

**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 8, 2024**

SONNET BIOTHERAPEUTICS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-35570

(Commission
File Number)

20-2932652

(IRS Employer
Identification No.)

**100 Overlook Center, Suite 102
Princeton, New Jersey 08540**
(Address of principal executive offices)

Registrant's telephone number, including area code: **(609) 375-2227**

Not Applicable

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 Par Value	SONN	The Nasdaq Capital Market LLC

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 8, 2024, Sonnet BioTherapeutics, Inc. and Sonnet BioTherapeutics CH SA, each a wholly-owned subsidiary of Sonnet BioTherapeutics Holdings, Inc. (collectively, the "**Company**"), entered into a License Agreement (the "**Agreement**") with Alkem Laboratories Limited, a company organized under the laws of India ("**Alkem**"). Pursuant to the Agreement, the Company granted Alkem an exclusive license (with the right to sublicense) to research, develop, manufacture, import, export, market, use and commercialize pharmaceutical products containing a specific recombinant human interleukin-6 (or any derivatives, fragments or conjugates thereof) (the "**Compounds**") (such products, the "**Products**") for the treatment of diabetic peripheral neuropathy (DPN) (the "**DPN Field**") and to manufacture, import, export, market, use and commercialize Products for the treatment of chemotherapy-induced peripheral neuropathy (CIPN) and autonomic neuropathy (together with the DPN Field, collectively, the "**Fields**") in India (the "**Exclusive Territory**"). Except as provided for in the Agreement, the Company has agreed not to develop, use, sell, offer or otherwise commercialize any Compounds or Products for use in the DPN Field in the Exclusive Territory during the term of the Agreement.

The Company retains all rights to manufacture Compounds and Products anywhere in the world. The Company and Alkem shall enter into a follow-on supply agreement pursuant to which the Company shall manufacture for Alkem Compounds and Products for development and commercialization thereof in accordance with the Agreement on terms to be negotiated by the parties.

Pursuant to the terms of the Agreement, Alkem will bear the cost of, and be responsible for, among other things, conducting clinical studies and additional non-clinical studies (if any, subject to both parties' approval), preparing and filing applications for regulatory approval and undertaking other developmental and regulatory activities for and commercializing Products in the DPN Field in the Exclusive Territory. Alkem will own and maintain all regulatory filings and approvals for Products in the Exclusive Territory. Upon payment of a Clinical Data Access Fee (as defined in the Agreement), the Company will have rights to access the data generated by the clinical trials conducted in connection with the Agreement.

In consideration of the license and other rights granted by the Company, Alkem will pay the Company, within twelve (12) weeks of the Effective Date of the Agreement, a

\$1,000,000 upfront non-refundable cash payment, as well as potential additional milestone payments to the Company totaling up to \$1,000,000 subject to the achievement of certain development and regulatory milestones. In addition, during the Royalty Term (as defined below), Alkem is obligated to pay the Company a royalty equal to a percentage in the low double digits of net sales less Alkem's actual cost of goods sold and Alkem's sales and marketing and related expenses of Products in the Territory. The " **Royalty Term**" means, on a Product-by-Product basis in the Exclusive Territory, the period commencing on the date of the First Commercial Sale (as defined in the Agreement) of such Product in the Exclusive Territory and continuing until Alkem ceases Commercialization (as defined in the Agreement) of such Product in the DPN Field. The Royalty Term shall expire upon the first commercial sale of a competitive Intermittent Low-Dose IL6 compound as set forth in the Agreement.

The Company retains the sole responsibility to pay its third party licensors to the extent such obligations are applicable to the rights granted to Alkem with respect to the Products and shall remain liable for all obligations under the license related to the Compounds and Products between the Company and ARES Trading SA.

The Agreement will remain in effect in perpetuity until terminated as a result of breach, bankruptcy or upon ninety (90) days prior written notice, in each case as set forth in the Agreement.

Pursuant to the Agreement, the parties agreed to form a joint development committee to provide strategic oversight of the parties' collaboration activities under the Agreement, including to coordinate the development of Products in the Territory.

The Agreement also contains customary representations, warranties and covenants by both parties, as well as customary provisions relating to indemnification, confidentiality and other matters.

The foregoing description of the terms of the Agreement is qualified in its entirety by reference to the copy of the Agreement attached herewith as Exhibit 10.1 to this Current Report on Form 8-K, which is incorporated herein by reference.

Item 7.01 Regulation FD.

On October 9, 2024, the Company issued a press release announcing the Agreement with Alkem for the development, marketing and commercialization of the Products as set forth in the Agreement.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission (the "SEC"), and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Events.

On October 9, 2024, the Company issued a press release announcing the Agreement with Alkem for the development, marketing and commercialization of the Products as set forth in the Agreement.

The Company entered into the Agreement with Alkem Laboratories Limited on October 8, 2024 for the research, development, manufacturing, marketing and commercialization of its molecule SON-080 for the treatment of DPN in India as well as the and the manufacturing, marketing and commercialization of SON-080 for the treatment of CIPN and autonomic neuropathy in India. SON-080 has the same mechanism of action for these three neuropathies.

SON-080 is the Company's proprietary version of recombinant human Interleukin-6 (rhIL-6) that builds upon previous work with atexakin alfa. Under the terms of the Agreement, Alkem will pay the Company \$1.0 million in upfront payments and up to an additional \$1.0 million in milestone payments as set forth in the Agreement. Additionally, the Company is entitled to receive a royalty equal to a percentage in the low double digits of the net sales of the product upon commercialization of SON-080 in India less certain expenses as set forth in the Agreement. Alkem will conduct all clinical trials it believes appropriate to obtain regulatory approval in India for SON-080 for the treatment of DPN. Upon payment of a Clinical Data Access fee for Phase 2 and Phase 3 clinical trials, the Company will be able to use this data for partnering in any geography outside of India.

DPN represents a significant unmet medical need, with a global market projected to reach approximately \$6.8 billion by 2030. The estimated market size of diabetic neuropathy in India was \$120.3 million in 2023 and is expected to reach \$246.7 million by 2030. DPN is a painful and extremely disabling disease that typically occurs in about 50% of diabetic patients. Current therapeutics focus primarily on pain symptoms due to lack of modulation treatments, however, such treatments do not address the non-pain symptoms resulting from nerve degeneration. Low dose IL-6 has been shown to stimulate peripheral nerve growth in preclinical models, thereby ameliorating motor and sensory functions and normalizing the associated pain or sensation disturbance of neuropathy.

SON-080 has undergone many years of development, in which previous clinical trials have generated safety data from over 200 patients. SON-080 has demonstrated compelling preclinical efficacy data in both DPN and CIPN, including reproducibly demonstrating the ability to prevent the development of neuropathy and reverse established neuropathy when assessed by nerve conduction, histological integrity and sensorimotor function measurements.

The Company recently announced encouraging data from the completed Phase 1b portion of its ongoing Phase 1b/2a clinical trial evaluating SON-080 for the treatment of CIPN (the "SB211 study"). The data demonstrated SON-080 to be well-tolerated at both doses, with no evidence of a pro-inflammatory cytokine response. Pain and quality of life survey results suggest the potential for rapid improvement of peripheral neuropathy symptoms and post-dosing durability with both doses, compared to placebo controls. For more information about the SB211 study, visit clinicaltrials.gov and reference identifier NCT05435742.

Forward-Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and Private Securities Litigation Reform Act, as amended, including those relating to the Agreement, the outcome of the Company's clinical trials, the Company's cash runway, the Company's product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
10.1*	License Agreement, dated October 8, 2024, between Sonnet BioTherapeutics, Inc., Sonnet BioTherapeutics CH SA and Alkem Laboratories Limited.
99.1	Press Release dated October 9, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Certain identified information has been excluded from this exhibit (indicated by asterisks) because it is both not material and the type of information that the Company treats as private or confidential, in accordance with the rules of the SEC

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.

Sonnet BioTherapeutics Holdings, Inc.

Date: October 9, 2024

By: /s/ Pankaj Mohan, Ph.D.

Name: Pankaj Mohan, Ph.D.

Title: Chief Executive Officer

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. INFORMATION THAT WAS OMITTED HAS BEEN NOTED IN THIS DOCUMENT WITH A PLACEHOLDER IDENTIFIED BY THE MARK “[***]”

LICENSE AGREEMENT

between

SONNET BIOTHERAPEUTICS, INC

and

ALKEM LABORATORIES LIMITED

Dated as of October 8, 2024

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EXECUTION COPY

LICENSE AGREEMENT

This License Agreement (hereinafter referred to as the “**Agreement**”) is made and effective as of the date of the last signature (the “**Effective Date**”), by and between SONNET BIOTHERAPEUTICS, INC. (hereinafter referred to as “**SONNET**”), a company organized under the laws of the state of New Jersey, USA and having its registered office at 100 Overlook Center, Suite 102, Princeton, New Jersey 08540 (which expression shall deem to mean and include its affiliates and successors), SONNET BIOTHERAPEUTICS CH SA, c/o Dr. Gael Hedou, Avenue du Temple 5, 1462 Yvonand, Switzerland, and ALKEM LABORATORIES LIMITED (hereinafter referred to as “**ALKEM**”), a company organized under the laws of India and having its registered office at Alkem House, Senapati Bapat Marg Road, Lower Parel (West), Mumbai 400013 India (which expression shall deem to mean and include its affiliates and successors). SONNET and ALKEM are each referred to herein as a “**Party**” and collectively as the “**Parties**”.

