SECURITIES AND EXCHANGE COMMISSION

FORM 6-K

Current report of foreign issuer pursuant to Rules 13a-16 and 15d-16 Amendments

Filing Date: **2024-04-26** | Period of Report: **2024-04-26**
SEC Accession No. 0001214659-24-007591

(HTML Version on secdatabase.com)

FILER

Biodexa Pharmaceuticals Plc
CIK:**1643918**| IRS No.: **000000000** | State of Incorp.:**X0** | Fiscal Year End: **1231**
Type: **6-K** | Act: **34** | File No.: **001-37652** | Film No.: **24879046**
SIC: **2834** Pharmaceutical preparations

Mailing Address
1 CASPIAN POINT
CASPIAN WAY
CARDIFF X0 CF10 4DQ

Business Address
1 CASPIAN POINT
CASPIAN WAY
CARDIFF X0 CF10 4DQ
44 (0)1235 888300

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 OF THE
SECURITIES EXCHANGE ACT OF 1934

For the month of April 2024
Commission File Number 001-37652

Biodexa Pharmaceuticals PLC

(Translation of registrant's name into English)

1 Caspian Point,
Caspian Way
Cardiff, CF10 4DQ, United Kingdom
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

The information included in this report on Form 6-K, including Exhibit 10.1 but excluding Exhibit 99.1, shall be deemed to be incorporated by reference into the registration statements on Form S-8 (File Number 333-209365) and Form F-3 (File Number 333-267932) of the Company (including any prospectuses forming a part of such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

EXPLANATORY NOTE

License and Collaboration Agreement

On April 25, 2024, Biodexa Pharmaceuticals PLC (the "Company") entered into a license and collaboration agreement (the "License Agreement") with Rapamycin Holdings, Inc. (dba Emtora Biosciences), a Delaware corporation ("Emtora"), relating to the license of eRapa™, an oral product formulation of rapamycin (sirolimus) (the "Product"), for use in the prevention, treatment, diagnosis, detection, monitoring and/or predisposition testing of all diseases, states or conditions in humans (the "Field"), that includes the nanoparticle and enteric coated finished pharmaceutical formulations developed at any time by Emtora and its affiliates (the "License"). Under the License, the Company obtained from Emtora an exclusive, worldwide, sublicensable right to develop, manufacture,

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

commercialize, or otherwise exploit products containing rapamycin (sirolimus) in the Field. Pursuant to the terms of the License Agreement, the Company and Emtora will establish a joint development committee, consisting of two designees of the Company and two designees of Emtora, as described therein.

As consideration for the License, the Company made an upfront payment to Emtora in the form of 378,163 of the Company's American Depositary Shares (equal to five percent (5%) of the Company's ordinary shares, nominal value £0.001 per share ("Ordinary Shares") calculated on a fully-diluted basis (including in-the-money warrants)). In addition, the Company will also be responsible for up to $41.5 million in sales milestones within the first six months of commercial sale of a first-approved indication of eRapa™ in certain markets, with decreasing milestones for subsequent approvals for additional indications. Further, the Company will also be obligated to pay Emtora single digit tiered royalties on net sales of eRapa, in addition to honoring Emtora's legacy royalty obligations and paying Emtora fees related to income derived from sublicensing and the partnering of eRapa. In addition, effective as of the closing, a promissory note previously issued by Emtora in favor of the Company in the amount of $250,000 will be forgiven. The Company will also include an additional $500,000 cash payment to Emtora to be used exclusively for a match to an advance from the Cancer Prevention and Research Institute of Texas.

Upon any change of control of the Company (as defined in the License Agreement), the Company shall issue Emtora a warrant exercisable for 1,604,328 American Depositary Shares, which may only be exercised upon such change of control.

The License Agreement also provides the Company with the exclusive option to acquire all of the capital stock of Emtora at a purchase price on commercially reasonable terms during the period beginning with the filing of a New Drug Application ("NDA") application for the Product with the U.S. Food and Drug Administration (the "FDA") and ending ninety (90) days after acceptance of the filing of the NDA by the FDA.

The foregoing description of the License Agreement is not complete and is qualified in its entirety by reference to the full text of the License Agreement, which is filed hereto as Exhibit 10.1, and is incorporated by reference herein.

SUBMITTED HEREWITH

Attached to the Registrant's Form 6-K filing for the month of April 2024 is:

Exhibit No.	Description
10.1*†	License and Collaboration Agreement, dated as of April 25, 2024, by and between Rapamycin Holdings, Inc. (dba Emtora Biosciences) and Biodexa Pharmaceuticals PLC.
99.1	Press release dated April 26, 2024.

* Non-material schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules and exhibits upon request by the SEC.
† Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) is the type that the Registrant treats as private or confidential.

SIGNATURE

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

Biodexa Pharmaceuticals PLC

Date: April 26, 2024

By: /s/ Stephen Stamp
Stephen Stamp
Chief Executive Officer and Chief Financial Officer

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

Exhibit 10.1

LICENSE AND COLLABORATION AGREEMENT

This License and Collaboration Agreement ("Agreement") is made and entered into this 25th day of April, 2024 (the "Effective Date").

BY AND BETWEEN

(1) **Rapamycin Holdings, Inc. (dba Emtora Biosciences)**, a Delaware corporation with its principal place of business at 16601 Blanco Road, Suite 120, San Antonio, Texas 78232 ("Emtora");

and

(2) **Biodexa Pharmaceuticals PLC**, a company incorporated under the laws of England and Wales with its principal place of business at 1 Caspian Point, Caspian Way, Cardiff, CF10 4DQ, United Kingdom ("Biodexa").

Background

WHEREAS, Emtora owns or Controls certain intellectual property rights with respect to the Product in the Territory; and

WHEREAS, subject to the terms and conditions of this Agreement, Biodexa desires to develop, distribute, market and sell the Product in the Territory; and

WHEREAS, Biodexa has previously loaned Emtora $250,000 pursuant to a promissory note dated March 6, 2024 (the "Promissory Note");

and

WHEREAS, Emtora wishes to grant to Biodexa, and Biodexa wishes to take, an exclusive license in and to Emtora's intellectual property in the Product, in the Field, in the Territory, subject to and in accordance with the terms of this Agreement.

Terms

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Emtora and Biodexa hereby agree to be legally bound as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 The words and expressions set out below shall have the following meanings when used in this Agreement (including the recitals):

"Accounting Standards"	means, with respect to a Party, that such Party shall maintain records and books of accounts in accordance with (a) United States Generally Accepted Accounting Principles or (b) to the extent applicable, International Financial Reporting Standards as issued by the International Accounting Standards Board, in each case, consistently applied;
"Acquired Affiliates"	means those entities which become an Affiliate of Emtora after the Effective Date as a result of an acquisition by a Third Party of at least a majority of the outstanding capital stock of Emtora (whether through merger, consolidation or otherwise);

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

"ADSs"	means American Depositary Shares of Biodexa issued pursuant to a Second Amended and Restated Deposit Agreement, effective as of December 18, 2023, among Biodexa, JPMorgan Chase Bank, N.A., as depositary thereunder, and the owners and holders of such American Depositary Shares from time to time, as such agreement may be amended or supplemented, with each such American Depositary Share representing 400 ordinary shares, nominal value £0.001 per share, of Biodexa (such ordinary shares, the "BDRX Ordinary Shares");
"Affiliate"	means any Person that directly or indirectly through one or more intermediaries' controls, is controlled by or is under common control with a Party to this Agreement. For purposes of this definition, 'control' shall mean (a) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares entitled to vote for the election of directors; and (b) in the case of non-corporate entities, direct or indirect ownership of the power to direct the management or policies of such non-corporate entities, whether through ownership of voting securities, by contract relating to voting rights or governance, or otherwise. For clarity, once a Person ceases to be an Affiliate of a Party then without any further action such Person shall cease to have any rights, including rights by operation of license or sublicense, under this Agreement by reason of being an Affiliate of such Party;
"Agreement"	has the meaning set forth in the preamble of this Agreement;
"Annual Net Sales"	means, on a country-by-country or whole Territory basis, as the context requires, all Net Sales during any Calendar Year during the Term;
"API"	means rapamycin (sirolimus), the active pharmaceutical ingredient for the Product, as more specifically described in Schedule 1;
"Applicable Laws"	means all applicable federal, state, local, foreign, national or multinational laws, statutes, ordinances, rules, regulations and/or any orders, rules, regulations, regulatory guidelines or other requirements of any court, regulatory agency or other governmental authority, any major national securities exchange or listing organisation or any similar provision having the force or effect of law that may be in effect from time to time during the Term and which is applicable to an activity or a Party under this Agreement, including all applicable regulatory laws;
"Biodexa"	has the meaning set forth in the preamble of this Agreement;
"Biodexa Indemnitees"	has the meaning set forth in Section 9.2;

"Biodexa Trade Marks"	means the trade mark applications and/or registrations, filed and/or registered in the name of Biodexa or an Affiliate in the Territory for the Product, or any other trade mark, trade name, brand name, logo, trade dress or domain name of Biodexa or an Affiliate, whether or not registered, agreed for use in connection with the marketing, distribution and sale of the Product in accordance with Section 12.3 of this Agreement and accepted by the relevant Regulatory Authority for such use and any related domain names;
"Blocking 3rd Party IP"	with respect to any country, a Patent or Know-How in such country Controlled by a Third Party that covers and would be infringed or misappropriated, as applicable, by the Exploitation of the Product;
"Business Day"	means any day other than (a) a Saturday or Sunday or (b) a day on which banking institutions located in New York, New York or London, England, are permitted or required by Applicable Laws to remain closed;
"Calendar Quarter"	means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

Date and end on the day immediately prior to July 1, 2024 and the last Calendar Quarter shall end on the last day of the Term;

"Calendar Year"	means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31, 2024, and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term;
"Change of Control"	means (a) the closing of the sale, transfer, exclusive license or other disposition of all or substantially all of Biodexa's assets or Intellectual Property Rights to which this Agreement relates, (b) the consummation of the merger or consolidation of a Party or any entity which directly or indirectly holds fifty percent (50%) or more of the outstanding voting stock of Biodexa (a "Parent") with or into another entity (except a merger or consolidation in which the holders of capital stock of Biodexa or Parent immediately prior to such merger or consolidation continue to hold at least fifty percent (50%) of the voting power of the capital stock of Biodexa or Parent or the surviving or acquiring entity of Biodexa or Parent), (c) the closing of the transfer (whether by merger, consolidation or otherwise), in one transaction or a series of related transactions, to a Person or group of Affiliated Persons (other than an underwriter of Biodexa's securities), of Biodexa's or Parent's securities if, after such closing, such Person or group of Affiliated Persons would hold fifty percent (50%) or more of the outstanding voting stock of Biodexa or Parent (or the surviving or acquiring entity of Biodexa or Parent) or (d) a liquidation, dissolution or winding up of Biodexa or Parent;

"Commercially Reasonable Efforts"	means, with respect to the efforts to be expended by a Party in carrying out activities for which it is responsible under this Agreement, the level of effort and resources applied hereunder consistent with the exercise of reasonable and diligent efforts and resources comparable to the efforts and resources that companies with reasonable financial resources and of a similar size in the pharmaceutical industry developing and commercializing human therapeutic drugs would typically devote, when using prudent scientific and business judgment, to the development and commercialization of other products and product candidates that are at a similar stage of development or commercialization and have similar market potential, taking into account efficacy, safety, patent and regulatory exclusivity, anticipated or approved labeling, present and future market potential, competitive market conditions, pricing and reimbursement issues, and other relevant factors commonly considered in similar circumstances;
"Confidential Information"	means any confidential scientific, technical, marketing, regulatory, business and/or financial information or data of a Party, including the terms of this Agreement, all information relating to the API and the Product and/or the development, sale and distribution of the Product including know-how, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, reagents and biological methodology, any strategy for the prosecution, maintenance, enforcement and defense of Patents and any confidential Intellectual Property Rights, which is/are disclosed by or on behalf of a Party to the other Party or its Affiliate, Sublicensee or representative, directly or indirectly, whether orally, visually, in writing, electronically or in any other form, pursuant to the terms of this Agreement or the Confidentiality Agreement between the Parties January 24, 2024, whether prior to, on or after the Effective Date, but excluding (i) any information that is, or becomes available, in the public domain from time to time, other than information which enters the public domain as a result of a breach by the receiving Party of its obligations under this Agreement; (ii) information that was known by or in the possession or control of the receiving Party without any obligation of confidentiality prior to the date of its actual receipt from the disclosing Party; (iii) information that is available, or becomes available, to the receiving Party from sources not bound by a similar confidentiality obligation with the disclosing Party; and (iv) information

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

that was or is subsequently independently developed by the receiving Party without use of the Confidential Information of the other Party as demonstrated by competent written records. Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party;

"Control"	means, with respect to any item of information (including Confidential Information), material or Intellectual Property Right, the possession of the right, whether directly or indirectly, and whether by ownership, license or covenant not to sue, to grant a license, sublicense or other right to or under such information (including Confidential Information), material or Intellectual Property Right, including without limitation all Intellectual Property Rights licensed under the UT License; provided that solely with respect to any such item of information (including Confidential Information), material or Intellectual Property Right developed, acquired or licensed by a Party after the Effective Date: (a) as provided for herein without violating the terms of any agreement or other arrangement with any Third Party; and (b) neither Party shall be deemed to Control any item of information (including Confidential Information), material or Intellectual Property Right of a Third Party if access by the other Party requires or triggers a payment obligation unless the other Party agrees to bear such payment obligation. In the event that Biodexa is acquired in a Change of Control by a Third Party (such Third Party, hereinafter referred to as an "Acquirer"), then the Intellectual Property Rights of such Acquirer held or developed by such Acquirer prior to or after such acquisition (other than Intellectual Property Rights developed by such Acquirer in the course of conducting Biodexa's activities under this Agreement) shall be excluded from the information, material or Intellectual Property Rights Controlled by Biodexa, and such Acquirer (and Affiliates of such Acquirer which are not controlled by (as defined under the Affiliate definition above) Biodexa itself) shall be excluded from the Affiliate definition solely for purposes of the applicable components of the information, material or Intellectual Property Rights Controlled by Biodexa. "Controlled" has a corresponding meaning;
"Cover" or "Covers"	means, with reference to a Patent in a country in the Territory, that the performance of one or more activities related to the development, registration, manufacture, use, sale, offer for sale, marketing, commercialization, distribution, importation or exportation of the Product would, but for the rights granted by Emtora to Biodexa under this Agreement, infringe, directly or indirectly, at least one claim of such Patent in such country in the Territory where such activities occur;
"CPRIT"	means the Cancer Prevention and Research Institute of Texas.

