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) August 27, 2021



BRICKELL BIOTECH, INC.

(Exact name of Registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation)

Instruction A.2. below):

000-21088 (Commission File Number) 93-0948554 (IRS Employer Identification No.)

5777 Central Avenue
Suite 102
Boulder, CO 80301
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (720) 505-4755

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 (see General

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, par value \$0.01 per share	BBI	The Nasdaq Stock Market LLC		
ndicate by check mark whether the registrant is an emerging grow Exchange Act of 1934 (§240.12b-2 of this chapter).	th company as defined in Rule 405 of the Securities Act of 193	3 (§230.405 of this chapter) or Rule 12b-2 of the Securities		
Emerging growth company \square f an emerging growth company, indicate by check mark if the accounting standards provided pursuant to Section 13(a) of the		eriod for complying with any new or revised financial		

Item 1.01. Entry into Material Definitive Agreement.

License and Development Agreement

On August 27, 2021 (the "Effective Date"), Brickell Biotech, Inc. (the "Company") entered into a License and Development Agreement (the "License Agreement") with Voronoi Inc. ("Voronoi"), pursuant to which the Company acquired exclusive, worldwide rights to research, develop and commercialize novel therapeutics generated from a proprietary DYRK1A inhibitor platform. In accordance with the terms of the License Agreement, in exchange for the license rights, within 30 days following the Effective Date, the Company will make a one-time payment of \$2.5 million in cash and issue 2,816,901 shares of its common stock (the "Shares") to Voronoi, which number of Shares was based on a price of \$0.89 per share, representing a premium of 35% to the 10-day trailing volume-weighted average trading price of the Company's common stock.

With respect to the first-generation compounds arising from the DYRK1A inhibitor platform, the License Agreement provides that the Company will make payments to Voronoi of up to \$211.0 million in the aggregate contingent upon achievement of specified development, regulatory and commercial milestones. With respect to the second-generation compounds arising from the DYRK1A inhibitor platform, the Company will make payments to Voronoi of up to \$107.5 million in the aggregate contingent upon achievement of specified development, regulatory and commercial milestones. Further, the License Agreement provides that the Company will pay Voronoi tiered royalty payments ranging from low single digits up to 10% of net sales of products arising from the DYRK1A inhibitor platform. All of the contingent payments and royalties are payable in cash except for \$1,000,000 of the development and regulatory milestone payments, which amount is payable in Company common stock.

Under the terms of the License Agreement, the Company will be responsible for, and bear the future costs of, worldwide development and commercialization of all the licensed compounds.

The foregoing summary of the License Agreement is qualified in its entirety by the full text of the License Agreement, a copy of which is attached hereto as Exhibit 10.1 and incorporated herein by reference.

Item 2.01. Completion of Acquisition or Disposition of Assets.

The information contained above in Item 1.01 is hereby incorporated by reference into this Item 2.01.

Item 3.02. Unregistered Sales of Equity Securities.

The information contained above in Item 1.01 related to the Common Stock is hereby incorporated by reference into this Item 3.02.

This issuance by the Company of the Shares is exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), under Section 4(a)(2) of the Securities Act and Regulation D thereunder. Voronoi has represented to the Company that it is an "accredited investor" as defined in the Securities Act and that the Shares are being acquired for investment purposes and not with a view to resale or distribution.

Item 7.01. Regulation FD.

On September 1, 2021, the Company issued a press release announcing the aforementioned transactions with Voronoi. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 7.01 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

- 10.1* <u>License and Development Agreement, dated as of August 27, 2021, by and between Voronoi Inc. and Brickell Biotech, Inc.</u>
- 99.1 Press release issued by Brickell Biotech, Inc. on September 1, 2021
- 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

^{*}Certain confidential information contained in this agreement has been omitted because it is both not material and is the type that the registrant treats as private or confidential.

SIGNATURES

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

Date: September 1, 2021 Brickell Biotech, Inc.

By: /s/ Robert B. Brown

Name: Robert B. Brown
Title: Chief Executive Officer

Exhibit 10.1
CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL
LICENSE AND DEVELOPMENT AGREEMENT
by and between
VORONOI INC.
and
BRICKELL BIOTECH, INC.

LICENSE AND DEVELOPMENT AGREEMENT

This **LICENSE AND DEVELOPMENT AGREEMENT** (the "<u>Agreement</u>") is entered into as of August 27, 2021 (the "<u>Effective Date</u>") by and between **VORONOI INC.**, a limited liability corporation organized under the laws of the Republic of Korea having a principal place of business at S 18thF, Songdogwahak-ro 32[IT Center], Yeonsu-gu, Incheon, Korea (including any Affiliates and successor entities) ("<u>Licensor</u>") and **BRICKELL BIOTECH, INC.**, a Delaware corporation having a principal place of business at 5777 Central Avenue, Boulder, Colorado, USA 80301 (including any Affiliates and successor entities) ("<u>Licensee</u>"). Licensor and Licensee are sometimes referred to individually as a "<u>Party</u>" and collectively as the "<u>Parties</u>".

RECITALS

WHEREAS, Licensor has rights to the dual specificity tyrosine-phosphorylation-regulated kinase 1A (DYRK1A) inhibitor known as VRN024219, which Licensor is developing for autoimmune and other potential indications, and to other DYRK1A inhibitors that are potentially suitable for [***];

WHEREAS, Licensee possesses resources and expertise in the global development, manufacture, marketing and commercialization of pharmaceutical products; and

WHEREAS, the Parties desire to enter into an exclusive license relating to VRN024219 and other DYRK1A inhibitors, all as set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

"1933 Act" has the meaning set forth in Section 10.2(r).

"1934 Act" has the meaning set forth in Section 10.1(h).

"Acquiror" has the meaning set forth in Section 15.5.

"Affiliate" means, with respect to either Party, any person, firm, trust, corporation, subsidiary, limited liability entity, partnership or other entity or combination thereof that directly or indirectly controls, is controlled by or is under common control with such Party; and for purposes of this definition, the term "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means direct or indirect ownership of fifty percent (50%) or more of the voting and equity rights of such person, firm, trust, corporation, subsidiary, limited liability entity, partnership or other entity or combination thereof, or the power to direct the management of such person, firm, trust, corporation, partnership or other entity or combination thereof. This definition applies to entities created under any country's laws.

"Agreement" has the meaning set forth in the Preamble.

"Application for Drug Approval" means, with respect to a Product, (i) in the United States, an NDA, and (ii) in any country or regulatory jurisdiction other than the United States, an application or set of applications for Drug Approval comparable to an NDA.

"Bankruptcy Code" means, as applicable, the U.S. Bankruptcy Code, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder or the bankruptcy laws of any Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder or any applicable bankruptcy laws of any other country or Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder.

"Breaching Party" has the meaning set forth in Section 13.2.

"Business Day" means any day other than a day on which the commercial banks in New York, New York, USA are authorized or required to be closed.

"Calendar Quarter" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term commences on the Effective Date and ends on the first to occur of March 31, June 30, September 30 and December 31 after the Effective Date, and the last Calendar Quarter ends on the last day of the Term.

"Calendar Year" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term commences on the Effective Date and ends on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term commences on January 1 of the year in which the Term ends and ends on the last day of the Term.

"Change of Control" means, with respect to either Party, (a) the sale of all or substantially all of such Party's assets or business relating to this Agreement; (b) a merger (including a reverse triangular merger), consolidation, share exchange or other similar transaction involving such Party and any Third Party which results in the holders of the outstanding voting securities of such Party, or any Affiliate that controls such Party directly or indirectly, immediately before such merger, consolidation, share exchange or other similar transaction ceasing to hold more than fifty percent (50%) of the combined voting power of the surviving, purchasing or continuing entity immediately after such merger, consolidation, share exchange or other similar transaction, or (c) the acquisition by a person or entity, or group of persons or entities acting in concert, of more than fifty percent (50%) of the outstanding voting equity securities of such Party; in all cases of clauses (a)–(c), where such transaction is to be entered into with any person or group of persons other than the other Party or its Affiliates.

"Claims" has the meaning set forth in Section 11.1.

"Clinical Study" means a research study using human subjects to evaluate biomedical or health-related outcomes, including a Phase 1 Study, a Phase 2 Study, a Phase 3 Study, a

phase 4 study or post-approval study, an observational study, or variations of such studies (e.g., Phase 2/3).