WITNESSETH:

WHEREAS, SONNET is engaged, among other activities, in the development of a low dose IL6 therapeutic for the treatment of diabetic peripheral neuropathy (“**DPN**”, as defined in Section 1.17) the rights to which were acquired by SONNET from Relief Therapeutics, SA pursuant to the Amendment to License Agreement and Settlement dated 27th October, 2021 between Sonnet BioTherapeutics CH SA and ARES TRADING SA, a subsidiary of Merck KGaA; and

WHEREAS, ALKEM is engaged in the development, marketing and sale of pharmaceutical products; and

WHEREAS, SONNET wishes to license to ALKEM, on an exclusive basis within the Exclusive Territory (as hereinafter defined), the right to research, Develop, manufacture, import, export, market, use and Commercialize the Product (as hereinafter defined) in the Field (as hereinafter defined);

NOW, THEREFORE, in consideration of the promises and mutual covenants contained herein, the Parties agree to as follows:

ARTICLE 1 - DEFINITIONS

The following terms shall have the following respective definitions:

- 1.1** “**Affiliate**” means a Person that controls, is Controlled by or is under common Control with a Party, but only for so long as such Control exists. For the purposes of this Section 1.1, the word “**Control**” (including, with correlative meaning, the terms “**Controlled by**” - save for its definition under Section 1.15 - or “**under the common Control with**”) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person or entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

- 1.2 “**Autonomic Neuropathy**” means Autonomic Neuropathy indication.
- 1.3 “**CIPN**” means chemotherapy-induced peripheral neuropathy.
- 1.4 “**Clinical Trial**” means a clinical trial in human subjects that has been approved by a Regulatory Authority, designed to measure the safety and/or efficacy of the Product. Clinical Trials shall include Phase I Trials, Phase II Trials and Phase III Trials. For avoidance of doubt, the Product will be administered to patients via the subcutaneous route of administration in a lyophilization (“lyo”) formulation if it is available at the onset of the first Clinical Trial in the Exclusive Territory, and in a liquid formulation if the lyo formulation has not been fully developed and qualified.
- 1.5 “**Collaboration**” means the activities contemplated under this Agreement related to the Development of the Product for use in the Field.
- 1.6 “**Combination Product**” means a Product, used in the context of the SONNET Patents, that: (a) includes one or more active ingredients in addition to the Compound; or (b) is combined with one or more products, devices, pieces of equipment or components.
- 1.7 “**Commercialization**” or “**Commercialize**” means any and all activities undertaken before and after Regulatory Approval of a Marketing Authorization Application (“MAA”) for the Product and that relate to the marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of the Product, and interacting with Regulatory Authorities regarding the foregoing.
- 1.8 “**Commercially Reasonable Efforts**” means: (a) with respect to the efforts to be expended by a Party with respect to any objective, such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances; and (b) with respect to the Product, efforts and resources similar to those employed by companies in a similar stage of development and available resources as ALKEM or SONNET to Develop, or Commercialize a product of similar market potential at a similar stage in its product life, taking into account, without limitation, commercial, legal and regulatory factors, target product profiles, product labeling, past performance, the regulatory environment and competitive market conditions in the therapeutic area, safety and efficacy of the Product, the strength of its proprietary position and such other factors as such companies may reasonably consider (including resource availability), all based on conditions then prevailing. For the avoidance of doubt, “Commercially Reasonable Efforts” with respect to the Product Development shall be assessed independently of ALKEMs’ or SONNET’s other activities that are not related to the Product Development and shall require what a diligent person would do to perform a sound and reasonable Development of the Product. For clarity, “Commercially Reasonable Efforts” will not mean that a Party guarantees that it will actually accomplish the applicable task or succeed in the targeted objective.
- 1.9 “**Compound**” means recombinant human interleukin-6 having the sequence set forth on Schedule 1.9, including any derivative, fragment or conjugate thereof.

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- 1.10 “**Confidential Information**” of a Party means any information relating to the business, operations or products of a Party or any of its Affiliates, including any Know-How and biological or chemical materials not known or generally available to the public, that such Party discloses to the other Party under this Agreement, or otherwise becomes known to the other Party by virtue of this Agreement. For any Party, this Agreement and the terms and conditions herein are deemed “Confidential Information” of the other Party.
- 1.11 “**Controlled**” means, with respect to (a) any Patent Right, (b) any Know-How or (c) any biological, chemical or physical material, that a Party or one of its Affiliates owns or has a license or sublicense to such Patent Right, Know-How or material (or in the case of material, has the right to physical possession of such material) and has the ability to grant a license or sublicense to, or to assign its right, title and interest in and to, such Patent Right, Know-How or material as provided for in this Agreement, without violating the terms of any agreement or other arrangement with any Third Party.
- 1.12 “**Cover**”, “**Covering**” or “**Covered**” means, with respect to the Product, that the use, sale, or offer for sale of the Product would, except for a license granted under this Agreement, infringe a Valid Claim in the country in which the activity occurs.
- 1.13 “**Development**” or “**Develop**” means, with respect to the Product, the performance of all pre-clinical and clinical developments (including toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis), Clinical Trials (excluding Clinical Trials conducted after Regulatory Approval of an NDA), manufacturing and regulatory activities that are required to obtain Regulatory Approval of the Product in the Territory.
- 1.14 “**DPN**” means diabetic peripheral neuropathy.
- 1.15 “**DPN Field**” means all prophylactic, palliative and therapeutic uses of the Product for the DPN indication in humans.
- 1.16 “**Executive Officers**” means, together, a member of the senior management of SONNET and the Chief Executive Officer of ALKEM.
- 1.17 “**Existing Third Party Agreement(s)**” means the agreement(s) set forth on Schedule 1.17.
- 1.18 “**Exclusive Territory**” means the following country: India
- 1.19 “**FDA**” means the United States Food and Drug Administration, or a successor federal agency thereto.
- 1.20 “**Field**” specifically means the DPN Field, the CIPN Field and the Autonomic Neuropathy Field.
- 1.21 “**First Commercial Sale**” means, Product-by-Product basis, the first commercial transfer or disposition for value of a Product in Exclusive Territory to a Third Party by ALKEM or any of its Sublicensees.

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- 1.22 “**Fiscal Quarter**” means each three (3) months period commencing April 1, July 1, October 1 or January 1 of any Fiscal Year; *provided, however*, that (a) the first Fiscal Quarter of the Term shall extend from the Effective Date to the end of the first full Fiscal Quarter thereafter, and (b) the last Fiscal Quarter of the Term shall end upon the expiration or termination of this Agreement.
- 1.23 “**Fiscal Year**” means the period beginning on the 1st of April and ending on the 3rd of March of the next year; *provided, however*, that (a) the first Fiscal Year of the Term shall commence on the Effective Date and end on March 31 of the next year and (b) the last Fiscal Year of the Term shall commence on April 1 of the Fiscal Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

- 1.24 **“Governmental Body”** means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.
- 1.25 **“IFRS”** means the International Financial Reporting Standards, which are the set of accounting standards and interpretations and the framework in force on the Effective Date and adopted by the European Union as issued by the International Accounting Standards Board (IASB) and the International Financial Reporting Interpretations Committee (IFRIC), as such accounting standards may be amended from time to time.
- 1.26 **“IND”** means an investigational new drug application submitted to any applicable Regulatory Authorities for approval to commence Clinical Trials in a given jurisdiction.
- 1.27 **“Know-How”** means any scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, that is not in the public domain or otherwise publicly known, including discoveries, inventions, trade secrets, devices, databases, practices, protocols, regulatory filings, methods, processes (including manufacturing processes, specification and techniques), techniques, concepts, ideas, specifications, formulations, formulae, data (including pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), case reports forms, medical records, data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), summaries and information contained in submissions to and information from ethical committees, or Regulatory Authorities, and manufacturing process and development information, results and data, whether or not patentable, all to the extent not claimed or disclosed in a patent or patent application. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, and/or a development relating to the item, is (and remains) not known to the public. “Know-How” includes any rights including copyright, database or design rights protecting such Know-How. “Know-How” excludes Patent Rights.

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- 1.28 **“Law” or “Laws”** means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.
- 1.29 **“Liquidation Event”** means any liquidation, dissolution, winding-up, or Change of Control of either Party, irrespective of its legal qualification.
- 1.30 **“Net Margin”** means Net Sales less ALKEM’s actual cost of goods sold for the Product less ALKEM’s sales and marketing and related expenses including but not limited to sales and marketing personnel cost and distribution expenses etc .
- 1.31 **“Net Sales”** means the gross amounts invoiced by ALKEM for sales of Product to independent or unaffiliated Third Party purchasers of such Product, less those deductions with respect to such sales that are either included in the billing as a line item as part of the gross amount invoiced, or otherwise documented as a deduction in accordance with IFRS to be specifically attributable to actual sales of such Product. Such deductions may also include any bad debt (provided that if such bad debt is subsequently collected it will be added to Net Sales).

For the purpose of this Agreement, IFRS is applicable to SONNET and local laws prevailing in the Exclusive Territory is applicable to ALKEM.

If a Product under this Agreement is sold in the form of a Combination Product, then Net Sales for such Combination Product shall be determined by mutual agreement of the Parties in good faith, taking into account the perceived relative value contributions of the Product and the other ingredient or component in the Combination Product, as reflected in their respective market prices. In case of disagreement, an independent expert designated by mutual agreement of both Parties or, failing such agreement, designated by the International Chamber of Commerce, shall determine such relative value contributions and such determination shall be final and binding upon the Parties.

In the event Product is “bundled” for sale together with one or more other products in a country (a**“Product Bundle”**), then Net Sales for such Product sold under such arrangement shall be determined by mutual agreement of the Parties in good faith taking into account the relative value contributions of the Product and the other products in the Product Bundle, as reflected in their individual sales prices. In case of disagreement, an independent expert designated by mutual agreement of both Parties or, failing such agreement, the International Chamber of Commerce shall determine such relative value contributions and such determination shall be final and binding upon the Parties.

- 1.32 **“Patent Right”** means: (a) an issued or granted patent, including any extension, supplemental protection certificate, registration, confirmation, reissue, reexamination, extension or renewal thereof; (b) a pending patent application, including any continuation, divisional, continuation-in-part, substitute or provisional application thereof; and (c) all counterparts or foreign equivalents of any of the foregoing issued by or filed in any country or other jurisdiction.

