (no need for professional administration)
 - No need for low temperature storage (freezer)
 - Potential for further reduction in side effects (greater safety)

Anticipated Development Milestones



- 0801**
 - T2DM: Phase 3 trials
 - NASH: Phase 2 completion
- 0901** • Bioavailability Study (T2DM) Initiation & Completion
- Leptin** • Phase I ex-USA Initiation

Funneling Huge Injectable Drug Markets to Novel Oral Formulations



Management Team



Nadav Kidron, Esq, MBA - CEO & Director

Many years of business experience as well as corporate law and technology



Miriam Kidron, PhD - CSO & Director

Senior Researcher at the Diabetes Unit of Hadassah Medical Center for more than 25 years



Avi Gabay, CPA - CFO

Extensive experience in corporate financial management



Josh Hexter - Chief Operating & Business Officer

More than 18 years of prominent leadership roles in biotech and pharma



Roy Eldor, MD - Chief Medical Advisor

Head of the Diabetes Unit at Tel-Aviv Sourasky Medical Center

Board of Directors

Kevin Rakin - Chairman

Co-Founder and Partner at HighCape Partners; former President of Regenerative Medicine at Shire plc

Leonard Sank

Entrepreneur and business leader; Director of Macsteel Service Centres SA (Pty) Ltd

Aviad Friedman

Director of public and private companies including Maayan Ventures, Capital Point and Rosetta Green Ltd.

Arie Mayer

Managing Director and Chairman of the Board of Merck Life Science Israel (formerly Sigma-Aldrich Israel Ltd.)

Xiaoming Gao

Chairman of HTIT, China

Nadav Kidron

CEO, Oramed

Miriam Kidron

CSO, Oramed

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Roy Eldor, MD, PhD

Director, Diabetes Unit, Institute of Endocrinology, Metabolism & Hypertension, Tel-Aviv Medical Center

Ele Ferrannini, MD, PhD

Professor, Internal Medicine, University of Pisa School of Medicine. Past President of the EASD

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Recognized authority in the metabolic and endocrine fields with extensive FDA experience.

Avram Herskho, MD, PhD; Nobel Laureate

Distinguished professor in the biochemistry unit in the B. Rappaport Faculty of Medicine, Technion, Haifa, Israel

Harold Jacob, MD

Chief Medical Officer, NanoVibronix. Previously, Director, Medical Affairs at Given Imaging.

Julio Rosenstock, MD


Director, Dallas Diabetes Research Center, Professor, University of Texas Southwestern Medical Center; Associate Editor, *Diabetes Care*.

Jay Skyler, MD, MCAP

Professor of Medicine, Division of Endocrinology, Diabetes & Metabolism, Department of Medicine, University of Miami.

Oramed (NASDAQ/TASE: ORMP)

Addressing the Multibillion-Dollar Injectable Drug Markets with Oral Formulations

- 
- **Proprietary oral protein delivery platform**
 - **Primary Indication: Insulin** - initially targeting the lucrative insulin market; additional markets in the pipeline
 - **Strong financial position** with over \$56M in cash and investments, no debt, 28.3M shares outstanding (33.9M fully diluted)¹
 - **Strong management** team backed by world-class scientific experts
 - **Multiple near-term value-creation catalysts** for this year
 - **Robust IP Portfolio**
 - Methods and compositions for oral administration of proteins
 - Methods and compositions for oral administration of exenatide
 - Methods and compositions (insulin + exenatide)
 - Improved protease inhibitors

¹ As of February 28, 2021



THANK YOU

www.oramed.com