

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

**FORM 8-K**

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **October 23, 2024**

**MONOPAR THERAPEUTICS INC.**

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-39070</u> (Commission File Number)	<u>32-0463781</u> (I.R.S. Employer Identification No.)
<u>1000 Skokie Blvd., Suite 350, Wilmette, IL</u> (Address of principal executive offices)		<u>60091</u> (Zip Code)

(847) 388-0349

Registrant's telephone number, including area code

N/A

(Former name or former address, if changed since last report)

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value	MNPR	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company

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

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

On October 23, 2024, Monopar Therapeutics Inc. (the “Company” or “Monopar”) executed a License Agreement effective October 23, 2024 (the “License Agreement”) with Alexion Pharmaceuticals, Inc. (“Alexion, AstraZeneca Rare Disease” or “Alexion”), pursuant to which Alexion, AstraZeneca Rare Disease granted the Company an exclusive worldwide license for the development and commercialization of ALXN-1840, a drug candidate for Wilson disease that has progressed through a Phase 3 clinical trial that met its primary endpoint (the “Licensed Product”).

As initial upfront consideration for the License Agreement, Alexion will receive 387,329 shares (the “Initial Shares”) of the Company’s common stock (the “Common Stock”) (representing a 9.9% beneficial ownership interest in the Company upon issuance) and the Company has agreed to make an upfront cash payment of \$4.0 million, which shall be payable in two installments, including a \$1.0 million cash payment at the time of signing and a \$3.0 million cash payment within ninety (90) days. Additionally, Alexion is eligible to receive milestones and royalties, as further described below.

The Initial Shares will be issued pursuant to a separate Common Stock Investment Agreement, also dated October 23, 2024, between the Company and Alexion (the “Equity Agreement”). Pursuant to the Equity Agreement, the Company agreed to anti-dilution provisions that entitle Alexion to additional shares (together with the Initial Shares, the “Shares”) of Common Stock so that the total number of Shares issued thereunder continue to represent 9.9% of outstanding shares after any subsequent issuances of Common Stock through the next \$25.0 million of common equity capital raised by the Company, subject to a maximum of 705,015 Shares (inclusive of the Initial Shares) unless the Company obtains stockholder approval. The Equity Agreement also entitles Alexion to customary registration rights and the Company agreed to file a resale registration statement within forty-five (45) days.

As additional consideration, the Company will be obligated to pay Alexion aggregate milestone payments of up to \$94.0 million, including regulatory approval and sales related milestone payments. Alexion is also entitled to receive tiered royalties based on net sales in the low to mid-double digit range. Alexion has a right of first negotiation regarding any rights that the Company intends to sublicense, and will receive a percentage in the mid-double digits of sublicensing income received by Company until the Licensed Product achieves sales.

The Company shall use commercially reasonable efforts to develop and commercialize the Licensed Product. Among other termination events described in the License Agreement, either party may terminate the agreement in the event of an uncured material breach of the agreement following written notice, and the Company may terminate the agreement for convenience upon 90 days prior written notice to Alexion. The Company is also assuming a third party agreement from Alexion under which the Company will owe the third party a single digit millions cash milestone payment upon regulatory approval in Europe and a single digit percentage royalty on net sales in Europe.

The above summary of the License Agreement and Equity Agreement is not complete and is subject to the full terms and conditions of such agreements, which are attached hereto as Exhibits 10.1 and 10.2 and incorporated herein by reference.

**Item 2.01 Completion of Acquisition or Disposition of Assets.**

The information set forth in Item 1.01 above is incorporated by reference into this Item 2.01.

**Item 2.03 Creation of a Direct Financial Obligation.**

The information set forth in Item 1.01 above is incorporated by reference into this Item 2.03.

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

The information set forth in Item 1.01 above is incorporated by reference into this Item 3.02. The Shares are being sold and issued without registration under the Securities Act of 1933, as amended (the “Securities Act”), in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as a transaction not involving a public offering.

**Item 7.01 Regulation FD Disclosure.**

On October 24, 2024, the Company issued a press release announcing it entered into a license agreement with Alexion, AstraZeneca Rare Disease. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

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## Item 8.01 Other Events.

Wilson disease is a rare and progressive genetic condition in which the body's pathway for removing excess copper is compromised. It affects one in 30,000 live births in the US. Over time this results in the build-up of toxic copper levels in the liver, brain, and other organs, leading to damage that greatly impacts a patient's life. Patients can develop a wide range of symptoms, including liver disease and/or psychiatric or neurological symptoms, such as personality changes, tremors and difficulty walking, swallowing or talking. In some cases, the damage and loss of function may be irreversible.

ALXN-1840 (bis-choline tetrathiomolybdate) is an investigational once-daily, oral medicine in development for the treatment of Wilson disease. This novel molecule is designed to selectively and tightly bind and remove copper from the body's tissues and blood. ALXN-1840 has been granted Orphan Drug Designation in the United States and orphan designation in the European Union for Wilson disease.

A pivotal Phase 3 trial with ALXN-1840 has been completed, which met its primary endpoint. The primary endpoint assessed copper mobilization over 48 weeks, defined as daily mean AUEC (Area Under the Effect Curve) for dNCC (directly measured non-ceruloplasmin-bound copper). In the trial, 214 patients were enrolled, and the trial was randomized, rater-blinded, and multi-centered, designed to evaluate the efficacy and safety of ALXN-1840 versus standard-of-care (SoC) in patients with Wilson disease aged 12 years and older. In the trial, people taking ALXN-1840 experienced rapid copper mobilization, with a response at four weeks and sustained through the 48 weeks. The primary endpoint demonstrated three-times greater copper mobilization from tissues compared to the SoC arm (Least Square Mean Difference [LSM Diff] 2.18  $\mu\text{mol/L}$ ;  $p < 0.0001$ ), including in patients who had been treated previously for an average of 10 years.

Alexion ended up terminating the ALXN-1840 program in Wilson disease based on review of results from Phase 2 mechanistic trials and discussions with regulatory authorities. The Phase 2 mechanism of action studies failed to meet their primary objectives of demonstrating net-negative copper balance in Wilson disease patients during short-term treatment with ALXN-1840 and reducing hepatic copper concentration after treatment with ALXN-1840. The decision not to progress the ALXN-1840 program in Wilson disease was not related to any safety signals.

In the near term, Monopar will be focusing on assembling a regulatory package and initiating discussions with the FDA. These activities will provide clarity on the additional capital needed for the program. As a result, the costs beyond the \$4.0 million due at signing and within ninety (90) days will largely be consultant time along with patent maintenance. The near-term expenses are estimated to be less than \$1.0 million to assemble the detailed regulatory package and maintain the patent portfolio.

The regulatory approval process can be lengthy, expensive and uncertain. The FDA and other regulatory agencies around the world could require us to perform additional nonclinical and/or clinical studies to obtain ALXN-1840 approval, which we may not be able to raise the capital to complete or the results of which may not meet the level of clinical or statistical significance required by the FDA and other regulatory agencies. What the FDA and other regulatory agencies require for approval could have a material impact on the timelines and/or capital required to get ALXN-1840 approved. Even if approved, market adoption could be slower or lower than expected, especially given competition from existing therapies or new ones that get approved. We are planning to initially focus on Wilson disease patients with more severe symptoms, and this population could end up being smaller than we are anticipating. This population could be further reduced in size if the FDA or other regulatory agencies give us a more narrow label than anticipated. Being an orphan indication, this could result in a very small eligible patient population. Additionally, if the currently filed patents do not end up providing sufficient protection, we will be heavily reliant on the orphan drug designation protections in the US and EU.

As of September 30, 2024, the Company's cash and cash equivalents were approximately \$6.0 million. Although this would allow us to make an upfront cash payment of \$4.0 million, which shall be payable in two installments, including a \$1.0 million cash payment at the time of signing and a \$3.0 million cash payment within ninety (90) days under the License Agreement, as a result of Company's continuing funding needs for its existing clinical and preclinical programs and operations along with additional spending expected to advance the ALXN-1840 program, the Company will require significant additional funding and expects to seek such additional capital in the near term. While we intend to pursue such additional funding through equity offerings, whether through methods that the Company has utilized in the past such as at-the-market sales programs or through additional methods such as marketed offerings, rights offerings or otherwise, we may also consider debt financing, strategic partnerships or other sources of capital that may be available. Absent significant additional funding in the near term, we expect that our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, will include language indicating substantial doubt about the Company's ability to continue as a going concern due to the need for additional financing in the next twelve (12) months.

## Item 9.01 Financial Statements and Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>10.1*</u>	<u><a href="#">License Agreement between Alexion and Monopar dated October 23, 2024</a></u>
<u>10.2</u>	<u><a href="#">Common Stock Investment Agreement between Alexion and Monopar dated as of October 23, 2024</a></u>
<u>99.1</u>	<u><a href="#">Press Release Dated October 24, 2024</a></u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

\* Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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## Forward-Looking Statements

This 8-K, and any documents we incorporate by reference, contain certain forward-looking statements that involve substantial risks and uncertainties. All statements contained in this Form 8-K and any documents we incorporate by reference, other than statements of historical facts, are forward-looking statements including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words “anticipate”, “believe”, “estimate”, “expect”, “intend”, “may”, “plan”, “predict”, “project”, “target”, “potential”, “will”, “would”, “could”, “should”, “continue” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- our near term ability to raise sufficient funds in order for us to support continued clinical, regulatory and commercial development of our programs and to make contractual upfront and future milestone payments, as well as our ability to further raise additional funds in the future to support any existing or future product candidate programs through completion of clinical trials, the approval processes and, if applicable, commercialization;
- our ability to raise funds on acceptable terms;
- our ability to find a suitable pharmaceutical partner or partners to further our development efforts, under acceptable financial terms;
- risks and uncertainties associated with our or any development partners' research and development activities, including preclinical studies, clinical trials, regulatory submissions, and manufacturing and quality expenses;
- known and unknown risks associated with developing radiopharmaceutical therapeutics and imaging agents and de-coppering therapies;
- the uncertainty of timeframes for our clinical trials and regulatory reviews for approval to market products;
- our ability to address the fulfillment and logistical challenges posed by the potential time-limited shelf-life of our current radiopharmaceutical programs or future drug candidates;
- our ability to obtain an adequate supply at reasonable costs of radioisotopes that we are currently using or that we may incorporate into our drug candidates;
- uncertainties related to the regulatory discussions we intend to initiate related to ALXN-1840 and the outcome thereof;
- the rate of market acceptance and competitiveness in terms of pricing, efficacy and safety, of any products for which we receive marketing approval, and our ability to competitively market any such products as compared to larger pharmaceutical firms;
- the difficulties of commercialization, marketing and product manufacturing and overall strategy;
- uncertainties of intellectual property position and strategy including new discoveries and patent filings;
- our ability to attract and retain experienced and qualified key personnel and/or to find and utilize external sources of experience, expertise and scientific, medical and commercialization knowledge to complete product development and commercialization of new products;
- the risks inherent in our estimates regarding the level of needed expenses, capital requirements and the availability of required additional financing at acceptable terms;
- the impact of the U.S. Presidential and Congressional election results affecting the economy and future government laws and regulations including increased governmental control of healthcare and pharmaceuticals, resulting in direct price controls driving lower prices, other governmental regulations affecting cost requirements and structures for selling therapeutic or imaging products, and recent governmental legislation affecting other industries which may indirectly increase our costs of obtaining goods and services and our cost of capital;
- the uncertain impact any resurgence of COVID-19 or another pandemic could have on our ability to advance our clinical programs and raise additional financing;
- the cumulative impact of domestic and global inflation, volatility in financial markets and/or the potential for an economic recession increasing our costs of obtaining goods and services or making financing more difficult to obtain on acceptable terms or at all;
- the uncertain impact of the Russia-Ukraine war or the Israel-Hamas war on our clinical material manufacturing expenses and timelines, as well as on general political, economic, trade and financial market conditions; and
- uncertainty of our financial projections and operational timelines and the development of new competitive products and technologies

Although we believe that the risk assessments identified in such forward-looking statements are appropriate, we can give no assurance that such risks will materialize. Any forward-looking statements in this Form 8-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances projected in this information.

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**SIGNATURE**

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

**Monopar Therapeutics Inc.**

Date: October 24, 2024

By: /s/ Karthik Radhakrishnan

Name: Karthik Radhakrishnan

Title: Chief Financial Officer

CERTAIN INFORMATION INDICATED BY [\*\*\*] IN THIS EXHIBIT HAS BEEN OMITTED AS NOT MATERIAL AND PRIVATE OR CONFIDENTIAL

**LICENSE AGREEMENT**

**Between**

**Alexion Pharmaceuticals, Inc.**

**and**

**Monopar Therapeutics Inc.**

**Dated as of            October 23, 2024**

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## LICENSE AGREEMENT

This License Agreement (the “**Agreement**”) is made and entered into effective as of October 23, 2024 (the “**Effective Date**”) by and between, **Alexion Pharmaceuticals, Inc.**, a Delaware corporation with a principal place of business at 121 Seaport Blvd., Boston, MA 02210 (“**Licensor**”), and **Monopar Therapeutics Inc.**, a Delaware corporation with a principal place of business at 1000 Skokie Blvd. Suite 350, Wilmette, IL USA 60091 (“**Licensee**”).

Licensor and Licensee are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

### BACKGROUND

**WHEREAS**, Licensor has certain intellectual property rights with respect to ALXN 1840, a tetrathiomolybdate, an oral, copper-binding agent, previously in late-stage clinical development for treatment of Wilson disease and the associated intellectual property rights; and

**WHEREAS**, Licensor wishes to grant to Licensee, and Licensee wishes to take, an exclusive License under Licensor’s Licensed Technology to research, develop, manufacture, and commercialize Licensed Compound and Licensed Products in the Territory defined below and in accordance with the terms and conditions set forth below.

**NOWHEREFORE**, the Parties agree as follows:

#### 1. DEFINITIONS

Unless otherwise specifically provided in this Agreement, the following terms shall have the following meanings:

- 1.1 “**Abbreviated Approval Laws**” means the U.S. “Drug Price Competition and Patent Term Restoration Act” of 1984 (Hatch-Waxman Act), the Biologics Price Competition and Innovation Act, or any other Applicable Law in the Territory providing an abbreviated approval pathway for Generic Products, as applicable.
- 1.2 “**Accounting Standards**” means, with respect to a Party or its Affiliates or its or their sublicensees, United States generally accepted accounting principles (“**GAAP**”), International Financial Reporting Standards or such other similar national standards as such Party, Affiliate, or its or their sublicensee adopts, in each case, consistently applied. In the case of Licensee, references to Accounting Standards shall refer to GAAP.
- 1.3 “**Affiliate**” means, with respect to a Party, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” means: (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).
- 1.4 [\*\*\*]
- 1.5 “**Applicable Law**” means all applicable laws, rules and regulations, statutes, ordinances, treaties, directives, administrative interpretations, rules of national stock exchanges, and any rules, regulations, guidelines or other requirements of any relevant Regulatory Authority or Governmental Authority, in each case, that may be in effect from time to time, including the applicable regulations and guidelines of the FDA and European Medicines Agency (and national implementations thereof) that constitute good laboratory practices, good manufacturing practices, and good clinical practices (and, if and as appropriate under the circumstances, International Conference on Harmonization (ICH) guidance or other comparable regulation and guidance of any applicable Regulatory Authority in the Territory) and all applicable laws and regulations regarding trade sanctions and export controls.



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- 1.6 “**Anti-Bribery and Anti-Corruption Laws**” means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.
- 1.7 “**Assigned Agreements**” has the meaning set out in Section 2.6 (Assigned Agreements).
- 1.8 “**Assigned Trademarks**” means those trademarks Controlled by Licensor and its Affiliates that are solely related to the Product and that Licensor has agreed to assign.
- 1.9 “**Assignment and Assumption Agreement**” means an assignment and assumption agreement to be entered into between Licensor and Licensee, with respect to the Assigned Agreements, in the form of Exhibit A.
- 1.10 “**Assigned Regulatory Documentation**” has the meaning set out in Section 4.1 (Regulatory Activities).
- 1.11 “**Breaching Party**” has the meaning set out in Section 13.2.2 (Termination; Material Breach).
- 1.12 “**Business Day**” means a day other than a Saturday or Sunday or a day on which banking institutions in New York, New York, London, England, Dublin, Ireland, Stockholm, Sweden, or Tokyo, Japan are permitted or required to be closed.
- 1.13 “**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 Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date and the last Calendar Quarter shall end on the last day of the Term.
- 1.14 “**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 of the year in which the Effective Date occurred 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.
- 1.15 “**Control**” means, with respect to any item of information, Regulatory Documentation, Patent or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 2), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party. For clarity, Licensor is not obligated to grant rights to Licensee in respect of Patent Rights, Know-How, Regulatory Documentation or otherwise which might belong to a Third Party and may have become part of Licensor’s holding Company through acquisitions or licenses.

- 1.16 **“Change of Control,”** with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Effective Date: (a) a Third Party (or group that includes one or more Third Parties acting in concert) becomes the legal or beneficial owner, directly or indirectly, of fifty percent (50%) or more of the voting power of the outstanding stock or securities of such Party; (b) such Party, directly or indirectly, consolidates with or merges into a Third Party or a Third Party, directly or indirectly, consolidates or merges into such Party, in either event pursuant to a transaction in which fifty percent (50%) or more of the total voting power of the outstanding stock or securities of the surviving entity normally entitled to vote is not held, directly or indirectly, by the Persons, directly or indirectly, holding more than fifty percent (50%) of the outstanding stock or securities of such Party immediately preceding such consolidation or merger; (c) a Third Party (or group that includes one or more Third Parties acting in concert), directly or indirectly, obtains the power to direct or cause the direction of the management and policies of such Party by any lawful means whatsoever; or (d) such Party conveys, transfers, leases, or disposes of all or substantially all of its assets to a Third Party.
- 1.17 **“Combination Product”** means a Licensed Product that is comprised of or contains a Licensed Compound as an active ingredient together with one or more other active ingredients or Delivery Systems that is sold either as a fixed dose/unit, as separate doses/units in a single package, or otherwise sold together for a single price.
- 1.18 **“Commercialization”** means any and all activities directed to the preparation for sale of, offering for sale of or sale of a Licensed Product, including activities related to marketing, promoting, detailing, distributing, warehousing, recalling, pricing, discounting, and importing such Licensed Product, and interacting with Regulatory Authorities regarding any of the foregoing, and medical affairs activities. When used as a verb, **“to Commercialize”** and **“Commercializing”** means to engage in Commercialization and **“Commercialized”** has a corresponding meaning. For the avoidance of doubt, Commercialization does not include Development or Manufacturing.
- 1.19 **“Commercially Reasonable Efforts”** means, with respect to the performance of any activities with respect to the Licensed Compound or a Licensed Products by Licensee at its, its Affiliates and its Sublicensees own expense, the carrying out of such activities in a sustained and diligent manner and using efforts and resources comparable to the efforts and resources of a similarly situated biopharmaceutical company of similar size would use for compounds or products of similar market potential at a similar stage in development or product life taking into account all scientific, commercial and other factors, 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 products) in the marketplace, the nature and extent of expected and actual market exclusivity (including patent coverage and regulatory exclusivity), actual or expected likelihood of Regulatory Approval, the patent and other proprietary position of the compound or product, and all other relevant factors. “Commercially Reasonable Efforts” shall be determined on a country-by-country (or region-by-region, product-by-product where applicable) and indication-by-indication basis, without regard to the particular circumstances of Licensee, including any other product opportunities of Licensee and without regard to any payments owed by Licensee to Licensor under this Agreement. It is anticipated that the level of effort may change over time, reflecting changes in the status of a Licensed Compound or Licensed Product, and the countries or markets involved.
- 1.20 **“Comparable Product”** has the meaning set out in Section 7.6 (Combination Products Adjustment).
- 1.21 **“Competitive Product”** has the meaning set out in Section 2.10.1 (Exclusivity Covenants).
- 1.22 **“Confidential Information”** has the meaning set out in Section 10.1 (Confidentiality Obligations).