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- 1.33 **“Person”** means any natural person, corporation, firm, business trust, joint venture, association, organization, partnership or other business entity, or any government or agency or political subdivision thereof.
- 1.34 **“Phase I Trial”** means a Clinical Trial in which the Product is administered to human subjects at multiple dose levels with the primary purpose of determining safety, metabolism, and pharmacokinetic and pharmacodynamics properties of the Product, and consistent with 21 CFR § 312.21(a) or its equivalent in the applicable country in the Exclusive Territory.
- 1.35 **“Phase IB/IIA Trial”** means a Clinical Trial in which the Product is administered to human subjects at multiple dose levels with the primary purposes of determining pharmacological or clinical activity (including dose response, dose escalation, duration of effect or kinetic/dynamic relationship assessments and to make a preliminary determination of efficacy and safety of the Product in the target patient population to permit the design of a Phase IIB or Phase III Trial as the case may be.
- 1.36 **“Phase II Trial”** means a Clinical Trial of the Product in human patients, the principal purposes of which are to make a preliminary determination that the Product is safe for its intended use, to determine its optimal dose, and to obtain sufficient information about the Product’s efficacy to permit the design of Phase III Trials, and consistent with 21 CFR 312.21(b) or its equivalent in the applicable country in the Exclusive Territory.
- 1.37 **“Phase III Trial”** means a human Clinical Trial of the Product, which trial is designed (a) to establish that the Product is safe and efficacious for its intended use; (b) to define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed; and (c) consistent with 21 CFR § 312.21(c) or its equivalent in the applicable country of the Exclusive Territory.
- 1.38 **“Product”** means any pharmaceutical product, including any formulation thereof, containing or comprising the Compound as claimed by any of the SONNET Patents.
- 1.39 **“Regulatory Authority”** means (a) the FDA, or (b) any regulatory body with similar regulatory authority over pharmaceutical or biotechnology products in any other jurisdiction anywhere in the world including the Exclusive Territory.

- 1.40 **“Regulatory Approval”** shall mean the receipt from a Regulatory Authority by ALKEM or its Sublicensees, of approval to lawfully market a Product in the corresponding jurisdiction in the Exclusive Territory.
- 1.41 **“Royalty Term”** means, Product-by-Product basis in the Exclusive Territory, the period from the First Commercial Sale of such Product in the Exclusive Territory until the Commercialization of the Product by ALKEM ceases in the DPN Field. Such Royalty Term shall expire upon the occurrence of the first commercial sale of a competitive Intermittent Low-Dose IL6 compound.

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- 1.42 **“Sale”** means the sale and transfer of the entire outstanding and issued share capital of ALKEM (100%) to any Third Party whatsoever in a single Transaction or series of related transactions.
- 1.43 **“Section”** means any section or Article of this Agreement.
- 1.44 **“SONNET Data”** means all existing pre-clinical and clinical data related to the Product in the DPN Field in possession or Control of SONNET as of the Effective Date and any additional preclinical data generated during the Term of this Agreement.
- 1.45 **“SONNET Know-How”** means all Know-How that relates to the Compound and that is Controlled by SONNET as of the Effective Date and any additional Know-How generated during the Term of this Agreement, and is necessary in the research, Development, use, or Commercialization of the Product in the DPN Field.
- 1.46 **“SONNET Patents”** means all Patent Rights set forth on Schedule 1.47 hereto, that are Controlled by SONNET as of the Effective Date and any additional Patents generated during the Term of this Agreement.
- Notwithstanding the above, if SONNET decides to file any new patent Covering the same uses of the Compound in the DPN Field as the Patent Rights set forth in Schedule 1.47, then such new patent(s) shall, immediately upon filing, become an integral part of the SONNET Patents licensed to ALKEM under Section 2.1. For clarity, if SONNET files any new patent covering the same uses as the SONNET Patents, but unrelated to the Compound, then such Patent Rights shall not fall within SONNET Patents within this Agreement.
- 1.47 **“SONNET Technology”** means the SONNET Know-How, the SONNET Data and the SONNET Patents.
- 1.48 **“Sublicensee”** means a Person other than an Affiliate of ALKEM, to which ALKEM has granted sublicense rights pursuant to Section 2.2; for the sake of clarity, “Sublicensee” shall exclude distributors.
- 1.49 **“Tax”** or **“Taxes”** means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, goods and services, alternative or add-on minimum, estimated, or other tax of any kind whatsoever imposed by any Governmental Body, including any interest, penalty, or addition thereto.
- 1.50 **“Territory”** collectively means the Exclusive Territory.
- 1.51 **“Third Party”** shall mean any Person other than a Party or an Affiliate of a Party.

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- 1.52 **“Valid Claim”** means a claim of an issued and unexpired SONNET Patent, filed in the related country in the Territory, which has not lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or governmental or supra-governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise.
- 1.53 **Other Terms.** The definition of each of the following terms is set forth in the Section of the Agreement indicated below:
- “Action”** has the meaning set forth in Section 6.5(b).
- “Commercialization Plan”** has the meaning set forth in Section 3.2.
- “Controlling Party”** has the meaning set forth in Section 6.6(c).
- “Development Plan”** has the meaning set forth in Section 3.1.
- “Joint Development Committee”** and **“JDC”** have the meanings set forth in Section 4.1.
- “ALKEM Indemnitees”** has the meaning set forth in Section 9.2.
- “SONNET Indemnitees”** has the meaning set forth in Section 9.1.
- “SONNET Royalty Rate”** has the meaning set forth in Section 5.2(a)
- “Term”** has the meaning set forth in Section 10.1.
- “Third Party Action”** has the meaning set forth in Section 6.6(a).

ARTICLE 2 - GRANT OF LICENSE

- 2.1 **Grant of License.** Subject to the terms and conditions of this Agreement, SONNET hereby grants to ALKEM an exclusive, transferable, royalty-bearing right and license (with the right to sublicense subject to Section 2.2) under the SONNET Technology, to Develop, manufacture, market, import, use and Commercialize the Product in the Field in the Exclusive Territory. For the avoidance of doubt, the license granted to ALKEM hereunder shall not include the right to export the Product outside the Exclusive Territory; *provided, however*, ALKEM shall, through its subsidiary or any third party, be granted the right to make or have made, to develop or have developed, to manufacture or have manufactured to market or have marketed, to use or have used and to commercialize or have commercialized the Product for use in the Field within the Exclusive Territory.

2.2 **Grant of Sublicense by ALKEM.** ALKEM shall have the right to grant sublicenses under the license granted in Section 2.1 in consultation with SONNET to its Affiliates, subsidiaries, sub-distributors or subcontractors or any third parties for the purpose of conducting Development, manufacturing, marketing, using or Commercialization activities in the Exclusive Territory. The granting by ALKEM of any sublicense shall not relieve ALKEM of its obligations hereunder.

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2.3 **Non-Compete.** Except as provided herein, SONNET hereby covenants not to practice, and not to permit or cause any of its Affiliates to develop, use, sell, have sold, offer for sale, or otherwise commercialize any Compound or Product for use in the DPN Field in the Exclusive Territory during the Term.

2.4 **No Implied Licenses.** Only those licenses expressly granted in this Agreement have effect. No license or other intellectual property interest or rights to the Compound or Product outside the DPN Field is granted by implication or any method that is not express. In addition, SONNET shall be deemed to retain such rights to the SONNET Technology as may be necessary or useful to the performance of SONNET's obligations hereunder.

2.5 **Technology Transfer.** Upon receipt of a written request by ALKEM, SONNET shall transfer to ALKEM, at ALKEM's cost and expense, all relevant SONNET Know-How and SONNET Data necessary for ALKEM to perform its obligations hereunder. Such technology transfer from SONNET to ALKEM shall take place in an orderly fashion and in manner such that the value, usefulness and confidentiality of the SONNET Know-How and SONNET Data are preserved by SONNET in all material respects throughout the transfer.

ARTICLE 3 - DEVELOPMENT AND COMMERCIALIZATION

3.1 **Development of the Product by ALKEM.** ALKEM shall have the exclusive right in the Exclusive Territory to research, Develop and Commercialize the Product and to conduct (either itself or through its Affiliates, agents, subcontractors and/or Sublicensees) all Clinical Trials and non-clinical studies ALKEM (with the approval of the JDC) believes appropriate to obtain Regulatory Approval for the Product in the DPN Field. All costs associated with the development and Commercialization of the Product in the DPN Field in the Exclusive Territory shall be borne by ALKEM for except Phase II Trial. In exchange for rights to the Phase II Trial data, SONNET shall be required to pay 50% of the total execution cost of the Phase II Trial in India ("**Clinical Data Access Fee**"). Such re-imbursment by SONNET shall occur on a quarterly basis. The Phase II Trial will be conducted in India only but would be guided by advice from both the US FDA and DCGI. The Phase III Trial as per the requirements by DCGI which is the local regulatory authority in India, will be conducted as per the design, methodology agreed by the applicable regulatory authority, by ALKEM. Such Phase III Trial will be performed on a good faith efforts basis in consultation with SONNET to match with the global standards. SONNET shall be required to pay Clinical Data Access Fee on a quarterly basis for accessing such Phase III Trial data which would be 50% of the total execution cost of the Phase III Trial. The Development of the Product shall be governed by a development plan, prepared and adopted by ALKEM, and approved by SONNET, that describes the proposed overall program of Development (the "**Development Plan**"), which Development Plan will be updated by ALKEM annually.

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3.2 **Commercialization.** Subject to the terms and conditions of this Agreement, ALKEM shall have the exclusive right to Commercialize the Product itself or through one or more Third Parties selected by ALKEM, in consultation with SONNET, in the Exclusive Territory in the Field. The Commercialization of the Product shall be governed by a commercialization plan that describes the contemplated overall program of Commercialization (the "**Commercialization Plan**"). Such Commercialization Plan shall thereafter be updated by ALKEM annually.

3.3 **Manufacturing and Supply.** Subject to the terms and conditions of this Agreement, SONNET shall manufacture the Compound and the Product itself, or through one or more Third Parties selected mutually by SONNET and Alkem, and subject to the last sentence in Section 2.1, and according to the Product development timeline that will be developed by the Parties and set forth in Schedule 3.3 hereto. SONNET shall supply Compound free of charge for Phase IIB clinical development. Validation and commercial batches shall be manufactured at cost as set forth in a Supply Agreement which shall be negotiated in good faith. The details of such standard cost of the Compound or Product would be disclosed to the ALKEM in the Supply Agreement, and such cost would be made available prior to initiation of manufacturing of validation and commercial lots.

