Exhibit 10.1  
[\*\*\*] CERTAIN INFORMATION IN THIS DOCUMENT HAS BEEN EXCLUDED PURSUANT TO REGULATION S-K, ITEM 601(B)(10). SUCH EXCLUDED INFORMATION IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.  
Execution Version  
Confidential  
 LICENSE AGREEMENT  
by and between  
MAYNE PHARMA LLC  
and  
THERAPEUTICSMD, INC.  
DATED AS OF DECEMBER 4, 2022  
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LICENSE AGREEMENT  
This LICENSE AGREEMENT (this “Agreement”) is made as of this 4th day of December, 2022, by and between Mayne Pharma LLC, a limited liability company formed under the laws of Delaware and located at 0000 Xxxxxx Xxxxx Xxxxx 000, Xxxxxxx XX 00000 (“Mayne”), and TherapeuticsMD, Inc., a corporation formed under the laws of Nevada and located at 000 Xxxxxx Xxxx, Xxxxx 000, Xxxx Xxxxx, Xxxxxxx 00000 (“TXMD”). TXMD and Xxxxx are each referred to individually as a “Party” and together as the “Parties.”  
RECITALS  
WHEREAS, simultaneously with this Agreement, the Parties are entering into a Transaction Agreement (“Transaction Agreement”) pursuant to which Mayne is acquiring the Transferred Assets in the Territory;  
WHEREAS, TXMD is the owner of the Licensed IP; and  
WHEREAS, the Transaction Agreement provides that TXMD shall xxxxx Xxxxx the right to use the Licensed IP in relation to the Products in the Territory pursuant to the terms of this Agreement.  
NOW THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants, and agreements contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:  
ARTICLE 1  
DEFINITIONS  
1.1 Definitions. The following terms, whenever used herein, shall have the following meanings for all purposes of this Agreement, or, if not defined below, as defined in the Transaction Agreement:  
“Agreement” has the meaning ascribed to it in the Preamble.  
“Bankruptcy Code” has the meaning ascribed to it in Section 10.2(a).  
“Catalent” means Catalent Pharma Solutions, LLC.  
“Contracting Party” has the meaning ascribed to it in Section 12.19.  
“Diligent Efforts” means the carrying out of such activities using efforts and resources comparable to the efforts and resources that Mayne would typically devote to products of similar market potential at a similar stage in development or product life, taking into account all scientific, commercial, and other factors that Mayne would typically take into account, including issues of safety and efficacy, expected and actual cost and time to develop, expected and actual profitability, expected and actual competitiveness of alternative Third Party products (including generic or biosimilar products) in the marketplace, the nature and extent of expected  
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and actual market exclusivity (including patent coverage and regulatory exclusivity), the expected likelihood of regulatory approval, the expected and actual reimbursability and pricing, and the expected and actual amounts of marketing and promotional expenditures required.  
“Fulfillment Services” has the meaning ascribed to it in Section 2.5.  
“Generic Product” means, with respect to a Product, a product that (a) obtained approval from a Regulatory Authority solely by means of an ANDA procedure (or any foreign equivalent thereto) under Section 505 (j) of the Federal Food, Drug, and Cosmetic Act, in the United States for establishing equivalence to such Product, with the Product as the reference listed drug, (b) is AB rated and legally substituted by pharmacies for such Product and (c) is marketed by an entity other than the Parties.   
“Going Concern Notice” has the meaning ascribed to it in Section 6.7(a).  
“Infringement” has the meaning ascribed to it in Section 9.4.  
“Licensed IP” has the meaning ascribed to it in the Transaction Agreement. Copies of the schedules of Licensed IP set forth in the Transaction Agreement are set forth in Exhibit 1.  
“XXX” has the meaning ascribed to it in Section 6.2(a).  
“Marked Products” has the meaning ascribed to it in Section 3.1.  
“Mayne” has the meaning ascribed to it in the Preamble.  
“Minimum Annual Royalty” has the meaning ascribed to it in Section 6.2(c)(i).  
“Net Sales” means the amount of gross invoiced sales of the Products in the Territory for a specified period less the following amounts actually and reasonably incurred by Mayne, its sublicensees or any of their respective Affiliates selling such Products:  
(a) customer directed commissions and quantity, trade and cash discounts actually allowed or given;  
(b) discounts, replacements, credits or refunds actually allowed for the return of rejected, outdated, damaged or returned Products;  
(c) rebates, chargebacks and price adjustments actually allowed or given;  
(d) costs of copay or patient savings card;  
(e) transactional hub fees per unit on a Product-by-Product basis;  
(f) sales or similar taxes (including duties or other governmental charges or assessments) levied, absorbed or otherwise imposed on the sale of Products;  
(g) charges for freight, handling, postage, transportation, insurance and other shipping charges;  
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(h) a reasonable allowance for bad debts to the extent actually written off and not to exceed five percent (5%) of such gross invoiced sales during the applicable period;  
(i) royalties paid by Mayne to PCI pursuant to the Population Council License as in effect immediately prior to the Closing; for clarity, in no event shall the amount of any deduction pursuant to this subsection (i) be higher than the amount that would be due and payable under the Population Council License in effect immediately prior to Closing irrespective of any modification, amendment or agreement made with respect to the Population Council License after the Closing;  
(j) the portion of administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers or Medicare Prescription Drug Plans relating to such Products, excluding annual membership or other fees not related to unit sales;  
(k) Third Party Payments; and  
(l) accrued estimates for each of (a)-(k) in accordance with IFRS or GAAP, as applicable;  
provided, however, that:  
(a) sales or transfers of Products between or among Mayne, any permitted sublicensee or any Affiliate of Mayne will be excluded from Net Sales calculations for all purposes;  
(b) Products that are made, sold or used in connection with any pre-clinical or clinical trials, or for any testing, quality control, evaluation or other development purposes, or distributed as samples, will be excluded from Net Sales calculations for all purposes;  
(c) Mayne will not, and will cause its Affiliates and permitted sublicensees to not, apply any discount to the price of the Products for bundled sales of the Products with any other product commercialized by Mayne, its Affiliates and permitted sublicensees; and  
(d) amounts relevant to the determination of Net Sales, and the timing of sales, will be determined from the books and records of Xxxxx (or, as applicable, any permitted sublicensee or any Affiliate of Mayne) which will be maintained in accordance with generally accepted accounting principles (“GAAP”) in the United States.  