"CPRIT Contract Close Out"	means the completion of the CPRIT Grant contract closure procedures as provided in the CPRIT Policies and Procedures Guide attached as Schedule 5;
"CPRIT Grant"	means the Cancer Research Grant Contract by and between Cancer Prevention and Research Institute of Texas and Rapamycin Holdings, Inc., dated 31 August 2022, as amended, including all Attachments thereto, a copy of which is attached hereto as Schedule 6;
"Debarred Entity"	has the meaning set forth in Section 8.1(d);
"Distributor"	means any Person appointed by Biodexa or any Sublicensee or any of their Affiliates to distribute, market and sell a Product, with or without packaging rights, in one or more countries in the Territory in circumstances where such Person purchased its requirements of Product from Biodexa or any Sublicensee or any of their Affiliates but does not otherwise make any royalty or other

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

	revenue-based payment to Biodexa or any Sublicensee or any of their Affiliates with respect to their intellectual property rights in connection with its sales of such Product;
"Effective Date"	has the meaning set forth in the preamble of this Agreement;
"EMA"	means European Medicines Agency and any successor agency thereto;
"Emtora"	has the meaning set forth in the preamble of this Agreement;
"Emtora Indemnitees"	has the meaning set forth in Section 9.1;
"Emtora Intellectual Property"	means all Intellectual Property Rights that are Controlled by Emtora or its Affiliates, excluding Acquired Affiliates, as of the Effective Date or during the Term and that are related to the development or commercialization of the Product in the Field in the Territory, which includes the Emtora Patents and the Intellectual Property Rights licensed by Emtora under the UT License;
"Emtora Know-How"	means all Know-How Controlled by Emtora or its Affiliates, excluding Acquired Affiliates, as of the Effective Date or during the Term and that is related to the development, manufacture or commercialization of the Product in the Field in the Territory;
"Emtora Noteholder Royalty"	means the royalties owed pursuant to the agreement attached as Schedule 7;
"Emtora Patents"	means all Patents that are Controlled by Emtora or its Affiliates, excluding Acquired Affiliates, as of the Effective Date or during the Term and that are related to the development, manufacture or commercialization of the Product in the Field in the Territory, which includes the UT Patents licensed by Emtora under the UT License and the Patents listed in Schedule 2;

"Emtora SPV Sale"	means, in the case that all of the rights to Develop and Commercialize the Product are contributed by the Parties to a newly-formed entity (the "SPV"), the sale of all of the equity interests of such SPV to a Third Party;
"Exploit"	to make, have made, import, use, sell or offer for sale, including to develop, commercialize, register, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of; it being understood that "Exploitation" means the act of Exploiting a compound, product or process;
"FAP"	means familial adenomatous polyposis as defined in the CPRIT Grant;
"FDA"	means the U.S. Food and Drug Administration, or any successor agency thereto;
"FD&C Act"	means the United States Federal Food, Drug, and Cosmetic Act;
"Field"	means the prevention, treatment, diagnosis, detection, monitoring and/or predisposition testing of all diseases, states, or conditions in humans;
"First Commercial Sale"	means, on a country-by-country basis, the first sale for monetary value by Biodexa or its Affiliates or their Sublicensees of the Product in such country in the Territory under this Agreement to a Third Party, after such Product has been granted Regulatory Approval (including for these purposes any pricing and reimbursement approval that may be required) by the applicable Regulatory Authority in such country in the Territory. Sales prior to receipt of all Regulatory Approvals for such Product in such country, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales" shall not be construed as a "First Commercial Sale". For the avoidance of doubt, First Commercial Sale excludes transfers or dispositions of a Product for charitable, promotional (including samples), pre-clinical, clinical or regulatory purposes;

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

"Force Majeure"	means any war, acts of war, revolution, civil commotion, act of terrorism, blockade, epidemic, pandemic, quarantine, embargo, riots, labor disturbance, strike or lock-out, scarcity of raw materials, shortage of power, flood, destruction of production facilities or materials by fire, earthquake, hurricane, tsunami, nuclear disaster, or similar event that is beyond the reasonable control of the Party affected;
"Fully-Diluted"	means, with respect to BDRX Ordinary Shares (including rights to acquire BDRX Ordinary Shares as a result of ownership of ADSs), that the total number of such BDRX Ordinary Shares would be calculated to include (i) the conversion of all issued and outstanding securities of Biodexa convertible into BDRX Ordinary Shares, and (ii) the exercise of all In-the-Money outstanding options and warrants to purchase BDRX Ordinary Shares, whether or not then exercisable;

"Generic Product"	means, on a country-by-country basis with respect to any Product, a pharmaceutical drug product independently developed and sold by a Third Party (which in no event will include Biodexa or any Sublicensee or any Affiliate of any of them) that: (a) contains the API; and (b) is approved in reliance on the prior approval of the Product as determined by the FDA (pursuant to an Abbreviated New Drug Application) or pursuant to any equivalent and comparable Regulatory Authority and authorization in any other country in the Territory;
"GMP"	means the Good Manufacturing Practice regulations promulgated by the FDA under the authority of the FD&C Act.
"Handover Trigger"	means the later of (a) receipt of the CPRIT Contract Close Out; or (b) receipt of final payment under the CPRIT Grant;
"IND"	means an investigational new drug application (including any amendment or supplement thereto) submitted to the FDA pursuant to U.S. 21 C.F.R. Part 312, including any variations and extensions thereto and any renewals thereof. References herein to IND shall include, to the extent applicable, any comparable filing(s) outside the U.S. for the investigation of any product in any other country or group of countries (such as a Clinical Trial Application in the EU);
"Indication"	means, with respect to the Product, any human disease or condition, or sign or symptom of a human disease or condition, in a particular target patient population;
"Intellectual Property Rights"	means all intellectual property and proprietary rights, wherever in the world arising, whether registered or unregistered (and including any application for registration), copyrights, Know-How, trade secrets, database rights, trade mark(s), service marks, goodwill, moral rights, Patents and rights to apply for any of the foregoing;
"In-the-Money"	means, with respect to an option or warrant to acquire securities that are traded or quoted on a national securities exchange in the United States, as of any measurement date, that the exercise price for such option or warrant is less than the average of the closing prices for such securities on their principal market for the five (5) trading days ending on the trading day immediately preceding the Effective Date;
"Inventions"	means all inventions, whether or not patentable, that are designed, discovered, generated, invented, conceived or reduced to practice by or on behalf of any Party or its respective Affiliates or Sublicensees or both Parties or their respective Affiliates or Sublicensees, whether solely or jointly with any Third Party, in the course of activities performed under this Agreement;

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

“Knowledge”	means actual knowledge following the good faith understanding of the facts and information in question;
“Know-How”	means any and all tangible, proprietary, confidential, research, technical and scientific information existing as of the Effective Date of this Agreement that is not in the public domain, including information relating to materials, discoveries, unpatented inventions, improvements, practices, methods, protocols, manufacturing techniques, operating manuals, databases, formulas, knowledge, trade secrets, technologies, processes, assays, sources, skills, experience, techniques, data and the results of experimentation and testing;
“Litigation Conditions”	has the meaning set forth in Section 9.4;
“Losses”	has the meaning set forth in Section 9.1;
“Major European Countries”	means United Kingdom, France, Germany, Spain and Italy;
“Milestone Payments”	has the meaning set forth in Section 4.2;
“NDA”	means a New Drug Application (as more fully described in U.S. 21 C.F.R. Parts 314.50 et seq. or its successor regulation) and all amendments and supplements thereto, submitted to the FDA, or any equivalent filing, including a marketing authorisation application, in a country or regulatory jurisdiction other than the U.S. with the applicable Regulatory Authority, or any similar application or submission for Regulatory Approval filed with a Regulatory Authority to obtain marketing approval for the Product, in a country or in a group of countries;
“Net Sales”	means, on a country-by-country and Product-by-Product basis in the Territory, with respect to any period for each country, the gross amounts invoiced by Biodexa, or its Affiliates (each, a “Selling Party”), as applicable, to unrelated Third Parties for sales of a Product in the Field in such country, less the following deductions to the extent included in the gross invoiced sales price for such Product or otherwise directly paid, incurred, allowed, accrued or specifically allocated by the Selling Parties with respect to the sale of such Product in such country and not otherwise recovered by or reimbursed to Biodexa, or its Affiliates: (a) discounts, including trade, quantity or cash discounts, bad debt deductions, credits, adjustments or allowances, including those granted on account of price adjustments, billing errors, rejected goods or damaged goods, which discounts are applied on a basis consistent with the Selling Party's practices with respect to the selling Person’s other pharmaceutical products in accordance with Accounting Standards; (b) rebates and chargebacks allowed, given or accrued (including cash, governmental and managed care rebates, hospital or other buying group chargebacks, cash

and non-cash coupons, retroactive price reductions, and governmental taxes in the nature of a rebate based on usage levels or sales of such Product); (c) sales, turnover, inventory, value-added, import, export, excise (including annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48) and other comparable laws) and other taxes levied on, absorbed, determined or imposed with respect to the sale of such Product (excluding income or net profit taxes or franchise taxes of any kind); (d) freight and insurance charges, customs charges, postage, shipping, handling, and other transportation costs incurred in shipping such Product; (e) amounts payable resulting from governmental, regulatory or agency mandated rebate programs and amounts paid or credited to customers for inventory management services; and (f) the portion of any third-party management fees paid during the relevant time period to group purchasing organizations, wholesalers and managed care organizations to the extent determined by sales or utilization of such Product. Net Sales will be determined in accordance with Accounting Standard. Without limiting the generality of the foregoing, transfers or dispositions of

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

a Product at or less than cost of manufacture for charitable, promotional (including samples), pre-clinical, clinical, or regulatory purposes will be excluded from Net Sales, as will sales or transfers of a Product among the Selling Parties. Subject to the above deductions, Net Sales shall be deemed to occur on, and only on, the first sale by a Selling Party to a Third Party.

If a Product is sold as part of a Combination Product (as defined below), Net Sales will be the product of (i) Net Sales of the Combination Product calculated as above (i.e., calculated as for a non-Combination Product) and (ii) the fraction (A/(A+B)), where:

"A" is the gross invoice price in such country during the period to which the Net Sales calculation relates of the Product comprising the API as the sole therapeutically active ingredient; and

"B" is the gross invoice price in such country during the period to which the Net Sales calculation relates of the other therapeutically active ingredients contained in the Combination Product.

If "A" or "B" cannot be determined by reference to non-Combination Product sales as described above, then Net Sales will be calculated as above, but the gross invoice price in the above equation shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining the same that takes into account, in the applicable country, variation in dosage units and the relative fair market value of each therapeutically active ingredient in the Combination Product. As used in this definition of "Net Sales," "Combination Product" means a Product that contains one or more additional active ingredients (whether co-formulated or co-packaged);

"Net Sales Report"	means the report that shall be provided to Emtora by Biodexa on a Calendar Quarterly basis in accordance with the terms and conditions of this Agreement. Such report shall include: (i) the sale volumes achieved during such Calendar Quarter in units of Product and turnover, (ii) gross sales, (iii) Net Sales, (iv) details of deductions, and (v) a calculation of the amount of payments due in accordance with Section 4 in respect of such Calendar Quarter, in each case on a country-by-country basis. Turnover, gross sales, Net Sales and deductions shall be provided in both local currency and converted to Dollars in accordance with Section 4.5;
"Orphan Drug Indication"	means any indication for a Product that meets the designation as an "Orphan Drug" under the Orphan Drug Act, 21 U.S.C. §§ 360aa-360ee, or its foreign equivalent;
"Party"	means Emtora or Biodexa, as the context requires (referred to collectively as the "Parties");
"Patent"	means any and all national, regional and international patents and patent applications in the Territory, including any provisional applications, continuations, continuations-in-part, divisionals, substitutions, reissues, re-examinations, revalidations, extensions (including pediatric exclusivity), restorations (including revalidations, reissues and re-examinations), registrations, supplementary protection certificates and renewals of any such patents or patent applications, in each case including (a) any patents, patent applications or provisional applications filed or claiming priority therefrom, and (b) any patents that have issued or in the future issue therefrom, and in each case that are necessary or useful for the research, development, manufacture, use and/or commercialization of the Product in the Field, including any utility models, petty patents, design patents and certificates of invention;
"Person"	means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government;

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

"Phase II"	means a human clinical trial of a Product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(b) or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States;

"Phase III"	means a human clinical trial of a Product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(c) and is intended to (a) gather additional information about the safety and efficacy of the Product for its intended use, (b) support Regulatory Approval for such Product, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States; and (c) such trial is a registration trial sufficient for filing an application for a Regulatory Approval for such Product as evidenced by (i) an agreement with or statement from the FDA on a Special Protocol Assessment or equivalent, or (ii) other guidance or minutes issued by the FDA, or (iii) such agreement, statement, guidance, minutes or similar as may be given by the EMA, for such registration trial;
"Product"	means any fully finished pharmaceutical product formulations containing the API for use in the Field that includes the nanoparticle and enteric coated finished pharmaceutical formulations developed at any time by Emtora and its Affiliates;
"Regulatory Approval"	means the approval, license or authorization of the applicable Regulatory Authority necessary for the marketing and sale of a Product for a particular Indication in any country or other jurisdiction in the Territory, including separate pricing or reimbursement approvals where legally required in order to sell the Product in such country (and for clarity does not include named patient approval);
"Regulatory Authorities"	means the applicable supra-national, federal, national, regional, state, provincial, governmental, regulatory or health authorities, agencies, departments, commissions or councils in the Territory responsible for granting Regulatory Approvals and otherwise regulating the manufacture, distribution, marketing and sale of pharmaceutical products in the Territory;
"Regulatory Exclusivity"	means, with respect to any country or other jurisdiction in the Territory (i) any period of regulatory data protection or equivalent that prevents a Third Party during such period from relying on the data submitted in support of an application for Regulatory Approval for a Product for an application for approval for a generic version of such Product or (ii) an additional market protection, other than Patent protection or Patent-related exclusivity, granted by a Regulatory Authority in such country or other jurisdiction which confers an exclusive commercialisation period during which Biodexa or its Affiliates or Sublicensees have the exclusive right to market and sell, and any other Third Party is prevented from marketing or selling, the Product or a generic version of such Product in such country or other jurisdiction including orphan drug protection;
"Regulatory Submissions"	means all applications (including all INDs and drug approval applications), filings, dossiers and the like submitted to a Regulatory Authority for the purpose of obtaining Regulatory Approval;

"Research Sales"	means sales of eRapa to academic and research institutes as well as current customers as of the Effective Date, in each case solely for non-clinical research purposes involving the Product;
"Research Sales Period"	means the period beginning on the Effective Date and ending on the earlier of (a) Biodexa's exercise of its option to acquire Emtora as provided in Section 7; and (b) the first Regulatory Approval of a Product in any country in the Territory;

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

"Royalty Term"	has the meaning set forth in Section 4.3;
"Sublicense Milestone Income"	means upfront, development and regulatory payments received by Biodexa from any Sublicensee; it being understood that the following amounts received from a Sublicensee shall be excluded from Sublicense Milestone Income: (a) royalties and milestones based on sales of Products; (b) net proceeds under a credit facility extended to Biodexa, but only to the extent said credit facility is at a market rate; (c) direct cost reimbursement for (i) any supply of Products by or on behalf of Biodexa, or (ii) reimbursement of the reasonable costs of any research or development activities for Products that Biodexa will perform on behalf of a Sublicensee; (d) reimbursement of actual out-of-pocket patent prosecution and patent maintenance expenses; and (e) net proceeds resulting from any sale of any securities of Biodexa to Sublicensees up to the fair-market valuation of said securities on the date of closing;
"Sublicensee"	means a Third Party (other than a Distributor) with whom Biodexa enters into a Third Party Sublicense pursuant to which Biodexa sublicenses rights granted by Emtora to Biodexa under this Agreement or any other rights to commercialize the Product;
"Term"	shall have the meaning set forth in Section 15.1;
"Territory"	means worldwide;
"Third Party"	means an entity other than Emtora or Biodexa or their Affiliates;
"Upfront Payment"	shall have the meaning set forth in Section 4.1.1.
"Upfront Cash Payment"	shall have the meaning set forth in Section 4.1.2.
"UT License"	means the Patent and Technology License Agreement by and between The University of Texas Health Science Center at San Antonio and Rapamycin Holdings, Inc., dated 27 September 2012, as amended on 6 June 2016;
"UT Patents"	means the Patents licensed to Emtora under the UT License.