3.4 **Regulatory Filings.** As between SONNET and ALKEM and subject to Section 10.5, ALKEM shall own and maintain all regulatory filings and Regulatory Approvals for the Product in the Exclusive Territory, including all INDs and MAAs.

3.5 **Diligence.** ALKEM will use Commercially Reasonable Efforts to Develop and Commercialize the Product within the Exclusive Territory in the DPN Field. For the avoidance of doubt, with respect to any pivotal Phase III Trials conducted in the Exclusive Territory, ALKEM shall use Commercially Reasonable Efforts to Develop, manufacture, market, import, export, use and Commercialize the Product.

3.6 **Annual Reporting.** ALKEM shall, on each anniversary of the Effective Date, provide SONNET with a written report summarizing in reasonable detail its Development conducted during the preceding Fiscal Year.

3.7 **Trademarks.** ALKEM shall have the sole authority to create, select and register trademarks in the Territory for any Product by ALKEM and shall own all such trademarks. However, ALKEM shall inform SONNET of any change in trademark of the Product commercialized by ALKEM.

ARTICLE 4 - DEVELOPMENT MANAGEMENT

4.1 **Joint Development Committee.** As soon as practicable after the Effective Date, the Parties shall establish a committee to facilitate the Development of the Product (the "Joint Development Committee" or "JDC") as follows:

(a) **Composition of the JDC.** The Collaboration shall be conducted under the direction of a JDC comprised of two (2) representatives of ALKEM and two (2) representatives of SONNET. Each Party shall appoint its respective representatives to the JDC from time to time, and may substitute one or more of its representatives, in its sole discretion, effective upon notice to the other Party of such change. Each Party shall have at least one JDC representative who is a senior employee (director level or above), and all JDC representatives shall have appropriate research, preclinical, manufacturing, clinical development or commercialization expertise and ongoing familiarity with the Collaboration. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend JDC meetings, subject to such representatives' and consultants' complying with the requirements of Article 7. Each Party shall bear its own expenses relating to attendance at such meetings by its representatives.

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(b) **JDC Chairperson.** The "JDC Chairperson" shall be a representative of ALKEM. The JDC Chairperson's responsibilities shall include (a) scheduling meetings; (b) setting agendas for meetings with solicited input from other members; (c) confirming and delivering minutes to the JDC for review and final approval; and (d) conducting effective meetings, including ensuring that objectives for each meeting are set and achieved.

(c) **Meetings.** The JDC shall meet in accordance with a schedule established by mutual written agreement of the Parties and from time to time promptly upon

the request of either Party, but no less frequently than twice per Fiscal Year, with the location for such meetings alternating between ALKEM and SONNET facilities (or such other locations as are determined by the JDC). Alternatively, the JDC may meet by means of teleconference, videoconference or other similar electronic media means of communication.

(d) JDC Responsibilities. The JDC shall have the following responsibilities with respect to the Collaboration:

- (1) determining the overall Development strategy for the Collaboration;
- (2) reviewing for approval (i) the annual update to the Development Plan and (ii) any modifications to such Development Plan in each case within thirty (30) days of each submission to the JDC;
- (3) determining each Party's responsibilities under the Development Plan consistent with Section 3.1;
- (4) facilitating the transfer of Know-How and Confidential Information from SONNET to ALKEM for purposes of conducting the Development Plan;
- (5) reviewing any new intellectual property filings and assessing the applicability of such patents to the Development Plan;
- (6) regularly assessing the progress of the Parties in their conduct of the Development Plan and against the timelines and budgets contained therein, reviewing relevant data, and considering issues of priority; and
- (7) performing such other activities as are contemplated under this Agreement and, subject to any Amendments pursuant to Section 12.10, that the Parties mutually agree shall be the responsibility of the JDC.

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4.2 Appointment of Subcommittees, Project Teams and Collaboration Managers. The JDC shall be empowered to create such subcommittees of itself and additional project teams as it may deem appropriate or necessary. Each such subcommittee and project team shall report to the JDC, which shall have authority to approve or reject recommendations or actions proposed thereby subject to the terms of this Agreement. Each Party shall also designate a "Collaboration Manager." The Collaboration Managers will be responsible for the day-to-day coordination of the Collaboration and will serve to facilitate communication between the Parties. Each Party may change its designated Collaboration Manager from time to time upon written notice to the other Party.

4.3 Reports and Minutes. Each Party will provide the members of the JDC with written copies of all materials they intend to present at the JDC meeting. The JDC may also request at any time specific data or information related to Development activities or that a written report be prepared in advance of any meeting summarizing certain material data and information arising out of the conduct of the Development activities and the Party or appropriate committee to whom such request is made shall promptly provide to the other Party or JDC such report, data or information. A secretary shall be appointed for each meeting and shall prepare minutes of the meeting, which shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the JDC.

4.4 Decision-Making and Dispute Resolution.

(a) Voting. With respect to decisions of the JDC, the representatives of each Party shall have collectively one vote on behalf of such Party. For each meeting of the JDC, at least two (2) representatives of each Party shall constitute a quorum. Action on any matter may be taken at a meeting, by teleconference, videoconference or by written agreement.

(b) Decision-Making. The JDC shall operate by consensus, subject to the dispute resolution process set forth in Section 4.4.3 below.

(c) Dispute Resolution. The JDC shall attempt to resolve any and all disputes relating to the Collaboration by unanimous consensus. In the event the JDC is unable to reach a unanimous consensus with respect to any such dispute, then the following dispute resolution provisions shall apply.

- (1) With respect to any dispute over which the JDC has authority pursuant to Section 4.1(d), except those disputes related to the scope of the JDC's powers under Section 4.1(d)(6), ALKEM shall have the final decision-making authority for the Development of the Product in the Exclusive Territory for use in the DPN Field following completion of the Phase II Trials. For clarity, Commercialization activities within the Exclusive Territory shall not be the responsibility of the JDC and shall be subject to ALKEM's final decision-making authority.
- (2) With respect to all other disputes between the Parties regarding the interpretation, construction or application of this Agreement, the dispute resolution process specified under Article 11 shall prevail.

4.5 Dissolution of JDC. The JDC shall be dissolved upon receipt of the Regulatory Approval of the Product to manufacture and market in the Exclusive Territory.

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ARTICLE 5 - FINANCIALS

5.1 a) Upfront Payment. In consideration of the rights and licenses granted herein, ALKEM shall pay SONNET a non-refundable amount totaling One Million Dollars (USD \$1,000,000) payable within twelve (12) weeks from the Effective Date of this Agreement; Sonnet shall provide all the information and relevant documents required by ALKEM to perform its obligations hereunder within this period.

b) Milestone Payments:

- i) Upon first patient enrollment for Phase 3 = Five Hundred Thousand Dollars (USD \$500,000)
- ii) Upon the successful regulatory approval for marketing by DCGI = Five Hundred Thousand Dollars (USD \$500,000).

5.2 Royalty; Monetary Third Party Obligations

(a) Royalty Rate. As consideration for the granting of rights to the SONNET Technology, ALKEM shall, during the Royalty Term, pay to SONNET a royalty equal to [***] percent ([***]%) of the Net Margin of the Product ("**SONNET Royalty Rate**"); *provided, however*, such Royalty Term shall expire upon the occurrence of the first commercial sale of a competitive Intermittent Low-Dose IL6 compound.

(b) Considerations under Existing Third Party Agreements. SONNET shall be obliged to and be responsible for paying all monetary obligations owed by SONNET or any of its Affiliates to Third Parties (the "**Monetary Third Party Obligations**") for the Product, including without limitation royalty and other payment obligations, under Existing Third Party Agreements.

(c) Royalty Reporting, Currency Conversion. Commencing with the Fiscal Quarter in which the First Commercial Sale of a Product is made by the ALKEM or any of its Sublicensee, ALKEM shall submit to SONNET with each royalty payment including any due royalty, a report detailing its computation of royalties for the SONNET Royalty Rate due on Net Margin for the corresponding Fiscal Quarter. Such Report and the associated payments shall be due within forty-five (45) days after the end of each Fiscal Quarter. All payments to SONNET hereunder shall be made in US dollars in the requisite amount to such bank account as SONNET may from time to time designate by written notice to ALKEM. With respect to sales not denominated in Dollars, any amounts owed to SONNET by ALKEM shall first be calculated in the currency of sale, and then such amounts shall be converted into US Dollars using the average of the month end daily currency exchange rates published by Bloomberg (or its successors) on the last day of the Fiscal Quarter to which the report relates. The Parties may vary the method of payment set forth herein at any time upon mutual agreement, and any change shall be consistent with the local law at the place of payment or remittance.

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(d) Record Retention, Inspection. ALKEM shall keep or cause its Sublicensees to keep complete and accurate records in sufficient detail to enable Net Sales and royalties payable under this Section 5.2, to be established for a period of sixty (60) months after the date that such amounts were payable. Such records shall be consistent with ALKEM's normal accounting principles. At the request of SONNET (but not more frequently than once each Fiscal Year) an independent chartered or certified public accountant chosen and paid by SONNET but approved by the ALKEM (which approval shall not be unreasonably withheld or delayed) shall be allowed access during ordinary business hours to such records pertaining to the preceding two (2) Fiscal Years solely to verify the accuracy of any payments made to SONNET under this Section 5.2. The accountant shall not disclose to SONNET any information other than that which should properly be contained in a report of matters relevant to Net Sales and royalty calculation arising under this Section 5.2.

5.3 Withholding Tax. All payments under this Agreement are net of tax and shall be subject to withholding tax, if any, as prescribed under the Applicable Laws in the Territory. ALKEM shall subtract the amount of the withholding tax from the payments due to SONNET hereunder, and provide SONNET with the requisite withholding tax certificate and with other reasonable assistance in order to allow SONNET to obtain tax benefit to minimize double taxation which may apply to such payments.