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- 1.23 **“Delivery System”** means any delivery or diagnostic system comprising equipment, instrumentation, one or more devices, or other components designed to assist in, or useful for, the use or administration of a pharmaceutical or biologic product.
- 1.24 **“Development”** means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, clinical studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of applications for Regulatory Approvals, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. When used as a verb, **“Develop”** means to engage in Development.
- 1.25 **“Development Plan”** has the meaning set out in Section 3.2 (Development Plan).
- 1.26 **“Dispute”** has the meaning set out in Section 14.6.1 (Disputes).
- 1.27 **“Distributor”** means any Person(s) appointed by Licensee or any of its Affiliates or its or their Sublicensees to distribute, market, and sell Licensed Product(s), with or without packaging rights, in one or more countries in the Territory, in circumstances where the Person purchases its requirements of Licensed Product(s) from Licensee or its Affiliates or its or their Sublicensees but does not otherwise make any royalty or other payment to Licensee or its Affiliates or its or their Sublicensees with respect to its intellectual property rights with respect to such Licensed Product(s).
- 1.28 **“Dollars”** or **“\$”** means United States Dollars.
- 1.29 **“Effective Date”** has the meaning set out in the preamble hereto.
- 1.30 **“European Markets”** means [\*\*\*].
- 1.31 **“Existing Confidentiality Agreement”** means that certain CDA between Licensee and AstraZeneca AB dated [\*\*\*].
- 1.32 **“Existing Patents”** means the Patent Rights set forth in Schedule 1 (Existing Patents).
- 1.33 **“Exploit”** means to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of.
- 1.34 **“Exploitation”** means the act of Exploiting a compound, product, or process.
- 1.35 **“FDA”** means the United States Food and Drug Administration and any successor agency thereto.
- 1.36 **“Field”** means all human therapeutic uses.
- 1.37 **“First Commercial Sale”** means, with respect to a Licensed Product and a country, the first sale for monetary value by Licensee, its Affiliate or its or their Sublicensee to a Third Party (other than a Sublicensee) for use or consumption by the end user of such Licensed Product in such country after Regulatory Approval for such Licensed Product has been obtained in such country. For clarity, only First Commercial Sale shall be considered in calculation of Net Sales.
- 1.38 [\*\*\*].

- 1.39 **“Generic Entry Quarter”** has the meaning set out in Section 7.5.1 (Generic Entry).
- 1.40 **“Generic Product”** means, with respect to a Licensed Product, any pharmaceutical or biological product that: (a) is sold or distributed by a Third Party (other than a Sublicensee) under a Regulatory Approval granted by a Regulatory Authority in reliance, in whole or in part, on the prior Regulatory Approval (or on safety or efficacy data submitted in support of the prior Regulatory Approval) of such Licensed Product, and (b) has received Regulatory Approval for the same indication as a Licensed Product as a “generic drug”, “generic medicinal product”, “bioequivalent” “biosimilar” or similar designation of interchangeability by the applicable Regulatory Authority with that Licensed Product.
- 1.41 **“Governmental Authority”** means any: (a) federal, state, local, municipal, foreign, or other government; (b) governmental or quasi-governmental authority of any nature (including any agency, board, body, branch, bureau, commission, council, department, entity, governmental division, instrumentality, office, officer, official, organization, representative, subdivision, unit, and any court or other tribunal); (c) multinational governmental organization or body; or (d) entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military, or taxing authority or power of any nature.
- 1.42 **“Indemnified Party”** has the meaning set out in Section 12.3 (Indemnification Procedures).
- 1.43 **“Indirect Tax”** means any value added, sales, consumption, goods and services taxes or other similar taxes required by Applicable Law to be disclosed as a separate item on the relevant invoice.
- 1.44 **“Inflation Reduction Act”** means the US, H.R. 5376 - 117th Congress (2021-2022): Inflation Reduction Act of 2022.
- 1.45 **“Infringement”** has the meaning set out in Section 8.3.1 (Notice of Infringement).
- 1.46 **“Know-How”** means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.
- 1.47 **“Knowledge”** means the actual knowledge of the applicable representatives of a Party and its Affiliates after performing a diligent investigation with respect to such facts and information. The Parties’ applicable representatives are set forth in Schedule 1.47 (Knowledge Representatives).
- 1.48 **“Licensee Know-How”** means all Know-How Controlled by Licensee or any of its Affiliates during the Term that is both: (i) developed by or on behalf of Licensee or any of its Affiliates under this Agreement after the Effective Date; and (ii) necessary for the Exploitation of a Licensed Compound or a Licensed Product.
- 1.49 **“Licensee Patent Rights”** means all of the Patent Rights Controlled by Licensee or any of its Affiliates during the Term: (i) made or conceived by or on behalf of Licensee or any of its Affiliates under this Agreement after the Effective Date; and (ii) that claim or cover a Licensed Compound, a Licensed Product.

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- 1.50“**Licensee Technology**” means the Licensee Know-How and the Licensee Patent Rights.
- 1.51“**Licensed Compound**” the pharmaceutical compound known as ALXN 1840, which is set forth in Schedule 2 (Licensed Compound).
- 1.52“**Licensed Product(s)**” means any pharmaceutical product that is comprised of or contains a Licensed Compound, or any derivative or modified version thereof, as an active ingredient, alone or in combination with one (1) or more other active ingredients, in any and all forms, presentations, Delivery Systems, dosages and formulations (including any improved version of such product).
- 1.53“**Licensed Product Agreement**” means, with respect to a Licensed Product, any agreement entered into by and between Licensee or any of its Affiliates or its or their respective Sublicensees, on the one hand and one or more Third Parties, on the other hand, that is necessary or reasonably useful for the Exploitation of such Licensed Product in the Field in the Territory, including any agreement pursuant to which Licensee, its Affiliates or its or their Sublicensees receives any license or other rights to Exploit such Licensed Product.
- 1.54“**Licensed Know-How**” means all Know-How Controlled by Licensor or any of its Affiliates as of the Effective Date that is reasonably necessary to Exploit the Licensed Compound or Licensed Product.
- 1.55“**Licensed Patent Rights**” means all of the Patent Rights Controlled by Licensor or any of its Affiliates as of the Effective Date that: (a) claim or cover a Licensed Compound or a Licensed Product; or (b) are necessary for the Exploitation of a Licensed Compound, a Licensed Product. The Licensed Patents include the Existing Patents.
- 1.56“**Licensed Technology**” the Licensed Know-How and Licensed Patent Rights. Licensed Technology shall exclude any trademarks Controlled by Licensor.
- 1.57“**Losses**” has the meaning set out in Section 12.1 (Indemnification of Licensor).
- 1.58[\*\*\*].
- 1.59“**Major Market**” means each of [\*\*\*].
- 1.60“**Manufacture**” and “**Manufacturing**” means all activities related to the production, manufacture, processing, filling, finishing, packaging, labelling, shipping and holding of the Licensed Compound, any Licensed Product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.
- 1.61“**Marketing Approval Application**” means an appropriate application or registration submitted to the applicable Regulatory Authority in a country to seek approval of the Commercialization of a Licensed Product in such country (e.g., an NDA submitted to the FDA in the United States).
- 1.62“**Material Anti-Bribery and Anti- Corruption Law Violation**” means a violation of an Anti-Bribery and Anti- Corruption Laws relating to the subject matter of this Agreement that would, if it were publicly known, in the reasonable view of Licensor, have a material adverse effect on Licensor or on the reputation of Licensor because of its relationship with Licensee.
- 1.63“**Materials**” means chemical, physical, biologic materials that may be provided by one Party to the other for use in connection with this Agreement.

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1.64 **“Maximum Fair Price”** means with respect to a year during a Price Applicability Period for a Selected Drug, the price negotiated pursuant to Section 1194 (and updated pursuant to Section 1195(b), as applicable) under the Inflation Reduction Act for such drug and year.

1.65 **“NDA”** means a new drug application filed with the FDA in the United States, and foreign counterparts in other countries within the Territory.

1.66 **“Net Sales”** means, with respect to a Licensed Product for any period, the gross amount billed or invoiced by Licensee, its Affiliates or its or their Sublicensees for the sale of a Licensed Product to Third Parties (including Distributors), less deductions for:

[\*\*\*]

[\*\*\*]

For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when proceeds from such sale are invoiced. Net Sales shall be based on First Commercial Sale and, subsequent sales and shall not include any Alternate Sales. Net Sales shall not include sales or transfers between or among Licensee, its Affiliates, or its or their Sublicensees.

Notwithstanding the foregoing or anything to the contrary herein, Net Sales shall be calculated in accordance with the standard internal policies and procedures of Licensee, its Affiliates or its or their Sublicensees, which are in accordance with Accounting Standards.

To the extent any accrued amounts used in the calculation of Net Sales are estimates, such estimates shall be true-up to actuals in accordance with Accounting Standards (including that, for any estimates of deductions that are later increased or decreased, the difference will be removed or added back to Net Sales, as applicable).

For the purposes of calculating Net Sales, all Net Sales made in a currency other than Dollars shall be converted into Dollars using Licensee’s, its Affiliate’s, or its Sublicensee’s standard conversion methodology consistent with Accounting Standards.

1.67 **“Net Sales Milestone Event”** has the meaning set out in Section 7.3.1 (Net Sales Milestones).

1.68 **“Net Sales Milestone Payment”** has the meaning set out in Section 7.3.1 (Net Sales Milestone).

1.69 **“Non-Breaching Party”** has the meaning set out in Section 13.2.2 (Material Breach).

1.70 **“Notice Period”** has the meaning set out in Section 13.2.2 (Material Breach).

1.71 **“Other Components”** has the meaning set out in Section 7.6 (Combination Products Adjustment).

1.72 **“Patent Rights”** means: (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and (d) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation, or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

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- 1.73 **“Payee”** has the meaning set out in Section 7.11.1 (Withholding Taxes).
- 1.74 **“Payor”** has the meaning set out in Section 7.11.1 (Withholding Taxes).
- 1.75 **“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, or any government, supranational, regional, regulatory or administrative body, authority, board, commission, agency, court, tribunal or arbitral body, or any committee exercising any executive, legislative, regulatory or administrative functions of government, whether local or national, or any department, agency, or subdivision thereof.
- 1.76 **“Personal Data”** has the meaning set out in Section 11.9.1 (Personal Data Covenant).
- 1.77 **“Price Applicability Period”** means, with respect to a qualifying single source drug, the period beginning in or after 2026 with respect to which such drug is a Selected Drug and the Maximum Fair Price applies to sales of such drug and ending with the last year during which such drug is a Selected Drug.
- 1.78 **“Product Trademarks”** means the trade mark(s), trade names(s) and logo(s) used or to be used by Licensee or its Affiliates or its or their Sublicensees exclusively for the Commercialization of Licensed Products in the Territory, including, as applicable, the Assigned Trademarks, and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names, or logos that include any corporate name or logo of the Parties or their Affiliates or its or their Sublicensees). For clarity, this excludes any trademark(s), trade names(s) and logo(s) Controlled by Licensor as of or prior to Effective Date.
- 1.79 **“Reference Rate”** has the meaning set out in Section 7.14 (Interest on Late Payments).
- 1.80 **“Regulatory Approval”** means with respect to a country or other jurisdiction in the Territory, all approvals, licenses, registrations, or authorizations of any Regulatory Authority necessary to Commercialize a pharmaceutical product in such country or other jurisdiction. With respect to Europe, a Regulatory Approval will include MA Approval.
- 1.81 **“Regulatory Authority”** means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of pharmaceutical and biologic products in the Territory.
- 1.82 **“Regulatory Documentation”** means all: (a) applications (including all investigational new drug applications, new drug applications, biologics license applications, and marketing approval applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files; and (c) clinical and other data contained or relied upon in any of the foregoing; in each case ((a), (b) and (c)) relating to the Licensed Compound or a Licensed Product.

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- 1.83 **“Royalty Term”** means, with respect to each Licensed Product and each country in the Territory, the period beginning on the Effective Date and ending on [\*\*\*]. For clarity, Royalty Term shall last on country-by-country basis until [\*\*\*].
- 1.84 **“Selected Drug”** means a drug that was selected for Medicare price negotiation and published by the Secretary of the U.S. Department of Health and Human Services, in each case, under the Inflation Reduction Act.
- 1.85 **“Senior Officer”** means, with respect to Licensor, [\*\*\*] and with respect to Licensee, its Chief Executive Officer.
- 1.86 **“Sublicensee”** means a Third Party, (a) to whom Licensee or any of its Affiliates has granted a sublicense under the License granted in Section 2.1 (Grant to Licensee ) with a right to Commercialize a Licensed Product (but excluding any Distributors) and (b) who has undertaken to make a royalty payment or other payment to Licensee or its Affiliates in consideration of such rights or who is subject to other contractual arrangements with Licensee or its Affiliates whereby Licensee or its Affiliate share in the profits or has an equivalent interest in the proceeds from the sale of the Licensed Product by such Third Party. For clarity, any Third Party that (i) is granted a sublicense under the license granted in Section 2.1 (Grant to Licensee ) solely to enable such Third Party to provide contract research or development services or contract manufacturing services for Licensee, its Affiliates or Sublicensees, and (ii) does not have the right to distribute, market or sell the Licensed Products shall not be a “Sublicensee” for the purposes of this Agreement.
- 1.87 **“Sublicensing Fees”** has the meaning set out in Section 7.8 (Sublicensing Income).
- 1.88 **“Sublicensing Income”** means, with respect to a Licensed Product in a particular country in the Territory for a particular period of time, all payments, directly or indirectly, by or on behalf of a Sublicensee to Licensee or any of its Affiliates relating to, or resulting from, in either case, directly or indirectly, [\*\*\*] in which such Sublicensee obtains from Licensee or any of its Affiliates a license (or sublicense) in respect of the Licensed Patent Rights or the Licensed Know-How to Exploit a Licensed Product other than [\*\*\*], including [\*\*\*].
- 1.89 **“Tax”** or **“Taxation”** means and includes all forms of taxation, levy, impost or duty and any similar charge, contribution, deduction or withholding and all penalties, charges, surcharges, fines, costs and interest included in, or relating to, any of the foregoing or to any obligation in respect of any of the foregoing.
- 1.90 **“Tax Authority”** means any government, state, or municipality or any local, state, federal or other fiscal, revenue, customs or excise authority, body or official anywhere in the world.
- 1.91 **“Tax Deductions”** means any deduction or withholding for or on account of Tax.
- 1.92 **“Tax Returns”**, each **“Tax Return”** means any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document, attachments, statements, or information filed with or submitted to, or required to be filed with or submitted to, any Tax Authority in connection with the determination, assessment, collection, or payment of any Tax.
- 1.93 **“Term”** has the meaning set out in Section 13.1 (Term and Expiration).
- 1.94 **“Terminated Territory”** has the meaning set out in Section 13.2.2.
- 1.95 **“Termination Notice”** has the meaning set out in Section 13.2.2 (Material Breach).



- 1.96“**Territory**” means the entire world.
- 1.97“**Third Party**” means any Person other than Licensor, Licensee, and their respective Affiliates.
- 1.98“**Third Party Claims**” has the meaning set out in Section 12.1 (Indemnification of Licensor).
- 1.99“**Third Party Infringement Claim**” has the meaning set out in Section 8.4.1 (Notice of Third Party Infringement Claims).
- 1.100“**Trademark Assignment Agreement**” means a trademark assignment agreement to be entered into between Licensor and Licensee after the Effective Date, with respect to the Assigned Trademarks, in a form mutually acceptable to the Parties.
- 1.101“**United States**” or “**U.S.**” means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).
- 1.102“**Upfront Payment**” has the meaning set out in Section 7.1.1 (Upfront Payment).
- 1.103“**Valid Claim**” means: (a) a claim of any issued and unexpired Patent Right whose validity, enforceability or patentability has not been affected by: (i) irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer; or (ii) 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; or (b) a claim of a pending patent application that was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application; *provided* that such patent application has not been pending for longer than [\*\*\*] since the earliest date to which such patent application claims priority.

## 2. GRANT OF RIGHTS; EXCLUSIVITY

- 2.1 **Grant to Licensee.** Licensor, on behalf of itself and its Affiliates, hereby grants to Licensee and its Affiliates an exclusive (including with regard to Licensor and its Affiliates), transferable (pursuant to Section 14.3 (Assignment)) license, with the right to grant sublicenses through multiple tiers (subject to Section 2.2 (Sublicenses)), under the Licensed Technology to: (a) Exploit the Licensed Compound and Licensed Products in the Field in the Territory; and (b) develop, manufacture, have manufactured and commercialize products or services as companion or complementary diagnostics in relation to Licensed Products.
- 2.2 **Sublicenses.** Subject to Section 5.4 (Right of First Negotiation), Licensee has the right to grant sublicenses through multiple tiers of sublicensees under the licenses granted in Section 2.1 (Grant to Licensee ), to other Persons, without need for Licensor’s consent; *provided* that any such sublicenses shall be consistent with the terms and conditions of this Agreement. Licensee hereby guarantees the performance of its Affiliates and Sublicensees and the grant of any such sublicense shall not relieve Licensee of its obligations under this Agreement, except to the extent they are satisfactorily performed by such Sublicensee. Licensee shall provide Licensor a copy of any sublicense agreement executed by Licensee within [\*\*\*] after its execution; provided that the financial terms of any such sublicense agreement to the extent not pertinent to an understanding of a Party’s obligations or benefits under this Agreement may be redacted.
- 2.3 **No Implied Rights.** Except as expressly provided herein, neither Party grants to the other any other right or License under this Agreement, including any rights or licenses to any Know-How, Patent Rights or other intellectual property not otherwise expressly granted herein, whether by implication, estoppel, or otherwise.

- 2.4 **Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Licensee or Licensor are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Licensee, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party’s possession, shall be promptly delivered to it: (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party’s written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement; or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.
- 2.5 **Combination Products.** Although the definition of Licensed Products allows for Licensed Products that (in addition to containing a Licensed Compound) incorporate active pharmaceutical ingredients other than a Licensed Compound, the definition of Licensed Technology and the licenses granted to Licensee hereunder will not include rights to any other active pharmaceutical ingredient of any product owned or Controlled by Licensor or its Affiliates other than the Licensed Compound.
- 2.6 **Assigned Agreements.** Licensor shall assign to Licensee Licensor’s rights in the agreements listed in Schedule 3 (“Assigned Agreements”) pursuant to the Assignment and Assumption Agreement.
- 2.7 **Assigned Trademarks.** Licensor shall assign to Licensee Licensor’s rights in the Assigned Trademarks pursuant to the Trademark Assignment Agreement. While Licensor will take all the reasonable efforts to assign the Assigned Trademarks as soon as practicable after the Effective Date, Licensee understands and agrees that such assignment might be impacted by some procedural delays relating to transfer.
- 2.8 **Disclosure of Know-How and Regulatory Documentation.** Licensor shall and shall cause its Affiliates and its and its Affiliates’ personnel to, without additional compensation, disclose and make available to Licensee, in whatever form Licensee may reasonably request (including by providing copies thereof) the Regulatory Documentation and Licensed Technology that is in existence as of the Effective Date, and shall use commercially reasonable efforts to disclose, including in readily editable formats such as PowerPoint and Word and Excel where helpful to Licensee, the foregoing within [\*\*\*] after the Effective Date including: (a) [\*\*\*]; and (b) copies of all correspondence, as of the Effective Date, to and from any Regulatory Authority that relates to the Licensed Compound or Licensed Products, including copies of all Regulatory Documentation for the Licensed Compound or Licensed Products. Both (a) and (b) shall be shared subject to local legal and regulatory data protection requirements and third-party approvals as applicable. For clarity, Licensor has no obligation to transfer any trademarks or information related thereto that do not constitute Assigned Trademarks or Licensed Know-How. [\*\*\*].
- 2.9 **Confirmatory Patent License.** Licensor shall if requested to do so by Licensee promptly enter into confirmatory License agreements in such form as may be reasonably requested by Licensee for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory as Licensee considers appropriate. In the event of any conflict between the terms of any such confirmation License agreement and the terms of this Agreement, the terms of this Agreement shall prevail.

2.10 **Exclusivity.**

2.10.1 **Exclusivity Covenant.** During the Term, except in the performance of activities under this Agreement, Licensee shall not and shall cause its Affiliates not to, (a) directly or indirectly, Develop, Manufacture, or Commercialize or (b) license, authorize, appoint or otherwise enable any Third Party to directly or indirectly, Develop, Manufacture, or Commercialize, in either case ((a) or (b)), any pharmaceutical product that contains [\*\*\*] (each, a “**Competitive Product**”) anywhere in the Territory other than Licensed Products.