"CMC Information" means Information related to the chemistry, manufacturing and controls of a product, as specified by the FDA, EMA and other applicable Regulatory Authorities.

"Combination Product" has the meaning set forth in the definition of Net Sales.

"Commercial Sublicense Agreement" means, with respect to any Product, an agreement pursuant to which Licensee grants to a Third Party a sublicense under the Series A License or Series B License, as applicable, that includes the right to Commercialize such Product in the Field in the Territory, but excluding any agreement that merely grants such Third Party the right to distribute such Product or to perform services with respect to such Product.

"Commercialization", with a correlative meaning for "Commercialize" and "Commercializing", means any and all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the commercialization and pre-launch, launch, promotion, detailing, labeling, bidding and listing, marketing, pricing, reimbursement, sale, selling, having sold, importing, having imported, exporting, having exported, distributing, having distributed, supply and distribution (including storage and handling) of Product, including strategic marketing, sales force detailing, advertising, and market and Product support, and all customer service and support, Product distribution, invoicing, conducting medical affairs, conducting post-marketing safety surveillance and reporting and sales activities.

"Commercially Reasonable Efforts" means, with respect to a Party's obligations or tasks under this Agreement with respect to the performance of any activities by a Party hereunder, the level of efforts and resources that a company within the pharmaceutical industry and similarly situated to such Party would reasonably devote to the Development and Commercialization of a comparable product of similar market potential or profit potential for the affected country or region resulting from its own research efforts, taking into account efficacy, safety, tolerability, patent and regulatory exclusivity, anticipated or approved labeling or laws, present and future market potential, competitive market conditions (including Generic Product and competitive or comparable product market penetration), the profitability of a Product in light of pricing and reimbursement and other considerations, including rebates or coupons under risk-sharing schemes, chargebacks, discounts of any type, loyalty programs, free samples, reference pricing, parallel pricing, cost of goods, supply chain dynamics, availability of partners and qualified personnel, and all other relevant scientific, technical, financial, marketing and commercial factors. Commercially Reasonable Efforts shall be determined by country-by-country basis and may include, but not be limited to, activities that support partnering or sublicensing arrangements, or the like, in certain countries where in Licensee's opinion it is more attractive or reasonable not to have a direct presence, or where applicable Law would not allow a direct presence or presence without a local partner.

"Competitive Product" means any compound or product whose intended mechanism of action is to [***] and that [***] thereto and [***]. Notwithstanding the foregoing, any compound or product [***] will be deemed a Competitive Product.

"Compound" means any Series A Compound or Series B Compound.

"Confidential Information" of a Party means any and all Information that is disclosed by or on behalf of such Party or its Affiliates to the other Party or its Affiliates under this Agreement, whether in oral, written, tangible, graphic, or electronic or other form(s), that can reasonably be expected by a Party to be treated as confidential and proprietary of the other Party or its Affiliates.

"Control" (including any variations such as "Controlled" and "Controlling") means, with respect to any material, Information, or intellectual property right, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement), right or covenant to such material, Information, or intellectual property right, and in each case, has the ability to grant to the other Party access, a license or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party (including the Principal Licensor).

"Cover" means, with respect to a Patent, a Compound, and a Product, that the manufacture, use, offer for sale, sale, export or import of such Compound or Product by an unlicensed Third Party would infringe a Valid Claim in such Patent; provided, however, that in determining whether a Valid Claim of a pending Patent application would be infringed, it shall be treated as if issued in the form then currently being prosecuted. "Cover" further refers to a Compound, Product or use or synthesis thereof that is specifically disclosed or encompassed by one or more genera or subgenera disclosed in a Licensor Patent, whether or not claimed. "Covered" and "Covering" shall have the correlative meanings.

"Cure Period" has the meaning set forth in Section 13.2.

"<u>Default Notice</u>" has the meaning set forth in <u>Section 13.2</u>.

"Develop" or "Development" means any and all activities relating to preparing and conducting non-Clinical Studies including nonclinical development, toxicology, pharmacology, statistical analysis, Clinical Studies, regulatory affairs, and regulatory activities (e.g., preparation of regulatory applications, responding to or interacting with regulators) that are necessary or useful to obtain and maintain Drug Approval of a Product (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).

"<u>Development Plan</u>" means a written plan that specifies the Development activities to be conducted in order to, at minimum, fulfill Licensee's diligence obligations under <u>Section 4.1</u>.

"Development/Regulatory Milestones" has the meaning set forth in Section 8.2(a).

"Dispute" has the meaning set forth in Section 14.1.

"Dollars" or "\$" means U.S. dollars.

"<u>Drug Approval</u>" means an approval granted by the appropriate Regulatory Authority to market a Product in the Field in any particular jurisdiction in the Territory, excluding any required Pricing and Reimbursement Approval.

"Effective Date" has the meaning set forth in the Preamble.

"EMA" means the European Medicines Agency or any successor entity.

"EU" means the European Union member states, as constituted on the Effective Date and as it may be expanded or contracted from time to time following such date.

"FD&C Act" means the U.S. Federal Food, Drug, and Cosmetic Act, as amended.

"FDA" means the U.S. Food and Drug Administration or any successor entity.

"Field" means all uses (including any and all uses for the diagnosis, prevention, control, amelioration, and treatment of any disease, disorder or medical condition in humans).

"First Commercial Sale" means, with respect to a particular product in a given country or regulatory jurisdiction, the first commercial transfer or disposition for monetary value for use or consumption by the end user of such product to a Third Party in a given country or regulatory jurisdiction after Drug Approval has been obtained in such jurisdiction. Sales of any type or form [***] shall not be construed as a "First Commercial Sale".

"GAAP" means U.S. generally accepted accounting principles, consistently applied.

"Good Clinical Practice" or "GCP" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority applicable to the Territory in which a Product is intended to be sold to the extent such standards are not less stringent than U.S. Good Clinical Practice, as such standards, practices and procedures may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"Generic Product" means, with respect to a Product (the "Reference Product"), any pharmaceutical product in a particular regulatory jurisdiction that (a) contains the same active pharmaceutical ingredient(s) as the Reference Product and has one or more Regulatory Authority-approved Indications in such jurisdiction equivalent to any of the Regulatory Authority-approved Indications for the Reference Product in such jurisdiction; and (b) is sold in such jurisdiction by a Third Party that is not a Sublicensee of Licensee or its Affiliates, and is not otherwise authorized by Licensee or any of its Affiliates, Sublicensees or distributors to sell such product.

"Good Laboratory Practice" or "GLP" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by the EMA or other Regulatory Authority applicable to the Territory in which a Product is intended to be sold to the extent such standards are not less stringent than U.S. Good Laboratory Practice, as such standards may be

updated from time to time, including applicable quality guidelines promulgated under the ICH.

"GMP" means the standards relating to current Good Manufacturing Practices for fine chemicals, active pharmaceutical ingredients, intermediates, bulk products or finished pharmaceutical products set forth in (i) 21 U.S.C. 351(a)(2)(B), in FDA regulations at 21 C.F.R. Parts 210 and 211, (ii) The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products, or (iii) the principles detailed in the ICH Guidelines relating to the manufacture of active pharmaceutical ingredient and finished pharmaceuticals, and (iv) the equivalent applicable law in any relevant country, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"Governmental Authority" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

"HSR Act" means the U.S. Hart-Scott-Rodino Antitrust Improvements Act of 1976.

"ICH" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"ICH Guidelines" means the guidelines of the ICH.

"IND" means an Investigational New Drug Application with the FDA, as defined in the FD&C Act, or any equivalent Regulatory Materials in a country other than the U.S. for use within the Field.

"Indemnified Party" has the meaning set forth in Section 11.3.

"Indemnifying Party" has the meaning set forth in Section 11.3.

"Indication" means any disease, disorder or condition that can be prevented, diagnosed or treated, or is otherwise approved in labeling for a pharmaceutical product by an applicable Regulatory Authority, in any area within the Field.

"Information" means all data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, discoveries, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing or other reports, strategic, business and operational plans, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test or study data and data resulting from non-Clinical Studies), CMC Information, Regulatory Materials, stability data, manufacturing data and other study data and procedures.

"Inventions" means all ideas, discoveries, inventions, modifications, improvements, enhancements or new uses, whether or not patentable, and whether or not reduced to practice, discovered, made, or conceived in the course of activities contemplated by this Agreement.