ARTICLE 6 - INVENTIONS, PATENTS AND CLINICAL DATA

6.1 Certification Under Drug Price Competition and Patent Restoration Act. Each Party shall immediately give written notice to the other Party of any certification filed pursuant to 21 U.S.C. Section 355(b)(2)(A) (or any amendment or successor statute thereto), of which it becomes aware and which claims either that any SONNET Patent, any Product or the Development, manufacture, use or Commercialization, of each of the foregoing, are invalid or unenforceable, or that infringement will arise from the Development, manufacture, use or Commercialization of any similar product by a Third Party in the Territory.

6.2 Listing of Patents. SONNET shall have the sole right to determine which of the SONNET Patents, if any, shall be listed for inclusion in the Approved Drug Products with "Therapeutic Equivalence Evaluations" pursuant to 21 U.S.C. Section 355, or any successor law in the United States, together with any comparable laws or regulations in the Exclusive Territory.

6.3 Title to Inventions. SONNET is and shall at all times be the sole and exclusive owner of all right, title and interest in and to the SONNET Technology, other than Joint Inventions and Joint Patent Rights. A Party shall have and retain all right, title and interest in any Invention made solely by one or more employees or agents of such Party and or its Affiliates or other persons acting under its authority. The Parties shall jointly own rights in any Invention made jointly by one or more employees or agents of each Party and/or such Party's Affiliates or other persons acting under its authority ("**Joint Inventions**") and Patent Rights therein ("**Joint Patent Rights**"). For clarity, Inventions developed exclusively by one Party and such Party's Affiliates shall not be considered Joint Inventions. Subject to the rights and licenses granted under this Agreement, each Party shall have the right to practice and use, and grant licenses to practice and use, any Joint Inventions and Joint Patent Rights without the other Party's consent and has no duty to account to the other Party for such practice, use or license, and each Party hereby waives any right it may have under the laws of any country to require any such consent or accounting. Each Party shall be liable with respect to its own employees for compliance with any applicable legislation and its own policies concerning employee inventions, including payment of employee invention awards (if any).

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6.4 Patent Prosecution and Maintenance.

(a) ALKEM. ALKEM shall have the right to file, prosecute and maintain each and all patents it owns or in-licenses from SONNET subject to this Agreement. ALKEM shall bear all costs and expenses of filing, prosecuting and maintaining such patents.

(b) SONNET Patents. SONNET shall have the first right, and the obligation, to file, prosecute and maintain each and all SONNET Patents within the Exclusive Territory. However, SONNET shall bear all costs and expenses of filing, prosecuting and maintaining the SONNET Patents in the Exclusive Territory and ALKEM will support in filing of SONNET Patents in the Exclusive Territory by providing all the additional information and knowledge. SONNET shall keep ALKEM informed about the course of the filing and prosecution of SONNET Patents or related proceedings (e.g., interferences, oppositions, reexaminations, reissues, revocations or nullification s) in the Exclusive Territory in a timely manner, and to take into consideration the advice and recommendations of ALKEM. At SONNET's request, ALKEM will provide SONNET with reasonable assistance in prosecuting SONNET Patents to the extent possible, in particular by providing to SONNET any data related to the SONNET Patents which is under ALKEM's Control and which is, in SONNET's reasonable judgment, needed to support the prosecution of any SONNET Patent; *provided, however*, that SONNET shall reimburse ALKEM for ALKEM's out-of-pocket expenses incurred in providing such assistance.

(c) Joint Patent Rights. Both parties shall have the right, but not the obligation, to prepare, file, prosecute and maintain all Joint Patent Rights, by counsel of SONNET's choice. The cost of prosecution of said Joint Patent Rights shall be shared equally by the Parties. SONNET shall keep ALKEM reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of the Joint Patent Rights, and shall provide to ALKEM copies of all material patent office submissions within a reasonable amount of time not exceeding fifteen (15) days following submission thereof by SONNET. In the event that SONNET desires to abandon or cease prosecution or maintenance of any Joint Patent Right, SONNET shall provide written notice to ALKEM of such intention to abandon promptly after SONNET makes such determination, which notice shall be given no later than thirty (30) days prior to the next deadline for any action that must be taken with respect to such Joint Patent Right in the relevant patent office. In such case, ALKEM shall have the right, in its discretion, exercisable upon written notice to SONNET delivered no later than thirty (30) days after receipt of notice from SONNET, to assume responsibility for prosecution and maintenance of such Joint Patent Right, at its sole cost and expense and by counsel of its own choice.

(d) Patent Report. On each anniversary of the Effective Date during the Term, SONNET shall inform ALKEM annually reflecting the status of the SONNET Patents in the Exclusive Territory.

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(e) Patent Term Extension. SONNET shall be responsible for obtaining patent term extensions wherever available for SONNET Patents ALKEM shall provide SONNET with all relevant information, documentation and assistance in this respect. Any such assistance, supply of information and consultation shall be provided promptly and in a manner that will ensure that all patent term extensions for Products are obtained wherever legally permissible, and to the maximum extent available. In the event that any election with respect to obtaining patent term extensions is to be made, ALKEM shall have the right to make such elections, and SONNET shall abide by all such

elections.

6.5 Enforcement of Patents.

(a) Notice. If either Party believes that any SONNET Patent is being infringed by a Third Party or if a Third Party claims that any SONNET Patent is invalid or unenforceable within the Exclusive Territory, the Party possessing such knowledge or belief shall notify the other Party and provide it with details of such infringement or claim that are known by such Party.

(b) Right to Bring an Action. As long as it owns the relevant SONNET Patent, SONNET shall have the exclusive right to attempt to resolve such infringement or claim, including by filing an infringement suit, defending against such claim or taking other similar action (each, an “**Action**”) and to compromise or settle such infringement or claim.

Notwithstanding the foregoing, each Party shall have the right to join an Action relating to a SONNET Patent, taken by the other Party at its own expense.

(c) Costs of an Action. Subject to the respective indemnification obligations set forth in Section 9, the Party taking an Action under Section 6.5(b) shall assume all costs associated with such Action, including any possible assistance as detailed under Section 6.5 (e), to the exception of the expenses that the other Party may incur if it elects to join such Action.

(d) Settlement. Neither Party shall settle or otherwise compromise any Action without the other Party’s prior written consent. The settlement will be treated in accordance with the law of the country to which the settlement relates.

(e) Reasonable Assistance. The Party who does not join an Action shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence and making its employees available, subject to the other Party’s reimbursement of any out-of-pocket expenses incurred by such assistance.

(f) Distribution of Amounts Recovered. Any amounts recovered by the Party taking an Action pursuant to this Section 6.5, whether by settlement or judgment, shall be allocated in the following order:

- (i) to reimburse the Party taking such Action for any costs incurred;
- (ii) to reimburse the Party not taking such Action for its costs incurred in such Action, if it joins such Action; and
- (iii) the remaining amount of such recovery shall be retained by the Party taking the Action.

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6.6 Third Party Actions Claiming Infringement.

(a) Notice. If a Party becomes aware of any claim or action by a Third Party against either Party that claims that the Product, or its use, Development, manufacture or Commercialization infringes such Third Party’s intellectual property rights (each, a “**Third Party Action**”) in the Exclusive Territory, such Party shall promptly notify the other Party of all details regarding such claim or action that is reasonably available to such Party.

(b) Right to Defend. SONNET shall have a first right, to defend, at its sole expense, a Third Party Action If SONNET declines or fails to assert its intention to defend such Third Party Action within a brief time period (i.e. with sufficient time for ALKEM to take whatever action may be necessary prior to the date on which such right to defend shall lapse), then ALKEM shall have the right to defend such Third Party Action. The Party defending such Third Party Action shall have the sole and exclusive right to select its own counsel for such Third Party Action.

(c) Consultation. The Party defending a Third Party Action pursuant to this Section 6.6 (the “**Controlling Party**”) shall consult with the non-Controlling Party on all material aspects of the defense. The non-Controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy. The Parties shall reasonably cooperate with each other in all such actions or proceedings.

(d) Appeal. In the event that a judgment in a Third Party Action is entered against the Controlling Party and an appeal is available, the Controlling Party shall have the first right, to file such appeal. If applicable law requires the other Party’s involvement in an appeal, the other Party shall be a nominal party of the appeal and shall provide reasonable cooperation to such Party at such Party’s expense.

(e) Costs of an Action. Subject to the respective indemnification obligations of the Parties set forth in Article 9, the Controlling Party shall pay all costs associated with such Third Party Action other than the expenses of the other Party if the other Party elects to join such Action. Each Party shall have the right to join a Third Party Action defended by the other Party, at its own expense.

(f) No Settlement Without Consent. No Controlling Party shall settle or otherwise compromise any Third Party Action by admitting that any SONNET Patent is invalid or unenforceable without the non-Controlling Party’s prior written consent.

6.7 Clinical Data and Clinical Data Access Fee. All clinical data resulting from human clinical studies in the DPN Field as conducted by ALKEM shall be jointly owned subject to payment of the Clinical Data Access Fee as set forth in Section 3.1.

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ARTICLE 7 - CONFIDENTIALITY

7.1 Confidentiality Obligations. Each Party agrees that in addition to and not in lieu of the confidentiality obligations set forth in the Mutual Non-Disclosure Agreement between the Parties dated January 16, 2023, it shall ensure that its officers, directors, employees and agents shall, keep completely confidential and not publish or otherwise disclose and not use for any purpose, except as expressly permitted hereunder, any Confidential Information disclosed to it by the other Party pursuant to this Agreement. The foregoing obligations shall not apply to any Confidential Information disclosed by a Party hereunder to the extent that the receiving Party can demonstrate that such Confidential Information:

- (i) was already known to the receiving Party or its Affiliates, other than under an obligation of confidentiality, at the time of disclosure;
- (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
- (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

- (iv) was subsequently lawfully disclosed to the receiving Party or its Affiliates by a Third Party without an obligation of confidentiality other than in contravention of a confidentiality obligation of such Third Party to the disclosing Party; or
- (v) was developed or discovered by employees or agents of the receiving Party or its Affiliates who had no access to the Confidential Information of the disclosing Party.