"Valid Claim"	means, with respect to a particular country, (a) a claim of a pending Patent claiming priority from any Patent that has been pending for no more than seven (7) years in Japan and five (5) years in all other countries, following the earliest priority filing date for such Patent and that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling or (b) a claim of an issued and unexpired Patent that has not been held permanently revoked, held unenforceable or invalid by a decision of a court or other governmental authority of competent jurisdiction, which decision is unappealed or unappealable within the time allowed for appeal and has not been irretrievably cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise. For clarity, a claim of a Patent that ceased to be a Valid Claim before it issued because it had been pending too long, but subsequently issued and is otherwise described by clause (a) of the foregoing sentence shall again be considered to be a Valid Claim once it issues. A Product is "Covered" by a Valid Claim if its registration, manufacture, use, sale, offer for sale, marketing, commercialization, distribution, importation or exportation by Biodexa in a given country in the Territory would, but for the rights granted by Emtora to Biodexa under this Agreement, infringe such a Valid Claim.

1.2 In this Agreement, unless the context requires otherwise:

1.2.1 references to Sections and Schedules are to Sections of and Schedules to this Agreement;

1.2.2 references to the singular shall include the plural and vice versa;

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

1.2.3 the Schedules will have the same force and effect as if expressly set out in the body of this Agreement;

1.2.4 headings are inserted for convenience only and shall not affect the construction or interpretation of this Agreement;

1.2.5 the words "including" or "includes" mean "including (or includes) without limitation";

1.2.6 reference to any legislation or law or to any provision thereof shall include references to any such law as it may, after the date hereof, from time to time, be amended, supplemented or re-enacted, and any reference to statutory provision shall include any subordinate legislation made from time to time under that provision;

1.2.7 when any number of days is prescribed in any document, the time period shall start on the next Business Day after the occurrence of the specified event. If the last day does not fall on a Business Day, then the last day shall be the next succeeding day which is a Business Day; and

1.2.8 all references to "Dollars" or "$" shall be deemed to be references to the lawful currency of the United States.

2. GRANT OF RIGHTS

2.1 License to Biodexa. Subject to the terms and conditions hereunder and the UT License, Emtora hereby grants Biodexa an exclusive license (exclusive even as to Emtora and its Affiliates, except that Emtora may conduct Research Sales during the Research Sales Period and perform development activities as contemplated by this Agreement and will, in collaboration with Biodexa, develop the product in FAP through to the Handover Trigger in accordance with the terms and conditions of this Agreement), which license is sublicensable (with right of sublicense through multiple tiers), in and to the Emtora Intellectual Property for the development, manufacture, importation, promotion and commercialization of the Product in the Field in the Territory (collectively, the "License").

2.2 Sublicenses. Biodexa will have the right to grant sublicenses to its Affiliates and Third Parties of any and all rights granted to Biodexa pursuant to Section 2.1. Biodexa will provide Emtora with a copy of each agreement containing any such sublicense within thirty (30) days of execution, with no more than reasonable redactions that will enable Emtora to reasonably monitor compliance with the terms and conditions of this Agreement; it being understood and agreed that Biodexa shall not enter into any sublicense with a Sublicensee prior to completion of the CPRIT Contract Close Out (x) without Emtora's prior written consent, not to be unreasonably withheld, conditioned, or delayed and (y) confirmation that such Sublicensee agrees to assume Biodexa's Development obligations for the Product under the terms and conditions of this Agreement. Any such sublicense shall be consistent with the terms of this Agreement and will include confidentiality, non-disclosure and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement. Biodexa will ensure that each Sublicensee complies with the terms of this Agreement. No sublicense will diminish, reduce or eliminate any obligation of Biodexa under this Agreement, and Biodexa will remain responsible for its obligations under this Agreement and will be responsible for the performance of the relevant Sublicensee as if such Sublicensee were the Party hereunder (including, without limitation, reporting obligations imposed upon Biodexa in accordance with this Agreement). Each sublicense granted by Biodexa, as the sublicensing Party, to any rights licensed to it hereunder will terminate immediately upon the termination of the original license with respect to such rights.

2.3 Cooperation. Each Party shall cooperate with the other and execute and deliver to the other such instruments and documents and take such other actions as may be reasonably requested by the other Party from time to time in order to carry out, give effect to or confirm the rights granted under Section 2.1 above.

2.4 License Rights. Neither Party grants to the other Party any right or license to use any of its Intellectual Property Rights, Know-How or other confidential and/or proprietary information, materials or technology, or to practice any of its Patents or trade marks, except as expressly set forth in this Agreement.

3. JOINT DEVELOPMENT COMMITTEE

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

3.1 Joint Development Committee. The Parties shall establish a joint development committee ("JDC") within thirty (30) days of the Effective Date that will have the responsibility for overseeing the timely and proper execution of the goals and objectives set forth in Attachment A to the CPRIT Grant ("CPRIT Goals and Objectives") in accordance with the budget set forth in Attachment B to the CPRIT Grant (the "Budget"), as each may be amended from time to time in accordance with the terms of this Agreement and the CPRIT Grant.

3.1.1 Joint Development Committee Membership. The Parties shall each designate two (2) (or such higher number as mutually agreed by the Parties) representatives to serve on the JDC by written notice to the other Party. The initial members shall be as attached in Schedule 3.1.1. Either Party may designate substitutes for its representatives if one (1) or more of such Party's designated representatives are unable to be present at a meeting. From time to time each Party may replace its representatives by written notice to the other Party specifying the prior representative(s) and their replacement(s). Each Party shall designate one of its representatives to serve as the co-chairpersons of the JDC. The co-chairpersons shall be responsible for (i) calling meetings, (ii) preparing and issuing minutes of each such meeting within thirty (30) days thereafter, and (iii) preparing and circulating an agenda for the upcoming meeting; provided that the co-chairpersons shall consider including any agenda items proposed by either Party no less than five (5) days prior to the next scheduled JDC meeting.

3.1.2 Joint Development Committee Meetings. The JDC shall hold at least one (1) meeting per Calendar Quarter at such times during such Calendar Quarter as it elects to do so; provided that, notwithstanding the foregoing, the JDC shall hold an initial meeting within fourteen (14) days of its formation. Meetings of the JDC shall be effective only if at least one (1) representative of each Party is present or participating. The JDC may meet either (i) in person at either Party's facilities or at such locations as the Parties may otherwise agree or (ii) by audio or video teleconference. Other representatives of each Party involved with the Product may attend meetings as non-voting participants, subject to the confidentiality provisions set forth in Section 11. Additional meetings of the JDC may also be held with the consent of each Party, or as required under this Agreement, and neither Party shall unreasonably withhold its consent to hold such additional meetings. Each Party shall be responsible for all of its own expenses incurred in connection with participating in the JDC meetings.

3.1.3 Joint Development Committee Term. The JDC's obligation to meet will begin as of the Effective Date and will expire upon the date of the Handover Trigger.

3.1.4 Reports to the Joint Development Committee. The Parties agree as follows with respect to applicable periods through the Calendar Quarter in which the Handover Trigger occurs:

a. No later than thirty (30) days following each Calendar Quarter, Emtora will deliver to the JDC and to Biodexa:

(i) Projected forecasts, prepared in good faith on a rolling Calendar Quarter basis for the next six (6) Calendar Quarters (itemized on a month-by-month basis), specifying the following: (A) payments for such period under the Budget in sufficient detail by line item for each vendor; (B) anticipated receipts from CPRIT for such period under the Budget; and (C) expected cash calls from Biodexa for such period under the Budget split between CPRIT Grant funding and non-CPRIT Grant funding amounts (the "Forecast");

(ii) A schedule itemizing all adjustments and reconciliations to the immediately preceding Forecast delivered to the JDC and Biodexa;

(iii) A written report summarizing activities, including regulatory activities, in respect of pharmaceutical development and manufacturing the Product in the Field in the Territory in the previous Calendar Quarter including regulatory activities relating thereto, in the subsequent twelve (12) month period. Such report shall include a summary of the work completed, a summary of the work in progress, the current schedule of anticipated milestone events, Regulatory Approvals and manufacturing efforts; and

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

(iv) A copy of read-outs from clinical trials conducted in relation to the Product for FAP within fifteen (15) days of such top-line final read-outs for the primary and secondary endpoints being available; (a) details of any significant adverse safety events or product recalls reported to Regulatory Authorities within ten (10) days of Emtora becoming aware of such events or the need for such recalls; and (b) copies of any reports submitted to or received from Regulatory Authorities, including supporting documents (e.g. regulatory drug lists, advertising and promotional documents, adverse event files and complaint files), promptly following submission or receipt. Emtora shall provide such further information relating to such reports and its activities under this Agreement as Biodexa may reasonably request in writing.

b. Biodexa Reports. Without limiting the information to be exchanged between the Parties, every Calendar Quarter Biodexa shall provide to Emtora:

(i) A written report summarizing its development activities, including regulatory activities, in respect of the Product in the Field in the Territory for any Indication other than FAP in the previous Calendar Quarter and a summary of its plans for the development and commercialization of the Product, including regulatory activities relating thereto, in the subsequent twelve (12) month period. Such report shall include a summary of the work completed, a summary of the work in progress, the current schedule of anticipated milestone events and Regulatory Approvals, sublicensing efforts, and no less than one year prior to expected filing of the first NDA, market plans for the introduction of the Product.

(ii) A copy of read-outs from clinical trials conducted in relation to the Product within fifteen (15) days of such top-line final read-outs for the primary and secondary endpoints being available; (a) details of any significant adverse safety events or product recalls reported to Regulatory Authorities within ten (10) days of Biodexa becoming aware of such events or the need for such recalls; and (b) copies of any reports submitted to or received from Regulatory Authorities, including supporting documents (e.g. regulatory drug lists, advertising and promotional documents, adverse event files and complaint files), promptly following submission or receipt. Biodexa shall provide such further information relating to such reports and its activities under this Agreement as Emtora may reasonably request in writing.

3.1.5 Biodexa Payments. Subject to the proviso to this sentence, Biodexa shall (i) pay any milestone, royalty, and other required payments owing and accruing after the Effective Date under the UT License, CPRIT Grant, and Emtora Noteholder Royalty; (ii) pay all remaining matching funds for FAP due under the CPRIT Grant, which amounts shall not exceed [***] in the aggregate and in any case shall be deposited in a separate, restricted account designated by the Parties (and subject to a customary deposit and control agreement with the applicable banking institution) on at least an annual basis for years two (2) and three (3) of the CPRIT Grant (as may be extended upon mutual agreement with CPRIT); and (iii) pay all remaining Phase II costs to complete the ongoing Phase II clinical trial of the Product in non-muscle invasive bladder cancer, as specified on Schedule 3.1.5 attached hereto; it being understood and agreed that all amounts owed by Biodexa for the CPRIT Grant under this Agreement shall be offset, dollar-for-dollar, by the amount of the Upfront Cash Payment of Five Hundred Thousand Dollars ($500,000.00) as a credit for the amounts for the CPRIT Grant under this Agreement.

3.1.6 Initial Dispute Resolution Procedures. Subject to the provisions of this Section 3.1.3, actions to be taken by the JDC shall be taken only following a unanimous vote, with each Party having one (1) vote. If the JDC fails to reach unanimous agreement on a matter before it for decision for a period in excess of thirty (30) days, the matter shall be resolved as provided in Sections 18.1 and 18.2.

3.2 Transfer of Regulatory Approvals and Regulatory Submissions; Third-Party Contracts.

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

3.2.1 Within sixty (60) days following the Handover Trigger, Emtora shall transfer ownership to Biodexa of any and all Regulatory Submissions and Regulatory Approvals (including the IND and any foreign counterpart thereof) for the Product in the Field in the Territory (and transfer all related correspondence to and from such Regulatory Authorities), and thereafter Biodexa (or its designee) shall file and hold title to all Regulatory Submissions and Regulatory Approvals and supplements thereto relating to the Product in the Field in the Territory. In the event of failure to assign such Regulatory Submissions and Regulatory Approvals to Biodexa as required by this Section 3.2, Emtora hereby consents and grants to Biodexa the right to access and reference (without any further action required on the part of Emtora, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such Regulatory Submissions and Regulatory Approvals for the purposes of developing and commercializing the Product in the Field in the Territory.