- "JAMS Rules" has the meaning set forth in Section 14.1.
- "Joint Inventions" has the meaning set forth in Section 9.1(a).
- "Korea FDA" shall mean the Ministry of Food and Drug Safety (MFDS), formerly known as the Korea Food & Drug Administration or KFDA.
 - "[***]" has the meaning set forth in Section 3.2(a).
- "Law" means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.
 - "Licensee" has the meaning set forth in the Preamble.
 - "Licensee Indemnitees" has the meaning set forth in Section 11.1.
 - "Licensee Inventions" has the meaning set forth in Section 9.1(a).
- "<u>Licensee Know-How</u>" means all Information that (a) is necessary or useful for the Development, manufacture or Commercialization of any Compound or Product in the Field and (b) is Controlled by Licensee or its Affiliates during the Term; *provided*, the use of "Affiliate" in this definition excludes any Third Party that becomes an Affiliate of Licensee after the Effective Date due to a Change of Control of Licensee, except to the extent such Third Party's Information is Controlled by Licensee (or its Acquiror) or any of its other Affiliates and is necessary for the Development, manufacture or Commercialization of any Compound or Product in the Field.
- "Licensee Patent" means any Patent (other than a Licensor Patent) that (a) Covers, generically or specifically, any Compound or Product, or the manufacture or use in the Field of any Compound or Product, and (b) which is Controlled by Licensee or its Affiliates during the Term; provided, the use of "Affiliate" in this definition excludes any Third Party that becomes an Affiliate of Licensee after the Effective Date due to a Change of Control of Licensee, except to the extent such Third Party's Information is Controlled by Licensee (or its Acquiror) or any of its other Affiliates and is necessary for the Development, manufacture or Commercialization of any Compound or Product in the Field.
 - "Licensee Prosecuted Patents" has the meaning set forth in Section 9.3(a).
 - "Licensee Technology" means the Licensee Know-How and Licensee Patents.
 - "Licensor" has the meaning set forth in the Preamble.
 - "Licensor Indemnitees" has the meaning set forth in Section 11.2.
 - "Licensor Inventions" has the meaning set forth in Section 9.1(a).
 - "Licensor Know-How" means the Licensor Series A Know-How and the Licensor Series B Know-How.

"Licensor Patent" means any Licensor Series A Patent or Licensor Series B Patent.

"<u>Licensor Series A Know-How</u>" means all Information that (a) is reasonably necessary or useful for the Development, manufacture or Commercialization of any Series A Compound or Series A Product in the Field and (b) (i) is Controlled by Licensor or its Affiliates as of the Effective Date or (ii) is Controlled by Licensor or its Affiliates during the Term (including, for the avoidance of doubt, Licensor Inventions to the extent applicable); *provided*, the use of "Affiliate" in this definition excludes [***].

"<u>Licensor Series A Patent</u>" means any Patent (other than a Licensee Patent) that (a) Covers, generically or specifically, any Series A Compound or Series A Product, or the manufacture or use in the Field of any Series A Compound or Series A Product and (b) (i) is Controlled by Licensor or its Affiliates as of the Effective Date, which such Patents are set forth in <u>Exhibit A</u> hereto, (ii) is Controlled by Licensor or its Affiliates during the Term and claims priority to a Patent Controlled by Licensor or its Affiliates as of the Effective Date, or (iii) is Controlled by Licensor or its Affiliates during the Term; *provided*, that the use of "Affiliate" in this definition excludes [***].

"<u>Licensor Series A Technology</u>" means the Licensor Series A Know-How and the Licensor Series A Patents. Notwithstanding anything to the contrary herein, Licensor Series A Technology shall not be deemed to include [***] Platform.

"<u>Licensor Series B Know-How</u>" means all Information that (a) is necessary or useful for the Development, manufacture or Commercialization of any Series B Compound or Series B Product in the Field and (b) (i) is Controlled by Licensor or its Affiliates as of the Effective Date or (ii) is Controlled by Licensor or its Affiliates during the Term (including, for the avoidance of doubt, Licensor Inventions to the extent applicable); *provided*, the use of "Affiliate" in this definition excludes [***].

"<u>Licensor Series B Patent</u>" means any Patent (other than a Licensee Patent) that (a) Covers, generically or specifically, any Series B Compound or Series B Product, or the manufacture or use in the Field of any Series B Compound or Series B Product and (b) (i) is Controlled by Licensor or its Affiliates as of the Effective Date, which such Patents are set forth in <u>Exhibit B.1</u> hereto, (ii) is Controlled by Licensor or its Affiliates during the Term and claims priority to a Patent Controlled by Licensor or its Affiliates as of the Effective Date, or (iii) is Controlled by Licensor or its Affiliates during the Term; *provided*, that the use of "Affiliate" in this definition excludes [***].

"<u>Licensor Series B Technology</u>" means the Licensor Series B Know-How and the Licensor Series B Patents. Notwithstanding anything to the contrary herein, Licensor Series B Technology shall not be deemed to include [***] Platform.

"Licensor Technology" means the Licensor Series A Technology and the Licensor Series B Technology.

"Major Market Countries" means the following countries: [***].

"Milestone Shares" has the meaning set forth in Section 8.2(a).

"Milestones" means collectively the Development/Regulatory Milestones and the Net Sales Milestones.

"NDA" means a New Drug Application filed with the FDA pursuant to 21 U.S.C. Section 357 and 21 C.F.R. Section 314 or any successor regulatory scheme.

"Negotiation Period" has the meaning set forth in Section 3.2(a).

"Negotiation Right" has the meaning set forth in Section 3.2(a).

"Net Sales" means, with respect to any Product, the total amount invoiced by Licensee or its Affiliates or Sublicensees (each, a "Selling Party") to each Third Party receiving such Product in arm's length transactions, less the following deductions from such total amounts that are actually incurred each as calculated in accordance with GAAP:

- (a) [***];
- (b) [***];
- (c) [***]
- (d) [***]; and
- (e) [***];

provided that, in each case ((a) through (e)), (i) each such deduction is calculated in a manner consistent with the Selling Party's customary practice for pharmaceutical products and in accordance with GAAP, consistently applied by the Selling Party, (ii) each such deduction is [***], or apportioned on a good faith, fair and equitable basis to [***] such that [***] of such deductions, and (iii) no particular amount identified above shall be deducted [***] in calculating Net Sales (*i.e.*, no [***] deductions).

For avoidance of doubt, [***], in each case, shall not be included in Net Sales.

In the event that a Product is sold in a given country together with one or more other therapeutically active ingredients or therapies not constituting a Product for a single price (regardless of their packaging) (a "Combination Product"), such Product shall be deemed to be sold in such country for an amount equal to [***].

In the event of any sale or other disposition of Product for any consideration other than exclusively monetary consideration on *bona fide* arm's-length terms, then for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to have been sold [***].

For this definition:

- (x) the transfer of Product by a Selling Party to [***] or Sublicensees is not considered a sale;
- (y) the transfer of Product by a Selling Party to [***] is not considered a sale; and

(z) [***] is not a sale under this definition.

For clarity, there is [***]. [***] are permitted within customary limits. The amount of Product transferred pursuant to subsections (x), (y) and (z) of this definition is determined from the books and records of the Selling Party, maintained in accordance with GAAP.

"Net Sales Milestones" has the meaning set forth in Section 8.2(b).

"Non-Breaching Party" has the meaning set forth in Section 13.2.

"Non-Governmental Authority" means any public or private body (including the National Institute of Clinical Excellence and the Scottish Medicines Consortium in the United Kingdom; the Institute for Quality and Efficiency in Healthcare in Germany; the Technical Scientific Commission in Italy; the Directorate of Pharmacy and Healthcare Products in Spain; the National Union of Health Insurance Funds and the National Authority of Health in France; and Health Canada in Canada) or non-Governmental Authority (including "Sick Funds" in Germany) with the authority to control, approve, recommend or otherwise determine pricing and reimbursement or the like related to pharmaceutical products, including those with authority to enter into risk-sharing schemes or to impose retroactive price reductions, discounts, rebates, chargebacks, or the like.

"Paragraph IV Notice" has the meaning set forth in Section 9.4(f).

"Party" or "Parties" has the meaning set forth in the Preamble.

"Patents" means (a) pending patent applications, including all provisionals, non-provisionals, international patent applications filed under the Patent Cooperation Treaty (PCT) and any foreign equivalents to any of the foregoing, issued patents, utility models and designs anywhere in the world; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; (c) any other patent or patent application claiming priority to any of the foregoing anywhere in the world; and (d) extension, renewal or restoration of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

"Payee" has the meaning set forth in Section 8.6.