Notwithstanding the above, a Party may disclose information to the extent that such disclosure is reasonably necessary in connection with:

- (vi) filing new patent applications or prosecuting or maintaining SONNET Patents, in accordance with the terms and conditions of this Agreement;
- (vii) seeking Regulatory Approval of the Product;
- (viii) complying with any applicable law, including securities law and the rules of any securities exchange or market on which a Party's securities are listed or traded.

In addition, in connection with any permitted filing by either Party of this Agreement with any Governmental Body, the filing Party shall endeavor to obtain confidential treatment of economic, trade secret information and such other information as may be requested by the other Party, and shall provide the other Party with the proposed confidential treatment request with reasonable time for such other Party to provide comments, and shall include in such confidential treatment request all reasonable comments of the other Party disclosures set forth in clauses (i) through (v) above, the disclosing Party shall, where reasonably practicable, give such advance notice to the other Party of such disclosure requirement as is reasonable under the circumstances and will use its reasonable efforts to cooperate with the other Party in order to secure confidential treatment of such Confidential Information required to be disclosed. The receiving party agrees that any Confidential Information disclosed by the disclosing party under this Agreement shall be maintained as confidential, during the duration of this Agreement and for a period of five (5) years after the termination or expiration of this Agreement, whichever is earlier.

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7.2 Publications. ALKEM shall have the right to publish any information relating to the Product after obtaining written concurrence of SONNET. If such information has already been publicly disclosed either prior to the Effective Date or after the Effective Date through no fault of ALKEM or otherwise not in violation of this Agreement, ALKEM shall provide SONNET with written notice prior to publication in a journal in which a submission is made by ALKEM. In any case, ALKEM shall submit to SONNET for SONNET's written approval (which approval shall be granted or denied in SONNET's sole discretion) any publication or presentation (including, without limitation, in any seminars, symposia or otherwise) of information related directly or indirectly to the Product for review and approval. SONNET shall have the right to publish any information relating to the Product in the Territory after obtaining written concurrence of ALKEM. If such information has already been publicly disclosed either prior to the Effective Date or after the Effective Date through no fault of SONNET or otherwise not in violation of this Agreement, SONNET shall provide ALKEM with written notice prior to publication in a journal in which a submission is made by SONNET. In any case, SONNET shall submit to ALKEM for ALKEM's written approval (which approval shall be granted or denied in ALKEM's sole discretion) any publication or presentation (including, without limitation, in any seminars, symposia or otherwise) of information related directly or indirectly to the Product for review and approval.

7.3 Press Releases and Disclosure. It is understood that SONNET intends to issue a press release announcing the execution of this Agreement at a mutually agreed upon time and content and that each Party thereafter may desire or be required to issue subsequent press releases relating to the Agreement or activities thereunder. Except as otherwise provided in this Section 7.3, neither Party may issue a press release relating to this Agreement or activities hereunder without the prior consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed) and without complying with this Section 7.3; *provided, however*, that either Party may issue such press releases as it determines, are strictly necessary to comply with laws or regulations or for appropriate market disclosure. If a Party wishes to issue a press release, it shall provide the other Party with a draft of such press release so that the other Party shall have sufficient time to review such release. If no comments are provided by the end of such a seven (7) working days period following the receipt of the draft, the release will be deemed to have been approved by the other Party. Following the initial press release announcing this Agreement, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

ARTICLE 8 - REPRESENTATIONS AND WARRANTIES

8.1 Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date:

- (1) such Party is duly organized and validly existing under the Laws of the jurisdiction of its incorporation or organization;
- (2) such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of each and all its obligations thereunder;

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- (3) this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement and applicable Law. The execution, delivery and performance of this Agreement by such Party does not conflict with, breach or create in any Third Party, the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound, and does not violate any Law of any Governmental Body having authority over such Party; and such Party has all right, power and authority to enter into this Agreement, to perform its obligations under this Agreement.

In addition to the above, SONNET expressly represents and warrants to ALKEM that it is in Control of, or is validly entitled to engage, each and all elements of the SONNET Technology transferred and/or licensed to ALKEM, pursuant to this Agreement. SONNET further covenants and agrees that it shall promptly provide a copy of the minutes of the scheduled pre-IND meeting related to the Product with the FDA which FDA meeting minutes shall be deemed Confidential Information of SONNET.

ARTICLE 9 - INDEMNIFICATION AND INSURANCE

9.1 Indemnification by ALKEM. ALKEM shall indemnify, defend and hold SONNET and its Affiliates and each of their respective employees, officers, directors and agents (the "SONNET Indemnitees") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees) to the extent arising out of Third Party claims or suits related to: (a) ALKEM's negligence or willful misconduct; (b) ALKEM's breach of its obligations under this Agreement; (c) breach by ALKEM of its representations or warranties set forth in Section 8.1; (d) the Development, manufacture and Commercialization of Products, *provided, however*, that ALKEM's obligations pursuant to this Section 9.1 shall not apply (i) to the extent such claims or suits result from the negligence or willful misconduct of any of the SONNET Indemnitees, or (ii) with respect to claims or suits arising out of breach by SONNET of its representations, warranties or covenants set forth in Section 8.1, or (iii) in case of infringement of intellectual property rights by SONNET.

9.2 Indemnification by SONNET. SONNET shall indemnify, defend and hold ALKEM and its Affiliates and each of their respective agents, employees, officers and directors (the “**ALKEM Indemnitees**”) harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorney’s fees) to the extent arising out of Third Party claims or suits (including Third Party Actions) related to: (a) SONNET’s negligence or willful misconduct; (b) SONNET’s breach of its obligations under this Agreement; or (c) breach by SONNET of its representations, warranties or covenants set forth in Section 8.1; *provided, however*, that SONNET’s obligations pursuant to this Section 9.2 shall not apply (i) to the extent that such claims or suits result from the negligence or willful misconduct of any of ALKEM Indemnitees or (ii) with respect to claims or suits arising out of a breach by ALKEM of its representations or warranties set forth in Section 8.1.

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9.3 No Consequential Damages. EXCEPT WITH RESPECT TO EACH PARTY’S INDEMNIFICATION OBLIGATIONS UNDER SECTION 9.1 OR SECTION 9.2, AS APPLICABLE, IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOSS OF PROFITS, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT SHALL LIMIT EITHER PARTY FROM SEEKING OR OBTAINING ANY REMEDY AVAILABLE UNDER LAW FOR ANY BREACH OF BY THE OTHER PARTY OF ITS CONFIDENTIALITY AND NON-USE OBLIGATIONS UNDER ARTICLE 7.

9.4 Notification of Claims; Conditions to Indemnification Obligations. Except for the specifics foreseen under the scope of Section 6.6, as a condition to a Party’s right to receive indemnification under this Article 9, it shall: (a) promptly notify the other Party as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto; (b) cooperate, and cause the individual indemnitees to cooperate, with the indemnifying Party in the defense, settlement or compromise of such claim or suit; and (c) permit the indemnifying Party to control the defense, settlement or compromise of such claim or suit, including the right to select defense counsel. In no event, however, may the indemnifying Party compromise or settle any claim or suit in a manner which admits fault or negligence on the part of the indemnified Party or any indemnitee without the prior written consent of the indemnified Party. Each Party shall reasonably cooperate with the other Party and its counsel in the course of the defense of any such suit, claim or demand, such cooperation to include without limitation using reasonable efforts to provide or make available documents, information and witnesses. The indemnifying Party shall have no liability under this Article 9 with respect to claims or suits settled or compromised without its prior written consent.

ARTICLE 10 - TERM AND TERMINATION

10.1 Term of Agreement. The term of this Agreement (the “**Term**”) shall commence on the Effective Date and unless earlier terminated as provided in this Section 10, shall continue in full force and effect till perpetuity.

10.2 Termination for Breach. Either Party may terminate this Agreement, and the rights and licenses granted hereunder, with a sixty (60) days prior notice to the other Party if the other Party breaches any provision of this Agreement, unless the other Party cures such breach within the period of such notice. Such termination shall be in addition to any other remedies available to the terminating Party at Law.

10.3 Termination for Bankruptcy. This Agreement may be terminated by either Party, forthwith, if the other party enters into liquidation whether compulsorily or voluntarily, or has a receiver appointed over all or part of its assets or ceases for any reason to carry on business.

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10.4 Termination for Bonafide Reasons. Notwithstanding anything stated herein, both Parties shall have right to terminate the Agreement by giving ninety (90) days prior written notice to the other Party by assigning a bonafide reason.

10.5 Effects of Termination.

(a) **Accrued Rights and Obligations.** Termination of this Agreement shall not release either Party from its obligations accrued prior to the effective date of termination nor deprive either Party from any rights that shall survive termination according to this Agreement.

(b) **Surviving Provisions.** Sections 5, 7, 9, 10.5, 11 and 12 shall survive any termination of this Agreement.

(c) **Consequences of Termination.**

(I) Upon any Termination of this Agreement by SONNET:

(I) on account of Section 10.2 or Section 10.3, as applicable within the Exclusive Territory

(i) All licenses granted to ALKEM under Section 2.1 shall terminate;

(ii) At SONNET’s sole discretion, SONNET has the right to assume legal responsibility for any Clinical Trials of the Product in the Exclusive Territory. ALKEM shall, upon written request by SONNET, transfer to SONNET all regulatory documentation and Regulatory Approvals prepared or obtained by or on behalf of ALKEM prior to the date of such termination, to the extent solely related to Products and transferable.

(iii) ALKEM shall return to SONNET all relevant records and materials in its possession or Control containing or comprising the SONNET Know-How or such other Confidential Information of SONNET.

(iv) ALKEM shall, at SONNET’s option, transfer to SONNET at ALKEM’s cost all chemical, biological or physical materials relating to or comprising the Products, including clinical supplies of Products, that are owned or Controlled by ALKEM, upon commercial terms to be mutually agreed upon between the Parties in good faith.

(v) To the extent not prohibited by Law, ALKEM shall wind down any ongoing Clinical Trials with respect to the Product, or at SONNET’s option, transfer such clinical trials to SONNET, in which case ALKEM shall provide SONNET with the relevant Clinical Trial supplies of the Product free of charge.