2.10.2 Notwithstanding the foregoing, if, as a result of a Change of Control, Licensee or any of its Affiliates merges or consolidates with, or is acquired by, a Third Party that is then engaged in activities that would otherwise constitute a breach of Licensee’s obligations under Section 2.10.1 (Exclusivity Covenant) by Licensee or any of its Affiliates (a “**Competitive Program**”), unless the Parties agree otherwise in writing, Licensee shall, within [\*\*\*] after the date of such Change of Control, notify Licensor that it intends to either: (a) terminate, or cause its relevant Affiliate to terminate, the Competitive Program, in which case Licensee or its Affiliate, as applicable, shall terminate such Competitive Program within [\*\*\*] (unless Applicable Law requires a longer termination period) after Licensee delivers such notice to Licensor, or (b) divest, or cause its relevant Affiliate to divest, whether by license or otherwise, the Competitive Program, in which case Licensee shall use all reasonable efforts to effect such divestiture as quickly as possible and, in any event, within [\*\*\*] after Licensee delivers such notice to Licensor (unless Applicable Law requires a longer divestiture period). During the period that Licensee or its Affiliate, as applicable, is terminating or divesting any Competitive Program, Licensee shall (i) ensure that all activities with respect to such Competitive Program (A) do not use or incorporate and are not based on any Licensed Technology, (B) are not covered by or otherwise related to and do not incorporate or reference any Licensed Technology, and (C) are kept separate from the activities performed under or in connection with this Agreement, and (ii) establish reasonable internal safeguards designed to prevent any Licensed Technology from being utilized in connection with such Competitive Program.

2.10.3 Licensee acknowledges and agrees that (a) this Section 2.9.3 has been negotiated by the Parties, (b) the geographical and time limitations on activities set forth in Section 2.10.1 (Exclusivity Covenant) are reasonable, valid and necessary in light of the Parties’ circumstances and necessary for the adequate protection of the business of the Licensed Compound and the Licensed Products and (c) Licensee would not have entered into this Agreement without the protection afforded it by this Section 2.9.3.

3. **DEVELOPMENT**

3.1 **Development; In General.** Subject to Section 5.2 (Diligence) as between the Parties, Licensee will have the sole right, at its sole cost and expense, to Develop, Manufacture and Commercialize the Licensed Compound and Licensed Products as enumerated below and make all decisions with respect thereto. Further, Licensee will have the right to subcontract any of its activities under this Agreement to one or more Third Parties.

3.2 **Development Plan.** Licensor may request [\*\*\*] a development plan from Licensee for the Licensed Product (the “**Development Plan**”), and Licensee shall timely provide upon such request its current Development Plan. [\*\*\*].

- 3.3 **Subcontracting.** Licensee will have the right to subcontract the Development activities to a Third Party without the prior written approval of Licensor. No such permitted subcontracting will relieve the Licensee of any obligations hereunder.
- 3.4 **Development Records.** Licensee shall maintain, and cause its Affiliates and subcontractors to maintain, in good scientific manner, complete and accurate books and records pertaining to its Development of Licensed Products hereunder, in sufficient detail to verify compliance with its obligations under this Agreement and which shall be appropriate for patent and regulatory purposes, in compliance with Applicable Law and properly reflect all work done and results achieved in the performance of such Development activities. Such books and records shall be retained by Licensee for [\*\*\*] after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. Licensor will have the right [\*\*\*], during normal business hours and upon reasonable notice, to inspect and copy all records of Licensee or its Affiliates or subcontractors maintained pursuant to this Section 3.4; *provided* that Licensor shall maintain such records and the information disclosed therein in confidence in accordance with Section 10 (Confidentiality and Non-Disclosure).
- 3.5 **Alliance Managers.** Each Party shall appoint a person(s) who shall oversee contact between the Parties for all matters arising under this Agreement and shall have such other responsibilities as the Parties may agree in writing after the Effective Date, which person(s) may be replaced at any time by notice in writing to the other Party. The Alliance Managers shall work together to manage and facilitate the communication between the Parties under this Agreement, including the resolution of issues between the Parties that arise in connection, and in accordance, with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement. While the Alliance Managers might be involved in negotiating an amendment to this Agreement, they shall not be entitled to legally bind either Party to an amendment to this Agreement.

#### 4. REGULATORY ACTIVITIES

- 4.1 **Regulatory Activities.** Licensor hereby assigns the Regulatory Documentation and Regulatory Approvals listed in Schedule 4 (“**Assigned Regulatory Documentation**”) to Licensee. Licensee will have the sole right to prepare, file, obtain, and maintain Regulatory Approvals (including the setting of the overall regulatory strategy), and other regulatory submissions and to conduct all correspondence and communications with Regulatory Authorities (including adverse event reporting), for Licensed Compound and Licensed Products in the Territory (which will include filings of or with respect to authorizations for the commencement of clinical studies and other filings or communications with the Regulatory Authorities with respect to Development activities. For clarity, all regulatory filings shall be done in the name of Licensee and shall be owned by the Licensee.
- 4.2 **Recalls, Suspensions, or Withdrawals.** Licensee shall use Commercially Reasonable Efforts to notify Licensor promptly following its determination that any event, incident, or circumstance has occurred that may result in the need for a recall, market suspension, or market withdrawal of a Licensed Product in the Territory. As between the Parties, Licensee shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension, or market withdrawal in the Territory. If a recall, market suspension, or market withdrawal is mandated by a Regulatory Authority in the Territory, as between the Parties, Licensee shall initiate such recall, market suspension, or market withdrawal in compliance with Applicable Law. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 4.2 (Recalls, Suspensions, or Withdrawals), as between the Parties, Licensee shall be solely responsible for the execution.
- 4.3 **Global Safety Database.** Licensee will establish, hold, and maintain (at Licensee’s cost and expense) the global safety database for Licensed Products.

**5. COMMERCIALIZATION AND DILIGENCE**

- 5.1 **Commercialization; In General.** As between the Parties, Licensee (itself or through its Affiliates or its or their Sublicensees) shall have the sole right to Commercialize Licensed Products in the Territory at its sole cost and expense.
- 5.2 **Diligence.** Licensee (itself or through its Affiliates or its or their Sublicensees) will use Commercially Reasonable Efforts to Develop and, following receipt of Regulatory Approval of a Licensed Product in the applicable country in the Territory, Commercialize, one (1) Licensed Product for use in humans in one (1) indication in at least one (1) of the Major Markets. For clarity, Licensee shall not be obligated to Develop, seek Regulatory Approvals for, or commercialize more than one (1) Licensed Product for use in humans in more than one (1) indication in any Major Market as defined in 1.47. Licensee's failure to fulfil any of the foregoing commercialization obligations shall constitute a material breach of this Agreement and would lead to Licensor's right to terminate this Agreement in accordance with Section 13.2.2.
- 5.3 **Licensee Annual Reports.** With respect to Development and Commercialization of Licensed Compound and Licensed Products performed by or on behalf of Licensee or its Affiliates or Sublicensees, if requested by Licensor in writing, Licensee will provide to Licensor a detailed report (within [\*\*\*]) of its Development and Commercialization activities relating to Licensed Compound and Licensed Products. Each Report shall contain sufficient detail to enable Licensor to assess Licensee's compliance with its obligations set forth in Section 5.2, including in each case: [\*\*\*].
- 5.4 **Right to First Negotiation.** If Licensee desires to grant a sublicense under any Licensed Technology to a Third Party, Licensee shall provide written notice thereof to Licensor including a summary of all clinical data generated by Licensee as of such time and, if applicable, the financial terms of such proposed sublicense. Upon receipt of such notice, Licensor would have the right to elect to exercise, by delivering a written notice to Licensee (the "**Exercise Notice**") within [\*\*\*] of receipt of Licensee's notice, a right of first negotiation ("**ROFN**") to regain the rights licensed under this Agreement on an exclusive basis. Following delivery of the Exercise Notice, Licensee will negotiate in good faith with Licensor (on an exclusive basis) an agreement for a period of [\*\*\*]. If the Parties, after using good faith efforts, are unable to agree on terms and execute a definitive agreement with respect to such transaction within such [\*\*\*] from the date of election of such right by the Licensor, Licensee will have the right to enter into discussions with and execute any such sublicense with respect to such Licensed Product in the Territory, provided that the terms of such sublicense shall be on no more favourable terms than the terms last offered to the Licensor.

**6. NO OBLIGATION TO MANUFACTURE BY LICENSOR**

Licensee understands that there is no inventory of Licensed Compound or Licensed Products which is available and further Licensor shall be under no obligation to Manufacture or have Manufactured, Licensed Compounds or Licensed Products.

**7. PAYMENTS AND MILESTONES**

**7.1 Upfront Payment.**

7.1.1 **Upfront Cash Payment.** Licensee will pay Licensor a one-time, non-creditable, non-refundable, upfront amount equal to four million Dollars (\$4,000,000.00) (the "**Upfront Payment**"), which shall be in two (2) instalments in accordance with this Section 7.1.1. [\*\*\*].

7.1.2 **Upfront Equity Payment; Additional Equity.** Simultaneous with this Agreement, the Parties are entering into a Common Stock Investment Agreement (the “**Investment Agreement**”), under which Licensee shall issue, to Licensor or its designated Affiliate, 387,329 shares of common stock of Licensee (the “**Shares**”) constituting a beneficial ownership of 9.9% in Licensee. Pursuant to the Investment Agreement, the Licensee has also agreed to issue additional shares of common stock to the Licensor to prevent dilution through an anti-dilution right to Licensee as enumerated under the terms and conditions set forth therein. The Parties acknowledge that the equity issuances under Investment Agreement constitute a portion of the Upfront Payment under this Agreement.

7.2 **Development Milestones.**

7.2.1 **Development Milestones.** Licensee will pay to Licensor the following one-time, non-refundable, milestone payments (each, a “**Milestone Payment**”) following achievement of each of the corresponding milestone events set out below (each, a “**Milestone Event**”) for the first Licensed Product to achieve such Milestone Event (whether achieved by or on behalf of Licensee, its Affiliates, or its Sublicensees):

<b>Number</b>	<b>Milestone Event</b>	<b>Milestone Payment (in USD)</b>
1.	Regulatory Approval of an NDA or equivalent with respect to a Licensed Product in [***]	[\$***]
2.	Regulatory Approval of an NDA equivalent with respect to a Licensed Product in [***]	[\$***]
3.	Regulatory Approval of an NDA equivalent with respect to a Licensed Product in [***]	[\$***]
<b>Total maximum if all of Milestone Events 1 – 3 are achieved:</b>		<b>[\$***]</b>

7.2.2 **Development Milestone Payments.** Each Milestone Payment in Section 7.2.1 (Development Milestones) shall be payable only upon the first achievement of the corresponding Milestone Event and no amounts shall be due for subsequent or repeated achievements of such Milestone Event, whether for the same or a different Licensed Product. Licensee shall give Licensor written notice of the achievement of each Milestone Event in Section 7.2.1 (Development Milestones) no later than [\*\*\*] after achievement thereof (or, with respect to Milestone Events achieved by Sublicensees, no later than [\*\*\*] after such achievement). Licensor shall submit an invoice to Licensee promptly, following receipt of such notice for the full amount of the corresponding Milestone Payment, which amount will be payable within [\*\*\*] after Licensee’s receipt of the applicable invoice.

7.3 Net Sales Milestones.

7.3.1 **Net Sales Milestones.** Licensee will pay the following one-time milestone payments (each, a “**Net Sales Milestone Payment**”) to Licensor upon the first achievement during the Term of the corresponding milestone event set out below (each a “**Net Sales Milestone Event**”) (whether achieved by or on behalf of Licensee, its Affiliates or its Sublicensees):

<b>Net Sales Milestone Event</b>	<b>Net Sales Milestone Payment (In USD)</b>
The first Calendar Year during which the total Net Sales of all Licensed Products throughout the Territory exceeds \$[***]	\$[***]
The first Calendar Year during which the total Net Sales of all Licensed Products throughout the Territory exceeds \$[***]	\$[***]
The first Calendar Year during which the total Net Sales of all Licensed Products throughout the Territory exceeds \$[***]	\$[***]
The first Calendar Year during which the total Net Sales of all Licensed Products throughout the Territory exceeds \$[***]	\$[***]
<b>Total maximum if all Net Sales Milestone Events are achieved:</b>	<b>\$[***]</b>

7.3.2 **Net Sales Milestone Payments.** Each Net Sales Milestone Payment will be payable only upon the first achievement of the corresponding Net Sales Milestone Event in a given Calendar Year and no amounts will be due for subsequent or repeated achievements of such Net Sales Milestone Event in the same or subsequent Calendar Years. If, in a given Calendar Year, more than one of the Net Sales Milestone Events are achieved for the first time, Licensee shall pay to Licensor the relevant Net Sales Milestone Payment with respect to each such Net Sales Milestone Event achieved in such Calendar Year.

7.3.3 **Net Sales Milestone Payment Procedure.** Licensee will give Licensor written notice of the achievement of a Net Sales Milestone Event no later than [\*\*\*] in which such milestone was achieved. Licensor shall submit an invoice to Licensee promptly, following receipt of such notice for the full amount of the corresponding Net Sales Milestone Payment, which amount will be payable within [\*\*\*] after License’s receipt of the invoice.

7.3.4 **Expiration of Royalty Term.** With respect to each Licensed Product in each country in the Territory, from and after the expiration of the Royalty Term for such Licensed Product in such country, Net Sales of such Licensed Product in such country will be excluded for purposes of calculating the Net Sales thresholds for the Net Sales Milestone Events set out in Section 7.3.1 (Net Sales Milestones).

**7.4 Royalties.**

**7.4.1 Royalty Rates.** Until the expiration of the Royalty Term on a country-by-country basis for each Licensed Product, Licensee will pay to Licensor a royalty on Net Sales of all Licensed Products by Licensee, its Affiliates and Sublicensees in the Territory during each Calendar Year at the following rates:

<b>Net Sales of a Licensed Product</b>	<b>Royalty Rate</b>
For that portion of total Net Sales of all Licensed Products in the Territory during any Calendar Year less than \$[***]	[***]%
For that portion of total Net Sales of all Licensed Products in the Territory during any Calendar Year equal to or greater than \$[***] but less than \$[***]	[***]%
For that portion of total Net Sales of all Licensed Products in the Territory during any Calendar Year equal to or greater than \$[***] but less than \$[***]	[***]%
For that portion of total Net Sales of all Licensed Products in the Territory during any Calendar Year equal to or greater than \$[***]	[***]%

Notwithstanding any other provision of this Agreement, with respect to each Licensed Product in each country in the Territory, from and after the expiration of the Royalty Term for such Licensed Product in such country, Net Sales of such Licensed Product in such country shall be royalty-free and shall be excluded for purposes of calculating the Net Sales thresholds and ceilings set out in this Section 7.4.1 (Royalty Rates).

Royalties shall be payable only once for any given unit of Licensed Product.

**7.5 Reductions.** Notwithstanding any other provision of this Agreement:

**7.5.1 Generic Entry.** If, at any time in a particular country in the Territory (a) a Generic Product is sold (the first Calendar Quarter in which such sale occurs being the “**Generic Entry Quarter**”); and (b) the aggregate number of units of the relevant Licensed Product sold in any Calendar Quarter following the Generic Entry Quarter decrease by more than [\*\*\*] compared to the Calendar Quarter immediately preceding the Generic Entry Quarter; then [\*\*\*] of the Net Sales of such Licensed Product in such country shall be disregarded solely for the purposes of calculating the royalties of such Licensed Product under Section 7.4.1 (Royalty Rates) as from the Calendar Quarter immediately following the Generic Entry Quarter and thereafter for the remainder of the Royalty Term for the Licensed Product in such country. The calculation of the royalty reduction under this Section 7.5.1 (Generic Entry) shall be conducted separately for each Licensed Product in each country.

**7.5.2 Right to Offset Third Party Payments.** If Licensee or any of its Affiliates or Sublicensees has to pay any [\*\*\*] to a Third Party in any country under a [\*\*\*], in order to Exploit a Licensed Product (or the Licensed Compound contained therein) in a country in the Territory, then Licensee shall be entitled to deduct from any royalties payable to Licensor hereunder with respect to such Licensed Product an amount equal to [\*\*\*] actually paid to such Third Party in respect of such agreement, solely to the extent that [\*\*\*]. The foregoing right to credit payments to such Third Party pursuant to this Section 7.5.2 (Right to Offset Third Party Payments) shall only apply with respect to [\*\*\*].



**7.5.3Lack of Valid Claim.** If, within any time period during the Royalty Term for a Licensed Product in a particular country, the Licensed Product is not covered by any Valid Claim within the Licensed Patent Rights that claims a Licensed Compound included in such Licensed Product as a composition of matter, then [\*\*\*] of the Net Sales during such time period in such country shall be disregarded solely for the purposes of calculating the royalties of such Licensed Product pursuant to Section 7.4.1 (Royalty Rates). The calculation of the royalty reduction under this Section 7.5.3 (Lack of Valid Claim) shall be conducted separately for each Licensed Product in each country.

**7.5.4Inflation Reduction Act Deductions.** If, during the Royalty Term for a Licensed Product in the US, such Licensed Product is designated as a Selected Drug by the Secretary of the US Department of Health and Human Services, and Licensee, its Affiliate or its or their Sublicensee is required to negotiate, and is ultimately subject to, a Maximum Fair Price that is equal to or less than [\*\*\*] of the then-current price (*i.e.*, prior to the time at which such Licensed Product is designated as a Selected Drug) that will apply to sales of such Licensed Product during the Price Applicability Period, then, for the purposes of calculating royalties of such Licensed Product pursuant to Section 7.4.1 (Royalty Rates), [\*\*\*] of the Net Sales of such Licensed Product in the US shall be disregarded during the Price Applicability Period. The calculation of the royalty reduction under this Section 7.5.4 (Inflation Reduction Act Deductions) shall be conducted separately for each Licensed Product in the U.S. Licensee shall have sole and absolute discretion with respect to any matters relating to the Exploitation of a Licensed Product which relate to or are affected by the Inflation Reduction Act, including without limitation negotiations with respect to a Maximum Fair Price. If, during the Royalty Term for a Licensed Product in any country (including the US), any Applicable Law similar or analogous in nature to the Inflation Reduction Act applies and results in the negotiation of, or automatic application of, a maximum price (or other similar or analogous mechanism) applicable to all or some sales of the Licensed Product, then the mechanism set out in this Section 7.5.4 (Inflation Reduction Act Deductions) shall apply with such adjustments as Licensee determines are reasonably necessary in relation to the relevant Applicable Law to achieve the same or substantially the same results as that contemplated by this Section 7.5.4 (Inflation Reduction Act Deductions).

**7.5.5Maximum Amount of Royalty Reduction.** In no event shall the royalties payable to Licensor under Section 7.4 (Royalties) be reduced by more than [\*\*\*] in any Calendar Quarter during the Royalty Term as a result of the reductions set out in this Agreement. [\*\*\*].

**7.6 Combination Products Adjustment.** If Licensor is entitled to receive royalties under this Agreement from any Licensed Product sold in the form of a Combination Product in any given country, then Net Sales for such Combination Product will be calculated by multiplying the actual Net Sales of such Combination Product in such country by the fraction  $A/(A+B)$ , where A is the standard sales price in such country of a Licensed Product containing the same Licensed Compound as the sole active ingredient as included in the Combination Product in question (a “Comparable Product”), if sold separately, and B is the standard sales price in the given country of the ready for sale form of a product containing the same amount of each other therapeutically active ingredient(s) in the Combination Product that is not a Licensed Compound (the “Other Components”), if sold separately. If, on a country-by-country basis, the Other Components are not sold separately in a country, Net Sales in such country for the purpose of determining royalties of the Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction  $A/C$  where A is the standard sales price in such country of a Comparable Product, if sold separately, and C is the standard sales price of the Combination Product in such country. If, on a country-by-country basis, a Comparable Product is not sold separately, Net Sales in such country for the purpose of determining royalties of the Combination Product shall be calculated by multiplying the actual Net Sales of such Combination Product by the fraction  $(C-B)/C$ , where B is the standard sales price in such country of the Other Components, if sold separately, and C is the standard sales price in such country of the Combination Product. For the purpose of the above, the standard sales price for a Comparable Product and for each Other Components shall be for a quantity comparable to that used in the Combination Product in question and of the same class, purity, and potency. If, on a country-by-country basis, neither a Comparable Product nor the Other Components are sold separately in a country, Net Sales in such country for the purposes of determining royalties of such Combination Product shall be determined by Licensee in its reasonable determination based on the relative fair market value (through an independent third party) of such Comparable Product and Other Components, taking into account the medical contribution to the Combination Product of, and all other factors reasonably relevant to the relative value of, the Licensed Compound, on the one hand, and all of the Other Components as applicable, collectively, on the other hand.