“New Technical IP” means, new formulations, modifications, improvements to, and new indications of, the Products (whether patentable or not) for the Territory developed or acquired by either Party, including any new combinations utilizing the Products.  
“Nonparty Affiliate” has the meaning ascribed to it in Section 12.19.  
“Party” or “Parties” has the meaning ascribed to it in the Preamble.  
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“Population Council License” means that certain License Agreement, dated July 30, 2018, by and between The Population Council, Inc. (“PCI”) and TXMD (or its successor or assign), as amended, including any amendment or successor agreement thereto pursuant to which a license is granted, in respect of the Product Annovera®.  
“Qualified Going Concern Opinion” means a note included in the audit opinion issued by Xxxxx’x or its Affiliates’ external auditors for its audited financial statements to the effect that such auditor has substantial doubts as to Xxxxx’x ability to remain solvent for a period of one year from the date of such opinion.  
“Reversion Right” has the meaning ascribed to it in Section 6.7(b).  
“Reversion Right Election Notice” has the meaning ascribed to it in Section 6.7(a).  
“Royalty Term” means the period of time commencing on the Closing Date and ending on the twentieth (20th) anniversary of the Closing Date.  
“Sale” has the meaning ascribed to it in Section 12.6.  
“Third Party Payments” has the meaning ascribed to it in Section 6.2(b).  
“Transaction Agreement” has the meaning ascribed to it in the Recitals.  
“TXMD” has the meaning ascribed to it in the Preamble.  
“Upcoming Minimum Royalty” has the meaning ascribed to it in Section 6.7(a).  
“Valid Claim” means a claim of any issued and unexpired Patent whose validity, enforceability, or patentability has not been affected by any of the following: (a) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (b) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding, or decision being final and unappealable or unappealed within the time allowed for appeal, provided that such prosecution has not been ongoing for more than three (3) years.  
1.2 Interpretive Provisions. Unless the express context otherwise requires:  
(a) the words “hereof,” “herein,” and “hereunder” and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement;  
(b) terms defined in the singular shall have a comparable meaning when used in the plural, and vice versa;  
(c) the terms “Dollars” and “$” mean United States Dollars;  
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(d) references herein to a specific Section, Article, or Recital shall refer, respectively, to Sections, Articles, or Recitals of this Agreement;  
(e) wherever the word “include,” “includes,” or “including” is used in this Agreement, it shall be deemed to be followed by the words “without limitation;”  
(f) references herein to any gender shall include each other gender;  
(g) with respect to the determination of any period of time, the word “from” means “from and including” and the words “to” and “until” each means “to but excluding;”  
(h) references herein to any Law or any license mean such Law or license as amended, modified, codified, reenacted, supplemented, or superseded, in whole or in part, and in effect, as of the time at which such Law or license is referenced;  
(i) references herein to any Law shall be deemed also to refer to all rules and regulations promulgated thereunder;  
(j) references to any agreement or contract are to that agreement or contract as amended, modified, or supplemented from time to time in accordance with the terms thereof;  
(k) “extent” in the phrase “to the extent” means the degree to which a subject or other thing extends, and such phrase does not mean simply “if;”  
(l) any documents or materials referred to herein as being “made available” to Mayne shall have been provided to Mayne or its counsel at least one (1) Business Day prior to the date hereof; and  
(m) a Party includes its permitted assignees and/or the respective successors in title to substantially the whole of its undertaking.  
ARTICLE 2  
LICENSE; SUPPLY  
2.1 License Grant. Subject to the terms and conditions of this Agreement, TXMD shall, and hereby does, grant to Mayne effective as of the Closing Date:  
(a) an exclusive, sublicensable, perpetual, irrevocable license (or sublicense to the extent that any Licensed IP is in-licensed by TXMD from any Third Party) under the Licensed IP to research, develop, register, manufacture, have manufactured, market, sell, use, and commercialize the Products in the Territory, including, for the avoidance of doubt, to commercialize new dosage forms and strengths of the Products including for additional or new indications; and  
(b) an exclusive, sublicensable, perpetual, irrevocable license (or sublicense to the extent that any Licensed IP is in-licensed by TXMD from any Third Party) under the Licensed IP to manufacture, have manufactured, import and have imported the Products outside the Territory for commercialization in the Territory.  
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2.2 Sublicensing. Mayne may sublicense the rights granted to it under this Agreement without the prior written consent of TXMD.  
2.3 Restriction of Rights. The Parties shall be subject to the restrictions set forth in Article 4 of the Transaction Agreement.  