"Pharmaceutical Affairs Act," means the South Korean Pharmaceutical Affairs Act, Act No. 14328, December 2, 2016, and as further amended.

"Phase 1 Study" means a human clinical trial with the endpoint of determining initial tolerance, safety or pharmacokinetic information in single dose, single ascending dose, multiple dose or multiple ascending dose regimens, as described in 21 C.F.R. § 312.21(a) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

"Phase 2 Study" means a human clinical trial with the principal purpose being a determination of safety and efficacy in the target patient population over a range of doses and dose regimens, as described in 21 C.F.R. § 312.21(b) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

"Phase 2a Study" means a Phase 2 Study of a Product conducted by Licensee that is designed to support the continued testing of a Product in one or more further Phase 2 Studies by demonstrating clinical "proof of concept" in a target patient population with a particular Indication.

"Phase 2b Study" means a controlled Phase 2 Study of a Product conducted by Licensee that is designed to determine the optimal dose for administration in a Phase 3 Study.

"Phase 3 Study" means a human clinical trial of a compound or product for an Indication on a sufficient number of subjects that is designed to establish with statistical significance that such compound or product is safe and efficacious for its intended use, and to determine contraindications, warnings, precautions and adverse reactions that are associated with the compound or product in the dosage range to be prescribed, and to support regulatory approval of such compound or product for such Indication or label expansion of such compound or product, as described in 21 C.F.R. § 312.21(c) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S. Without limiting the foregoing, [***].

"Pricing and Reimbursement Approval" means (a) the governmental approval, agreement, determination or decision establishing prices or value for a Product that can be charged in regulatory jurisdictions where the applicable Governmental Authorities approve or determine the price of pharmaceutical products, and (b) the approval, agreement, determination or decision recommending or approving a Product for use or establishing the prices for a Product that can be reimbursed in regulatory jurisdictions where the applicable Governmental Authority or Non-Governmental Authority approves, determines or recommends the reimbursement or use of pharmaceutical products; *provided*, that in all cases [***].

"Principal License Agreement" means the Revised Technology Transfer Agreement, dated April 17, 2018, between the Principal Licensor and Licensor relating to the Licensor Series A Patents, as contained in its redacted form in Exhibit C.

"Principal Licensor" means, collectively, the [***], the joint licensors under the Principal License Agreement.

"Product" means any Series A Product or Series B Product.

"Program" means the Series A Program or the Series B Program.

"Prosecution and Maintenance" has the meaning set forth in Section 9.3(a).

"Reference Product" has the meaning set forth in the definition of Generic Product.

"Regulatory Approval" means (a) Drug Approval and all other approvals necessary for the commercial sale of a Product in a given country or regulatory jurisdiction; and (b) Pricing and Reimbursement Approval (but only in those countries or regulatory jurisdictions where Pricing and Reimbursement Approval is required by Law for commercial sale).

"Regulatory Approval OUS" means Regulatory Approval in any Major Market Country other than the U.S.

"Regulatory Authority" means, in a particular country or jurisdiction, any applicable Governmental Authority or Non-Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

"Regulatory Exclusivity" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or jurisdiction in the Territory, other than a Patent, that limits or prohibits a Person from (i) relying on pivotal safety or efficacy data generated with respect to a Product in an application for Regulatory Approval of a Generic Product or (ii) Commercializing a Generic Product, [***].

"Regulatory Materials" means regulatory applications, request, Information exchanges submissions, notifications, communications, correspondence, registrations, INDs, Drug Approvals or other filings made to, received from, or otherwise conducted with, a Regulatory Authority to research, Develop, manufacture, market, sell or otherwise Commercialize any Product in a particular country or jurisdiction.

"Royalty Term" has the meaning set forth in Section 8.3(b).

"SEC" has the meaning set forth in Section 12.4(d).

"SEC Filings" has the meaning set forth in Section 10.1(h).

"Section 365(n)" means Section 365(n) of the U.S. Bankruptcy Code or analogous provisions of the bankruptcy laws of any Governmental Authority.

"Selling Party" has the meaning set forth in the definition of Net Sales.

"Series A Compound" means (a) the compound known as VRN024219 that is an inhibitor of DYRK1A kinase activity, the chemical structure of which is set forth in Exhibit D, (b) any other compound of which the composition of matter is Covered by any Licensor Series A Patent, and (c) any metabolite or stereoisomer thereof, and any salt form, crystal form or prodrug of any of the foregoing.

"Series A License" has the meaning set forth in Section 2.1(a).

"Series A Product" means any pharmaceutical product preparation (including any and all forms, presentations, dosages, and formulations) for use for any and all Indications in the Field containing any Series A Compound, in any mode of administration, alone or in combination with any other active agent, including any new dosage strengths, presentations, formulations, methods of administration and line extensions developed by Licensor or Licensee pursuant to the terms of this Agreement.

"Series A Program" means the Development and Commercialization of one or more Series A Products.

"Series B Compound" means (a) any compound of which the composition of matter is Covered by any Licensor Series B Patent, and (b) any metabolite or stereoisomer thereof, and any salt form, crystal form or prodrug of any of the foregoing.

"Series B License" has the meaning set forth in Section 2.2(a).

"Series B Product" means any pharmaceutical product preparation (including any and all forms, presentations, dosages, and formulations) for use for any and all Indications in the Field containing any Series B Compound, in any mode of administration, alone or in combination with any other active agent, including any new dosage strengths, presentations, formulations, methods of administration and line extensions developed by Licensor or Licensee pursuant to the terms of this Agreement.

"Series B Program" means the Development and Commercialization of one or more Series B Products.

"Shares" has the meaning set forth in Section 8.2(a).

"[***] Consideration" means, with respect to any [***], all consideration received by Licensee and its Affiliates from the [***] that is reasonably allocable to the grant or exercise of the applicable [***], including [***].

"Sublicensed Rights" means the Patents, Information and other rights, if any, licensed by the Principal Licensor to Licensor pursuant to the Principal License Agreement and, in turn, sublicensed by Licensor to Licensee pursuant to this Agreement.

"Sublicensee" means any entity, other than an Affiliate of Licensee, to whom Licensee assigns, grants, conveys, licenses, or transfers any rights to research, Develop, Commercialize, manufacture or otherwise exploit a Product.

"Term" has the meaning set forth in Section 13.1.

"Territory" means all countries and territories in the world.

"Territory Infringement" has the meaning set forth in Section 9.4(a).

"Third Party" means any entity other than Licensor or Licensee or an Affiliate of either of them, or any contractor.

"Third Party Patent Claim" has the meaning set forth in Section 9.5.

"Upfront Shares" has the meaning set forth in Section 8.1(b).

"U.S." means the United States of America, including all possessions and territories thereof.

"<u>Valid Claim</u>" means a pending claim or claim of any issued and unexpired Patent whose validity, enforceability or patentability has not been affected by (a) irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer or (b) a holding, finding or decision of invalidity, unenforceability or non-patentability by a court, Governmental

Authority, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal (other than a petition to the United States Supreme Court for a writ of certiorari), *provided* that if any such pending claim does not issue within [***] years from its earliest priority date, such pending claim will cease to be a Valid Claim unless and until actually issued.

"[***] Platform" means [***], a description of which is set forth in Exhibit E.

"Wind-down Period" has the meaning set forth in Section 13.3(c)(vi).

ARTICLE 2

LICENSES GRANTS

2.1 <u>Series A License</u>.

- (a) Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive (even as to Licensor) royalty-bearing license, with the right to grant sublicenses as permitted herein, under the Licensor Series A Technology to research, Develop, make, have made, register, use, sell, offer for sale, import, export and otherwise Commercialize Series A Compounds and Series A Products in the Field in the Territory (the "Series A License"). [***].
- (b) Licensee may grant sublicenses under the Series A License through multiple tiers to any Affiliate or Third Party without the approval of Licensor or the Principal Licensor [***]; provided, that in all events (i) Licensee shall remain responsible for the performance of its Sublicensees hereunder and must not grant any rights that are inconsistent with the rights granted to and obligations of Licensee hereunder; and (ii) Licensee shall, upon Licensor's written request, provide Licensor with a copy of any sublicense agreement, which may be redacted by Licensee to protect confidential or proprietary information that is not required for Licensor to confirm amounts of [***], which copy shall be treated as Confidential Information of Licensee hereunder.
- (c) Licensee will not (and will not permit any of its Affiliates or Sublicensees to) use or practice any Licensor Series A Technology outside the scope of the Series A License.