(vi) ALKEM and its Sublicensees shall be entitled, to sell any commercial inventory of Product which remains on hand as of the date of the termination, so long as ALKEM pays to SONNET the royalties applicable for said subsequent sales in accordance with the terms and conditions set forth in this Agreement.

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(2) on account of Section 10.4 within the Exclusive Territory:

- (i) ALKEM shall retain the licenses granted under Section 2.1;
- (ii) ALKEM shall cease to pay any pending milestone payments and/or royalty to SONNET.
- (iii) ALKEM shall safeguard and be liable for the compliant use of the Product to ensure patients safety.
- (iv) ALKEM shall retain all regulatory documentation and Regulatory Approvals prepared or obtained by or on behalf of ALKEM prior to the date of such termination, to the extent solely related to Product and transferable.
- (v) ALKEM shall retain all relevant records and materials in its possession or Control containing or comprising the SONNET Know-How or such other Confidential Information of SONNET.
- (vi) ALKEM shall retain all chemical, biological or physical materials relating to or comprising the Product, including clinical supplies of Product, that are owned or Controlled by ALKEM, upon commercial terms to be mutually agreed upon between the Parties in good faith.
- (vii) ALKEM shall neither wind down any ongoing Clinical Trials with respect to the Product, nor transfer such clinical trials to SONNET.
- (viii) ALKEM and its Sublicensees shall be entitled, to sell any commercial inventory of Product which remains on hand as of the date of the termination, so long as ALKEM pays to SONNET the royalties applicable for said subsequent sales in accordance with the terms and conditions set forth in this Agreement.

(II) Upon any termination of this Agreement by ALKEM

(1) on account of Section 10.2 or Section 10.3, as applicable within the Exclusive Territory

- (i) All licenses granted to ALKEM under Section 2.1 shall be retained by ALKEM;
- (ii) ALKEM shall cease to pay any pending milestone payments and/or royalty (if applicable) to SONNET.
- (iii) ALKEM shall retain all regulatory documentation and Regulatory Approvals prepared or obtained by or on behalf of ALKEM prior to the date of such termination, to the extent solely related to Product and transferable.

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- (iv) ALKEM shall retain all relevant records and materials in its possession or Control containing or comprising the SONNET Know-How or such other Confidential Information of SONNET.
- (v) ALKEM shall retain all chemical, biological or physical materials relating to or comprising the Product, including clinical supplies of Product, that are owned or Controlled by ALKEM, upon commercial terms to be mutually agreed upon between the Parties in good faith.
- (vi) ALKEM shall neither wind down any ongoing Clinical Trials with respect to the Product, nor transfer such Clinical Trials to SONNET.
- (vii) SONNET shall reimburse ALKEM the outstanding Clinical Data Access Fee as set forth in Section 3.1. Such clinical costs incurred by ALKEM for which the data was made accessible to SONNET for its use in securing global partners.
- (viii) ALKEM and its Sublicenses shall be entitled, to sell any commercial inventory of Product which remains on hand as of the date of the termination, so long as ALKEM pays to SONNET the royalties applicable for said subsequent sales in accordance with the terms and conditions set forth in this Agreement.

(2) on account of Section 10.4 within the Exclusive Territory:

- (i) ALKEM shall return the licenses granted under Section 2.1;
- (ii) ALKEM shall pay any pending milestone payments and/or royalty (if applicable) to SONNET.
- (iii) ALKEM shall, upon written request by SONNET, transfer to SONNET, all regulatory documentation and Regulatory Approvals prepared or obtained by or on behalf of ALKEM prior to the date of such termination, to the extent solely related to Product and transferable.
- (iv) ALKEM shall return all relevant records and materials in its possession or Control containing or comprising the SONNET Know-How or such other Confidential Information of SONNET.
- (v) ALKEM shall, at SONNET's option, transfer to SONNET and/or return all chemical, biological or physical materials relating to or comprising the Product, including clinical supplies of Product, that are owned or Controlled by ALKEM, upon commercial terms to be mutually agreed upon between the Parties in good faith.
- (vi) To the extent not prohibited by Law, ALKEM shall wind down any ongoing Clinical Trials with respect to the Product, or at SONNET's option, transfer such Clinical Trials to SONNET, in which case ALKEM shall provide SONNET with the relevant Clinical Trial supplies of the Product free of charge.

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ARTICLE 11 - DISPUTE RESOLUTION - JURISDICTION

11.1 Disputes. The Parties agree to first establish and follow procedures to facilitate the resolution of disputes arising out of or in relation with this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event that the Parties are unable to resolve such dispute through diligent review and deliberation by their respective senior executives within thirty (30) days from the day that one Party had notified the issue as a dispute in written notice to the other Party, then either Party shall have the right to escalate such matter to their respective Executive Officers as further detailed under Section 11.2.

- 11.2 Escalation to Executive Officers.** Either Party may, by written notice to the other Party, request that a dispute arising out of or in relation with this Agreement that remains unresolved by the respective senior executives of the Parties for a period of thirty (30) days be resolved by the Executive Officers, within fifteen (15) days after referral of such dispute to them. If the Executive Officers cannot resolve such dispute within fifteen (15) days after referral of such dispute to them, then, at any time after such fifteen (15) day period, either Party may proceed to enforce any and all of its rights with respect to such dispute.
- 11.3 Dispute Resolution.** The Parties hereby agree that they will attempt in good faith to resolve any controversy or claim arising out of or relating to this Agreement promptly by negotiations as provided above. Any dispute, controversy or claim initiated by either party arising out of, resulting from or relating to this Agreement, or the performance by either party of its obligations under this Agreement (other than bona fide Third Party actions or proceedings filed or instituted in an action or proceeding by a Third Party against a party), whether before or after termination of this Agreement, shall be settled by binding arbitration by submitting the same for arbitration pursuant to the rules of the International Chamber of Commerce (the “**ICC**”), and shall be finally settled under the Arbitration Rules of the ICC. The arbitration shall be conducted before a panel of three arbitrators. The complainant and the respondent to such dispute shall each select one arbitrator within thirty (30) days after giving or receiving the demand for arbitration. Such arbitrators shall be freely selected, and the parties shall not be limited in their selection to any prescribed list. Such two arbitrators shall select the third arbitrator. If either party to the arbitration does not appoint an arbitrator who has consented to participate within thirty (30) days after selection of the first arbitrator, the relevant appointment shall be made in accordance with the rules of the ICC. The place and location of the arbitration shall be London, England. The language to be used in the arbitral proceeding shall be English. The arbitrators shall be bound to the strict interpretation and observation of the terms of this Agreement and shall be specifically empowered to grant injunctions and to allocate between the parties the costs of arbitration, as well as reasonable attorneys’ fees and costs, in such equitable manner as the arbitrator may determine. The arbitration tribunal shall apply the Arbitration Rules of the ICC in effect at the time of the arbitration. However, if such rules are in conflict with the provisions of this Section 11.3, including the provisions concerning the appointment of arbitrators, the provisions of this Section 11.3 shall prevail. The arbitrators shall decide any dispute submitted by the parties to the arbitration strictly in accordance with the substantive law of England and Wales and shall not apply any other substantive law. Each party hereto shall cooperate with any party to the dispute in making full disclosure of and providing complete access to all information and documents requested by such party in connection with such arbitration proceedings, subject only to any confidentiality obligations binding on the party receiving the request. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based upon such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Notwithstanding any of the foregoing, either party shall have the right, without waiving any right or remedy available to such party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such party.

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- 11.4 Injunctive Relief.** No provision herein shall be construed as precluding a Party from bringing an action for injunctive relief or other equitable relief prior to the initiation or completion of the above procedure.

ARTICLE 12 - MISCELLANEOUS

- 12.1 Relationship of the Parties.** Nothing in this Agreement is intended or shall be deemed, for financial, tax, legal or other purposes, to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties.
- 12.2 Assignment.**
- (a) Either Party may assign this Agreement, in whole or in part, to any Affiliate or Third Party with prior written consent of the other Party. For clarity, a Sale is not deemed an assignment in the meaning of this Section 12.2(a).
 - (b) No assignment under this Section 12.2 shall relieve the assigning Party of any of its responsibilities or obligations hereunder and provided, further, that as a condition of such assignment, the assignee shall agree to be bound by all obligations of the assigning Party hereunder.
 - (c) This Agreement shall be binding upon the successors and permitted assigns of the Parties.
 - (d) Any assignment not in accordance with this Section 12.2 shall be null and void.
- 12.3 Further Actions.** 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.

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- 12.4 Accounting Procedures.** SONNET shall calculate all amounts hereunder and perform other accounting procedures required hereunder and applicable to it in accordance with either, as applicable (a) United States generally accepted accounting principles (US GAAP) or (b) International Financial Reporting Standard (IFRS), whichever is normally used by SONNET to calculate its financial position, and in each case consistently applied by such Party. ALKEM shall calculate all amounts hereunder and perform other accounting procedures required hereunder and applicable to it in accordance with applicable local laws in the Exclusive Territory.
- 12.5 Force Majeure.** Neither Party shall be liable to the other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes fire, flood, pandemic, or any other reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and will use Commercially Reasonable Efforts to overcome the difficulties created thereby and will resume performance of its obligations hereunder as soon as practicable. If the force majeure event continues for more than six (6) months, either Party may terminate this Agreement by giving thirty (30) days prior written notice to the other Party. In the event of termination of the Agreement pursuant to this clause 12.5, consequences of termination as specified in clause 10.5(I)(2) or 10.5(II)(2) above, as the case may be, shall apply.
- 12.6 No Trademark Rights.** No right, express or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name or trademark of the other Party in connection with the performance of this Agreement or otherwise.
- 12.7 No Sale for Resale.** SONNET shall make all reasonable best efforts to prevent the sale or distribution of the Product by any entity other than ALKEM inside the Exclusive Territory and shall not knowingly sell Product to anyone outside the Exclusive Territory for sale inside the Exclusive Territory. Neither ALKEM nor any Sublicensee of ALKEM will knowingly sell, market, promote, distribute, or license rights to any Compound or Product to any entity outside the Exclusive Territory or in the Exclusive Territory for subsequent distribution or resale outside the Exclusive Territory, and ALKEM will take all reasonable precautions to prevent such license, distribution or resale outside the Exclusive Territory.
- 12.8 Conflicting Rights.** Neither Party will grant any right to any third party which would violate the terms of or conflict with the rights granted by such party to the other party pursuant to this Agreement.