2.4 Retained Right. Notwithstanding the scope of the exclusive license set forth in Section 2.1, TXMD shall retain the right to use and reference the Product NDAs, Product INDs and Licensed IP (a) to exercise TXMD’s rights and perform TXMD’s obligations under this Agreement, the Transaction Agreement and the other Ancillary Agreements, (b) to comply with TXMD’s (and its Affiliates’) obligations under Law, (c) to the extent it is necessary or useful for the defense or prosecution of any legal or regulatory proceeding in which TXMD or any of its Affiliates is a party or a potential party, (d) to fulfill its obligations to Other Partners under the Ex-US License Agreements, and/or (e) to manufacture and import or have manufactured and imported the Ex-Territory Product in the Territory for commercialization outside the Territory.  
2.5 Fulfillment Services. TXMD shall, and hereby does, appoint Mayne as its subcontractor under the Ex-US License Agreements with Knight Therapeutics Inc. and Theramex HQ UK Limited, and Mayne shall, and hereby does, accept such appointment as TXMD’s subcontractor, to coordinate with, and assist in the fulfilment of supply by Catalent of the applicable Products to, Knight Therapeutics Inc. and Theramex HQ UK Limited, to fulfill certain of TXMD’s obligations under the Ex-US License Agreements (the “Fulfillment Services”). The Parties shall work together in good faith to determine a process by which Xxxxx will perform the Fulfillment Services. Mayne shall provide to TXMD all reasonable documents and reasonable information required for TXMD to fulfill its obligations under the Ex-US License Agreements. Mayne undertakes the obligations under this Section 2.5 as an accommodation to TXMD, and TXMD disclaims any and all Claims against Mayne other than for Xxxxx’x intentional breach, and indemnifies and holds Xxxxx harmless from and against any and all Losses incurred by Xxxxx, in each case in connection with Xxxxx’x obligations under this Section 2.5 and as a subcontractor under the applicable Ex-US License Agreements.  
ARTICLE 3  
APPLICATION AND USE OF LICENSED TRADEMARKS  
3.1 Application of Licensed Trademarks. Nothing in this Agreement shall require or oblige Mayne to use any Licensed Trademarks in relation to the Products, provided, however, that the manufacture, marketing, promotion, sale, use, distribution, and other commercialization by Mayne of the Products that carry, or are sold by reference to, a Licensed Trademark (“Marked Products”) shall be governed by the relevant provisions of this Agreement.  
3.2 Marked Product(s). Subject to the terms and conditions set forth in the Transaction Agreement, no trademark other than the Licensed Trademarks may be affixed to or used in connection with any Marked Product(s). Following the Closing Date, Mayne may use its trade name on any packaging, leaflets, advertising, or promotional materials used for or in connection with the Marked Product(s). Effective as of the date on which Mayne changes any packaging leaflets, advertising, or promotional materials used for or in connection with the Marked Product(s), it shall include on such packaging, leaflets, advertising, and promotional materials, as  
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applicable, (if and to the extent reasonably practicable and otherwise as required by applicable Law) on which any of the Licensed Trademarks appear a statement that the Licensed Trademarks are used under license, in a form approved by TXMD.  
3.3 Use of Licensed Trademarks. Mayne shall use the Licensed Trademarks (a) only as permitted by the license granted herein, (b) in each case solely in the form and manner in which such Licensed Trademarks are registered, and (c) in accordance with applicable Law.  
ARTICLE 4  
NEW TECHNICAL IP  
4.1 New Technical IP. Mayne shall own any New Technical IP which it or its Affiliates develop or otherwise acquire after the Closing Date.  
ARTICLE 5  
FURTHER OBLIGATIONS  
5.1 Actions. Neither Party shall do or omit to do anything that would substantially diminish or impair the rights of the other Party in the Licensed IP. If either Party becomes aware of any claim or challenge to the validity of Licensed IP, it shall promptly inform the other Party.  
5.2 Further Assurances. Each Party shall execute and deliver to the other Party, upon either Party’s request, all documents that are reasonably necessary or desirable to secure, preserve, or implement each Party’s rights pursuant to this Agreement.  
5.3 Efforts. After the Closing Date and during the Royalty Term, Mayne shall use Diligent Efforts to commercialize the Products in the Territory.  
ARTICLE 6  
MILESTONES; ROYALTIES  
6.1 Net Sales Milestones. In partial consideration of the rights granted by TXMD to Mayne hereunder and subject to the terms and conditions set forth in this Agreement, Xxxxx shall make the following one-time, milestone payments to TXMD when the aggregate Net Sales of all Products in the Territory first reach the specified amount listed in the “Milestone Event” column below in any calendar year. For clarity, the milestone payments in this Section 6.1 will each be paid only once.  
 Milestone Event Milestone Payment   
Net Sales of Product in a calendar year in the Territory equal or exceed one hundred million Dollars ($100,000,000)  
 $ 5,000,000   
Net Sales of Product in a calendar year in the Territory equal or exceed two hundred million Dollars ($200,000,000)  
 $ 10,000,000   
Net Sales of Product in a calendar year in the Territory equal or exceed three hundred million Dollars ($300,000,000)  
 $ 15,000,000   
6.2 Royalties.  
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(a) Royalty Rates. Mayne shall, during the Royalty Term, pay to TXMD royalties on Net Sales of all Products in the Territory, at a royalty rate of (i) 8% on the first eighty million Dollars ($80,000,000) of Net Sales of Products in the Territory per calendar year and (ii) 7.5% on Net Sales of Products in the Territory after the first eighty million Dollars ($80,000,000) in such calendar year; provided, on a Product-by-Product basis, the royalty rate shall be reduced to two percent (2%) upon the earlier to occur of (A) the expiration or revocation of the last Valid Claim covering a Product, and (B) a Generic Product launching in the Territory (the first to occur of (A) and (B), “XXX”). Upon the expiry of the Royalty Term for a Product, the licenses granted to Mayne pursuant to Section 2.1 will become a fully paid-up and royalty free license for that Product.  