2.2 <u>Series B License</u>.

(a) Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive (even as to Licensor) royalty-bearing license, with the right to grant sublicenses as permitted herein, under the Licensor Series B Technology to research, Develop, make, have made, register, use, sell, offer for sale, import, export and otherwise Commercialize Series B Compounds and Series B Products in the Field in the Territory (the "Series B License").

- (b) Licensee may grant sublicenses under the Series B License through multiple tiers to any Affiliate or Third Party without the approval of Licensor; *provided*, that in all events (i) Licensee shall remain responsible for the performance of its Sublicensees hereunder and must not grant any rights that are inconsistent with the rights granted to and obligations of Licensee hereunder; and (ii) Licensee shall, upon Licensor's written request, provide Licensor with a copy of any sublicense agreement, which may be redacted by Licensee to protect confidential or proprietary information that is not required for Licensor to confirm amounts of [***], which copy shall be treated as Confidential Information of Licensee hereunder.
- (c) Licensee will not (and will not permit any of its Affiliates or Sublicensees to) use or practice any Licensor Series B Technology outside the scope of the Series B License.
- 2.3. <u>No Implied Licenses</u>. Each Party acknowledges that the licenses granted under this Article 2 are limited to the scope expressly granted, and all other rights to Licensor's Know-How and/or Patent Rights are expressly reserved to Licensor. Without limiting the foregoing, it is understood that Licensor retains all of its rights to the Licensor Technology for all purposes not expressly licensed.

ARTICLE 3

EXCLUSIVITY; RIGHT OF NEGOTIATION

3.1 <u>Exclusivity</u>. Licensor and its Affiliates will not, directly or through any Third Party, other than pursuant to this Agreement, research, develop, register, manufacture, have manufactured, import, export, market, distribute or sell in the Territory any Competitive Product until the earliest of (i) the [***] anniversary of the Effective Date of this Agreement or (ii) the expiration or termination of this Agreement. For clarity, the provisions of this <u>Section 3.1</u> shall continue to apply with respect to those Products and those jurisdictions where this Agreement remains in effect in the event of a partial termination of this Agreement. Notwithstanding the foregoing, in the event of a Change of Control of Licensor, nothing in this <u>Section 3.1</u> shall be construed to limit or restrict the activities or operations of the Acquiror or its Affiliates (other than Licensor and the pre-acquisition Affiliates of Licensor).

3.2 Right of First Negotiation.

(a) Prior to Licensee negotiating a term sheet with any Third Party with respect to any grant of exclusive rights to develop or commercialize a Series A Product in a territory that would include [***], within [***] days after the availability of the final clinical study report containing the complete results and data for the [***] in an Indication, Licensee shall deliver to Licensor a copy of, or otherwise provide Licensor reasonable access to, such clinical study report. For a period of [***] days after receipt of such report, Licensor may elect, by delivery of written notice to Licensee, to exercise a right of first negotiation (the "Negotiation Right") to obtain exclusive Development and Commercialization rights to such Series A Product in such Indication in [***]. If Licensor timely exercises the Negotiation

Right, then (i) the Parties shall negotiate in good faith on an exclusive basis the grant of such rights to Licensor for a period of up to [***] days after such exercise (the "Negotiation Period") regarding the terms and conditions of the [***] (it being understood that neither Party shall have any obligation to enter into a definitive agreement with respect thereto), and (ii) Licensee shall use reasonable efforts during the Negotiation Period to answer questions from Licensor about such Series A Product in such Indication (it being understood that such reasonable efforts shall not require Licensee to perform any additional research or development activities). If Licensor fails to timely exercise its Negotiation Right or the Parties fail to enter into a definitive agreement for the [***] before expiration of the Negotiation Period, then Licensor shall have no further rights, and Licensee shall have no further obligations, under this Section 3.2.

(b) For clarity, the Negotiation Right shall apply only once, in connection with the [***], and not in connection with any subsequent [***] that Licensee may conduct, either with respect to the same Series A Product in a different Indication, a different Series A Product, or otherwise.

ARTICLE 4

PRODUCT DEVELOPMENT

- 4.1 <u>Overview; Diligence.</u> Subject to the terms and conditions of this Agreement, Licensee shall be solely responsible, at its sole cost and effort, for the Development of Product(s) in the Field in the Territory. Licensee shall use Commercially Reasonable Efforts to (a) [***]; and (b) [***].
- 4.2 <u>Development Plan</u>. Without expanding the obligations of Licensee set forth in <u>Section 4.1</u>, Licensee shall [***] pursuant to the Development Plan, an initial version of which, [***], shall be prepared by Licensee and provided to Licensor within [***] days after the Effective Date. From time to time during the Term, Licensee shall prepare updates and amendments, as appropriate, to the then-current Development Plan (including, at such time as Licensee determines to be appropriate, Development activities relating to [***]) and will provide a copy thereof to Licensor for its review and comment. Licensee shall be solely responsible for all decisions regarding the day-to-day Development of the Products.
- 4.3 <u>Development Reports.</u> On or before [***] of each Calendar Year, Licensee shall provide Licensor with a written report that summarizes, in reasonable detail, material Development activities performed during the preceding Calendar Year and anticipated to be performed in the current Calendar Year on any covered Compound or Product including any material interactions with Regulatory Authorities. In addition, upon written request of Licensor not more than [***] in any Calendar Year, Licensee shall provide Licensor a high-level update report on the foregoing Development activities. Licensee shall also promptly provide Licensor with any additional appropriate and relevant information reasonably requested by Licensor regarding the Development of any Product. All such reports and information shall be solely owned by, and deemed the Confidential Information of, Licensee.

- 4.4 <u>Data Exchange and Use</u>. Subject to the terms and conditions of this Agreement, Licensor will (a) promptly provide to Licensee all Information obtained or possessed by Licensor or any of its licensees or sublicensees related to the Compounds and/or Products and (b) cooperate in good faith to provide Licensee access to and reasonable assistance with all Licensor Technology and other Confidential Information as may be required for Licensee to exercise the rights and licenses granted to it, and to perform its obligations, under this Agreement.
- 4.5 <u>Compliance with Laws</u>. Licensee will conduct its activities under this Agreement in a good scientific manner and comply in all material respects with all applicable Laws, including applicable national and international guidelines such as ICH, GCP, GLP, current standards for pharmacovigilance practice, GMP and all applicable requirements relating to the protection of human subjects, in each case, to extent applicable to a given activity.

ARTICLE 5

REGULATORY MATTERS

5.1 Regulatory Responsibilities.

- (a) As between the Parties, Licensee will be solely responsible for all regulatory submissions and exchanges and will direct and control all regulatory activities with respect to Compounds and Products in the Territory, including responses and correspondence, safety reporting, negotiation, analysis, and strategy. Licensor will provide timely and appropriate support to Licensee with respect to such regulatory activities [***] and will, at Licensee's request, promptly transfer all Regulatory Materials and Information in Licensor's possession or under Licensor's Control related to any Compound or Product to Licensee.
- (b) Licensee will be the primary interface with and will otherwise handle all correspondence, meetings and other interactions with the relevant Regulatory Authorities concerning regulatory or other activities related to Compounds or Products in the Field in the Territory, and Licensee will prepare and file any and all Regulatory Materials for each Compound or Product in the Field in the Territory [***]. Licensor will assist and cooperate, in a timely manner, [***], with Licensee in connection with the preparation and filing of such Regulatory Materials, as reasonably requested by Licensee. Such cooperation will include promptly responding within procedural or other timelines set by Regulatory Authorities or any applicable Law to any reasonable request from Licensee for Licensor Know-How or other Information needed for the Regulatory Materials.
- (c) Unless the Parties otherwise agree in writing: (i) except as expressly contemplated by this <u>Section 5.1</u>, Licensor will not communicate with respect to any Compound or Product in the Field with any Regulatory Authority having jurisdiction in the Territory, unless so ordered by such Regulatory Authority, or required by applicable Law, in which case Licensor will provide prompt (but in any event within [***] Business Days) notice to Licensee of such order, or upon realizing such requirement is imposed by Law, and

all details thereof; and (ii) except as expressly contemplated by this <u>Section 5.1</u>, Licensor will not submit any Regulatory Materials or seek Regulatory Approvals by or for itself for any Compound or Product in the Field in the Territory.