3.2.2 As of the Effective Date, Emtora shall assign to Biodexa all written agreements with Third Parties regarding the Product which are set forth on Schedule 3.2.2, or where such agreements are not freely assignable or not solely related to the Product, cooperate with Biodexa to transfer or otherwise replace such agreement with the Third Party (provided that Emtora shall remain liable for liabilities related to any breaches, defaults, acts or omissions occurring prior to the date of such transfer).

3.3 Cooperation. Emtora shall provide, at Biodexa's cost, reasonably required documents (to the extent in the possession or Control of Emtora) to Biodexa for use in making Regulatory Submissions to Regulatory Authorities for the Product in the Field in the Territory and maintaining such Regulatory Approvals.

3.4 Correspondence from a Regulatory Authority. Each Party shall promptly (and in any event, within fifteen (15) calendar days of the date of receipt of notice) notify the other Party in writing of, and shall provide the other Party with copies of, any material correspondence received from a Regulatory Authority in the Territory relating to the Product. In the event that a Party receives any material regulatory letter relating to the Product requiring a response, the other Party will reasonably cooperate with the receiving Party in preparing such response and will promptly provide the receiving Party with any data or information in its possession required by the receiving Party in preparing any such response.

3.5 Emtora Intellectual Property and Materials Transfer. Emtora has disclosed to Biodexa true, accurate and complete copies of all Emtora Intellectual Property reasonably considered by Emtora to be necessary for the development, manufacture and commercialisation of the Product in the Field in the Territory, in each case to the extent developed on or prior to the Effective Date and in its current (electronic or other) format as Biodexa may reasonably request (including by download of digital files to a secure website or e-room designated and controlled by Biodexa, or transfer of hard copies of any documents not in electronic format). Within a reasonable time not to exceed sixty (60) days following the Handover Trigger, Emtora will furnish to Biodexa any tangible materials Controlled by Emtora that relate to or embody the Product, including all research grade samples of all Product discovered or developed by Emtora prior to the Handover Trigger ("Tangible Materials"). Biodexa acknowledges and accepts that any Tangible Materials provided by Emtora under this Agreement are provided in their condition and form as of the Effective Date; Emtora gives no warranty or representation as to the suitability of such Tangible Materials for any given purpose. On a Calendar Quarter basis, or more frequently at the reasonable request of Biodexa during the Term, Emtora, to the extent not previously provided to Biodexa, will provide to Biodexa a written summary of all Emtora Intellectual Property that comes into the Control of Emtora and/or its Affiliates following the Effective Date that relates to the development of the Product. Further, Emtora will make appropriate personnel (directly, or through an Affiliate) available to Biodexa at reasonable times and places, and upon reasonable prior notice for the purpose of assisting Biodexa to understand and use the Emtora Intellectual Property for the Product. Emtora shall provide to Biodexa copies of all clinical data and results from any and all completed clinical trials for the Product ("Clinical Data"), in electronic form or other mutually agreeable alternate form within sixty (60) days following the Effective Date. Emtora will also provide to Biodexa copies of all manufacturing data in its possession, in electronic form or other mutually agreeable alternate form within sixty (60) days following the Effective Date, and facilitate access to any Third Party subcontractors (such as CMOs) for access to manufacturing data in their possession.

4. FINANCIAL TERMS

4.1 Upfront Payments.

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

4.1.1 In consideration for the exclusive rights granted by Emtora to Biodexa under the Emtora Intellectual Property to develop, distribute, market and sell the Product in the Field in the Territory pursuant to Section 2.1, and in consideration of the other transactions contemplated under this Agreement, Biodexa hereby agrees to pay to Emtora consideration equal to $787,403.88 in cash (the "Upfront Payment").

4.1.2 At Biodexa's option, the liability to pay the Upfront Payment may be settled and satisfied by (x) payment of Five Hundred Thousand Dollars ($500,000.00) in cash in immediately available funds to an account designated by Emtora, which amount Biodexa shall initiate transfer on the Effective Date (the "Upfront Cash Payment"); (y) an issuance of ADSs fully paid up to Emtora, on or prior to the fifth (5^{th}) Business Day following the Effective Date, of 378,163 ADSs (calculated as set forth on Schedule 4.1); and (z) the release and waiver of all the amounts owed to Biodexa (including interest) under the Promissory Note, which are hereby forgiven effective as of the Effective Date.

4.2 Milestones. Subject to Section 4.4.5(b) below, Biodexa shall promptly notify Emtora in writing of the occurrence of the milestone triggers set out in the following tables. Biodexa shall pay Emtora the applicable milestone payments set forth in this Section 4.2 (each, a "Milestone Payment") within thirty (30) days following satisfaction of the conditions to payment set forth in this Section 4.2 by Biodexa, its Affiliates or their Sublicensees. The Parties understand and agree that each Milestone Payment will be made one time only upon the first realization of the relevant conditions set forth in this Section 4.2. The applicable Milestone Payment shall become payable in accordance with this Section 4.2 when the relevant milestone trigger occurs, as provided for in the following tables.

General Milestones (subject to Section 4.4.5(b) below):

Sales Milestone:

[***]

Quarterly Payment:

On the first day of the Calendar Quarter following the Effective Date, and on the first day of each Calendar Quarter thereafter prior to the Handover Trigger , Biodexa shall pay Emtora two [***], less [***] of any Research Sales by Emtora in the applicable Calendar Quarter (the "Gross Profit Reduction"), which percentage represents the good faith estimate of anticipated gross margin associated with such anticipated Research Sales (each such payment, the "Quarterly Payment") (provided that these amounts shall be pro-rated accordingly for any period that is less than a full Calendar Quarter); provided that Biodexa may in its sole discretion settle the payment due to Lumabridge, LLC (as specified on Schedule 4.2 attached hereto), in which case such payment shall reduce the Quarterly Payment to no less than [***] for each Quarterly Payment after the initial Quarterly Payment (before giving effect to the Gross Profit Reduction).

4.3 Royalties. During the Royalty Term (but subject to Section 4.4.5 and Section 4.7 below), Biodexa shall pay Emtora non-refundable, non-creditable royalties on Annual Net Sales by Biodexa, its Sublicensees and any of their respective Affiliates, on a country-by-country basis, equal to the following portions of Annual Net Sales multiplied by the applicable royalty rate described below for such portion:

[***]

The Royalty Rates set forth in the table above shall each increase by [***] when the royalties payable under Attachment D to the CPRIT Grant are reduced to [***] in accordance with the terms set forth in Attachment D to the CPRIT Grant. Royalties shall be payable, on a country-by-country basis, commencing upon First Commercial Sale and ending upon the latest of (i) the expiration of the last-to-expire Valid Claim in the Patents within the Emtora Intellectual Property that Covers the Product in such country; (ii) the expiration of all Regulatory Exclusivity for such Product in such country, and (iii) the tenth (10^{th}) anniversary of the First Commercial Sale of the Product in such country (the "Royalty Term"). Within forty-five (45) days after the end of each Calendar Quarter commencing with the First Commercial Sale of the Product in the Territory, Biodexa shall provide Emtora

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

with a Net Sales Report. Biodexa shall pay to Emtora the royalty amounts due with respect to a given Calendar Quarter within forty-five (45) days after the end of such Calendar Quarter.

4.4 Royalty Reductions; Sharing of Sublicense Milestone Income.

4.4.1 Biodexa's royalty obligations to Emtora under Section 4.3 shall be reduced in respect of Net Sales made in any country in the Territory, to [***] of the amounts otherwise payable pursuant to Section 4.3 during any portion of the Royalty Term in which there is not at least one (1) Valid Claim of a Patent within the Emtora Intellectual Property that Covers the Product in such country.

4.4.2 If, during the Term, Biodexa determines, in its reasonable judgment, that it is necessary to obtain rights under any Blocking 3rd Party IP in order to Exploit a Product in accordance with this Agreement, then Biodexa shall promptly notify Emtora. In the event a license or acquisition of Blocking 3rd Party IP is obtained, and any royalties, milestones, or other payments are paid by Biodexa to any Third Party to license or acquire such Blocking 3rd Party IP ("Third Party Payments"), Biodexa shall have the right to reduce the royalties, milestones, and other payments otherwise payable to Emtora under this Agreement in a given period by up [***] of the Third Party Payments made in such period (and any remaining amounts may be carried forward and applied as deductions from time to time in accordance with this Section 4.4), subject to Section 4.4.4 below.

4.4.3 If, at any time during the Term, (a) one or more Generic Products receives Regulatory Approval in a given country and is sold in that country by one or more Third Parties, and (b) on a Calendar Quarter-by-Calendar Quarter basis, there is a [***] decrease in amounts (as measured by unit volume) invoiced by Biodexa or its Affiliates on sales of the Product to Third Party purchasers in any given Calendar Quarter as compared to the amounts (as measured by unit volume) invoiced by Biodexa or any of its Affiliates on sales of the Product during any of one (1) of the immediately preceding four Calendar Quarters, then Biodexa's royalty obligations to Emtora under Section 4.3 in respect of that country shall be reduced to [***] of the amounts otherwise payable pursuant to Section 4.3 for the remainder of the Term, *provided* that in the event such Generic Product is no longer offered for sale in a given country, any reduction applied in such country in accordance with this Section 4.4.3 shall be disapplied until such time that subparagraphs (a) and (b) of this Section arise.

4.4.4 In no event will the reductions under Sections 4.4.1, 4.4.2 and 4.4.3 reduce the royalties payable to Emtora under this Agreement in any Calendar Quarter by greater than [***] in aggregate of the amounts otherwise payable under Section 4.3 (without reduction); provided that any deductions not permitted to be made in respect of a given Calendar Quarter as a result of this Section shall be carried forward for deduction in respect of royalties for future Calendar Quarters until fully exhausted.

4.4.5 On a country-by-country basis, in the event of any sublicense by Biodexa to a Sublicensee who is a Third Party of any and all rights to commercialize the Product pursuant to Section 2.1 (a "Third Party Sublicense") during the Royalty Term, the Parties hereby agree as follows:

(a) Biodexa shall pay to Emtora, within thirty (30) days following receipt of any of the following during the Term: (i) prior to any Change of Control Closing Date (as defined in the warrant attached as Exhibit 1), [***] of all Sublicense Milestone Income (whether or not cash) received from such Third Party in accordance with the definitive agreement for such Third Party Sublicense; (ii) prior to any Change of Control Closing Date, [***] of all cash and equity consideration (including any earn-outs) in connection with an Emtora SPV Sale; and (iii) effective as of the Change of Control Closing Date, a warrant in the form attached hereto as Exhibit 1 covering the number of ADSs equal to [***] of BDRX Ordinary Shares (calculated on a Fully-Diluted basis as set forth in the warrant in Exhibit 1), which has a strike price equal to the offering price set forth in the warrant and which is only exercisable upon a Change of Control (as defined in the warrant attached as Exhibit 1); and

(b) [***] of all such amounts described in clause (a) of this Section 4.4.5 above shall be fully creditable against the Milestone Payments described in Section 4.2 (other than the Sales Milestone referred to above) which have not been previously paid.

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

4.5 All payments to either Party under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as the receiving Party may from time to time designate by notice to the paying Party. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate's or Sublicensee's standard conversion methodology consistent with Accounting Standards.

4.6 Financial Records. Biodexa shall, and shall cause its Affiliates and Sublicensees to, keep complete, true and accurate books and records in accordance with Accounting Standards pertaining to Net Sales of Product, royalties and other sums payable under this Agreement in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its obligations under this Agreement. Such books and records shall be retained by Biodexa and its Affiliates and Sublicensees until the later of (a) three (3) years after the end of the Calendar Year to which such books and records pertain, and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

4.7 Audit. At the request of Emtora, Biodexa shall, and shall cause its Affiliates and Sublicensees to, permit an independent public accounting firm of nationally recognized standing designated by Emtora, at reasonable times during normal business hours and upon reasonable notice, to audit the relevant reports, statements, books and records maintained pursuant to Section 4.6 to ensure the accuracy of all reports and payments, including Net Sales and royalty calculations, made hereunder. Such examinations may not (a) be conducted more than once with respect to any specific period of time, or (b) be conducted more than once in any twelve (12) month period (other than any year in which a change of control of Biodexa occurs, in which year such right may be exercised twice). Biodexa shall, and shall cause its Affiliates and Sublicensees to, provide reasonable assistance to the accounting firm to enable the accounting firm to carry out such audit. The accounting firm shall disclose to Emtora only whether the reports are correct or not, and the specific details concerning any discrepancies. No other information shall be shared. In the event that the audit reveals a variance of more than five percent (5%) from the amounts in the Net Sales Report, Biodexa shall bear the cost of the audit. In the event that the audit reveals a variance of less than five percent (5%) from the amounts in the Net Sales Report, Emtora shall bear the cost of the audit. If such audit concludes that (a) additional amounts were owed by Biodexa, Biodexa shall pay the additional amounts, or (b) excess payments were made by Biodexa, in Biodexa's sole and exclusive discretion, either Emtora shall reimburse such excess payments or future amounts owed by Biodexa will be reduced by the amount of such excess payments, in either case ((a) or (b)), within sixty (60) days after the date on which such audit is completed by Emtora's designated accounting firm.

4.8 No Limitation. For clarity, nothing contained in this Section 4 shall in any way limit a Party's right to recover damages for breach of this Agreement.

4.9 Withholding Taxes. The amounts payable pursuant to this Agreement shall not be reduced on account of any taxes unless required by Applicable Law. Where any sum due to be paid to either Party hereunder is subject to any withholding or similar tax, the Parties shall use their Commercially Reasonable Efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, the payor shall remit such withholding or similar tax to the appropriate government authority in a timely manner, deduct the amount paid from the amount due to payee and secure and send to payee the best available evidence of the payment of such withholding or similar tax within sixty (60) days following that payment. In the event that a government authority retroactively determines that a payment made by a Party to the other pursuant to this Agreement should have been subject to withholding or similar (or to additional withholding or similar) taxes, and such Party (the "Withholding Party") remits such withholding or similar taxes to the government authority, including any interest and penalties that may be imposed thereon (together with the tax paid, the "Withholding Amount"), the Withholding Party will have the right (a) to offset the Withholding Amount, against future payment obligations of the Withholding Party under this Agreement, (b) to invoice the other Party for the Withholding Amount (which shall be payable by the other Party within sixty (60) days of its receipt of such invoice) or (c) to pursue reimbursement by any other available remedy.