(b) Net Sales Deduction for Third Party Infringement Claims. If Xxxxx, upon the advice of counsel and with respect to a Product as it exists on the Closing Date, deems it necessary to obtain a license from a Third Party to develop, manufacture or commercialize such Product in the Territory, then Mayne may deduct any royalties, milestones, or other fees required to be paid by Mayne to such Third Party under such license (“Third Party Payments”) from the calculation of Net Sales. For clarity, this Section 6.2(b) shall only apply to intellectual property not already licensed to TXMD as of the date hereof.  
(c) Minimum Annual Royalty.  
(i) Beginning on January 1st of each calendar year following the Closing Date, Mayne shall owe to TXMD a minimum annual royalty, as follows (the “Minimum Annual Royalty”):  
 Payment Date Minimum Annual  
Royalty Quarterly  
Amount of  
Minimum  
Annual Royalty   
January 1, 2023  
 $ 3,000,000.00 $ 750,000.00   
January 1, 2024  
 $ 3,090,000.00 $ 772,500.00   
January 1, 2025  
 $ 3,182,700.00 $ 795,675.00   
January 1, 2026  
 $ 3,278,181.00 $ 819,545.25   
January 1, 2027  
 $ 3,376,526.43 $ 844,131.61   
January 1, 2028  
 $ 3,477,822.22 $ 869,455.56   
January 1, 2029  
 $ 3,582,156.89 $ 895,539.22   
January 1, 2030  
 $ 3,689,621.60 $ 922,405.40   
January 1, 2031  
 $ 3,800,310.24 $ 950,077.56   
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Payment Date Minimum Annual  
Royalty Quarterly  
Amount of  
Minimum  
Annual Royalty   
January 1, 2032  
 $ 3,914,319.55 $ 978,579.89   
January 1, 2033  
 $ 4,031,749.14 $ 1,007,937.29   
January 1, 2034  
 $ 4,152,701.61 $ 1,038,175.40   
The Minimum Annual Royalty owing for a calendar year shall be credited solely against royalties due in such calendar year, applied and, if owed, paid on a calendar quarter basis in accordance with Section 6.2(d). For clarity, the total amount of Minimum Annual Royalties payable under this Agreement, subject to the potential reductions set forth in this Section 6.2(c), is $42,576,088.68.  
(ii) The Minimum Annual Royalty shall be reduced by fifty percent (50%) if at any time XXX for the Product Annovera® occurs in the Territory.  
(iii) The Minimum Annual Royalty shall no longer be due and payable to TXMD in the event of actions of the FDA that prevents the further sale of Product Annovera®, including the FDA withdrawing its approval of the Product Annovera® NDA, or Mayne withdrawing the Product Annovera® NDA in response to communications with the FDA regarding the FDA’s concerns with respect to the safety and/or safety and efficacy of Product Annovera®, which concerns would cause a reasonable person knowledgeable in the industry and field to determine that the prudent pathway forward would be to withdraw the Product Annovera® NDA.  
(d) Royalty Reports and Payments. Within thirty (30) days following the end of each calendar quarter, commencing with the calendar quarter in which the Closing Date occurs, Mayne shall provide TXMD with a report containing the following information for such calendar quarter, on a Product-by-Product basis: (i) the amount of gross sales of Products in the Territory, (ii) units sold of Products, (iii) reconciliation, if any, of estimated to actual sales due to timing of financial reporting, (iv) an itemized calculation of Net Sales in the Territory showing deductions provided for in the definition of “Net Sales” and any rebates that are known to be required in respect of the calendar quarter in question, (v) the calculation of the royalty payment due on such sales, showing the application of the reduction, if any, and (vi) additional amounts due, if any, in order to satisfy any accrued, but unpaid, quarterly amount of the Minimum Annual Royalty for the elapsed portion of the applicable calendar year. Concurrent with the delivery of the applicable quarterly report, Mayne shall pay in Dollars all amounts due to TXMD pursuant to this Section 6.2 with respect to Net Sales by Mayne, its Affiliates and their respective sublicensee for such calendar quarter, including any Minimum Annual Royalties due for such calendar quarter. The reports provided for in this Section 6.2(d) shall be the Confidential Information of Mayne. For clarity, the Minimum Annual Royalties will accrue on a calendar quarter basis and will be offset against cumulative royalty payments on Net Sales of Products for the elapsed portion of the calendar year.  
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By way of example only, (A) if the royalty payment on Net Sales of Products for the first quarter of 2023 is $800,000, no true-up will be required to satisfy the portion of the Annual Minimum Royalty for the first quarter of 2023, and (B) if the royalty payment on Net Sales of Products for the second quarter of 2023 is $600,000, the true-up amount to satisfy the portion of the Annual Minimum Royalty for the first and second quarter of 2023, will be $100,000 ([$750,000 + $750,000 = $1,500,000] - [$800,000 + $600,000 = $1,400,000] = $100,000).  