- 5.2 <u>Regulatory Costs.</u> Licensee will pay [***] of its costs and expenses related to the preparation, filing and maintenance of all Regulatory Materials and Regulatory Approvals for each Product in the Field in the Territory.
- 5.3 Regulatory Materials. During the Term, Licensor will provide Licensee with access, free of charge, to all Licensor Know-How then in existence and in Licensor's possession that constitutes pre-clinical or clinical data, CMC Information and manufacturing data relating to any Compound or Product, or that would otherwise be reasonably helpful to Licensee in the Development of a Compound or Product. Licensor will support Licensee, [***], in obtaining and maintaining Regulatory Approvals in the Territory, including providing necessary documents, Information and other materials required by Laws or that would be reasonably useful in Licensee's opinion to obtain (and maintain) Regulatory Approval(s) in the Territory, all in accordance with the terms and conditions of this Agreement.

ARTICLE 6

MANUFACTURE AND SUPPLY

- 6.1 <u>Supply Agreements</u>. Licensor will, within [***] days after the Effective Date, enable and assist Licensee to enter into an agreement with each existing Third-Party manufacturer of the Compound(s) or Product(s), if desired by Licensee.
- 6.2 <u>Transfer of Materials and Information</u>. Licensor will, within [***] days after the Effective Date, transfer at no additional cost to Licensee, Licensor's (a) [***], (b) [***]; and (c) [***]. <u>Exhibit F</u> sets forth a substantially complete list of [***] to be transferred by Licensor to Licensee in accordance with <u>Article 5</u> and <u>Article 6</u>. For avoidance of doubt, [***].

ARTICLE 7

COMMERCIALIZATION

- 7.1 Overview. Subject to the terms and conditions of this Article 7, as between the Parties, Licensee shall be solely responsible for all aspects of the Commercialization of Products in the Field in the Territory. Licensee shall bear [***] the costs and expenses incurred in connection with such Commercialization activities.
- 7.2 <u>Diligence</u>. Upon obtaining Regulatory Approval of a Product in a Major Market Country, Licensee will use Commercially Reasonable Efforts to Commercialize such Product in the approved Indication in such Major Market Country. Notwithstanding anything herein to the contrary, Licensee's commitment to use Commercially Reasonable Efforts as set

forth herein shall not preclude the suspension or discontinuance of the Development or Commercialization of any Product, if appropriate, based on the application of Commercially Reasonable Efforts or Licensee's assessment of the attractiveness of the market in any Major Market Country during the Term of this Agreement. Licensor hereby acknowledges and agrees that Licensee and its Affiliates make (and have made) no covenant, representation or warranty, either express or implied, at Law or in equity, that they will be able to successfully achieve the Milestones, or that they will be able to achieve any amount of Net Sales, and Licensor specifically disclaims that it is relying upon or has relied upon any such covenants, representations or warranties that may have been made by any individual or entity. Nothing in this Agreement shall limit or restrict the right of Licensee or its Affiliates to Develop, make regulatory filings, obtain Regulatory Approvals with respect to, or Commercialize any product or to engage in any business or other activity.

7.3 <u>Pricing.</u> Licensee will determine all pricing and related aspects including but not limited to discounting, rebating and the like of Products in the Field in the Territory. For the avoidance of doubt, Licensor does not have any right to [***] pricing or related activities surrounding the pricing of Products in the Field in the Territory.

ARTICLE 8

COMPENSATION

- 8.1 <u>Upfront Consideration</u>. Upfront payment shall not be refundable or creditable against any future payments by Licensee to Licensor under this Agreement.
- (a) <u>Cash Consideration</u>. Licensee will pay to Licensor, [***] days following the Effective Date, (i) in consideration of the [***], a one-time, non-refundable and non-creditable, upfront fee [***], and (ii) in consideration of the [***], a one-time, non-refundable and non-creditable, upfront fee of [***].
- (b) <u>Equity Consideration</u>. Licensee will issue to Licensor, [***] days following the Effective Date, (i) in consideration of the [***], [***] shares of Licensee's common stock, and (ii) in consideration of the [***], [***] shares of Licensee's common stock (collectively, the "<u>Upfront Shares</u>").
 - 8.2 <u>Milestone Payments</u>. In addition to the consideration set forth in <u>Section 8.1</u>:
- (a) <u>Development/Regulatory Milestone Payments</u>. Licensee will pay the following one-time Development/regulatory milestone payments (the "<u>Development/Regulatory Milestones</u>") to Licensor, each within [***] days after the first achievement of each Development/Regulatory Milestone Event set forth in the table below. For the avoidance of doubt, the payments set forth in the column headed "Series A Product Payments" will be made upon the first achievement of the applicable Development/Regulatory Milestone Event with respect to only a Series A Product and the payments set forth in the column headed "Series B Product Payments" will be made upon the first achievement of the applicable Development/Regulatory Milestone Event with respect to only a Series B Product. Each such payment will be made in cash, in Dollars, except that

\$1,000,000 of [***] shall be made in shares of Licensee's common stock (the "Milestone Shares" and together with the Upfront Shares, the "Shares"), with the number of Milestone Shares calculated by dividing (a) \$1,000,000 by (b) [***] multiplied by [***] prior to satisfaction of [***], provided that in no event will the price used for the calculation be less than the Minimum Price of Licensee's common stock as determined by Rule 5635(d) of the Nasdaq Stock Market. Notwithstanding the foregoing, if the number of Milestone Shares as calculated pursuant to this Section 8.2(a) would exceed 14,366,187 (the "Share Cap"), then the number of Milestone Shares shall be equal to the Share Cap, and the remainder of the [***] that would otherwise have been payable by Licensee to Licensor in Milestone Shares shall be payable in cash.

No.	Development/Regulatory Milestone Event	Series A Product Payments	Series B Product Payments
[***]			

The Development/Regulatory Milestone payments are payable only once with respect to Series A Products and only once with respect to Series B Products. The Development/Regulatory Milestone payments shall not be refundable or creditable against any future payments by Licensee to Licensor under this Agreement. For clarity, this means that the total maximum amount of Development/Regulatory Milestone payments payable assuming achievement of each Development/Regulatory Milestone Event for (i) Series A Products is [***] and (ii) Series B Products is [***].

(b) Net Sales Milestone Payments. Licensee will pay the following one-time Net Sales milestone payments (the "Net Sales Milestones") to Licensor when the aggregate Net Sales in the Territory in any Calendar Year first reach the specified amount listed in the "Net Sales Milestone Event" column in the table below. For the avoidance of doubt, the payments set forth in the column headed "Series A Product Payments" will be made upon the first achievement of the applicable Net Sales Milestone Event with respect to only a Series A Product and the payments set forth in the column headed "Series B Product Payments" will be made upon the first achievement of the applicable Net Sales Milestone Event with respect to only a Series B Product. Licensee will notify Licensor in writing within [***] days after the end of the Calendar Quarter in which the applicable Net Sales Milestone Event is achieved and payment shall accompany [***]. Each such payment shall be made in cash, in Dollars.

No.	Net Sales Milestone Event	Series A Product Payments	Series B Product Payments

[***]

The Net Sales Milestone payments are payable only once with respect to Series A Products and only once with respect to Series B Products. The Net Sales Milestone payments shall not be refundable or creditable against any future payments by Licensee to Licensor under this Agreement. For clarity, this means that the total maximum amount of Net Sales Milestone

payments payable assuming achievement of each Net Sales Milestone Event for (i) Series A Products is [***] and (ii) Series B Products is [***].

8.3 Royalties.

(a) <u>Royalty Rates</u>. Licensee will pay to Licensor royalties on Net Sales in the Territory during the Royalty Term, as calculated by multiplying the applicable royalty rate set forth below (subject to reductions as set forth herein) by the corresponding amount of aggregated Net Sales of all Series A Products or all Series B Products, as applicable, in the Territory in such Calendar Year. For the avoidance of doubt, the royalty rates set forth in the column headed "Series A Product Royalty Rates" will be paid on Net Sales of all Series B Products and the royalty rates set forth in the column headed "Series B Product Royalty Rates" will be paid on Net Sales of all Series B Products.