- 7.7 **Royalty Payments and Reports.** During the Royalty Term, Licensee shall calculate all amounts payable to Licensor pursuant to Section 7.4 (Royalties) at the end of each Calendar Quarter, which amounts (if initially in a currency other than Dollars) shall be converted to Dollars, in accordance with Section 9 (Mode of Payment). Licensee shall provide to Licensor a written statement (the “**Royalty Report**”) with respect to a given Calendar Quarter within [\*\*\*] after the end of such Calendar Quarter. Each Royalty Report shall include, on a Licensed Product-by-Licensed Product basis, the amount of invoiced Sales, Net Sales and deductions taken to arrive at Net Sales attributable to each Licensed Product in each country in the Territory during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter. Licensor shall, promptly after (but not before) its receipt of the Royalty Report, submit an invoice to Licensee for the full amount of the corresponding royalty payment, which amount shall be payable within [\*\*\*] after Licensee’s receipt of a valid invoice.
- 7.8 **Sublicensing Income.** In the event Licensee sublicenses rights to a Licensed Product to a Third Party prior to its First Commercial Sale, or First Alternate Sale as case may be then Licensee shall pay Licensor [\*\*\*] of all Sublicensing Income that Licensee receives under each such sublicense (“**Sublicensing Fees**”) in addition to all milestones and royalties outlined above in Section 7.
- 7.9 **Sublicensing Income Payments; Reports.** Licensee shall calculate all Sublicensing Fees payable to Licensor pursuant to Section 7.8 on Sublicensing Income received by Licensee during a Calendar Quarter at the end of such Calendar Quarter. Licensee shall pay to Licensor the Sublicensing Fees due with respect to Sublicensing Income received during a given Calendar Quarter within [\*\*\*]. Each payment of Sublicense Fees due to Licensor shall be accompanied by a statement specifying the amount of Sublicense Income received by Licensee or any of its Affiliates during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of payment due to Licensor on such Sublicense Income for such Calendar Quarter. Without limiting the foregoing, Licensee shall require its Affiliates to account for their Sublicense Income and to provide such reports with respect thereto, as if such amounts were received by Licensee.
- 7.10 **Mode of Payment; Offsets.** 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 its Accounting Standards.

7.11 Taxes.

7.11.1 **Withholding Taxes.** The Parties agree that all charges under this Agreement are inclusive of all Taxes imposed or payable to any Tax Authority except Indirect Taxes. All amounts payable by one Party (the “**Payor**”) to another (the “**Payee**”) pursuant to this Agreement shall be paid by the Payor without any Tax Deductions unless the Payor is required to make a Tax Deduction by Applicable Law. For clarity, the Payee alone shall be responsible for paying to the appropriate Tax Authority all Taxes (other than any Tax Deductions required by Applicable Law) levied on account of, or measured in whole or in part by reference to, any payments the Payee is entitled to receive. Subject to the foregoing, where the Payor is required to make a Tax Deduction by Applicable Law from a payment, the Payor shall make that Tax Deduction and any payment required in connection with that Tax Deduction within the time allowed, and in the amount required, by Applicable Law. The Payor shall notify the Payee in writing at least [\*\*\*] before any payment is due where it expects to make any Tax Deduction. Such notification shall contain sufficient details to enable the Payee, acting reasonably, to ascertain whether it is entitled under a tax treaty or otherwise to any reduction or elimination of such Tax Deduction. If the Payee is entitled under any applicable tax treaty to a reduction in the rate of, or the elimination of, a Tax Deduction, it may deliver to the Payor or the appropriate Tax Authority (with the assistance of the Payor to the extent that such is reasonably required) the prescribed forms necessary to reduce the applicable rate of such Tax Deduction or to relieve the Payor of its obligation to make such Tax Deduction, and the Payor shall apply the reduced rate of Tax Deduction, or make that payment without a Tax Deduction, as the case may be, provided that the Payor has received evidence, in a form reasonably satisfactory to it, of the Payee’s delivery of all applicable forms at least [\*\*\*] prior to the time that the payments are due. Within [\*\*\*] of making a Tax Deduction or any payment required in connection with that Tax Deduction, the Payor shall deliver to the Payee evidence reasonably satisfactory to the Payee that the Tax Deduction has been made or (as applicable) any appropriate payment paid to the relevant Tax Authority. If a Payor makes a Tax Deduction while the Payee is entitled under any applicable tax treaty to a reduction in the rate of, or the elimination of, such Tax Deduction, the Payor shall cooperate with the Payee with respect to any documentation or procedural formalities required by the appropriate Tax Authority or reasonably requested by the Payee to secure a reduction in the rate of, or the elimination of, such Tax Deduction or to obtain a recovery of that Tax Deduction from the applicable Tax Authority.

7.11.2 **Indirect Taxes.** All payments under this Agreement are stated exclusive of Indirect Taxes. If by Applicable Law any Indirect Tax is payable by the recipient of any supply made under this Agreement, the recipient has the sole responsibility to pay the Indirect Tax without recourse to the supplier. If any Indirect Taxes are chargeable in respect of any payments due under this Agreement, the Payor shall pay such Indirect Taxes at the applicable rate in respect of any such payments following the receipt, where applicable, of a valid invoice issued in the appropriate form by the Payee in respect of those payments to which such Indirect Taxes relate, such Indirect Taxes to be payable on the due date of the payment to which such Indirect Tax relates. The Parties shall issue invoices for all goods and services supplied under this Agreement consistent with the law governing such Indirect Tax and irrespective of whether the sums may be netted for settlement purposes, and to the extent any invoice is not initially issued in an appropriate form the Parties shall cooperate to provide such information or assistance as may be necessary to enable the issuance of such invoice consistent with the law governing such Indirect Tax. Where a supply is cancelled or the value of a supply under this Agreement is adjusted the supplying Party shall issue to the recipient an adjustment note or other such document in accordance with the law governing such Indirect Tax. If any Indirect Tax originally paid or otherwise borne by the paying Party is 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 Tax Authority and any amount of undue Indirect Taxes repaid by such authority to the receiving Party will be transferred to the paying Party within [\*\*\*] of receipt. Where under the terms of this Agreement one Party is liable to indemnify or reimburse another Party (or an Affiliate of that other Party) in respect of any costs, charges or expenses, the payment shall include an amount equal to any Indirect Tax thereon not otherwise recoverable by the other Party (or its Affiliate) or the representative member of any Indirect Tax group of which it forms part, subject to that Party or Affiliate or representative member using all reasonable endeavours to recover such amount of Indirect Tax as may be practicable.

**7.11.3 Tax Cooperation.** The Parties shall procure that their group tax functions shall fully cooperate with each other in relation to any reasonable request in connection with any matter relating to Tax arising from this Agreement, including information required for the preparation and filing of any Tax Return or the conduct of any audit, investigation, dispute or appeal or any other communication with any Tax Authority, in each case if and to the extent: (i) legally permissible; and (ii) that such disclosure would not breach any duty of confidentiality or waive privilege. The requesting Party shall be responsible for any third party costs properly incurred by the other Party in complying with this Section 7.11.3 (Tax Cooperation).

**7.12 Prevention of Facilitation of Tax Evasion.** In this Section 7.12, (Prevention of Facilitation of Tax Evasion), references “to “committing tax evasion” shall include: (a) fraudulently failing to pay any amount of Tax to the relevant Tax Authority within any applicable time limit for the payment of such Tax without incurring interest or penalties; and (b) fraudulently claiming any relief, allowance, credit, deduction, exemption or set-off in respect of any Tax (or relevant to the computation of any income, profits or gains for the purposes of any Tax), or any right to or actual repayment of or saving of Tax.

7.12.1 Each Party represents, warrants and undertakes that: (a) neither it nor its Affiliates shall commit tax evasion in relation to any Tax for which it is responsible arising out of the transactions contemplated by this Agreement; (b) neither it nor its Affiliates shall undertake any activities which would facilitate or otherwise result in another Person committing tax evasion in relation to any Tax for which it is responsible arising out of the transactions contemplated by this Agreement; and (c) it and its Affiliates shall maintain reasonable procedures designed to prevent any employees, agents, or other Persons who perform services for them or on their behalf from undertaking any activities which would facilitate or otherwise result in another Person committing tax evasion in relation to any Tax for which it is responsible arising out of the transactions contemplated by this Agreement.

7.12.2 Licensor shall promptly report any apparent breach of Section 7.12 (Prevention of Facilitation of Tax Evasion) to Licensee. Licensee shall promptly report any apparent breach of Section 7.12 (Prevention of Facilitation of Tax Evasion) to Licensor.

7.12.3 Each Party shall: (a) answer, in reasonable detail, any written or oral inquiry from the other Party related to such Party’s compliance with this Section 7.12 (Prevention of Facilitation of Tax Evasion); (b) facilitate the interview of staff employed by such Party (or any agent of such Party) at any reasonable time specified by the other Party related to such Party’s compliance with this Section 7.12 (Prevention of Facilitation of Tax Evasion); and (c) co-operate with the other Party or any regulator or public authorities in relation to any investigation relating to the matters referred to in this Section 7.12 (Prevention of Facilitation of Tax Evasion).

- 7.13 **Re-domiciliation or Assignment.** If a Party's re-domiciliation to (or assignment of this Agreement to an entity resident for purposes of an applicable Tax treaty in) a jurisdiction other than the jurisdiction in which such Party is resident for such purposes as of the date of this Agreement (but not, for the avoidance of doubt, a change in Applicable Law), leads to the imposition of withholding Tax liability on the other Party that would not have been imposed in the absence of such action then such Party will reimburse the other Party for any such additional or increased withholding Tax liability (except to the extent that the other Party can reclaim it, provided that the other Party will be reimbursed for any reasonable out of pocket costs incurred in the reclaim).
- 7.14 **Interest on Late Payments.** If any payment due to either Party under this Agreement is not paid when due, then the receiving Party shall be entitled to charge interest thereon (before and after any judgment) at an annual rate equal to the lesser of (a) [\*\*\*] above the Reference Rate, and (b) the maximum rate permitted under Applicable Law. Any interest will accrue from day to day and is calculated based on the actual number of days elapsed from the payment due date to the actual payment date and a year of three hundred and sixty-five (365) days. Interest is compounded daily. "Reference Rate" means the greater of (i) [\*\*\*]; and (ii) zero. "Late Payment Business Day" means any day which is not in the United States of America a Saturday, a Sunday, a legal holiday or a day on which banking institutions are closed.
- 7.15 **Financial Records.** Licensee shall and shall cause its Affiliates and its and their Sublicensees to, keep complete and accurate financial books and records pertaining to the Development and Commercialization of Licensed Products hereunder. Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, retain such books and records until the later of (i) [\*\*\*], and (ii) such period as may be required by Applicable Law.

7.16 **Audit.**

- 7.16.1 **Procedures.** At the request of a Party, the other Party shall and shall cause its Affiliates to use reasonable efforts to cause its and their sublicensees to, permit an internationally recognized independent auditor designated by the auditing Party and reasonably acceptable to the audited Party at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 7.14 (Financial Records) to ensure the accuracy of all reports and payments made hereunder. Such examinations may not (a) be conducted for any Calendar Quarter more than [\*\*\*] after the end of such Calendar Quarter, (b) be conducted more than [\*\*\*] period (unless a previous audit during such [\*\*\*] period revealed a underpayment (or with respect to any reimbursement, a overpayment) with respect to such period), or (c) be repeated for any Calendar Quarter. Except as provided below, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a variance of more than [\*\*\*] from the reported amounts, in which case the audited Party shall bear the cost of the audit. If such audit concludes that (i) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 7.14 (Interest on Late Payments), or (ii) excess payments were made by the audited Party, the auditing Party shall reimburse such excess payments, in either case ((i) or (ii)), within [\*\*\*] after the date on which such audit is completed by the auditing Party.
- 7.16.2 **Confidentiality.** The receiving Party shall treat all Confidential Information of the audited Party received or inspected pursuant to this Section 7.16 (Audit) in accordance with the confidentiality provisions of Section 10 (Confidentiality and Non-Disclosure) and the Parties shall cause the auditor 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.

7.17[\*\*\*].

## 8. INTELLECTUAL PROPERTY

### 8.1 Ownership of Intellectual Property.

8.1.1 **Ownership of Solely Invented Technology.** Each Party will own and retain all right, title, and interest in and to any and all Know-How and other inventions that are conceived, discovered, developed, or otherwise made solely by or on behalf of such Party (or its Affiliates) under or in connection with this Agreement, whether or not patented or patentable and any and all Patents and other intellectual property rights with respect thereto.

8.1.2 **Licensee Technology.** Licensee shall own and retain all right, title, and interest in and to any and all Licensee Technology.

8.1.3 **United States Law.** The determination of whether Know-How and inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States irrespective of where such conception, discovery, development, or making occurs.

8.1.4 **Assignment of Rights.** Each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Know-How and other inventions as well as any Patents, copyright or other intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the provisions of this Section 8.1 (Ownership of Intellectual Property), to the extent not already effected by operation of law. Each Party shall cause all Persons who conceive, discover, develop or otherwise make any Know-How or inventions by or on behalf of either Party or its Affiliates under or in connection with this Agreement to be under an obligation to assign their rights in any Know-How and inventions resulting therefrom to such Party, and any Patents, copyright or other intellectual property rights with respect thereto as is necessary to fully effect the provisions of this Section 8.1 (Ownership of Intellectual Property), except where prohibited by Applicable Law.

### 8.2 Maintenance and Prosecution of Patents.

8.2.1 **Patent Prosecution and Maintenance of Licensed Patent Rights.** As agreed between the Parties, Licensee shall be responsible for, using counsel of its own choice, the preparation, filing, prosecution, and maintenance of the Licensed Patent Rights worldwide and for any related interference, re-issuance, re-examination, and opposition proceedings, in each case, at Licensee's sole cost and expense. At Licensor's written request from time to time, Licensee will inform Licensor of all material steps with regard to the preparation, filing, prosecution, and maintenance of Licensed Patent Rights in the Territory, including by providing Licensor with a copy of material communications to and from any patent authority in the Territory regarding such Licensed Patent Rights and by providing Licensor drafts of any requested material filings or responses to be made to such patent authorities in the Major Markets. Licensee shall consider in good faith any requests and suggestions of Licensor with respect to such drafts and with respect to strategies for filing and prosecuting the Licensed Patent Rights in the Territory, *provided* that Licensee will have the final decision-making authority with respect thereto. If, as between the Parties, Licensee decides not to prepare, file, prosecute, or maintain a Licensed Patent Right in a country in the Territory, Licensee shall provide reasonable prior written notice to Licensor of such intention and Licensor shall thereupon have the option, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such Licensed Patent Rights at its sole cost and expense in such country.

8.2.2**Patent Prosecution and Maintenance of Licensee Patent Rights.** As between the Parties, Licensee will have the sole right, but not the obligation, to prepare, file, prosecute, and maintain the Licensee Patent Rights worldwide, and to be responsible for any related interference, re-issuance, re-examination, and opposition proceedings, in each case, at its sole cost and expense and using counsel of its own choice.

8.2.3**Patent Term Extension and Supplementary Protection Certificates.** As between the Parties, Licensee will have the sole right to make decisions regarding, and to apply for, patent term extensions in the Territory, including the United States with respect to extensions pursuant to 35 U.S.C. §156 et. Seq. and in other jurisdictions pursuant to supplementary protection certificates (including pediatric extensions thereto), and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for the Licensee Patent Rights, Licensed Patent Rights and with respect to the Licensed Compound and the Licensed Products, in each case including whether or not to do so. Licensor will provide prompt and reasonable assistance, as requested by Licensee, including by taking such action as patent holder as is required under any Applicable Law to obtain such extension or supplementary protection certificate.

### 8.3 Enforcement of Patents.

8.3.1**Notice of Infringement.** Each Party shall promptly notify the other Party in writing of (a) any alleged or threatened infringement of the Licensed Patent Rights or Licensee Patent Rights in any jurisdiction in the Territory, (b) unauthorized use or misappropriation of any Licensed Know-How or Licensee Know-How, or (c) any certification filed under applicable Abbreviated Approval Laws claiming that any Licensed Patent Rights or Licensee Patent Rights, are invalid or unenforceable or claiming that any Licensed Patent Rights or Licensee Patent Rights would not be infringed by the making, use, offer for sale, sale, or import of a product for which an application under applicable Abbreviated Approval Laws is filed or any equivalent or similar certification or notice in any other jurisdiction in the Territory, in each case ((a) through (c)) of which such Party becomes aware (an “**Infringement**”).

8.3.2**Enforcement of Licensed Patent Rights.** As between the Parties, Licensee will have the first right, but not the obligation, to prosecute any Infringement with respect to the Licensed Patent Rights, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Licensee’s sole cost and expense, using counsel of its own choice. In the event Licensee prosecutes any such Infringement, Licensor will have the right to join as a party to such claim, suit, or proceeding in the Territory and participate with its own counsel at its sole cost and expense; *provided* that Licensee shall retain control of the prosecution of such claim, suit, or proceeding, including the response to any defense or defense of any counterclaim raised in connection with the foregoing. If Licensee or its designee does not take commercially reasonable steps to prosecute an Infringement (a) within [\*\*\*] following the first notice provided above with respect to such Infringement or (b) provided such date occurs after the first such notice of such Infringement is provided, [\*\*\*] before the time limit, if any, set out in appropriate laws and regulations for filing of such actions, whichever comes first, then (i) Licensee will so notify Licensor and (ii) upon Licensee’s written consent, Licensor may prosecute such alleged or threatened infringement at its sole cost and expense.

- 8.3.3**Enforcement of Licensee Patent Rights.** As between the Parties, Licensee shall have the sole right, but not the obligation, to prosecute any and all Infringements with respect to the Licensee Patent Rights, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Licensee 's sole cost and expense, using counsel of its own choice, and Licensee shall retain control of the prosecution of such suit.
- 8.3.4**Cooperation.** If a Party is entitled to, and pursues an action against an Infringement in accordance with this Section 8.3 the other Party shall, and shall cause its Affiliates to, cooperate fully, including being joined as a necessary party to such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours, (b) the Party pursuing any action against an Infringement shall consult with the other Party as to the strategy for such action and (c) such Party shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken with respect to such action.
- 8.3.5**Settlement.** The Party that is entitled to and pursues an action against an Infringement in accordance with this Section 8.3 shall have the right to control any settlement of such claim; provided that no settlement shall be entered into without the prior consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed) if such settlement would reasonably be expected to have a material adverse effect on the rights or interest of the other Party or any of its Affiliates or impose any costs or liability on or involve any admission by, the other Party or any of its Affiliates.
- 8.3.6**Cost Recovery** Each Party shall bear its own costs and expenses relating to any Infringement action commenced pursuant to this Section 8.3; provided that, except as set forth in Section 8.3.2 (Enforcement of Licensed Patent Rights) the pursuing Party shall reimburse the other Party for the costs and expenses incurred by the other Party for any assistance requested by the pursuing Party for such Infringement action. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such litigation described above in this Section 8.3 (whether by way of settlement or otherwise) shall be first, allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the pursuing Party; provided, however, that to the extent that any award or settlement is attributable to loss of sales or profits with respect to a Licensed Product, the Parties shall negotiate in good faith an appropriate allocation of such remainder to reflect the economic interests of the Parties under this Agreement with respect to such Licensed Product.

#### 8.4 Infringement Claims by Third Parties.

- 8.4.1**Notice of Third Party Infringement Claims.** If the Exploitation of a Licensed Product in the Territory pursuant to this Agreement results in, or is reasonably expected to result in, any claim, suit, or proceeding by a Third Party alleging infringement by Licensee or any of its Affiliates or its or their Sublicensees, Distributors or customers (a "**Third Party Infringement Claim**"), including any defense or counterclaim in connection with an Infringement action initiated pursuant to Section 8.3 (Enforcement of Patents), the Party first becoming aware of such alleged infringement shall promptly notify the other Party thereof in writing.



**8.4.2 Defense of Third Party Infringement Claims.** As between the Parties, Licensee or its designee shall have the first right, but not the obligation, to defend and control the defense of any such Third Party Infringement Claim at its sole cost and expense (but subject to deduction as provided below), using counsel of its own choice. Licensor may participate in any such claim, suit, or proceeding with counsel of its choice at its sole cost and expense. If Licensee or its designee elects (in a written communication submitted to Licensor within a reasonable amount of time after notice of the alleged patent infringement) not to defend or control the defense of, or otherwise fails to initiate and maintain the defense of, any such Third Party Infringement Claim, within such time periods so that Licensor is not prejudiced by any delays, Licensor may conduct and control the defense of any such claim, suit, or proceeding at its sole cost and expense.

**8.5 Invalidity or Unenforceability Actions.**

**8.5.1 Notice of Invalidity or Unenforceability Actions.** Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Licensed Patent Rights or Licensee Patent Rights by a Third Party of which such Party becomes aware.