(e) Late Payments. In addition to any other remedies available to TXMD, any failure by Mayne to make a payment when due shall obligate Mayne to pay computed interest, the interest period commencing on the due date and ending on the actual payment date, to TXMD at a rate per annum (but with interest accruing on a monthly basis) equal to the lesser of (a) [\*\*\*] percent ([\*\*\*]%), calculated daily on the basis of a 365-day year, or (b) the maximum rate permitted by Law. In the event of default in payment of any payment owing to TXMD under the terms of this Agreement, and if it becomes necessary for TXMD to undertake legal action to collect said payment, Mayne shall pay attorneys’ fees and costs incurred in connection therewith.  
6.3 Records. Each Party shall keep (and shall ensure that its Affiliates and sublicensee keep) such records as are required to determine, in accordance with GAAP or IFRS principles, as applicable, and this Agreement, the sums or credits due under this Agreement, including Net Sales. Such Party shall retain all such books, records and accounts until the later of (a) three (3) years after the end of the period to which such books, records and accounts 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 Laws. Each Party shall require its sublicensees to provide to it a report detailing the foregoing expenses and calculations incurred or made by such sublicensee, which report will be made available to the other Party in connection with any audit conducted by such other Party.  
6.4 Audit. At the request of TXMD, Mayne shall, and shall cause its Affiliates to, permit an independent public accounting firm of nationally recognized standing designated by TXMD and reasonably acceptable to Mayne, at reasonable times during normal business hours and upon reasonable notice, to audit the books and records maintained pursuant to this Section 6.4 to ensure the accuracy of all reports and payments made hereunder. Such examinations may not (a) be conducted for any calendar quarter more than three (3) years after the end of such quarter, (b) be conducted more than once in any twelve (12) month period, or (c) be repeated for any calendar quarter. The accounting firm shall disclose only whether the reports are correct or not, and the specific details concerning any discrepancies. No other information shall be shared. The Parties shall cause the accounting firm to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement. Except as provided below, the cost of this audit shall be borne by TXMD, unless the audit reveals a variance of at least five percent (5%), for any calendar quarter between the amount of royalties Mayne has paid under this Agreement and the amount of royalties actually owed to TXMD under this Agreement, in which case Mayne shall bear the cost of the audit. Unless disputed pursuant to Section 6.5 below, if such audit concludes that (i) additional amounts were owed by Xxxxx, Mayne shall pay the additional amounts with interest from the date originally due, or (ii) excess payments were made by Xxxxx, TXMD shall reimburse such excess payments, in either case ((i) or (ii)), within sixty (60) days after the date on which such audit is completed by TXMD. Mayne will include substantially the same audit rights in any sublicense it grants in order to verify the correctness of any payment due hereunder.  
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6.5 Audit Dispute. In the event of a dispute with respect to any audit under Section 6.4, Mayne and TXMD shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party’s certified public accountants or to such other Person as the Parties shall mutually agree (the “Audit Arbitrator”). The decision of the Audit Arbitrator shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Audit Arbitrator shall determine. Not later than thirty (30) days after such decision and in accordance with such decision, the audited Party shall pay the additional amounts, with interest from the date originally due, or the auditing Party shall reimburse the excess payments, as applicable.  
6.6 Withholding Tax. Mayne shall be entitled to deduct and withhold for or on account of any Taxes on or with respect to any payments under this Agreement as required by applicable Law; provided, however, that there shall be no deductions or withholdings to the extent the payee provides a properly completed and duly executed U.S. Internal Revenue Service Form W-9.  
6.7 Reversion Right.  
(a) If there is a Qualified Going Concern Opinion, Mayne shall promptly, and in no event more than ten (10) Business Days after Xxxxx’x receipt of the Qualified Going Concern Opinion, notify TXMD in writing that Xxxxx has received the Qualified Going Concern Opinion (a “Going Concern Notice”) each and every time a Going Concern Notice is received by Mayne. TXMD shall promptly, and in no event more than ten (10) Business Days after TXMD has received a Going Concern Notice from Mayne, notify Mayne in writing whether TXMD elects to exercise its Reversion Right (a “Reversion Right Election Notice”). Xxxxx shall promptly, and in no event more than thirty (30) days after Xxxxx has Received a Reversion Right Election Notice, either (i) comply with the provisions of this Section 6.7 in respect of the Reversion Right, or (ii) pay to TXMD an amount equal to the Minimum Annual Royalty for the upcoming calendar year (the “Upcoming Minimum Royalty”), provided only a single Upcoming Minimum Royalty payment will be due each calendar year irrespective of multiple Going Concern Notices. In the event Mayne elects to pay the Upcoming Minimum Royalty, TXMD shall have no further Reversion Right for the calendar year in which the Upcoming Minimum Royalty is paid by Mayne to TXMD and the provisions of Sections 6.7(b) and 6.7(c) shall not apply, and shall be of no further force or effect for the calendar year in which the Upcoming Minimum Royalty is paid by Mayne to TXMD.  
(b) In the event Mayne receives a Qualified Going Concern Opinion and Mayne does not pay the Upcoming Minimum Royalty in accordance with Section 6.7(a), TXMD shall have the right, but not the obligation, to require Mayne to transfer the Population Council License to TXMD, and Mayne hereby agrees to transfer the Population Council License to TXMD upon TXMD’s election to exercise such right, for the amount listed in Schedule 6.7 in respect of the then applicable calendar year (the “Reversion Right”). The Reversion Right shall expire on December 31, 2034.  
(c) In connection with the Reversion Right in accordance with Section 6.7(b), Mayne shall provide such reasonable assistance, as reasonably necessary, for TXMD to assume  
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the Population Council License, including assigning or amending as appropriate, upon the reasonable request of TXMD, any agreements or arrangements with suppliers necessary for TXMD to resume commercializing the Product Annovera®.  