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

4.10 Indirect Taxes. All payments are exclusive of value added taxes, sales taxes, consumption taxes and other similar taxes (the "Indirect Taxes"). If any Indirect Taxes are chargeable in respect of any payments, the paying Party shall pay such Indirect Taxes at the applicable rate in respect of such payments following receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by the receiving Party in respect of those payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes. If the Indirect Taxes originally paid or otherwise borne by the paying Party are in whole or in part subsequently determined not to have been chargeable, all necessary steps will be taken by the receiving Party to receive a refund of these undue Indirect Taxes from the applicable Governmental Authority or other fiscal authority and any amount of undue Indirect Taxes repaid by such authority to the receiving Party will be transferred to the paying Party within sixty (60) days of receipt.

5. DILIGENCE

5.1 Prior to the Handover Trigger, the Parties shall cooperate and be responsible for using Commercially Reasonable Efforts to develop and commercialise the Product (either itself or through its Affiliates and Sublicensees) in the Territory, for FAP in accordance with the CPRIT Grant, including the CPRIT Goals and Objectives and the Budget. Following the Handover Trigger, Biodexa shall be responsible for using Commercially Reasonable Efforts to develop and commercialise the Product (either itself or through its Affiliates and Sublicensees) in the Territory.

6. MANUFACTURE

6.1 From the date of the Handover Trigger, Biodexa shall be responsible for the manufacture and supply, at its expense, of all requirements of API and Product for the performance of all development, clinical and commercial activities under this Agreement. Biodexa will use its Commercially Reasonable Efforts to cause Products manufactured and supplied by or on behalf of Biodexa pursuant to this Agreement to be manufactured in accordance with GMP and to otherwise comply with Applicable Laws.

6.2 Biodexa shall have the sole right and responsibility to determine and initiate all recalls, market suspensions or market withdrawals that may be necessary and for handling all returns, recalls or withdrawals, order processing, invoicing, collection, distribution, and inventory management with respect to the Product in the Field in the Territory. If any Regulatory Authority seizes any Product or requests the recall of any Product, then the Party becoming aware of such seizure or receiving notice of such recall from such Regulatory Authority, as the case may be, shall notify the other Party promptly of such seizure or recall. Biodexa shall ensure timely compliance with all Applicable Laws with respect to such seizure or recall and use their Commercially Reasonable Efforts to repossess the Product.

6.3 Biodexa shall bear all costs relating to all recalls and market withdrawals whether voluntary or requested or required by Applicable Laws or by any Regulatory Authority.

6.4 Each Party shall notify the other Party promptly if such Party becomes aware of any of the following: (a) any pending or threatened litigation, governmental investigation, proceeding or action involving the Product; (b) any defective, adulterated or misbranded Product or any information which may suggest that any Product is or may be defective, adulterated or misbranded; (c) any other event which such Party believes is likely to materially adversely affect any Product.

7. BIODEXA OPTION TO ACQUIRE EMTORA

7.1 Beginning upon the acceptance of the filing of an NDA application for the Product with the FDA and ending ninety (90) days after acceptance of the filing of the NDA by the FDA (the "Option Period"), Emtora shall exclusively negotiate with Biodexa in good faith for the acquisition of all of the capital stock (and derivative rights thereto) of Emtora by Biodexa at a purchase price on commercially reasonable terms (the "Purchase Price"), which shall include delivery of Emtora and its assets free of payables and other liabilities (the "Option"). The Parties shall be obligated to exclusively negotiate in good faith during the Option Period to agree upon the Purchase Price and terms of sale with the intent of closing the sale of all Emtora's capital stock to Biodexa (the "Emtora Sale") as soon as practicable thereafter. Upon the closing of the Emtora Sale, all milestone payments, royalties, and other amounts due from Biodexa to Emtora under Section 4 shall be extinguished in exchange for the Purchase

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

Price. If Biodexa does not exercise the Option during the Option Period or the Emtora Sale fails to close following Biodexa's exercise of its Option, (i) the Quarterly Payments to Emtora shall continue until the First Commercial Sale of the Product; and (ii) Emtora may negotiate with Third Parties regarding an acquisition of Emtora and/or Emtora's rights to receive payments under this Agreement.

8. REPRESENTATIONS AND WARRANTIES AND COVENANTS

8.1 Each Party hereby represents and warrants to the other Party as follows:

(a) Such Party is a company/corporation, duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent such Party from performing its obligations under this Agreement;

(b) The execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary corporate or organizational action. This Agreement is a legal and valid obligation binding on such Party and enforceable in accordance with its terms and does not (i) to such Party's knowledge, violate any law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over such Party, or (ii) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which such Party is a party or by which it is bound;

(c) Other than the Regulatory Approvals, no government authorization, consent, approval, license, exemption of, or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Laws currently in effect, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements;

(d) Such Party is (i) not, and during the Term shall not be, a Debarred Entity; and (ii) not currently using, and will not in the future use, in any capacity, in connection with the performance of its duties or obligations hereunder, the services of any person or entity debarred or subject to debarment under 21 U.S.C. § 335a or otherwise disqualified or suspended from performing services or otherwise subject to any restrictions or sanctions by the FDA (a "Debarred Entity"). Such Party shall immediately notify the other Party in writing if either such Party or any person or entity who is performing services on its behalf hereunder is or becomes a Debarred Entity or if any action, claim, investigation, or other legal or administrative proceeding is pending or, to the best of such Party's knowledge, threatened, that would make the other Party or any person or entity performing services hereunder a Debarred Entity;

(e) Such Party will not take or permit its Affiliates to take, any action to make the Product unfit for commerce under any applicable regulatory requirements in the Territory (including, but not limited to, being adulterated or misbranded as defined under the FD&C Act or becoming an article that may not, under the FD&C Act, be introduced into interstate commerce);

(f) as of the Effective Date there are no litigation proceedings, investigations or claims of any nature pending against, or to its Knowledge, threatened by or against, such Party that may affect fulfilment of the rights and obligations of the Parties under this Agreement; and

(g) Anti-Bribery and Anti-Corruption Compliance. Each Party and its Affiliates (i) have complied and shall comply with all Applicable Law governing bribery, money laundering, and other corrupt practices and behaviour (including, as applicable, the U.S. Foreign Corrupt Practices Act and UK Bribery Act) and (ii) shall not, directly or indirectly, offer, give, pay, promise to pay, or authorize the payment of any bribes, kickbacks, influence payments, or other unlawful or improper inducements to any Person in whatever form (including gifts, travel, entertainment, contributions, or anything else of value).

8.2 Each Party covenants, as the case may be, to the other Party that such Party shall perform its respective obligations under this Agreement in compliance in all material respects with all Applicable Laws.

8.3 Emtora represents, warrants and/or covenants, as the case may be, to Biodexa that:

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

a. to its Knowledge, as of the Effective Date, the manufacturing, commercialization, selling and/or marketing of the Product in the Territory, will not infringe or misappropriate any Intellectual Property Rights, including Patents, of Third Parties;

b. as of the Effective Date it has not received a claim by a Third Party that the Product, its manufacturing process, and/or its use would be encompassed by a Patent or patent application or other Intellectual Property Rights owned or controlled by such Third Party in the Territory;

c. as of the Effective Date, Emtora has the full right, power and authority to grant all the rights, title and interests under this Agreement to Biodexa; and

d. Schedule 2 sets forth a complete list of all Emtora Patents as of the Effective Date that Cover the Product in the Territory. Except as set forth on Schedule 2, Emtora, together with its Affiliates, is the sole and exclusive owner of, or otherwise has the sole and exclusive right, title and interest in and to, the Patents listed on Schedule 2.

8.4 Covenants. Biodexa agrees that it will use its Commercially Reasonable Efforts to undertake and update and maintain during the Term an internal compliance program under which its (or its Affiliates') employees are required to comply with all Applicable Law, including applicable local and international anti-bribery and anti-corruption laws and regulations. Biodexa will ensure that its respective employees and agents are regularly trained, and will continue to be regularly trained, on the requirements of its compliance program and compliance with applicable anti-bribery and anti-corruption laws.

8.5 EXCEPT AS OTHERWISE SPECIFICALLY STATED IN THIS AGREEMENT, NEITHER PARTY GIVES ANY OTHER REPRESENTATIONS OR WARRANTIES, COVENANT OR AGREEMENT (WHETHER EXPRESS OR IMPLIED). ANY REPRESENTATION, WARRANTY, COVENANT OR AGREEMENT SET FORTH IN THIS AGREEMENT IS EXCLUSIVE AND IN LIEU OF ANY OTHER WARRANTIES, WRITTEN OR ORAL, DIRECT, OR IMPLIED OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, EXPRESS OR IMPLIED WARRANTIES FOR MERCHANTIBILITY, QUALITY OR FITNESS FOR A PARTICULAR PURPOSE. FOR THE SAKE OF CLARITY, MANDATORY STATUTORY WARRANTIES ARE NOT EXCLUDED.

9. INDEMNIFICATION; LIMITATIONS ON LIABILITY

9.1 Biodexa shall indemnify and hold harmless each of Emtora and its Affiliates and their respective directors, officers, stockholders, partners, employees, agents, successors and permitted assigns ("Emtora Indemnitees") from and against any and all losses, damages, obligations, liabilities, claims, actions, judgments, settlements, interest, awards, penalties, fines, fees, costs, or expenses of whatever kind, including reasonable attorneys' fees, fees and the costs of enforcing any right to indemnification under the Agreement and the cost of pursuing any insurance providers (collectively, "Losses"), resulting from, based on, or arising out of Third Party claims arising from: (i) the alleged or actual gross negligence, fraud or wilful misconduct of Biodexa or its Affiliates; (ii) any breach by Biodexa of its representations, warranties or obligations pursuant to this Agreement; (iii) the manufacturing, development and commercialization activities (including packaging and storage of the Product) relating to the Product conducted by or on behalf of Biodexa, its Affiliates or their Sublicensees; and (iv) any Third Party Intellectual Property Rights infringement action in respect of the Biodexa Trade Marks; and (v) the packaging of the Products. Notwithstanding the foregoing, Biodexa shall have no obligations under this Section 9.1 with respect to any Losses for which Emtora is required to indemnify the Biodexa Indemnitees under Section 9.2 or which are the result of any fraud or wilful misconduct of Emtora.

9.2 Emtora shall indemnify and hold harmless each of Biodexa and its Affiliates and their respective directors, officers, stockholders, partners, employees, agents, successors and permitted assigns ("Biodexa Indemnitees") from and against any and all Losses resulting from, based on, or arising out of Third Party claims arising from: (i) the alleged or actual gross negligence, fraud or wilful misconduct of Emtora or its Affiliates; (ii) any breach by Emtora of its representations or warranties pursuant to this Agreement; and (iii) any amounts owed by Emtora under the CPRIT Grant, UT License and Emtora Noteholder Royalty prior to the Effective Date. Notwithstanding the foregoing, Emtora shall have no obligations under this Section 9.2 with respect to any Losses for which Biodexa is required to indemnify the Emtora Indemnitees under Section 9.1 or which are the result of any fraud or wilful misconduct of Biodexa.

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

9.3 Neither Party shall be liable to compensate the other Party for any indirect, incidental, special, punitive, exemplary, speculative or consequential damages arising out of or in connection with this Agreement including, but not limited to, any loss of use, loss of opportunity, indirect loss of income or profit from third parties, irrespective of whether it had an advance notice of the possibility of any such damages. The foregoing limitations of liability shall not apply with respect to a Party's fraud, gross negligence or wilful misconduct or breach of Section 11 (Confidential Information) or to indemnification for amounts paid or payable to Third Parties in respect of any Third Party claim for which indemnification hereunder is otherwise required or to any liability that may not be excluded under Applicable Law including liability for death or personal injury caused by a Party's gross negligence.

9.4 All indemnification claims in respect of a Party, its Affiliates, or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "Indemnified Party"). A Party that intends to claim indemnification under this Section 9 shall promptly inform the indemnifying Party in writing of any Third Party claim, in respect of which the indemnitee intends to claim such indemnification. Any such indemnification notice shall contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party claims. The Indemnified Party shall provide the indemnifying Party with reasonable assistance, at the indemnifying Party's expense, in connection with the defense of the Third Party claim for which indemnity is being sought, including providing such records, information, testimony, or witnesses and attending such meetings, proceedings, hearings, trials and appeals as may be reasonably requested. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing, which participation shall be at such Party's sole expense *except* where (a) the appointment of such counsel for such purpose is authorised in writing by the indemnifying Party, (b) the indemnifying Party has failed to assume such defense, or (c) the interests of the Indemnified Party and indemnifying Party are sufficiently adverse to prohibit their representation by the same counsel. In the event of (a) to (c), the reasonable costs and expenses incurred by the Indemnified Party in connection with the Third Party claim shall be reimbursed by the indemnifying Party on a Calendar Quarter basis in arrears. At its option so long as the Litigation Condition described below is satisfied, the indemnifying Party shall have the right to assume and conduct the defense of the Third Party claim with counsel of its choice reasonably acceptable to the Indemnified Party, by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an indemnification notice. The assumption of the defense of a Third Party claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. If it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party claim, the Indemnified Party shall reimburse the indemnifying Party for any Losses incurred by the indemnifying Party in its defense of the Third Party claim, including any costs and expenses paid by the indemnifying Party to the Indemnified Party in accordance with this Section.

In the event the indemnifying Party assumes the defense of a Third Party claim made against the Indemnified Party hereunder: (a) with respect to any Losses relating solely to the payment of money damages in connection with such Third Party claim (i.e. that shall not result in the Indemnified Party becoming subject to injunctive or other relief), the indemnifying Party shall have the sole right to enter into any settlement or otherwise dispose of such claim so long as the Indemnified Party is not subject to any liability or obligation to pay any amounts (the "Litigation Condition"); and (b) in respect of any other Losses, the indemnifying Party shall not enter into a settlement or otherwise dispose of the claim without obtaining the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim, provided that the Indemnified Party may not admit any liability with respect to, or settle, compromise or dispose of, any Third Party claim without the prior written consent of the indemnifying Party, which consent shall not be unreasonably withheld, conditioned or delayed.

The failure to deliver written notice to the indemnitor within a reasonable time after the commencement of any action with respect to a Third Party claim shall only relieve the indemnitor of its indemnification obligations under this Section 9 if and to the extent the indemnitor is actually prejudiced thereby.