**8.5.2 Defense of Invalidity or Unenforceability Actions.** As between the Parties, Licensee will have (a) the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Licensed Patents and (b) the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Licensee Patent Rights, in each case ((a) and (b)), at its sole cost and expense in the Territory and using counsel of its own choice, including when such invalidity or unenforceability is raised as a defense or counterclaim in connection with an Infringement action initiated pursuant to Section 8.3 (Enforcement of Patents). Licensor may participate in any such claim, suit, or proceeding in the Territory with counsel of its choice at its sole cost and expense; *provided* that Licensee shall retain control of the defense in such claim, suit or proceeding. If Licensee or its designee elects not to defend or control the defense of the Licensed Patent Rights in a suit brought in the Territory or otherwise fails to initiate and maintain the defense of any such claim, suit, or proceeding, then Licensor may conduct and control the defense of any such claim, suit, or proceeding at its sole cost and expense.

**8.5.3 Cooperation.** Where a Party controls such a defense action pursuant to this Section 8.5 (Invalidity or Unenforceability Actions), the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time, in connection with its activities set out in this Section, including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours and, where relevant, to appear as witnesses in proceedings; *provided* that the controlling Party shall reimburse such other Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection with the foregoing. If, in relation to this Agreement, the Parties disclose to one another privileged communications with counsel, such disclosures are made with the understanding that they shall remain confidential in accordance with Section 10 (Confidentiality and Non-Disclosure) and shall not be deemed to waive any privilege.

**8.5.4 UPC.** With respect to the Licensed Patent Rights and Licensee Patent Rights, Licensee will have the sole right to determine whether to opt in or opt out (and to opt in again) of the Unified Patent Court system and, if requested by Licensee, Licensor will, as soon as reasonably practicable:

- a. lodge an application with the Registry of the Unified Patent Court in the manner specified by Rule 5 of the Rules of Procedure of the Unitary Patent Court requesting the UPC opt-out or the withdrawal of the opt-out (as the case may be), as specified by Licensee, of any Licensed Patent Right(s);
- b. pay the prescribed fee (to be reimbursed by Licensee subject to provision of proof of payment) and make such submissions; and
- c. take such other actions as may be necessary or useful to secure the opt out or withdrawal of the opt out, as applicable, of such Licensed Patent Right including making any declarations required by Rule 5(3)(e) of the Rules of Procedure of the Unitary Patent Court.

## 9. PRODUCT TRADEMARKS

- 9.1 **Ownership of Product Trademarks.** As between the Parties, Licensee will have the sole right to determine and will own all right, title, and interest in and to the Product Trademarks. Licensee shall be responsible for the recordation of the Assigned Trademarks and all associated costs thereof throughout the Territory. Licensee will not and will not permit its Affiliates to, (a) use in their respective businesses, any Product Trademark that is confusingly similar to, misleading or deceptive with respect to Licensor's trademarks or corporate names or (b) do any act that endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to such trademarks.
- 9.2 **Prosecution of Product Trademarks.** Licensee shall be solely responsible for the registration, prosecution, maintenance, enforcement and defense of the Product Trademarks using counsel of its own choice; provided that Licensor shall have the right to provide input on the overall strategy for such registration, prosecution and maintenance and Licensee shall consider such input in good faith. All costs and expenses of registering, prosecuting and maintaining the Product Trademarks shall be borne solely by Licensee.

### 9.3 Enforcement of Product Trademarks.

- 9.3.1 Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Trademarks in the Territory and of any actual or threatened claim that the use of the Product Trademarks in the Territory violates the rights of any Third Party, in each case, of which such Party becomes aware.
- 9.3.2 Licensee shall have the sole right to take such action as Licensee, after consultation with Licensor, deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party in the Territory at its sole cost and expense and using counsel of its own choice; provided that Licensor shall have the right, but not obligation, to provide input on the overall strategy for such action and Licensee shall consider such input in good faith. Licensee shall retain any damages or other amounts collected in connection therewith; provided, however, that to the extent that any award or settlement (whether by judgment or otherwise) with respect to a Product Trademark is attributable to loss of sales or profits with respect to a Licensed Product, the Parties shall negotiate in good faith an appropriate allocation of such remainder to reflect the economic interests of the Parties under this Agreement with respect to such Licensed Product.

## 10. CONFIDENTIALITY AND NON-DISCLOSURE

**10.1 Confidentiality Obligations.** At all times during the Term and for a period of [\*\*\*] following termination or expiration hereof in its entirety, each Party shall and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. “**Confidential Information**” means any technical, business, or other information provided by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on or after the Effective Date, including the terms of this Agreement, information relating to the Licensed Compound or any Licensed Product (including the Regulatory Documentation), any Development or Commercialization of the Licensed Compound or any Licensed Product, any Know-How with respect thereto developed by or on behalf of the disclosing Party or its Affiliates or, in the case of Licensee, its or their Sublicensees (including Licensee Know-How and Licensed Know-How, as applicable) or the scientific, regulatory, or business affairs or other activities of either Party. Notwithstanding the foregoing, Confidential Information constituting Assigned Regulatory Documentation, Licensed Know-How relating to any Licensed Compound or any Licensed Product, and the terms of this Agreement shall be deemed to be the Confidential Information of both Parties (and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto).

**10.2 Exceptions.** Notwithstanding Section 10.1 (Confidentiality Obligations), Confidential Information shall not include any information that:

- 10.2.1 is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no breach of this Agreement by the receiving Party;
- 10.2.2 can be demonstrated by documentation or other competent proof to have been in the receiving Party’s possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information;
- 10.2.3 is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information;
- 10.2.4 has been published by a Third Party or otherwise enters the public domain through no fault of the receiving Party in breach of this Agreement; or
- 10.2.5 can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party’s Confidential Information.

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. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

**10.3 Permitted Disclosures.** Each Party may disclose Confidential Information to the extent that such disclosure is reasonably necessary in the following instances:

- 10.3.1 in response to a valid order of a court of competent jurisdiction or other Governmental Authority or Regulatory Authority of competent jurisdiction; *provided, however,* that where legally permitted to do so, the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided, further,* that the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;
- 10.3.2 if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law (including by the rules of a stock exchange on which its securities are listed, or to which an application for listing has been submitted); *provided, however,* that (where legally permitted to do so) the receiving Party shall submit the proposed disclosure in writing to the disclosing Party as far in advance as reasonably practicable (and in no event less than [\*\*\*] prior to the anticipated date of disclosure) so as to provide the disclosing Party a reasonable opportunity to comment thereon;
- 10.3.3 to a patent authority as may be reasonably necessary or useful for purposes of obtaining or enforcing a Licensed Patent Right in accordance with this Agreement;
- 10.3.4 to prosecute or defend litigation as contemplated by this Agreement;
- 10.3.5 to obtain or maintain Regulatory Documentation or Regulatory Approvals for the Licensed Products and to interact with Regulatory Authorities with respect to the Licensed Products;
- 10.3.6 disclosure to its Affiliates and to its and their respective officers, directors, employees, consultants, contractors, and agents, in each case on a need-to-know basis in connection with the performance of this Agreement in accordance with its terms (and to its or their respective professional advisers for the purposes of advising on this Agreement and its operation), in each case under written obligations of confidentiality and non-use at least as stringent as those herein or where such Persons are otherwise bound by an equivalent employment or professional duties of confidentiality; or
- 10.3.7 to bona fide potential or actual investors, lenders or acquirers of the receiving Party (and their respective professional advisers) as may be necessary in connection with their evaluation of such potential or actual investment, loan or acquisition; *provided, however,* 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 10 (Confidentiality and Non-Disclosure) (with a duration of confidentiality and non-use obligations as appropriate for the context in which such Confidential Information is disclosed).

**10.4 Additional Permitted Disclosures by Licensee.** Licensee and its Affiliates and its and their Sublicensees may disclose Confidential Information of Licensor as may be necessary in connection with the Exploitation of any of the Licensed Compound, Licensed Products or otherwise in connection with the performance of its obligations or exercise of Licensee's rights as contemplated by this Agreement, including to existing or potential patients, Distributors, Sublicensees, collaboration partners, investors or acquirers of Licensee or of the business to which this Agreement relates. Where practical, Licensee shall use commercially reasonable efforts to impose no less but similar confidentiality obligations on the recipients to ensure there is no breach of confidentiality, [\*\*\*].

- 10.5 Use of Name.** Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or trademark of the other Party or any of its Affiliates or any of its or their Sublicensees (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 10.5 (Use of Name) shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law, including pursuant to the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted).
- 10.6 Public Announcements.** Either Party may issue a press release substantially in the form(s) attached hereto as Schedule 5 (Press Release), the release of which the Parties shall coordinate in order to accomplish such release promptly following execution of this Agreement. Neither Party shall issue any other public announcement, press release, or other public disclosure regarding the terms of this Agreement 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 (or to which an application for listing has been submitted). In the event a Party is, in the reasonable opinion of its counsel, required by Applicable Law (including pursuant to the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted)) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (to the extent possible, at least [\*\*\*] prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon. Nothing in the foregoing section shall limit Licensee's rights to disclose information in accordance with Section 10.4 (Additional Permitted Disclosures by Licensee) hereto. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party in accordance with this Section 10.6 (Public Announcements), *provided* that such information remains accurate and complete.
- 10.7 Publications.** The Parties recognize the desirability of publishing and publicly disclosing the results of and information regarding the Licensed Compound, the Licensed Product and activities under this Agreement. Accordingly, Licensee shall be free to publicly disclose the results of and information regarding Licensed Compound, Licensed Product and activities under this Agreement, subject to prior review by Licensor for issues of patentability and protection of its Confidential Information, in a manner consistent with Applicable Law and industry practices, as provided in this Section 10.7 (Publications). Accordingly, prior to publishing or disclosing any of Licensor's Confidential Information, Licensee shall provide Licensor with drafts of proposed abstracts, manuscripts or summaries of presentations that cover such Confidential Information. Licensor shall respond promptly through its designated representative and in any event no later than [\*\*\*] after receipt of such proposed publication. Licensee agrees to allow a reasonable period (not to exceed [\*\*\*]) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of Licensor. In addition, Licensee will reasonably consider any timely comments furnished by Licensor regarding such proposed publication. Licensor shall not and shall cause each of its Affiliates and its and their licensees and sublicensees not to, make any publications or public disclosures regarding the Licensed Compound or Licensed Products or any Confidential Information of Licensee without Licensee's prior written consent.
- 10.8 Return of Confidential Information.** Upon the effective date of the termination of this Agreement for any reason or upon the expiry of this Agreement, either Party may request in writing and the non-requesting Party shall, at the non-requesting Party's option, either, with respect to Confidential Information to which such non-requesting Party does not retain rights under the surviving provisions of this Agreement: (a) promptly destroy all copies of such Confidential Information in the possession or control of the non-requesting Party and confirm such destruction in writing to the requesting Party; or (b) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the non-requesting Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain such Confidential Information: (i) to the extent necessary for purposes of performing any continuing obligations or exercising any ongoing rights hereunder, or to comply with Applicable Laws, and, in any event, a single copy of such Confidential Information for archival purposes; and (ii) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set out in Section 10.1 (Confidentiality Obligations).

**10.9 Existing Confidentiality Agreement.** This Agreement supersedes the Existing Confidentiality Agreement, which shall – as between Licensee and Licensor – cease to have any force or effect as from the Effective Date, it being agreed and understood, however, that any Confidential Information disclosed by one Party to the other Party under any of the Existing Confidentiality Agreement shall be deemed Confidential Information as defined in this Agreement and the provisions set out in this Section 10 (Confidentiality and Non-Disclosure) shall apply with respect to such Confidential Information as if it has been disclosed under this Agreement.

## 11. REPRESENTATIONS AND WARRANTIES

**11.1 Mutual Representations and Warranties.** Licensor and Licensee each represents and warrants to the other, as of the Effective Date, that:

- 11.1.1 It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement;
- 11.1.2 The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (a) such Party's charter documents, bylaws, or other organizational documents; (b) in any material respect, any agreement, instrument, or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law; or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party;
- 11.1.3 This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

**11.2 Additional Representations and Warranties of Licensor.** Licensor further represents and warrants to Licensee, as of the Effective Date, that: (a) Licensor Controls the Licensed Technology as of the Effective Date and has the right to grant the licenses specified herein; (b) Licensor has not received any written claim or written demand alleging that (i) the Licensed Patent Rights are invalid or unenforceable or (ii) the Development, Manufacture or Commercialization of the Licensed Compound or Licensed Product as contemplated herein infringes any Patent Rights owned by any Third Party; (c) to Licensor's Knowledge, no Person is infringing or threatening to infringe the Licensed Patent Rights in the Field; (d) to Licensor's Knowledge, all material filings with and material submissions to the Regulatory Authorities related to the Licensed Compound or Licensed Product, whether written or electronically delivered, were true and accurate as of the date made; (e) the Assigned Agreements are in full force and affect in accordance with their terms, and Licensor has the right to assign the Assigned Agreements to Licensee; and (f) to Licensor's Knowledge, the Licensed Technology represents all Patent Rights and Know-How Controlled by Licensor as of the Effective Date that are necessary for Licensee's Development, Manufacture or Commercialization of the Licensed Compounds and Licensed Products contemplated by this Agreement.

- 11.3 **Additional Representations and Warranties of Licensee.** Licensee further represents and warrants to Licensor, as of the Effective Date, that Licensee: (a) has conducted its own investigation and analysis of (i) the Patent and other proprietary rights of Third Parties as such rights relate to the Exploitation of the Licensed Compound and Licensed Products as contemplated hereunder and (ii) the potential infringement thereof; (b) understands the complexity and uncertainties associated with possible claims of infringement of Patent or other proprietary rights of Third Parties, particularly those relating to pharmaceutical products; and (c) subject to the representations and warranties made by Licensor pursuant to Section 11, acknowledges and agrees that it is solely responsible for the risks of such claims; and (c) has conducted independent due diligence of the Assigned Agreements, regulatory filings and other documentation as provided by the Licensor.
- 11.4 **DISCLAIMER OF WARRANTIES.** EXCEPT FOR THE EXPRESS WARRANTIES SET OUT IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS AND TRADEMARKS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS INCLUDING TRADEMARKS OF THIRD PARTIES.
- 11.5 **ADDITIONAL WAIVER.** SUBJECT TO WARRANTIES LISTED OUT IN THIS SECTION 11, LICENSEE AGREES THAT: (A) THE LICENSOR PATENTS AND TRADEMARKS ARE LICENSED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND LICENSEE EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST LICENSOR FOR MISREPRESENTATION OR FOR BREACH OF PROMISE, GUARANTEE OR WARRANTY OF ANY KIND RELATING TO THE LICENSOR PATENTS AND TRADEMARKS; (B) LICENSEE AGREES THAT LICENSOR WILL HAVE NO LIABILITY TO LICENSEE FOR ANY ACT OR OMISSION IN THE PREPARATION, FILING, PROSECUTION, MAINTENANCE, ENFORCEMENT, DEFENSE OR OTHER HANDLING OF THE LICENSEE PATENTS AND TRADEMARKS; AND (C) LICENSEE IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE LICENSEE PATENTS AND TRADEMARKS HAVE APPLICABILITY OR UTILITY IN LICENSEE'S CONTEMPLATED EXPLOITATION OF THE LICENSED PRODUCTS AND LICENSEE ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION. THE WAIVER SET FORTH IN THIS SECTION 11.4 SHALL NOT APPLY TO FRAUD OR INTENTIONAL MISREPRESENTATION BY LICENSOR.

**11.6 Anti-Bribery and Anti-Corruption Compliance.** Licensee agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants and subcontractors hired in connection with the subject matter of this Agreement (“**Representatives**”) that for the performance of its obligations hereunder:

11.6.1 Licensee and its Representatives shall comply with the Anti-Corruption Laws and shall not take any action that will, or would reasonably be expected to, cause Licensor or its Affiliates to be in violation of any Anti-Corruption Laws; and

11.6.2 Licensee shall promptly provide Licensor with written notice of the following events: (a) upon becoming aware of any breach or violation by Licensee or its Representative of any representation, warranty or undertaking set forth in Section 11.6.1, or (b) upon receiving a formal notification that it is the target of a formal investigation by a governmental authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of its Representatives connected with this Agreement that any of them is the target of a formal investigation by a governmental authority for a Material Anti-Corruption Law Violation.

**11.7 Cyber Security.**

11.7.1 The Parties will each maintain adequate administrative, technical, and physical measures, controls, tools, systems, policies, and procedures in accordance with good cyber security industry practices to protect all data and sufficient to perform their respective obligations under this Agreement. As a mitigation strategy for sharing information between the Parties, ALXN and Monopar shall agree and implement appropriate IT security risk measures prior to sharing of GxP information with Monopar.

11.7.2 Each Party will notify the other Party in writing about any security incident or cyber attack affecting or which may affect any IT infrastructure, or any other data or facilities owned, leased or used by it, which may affect in any material respect the affected Party’s ability to comply with its obligations under this Agreement, without undue delay and in any event within twenty-four (24) hours after it becomes aware of or suspects that such security incident or cyber attack has occurred. With respect to any notification to Licensor, such notification will be sent by e-mail to SOCITSecurity@astrazeneca.com and promptly followed up by telephone to 0044 1625 513080. With respect to any notification to Licensee, such notification will be sent by e-mail to contracts@monopartx.com and promptly followed up by telephone to 1-847-469-1419.

**11.8 Debarment Notice.** Each Party warrants and represents that neither it nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates will use in any capacity, in connection with the activities to be carried out under this Agreement, any Person who has been debarred pursuant to Section 306 of the United States Food, Drug and Cosmetic Act or who is the subject of a conviction described in such section. Each Party agrees to inform the other Party in writing promptly if it or any such Person who is performing services in connection with the activities to be carried out under this Agreement is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates’ Knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services in connection with the activities to be carried out under this Agreement.



**11.9 Personal Data Covenant**

11.9.1 In connection with this Agreement, each Party and its Affiliates, and any Person acting for or on its or their behalf, shall comply with all Applicable Law relating to privacy and the processing and protection of any information relating to an identified or identifiable individual (such information, "**Personal Data**").

11.9.2 The Parties shall comply with their respective obligations set out in Schedule 6 (Data Privacy) with respect to the transfer and processing of Personal Data in connection with this Agreement.

11.9.3 To the extent of any conflict between this Section 11.9 (Personal Data Covenant) and the terms of Schedule 6, the terms of Schedule 6 shall prevail.

11.10 **Compliance with Laws.** Each Party shall and shall cause its Affiliates to, comply in all material respects with all Applicable Law with respect to the Exploitation of Licensed Products hereunder.

**12. INDEMNITY AND LIABILITY**

12.1 **Indemnification of Licensor** Licensee shall indemnify Licensor its Affiliates, and its and their respective directors, officers, employees and agents (the "**Licensor Indemnitees**") and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") to the extent arising from or occurring as a result of: (a) the breach by Licensee of this Agreement, including the enforcement of Licensee's rights under this Section 12.1 (Indemnification of Licensor); (b) the negligence, or wilful misconduct by Licensee or its Affiliates or its or their Sublicensees or its or their respective directors, officers, employees, contractors or agents in performing its obligations under this Agreement; (c) the Exploitation by or on behalf of Licensee or any of its Affiliates or its or their Sublicensees or its or their distributors or contractors of any Licensed Product or the Licensed Compound in or for the Territory, except for those Losses for which Licensor has an obligation to indemnify Licensee pursuant to Section 12.2 (Indemnification of Licensee), as to which Losses each Party shall indemnify the other to the extent of their respective liability, or (d) any failure by Licensee or any of its Affiliates or Sublicensees or its or their distributors or contractors to comply with the Applicable Laws.