ARTICLE 7  
REPRESENTATIONS AND WARRANTIES  
7.1 TXMD Representations. TXMD’s representations and warranties are as set forth in the Transaction Agreement.  
7.2 Mayne Representations. Xxxxx’x representations and warranties are as set forth in the Transaction Agreement.  
7.3 DAMAGES. NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, OR OTHERWISE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES AND ANY DAMAGES THAT ARE SPECULATIVE OR NOT REASONABLY FORESEEABLE AS A PROXIMATE RESULT OF THE BREACH BY A PARTY OF ANY OF ITS REPRESENTATIONS, WARRANTIES, COVENANTS, OR AGREEMENTS UNDER THIS AGREEMENT, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER ARTICLE 12 OF THE TRANSACTION AGREEMENT, BUT SUBJECT TO ANY RELATED LIMITATION ON LIABILITY SET OUT THEREIN.  
ARTICLE 8  
INDEMNIFICATION  
8.1 Indemnification. Subject to the express limitations on liability set forth in Section 7.3 and this ARTICLE 8 of this Agreement, the indemnification provisions in Article 12 of the Transaction Agreement shall apply to this Agreement.  
ARTICLE 9  
MAINTENANCE, DEFENSE AND INFRINGEMENT OF LICENSED IP BY THIRD PARTIES  
9.1 Maintenance of Licensed Patents. Until such time as the Minimum Annual Royalty is no longer due, Mayne shall, in its sole discretion, be responsible for the maintenance of all of the existing registrations (including all prosecution and maintenance activities) of the Licensed Patents in the Territory, at its sole cost and expense. Thereafter, maintenance and prosecution of Licensed Patents shall be at the sole discretion of Xxxxx.  
9.2 Maintenance of Licensed Trademarks. Promptly following a request by Xxxxx, TXMD shall provide a sample of the current use of each Licensed Trademark and a certificate of an officer of Mayne that is consistent with the U.S. Patent and Trademark Office’s Section 8 Affidavit of Use (or successor form) upon which Xxxxx shall be entitled to rely in filing its own such affidavit. Until such time as the Minimum Annual Royalty is no longer due, Mayne shall be responsible for the maintenance of the existing registration of the Licensed Trademarks in the Territory, at its sole cost and expense, to the extent permitted by Law; provided that Mayne may abandon any of the Licensed Trademarks in its sole discretion. Thereafter, maintenance and prosecution of Licensed Trademarks shall be at the sole discretion of Xxxxx.  
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9.3 Registration of License. In the event that a Party desires to make application(s) to the appropriate Regulatory Authority in the Territory for either the registration of this Agreement as a license or the registration of Mayne as a registered user of the Licensed Patents or the Licensed Trademarks, the Parties shall cooperate to that effect and the Party that initiated such application(s) shall bear the respective costs and expenses.  
9.4 Infringement. Each Party shall promptly notify the other Party of any actual or suspected claim, challenge, or unauthorized use within the Territory or challenge to the validity of Licensed IP relating to the Products (an “Infringement”) that comes to its attention.  
9.5 Right to Bring Action. Xxxxx shall have the sole right to send notices, defend, prosecute, and bring and conduct actions relating to an Infringement of the Licensed IP. Mayne shall bear the costs of any such legal proceedings, and shall be entitled to any damages, account of profits, and/or awards of costs recovered. TXMD will, at Xxxxx’x sole cost and expense, cooperate fully with Xxxxx in taking all reasonable steps requested by the enforcing Party in connection with any Infringement action, including joining in legal proceeding where necessary and to give the Mayne reasonable assistance and authority to file and prosecute the proceedings. TXMD may, at TXMD’s sole cost and expense, join such proceedings as a party plaintiff where necessary for TXMD to seek lost profits or other appropriate damages or compensation with respect to such Infringement.  
9.6 Settlements. TXMD may not enter a settlement, consent judgment or other voluntary final disposition of a suit under Section 9.4 or Section 9.5 that disclaims, limits the scope of, admits the invalidity or unenforceability of, or grants a license, covenant not to sue or similar immunity under any Licensed IP controlled by Mayne or its Affiliates without first obtaining the written consent of Xxxxx.  
9.7 Extensions of Patent Terms. Mayne shall have the sole right, but not the obligation, under the Licensed Patents solely and exclusively relating to the Products contained in the Licensed IP to seek, in TXMD’s name if so required, patent term extensions or the equivalent in all jurisdictions under applicable Law for the Products in the Territory. Xxxxx, its agents, and attorneys will give due consideration to all suggestions and comments of TXMD regarding any such activities, including the choice of which Patents to apply term extensions to.  
ARTICLE 10  
TERM AND TERMINATION  
10.1 Term. This Agreement shall come into force on the Closing Date and shall continue in full force and effect in perpetuity.  
10.2 Rights in Bankruptcy.  
(a) Applicability of 11 U.S.C. § 365(n). All Licensed IP granted under or pursuant to this Agreement, including all rights and licenses to use improvements or enhancements developed during the term of this Agreement, are intended to be, and shall otherwise be deemed  
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to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the “Bankruptcy Code”) or any analogous provisions in any other country or jurisdiction, licenses of rights to “intellectual property” as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that the licensee of such intellectual property under this Agreement shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code, including Section 365(n) of the Bankruptcy Code, or any analogous provisions in any other country or jurisdiction. All of the rights granted to either Party under this Agreement shall be deemed to exist immediately before the occurrence of any bankruptcy case in which the other Party is the debtor.  