10. INSURANCE

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

At all times during the Term through the Handover Trigger, Emtora will maintain adequate commercial general liability insurance and product liability insurance in respect of any claims which may be brought against it in relation to the performance of its activities hereunder and, thereafter, shall either continue such coverage for an additional three (3) years or purchase a tail insurance policy with a claims period of at least three (3) years. Biodexa will at all times during the Term of this Agreement, and for three (3) years thereafter (or at its option purchase a tail insurance policy with a claims period of three (3) years), maintain adequate commercial general liability insurance and product liability insurance in respect of any claims which may be brought against it in relation to the performance of its activities hereunder, including development, manufacture commercialization and distribution of the Products in the Territory. The Parties will each supply the other Party with a copy of the relevant insurance certificate on request. Such insurance shall not be construed to create a limit of a Party's liability with respect to its indemnification obligations under Section 9. Each Party shall provide the other with prompt written notice of cancellation, non-renewal or material change in such insurance or self-insurance that could materially adversely affect the rights of such other Party hereunder, and shall provide such notice within thirty (30) days after any such cancellation, non-renewal or material change.

11. CONFIDENTIAL INFORMATION

11.1 Each Party acknowledges that the Confidential Information constitutes and is comprised of valuable confidential proprietary information belonging to or licensed to the Parties. During the term of this Agreement, and for as long as the Confidential Information remains confidential, each Party shall and shall cause its officers, directors, employees, consultants and agents to, keep secret and confidential all Confidential Information belonging to the other, and neither of them shall:

11.1.1 disclose or make any Confidential Information belonging to the other available to any person or entity except to the extent permitted by Section 11.2 or Section 11.3(c); nor

11.1.2 use any Confidential Information belonging to the other for any purpose other than as expressly permitted pursuant to this Agreement.

Each Party will take such precautions as it normally takes with its own confidential or proprietary information to prevent the improper disclosure of Confidential Information disclosed to it pursuant to this Agreement, such precautions to be at a minimum commercially reasonable precautions.

11.2 Notwithstanding Section 11.1, each Party may, to the extent reasonably necessary in order to fulfil its obligations or exercise its rights under this Agreement, disclose Confidential Information of the other Party to, or permit its use by, its directors, officers, employees or consultants or agents provided that each Party shall prior to such disclosure:

11.2.1 inform the recipient as to the confidential nature of the Confidential Information;

11.2.2 direct any such recipient to treat and hold the Confidential Information as secret and confidential; and

11.2.3 ensure that employment contracts or consultancy contracts between itself and the recipients of the Confidential Information all include a confidentiality covenant providing that the recipient shall not disclose Confidential Information to any person or entity other than for the purpose of performing its obligations to the disclosing Party in connection with the performance of the disclosing Party's obligations under this Agreement.

11.3 Notwithstanding the foregoing:

a. The Parties may agree upon the content of a joint press release announcing this Agreement, the release of which press release the Parties shall coordinate. Neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed. In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

reasonably practicable (and, if permissible, in no event less than three (3) Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon.

b. Except as expressly provided herein or as required by Applicable Law, legal process, or stock exchange rule, neither Party shall mention or otherwise use the name of the other, its Affiliates or Sublicensees in any publication, press release, marketing or promotional material, or other form of publicity without the prior written approval of such other Party in each instance.

c. Biodexa, its Affiliates and their Sublicensees shall have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding the Product by publication, presentation or otherwise, provided, that (a) such disclosure is subject to the provisions of this Section 11 with respect to Emtora's Confidential Information, and (b) except as required by Applicable Law, Biodexa shall not use the name of Emtora (or insignia, or any contraction, abbreviation or adaptation thereof) without Emtora's prior written permission.

d. Each Party may disclose Confidential Information to the extent that such disclosure is:

(i) in the reasonable opinion of the receiving Party's legal counsel, required to be disclosed pursuant to law, regulation or a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental body of competent jurisdiction; provided, that the receiving Party shall first have given prompt written notice (and to the extent possible, at least five (5) Business Days' notice) to the disclosing Party and given the disclosing Party a reasonable opportunity to take whatever action it deems necessary to protect its Confidential Information (e.g. to obtain a protective order or confidential treatment) and that such disclosure is limited to that which is legally required to be disclosed;

(ii) made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for any Regulatory Approval in accordance with the terms of this Agreement; provided, that reasonable measures shall be taken to ensure confidential treatment of such Confidential Information to the extent practicable and consistent with Applicable Law; or

(iii) made by the receiving Party or its Affiliates to potential or actual investors or acquirers as may be necessary in connection with their evaluation of such potential or actual investment or acquisition; provided that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 11. Emtora shall have the right to disclose the terms of this Agreement to The University of Texas Health Science Center at San Antonio.

11.4 Each Party shall be responsible for ensuring compliance by their Affiliates, Sublicensees and representatives receiving Confidential Information hereunder with the foregoing confidentiality provisions and shall be liable for any breach of the confidentiality terms and conditions of this Agreement by any such Affiliates, Sublicensees or representatives receiving Confidential Information.

11.5 Upon the termination or expiration of this Agreement, upon the written request of the disclosing Party, the recipient of Confidential Information shall promptly redeliver to the disclosing Party all Confidential Information provided to the recipient in tangible form or destroy the same and certify in writing within thirty (30) days from the request of the disclosing Party or termination of the Agreement, as the case may be, that such destruction has occurred; provided, however, that nothing in this Agreement shall require the alteration, modification, deletion or destruction of computer backup tapes made in the ordinary course of business. Notwithstanding the foregoing, the recipient shall be permitted to retain in its files one copy of all

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

Confidential Information (a) to evidence the scope of and to enforce the Party's obligation of confidentiality under this Section 11; and (b) for the performance of any continuing obligations hereunder.

12. INTELLECTUAL PROPERTY RIGHTS

12.1 Subject to the UT License, Biodexa, at its sole cost and expense, shall be responsible for making all filings and listings of Patents in respect of the Product, if listable, with Regulatory Authorities in the Territory.

12.2 Inventorship of Inventions shall be determined by application of U.S. patent law pertaining to inventorship, and ownership shall follow inventorship.

12.3 Subject to Section 2, as between the Parties, each Party shall own and retain all right, title, and interest in and to any and all Intellectual Property Rights, Confidential Information and other information that are conceived, reduced to practice, discovered, developed, or otherwise made by such Party (or its Affiliates or Sublicensees) under or in connection with this Agreement, or Controlled (other than pursuant to the license in Section 2) by such Party or its Affiliates. Biodexa and/or its designee shall at all times have the right, but not the obligation, to register Biodexa Trade Marks relating to the commercialization of the Product in the Territory.

12.4 If Emtora or Biodexa becomes aware of misappropriation or infringement or threatened misappropriation or infringement of any Intellectual Property Rights relating to the Product (including Emtora Intellectual Property and Emtora Patents) by a Third Party in the Territory, such Party shall promptly notify the other Party in writing to that effect and provide a summary of the relevant facts and circumstances known to such Party relating to such infringement. Biodexa shall, in consultation with Emtora, have the right (but not the obligation) to control any claim, litigation or proceeding commenced against any such Third Party for infringement of Intellectual Property Rights with respect to the Product that is Controlled by Biodexa, Emtora or their respective Affiliates, at Biodexa's sole cost and expense. However, Biodexa shall obtain Emtora's consent prior to taking any actions that would materially affect Emtora's Intellectual Property Rights. Emtora shall have the right, at its own cost and expense, to join as a party to, and be represented in, any such action by counsel of its own choice. Biodexa shall keep Emtora reasonably informed of any actions or proceedings commenced against any such Third Party. Emtora shall cooperate fully with Biodexa with respect to such actions or proceedings, at Biodexa's cost. If Biodexa fails to initiate a claim, litigation or proceeding within thirty (30) days after written notice of such infringement is first provided by a Party under this Section 12.4 Emtora will have the right to initiate and control a claim, litigation or proceeding with respect to such infringement by counsel of its own choice, at its own cost expense and Biodexa will have the right, at its own cost and expense, to be represented in any such action by counsel of its own choice. Emtora shall keep Biodexa reasonably informed of any actions or proceedings commenced against any such Third Party. Biodexa shall cooperate fully with Emtora with respect to such actions or proceedings. If Biodexa ceases to pursue or intends to withdraw from a claim, litigation or proceeding instituted pursuant to this Section 12.4, it will promptly notify Emtora (in good time to enable Emtora to meet any deadlines by which any action must be taken to preserve any rights in such claim, litigation or proceeding) and Emtora may substitute itself for Biodexa and proceed under the terms and conditions of this Section. Any damages or other monetary awards recovered with respect to a claim, litigation or proceeding brought pursuant to this Section 12.4 will be shared as follows: (a) the amount of such recovery will first be applied to the Parties' reasonable out-of-pocket costs incurred in connection with such claim, litigation or proceeding (which amounts will be allocated pro rata if insufficient to cover the totality of such expenses); (b) then any remaining proceeds will be allocated between the Parties as follows: Biodexa will retain sixty percent (60%) of such proceeds and Emtora will receive forty percent (40%) of such proceeds. Biodexa shall have the sole right to control any claim, litigation or proceeding commenced against any Third Party for infringement of the Biodexa Trade Marks, at its sole cost and expense. Emtora agrees to provide any reasonable assistance requested by Biodexa at the relevant time in relation to such action or defense at Biodexa's expense. If responsible for controlling any such claim, suit, or proceeding, Emtora shall not settle, compromise or withdraw from such claim, suit or proceeding without the prior written consent of Biodexa, which shall not be unreasonably withheld, conditioned or delayed.

12.5 Biodexa shall have sole control of and shall be required to defend, at its sole cost and expense, any claim, litigation or proceeding that may arise related to a Third Party Patent or other Third Party Intellectual Property Right that is infringed or alleged to be infringed by the Product (or its manufacture, sale or use) as well as all negotiations for its settlement or compromise, provided that Biodexa shall not settle or compromise any claim, litigation or proceedings or enter into any consent order for the settlement or compromise thereof without the prior written consent of Emtora, which consent shall not be unreasonably withheld, conditioned or delayed. Emtora shall also have the right, but not the obligation, to participate, at its own expense, in

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

the defence thereof with counsel of its choice. Biodexa will keep Emtora reasonably informed about such proceedings. Emtora shall cooperate to the extent reasonably necessary and at Biodexa's cost to assist Biodexa in defending, contesting or otherwise protesting against any such actions. Except as otherwise set forth in this Section 12.5 and subject to any claim for indemnification pursuant to Section 9.1 and Section 9.2, each Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings including the reasonable fees and expenses of that Party's counsel.

12.6 If a Party initiates a claim, litigation or proceeding in accordance with Section 12.4, the other Party agrees to be joined as a party plaintiff where necessary under Applicable Law for such initiating Party to initiate and maintain such claim, litigation or proceeding. Each Party agrees to provide the other Party with reasonable assistance and cooperation with respect to any claims, litigations or proceedings conducted under Sections 12.5 and 12.6, with the reasonable internal and out-of-pocket costs and expenses of providing such assistance and cooperation to be borne as set forth in Sections 12.5 and 12.6, accordingly.

12.7 In consultation with Emtora, Biodexa shall have the right, but not the obligation, to prepare, file, prosecute, defend in any oppositions or post-grant proceedings, and maintain the Emtora Patents and any other Patents relating to inventions developed by or on behalf of or otherwise Controlled by Biodexa, its Affiliates or their sublicensees ("Arising Patent"), at Biodexa's sole cost and expense. The Parties agree to cooperate fully in the preparation, filing, prosecution, defense in oppositions or post-grant proceedings, and maintenance of the Emtora Patents and Arising Patents in the Territory, and to promptly inform one another of any matters coming to their attention that may materially affect such activities. Biodexa shall keep Emtora fully informed of all material steps with regard to the preparation, filing, prosecution, defense, and maintenance of such Patents, including by providing Emtora with a copy of material communications to and from any patent authority in the Territory, and by providing Emtora drafts of any material filings or responses to be made to such patent authorities in the Territory sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Emtora to review and comment thereon. Biodexa shall consider in good faith the requests and suggestions of Emtora with respect to such drafts and with respect to strategies for filing and prosecuting such Patents in the Territory. Biodexa shall promptly inform Emtora of any adversarial patent office proceeding or sua sponte filing, including a request for, or filing or declaration of, any opposition, reexamination or other post-grant challenges or proceedings relating to such Patents in the Territory. The Parties shall thereafter consult and cooperate to determine a course of action with respect to any such proceeding in the Territory and Biodexa shall consider in good faith all comments, requests and suggestions provided by Emtora. If Biodexa decides not to prepare, file, prosecute, defend in an opposition or post-grant proceeding, or maintain an Emtora Patent or Arising Patent in a country or other jurisdiction in the Territory, Biodexa shall provide reasonable prior written notice to Emtora of such intention. Emtora shall thereupon have the right, but not the obligation, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution, defense, and maintenance of such Patents at its expense in such country or other jurisdiction. In the event Emtora assumes such control, within thirty (30) days Biodexa shall promptly deliver to Emtora or its designee copies of all necessary files related to such Patent and take all actions and execute all documents reasonably necessary for Emtora to assume such control. The Parties shall execute all papers and instruments, or require their employees or contractors to execute such papers and instruments, so as to (a) effect the ownership of Intellectual Property Rights set forth in this Section 12; (b) enable the other Party to apply for and to prosecute Patent applications in the Territory; (c) obtain and maintain any Patent term extensions, supplementary protection certificates, and the like with respect to such Patents in the Territory; and(d) provide assistance necessary for registering any license, transfer or assignment with applicable governmental authorities, in each case ((a), (b), and (c)) to the extent provided for in this Agreement.

12.8 Biodexa shall have the sole right, but not the obligation, to seek, at its cost, in Emtora's name if so required, Patent term extensions, including any supplementary protection certificates and the like available under Applicable Laws for the Product in the Field in the Territory. Biodexa will keep Emtora reasonably informed of its efforts to obtain such extensions. Emtora shall cooperate in connection with all such activities. Biodexa, its agents and attorneys will give due consideration to all suggestions and comments of Emtora regarding any such activities, including the choice of which Patent to apply term extensions to, but in the event of a disagreement between the Parties, Biodexa shall have the final decision-making authority.

12.9 The Parties shall discuss and agree upon an approach regarding the opt-in or opt-out under Article 83(4) of the Agreement on a Unified Patent Court between the participating Member States of the European Union (2013/C 175/01), with respect to any Emtora Patents. Biodexa shall have the right to make decisions regarding the opt-in or opt-out with respect to Arising Patents. Biodexa shall pay all fees associated with such decisions.