12.2 **Indemnification of Licensee.** Licensor shall indemnify Licensee, its Affiliates and their respective directors, officers, employees and agents (the "**Licensee Indemnitees**") and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims to the extent arising from or occurring as a result of: (a) the breach by Licensor of this Agreement, including the enforcement of Licensee's rights under this Section 12.2 (Indemnification of Licensee); (b) the negligence or wilful misconduct by Licensor or its Affiliates or its or their respective directors, officers, employees, contractors or agents in performing its obligations under this Agreement; or (d) all liabilities and obligations incurred prior to the Effective Date under the Assigned Agreements except, in each case ((a) and (b)), for those Losses for which Licensee has an obligation to indemnify Licensor pursuant to 12.1 (Indemnification of Licensor), as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

- 12.3 Indemnification Procedures.** All indemnification claims in respect of a Licensor Indemnitee or Licensee Indemnitee shall be made solely by Licensor or Licensee, as applicable (each of Licensor or Licensee in such capacity, the “**Indemnified Party**”). The Indemnified Party shall give the indemnifying Party prompt written notice (an “**Indemnification Claim Notice**”) of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Section 12, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice except to the extent the Indemnifying Party is actually prejudiced thereby. Each Indemnification Claim Notice must 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 indemnifying Party shall have the right to assume the defense of any such Third Party Claim, including the right to select counsel of its choosing and the right to compromise or settle any Third Party Claim, by giving written notice to the Indemnified Party within [\*\*\*] after the indemnifying Party’s receipt of an Indemnification Claim Notice; *provided, however*, that the indemnifying Party shall not make any compromise or settlement admitting fault, subjecting the Indemnified Party to injunctive or other relief, adversely affecting the business of the Indemnified Party or any Licensor Indemnitee or Licensee Indemnitee, as applicable, or incurring any liability on the part of the Indemnified Party or any Licensor Indemnitee or Licensee Indemnitee, as applicable, without the Indemnified Party’s prior written consent, such consent not to be unreasonably conditioned, withheld, or delayed. The Indemnified Party shall be entitled to retain counsel of its choice (at its own expense) to participate in, but not control, the defense of any Third Party Claim. Except as provided in the immediately preceding sentence, the costs and expenses, including reasonable fees and disbursements of counsel, incurred by the Indemnified Party and any Licensor Indemnitee or Licensee Indemnitee, as applicable, in connection with any Third Party Claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party. If the indemnifying Party is required to defend any Third Party Claim, the Indemnified Party shall, and shall cause its employees and agents to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith.
- 12.4 Limitation of Liability.** NEITHER LICENSOR NOR LICENSEE, NOR ANY OF THEIR RESPECTIVE AFFILIATES, WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES UNDER OR IN CONNECTION WITH THIS AGREEMENT FOR ANY: (I) INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY LOSS OR DAMAGES; or (II) LOST PROFITS OR LOST REVENUES; IN EACH CASE ((I) and (II)) WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY, CONTRIBUTION, BREACH OF STATUTORY DUTY OR OTHERWISE, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF ANY SUCH LOSS OR DAMAGE. NOTWITHSTANDING THE FOREGOING SENTENCE, NOTHING IN THIS SECTION 12.4 (LIMITATION OF LIABILITY) IS INTENDED TO OR SHALL LIMIT OR RESTRICT: (A) AN INDEMNIFIED PARTY’S RIGHT TO RECOVER DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY SUCH INDEMNIFIED PARTY FOR WHICH IT IS ENTITLED TO INDEMNIFICATION UNDER SECTION 12.1 (INDEMNIFICATION OF LICENSOR) OR SECTION 12.2 (INDEMNIFICATION OF LICENSEE ), AS APPLICABLE, IN CONNECTION WITH ANY THIRD PARTY CLAIMS, TOGETHER WITH SUCH INDEMNIFIED PARTY’S REASONABLE ATTORNEY FEES ASSOCIATED WITH THE DEFENSE OR SETTLEMENT OF SUCH THIRD PARTY CLAIM; OR (B) DAMAGES AVAILABLE FOR A PARTY’S GROSS NEGLIGENCE, WILFUL MISCONDUCT, FRAUD, OR BREACH OF SECTION 10 (CONFIDENTIALITY AND NON-DISCLOSURE), OR BREACH OF SECTION 11.6 (ANTI-BRIBERY AND ANTI-CORRUPTION COMPLIANCE)OR BREACH OF SECTION 2.10.1 (EXCLUSIVITY COVENANT).
- 12.5 Insurance.** Licensee shall have and maintain such types and amounts of insurance covering its Exploitation of the Licensed Compound and Licensed Products as is (a) normal and customary in the biopharmaceutical industry generally for parties similarly situated and (b) otherwise required by Applicable Law. Upon request by Licensor, Licensee shall provide to Licensor evidence of its insurance coverage, including copies of applicable insurance policies.

### 13. TERM AND TERMINATION

13.1 **Term and Expiration.** This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until the date of expiration of the last Royalty Term for the last Licensed Product (such period, the “**Term**”). Following the expiration of the Royalty Term for a Licensed Product in a country, the grants in Section 2.1 (Grant to Licensee ) shall become fully-paid, royalty-free, perpetual, and irrevocable for such Licensed Product in such country. For clarity, upon the expiration of the Term, the grants in Section 2.1 (Grant to Licensee) shall become fully-paid, royalty-free, perpetual and irrevocable in their entirety.

#### 13.2 Termination.

13.2.1 **Termination for Convenience.** Licensee shall have the right to terminate the Agreement in whole at any time by giving no less than [\*\*\*] notice to Licensor of such Termination.

13.2.2 **Material Breach.** In the event that either Party (the “**Breaching Party**”) shall be in material breach of this Agreement, in addition to any other right or remedy the other Party (the “**Non-Breaching Party**”) may have, the Non-Breaching Party may terminate this Agreement by providing [\*\*\*] (the “**Notice Period**”) prior written notice (the “**Termination Notice**”) to the Breaching Party and specifying the breach and its claim of right to terminate; *provided that* if the material breach relates to one or more, but not all, of the countries in the Territory, the Non-Breaching Party may terminate this Agreement solely with respect to the countries where the material breach occurs (each, a “**Terminated Territory**”); *provided further* that the termination shall not become effective at the end of the Notice Period if: (a) the Breaching Party cures the breach specified in the Termination Notice during the Notice Period; or (b) capable of being cured but such breach cannot be cured within the Notice Period but the Breaching Party commences actions to cure such breach within the Notice Period and thereafter diligently continues such actions) and then cures the breach within [\*\*\*] following the end of the Notice Period; *provided further*, to the extent that any such termination is in connection with an alleged breach of Section 5.2 (Diligence), Licensor may only terminate if such material breach is directly related to the Licensed Product in the United States (without limiting Licensor’s right to terminate for material breach under any other provision). Notwithstanding the foregoing, if the Breaching Party reasonably and in good faith disputes whether there has been a material breach, the Breaching Party may contest the claim of breach in accordance with Section 14.6 (Dispute Resolution), and the Notice Period shall toll until the Dispute Resolution has been completed, it being understood and acknowledged that, during the Notice Period, including any tolling of the Notice Period, all of the terms and conditions of this Agreement shall remain in effect, and the Parties shall continue to perform all of their respective obligations under this Agreement.

#### 13.2.3 Termination by Licensor.

- a. If Licensee or any of its Affiliates or Sublicensees, anywhere in the Territory, institutes, prosecutes or otherwise participates in (or in any way aids any Third Party in instituting, prosecuting or participating in), at law or in equity or before any administrative or regulatory body, including the U.S. Patent and Trademark Office or its foreign counterparts, any claim, demand, action or cause of action for declaratory relief, damages or any other remedy or for an injunction, injunction or any other equitable remedy, including any interference, re-examination, opposition or any similar proceeding, alleging that any claim in a Licensed Patent Right is invalid, unenforceable or otherwise not patentable or would not be infringed by Licensee’s activities absent the rights and licenses granted hereunder, Licensor shall have the right to immediately terminate this Agreement in its entirety, including the rights of any Sublicensees, upon written notice to Licensee.
- b. If (i) Licensee (and its Affiliates and Sublicensees) ceases Development of all Licensed Products in a country for a period of [\*\*\*], (ii) a Licensed Product is not being Commercialized anywhere in the Territory by or on behalf of Licensee, and (iii) Licensee is not actively engaged in Development activities for the United States market, Licensor shall have the right to terminate this Agreement in its entirety by providing [\*\*\*] prior written notice to Licensee; *provided that* such termination shall not be effective if Licensee, its Affiliate or Sublicensee re-starts Development within such [\*\*\*] notice period. Notwithstanding the foregoing, the normal pauses or gaps between or following clinical studies or other studies for the analysis of data, preparation of reports and design of future clinical studies or preparation of regulatory filings and other customary development functions not constituting clinical studies do not constitute a cessation of development.

13.2.4 **Termination for Insolvency.** In the event that either Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [\*\*\*] after such filing, (d) is a party to any dissolution or liquidation, (e) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [\*\*\*] of the filing thereof, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

#### 13.3 Consequences of Termination.

[\*\*\*].

13.4 **Remedies.** Except as otherwise expressly provided herein, expiry or termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

13.5 **Accrued Rights.** Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration.

13.6 **Surviving Obligations.** Termination or expiration of this Agreement shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Sections [\*\*\*] of this Agreement shall survive the termination or expiration of this Agreement for any reason.

### 14. MISCELLANEOUS

14.1 **Force Majeure.** Neither Party shall be held liable or responsible to the other Party or be deemed to have breached this Agreement for failure or delay in fulfilling or performing its obligations if and to the extent that such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, pandemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labour disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any Governmental Authority. The non-performing Party shall notify the other Party of such force majeure within [\*\*\*] after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The non-performing Party shall use Commercially Reasonable Efforts to remedy its inability to perform.

**14.2 Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party or any products using such technical information to a location or in a manner that at the time of export requires an export License or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other Governmental Authority in accordance with Applicable Law.

**14.3 Assignment.** Neither Party may assign its rights or, except as expressly permitted under this Agreement, delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party. Notwithstanding the foregoing, (a) either Party shall have the right, without such consent, to (i) perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates and (ii) assign any or all of its rights and delegate any or all of its obligations under this Agreement to any Person who acquires all or substantially all of the business to which this Agreement relates, and (b) each Party shall have the right, without prior consent, to assign any or all of its rights and delegate any or all of its obligations under this Agreement to any of its Affiliates or to any successor in interest as a result of a Change of Control; provided that each Party shall provide written notice to the other Party within [\*\*\*] after such assignment or delegation. Any permitted successor of a Party or any permitted assignee of all of a Party's rights under this Agreement that has also assumed all of such Party's obligations hereunder in writing shall, upon any such succession or assignment and assumption, be deemed to be a party to this Agreement as though named herein in substitution for the assigning Party, whereupon the assigning Party shall cease to be a party to this Agreement and shall cease to have any rights or obligations under this Agreement. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 14.3 shall be void and of no effect.

**14.4 Severability.** If any provision of this Agreement is declared by any judicial or other competent authority to be void, voidable, illegal or otherwise unenforceable then the remaining provisions of this Agreement shall continue in full force and effect. The judicial or other competent authority making such determination shall have the power to limit, construe or reduce the duration, scope, activity or area of such provision, or delete specific words or phrases as necessary to render such provision enforceable.

**14.5 Performance by Affiliates.** A Party may perform any obligation or exercise any right under this Agreement through any of such Party's Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations. Each Party will remain fully liable for any acts or omissions of any of its Affiliates in breach of this Agreement.

**14.6 Dispute Resolution.**

**14.6.1 Disputes.** Subject to Section 14.11 (Equitable Relief), if a dispute arises between the Parties in connection with or relating to this Agreement (including in relation to the existence, validity or termination of this Agreement) (a "**Dispute**"), then no Party shall have the right to initiate litigation in accordance with Section 14.7 (Governing Law, Jurisdiction and Service) unless: (a) a Party has referred such Dispute to the Senior Officers by giving written notice to the other Party to request that the Senior Officers attempt to resolve the Dispute by good faith negotiations; and (b) a period [\*\*\*] from the date upon which such notice was deemed to have been given has expired. The Parties agree to cause their respective Senior Officers to attempt to resolve the Dispute in good faith.

**14.7 Governing Law, Jurisdiction and Service**

14.7.1 **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

14.7.2 **Jurisdiction.** Subject to Section 14.6.1 (Disputes) and Section 14.11 (Equitable Relief), the Parties irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of Delaware for any action, suit, or proceeding arising out of or relating to this Agreement or its subject matter or formation (and including non-contractual disputes or claims) and agree not to commence any action, suit, or proceeding related thereto except in such courts. THE PARTIES IRREVOCABLY AND UNCONDITIONALLY WAIVE THEIR RIGHT TO A JURY TRIAL.

14.7.3 **Venue.** The Parties further irrevocably and unconditionally waive any objection to the laying of venue of any action, suit, or proceeding arising out of or relating to this Agreement in the courts of the State of Delaware and further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit, or proceeding brought in any such court has been brought in an inconvenient forum.

14.7.4 **Service.** Each Party further agrees that service of any process, summons, notice or document by registered mail to its address referred to Section 14.8.2 (Address for Notices) shall be effective service of process for any action, suit, or proceeding brought against it under this Agreement.

**14.8 Notices.**

14.8.1 **Notice Requirements.** Any notice or other communication required or permitted to be given by either Party under this Agreement shall be in writing in English and shall be deemed given as of (a) the date delivered if delivered by hand, or reputable courier service, (b) the date sent if sent by email (with transmission confirmed), (c) the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service, or (d) the fifth (5<sup>th</sup>) Business Day after mailing if mailed by registered or certified mail, postage prepaid and return receipt requested; in each case addressed to the other Party at the addresses specified below, or if a Party notifies the other Party of a different address for receipt of notices in accordance with this Section 14.8 (Notices), then to such other address. This Section 14.8.1 (Notice Requirements) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

14.8.2 Address for Notices.

Licensors	To:	With a copy to:
	***	***
Licensee	***	***
	If by Mail: *** Monopar Therapeutics Inc. 1000 Skokie Blvd., Suite 350, Wilmette, IL 60091	If by Mail: *** Monopar Therapeutics Inc. 1000 Skokie Blvd., Suite 350, Wilmette, IL 60091

14.9 **Entire Agreement; Amendments.** This Agreement, together with the attached Schedules, the Assignment & Assumption Agreement, and the Investment Agreement, sets out and constitutes the entire agreement and understanding between the Parties with respect to its subject matter and supersedes all prior agreements, understandings, promises, and representations, whether written or oral, with respect to this Agreement. Each Party confirms that it is not relying on any statements, representations or warranties of the other Party (including any negligent misrepresentation but excluding any fraudulent misrepresentation) except as specifically set out in this Agreement. All statements, representations, warranties, terms, conditions and provisions (including, any implied by statute, common law or otherwise and any implied warranties or conditions), other than fraudulent misrepresentations and the provisions set out in this Agreement, are excluded to the maximum extent permissible by law. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

14.10 **English Language.** This Agreement shall be written and executed in and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

14.11 **Equitable Relief.** Notwithstanding any other term of this Agreement, where a Party wishes to apply for interim or interlocutory relief in relation to any breach or anticipatory breach of the provisions of this Agreement, the non-breaching Party shall be entitled to seek the same from any court of competent jurisdiction. Both Parties agree to waive any requirement that the other Party (a) post a bond or other security as a condition for obtaining any such relief, or (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 14.11 (Equitable Relief) is intended or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

14.12 **Waiver and Non-Exclusion of Remedies.** No waiver of any term or condition of this Agreement shall be effective unless set out in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right or remedy under this Agreement shall not be deemed a waiver of any other right or remedy. The rights and remedies provided under this Agreement are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set out in this Agreement.

14.13 **No Benefit to Third Parties.** Except for the rights of the indemnitees in Section 12 (Indemnity and Liability) in their own right to enforce and rely on the provisions in Section 12, this Agreement does not create any right enforceable by any Person who is not a party to it. The Parties may amend, renew, terminate or otherwise vary all or any of the provisions of this Agreement without the consent of any third party.

- 14.14**Further Assurance.** 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 of this Agreement.
- 14.15**Relationship of the Parties.** Licensor and Licensee are independent contractors and their relationship shall not constitute a partnership, joint venture, or agency. Neither Licensor nor Licensee shall have the authority to make any statements, representations, or commitments of any kind or to take any action that will be binding on the other (or represent that it has the authority to do any of the foregoing) without the other Party's prior written consent. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.
- 14.16**References.** Unless otherwise specified, references in this Agreement to: (a) any Section or Schedule mean references to such Section or Schedule of this Agreement; (b) any clause mean references to the clause in the Section in which it appears; (c) any agreement, instrument, or other document refer to such agreement, instrument or other document as may be amended from time to time; and (d) legislation shall be construed as a reference to that legislation as amended, re-enacted or replaced whether in whole or in part, and to any legislation implementing the foregoing.
- 14.17**Construction.** Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, and the use of any gender shall be applicable to all genders. Whenever this Agreement refers to a number of days, unless otherwise specified as Business Days, such number refers to calendar days. The headings of this Agreement are for convenience only and shall not affect its interpretation. The term "including," "include," or "includes" as used in this Agreement shall mean including, without limiting the generality of any description preceding such term. References to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement.
- 14.18**Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

[Signature Page Follows]

**THIS AGREEMENT IS EXECUTED** by the authorized representatives of the Parties as of the date first written above.

**ALEXION PHARMACEUTICALS, INC.**

**MONOPAR THERAPEUTICS INC.**

By: /s/ Todd Spalding  
Name: Todd Spalding  
Title: Secretary

By: /s/ Chandler D. Robinson  
Name: Chandler D. Robinson  
Title: Chief Executive Officer





**COMMON STOCK INVESTMENT AGREEMENT**

This Common Stock Investment Agreement (the “**Agreement**”), dated as of October 23, 2024, by and among Monopar Therapeutics Inc., a Delaware corporation (the “**Company**”), and Alexion Pharmaceuticals, Inc., a Delaware corporation (the “**Licensor**”). Capitalized terms used herein but not otherwise defined shall have the meanings given to them in the License Agreement (as defined below).

**RECITALS**

- A. On the date hereof, the Company and the Licensor are entering into that certain License Agreement (the “**License Agreement**”), pursuant to which Licensor grants to the Company an exclusive license (the “**License**”) under Licensor’s Licensed Technology to research, develop, manufacture, and commercialize Licensed Compound and Licensed Products in the Territory, each as defined therein, and in accordance with the terms and conditions set forth therein.
- B. As part of the consideration for the License, as provided by Section 7.1.2 of the License Agreement, the Company has agreed to issue shares of its common stock, par value \$0.001 per share (the “**Common Stock**”), to the Licensor.
- C. On the terms and subject to the conditions set forth in this Agreement and pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the “**Securities Act**”), the Company desires to issue, and agrees to issue, Shares, in accordance with the terms of this Agreement.

**AGREEMENT**

**NOW, THEREFORE, IN CONSIDERATION** of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Company and the Licensor agree as follows:

**ARTICLE I****ISSUANCE OF SHARES**1.1 Issuance of Initial Shares; Agreement to Issue Additional Shares

(a) Subject to the terms and conditions of this Agreement, as part of the consideration for the License, the Company agrees to issue to the Licensor 387,329 shares of Common Stock (with such shares of Common Stock representing 9.9% of the Company’s outstanding shares of Common Stock immediately after their issuance) (the “**Initial Shares**”). On the date hereof, the Company shall irrevocably instruct VStock Transfer, LLC, the Company’s transfer agent (the “**Transfer Agent**”), to issue the Initial Shares to the Licensor in book-entry format on the Company’s share register, free and clear of all restrictive and all other legends, except as provided in Section 3.5 hereof. The Company shall cause the Transfer Agent to provide evidence (including an account statement reflecting the issuance) of the same to the Licensor as soon as reasonably practicable.

(b) In addition to the Initial Shares, as additional consideration for the License, in the event that the Company issues additional shares of Common Stock to any third party, the Company agrees to promptly issue additional shares of Common Stock ("**Additional Shares**") and together with the Initial Shares, the "**Shares**") to the Licensor as is necessary so that the aggregate number of Shares issued to the Licensor under this Agreement (for the avoidance of doubt, calculated without regard to whether the Licensor has already sold any previously issued Shares) continues to equal 9.9% of the Company's outstanding shares of Common Stock after giving effect to future issuances of Common Stock, provided, that, to the extent (i) such additional shares of Common Stock are issued to directors, officers, employees or consultants pursuant to an equity incentive plan described in the SEC Documents or (ii) such additional shares of Common Stock are issued pursuant to an at-the-market sales program or other similar continuous offering in an amount that does not constitute 2.5% or more of the outstanding shares of Common Stock as of the date of such issuance, the Company shall not be required to issue the Additional Shares more than once per calendar quarter (ending with March 31, June 30, September 30, and December 31) (any date on which Additional Shares are issued, an "**Additional Shares Closing Date**"); provided that the Licensor may defer receipt of any Additional Shares by providing written notice to the Company and upon receipt of such notice, the Company shall agree to issue such Additional Shares to Licensor on a date as may subsequently be designated by Licensor. On each Additional Shares Closing Date, the Company shall irrevocably instruct the Transfer Agent, to issue the applicable number of Additional Shares to the Licensor in book-entry format on the Company's share register, free and clear of all restrictive and all other legends, except as provided in Section 3.5 hereof and the Company shall cause the Transfer Agent to provide evidence (including an account statement reflecting the issuance) of the same to the Licensor as soon as reasonably practicable following the Additional Shares Closing Date. The Company's obligation to issue Additional Shares will immediately terminate on the earliest to occur of the following: (A) the Company has issued after the date hereof Common Stock for cash consideration with an aggregate value of \$25,000,000 based on the sale price in each such cash issuance (for clarity, excluding any cash consideration received by the Company in connection with the issuance of convertible securities, warrants, preferred stock, or other similar securities, or instruments convertible or exchangeable into Common Stock (collectively, "**Convertible Securities**") until such time that such Convertible Securities are converted or exchanged for Common Stock, at which time the amount paid directly to the Company for such Convertible Securities (excluding any amount paid attributable to other securities or assets) plus any exercise or conversion price will be included in the aggregate value described in clause (A)); (B) a Change of Control occurs in which all or substantially all of the Company's shares of Common Stock receive cash or publicly traded securities of a third party purchaser in exchange for their shares of Common Stock and the Licensor has the right to participate in such transaction on the same terms as the Company's other stockholders and has received all Additional Shares due to it prior to such Change of Control; or (C) a termination of the License Agreement by Company due to material breach of the Licensor pursuant to Section 13.2.2 of the License Agreement. The Company shall not by any action or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Agreement, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Licensor as set forth in this Agreement against impairment.