Annual Net Sales in the Territory	Series A Product Royalty Rates Series B Product Royalty Rates
[***]	

(b) <u>Royalty Term.</u> Licensee will pay to Licensor royalties on Net Sales of Products under this <u>Section 8.3</u> [***] basis during the period commencing on [***] and ending on [***] (the "<u>Royalty Term</u>"). Upon expiration of the Royalty Term with respect to a Product in a given country, the license granted to Licensee pursuant to <u>Article 2</u> will become a fully paid-up and royalty-free license for such Product in such country.

(c) Royalty Reductions.

- (i) <u>Valid Claim and Regulatory Exclusivity Coverage.</u> In any Calendar Quarter in which a Product is not Covered by a Valid Claim of a Licensor Patent in a country where such Product is sold but such Product has Regulatory Exclusivity in such country, the applicable royalty rate set forth in <u>Section 8.3(a)</u> with respect to such Product and such country shall be reduced by [***], subject to <u>Section 8.3(d)</u>.
- (ii) <u>Valid Claim Coverage.</u> In any Calendar Quarter in which a Product is not Covered by a Valid Claim of a Licensor Patent in a country where such Product is sold and such Product does not have Regulatory Exclusivity in such country, the applicable royalty rate set forth in <u>Section 8.3(a)</u> with respect to such Product and such country shall be reduced by [***], subject to <u>Section 8.3(d)</u>.
- (iii) <u>Generic Products.</u> If, with respect to any Product in any country, sales of Generic Products account for [***] or more of the aggregate combined sales, on a unit basis, of such Product and such Generic Products in such country in a Calendar Quarter, as determined by reference to sales data obtained from a reputable independent source (e.g., IQVIA), then for the remainder of the Royalty Term for such Product in such country, the applicable royalty rate set forth in <u>Section 8.3(a)</u> with respect to such Product and such country shall be reduced by [***], subject to <u>Section 8.3(d)</u>.
- (iv) <u>Third Party Payments.</u> If Licensee reasonably determines that it is necessary to seek or obtain a license from any Third Party to Develop or Commercialize

- a Product in any country in the Territory, then Licensee may offset against royalties otherwise due to Licensor under this Agreement with respect to such country an amount equal to [***] of any royalties or other license fees/payments actually paid by Licensee to such Third Party under such license, subject to Section 8.3(d).
- (d) <u>Royalty Floor</u>. In no event will the royalties payable by Licensee in any Calendar Quarter with respect to any Product in a given country be reduced by more than an aggregate [***] as a result of the royalty reductions set forth in <u>Section 8.3(d)</u>. Notwithstanding the foregoing, any excess amounts that would have otherwise been deducted in such Calendar Quarter pursuant to <u>Section 8.3(c)</u> shall be deducted from royalties otherwise due to Licensor under this Agreement in successive Calendar Quarters until the credit has been realized in full.
- (e) Royalty Reports and Payments. Within [***] days following the end of each Calendar Quarter commencing with the Calendar Quarter in which the First Commercial Sale of any Product is made anywhere in the Territory, Licensee shall provide Licensor with a report containing the following information for such Calendar Quarter, on a [***] basis: [***]. If and to the extent that Licensee identifies an error in a prior royalty report, it shall set forth the error and related calculations in the current royalty report. Concurrent with the delivery of the applicable quarterly royalty report, Licensee shall pay [***] to Licensor pursuant to this Section 8.3 with respect to Net Sales by Licensee, its Affiliates and their respective Sublicensees for such Calendar Quarter.

8.4 [***] Consideration.

- (a) <u>Payment Amounts</u>. In addition to payments in Section 8.1, 8.2 and 8.3, Licensee will pay to Licensor [***] Consideration received by Licensee pursuant to any [***] by Licensee for any [***]. If such [***] is [***] prior to initiation of [***], the percentage will be [***] percent ([***]%); if such [***] is entered into after initiation of [***], the percentage will be [***] percent ([***]%).
- (b) Reports and Payments. Within [***] days following execution by Licensee of any [***], Licensee will provide to Licensor a true and complete copy of such [***], which may be [***] to protect confidential or proprietary information that is not reasonably necessary for Licensor to confirm the amounts of [***] Consideration. Within [***] days following the end of each Calendar Quarter in which Licensee has received [***] Consideration, Licensee will provide Licensor with a report [***] Consideration received and a calculation of the payment due to Licensor pursuant to Section 8.4(a), which payment [***].
- 8.5 <u>Foreign Exchange</u>. Conversion of sales recorded in local currencies to Dollars will be calculated, on a quarterly basis, using the average of rates on the last [***] Business Days of the Calendar Quarter to which such amounts pertain, as published in The Wall Street Journal, Internet Edition at www.wsj.com.
- 8.6 <u>Payment Method; Late Payments</u>. All amounts specified in this Agreement are in Dollars and all cash payments by one Party to the other Party under this Agreement shall be paid in Dollars by wire transfer of immediately available funds into an account designated by the Party that is owed such payment (such Party, the "<u>Payee</u>"). If the Payee

does not receive payment of any sum due to it on or before the due date, simple interest will thereafter accrue on the sum due to the Payee from the date such payment was originally due until the date of payment at the per annum rate of [***], or the maximum rate allowable by Laws, whichever is lower. Notwithstanding the foregoing, a Party making a payment (the "Payor") pursuant to this Agreement shall not be deemed to have made a late payment, and no interest shall be due pursuant to this Section 8.6, if the payment is not made by the due date as a result of the Payee's efforts to reduce or eliminate a tax applicable to such payment pursuant to Section 8.9(c), provided the Payor makes the required payment (net of applicable withholding taxes) as soon as practicable after the tax issue is resolved.

- 8.7 Records. Each Party will keep (and will ensure that its Affiliates and sublicensees keep) such records as are required to determine, in accordance with GAAP or international financial reporting standards, as applicable, and this Agreement, the sums or credits due under this Agreement, including Net Sales and [***] Consideration. Each Party will retain all such books, records and accounts until the later of (a) [***] years after the end of the period to which such books, records and accounts pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Laws. Each Party will require its sublicensees to provide to it a report detailing the foregoing expenses and calculations incurred or made by such sublicensee, which report will be made available to the other Party in connection with any audit conducted by such other Party pursuant to Section 8.8.
- Audits. Each Party may have an independent regional or national certified public accounting firm, reasonably acceptable to the audited Party, have access during normal business hours, and upon reasonable prior written notice, to examine only those records of the audited Party (and its Affiliates and sublicensees) as may be reasonably necessary to determine, with respect to any Calendar Year ending not more than [***] years before such Party's request, the correctness or completeness of any report or payment made under this Agreement. The foregoing right of review may be exercised only once per year and only once with respect to each such periodic report and payment. Reports of the results of any such examination will be (a) limited to details of any discrepancies in the audited Party's records relating to Product together with an explanation of the discrepancy and the circumstances giving rise to the discrepancy (b) made available to both Parties and (c) subject to Article 12. If the audit report concludes that (i) additional amounts were owed by the audited Party, the audited Party will pay the additional amounts, with interest from the date originally due as provided in Section 8.6 or (ii) excess payments were made by the audited Party, the auditing Party will reimburse such excess payments, without interest, in either case ((i) or (ii)), within [***] days after the date on which such audit report is delivered to both Parties. The Party requesting the audit will bear the full cost of the performance of any such audit, unless such audit, which covers the entire Calendar Year, discloses a variance to the detriment of the auditing Party of more than [***] from the amount of the original report, royalty or payment calculation, in which case the audited Party will bear the full cost of the performance of such audit. The results of such audit will be final, absent manifest error.

8.9 <u>Taxes</u>.

(a) <u>Taxes on Income</u>. Each Party will pay all taxes (including related interest and penalties) imposed on its share of income arising directly or indirectly from the

efforts of, or the accrual, receipt or deemed receipt of any payment by, such Party under this Agreement.