13. FORCE MAJEURE

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

13.1 If the performance of any obligation under this Agreement (other than delays or non-performance by a Party as and to the extent caused by the intentional act or omission of such Party or an obligation for the payment of money) is prevented, restricted or interfered with by reason of any Force Majeure event, then the Party so affected shall be excused, upon giving written notice to the other Party within thirty (30) days of such Force Majeure event, from such performance to the extent of such prevention, restriction or interference and such non-performance shall not be considered a default or breach of this Agreement, provided that the Party so affected shall use Commercially Reasonable Efforts to avoid or remove such causes of non-performance and shall continue performance to the extent reasonably possible and, in any event, at such time as the Force Majeure conditions come to an end. Written notice provided in accordance with this Section 13.1 shall state the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect.

13.2 If the Force Majeure conditions prevent performance completely and such prevention continues for more than sixty (60) days, then the Parties shall meet to discuss the anticipated duration of any further delay and any amendments to this Agreement proposed by a Party in good faith in light of the anticipated duration of any further delay.

14. ASSIGNMENT

14.1 Neither Party may assign, sell, transfer, delegate, pledge or otherwise dispose of its rights or obligations under this Agreement, in part or in whole to a Third Party, without the prior written consent of the other Party; provided that notwithstanding the foregoing, either Party may assign its rights and obligations under this Agreement without the consent of the other Party to an Affiliate; provided that such Party shall remain liable for the performance by its Affiliate(s) of its obligations hereunder. Either Party may also, without such consent, assign its rights and obligations under this Agreement in connection with a merger, consolidation or sale of all or substantially all of the business to which this Agreement relates provided that the assignee agrees to be bound by the terms of this Agreement. Any purported assignment in violation of this Section shall be null and void. For the avoidance of any doubt, Biodexa may delegate its rights and obligations under this Agreement to any of its Affiliates in order to carry out activities contemplated by this Agreement; it being understood that Biodexa shall remain liable for the performance by any such Affiliate(s) of its obligations hereunder and nothing herein shall discharge Biodexa from performing its obligations under this Agreement.

15. TERM AND TERMINATION

15.1 This Agreement shall become effective on the Effective Date and, subject to Sections 15.2, 15.3, and 15.4, shall continue in full force and effect on a country-by-country basis until the expiration of the Royalty Term in each such country in the Territory (the "Term"). After expiration of the Term on a country-by-country basis, the rights and licenses granted by Emtora to Biodexa under Section 2.1 to develop, manufacture and commercialize the Product in the Field throughout the Territory shall convert to an irrevocable, exclusive, royalty-free, fully paid-up, non-terminable right and license, with the right to grant sublicenses (through multiple tiers).

15.2 This Agreement may be terminated at any time by either Party on written notice if:

15.2.1 the other Party is in material breach of any obligations, terms or conditions hereunder and, in the case of a breach capable of remedy, it shall not have been remedied by the defaulting Party within sixty (60) days of written notice specifying the breach and requiring its remedy; or

15.2.2 if the other Party (a) voluntarily commences any action or seeks any relief regarding its liquidation or dissolution under any bankruptcy or insolvency or similar law, (b) proposes a written agreement of composition or extension of its debts, or (c) admits in writing its inability generally to meet its obligations as they fall due in the general course; or

15.2.3 if a proceeding is commenced or an order, judgement or decree is entered seeking the liquidation, reorganization, dissolution or similar act or any other relief under any bankruptcy, insolvency or similar law against the other Party, without its consent, which continues un-dismissed or un-stayed for a period of sixty (60) days.

15.3 Biodexa may terminate this Agreement by providing Emtora with one hundred and eighty (180) days' prior written notice, provided that no such termination notice may be issued until on or after the first anniversary of the Effective Date.

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

15.4 To the extent not prohibited by Applicable Law, Emtora may terminate this Agreement immediately upon written notice to Biodexa if Biodexa, its Affiliates, or its Sublicensees bring, or actively support a Third Party's efforts to bring, an action (including any interference or opposition proceedings) in a patent office or court challenging the validity, scope, enforceability or extension of any Patents forming part of the Emtora Intellectual Property.

16. RIGHTS ON TERMINATION

16.1 Any provisions required for the interpretation or enforcement of this Agreement shall survive the expiration or termination of this Agreement. Expiration or termination of this Agreement shall not relieve any Party of any obligations that are expressly indicated to survive expiration or termination and shall be without prejudice to any rights that have accrued to the benefit of a Party prior to such termination or expiration. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination, and for the avoidance of doubt, the provisions of Sections 1, 9, 10, 11, 12, 14, 16, and 17 through 20 shall survive the expiration or termination of the Agreement.

16.2 In the event of termination of this Agreement by either Party:

a. Subject to Biodexa's right to sell remaining inventory as described herein, all rights and licenses granted by the Parties hereunder shall terminate on the effective date of expiration or termination of this Agreement. In the event of termination by Biodexa in accordance with Section 15.3, from and after the effective date of expiration or termination of this Agreement and for a period of six (6) months, notwithstanding anything contained herein to the contrary, Biodexa shall be permitted, on a non-exclusive basis, to continue distributing, marketing and selling remaining inventory of Product held by Biodexa; provided, that Biodexa shall continue to be obligated to pay Emtora in respect of such Product in accordance with Section 4 during such time period.

b. Biodexa shall and hereby does effective as of the effective date of termination (other than any expiration pursuant to Section 15.1 or termination by Biodexa pursuant to Section 15.2), and shall procure that its Affiliates and Sublicensees shall:

(i) negotiate with Emtora to grant Emtora an exclusive license, with the right to grant multiple tiers of sublicenses, under any Intellectual Property Rights Controlled by Biodexa, its Affiliates and its Sublicensees necessary or useful for the development and commercialisation of the Product in the Field in the Territory, provided that: (1) the foregoing license shall exclude any license or other rights with respect to any active ingredient that is not the API unless the Product has been granted Regulatory Approval for use in combination with such other active ingredient in which case the license will include a license to the Intellectual Property Rights Controlled by Biodexa, its Affiliates or Sublicensees necessary to allow Emtora to continue to commercialize such Product for use in such combination; and (2) Emtora shall be solely responsible for any payments (including royalties, milestones and other amounts) payable to Third Parties in respect of Third Party Intellectual Property Rights relating to the Product, insofar as such payments relate to the Intellectual Property Rights of Biodexa, its Affiliates or their Sublicensees that are the subject of the license in this Section 16.2(b); and (3) each of Emtora and Biodexa shall negotiate the applicable royalty rates for such license in good faith.

(ii) where permitted by Applicable Law, transfer to Emtora all right, title, and interest in all Regulatory Submissions and Regulatory Approvals then Controlled by Biodexa, its Affiliates or their Sublicensees and related to the Products, and provide to Emtora copies of all such Regulatory Submissions and Regulatory Approvals including correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

communications with any Regulatory Authority), all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotional documents, adverse event files, complaint files, and clinical data and other data contained or relied upon in any of the foregoing;

(iii) notify the applicable Regulatory Authorities and take any other action reasonably necessary to effect the transfer set forth in subparagraph (ii) above;

(iv) Biodexa shall assign to Emtora for no charge all Biodexa Trade Marks that are being used exclusively in relation to the Product;

(v) unless otherwise required by Applicable Law, at Emtora's election, Biodexa shall transfer control to Emtora of all clinical studies with respect to the Products and Biodexa shall continue to conduct such studies, at Emtora's cost, for up to six (6) months to enable such transfer to be completed without interruption of any such clinical study; provided that (1) Emtora shall not have any obligation to continue any clinical study except if required by Applicable Law, and (2) with respect to any clinical study for which such transfer would be inconsistent with Applicable Law or which relates to the API in combination with any other agent, Biodexa shall, at Emtora's request, continue to conduct such clinical study to completion, at Emtora's cost; and

(vi) the Parties shall negotiate in good faith the terms and conditions of a written transition agreement ("Transition Agreement") pursuant to which they will effectuate and coordinate a smooth and efficient transition of relevant obligations and rights to Emtora as reasonably necessary for Emtora to exercise its licenses pursuant to Section 16.2(b). Such Transition Agreement shall include provisions to ensure the transfer to Emtora, or a Third Party nominated by Emtora, of the manufacturing process then being used by or on behalf of Biodexa to make the Product.

17. NOTICES

17.1 All notices and other communications in connection with this Agreement shall be in writing and shall be sent to the respective Parties at the following addresses, or to such other addresses as may be designated by the Parties in writing from time to time in accordance with this Section 17.1, by (a) registered or certified mail, postage prepaid, or by express courier service, service fee prepaid or (b) sent by email (with confirmation of receipt).

To Emtora:

Rapamycin Holdings, Inc. dba Emtora Biosciences, Inc.
16601 Blanco Road, Suite 120
San Antonio, Texas 78232
Attention: Mark Horsey, CFO

With a copy to:
Email: [***]

With a copy to:
Rosenthal Pauerstein Sandoloski Agather LLP
755 E. Mulberry Ave., Suite 200
San Antonio, TX 78209 USA
Attn: Samantha V. Rodriguez
Email: [***]

To Biodexa:

Biodexa Pharmaceuticals PLC
1 Caspian Point, Caspian Way
Cardiff, CF10 4DQ
United Kingdom
Attention: Chief Executive Officer

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

With a copy to:
Orrick, Herrington & Sutcliffe LLP
2100 Pennsylvania Ave N.W.
Washington, D.C. 20037
Attention: David Schulman
Email: [***]

All notices or communications shall be deemed given and received (a) if delivered by hand, immediately, (b) if sent by mail, ten (10) Business Days after posting, (c) if delivered by express courier service, three (3) Business Days in the jurisdiction of the recipient, or (d) if delivered by email, the date of transmission if delivered via email prior to 5:30 p.m. in the time zone of the recipient and otherwise the next day thereafter.

18. DISPUTE RESOLUTION

18.1 If any dispute arises between the Parties in regard to any aspect of this Agreement or the termination or purported termination of this Agreement, the Parties agree to attempt to resolve the matter amicably. If the Parties are unable to find a resolution within thirty (30) days from the notice of a dispute, then each Party shall refer the dispute to their respective senior officers. The Parties shall then have a further thirty (30) days to resolve the dispute. Any final decision mutually agreed by the senior officers shall be conclusive and binding on the Parties. If the Parties cannot resolve any dispute pursuant to this Section 18.1, either Party may seek to resolve the dispute in accordance with Section 18.2.

18.2 If any dispute is not resolved as provided in the preceding paragraph, whether before or after termination of this Agreement, it shall be referred to and finally resolved by binding arbitration under the Commercial Arbitration Rules of the American Arbitration Association ("AAA"), which Rules are deemed to be incorporated by reference into this Section 18. The number of arbitrators shall be one if the Parties can jointly select a single arbitrator. If, within thirty (30) days following the date upon which a claim is received by the respondent, the Parties cannot agree on a single arbitrator, the number of arbitrators will be three determined as follows: one arbitrator will be appointed by each Party and the third arbitrator will be appointed by the two Party-appointed arbitrators. If either Party fails to select an arbitrator, or if the Party-appointed arbitrators cannot agree on a third arbitrator within sixty (60) days of the respondent receiving the claim, such arbitrator will be appointed by the AAA, according to its Rules. The seat, or legal place, of arbitration shall be Wilmington, Delaware. The language to be used in the arbitration shall be English. Notwithstanding the provisions of this Section 18.2: (a) each Party shall have the right to seek interim, preliminary or provisional relief, including injunctive relief or other equitable relief in any court of competent jurisdiction as such Party deems necessary to preserve its rights and to protect its interests and to enforce any arbitral award in any court of competent jurisdiction, and (b) any dispute in respect of the validity of Intellectual Property Rights shall not be subject to this Section 18.2, but shall be determined by the national court of the country in which such Intellectual Property Right exists.

19. GOVERNING LAW & JURISDICTION

19.1 All issues and questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by, construed exclusively in accordance with, and enforced in accordance with the laws of the state of Delaware without reference to conflicts of laws principles.

20. GENERAL

20.1 No amendment, change, modification, extension, termination or waiver of the Agreement, or any of the provisions herein contained, shall be valid unless made in writing and signed by duly authorized representatives of the Parties hereto.

20.2 The waiver by either Party hereto of any right hereunder or the failure to perform, or of a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise. Any such waiver shall not be effective unless set forth in writing duly executed by or on behalf of the Party providing such waiver.

20.3 This Agreement together with its Schedules attached hereto, embodies the entire understanding between the Parties and supersedes any prior understanding and agreements between and among them respecting the subject matter hereof. There are no

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

representations, agreements, arrangements or understandings, oral or written, between the Parties hereto relating to the subject matter of the Agreement which are not fully expressed herein.

20.4 Any of the provisions of the Agreement which are determined to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof and without affecting the validity or enforceability of any of the terms of the Agreement in any other jurisdiction and, in lieu of such invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties.

20.5 Except as provided in Section 9, this Agreement shall be binding upon and inure solely to the benefit of the Parties and each Party's respective heirs, successors, permitted assigns and representatives, and nothing herein, express or implied, is intended to or shall confer upon any other Person any legal or equitable right, benefit or remedy hereunder.

20.6 It is expressly agreed that Emtora and Biodexa shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture, or agency, including for all tax purposes. Each Party acknowledges and agrees that such Party is not authorized to, and shall not, incur any liability for which the other Party may become directly, indirectly or contingently liable, nor shall it, except as explicitly provided in this Agreement, hold themselves out as having authority to represent or act on behalf of the other Party in any capacity whatsoever, nor shall the relationship between the Parties be construed as a co-partnership, joint venture or principal-agent relationship. The relationship of Emtora and Biodexa under this Agreement shall be that of independent contractor.

20.7 Notwithstanding anything contained in this Agreement to the contrary, in the event of any actual or threatened breach of any of the covenants or agreements in this Agreement, the Party who is or is to be thereby aggrieved shall have the right of specific performance and injunctive relief giving effect to its rights under this Agreement, in addition to any and all other rights and remedies at law or in equity. The Parties agree that any such breach or threatened breach would cause irreparable injury, that the remedies at law for any such breach or threatened breach, including monetary damages, are inadequate compensation for any loss and that any defense in any action for specific performance that a remedy at law would be adequate is waived.

20.8 Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

20.9 This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

20.10 The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, and may be delivered to the other Party by facsimile or electronic transmission thereof and such electronic signatures shall be deemed to bind each Party hereto as if they were original signatures.