(c) The Company shall provide Licensor with ten (10) Business Days' advanced written notice prior to repurchasing any shares of Common Stock outstanding or taking any actions that would result in (i) the decrease of the total number of Common Stock outstanding, or (ii) an increase to the percentage of Licensor's beneficial ownership of any equity securities of the Company above 9.9%, in each case without Licensor's consent.

(d) At Licensor's request, Company shall promptly provide to Licensor (i) information on the terms of the Convertible Securities, including number of Convertible Securities and shares issuable term under, any consideration paid or payable for the Convertible Securities or conversion thereof, and any other key terms of such Convertible Securities as Licensor may reasonably request, and (ii) the Company's calculation of issuances and related consideration contributing towards the \$25,000,000 threshold set forth in Section 1.1(b)(A).

(e) Notwithstanding anything in this Agreement to the contrary, the Company shall not be required to issue Additional Shares to the extent, and only to the extent, it would result in the total number of Shares issued hereunder to exceed of 19.99% of the issued and outstanding shares of Common Stock as of the date hereof prior to any issuance of Shares hereunder without stockholder approval required by The Nasdaq Stock Market (regardless of whether or not the Common Stock remains listed on The Nasdaq Stock Market at such time). To the extent that Licensor, under Section 1.1(b) hereunder, would be entitled to receive Additional Shares in excess of 19.99% of the issued and outstanding shares of Common Stock as of the date hereof prior to any issuance of Shares hereunder but for the preceding sentence, the Company shall make commercially reasonable efforts to obtain stockholder approval in accordance with the requirements of The Nasdaq Stock Market prior to issuing such excess Additional Shares. In any such stockholder vote, the Shares issued hereunder shall not be entitled to vote.

(f) The parties hereto shall execute and deliver or cause to be executed and delivered such additional documents that take such additional actions as the parties may reasonably deem to be practical and necessary in order to consummate the transactions contemplated hereby.

## ARTICLE II REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Subject to and except as set forth in the SEC Documents (as defined below), the Company hereby represents and warrants to the Licensor as of the date hereof, as follows.

2.1 Organization, Good Standing and Power. The Company is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware and has the requisite corporate power to own, lease and operate its properties and assets and to conduct its business as it is now being conducted and as described in the reports filed by the Company with the United States Securities and Exchange Commission (the "**Commission**") pursuant to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), including, without limitation, the Company's Annual Report on Form 10-K for the year ended December 31, 2023 and its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2024 and June 30, 2024. The Company is qualified to do business as a foreign corporation and is in good standing in every jurisdiction in which the failure to be so qualified would have or would reasonably be expected to have, individually or in the aggregate, a material adverse effect upon the business, properties, assets, liabilities, operations, financial condition or results of operations of the Company, or the ability of the Company to perform its obligations under the Agreement (a "**Material Adverse Effect**").

2.2 Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and perform this Agreement and the License Agreement and to issue and sell the Shares to the Licensor in accordance with the terms hereof. The execution, delivery and performance of this Agreement and the License Agreement by the Company and the consummation by it of the transactions contemplated hereby have been duly and validly authorized by all necessary corporate action, and no further consent or authorization of the Company, its board of directors (the “**Board**”) or stockholders is required. When executed and delivered by the Company, this Agreement is a legal, valid, and binding obligation of the Company enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

2.3 Valid Issuance of Securities.

The Shares, when issued and delivered in accordance with the terms and for the consideration set forth in this Agreement and the License Agreement, will be validly issued, fully paid and nonassessable and free and clear of all liens, claims, charges, security interests or agreements, pledges, assignments, covenants, restrictions or other encumbrances created by, or imposed by, the Company and rights of refusal of any kind imposed by the Company (other than restrictions on transfer under applicable securities laws) and the Licensor, as the holder of the Shares when issued, shall be entitled to all rights accorded to a holder of Common Stock.

2.4 No Conflicts; Governmental Approvals. The execution, delivery and performance of the Agreement by the Company and the consummation by the Company of the transactions contemplated hereby do not and will not (i) violate any provision of the Company’s certificate of incorporation or bylaws as currently in effect, (ii) conflict with, or constitute a default (or an event which, with notice or lapse of time or both, would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, mortgage, deed of trust, indenture, note, bond, license, lease agreement, instrument or obligation to which the Company is a party or by which the Company’s properties or assets are bound, or (iii) result in a violation of any law, rule, regulation, order, judgment or decree (including United States federal and state securities laws and regulations and regulations of any self-regulatory organizations) applicable to Company. The Company is not required under federal, state, foreign or local law, rule or regulation to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency in order for it to execute, deliver or perform any of its obligations under this Agreement or issue and sell the Shares to the Licensor in accordance with the terms hereof, other than filings that have been made, or will be made, or consents that have been obtained, or will be obtained, pursuant to the rules and regulations of the Commission and The Nasdaq Stock Market, which the Company undertakes to file within the applicable time periods.

2.5 Capitalization. There are 3,525,079 shares of Common Stock outstanding as of the date hereof (without giving effect to the issuance of Initial Shares contemplated by this Agreement). The issued and outstanding shares of capital stock of the Company have been validly issued, are fully paid and nonassessable and are not subject to any preemptive rights, rights of first refusal or similar rights. Other than in accordance with this Agreement and pursuant to awards under equity incentive plans described in the SEC Documents, no person has the right (exercisable now or in the future and whether contingent or not) to call for the issuance of any securities of Company. The Company has an authorized capitalization as set forth in its most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Except as disclosed in such reports as of the date hereof, the Company does not have any outstanding options to purchase, or any rights or warrants to subscribe for, or any securities or obligations convertible into, or exchangeable for, or any contracts or commitments to issue or sell, any shares of capital stock or other securities (other than the grant of additional awards under the Company's equity incentive plans).

2.6 SEC Documents, Financial Statements. The Company represents and warrants that as of the date hereof, the Common Stock is registered pursuant to Section 12(b) of the Exchange Act. Since January 1, 2023, the Company has timely filed all reports, schedules, forms, statements and other documents required to be filed by it with the Commission pursuant to the reporting requirements of the Exchange Act (the "**SEC Documents**"). At the times of their respective filing, all such reports, schedules, forms, statements and other documents of the Company conformed in all material respects with the requirements of the Exchange Act and the rules and regulations of the Commission promulgated thereunder. Except as disclosed in the SEC Documents, at the times of their respective filings, such reports, schedules, forms, statements and other documents of the Company did not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. As of their respective dates, the financial statements of the Company included in the SEC Documents complied in all material respects with applicable accounting requirements and the published rules and regulations of the Commission or other applicable rules and regulations with respect thereto. Such financial statements have been prepared in accordance with generally accepted accounting principles in the United States applied on a consistent basis during the periods involved (except (i) as may be otherwise indicated in such financial statements or the notes thereto or (ii) in the case of unaudited interim statements, to the extent they may not include footnotes or may be condensed or summary statements), and fairly present in all material respects the consolidated financial position of the Company as of the dates thereof and the results of operations and cash flows for the periods then ended (subject, in the case of unaudited statements, to normal year-end audit adjustments).

2.7 Internal Controls. The Company has established and maintains a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles in the United States and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company's internal control over financial reporting is effective and the Company is not currently aware of any material weaknesses in its internal control over financial reporting.

2.8 Disclosure Controls. The Company has established and maintains disclosure controls and procedures (as such term is defined in Rules 13a-15 and 15d-15 under the Exchange Act) that are designed to comply with the requirements of the Exchange Act applicable to the Company; such disclosure controls and procedures have been designed to ensure that material information relating to the Company is made known to the Company's principal executive officer and principal financial officer by others within those entities; and such disclosure controls and procedures are effective in all material respects to perform the functions for which they were established. The Company has conducted evaluations of the effectiveness of its disclosure controls and procedures as required by Rule 13a-15 of the Exchange Act. Since the date of the most recent evaluation of such disclosure controls and procedures, there have been no significant changes in internal controls or in other factors with respect to the Company that could significantly affect the Company's internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses. The Company is in compliance in all material respects with all provisions currently in effect and applicable to the Company of the Sarbanes-Oxley Act of 2002, and all rules and regulations promulgated thereunder or implementing the provisions thereof, and the applicable rules of The Nasdaq Stock Market.

2.9 No Material Adverse Change. Except as disclosed in the SEC Documents or to the Licensor, since December 31, 2023, there has not been:

(a) any change in the assets, liabilities, financial condition or operating results of the Company from that reflected in the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 and subsequent Quarterly Reports on Form 10-Q, except for changes in the ordinary course of business which have not had and would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect;

(b) any declaration or payment by the Company of any dividend, or any authorization or payment by the Company of any distribution, on any of the capital stock of the Company, or any redemption or repurchase by the Company of any securities of the Company;

(c) any material damage, destruction or loss, whether or not covered by insurance, to any assets or properties of the Company;

(d) any waiver, not in the ordinary course of business, by the Company of a material right or of a material debt owed to it;

(e) except as described in the SEC Documents, any change or amendment to the Company's Certificate of Incorporation or Bylaws, or termination of or material amendment to any contract of the Company that the Company is required to file with the Commission pursuant to Item 601(b)(10) of Regulation S-K;

(f) except as described in the SEC Documents, any material transaction entered into by the Company other than in the ordinary course of business;

(g) any admission by Company in writing of its inability to pay its debts generally as they become due, filed or consented to the filing against it of a petition in bankruptcy or a petition to take advantage of any insolvency law, made an assignment for the benefit of creditors, consented to the appointment of a receiver for itself or for the whole or any substantial part of its property, or had a petition in bankruptcy filed against it, been adjudicated a bankrupt, or filed a petition or answer seeking reorganization or arrangement under the United States federal bankruptcy or insolvency laws; or

(h) any other event or condition that has had or would reasonably be expected to have a Material Adverse Effect.

2.10 No Undisclosed Events or Circumstances. Except as disclosed in the SEC Documents, since December 31, 2023, except for the consummation of the transactions contemplated herein, to the Company's knowledge, no event or circumstance has occurred or exists with respect to the Company or its businesses, properties, prospects, operations or financial condition, which, under applicable law, rule or regulation, requires public disclosure or announcement by the Company but which has not been so publicly announced or disclosed.

2.11 Litigation. Except as disclosed in the SEC Documents or otherwise disclosed to the Licensor, no action, suit, proceeding or investigation is currently pending or, to the knowledge of the Company, has been threatened in writing against the Company that: (i) concerns or questions the validity of this Agreement or the License Agreement; (ii) concerns or questions the right or authority of the Company to enter into this Agreement or the License Agreement and to perform its obligations thereunder; or (iii) is reasonably likely to have a Material Adverse Effect.

2.12 Private Placement. Assuming the accuracy of the Licensor's representations and warranties set forth in Article III hereof, no registration under the Securities Act is required for the offer and sale of the Shares by the Company to the Licensor hereunder. The Shares (i) were not offered by any form of general solicitation or general advertising (as such terms are defined in Regulation D under the Securities Act) and (ii) are not being offered in a manner involving a public offering under, or in a distribution in violation of, the Securities Act or any state securities laws or that would otherwise require registration of the offer and issuance thereof. The Company has not engaged any brokers, finders or agents, or incurred, or will incur, directly or indirectly, any liability for brokerage or finder's fees or agents' commissions or any similar charges in connection with this Agreement and the transactions contemplated hereby.

2.13 No Integrated Offering. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security that would be integrated with the offer or sale of the Shares in a manner that would require the registration under the Securities Act.

2.14 Investment Company Act. Neither Company nor any of its subsidiaries is, and immediately after issuance of the Shares hereunder, neither Company nor any of its subsidiaries will be, an "investment company" or an entity "controlled" by an "investment company," within the meaning of the Investment Company Act of 1940, as amended.



## 2.15 Compliance with Laws and Permits.

(a) Company and its subsidiaries are and have been in material compliance with all applicable laws applicable to their businesses, including all laws applicable to the research, nonclinical and clinical testing, development, manufacturing, ownership, operation, storage, import, export, warehousing, packaging, and handling of pharmaceutical products, except where the failure to be so in compliance would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Since January 1, 2023, neither Company nor any of its subsidiaries has received any written notice of any violation or alleged violation of any such applicable laws, from any U.S. or non-U.S. federal, national, state, local or other governmental or regulatory authority, agency or body, court, arbitrator or self-regulatory organization having jurisdiction over the Company or any of its subsidiaries or any of their respective properties, assets, or operations (a “**Governmental Authority**”), except for such violations or alleged violations that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(b) Company and its subsidiaries have obtained and are in compliance in all material respects with all permits, licenses, franchises, approvals, authorizations and registrations issued or granted by Governmental Authorities that are required for the conduct by Company and its subsidiaries of their respective businesses and ownership of their respective properties (each, a “**Company Permit**”). No proceeding is pending or, to the knowledge of Company, threatened to revoke, suspend, cancel, terminate, or adversely modify any such Company Permit, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(c) None of Company or its subsidiaries or, to the knowledge of Company, any director, employee or other person acting on behalf of Company or any of its subsidiaries, has (i) taken any action in furtherance of an offer, payment, promise to pay, or authorization or approval of the payment or giving of money, property, gifts or anything else of value, directly or indirectly, to any “government official” (including any officer or employee of a government or government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office) to improperly influence official action or secure an improper advantage for the benefit of Company; (ii) violated in any material respect the United States Foreign Corrupt Practices Act of 1977, as amended, any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act 2010 of the United Kingdom, or any other applicable anti-bribery or anti-corruption law; or (iii) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any payoff, influence payment, kickback or other unlawful or improper payment or benefit.

(d) The operations of Company and its subsidiaries are and have been conducted at all times in material compliance with all applicable financial recordkeeping and reporting requirements, including those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT ACT), and the applicable anti-money laundering statutes of jurisdictions where Company and its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “**Anti-Money Laundering Laws**”), and no action, suit or proceeding by or before any court or Governmental Authority or body or any arbitrator involving Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of Company, threatened.

(e) (i) Neither Company nor any of its subsidiaries, nor, to the knowledge of Company, any director, officer, or employee, agent, Affiliate or representative of Company or any of its subsidiaries, is an individual or entity ("**Company Person**") that is, or is owned or controlled by a Company Person that is: (A) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, His Majesty's Treasury, or other relevant sanctions authority (collectively, "**Sanctions**"), nor (B) located, organized or resident in a country or territory that is the subject of Sanctions, and (ii) for the past three years, Company and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any Company Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

2.16 Intellectual Property. Company and its subsidiaries to their knowledge own, or have valid, binding and enforceable licenses or other rights under the patents and patent applications and know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information) and all other intellectual property rights necessary for, or used in the conduct of, their respective businesses in all material respects (collectively, "**Intellectual Property**"). The Intellectual Property has not been adjudged by a court of competent jurisdiction to be invalid or unenforceable, in whole or in part. No action, suit, or other proceeding is pending, or, to the knowledge of Company, is threatened: (a) challenging Company's or its subsidiaries' rights in or to any of the Intellectual Property, (b) challenging the validity, enforceability or scope of any of the Intellectual Property or (c) alleging that Company or any of its subsidiaries infringes, misappropriates, or otherwise violates any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others. Company and its subsidiaries to their knowledge have complied in all material respects with the terms of each agreement pursuant to which the Intellectual Property has been licensed to Company or any of its subsidiaries, and to the knowledge of Company, all such agreements are in full force and effect.

2.17 Licensor not Deemed an Affiliate. The Company agrees not to take the position that the combination of Licensor's receipt of the Shares and rights pursuant to this Agreement and its rights pursuant to the License Agreement, taken alone, result in Licensor's being an "affiliate" of Company for purposes of Rule 144.

### ARTICLE III

#### REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE LICENSOR

The Licensor hereby represents, warrants and covenants to the Company as of the date hereof, as follows:

3.1 Authorization and Power. The Licensor is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement. The execution and delivery of this Agreement and the performance by the Licensor of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (a) the Licensor's charter documents, bylaws, or other organizational documents; (b) in any material respect, any agreement, instrument, or contractual obligation to which the Licensor is bound; (c) any requirement of any Applicable Law; or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to the Licensor. When executed and delivered by the Licensor, this Agreement is a legal, valid, and binding obligation of the Licensor enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

3.2 Sophistication; Accredited Investor. The Licensor (a) is knowledgeable, sophisticated and experienced in making, and is qualified to make decisions with respect to, investments in securities presenting an investment decision like that involved in the purchase of the Shares, and has requested, received, reviewed and considered all information it deemed relevant in making an informed decision to purchase the Shares; (b) in connection with its decision to purchase the Shares, relied only upon the SEC Documents, other publicly available information, and the representations and warranties of the Company contained herein; (c) is an “accredited investor” pursuant to Rule 501 of Regulation D under the Securities Act; (d) is acquiring the Shares for its own account for investment only and with no present intention of distributing any part thereof or any arrangement or understanding with any other persons regarding the distribution of the same; (e) has not been organized, reorganized or recapitalized specifically for the purpose of investing in the Shares; (f) will not, directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire to take a pledge of) any of the Shares except in compliance with the Securities Act; (g) understands that the Shares are being offered and sold to it in reliance upon specific exemptions from the registration requirements of the Securities Act, and that the Company is relying upon the truth and accuracy of, and the Licensor’s compliance with, the representations, warranties, agreements, acknowledgments and understandings of the Licensor set forth herein in order to determine the availability of such exemptions and the eligibility of the Licensor to acquire the Shares; (h) understands that its investment in the Shares involves a significant degree of risk; and (i) understands that no United States federal or state agency or any other government or governmental agency has passed upon or made any recommendation or endorsement of the Shares.

3.3 Private Placement. The Licensor acknowledges and agrees that the Shares are being offered in a transaction not involving a public offering within the meaning of the Securities Act and that the Shares have not been registered under the Securities Act. The Licensor acknowledges and agrees that the Shares may not be offered, resold, transferred, pledged or otherwise disposed of absent an effective registration statement under the Securities Act or an applicable exemption from the registration requirements of the Securities Act, including Rule 144 promulgated thereunder.

3.4 Ownership of Common Stock. Except as previously disclosed to the Company in writing or by email and excluding the Shares, the Licensor and its Affiliates beneficially own no shares of Common Stock as of the date hereof.

3.5 Legends.

Subject to Section 4.2 (Removal of Legends), the Licensor acknowledges that book-entries evidencing the Shares shall bear a restrictive legend notation in substantially the following form:

THESE SECURITIES HAVE NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS OR BLUE SKY LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE COMPANY.

3.6 No Legal, Tax or Investment Advice.

The Licensor understands that nothing in this Agreement or any other materials presented by or on behalf of the Company to the Licensor in connection with the purchase of the Shares constitutes legal, tax or investment advice. The Licensor has consulted such legal, tax and investment advisors as it, in its sole discretion, has deemed necessary or appropriate in connection with its purchase of the Shares.

3.7 No General Solicitation; Pre-Existing Relationship.

The Licensor is not purchasing the Shares as a result of any advertisement, article, notice or other communication regarding the Shares published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or any other general solicitation or general advertisement (as defined in Regulation D under the Securities Act). The Licensor also represents that it was contacted regarding the sale of the Shares by the Company (or a representative of the Company) and the Shares were offered to the Licensor solely by direct contact between the Licensor and the Company (or an authorized representative of the Company) as part of the negotiation of the License Agreement.