10.3 Rights of non-Debtor Party in Bankruptcy. If a bankruptcy proceeding is commenced by or against TXMD under the Bankruptcy Code or any analogous provisions in any other country or jurisdiction, Mayne shall be entitled to a complete duplicate of (or complete access to, as appropriate) any Licensed IP and all embodiments of such Licensed IP, which, if not already in Mayne’s possession, shall be delivered to Mayne within five (5) Business Days of such request.  
ARTICLE 11  
CONFIDENTIALITY; PRESS RELEASE  
11.1 Confidentiality; Press Releases. The confidentiality and press release provisions in Article 9 of the Transaction Agreement shall apply to this Agreement.  
ARTICLE 12  
MISCELLANEOUS  
12.1 Expenses. Except as otherwise expressly provided herein, in the Transaction Agreement, or in any Ancillary Agreement, all costs and expenses incurred in connection with this Agreement, the Ancillary Agreements, and the transactions contemplated hereby and thereby shall be paid by the Party incurring such costs and expenses.  
12.2 Waiver and Amendment. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified except by an instrument in writing signed by each of the Parties.  
12.3 Entire Agreement. This Agreement, the Transaction Agreement, and the Ancillary Agreements, and any other documents delivered pursuant to this Agreement, the Transaction Agreement, and the Ancillary Agreements, constitute the entire agreement among the Parties with respect to the subject matter hereof and thereof, and supersede all prior communications, representations, agreements, and understandings, both oral and written, among the Parties with respect to the subject matter hereof and thereof. There are no contracts, agreements, representations, warranties, promises, covenants, or arrangements among the Parties hereto with respect to the transactions contemplated hereby, other than those expressly set forth in this Agreement, the Transaction Agreement, the Ancillary Agreements, and any other documents delivered pursuant to this Agreement, the Transaction Agreement, and the Ancillary Agreements.  
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12.4 Headings. The headings contained in this Agreement are intended solely for convenience and shall not affect the rights of the Parties.  
12.5 Notices. All notices, consents, waivers and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt, or (a) personal delivery to the Party to be notified, (b) upon receipt of delivery confirmation, if sent by electronic mail, or (c) one (1) Business Day after deposit with an internationally recognized overnight courier, freight prepaid, specifying next Business Day delivery, providing proof of delivery. The recipient shall promptly confirm its receipt of any such electronic mail. All communications shall be sent to the respective Parties as set forth below or to such other Person or address as any Party shall specify by notice in writing to the other Party.  
If to TXMD:  
TherapeuticsMD, Inc.  
000 Xxxxxx Xxxx, Xxxxx 000  
Xxxx Xxxxx, Xxxxxxx 00000  
 Attention:  
Xxxxxx X. Xxxxxx  
Email:  
With a copy to:  
DLA Piper LLP (US)  
000 Xxxxx Xxxxxxxx Xxxxxxxxx  
Xxxxx 0000  
 Attention:  
Xxxxxx X. Xxxxx  
Email: xxxxxx.xxxxx@xxxxxxxx.xxx  
If to Mayne:  
Mayne Pharma LLC  
0000 Xxxxxx Xxxxx Xxxxx 000  
Xxxxxxx XX 00000  
 Attention:  
General Counsel  
Email:  
With a copy to:  
Xxxxxx & Xxxxxx Xxxx Xxxxxxx LLP  
000 Xxxx 00xx Xxxxxx  
Xxx Xxxx, XX 00000  
 Attention:  
Xxxxx Xxxxxx and Xxxx Xxxxxxx  
 Email:  
xxxxx.xxxxxx@xxxxxxxxxxxx.xxx  
 xxxx.xxxxxxx@xxxxxxxxxxxx.xxx  
12.6 Binding Effect; Assignment. This Agreement shall be binding upon and shall inure to the benefit of the Parties and their permitted successors and assigns. No Party may assign or  
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delegate, by operation of law or otherwise, all or any portion of its rights, obligations or liabilities under this Agreement without the prior written consent of the other Party; provided, however, that Mayne may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of TXMD; and (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates (a “Sale”). Notwithstanding the foregoing, TXMD’s prior written consent shall be required to assign this Agreement in connection with a Sale if Minimum Annual Royalties may still be owed under the terms of this Agreement, which consent shall not be unreasonably withheld, conditioned or delayed. Any permitted assignee shall assume all obligations of its assignor under this Agreement (or related to the assigned portion in the case of a partial assignment to an Affiliate of Xxxxx), and no permitted assignment shall relieve the assignor of liability hereunder. Any purported assignment without such prior written consent shall be void and of no force or effect.  
12.7 No Third Party Beneficiary. Except for the rights of the TXMD Indemnified Parties and the Mayne Indemnified Parties under ARTICLE 8 of this Agreement and Article 12 of the Transaction Agreement, nothing in this Agreement shall confer any rights, remedies, or claims upon any Person not a Party or a permitted assignee of a Party.  
12.8 Counterparts. This Agreement may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of this Agreement. Delivery of an executed counterpart of this Agreement by facsimile transmission or by electronic mail in portable document format (.pdf) shall be as effective as delivery of a manually executed counterpart hereof.  
12.9 Force Majeure. If and to the extent that either Party is prevented or delayed by Force Majeure from performing any of its obligations under this Agreement and promptly so notifies in writing the other Party, specifying the matters constituting Force Majeure together with such evidence in verification thereof as it can reasonably provide and specifying the period for which it is estimated that the prevention or delay will continue, then the Party so affected shall be relieved of liability to the other for failure to perform or for delay in performing such obligations (as the case may be), but shall nevertheless use its commercially reasonable efforts to resume full performance thereof.  