21. CPRIT GRANT AND UPFRONT CASH PAYMENT USES

21.1 Emtora agrees that: (a) any amounts awarded under the CPRIT Grant, as well as the Upfront Cash Payment, shall only be deposited into a segregated deposit account ("Deposit Account") that is subject to an agreement between Biodexa, Emtora, and the applicable account bank in the form attached as Exhibit 2 (the "Deposit Account Control Agreement") following the creation of such Deposit Account, pursuant to which, among other things, such deposited CPRIT Grant amounts may only be withdrawn by the mutual written consent of Biodexa and Emtora; and (b) the Upfront Cash Payment shall only be used for the express purposes of the CPRIT Grant.

[*Signature Page Follows*]

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

IN WITNESS WHEREOF, the Parties have signed this Agreement as of the Effective Date.

BIODEXA PHARMACEUTICALS PLC

By: /s/ Stephen A. Stamp
Name: Stephen A. Stamp
Title: CEO

RAPAMYCIN HOLDINGS, INC. (DBA EMTORA BIOSCIENCES, INC.)

By: /s/ Frank Taffy
Name: Frank Taffy
Title: CEO & Board Member

Schedule 1

Rapamycin

[***]

Schedule 2

Emtora Patents and Patent Applications

Patents and Patent Applications

[***]

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

Trade Marks and Trade Mark Applications

Copyright

Schedule 3.1.1

[***]

Schedule 3.1.5

Biodexa Payments
Estimate of Remaining Expense on Non-Muscle Invasive Bladder Cancer Study

Outstanding Accounts Payable March 22nd, 2024:

[***]

Remaining Expenses due per Emtora Work Order #7 Issued to Lumabridge, LLC (formerly Cancer Insight, LLC) & Clinical Trial Material from Southwest Research Institute for supply thru Q2'25:

[***]

Schedule 3.2.2

Third-Party Contracts

Non-Muscle Invasive Bladder Study work orders to be transferred:

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

Item	Vendor
Emtora Work Order #7 Issued to Cancer Insight dated 5.8.2020	**Lumabridge, LLC**
Upcoming Placebo batch at Southwest Research Institute	**Southwest Research Institute**

Schedule 4.1

Upfront Payment ADSs

[***]

Schedule 4.2

Payment Due to Lumabridge under 8.22.2023 Memorandum of Understanding

[***]

Schedule 5

CPRIT Policies and Procedures Guide

Schedule 6

CPRIT Grant

Schedule 7

Emtora Noteholder Royalty

Rapamycin Holdings, Inc. dba Emtora Biosciences Noteholder Royalty Schedule

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

[***]

Exhibit 1

Form of Warrant

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

Exhibit 99.1

April 26, 2024

Biodexa Pharmaceuticals PLC
("Biodexa" or the "Company")

Biodexa Enters Into Exclusive License to eRapa™, a Phase 3 Ready Asset for the Treatment of Familial Adenomatous Polyposis (FAP)

Worldwide rights come with $17 million in non-dilutive grant funding for Pivotal Phase 3 trial in FAP

An estimated 100,000 in U.S. and Europe are afflicted with FAP, precancerous polyps that typically lead to surgical removal of the colon and/or rectum

In FAP, eRapa holds the potential of delaying or preventing surgical intervention

Multiple opportunities seen in other indications, including bladder and prostate cancers

- FAP is a substantially genetic orphan disease for which there are no approved therapeutic options; the current standard of care is surveillance and surgery
- Phase 3 FAP program is supported by a $17 million grant awarded from the Cancer Prevention and Research Institute of Texas ("CPRIT") in a competitive process
- Phase 2 results in FAP to be presented at two leading scientific conferences in Q2 '24
- Ongoing Phase 2 study in Non-muscle Invasive Bladder Cancer expected to read-out in Q2 '25
- Phase 2 study in NMI Bladder Cancer supported by $3 million grant from National Cancer Institute, part of the National Institutes of Health

Biodexa Pharmaceuticals PLC, (Nasdaq: BDRX), an acquisition-focused clinical stage biopharmaceutical company developing a pipeline of innovative products for the treatment of diseases with unmet medical needs, announced it entered into a definitive agreement with Rapamycin Holdings Inc. (d/b/a Emtora Biosciences) ("Emtora") for the rights to eRapa under an exclusive, worldwide license (with the ability to grant sublicenses) to develop, manufacture, commercialize and otherwise advance the clinical potential of eRapa.

Stephen Stamp, CEO and CFO of Biodexa said, "Acquiring a Phase 3 ready asset, particularly one supported by $17 million of non-dilutive grant funding, significantly advances Biodexa's oncology pipeline and adds numerous valuation catalysts for our stakeholders. We are delighted to be working with the Emtora team which has excelled in bringing eRapa close to the end of Phase 2 in Non-muscle Invasive Bladder Cancer and to the beginning of a Phase 3 trial in FAP, a devastating disease for which there is currently no approved pharmacological agent for altering its progression. Left untreated, it almost always leads to incredibly invasive surgery and a major deterioration in the quality of life.*"*

Stephen Dufilho, Executive Chairman of Emtora added, "The transaction with Biodexa is the culmination of a decade-long effort to advance our potentially game-changing eRapa to a registrational Phase 3 trial - and ultimately to patients in need. Our story began in San Antonio – where eRapa was originally invented at the University of Texas and funded in part by grants from the Cancer Prevention Research Institute of Texas. We thank the scientists, clinicians, investors and biotech executives that supported our efforts to reach this important milestone. We look forward to working with the Biodexa team as we embark upon this next chapter.**"**

About eRapa
eRapa is a proprietary oral tablet formulation of rapamycin, also known as sirolimus. Rapamycin is an mTOR (mammalian Target Of Rapamycin) inhibitor. mTOR has been shown to have a significant role in the signalling pathway that regulates cellular metabolism, growth and proliferation and is activated during tumorgenesis[1]. Rapamycin is approved in the US for organ rejection in renal transplantation as Rapamune®(Pfizer). Through the use of nanotechnology and pH sensitive polymers, eRapa is designed to address the poor bioavailability, variable pharmacokinetics and toxicity generally associated with the currently available forms of rapamycin. eRapa

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

is protected by a number of issued patents which extend through 2035, with other pending applications potentially providing further protection beyond 2035.

eRapa in FAP

FAP is characterized as a proliferation of polyps in the colon and/or rectum, usually occurring in mid-teens. There is no approved therapeutic option for treating FAP patients, for whom active surveillance and surgical resection of the colon and/or rectum remain the standard of care. If untreated, FAP typically leads to cancer of the colon and/or rectum. There is a significant hereditary component to FAP with a reported incidence of one in 5,000 to 10,000 in the US[2] and one in 11,300 to 37,600 in Europe[3]. eRapa has received Orphan Designation in the US with plans to seek such designation in Europe. Importantly, mTOR has been shown to be over-expressed in FAP polyps – thereby underscoring the rationale for using a potent and safe mTOR inhibitor like eRapa to treat FAP.

Emtora is currently completing an open-label, multi-center Phase 2 study in 30 patients with confirmed FAP with the primary endpoints of safety and tolerability, and percentage change in polyp burden after six months of treatment with eRapa. The Phase 2 study was partially funded by a $3.0 million grant from CPRIT.

The results of the Phase 2 study will be presented at two leading scientific conferences in Q2 24. Following a positive end of Phase 2 meeting with the FDA and, Emtora plans to initiate a Phase 3 multi-center, double-blind, placebo-controlled study in FAP. The Phase 3 study, which is expected to be registrational, plans to recruit approximately 140 patients across thirty or more sites, with a primary endpoint being time to a progression free survival event (the occurrence of which is related to the reduction in polyp burden studied in the earlier Phase 2 trial). The study is expected to recruit over 15 months and is supported by a further non-dilutive grant of $17.0 million from CPRIT.

eRapa in Non-Muscle Invasive Bladder Cancer

Non-muscle Invasive Bladder Cancer (“NMIBC”) refers to tumors found in the tissue that lines the inner surface of the bladder. The most common treatment is transurethral resection of the bladder tumor followed by intravesical Bacillus Calmette-Guerin (“BCG”) with chemotherapy depending upon assessment of risk of recurrence. NMIBC is the fourth most common cancer in men with an incidence of 10.1 per 100,000 and 2.5 per 100,000 in women[4].

Emtora’s ongoing multi-center, double-blind, placebo-controlled Phase 2 study in NMIBC is expected to enroll up to 166 patients with primary endpoints of safety/tolerability and relapse free survival after 12 months of treatment. The Phase 2 study, which is supported by a $3.0 million non-dilutive grant from the National Cancer Institute, part of the National Institutes of Health, is expected to read out in Q2 ’25.

Other Potential Indications for eRapa

A number of rare/orphan gastro-intestinal diseases (other than FAP) have been identified that share the strong scientific rationale (relating to mTOR inhibition) and support the potential utility of eRapa in FAP. Biodexa intends to evaluate such opportunities over the coming months, including by leveraging low-cost, investigator-sponsored trials to produce initial proof of concept data.

The License Transaction

The transaction terms include the issuance to Emtora of 378,163 of the Company’s American Depository Shares (representing 5% of the Company’s issued and outstanding ordinary shares on a fully-diluted basis (including in-the-money warrants)) at close. In addition, the Company may pay up to $41.5 million in sales milestones within the first six months of the first commercial sale of a first-approved indication of eRapa in major markets, with decreasing milestones for subsequent approvals for additional indications. The Company is also obligated to pay single digit tiered royalties on net sales of eRapa™ in addition to meeting Emtora’s legacy royalty obligations and paying Emtora a certain (stage-dependent) percentage of income derived from sublicensing and partnering of eRapa.

Ladenburg Thalmann & Co. Inc. acted as financial advisor to BioDexa in connection with this transaction.

The Cancer Prevention and Research Institute of Texas

To date, CPRIT has awarded $2.9 billion in grants to Texas research institutions and organizations through its academic research, prevention and product development research programs. CPRIT has recruited 237 distinguished researchers, supported the establishment, expansion or relocation of 43 companies to Texas and generated over $5.7 billion in additional public and private investment. CPRIT

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

funding has advanced scientific and clinical knowledge and provided 7.4 million life-saving cancer prevention and early detection services reaching Texans from all 254 counties. On November 5, 2019, Texas voters overwhelmingly approved a constitutional amendment to provide an additional $3 billion to CPRIT for a total $6 billion investment in cancer research and prevention. Learn more at https://cprit.texas.gov/.

1. Tian et al., mTOR Signaling in Cancer and mTOR Inhibitors in Solid Tumor Targeting Therapy, Int J Mol Sci. 2019 Feb; 20(3): 755
2. www.rarediseases.org
3. www.orpha.net
4. Cassell et al., World J Oncol. 2019 Jun; 10(3): 123–131

For more information, please contact:

Biodexa Pharmaceuticals PLC
Stephen Stamp, CEO, CFO
Tel: +44 (0)29 20480 180
www.biodexapharma.com

Emtora Biosciences
Mark Horsey, CFO
Tel: +1 210 381 2486
www.emtorabio.com

About Biodexa Pharmaceuticals PLC

Biodexa Pharmaceuticals PLC (listed on NASDAQ: BDRX) is a clinical stage biopharmaceutical company developing a pipeline of innovative products for the treatment of diseases with unmet medical needs. The Company's lead development programmes include tolimidone, under development as a novel agent for the treatment of type 1 diabetes and MTX110, which is being studied in aggressive rare/orphan brain cancer indications, and

Tolimidone is an orally delivered, potent and selective inhibitor of lyn kinase. Lyn is a member of the Src family of protein tyrosine kinases, which is mainly expressed in hematopoietic cells, in neural tissues, liver, and adipose tissue. Tolimidone demonstrates glycemic control via insulin sensitization in animal models of diabetes and has the potential to become a first in class blood glucose modulating agent.

MTX110 is a solubilised formulation of the histone deacetylase (HDAC) inhibitor, panobinostat. This proprietary formulation enables delivery of the product via convection-enhanced delivery (CED) at chemotherapeutic doses directly to the site of the tumour, by-passing the blood-brain barrier and potentially avoiding systemic toxicity.

Biodexa is supported by three proprietary drug delivery technologies focused on improving the bio-delivery and bio-distribution of medicines. Biodexa's headquarters and R&D facility is in Cardiff, UK. For more information visit www.biodexapharma.com.

About Emtora

Emtora Biosciences is a clinical stage biopharmaceutical company headquartered in San Antonio, Texas. The company is developing eRapaTM, amicro-encapsulated formulation of the previously approved rapamycin, for the treatment of rare genetic diseases and cancer. Emtora's lead indication is Familial Adenomatous Polyposis. The ubiquitous mTOR protein, involved in multiple signaling pathways, is overexpressed in FAP polyps. eRapaTM is a potent mTOR inhibitor believed to provide several significant advantages over rapamycin including: targeted delivery to the site of active disease (in addition to systemic exposure); reduced toxicity and improved tolerability; consistent pharmacokinetics (potentially eliminating the need for drug level monitoring) and improved bioavailability. eRapaTM was originally developed at University of Texas Health San Antonio and is currently the subject of two ongoing and grant-funded Phase 2 trials. For more information, please visit www.emtorabio.com.

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

Forward-Looking Statements

Certain statements in this announcement may constitute “forward-looking statements” within the meaning of legislation in the United Kingdom and/or United States. Such statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and are based on management’s belief or interpretation. All statements contained in this announcement that do not relate to matters of historical fact should be considered forward-looking statements. In certain cases, forward-looking statements can be identified by the use of words such as “plans”, “expects” or “does not anticipate”, or “believes”, or variations of such words and phrases or statements that certain actions, events or results “may”, “could”, “would”, “might” or “will be taken”, “occur” or “be achieved.” Examples of forward-looking statements include, among others, statements we make regarding the assignment of rights to eRapa and related license from Emtora and the Company’s ability to close the transaction, potential uses by the Company of eRapa, information related to clinical trials, and potential benefits of eRapa.Forward-looking statements and information are subject to various known and unknown risks and uncertainties, many of which are beyond the ability of the Company to control or predict, that may cause their actual results, performance or achievements to be materially different from those expressed or implied thereby, and are developed based on assumptions about such risks, uncertainties and other factors set out herein.

Reference should be made to those documents that Biodexa shall file from time to time or announcements that may be made by Biodexa in accordance with the rules and regulations promulgated by the SEC, which contain and identify other important factors that could cause actual results to differ materially from those contained in any projections or forward-looking statements. These forward-looking statements speak only as of the date of this announcement. All subsequent written and oral forward-looking statements by or concerning Biodexa are expressly qualified in their entirety by the cautionary statements above. Except as may be required under relevant laws in the United States, Biodexa does not undertake any obligation to publicly update or revise any forward-looking statements because of new information, future events or events otherwise arising.

Copyright © 2024 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document