ARTICLE IV  
COVENANTS OF THE PARTIES

4.1 Registration Rights.

(a) The Company agrees that within forty five (45) calendar days after the date hereof (the **‘Filing Deadline’**), the Company will file with the Commission (at the Company’s sole cost and expense) a registration statement (the **“Registration Statement”**), which shall be on Form S-3 (or if the Company is not eligible to use such form, on such other form as is then available to Company), registering the resale of the Initial Shares. The Company shall use its commercially reasonable efforts to have the Registration Statement declared effective as soon as practicable after the filing thereof, but no later than the 30<sup>th</sup> calendar day (or 60<sup>th</sup> calendar day if the SEC notifies the Company that it will “review” the Registration Statement) following the Filing Deadline (such date, the **“Effectiveness Date”**); provided, however, that the Company’s obligations are contingent upon the Licensor furnishing in writing to the Company such information regarding the Licensor, the securities of the Company held by the Licensor and the intended method of disposition of the Initial Shares as shall be reasonably requested by the Company to effect the registration of the Initial Shares, and shall execute such documents in connection with such registration as the Company may reasonably request that are customary of a selling stockholder in similar situations. The Licensor will not be identified as a statutory underwriter in the Registration Statement unless in response to a comment or request from the staff of the Commission or another regulatory agency; provided, that Company shall use commercially reasonable efforts to advocate to the Commission for the registration of the resale of all of the Initial Shares. If, despite Company’s foregoing efforts, the Commission continues to request that the Licensor be identified as a statutory underwriter in the Registration Statement, the Licensor will have an opportunity to request that the Company withdraw the Registration Statement or amend the Registration Statement to (i) remove from the Registration Statement only such portion of the Shares necessary (the **“Cut Back Shares”**) and/or (ii) agree to such restrictions and limitations on the registration and resale of the Initial Shares, in each of (i) and (ii), as the Commission requires to assure Company’s compliance with the requirements of Rule 415; provided, however, that Company shall not agree to name Licensor as an “underwriter” in such Registration Statement without the prior written consent of Licensor. The Company will use its commercially reasonable efforts to maintain the continuous effectiveness of the Registration Statement until the date on which all of the Shares have actually been sold or all of the Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such securities and without volume or manner-of-sale restrictions and the legends have been removed from such securities pursuant to Section 4.2 hereof (the **“Effectiveness Period”**). During the Effectiveness Period, the Company shall use reasonable best efforts to (i) make and keep public information available, as those terms are understood and defined in Rule 144, (ii) file in a timely manner all reports and other documents with the Commission required under the Exchange Act, as long as the Company remains subject to such requirements, and (iii) provide all customary and reasonable cooperation necessary, in each case as required to enable the undersigned to resell the Shares pursuant to Rule 144 of the Securities Act. The Company shall, promptly upon request of Licensor, furnish a written statement by the Company as to its compliance with the reporting requirements of Rule 144 and of the Securities Act and the Exchange Act, a copy of the most recent annual or quarterly report of the Company, and such other reports and documents so filed or furnished by the Company as such holder may request in connection with the sale of any Shares without registration.

(b) If any Additional Shares are issued that are not included in the Registration Statement, the Company agrees to file with the Commission (at the Company’s sole cost and expense) an additional Registration Statement within thirty (30) calendar days after issuance thereof (but no earlier than sixty (60) calendar days after the date hereof), and the Company shall use its commercially reasonable efforts to have such additional Registration Statement declared effective as soon as practicable after the filing thereof, but no later than the 30<sup>th</sup> calendar day (or 60<sup>th</sup> calendar day if the SEC notifies the Company that it will “review” the Registration Statement) following the aforementioned filing deadline. All other provisions of this Section 4.1 apply to such additional Registration Statement.

(c) Notwithstanding anything to the contrary in this Agreement, the Company shall be entitled to delay or postpone the effectiveness of a Registration Statement, and from time to time to require the Licensor not to sell under such Registration Statement or to suspend the effectiveness thereof, if the negotiation or consummation of a transaction by the Company or its subsidiaries is pending or an event has occurred, which negotiation, consummation or event, the Company's board of directors reasonably believes, upon the advice of legal counsel, would require additional disclosure by the Company in such Registration Statement of material information that the Company has a bona fide business purpose for keeping confidential and the non-disclosure of which in such Registration Statement would be expected, in the reasonable determination of the Company's board of directors, upon the advice of legal counsel, to cause such Registration Statement to fail to comply with applicable disclosure requirements (each such circumstance, a "**Suspension Event**"); provided, however, that the Company may not delay or suspend any Registration Statement on more than two (2) occasions or for more than sixty (60) consecutive calendar days, or more than ninety (90) total calendar days, in each case during any twelve (12) month period. Upon receipt of any written notice from the Company of the happening of any Suspension Event (which notice shall not contain material non-public information) during the period that a Registration Statement is effective or if as a result of a Suspension Event a Registration Statement or related prospectus contains any untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made (in the case of the prospectus) not misleading, the Licensor agrees that (i) it will immediately discontinue offers and sales of the Shares under such Registration Statement (excluding, for the avoidance of doubt, sales conducted pursuant to Rule 144) until the Licensor receives copies of a supplemental or amended prospectus (which the Company agrees to promptly prepare) that corrects the misstatement(s) or omission(s) referred to above and receives notice that any post-effective amendment has become effective or unless otherwise notified by the Company that it may resume such offers and sales, and (ii) it will maintain the confidentiality of any information included in such written notice delivered by the Company unless otherwise required by law or subpoena.

(d) The Company shall indemnify and hold harmless the Licensor, its directors and officers and each person who controls the Licensor (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) to the fullest extent permitted by applicable law, from and against any and all losses, claims, damages, liabilities, costs (including, without limitation, reasonable attorneys' fees) and expenses (collectively, "**Losses**"), as incurred, that arise out of or are based upon any untrue or alleged untrue statement of a material fact contained in the Registration Statement (or incorporated by reference therein), any prospectus included in the Registration Statement or any form of prospectus or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein (in the case of any prospectus or form of prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading, except to the extent, that such untrue statements or alleged untrue statements, omissions or alleged omissions are based solely upon information regarding the Licensor furnished in writing to the Company by the Licensor expressly for use therein.

(e) The Licensor shall indemnify and hold harmless the Company, its directors and officers and each person who controls the Company (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), to the fullest extent permitted by applicable law, from and against all Losses, as incurred, arising out of or are based upon any untrue or alleged untrue statement of a material fact contained in any Registration Statement, any prospectus included in the Registration Statement, or any form of prospectus, or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any prospectus, or any form of prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading to the extent, but only to the extent, that such untrue statements or omissions are contained in any information regarding the Licensor furnished in writing to the Company by the Licensor expressly for use therein.

4.2 Removal of Legends. The legend set forth in Section 3.5 above shall be removed if (i) such Shares are registered for resale under the Securities Act, (ii) such Shares are sold or transferred pursuant to Rule 144, or (iii) such Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such securities and without volume or manner-of-sale restrictions. Following the earlier of (i) the effective date of the Registration Statement or (ii) Rule 144 becoming available for the resale of Shares, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such securities and without volume or manner-of-sale restrictions, the Company shall, at its sole expense, cause the Company's counsel, upon delivery by the Licensor of a customary representation letter with respect to the legend removal to Company counsel and/or the Transfer Agent, (i) while the Registration Statement is effective, to issue to the Transfer Agent a legal opinion that the Registration Statement covering resales of the Shares has been declared effective by the Commission under the Securities Act, and (ii) provide all other opinions as may reasonably be required by the Transfer Agent in connection with the removal of legends (a) in connection with a sale made pursuant to an effective Registration Statement or (b) pursuant to Rule 144. Following the effective date of the Registration Statement, or at such earlier time as a legend is no longer required for certain Shares, the Company will cause the Transfer Agent, as soon as reasonably practicable after the Licensor's delivery of a signed customary representation letter to the Company's counsel and/or the Transfer Agent, to remove such legends.

4.3 No Integration. The Company shall not, and shall use its commercially reasonable efforts to ensure that no Affiliate of the Company shall, sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that will be integrated with the offer or sale of the Shares in a manner that would require the registration under the Securities Act of the issuance of the Shares to the Licensor, or that will be integrated with the offer or sale of the Shares for purposes of the rules and regulations of the Nasdaq Stock Market LLC such that it would require stockholder approval prior to the closing of such other transaction unless stockholder approval is obtained before the closing of such subsequent transaction.

4.4 Non-Public Information. Except with respect to the material terms and conditions of the transactions contemplated by this Agreement and the License Agreement, the Company covenants and agrees that neither it, nor any other person acting on its behalf, will provide the Licensor or its agents or counsel with any information regarding the Company that the Company believes constitutes material non-public information without the express written consent of the Licensor.

4.5 Nasdaq Listing. The Company shall use its commercially reasonable efforts to continue the listing and trading of its Common Stock on the Nasdaq Capital Market and, in accordance therewith, will use commercially reasonable efforts to comply in all material respects with the Company's reporting, filing and other obligations under the bylaws or rules of The Nasdaq Stock Market, as applicable.

## ARTICLE V

### MISCELLANEOUS

5.1 Governing Law, Jurisdiction and Service. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of Delaware for any action, suit, or proceeding arising out of or relating to this Agreement or its subject matter or formation (and including non-contractual disputes or claims) and agree not to commence any action, suit, or proceeding related thereto except in such courts. The Parties further irrevocably and unconditionally waive any objection to the laying of venue of any action, suit, or proceeding arising out of or relating to this Agreement in the courts of the State of Delaware and further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit, or proceeding brought in any such court has been brought in an inconvenient forum. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address referred to in Section 5.3 (Notices) shall be effective service of process for any action, suit, or proceeding brought against it under this Agreement.

5.2 Waiver of Jury Trial. THE PARTIES IRREVOCABLY AND UNCONDITIONALLY WAIVE THEIR RIGHT TO A JURY TRIAL.

5.3 Notices. Any notice or other communication required or permitted to be given by either Party under this Agreement shall be in writing in English and shall be deemed given as of (a) the date delivered if delivered by hand, or reputable courier service, (b) the date sent if sent by email (with transmission confirmed), (c) the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service, or (d) the fifth (5<sup>th</sup>) Business Day after mailing if mailed by registered or certified mail, postage prepaid and return receipt requested; in each case addressed to the other Party at the addresses specified below, or if a Party notifies the other Party of a different address for receipt of notices, then to such other address. “**Business Day**” means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which The Nasdaq Stock Market and banking institutions in the State of Illinois are authorized or required by law or other governmental action to close.



<b>Licensor</b>	To:	With a copy to:
<b>Licensee</b>	If by Mail: Attention: Monopar Therapeutics Inc. 1000 Skokie Blvd., Suite 350, Wilmette, IL 60091	If by Mail: Attention: Monopar Therapeutics Inc. 1000 Skokie Blvd., Suite 350, Wilmette, IL 60091

5.4 Assignment. Neither Party may assign its rights or, except that Licensor may assign this Agreement together with all of the Shares it then owns to any Affiliate of Licensor and any such assignee may assign the Agreement together with all of the Shares it then owns (subject to Section 4) to Licensor or any Affiliate of Licensor, in any such case, without such consent provided that the assignee agrees to assume Licensor's obligations under this Agreement and provided further that any assignment of Shares complies in all respects with the Securities Act. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 5.4 shall be void and of no effect.

5.5 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. In the event of such invalidity, the Parties will seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.

5.6 Entire Agreement; Amendments. This Agreement and the License, together with any schedules or appendices, sets out and constitutes the entire agreement and understanding between the Parties with respect to its subject matter and supersedes all prior agreements, understandings, promises, and representations, whether written or oral, with respect to this Agreement. Each Party confirms that it is not relying on any statements, representations or warranties of the other Party (including any negligent misrepresentation but excluding any fraudulent misrepresentation) except as specifically set out in this Agreement. All statements, representations, warranties, terms, conditions and provisions (including, any implied by statute, common law or otherwise and any implied warranties or conditions), other than fraudulent misrepresentations and the provisions set out in this Agreement, are excluded to the maximum extent permissible by law. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

5.7 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

5.8 Third Party Beneficiaries. This Agreement is intended for the benefit of the Parties hereto, their respective permitted successors and assigns, and is not for the benefit of, nor may any provision hereof be enforced by, any other person.

5.9 Further Assurances. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

5.10 No Strict Construction. The language used in this Agreement is deemed to be the language chosen by the Parties to express their mutual intent, and no rules of strict construction will be applied against a Party.

5.11 Equitable Relief. Company recognizes that, if it fails to perform or discharge any of its obligations under this Agreement, any remedy at law may prove to be inadequate relief to Licensor. Company therefore agrees that, notwithstanding anything set forth in this Agreement to the contrary, Licensor is entitled to seek temporary and permanent injunctive relief or specific performance in any such case from any court having jurisdiction over the Parties. Licensor also recognizes that, if it fails to perform or discharge any of its obligations under this Agreement, any remedy at law may prove to be inadequate relief to Company. Licensor therefore agrees that, notwithstanding anything set forth in this Agreement to the contrary, Company is entitled to seek temporary and permanent injunctive relief or specific performance in any such case from any court having jurisdiction over the Parties.

5.12 Expenses. Company and Licensor are each liable for, and will pay, their own expenses incurred in connection with the negotiation, preparation, execution and delivery of this Agreement, including, without limitation, attorneys' and consultants' fees and expenses.

[SIGNATURE PAGES TO FOLLOW]

IN WITNESS WHEREOF, the parties hereto have caused this Common Stock Investment Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

**THE COMPANY:**  
**MONOPAR THERAPEUTICS INC.**

By: /s/ Chandler D. Robinson  
Name: Chandler D. Robinson  
Title: Chief Executive Officer

IN WITNESS WHEREOF, the parties hereto have caused this Common Stock Investment Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

**THE LICENSOR:**  
**ALEXION PHARMACEUTICALS, INC.**  
By: /s/ Todd Spalding  
Name: Todd Spalding  
Title: Secretary



## Monopar Announces Agreement with Alexion, AstraZeneca Rare Disease For Late-Stage Wilson Disease Drug Candidate

WILMETTE, Ill., October 24, 2024 — Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biotechnology company focused on developing innovative treatments for patients with unmet medical needs, today announced that it has entered into an agreement with Alexion, AstraZeneca Rare Disease for an exclusive worldwide license to ALXN-1840 (bis-choline tetrathiomolybdate), a drug candidate for Wilson disease that Alexion has progressed through a Phase 3 clinical trial that met its primary endpoint. Monopar will be responsible for all future global development and commercialization activities.

Chandler D. Robinson, MD, Co-Founder and Chief Executive Officer of Monopar previously researched tetrathiomolybdate at the laboratory bench, published his results in *Science*, and helped launch a company around what became known as ALXN-1840. The focus was on Wilson disease. Dr. Robinson came to know the Wilson disease community well through his efforts. At the Wilson Disease Association's request, he delivered the keynote address at their 2013 Annual Conference celebrating their 30<sup>th</sup> anniversary, sharing his experience helping advance ALXN-1840 from the laboratory bench to patients. In 2023, Alexion terminated the ALXN-1840 program in Wilson disease based on review of results from Phase II mechanistic trials and discussions with regulatory authorities.

Chris Starr, PhD, Co-Founder and Executive Chair of Monopar said, "Upon the 2023 announcement, Chandler, due to his long history with the program and the continued high level of unmet medical need, was contacted by Wilson disease patients, executives and board members of the Wilson Disease Association, as well as physicians regarding the potential for Monopar to obtain rights to ALXN-1840. Due in no small measure to the testimonials Chandler received from clinical trial patients who reported benefit while on the drug for years, we decided that this was an opportunity Monopar needed to pursue, and it fits well with my rare disease drug development and commercialization background as well as Chandler's background." Dr. Starr also previously co-founded the orphan drug companies BioMarin and Raptor Pharma (acquired by Horizon Pharma, now a part of Amgen).

Dr. Robinson commented, "Alexion has generated a substantial clinical data package on ALXN-1840, including a completed Pivotal Phase 3 clinical trial. The medical data gathered from Alexion's clinical trials furthers our understanding of Wilson disease and stands to benefit this community."

Under the terms of the license agreement, Monopar will pay Alexion an upfront in the form of a cash payment and equity in Monopar. Future payments are based on tiered royalties on net sales and pre-determined regulatory and sales milestones.

"We are excited to have Alexion and AstraZeneca as partners of Monopar as, in addition to Alexion's work in Wilson disease, AstraZeneca maintains a significant presence in the radiopharma field, in which Monopar is committed to continue growing as Monopar recently announced positive human clinical data with our novel radiopharma program (link)," stated Andrew Cittadine, Chief Operating Officer of Monopar.

### About Wilson Disease

Wilson disease is a rare and progressive genetic condition in which the body's pathway for removing excess copper is compromised.<sup>1</sup> It affects one in 30,000 live births in the US.<sup>1</sup> Over time this results in the build-up of toxic copper levels in the liver, brain, and other organs, leading to damage that greatly impacts a patient's life.<sup>1</sup> Patients can develop a wide range of symptoms, including liver disease and/or psychiatric or neurological symptoms, such as personality changes, tremors and difficulty walking, swallowing or talking.<sup>1</sup> In some cases, the damage and loss of function may be irreversible.<sup>1,2,3</sup>

### About ALXN-1840

ALXN-1840 (bis-choline tetrathiomolybdate) is an investigational once-daily, oral medicine in development for the treatment of Wilson disease. This novel molecule is designed to selectively and tightly bind and remove copper from the body's tissues and blood. ALXN-1840 has been granted Orphan Drug Designation in the United States and orphan designation in the European Union for Wilson disease.

### About the Phase 3 "FoCus" Clinical Trial

The FoCus trial was a pivotal Phase 3, randomized, rater-blinded, multi-center clinical trial designed to evaluate the efficacy and safety of ALXN-1840 versus standard-of-care (SoC) in patients with Wilson disease aged 12 years and older. The primary endpoint assessed copper mobilization over 48 weeks, defined as daily mean AUEC (Area Under the Effect Curve) for dNCC (directly measured non-ceruloplasmin-bound copper). In the trial, 214 patients were enrolled in one of two cohorts on a 3:1 basis (treatment-experienced:treatment-naïve). Each cohort was then randomized 2:1 (ALXN1840:SoC). The first cohort enrolled 161 patients who received SoC (chelation therapy with penicillamine or trientine, zinc therapy or a combination of both chelation and zinc therapy) for more than 28 days and the second cohort enrolled 53 patients who were treatment-naïve or had received SoC for 28 days or less. The FoCus trial met its primary endpoint demonstrating three-times greater copper mobilization from tissues compared to the SoC arm (Least Square Mean Difference [LSM Diff] 2.18  $\mu\text{mol/L}$ ;  $p < 0.0001$ ), including in patients who had been treated previously for an average of 10 years. In the trial, people taking ALXN-1840 experienced rapid copper mobilization, with a response at four weeks and sustained through the 48 weeks. ALXN-1840 was generally well-tolerated with most reported adverse events considered mild to moderate, and no neurological worsening upon initiation of treatment was observed. In the ALXN-1840 treatment group, the most frequently reported adverse event was a reversible increase in transaminase levels.

### About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biotechnology company with late-stage ALXN-1840 for Wilson disease, and radiopharma programs including Phase 1-stage MNPR-101-Zr for imaging advanced cancers, and Phase 1a-stage MNPR-101-Lu and late preclinical-stage MNPR-101-Ac225 for the treatment of advanced cancers. For more information, visit: [www.monopar.com](http://www.monopar.com).

### Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Examples of these forward-looking statements include statements concerning: the medical data gathered from Alexion's clinical trials furthers our understanding of Wilson disease and stands to benefit this community; ALXN-1840 was generally well-tolerated with most reported adverse events considered mild to moderate, and no neurological worsening upon initiation of treatment; and the most frequently reported adverse event for the ALXN-1840 treatment group was a reversible increase in transaminase levels. The forward-looking statements involve risks and uncertainties including, but not limited to: our near term ability to raise sufficient funds in order for us to support continued clinical, regulatory and commercial development of our programs and to make contractual upfront and future milestone payments, as well as our ability to further raise additional funds in the future to support any existing or future product candidate programs through completion of clinical trials, the approval processes and, if applicable, commercialization; uncertainties related to the regulatory discussions we intend to initiate related to ALXN-1840 and the outcome thereof; the rate of market acceptance and competitiveness in terms of pricing, efficacy and safety, of any products for which we receive marketing approval, and our ability to competitively market any such products as compared to larger pharmaceutical firms; and the significant general risks and uncertainties surrounding the research, development, regulatory approval, and commercialization of imaging agents and therapeutics. Actual results may differ materially from those expressed or implied by such

forward-looking statements. Risks are described more fully in Monopar's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Monopar undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made. Any forward-looking statements contained in this press release represent Monopar's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

**CONTACT:**

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**References:**

1. Patil, M., et al. (2013) J Clin Exp Hepatol, 3, 321-336.
2. Roberts, E.A., Schilsky, M.L. American Association for the Study of Liver D. (2008). Diagnosis and treatment of Wilson disease: An update. Hepatology, 47(6), 2089-2111.
3. European Association for the Study of the Liver. (2012). EASL clinical practice guidelines: Wilson's disease. J Hepatol, 56(3), 671-685.