12.9 Entire Agreement of the Parties; Amendments. This Agreement and the Schedules and Exhibits hereto constitute and contain the entire understanding and agreement of the Parties with respect to the subject matter hereof and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter except that the Mutual Confidentiality Agreement between the Parties dated January 16, 2023 shall remain in full force and effect. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

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12.10 Captions. The captions to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement.

12.11 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of England and Wales, excluding application of any conflict of laws principles that would require application of the Laws of a jurisdiction outside of the United Kingdom. Each Party irrevocably consent to the jurisdiction of London, United Kingdom.

12.12 Notices and Deliveries. Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by facsimile (receipt verified) or by express courier service (signature required) to the Party to which it is directed at its address or facsimile number shown below or such other address or facsimile number or electronic mail as such Party shall have last given by notice to the other Party.

If to SONNET, addressed to: Pankaj Mohan, Ph.D.
CEO and Founder
100 Overlook Center, Suite 102
Princeton, New Jersey 08540
Email ID:

If to ALKEM, addressed to: Akhilesh Sharma, M.D.
President & Chief Medical Officer
Alkem House, Senapati
Bapat Road, Lower Parel,
Mumbai - 400013
Email ID:

12.13 Waiver. A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

12.14 Severability. When 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. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

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12.15 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile copy of this Agreement, including the signature pages, will be deemed an original.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed and delivered in duplicate by their duly authorized representatives with legal and binding effect as of the date first above written.

ALKEM LABORATORIES LTD

By: /s/ Akhilesh Sharma, M.D.

Its: Akhilesh Sharma, M.D.
President and Chief Medical Officer

Date: October 8, 2024

SONNET BIOTHERAPEUTICS, INC.

By: /s/ Pankaj Mohan, Ph.D.

Its: Pankaj Mohan, Ph.D.
Chief Executive Officer & Founder

Date: October 8, 2024

SONNET BIOTHERAPEUTICS CH SA

By: /s/ Pankaj Mohan, Ph.D.

Its: Pankaj Mohan, Ph.D.
Chairman of the Board of Directors

Date: October 8, 2024

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SCHEDULE 1.11

AMINO ACID SEQUENCE OF INTERLEUKIN-6

[***]

SCHEDULE 1.17

EXISTING THIRD PARTY AGREEMENTS

[***]

SCHEDULE 1.47

ISSUED PATENTS

[***]

PROVISIONAL PATENTS

[***]

SCHEDULE 3.3

IL6 PRODUCT DEVELOPMENT TIMELINE

[***]



Sonnet BioTherapeutics Inc. Enters into Licensing Agreement with Alkem Laboratories Limited to Develop and Commercialize SON-080 for Diabetic Peripheral Neuropathy (DPN) in India

Sonnet to receive \$1.0 million in upfront payment and up to an additional \$1.0 million in milestone payments with a royalty in the low double digits on net sales, less certain expenses, in the India market

Alkem to fund, develop and commercialize SON-080 for the treatment of DPN in India and commercialize SON-080 for the treatment of Chemotherapy Induced Neuropathy (CIPN) and Autonomic Neuropathy in India

The estimated market size of diabetic neuropathy in India was \$120.3 million in 2023 and is expected to reach \$246.7 million by 2030

Sonnet recently announced data from the completed Phase 1b portion of its ongoing Phase 1b/2a clinical trial evaluating SON-080 for CIPN

Pankaj Mohan, CEO of Sonnet discusses what this transaction means in a Virtual Investor "What This Means" segment; access here

PRINCETON, NJ / Globe Newswire / October 9, 2024/ Sonnet BioTherapeutics Holdings, Inc. (the "Company" or "Sonnet") (NASDAQ: SONN), a clinical-stage company developing targeted immunotherapeutic drugs, today announced that it has entered into a licensing agreement (the "Licensing Agreement") with Alkem Laboratories Limited ("Alkem") for the research, development, manufacturing, marketing and commercialization of its molecule SON-080 for the treatment of diabetic peripheral neuropathy (DPN) in India and the manufacturing, marketing and commercialization of chemotherapy induced neuropathy (CIPN) and autonomic neuropathy in India. SON-080 has the same mechanism of action for these three neuropathies. Additionally, the Company announced the release of a "What This Means" segment to discuss the transaction which is now available here.

SON-080 is Sonnet's proprietary version of recombinant human Interleukin-6 (rhIL-6) that builds upon previous work with atexakin alfa. Under the terms of the Licensing Agreement, Alkem will pay Sonnet \$1.0 million in upfront payments and up to an additional \$1.0 million in milestone payments as set forth in the Licensing Agreement. Additionally, Sonnet is entitled to receive a royalty equal to a percentage in the low double digits of the net sales of the product upon commercialization of SON-080 in India less certain expenses as set forth in the Licensing Agreement. Alkem will conduct all clinical trials it believes appropriate to obtain regulatory approval in India for SON-080 for the treatment of DPN. Upon payment of a Clinical Data Access fee for Phase 2 and Phase 3 clinical trials, Sonnet will be able to use this data for partnering in any geography outside of India.

Pankaj Mohan, Founder and Chief Executive Officer of Sonnet, commented, "We are excited to partner with Alkem and look forward to advancing SON-080 into Phase 2 clinical development. We believe that Alkem is the ideal partner with significant experience and expertise. Additionally, the data generated from Alkem's planned Phase 2 study will enable us to establish additional partnerships in other key markets for a clinical data access fee and potentially provide patients with DPN a much-needed therapeutic option. We believe DPN represents a significant unmet medical need, with a global market projected to reach approximately \$6.8 billion by 2030."

Dr. Akhilesh Sharma, President and Chief Medical Officer of Alkem added, "We are very pleased to partner with Sonnet for this important program. We believe SON-080 is a unique asset that has demonstrated promising disease modification potential for DPN a high unmet medical need. There is a large prevalence of DPN in India, which we believe underscores the need for its development in this territory and potential value."

DPN is a painful and extremely disabling disease that typically occurs in about 50% of diabetic patients. Current therapeutics focus primarily on pain symptoms due to lack of modulation treatments, however, such treatments do not address the non-pain symptoms resulting from nerve degeneration. Low dose IL-6 has been shown to stimulate peripheral nerve growth in preclinical models, thereby ameliorating motor and sensory functions and normalizing the associated pain or sensation disturbance of neuropathy.

SON-080 has undergone many years of development, in which previous clinical trials have generated safety data from over 200 patients. SON-080 has demonstrated compelling preclinical efficacy data in both DPN and CIPN, including reproducibly demonstrating the ability to prevent the development of neuropathy and reverse established neuropathy when assessed by nerve conduction, histological integrity and sensorimotor function measurements.

The Company recently announced encouraging data from the completed Phase 1b portion of its ongoing Phase 1b/2a clinical trial evaluating SON-080 for the treatment of CIPN (the "SB211 study"). The data demonstrated SON-080 to be well-tolerated at both doses, with no evidence of a pro-inflammatory cytokine response. Pain and quality of life survey results suggest the potential for rapid improvement of peripheral neuropathy symptoms and post-dosing durability with both doses, compared to placebo controls. For more information about the SB211 study, visit clinicaltrials.gov and reference identifier NCT05435742.

About Alkem Laboratories Limited:

Alkem Laboratories Limited is a leading Indian pharmaceutical company with a legacy of 50 years in providing high quality medicines to patients. It is the fifth largest pharmaceutical company in the Indian market with a dominant position in the therapy areas of anti-infectives, gastrointestinal, pain management drugs and supplements. It also has a growing portfolio of products in chronic therapies such as diabetes, neurology, cardiology, dermatology and urology. It has 19 state-of-the-art manufacturing facilities and cutting-edge research and development (R&D) centers across India and the US to develop and manufacture generic formulations, active pharmaceutical ingredients (APIs) and biosimilars. Apart from India, the company has meaningful presence in the US, Latin America, Australia and several Asian countries. "Inspiring Healthier Lives" is at the core of the values and culture of the organisation and reinforces its steadfast commitment to global health improvement. For more information, please visit www.alkemlabs.com and follow us on [LinkedIn](#), [X](#), [Facebook](#), [Instagram](#).

About Sonnet BioTherapeutics Holdings, Inc.

Sonnet is an oncology-focused biotechnology company with a proprietary platform for developing targeted biologic drugs with single or bifunctional action. Known as F_HAB (Fully Human Albumin Binding), the technology utilizes a fully human single chain antibody fragment (scFv) that binds to and "hitch-hikes" on human serum albumin (HSA) for transport to target tissues. Sonnet's F_HAB was designed to specifically target tumor and lymphatic tissue, with an improved therapeutic window for optimizing the safety and efficacy of immune modulating biologic drugs. F_HAB platform is the foundation of a modular, plug-and-play construct for potentiating a range of large molecule therapeutic classes, including cytokines, peptides, antibodies and vaccines.

Sonnet's lead program, SON-1010, or IL-12-F_HAB, is in development for the treatment of solid tumors and ovarian cancer. SON-1010 is being evaluated in an ongoing Phase 1/2a study through a Material Supply Agreement with Roche in combination with atezolizumab (Tecentriq[®]) for the treatment of Platinum-Resistant Ovarian Cancer (PROC). The Company is also evaluating its second program, SON-1210, an IL12-F_HAB-IL15 for solid tumors, in collaboration with the Sarcoma Oncology Center to commence an investigator-initiated and funded Phase 1/2a study for the treatment of Pancreatic Cancer.

The Company's SON-080 program is a low dose of rhIL-6 in development for CIPN and DPN. SON-080 demonstrated encouraging results in a Phase 1b/2a clinical trial, being well tolerated with no evidence of a pro-inflammatory cytokine response. Sonnet is currently seeking partnership opportunities to support a Phase 2 trial.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Licensing Agreement, the Company's cash runway, the Company's product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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