12.10 Governing Law and Jurisdiction. This Agreement and any claim or controversy hereunder shall be governed by and construed under the laws of the State of Delaware, without giving effect to the conflict of laws provision thereof. Any claim or dispute arising out of or relating to this Agreement shall be subject to the exclusive jurisdiction of the United States District Court for the State of Delaware, so long as it shall have subject matter jurisdiction over such claim or dispute and otherwise the state courts located in the State of Delaware. Each Party irrevocably agrees and consents to the jurisdiction of the courts set forth in this Section 12.10 and waives any objection it may have to the venue of such courts, including with respect to the convenience of the forum and jurisdiction.  
12.11 WAIVER OF JURY TRIAL. EACH OF THE PARTIES HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING (WHETHER BASED ON CONTRACT, TORT, OR ANY  
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OTHER THEORY) DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT, ANY ANCILLARY AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREBY AND THEREBY, OR THE NEGOTIATION, ADMINISTRATION, PERFORMANCE, OR ENFORCEMENT HEREOF OR THEREOF. EACH PARTY HERETO (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT, OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.  
12.12 Severability. If any term, provision, agreement, covenant, or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, void, or unenforceable, the remainder of the terms, provisions, agreements, covenants, and restrictions of this Agreement shall remain in full force and effect and shall in no way be affected, impaired, or invalidated. Upon such a determination, the Parties shall negotiate in good faith to modify this Agreement so as to affect the original intent of the Parties as closely as possible in a reasonably acceptable manner so that the transactions contemplated hereby may be consummated as originally contemplated to the fullest extent possible.  
12.13 Specific Performance. The Parties agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with the terms hereof and that the Parties shall be entitled to specific performance of the terms hereof, in addition to any other remedy to which they are entitled at law or in equity. It is therefore agreed that the Parties shall be entitled to seek a temporary, preliminary and/or permanent injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the performance of the terms of this Agreement, without posting any bond or other undertaking, in addition to any other remedy to which they are entitled at law or in equity.  
12.14 Relationship of the Parties. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between TXMD and Mayne, or to constitute one as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any Tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind or commit the other.  
12.15 Extension to Affiliates. Mayne shall have the right to extend the rights, immunities, and obligations granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to Mayne. Mayne shall remain primarily liable for any acts or omissions of its Affiliates.  
12.16 Compliance with Law. Each Party shall perform its obligations under this Agreement in accordance with all applicable laws. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable law.  
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12.17 English Language. This Agreement is written and executed in the English language. Any translation into any other language shall not be an official version of this Agreement and in the event of any conflict in interpretation between the English version and such translation, the English version shall prevail.  
12.18 Construction. The Parties agree that the terms and conditions of this Agreement are the result of negotiations between the Parties and that this Agreement shall not be construed in favor of or against any Party by reason of the extent to which any Party participated in its preparation.  
12.19 No Recourse Against Nonparty Affiliates. All claims, obligations, liabilities, or causes of action (whether in contract, tort, law or equity, or granted by statute) that may be based upon, in respect of, arise under, out or by reason of, be connected with, or relate in any manner to this Agreement, or the negotiation, execution, or performance of this Agreement (including any representation or warranty made in, in connection with, or as an inducement to, this Agreement), may be made only against (and are those solely of) the entities that are expressly identified as Parties in the preamble to this Agreement (or their permitted assignees) (“Contracting Party”). No Person who is not a Contracting Party, including any director, officer, employee, incorporator, member, partner, manager, unitholder, stockholder, Affiliate, agent, attorney, or representative of, and any financial advisor or lender to, any Contracting Party, or any director, officer, employee, incorporator, member, partner, manager, unitholder, stockholder, Affiliate, agent, attorney, or representative of, and any financial advisor or lender to, any of the foregoing (“Nonparty Affiliates”), shall have any liability (whether in contract, tort, law or equity, or granted by statute) for any claims, causes of action, obligations, or liabilities arising under, out of, in connection with, or related in any manner to this Agreement or based on, in respect of, or by reason of this Agreement or its negotiation, execution, performance, or breach; and, to the maximum extent permitted by Law, each Contracting Party hereby waives and releases all such liabilities, claims, causes of action, and obligations against any such Nonparty Affiliates. Without limiting the foregoing, to the maximum extent permitted by Xxx, (a) each Contracting Party hereby waives and releases any and all rights, claims, demands, or causes of action that may otherwise be available at law, in equity, or granted by statute, to avoid or disregard the entity form of a Contracting Party or otherwise impose liability of a Contracting Party on any Nonparty Affiliate whether granted by statute or based on theories of equity, agency, control, instrumentality, alter ego, domination, sham, single business enterprise, piercing the veil, unfairness, undercapitalization, or otherwise; and (b) each Contracting Party disclaims any reliance upon any Nonparty Affiliates with respect to the performance of this Agreement or any representation or warranty made in, in connection with, or as an inducement to this Agreement.  
[Remainder of page intentionally left blank]  
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IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement as of the date first above written.  
 MAYNE PHARMA LLC  
By:   
/s/ Xxxxxxxx Xxxxxx  
Name: Xxxxxxxx Xxxxxx  
Title: Authorized Signatory  
 [Signature Page to License Agreement]  
THERAPEUTICSMD, INC.  
By:   
/s/ Xxxxx Xxxxxxxx  
Name: Xxxxx Xxxxxxxx  
Title: Executive Chairman  
 [Signature Page to License Agreement]