- (b) Tax Withholding. If any taxes (including related interest and penalties) are required by Laws to be withheld by the Payor with respect to an amount payable to the Payee, the Payor will: (a) withhold such taxes from the payment made to the Payee; (b) timely pay the withheld taxes to the proper taxing authority; (c) send proof of payment with official receipts issued by the appropriate governmental agency or such other evidence as is reasonably requested by the Payee to the Payee; and (d) reasonably assist the Payee in its efforts to obtain a refund of or credit for such tax payment in accordance with Section 8.9(c). Any amount actually withheld and remitted by the Payor to a taxing authority pursuant to this Section 8.9(b) will be treated for all purposes of this Agreement as paid to the Payee. If the Payor makes a payment without deduction for tax withholding and an amount of tax should have been withheld from such payment, the Payor shall be entitled to recover the under-withheld tax (and any penalties, additions to tax and interest related thereto and any penalties, additions to tax and interest payable by the Payor due to the failure to timely withhold) by an additional withholding from any amount payable to the Payee under this Agreement, and to the extent such recovery is insufficient, such Party may make a claim pursuant to ARTICLE 11. No amount shall be withheld, or a reduced amount shall be withheld, as applicable, if, in accordance with Section 8.9(c), a Party that is entitled to a payment timely furnishes the other Party with the necessary tax forms and other documents prescribed by applicable Laws, which shall be in a form reasonably satisfactory to the Party receiving the documents, identifying that the relevant payment is exempt from tax or subject to a reduced tax rate.
- (c) <u>Tax Cooperation</u>. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by one Party to the other Party under this Agreement. The Party entitled to a payment will provide the paying Party with any tax forms that may be reasonably necessary in order for the paying Party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty or other applicable Laws. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.
- 8.10 <u>Stock De-Listing</u>. If Licensee's common stock is de-listed from the Nasdaq stock market prior to the [***] anniversary of the Effective Date, then Licensee will pay to Licensor an amount equal to:
 - (a) for each of the [***] between the date of such de-listing and the date of re-listing on Nasdaq, \$[***];
 - (b) for each of the [***] between the date of such de-listing and the date of re-listing on Nasdaq, \$[***]; and
 - (c) for each of the [***] between the date of such de-listing and the date of re-listing on Nasdaq, \$[***].

The aggregate amount of such payment shall not exceed \$[***]. Any such payment required to be made shall be due and payable within [***] days after the earlier of (i) [***], and (ii) the [***].

ARTICLE 9

INTELLECTUAL PROPERTY MATTERS

9.1 Ownership of Inventions.

- (a) Ownership by Inventorship. Licensee will solely own any Inventions independently conceived, developed or reduced to practice by or on behalf of its own employees including agents, Contract Research Organizations (CROs) and independent contractors in the course of conducting activities under this Agreement, together with all intellectual property rights therein ("Licensee Inventions"). Licensor will solely own any Inventions conceived, developed or reduced to practice by or on behalf of its own employees including agents, CROs and independent contractors in the course of conducting activities under this Agreement, together with all intellectual property rights therein ("Licensor Inventions"). Licensee and Licensor jointly will own any Inventions conceived or reduced to practice jointly by employees, agents or independent contractors of each Party in the course of conducting activities under this Agreement, together with all intellectual property rights therein ("Joint Inventions").
- (b) <u>United States Law.</u> The determination of ownership rights of Inventions shall, for the purposes of this Agreement, be made in accordance with applicable Law in the U.S. Each Party shall, and does hereby, assign, and shall cause its Affiliates and their sublicensees and Sublicensees to so assign, promptly, to the other Party, without additional compensation, all right, title and interest in and to any Information and other Inventions as necessary to fully effect the ownership provided for in <u>Section 9.1(a)</u>.
- 9.2 Assignment Obligation. Each Party shall cause all persons who perform activities for such Party under this Agreement or who conceive, discover, develop or otherwise make any Inventions by or on behalf of either Party or its Affiliates or its or their sublicensees (or Sublicensees) under or in connection with this Agreement to be under an obligation to assign (or, if such Party is unable to cause such person to agree to such assignment obligation despite such Party's using commercially reasonable efforts to negotiate such assignment obligation, then to grant an exclusive, non-royalty bearing, worldwide license under) their rights in any Inventions resulting therefrom to such Party, except where applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case, a suitable license or right to obtain such a license, shall be obtained by the Party who would otherwise have assigned). In addition, each Party shall require (and shall cause its Affiliates and sublicensees to require) that any Third Party collaborator assign to such Party all of its rights, title and interest in and to any Inventions so to fully effect the ownership provided for in Section 9.1(a).

9.3 Prosecution of Patents.

- Subject to Section 9.3(b), as between the Parties, Licensee will have the first right to prepare, file, prosecute and maintain the Licensee Patents, the Licensor Patents and any Patents Covering Inventions (whether Licensee Inventions, Licensor Inventions or Joint Inventions) directed to any Compound or Product, including the manufacture or use thereof (collectively, the "Licensee Prosecuted Patents"), including handling re-examinations and reissues together with the conduct of interferences, derivation proceedings, pre-and postgrant opposition proceedings, post-grant patent proceedings (such as inter partes review and post grant review) (collectively, the "Prosecution and Maintenance"). Licensor hereby delegates to Licensee all of Licensor's rights, subject to all of Licensor's obligations, under the Principal License Agreement to Prosecute and Maintain all Patents included in the Sublicensed Rights. As between the Parties, [***] incurred after the Effective Date only in connection with the Prosecution and Maintenance of any Licensee Prosecuted Patent that Licensee chooses to Prosecute and Maintain in the Territory. Before any substantive prosecution filing, Licensee shall provide Licensor with a reasonable opportunity to review and comment on such prosecution efforts regarding the Licensee Prosecuted Patents as follows: Licensee shall provide Licensor with copies of all material communications from any patent authority regarding the Licensee Prosecuted Patents, and will provide Licensor, for its review and comment, with drafts of any material filings or responses to be made to such patent authorities in a reasonable amount of time in advance of submitting such filings or responses. Licensee shall consider in good faith any reasonable comments thereto provided by Licensor in connection with the prosecution of the Licensee Prosecuted Patents. Each Party shall provide the other Party all reasonable assistance and cooperation (at the other Party's cost) in the Patent Prosecution and Maintenance efforts provided in this Section 9.3(a), including executing any other required documents or instruments for such filings, Prosecution and Maintenance. For purpose of clarity, Licensee may at its discretion file one or more new Patent applications and may include in such applications data or discoveries included within the Licensed Know-How or other Information and such new Patent application(s)s will be Licensed Patents.
- (b) If Licensee decides not to Prosecute and Maintain, or to abandon, any Licensee Prosecuted Patent anywhere in the Territory, Licensee will promptly, but in no event later than [***] days prior to any deadline (and, if the deadline is extendable, the first such deadline without taking into account any available extension(s)) that must be met in order to avoid such abandonment, notify Licensor with written notice and Licensor may assume Licensee's rights and responsibilities under this Section 9.3(a) with respect to such Licensee Prosecuted Patent, and in connection with assuming such rights and responsibilities, including responsibility for costs, Licensor may Prosecute and Maintain such Licensee Prosecuted Patent in the Territory; provided that any such Licensee Prosecuted Patent that is a Licensor Patent shall thereafter be excluded from the definition of "Licensor Patents" for purposes of the applicable license grant in Article 2.
- (c) As between the Parties, Licensee will be solely responsible for deciding on strategy, selecting which Patent(s) to involve, and obtaining patent term restoration in any country in the Territory under any statute or regulation equivalent or similar to 35 U.S.C. §156, where applicable to a Licensed Product. In exercising the foregoing right and responsibility Licensee will solely determine which relevant Licensed

Patent will be extended (including by filing supplementary protection certificates and any other extensions that are now or in the future become available). Licensor will abide by Licensee's determination and cooperate, as reasonably requested by Licensee, in connection with the foregoing (including by providing appropriate information and executing appropriate documents) at Licensee's cost.

9.4 Patent Enforcement.

- (a) <u>Notification</u>. If either Party becomes aware of any existing or threatened infringement of any of the Licensee Patents or the Licensor Patents in the Field anywhere in the Territory by a Third Party, including any declaratory judgment, attempt at injunctive or other equitable relief, and opposition, post-grant administrative proceedings, or similar action from a Third Party alleging the invalidity, unenforceability, or non-infringement of any of the Licensee Patents or Licensor Patents ("<u>Territory Infringement</u>"), such Party will promptly, in any case no later than [***] business days after becoming aware of any such action, notify the other Party in writing to that effect and the Parties will consult and cooperate with each other regarding any actions to be taken with respect to such Territory Infringement.
- (b) Enforcement Rights. For any Territory Infringement, each Party will share with the other Party all Information available to it regarding such actual or alleged infringement. As between the Parties, Licensee may bring an appropriate suit or other action against any person or entity engaged in or threatening any such Territory Infringement which infringes (or would infringe) any Licensee Patent or any Licensor Patent that includes claims directed to any Product, at Licensee's cost and expense. Licensor will take appropriate and timely action to enable Licensee to commence a suit or petition for equitable relief or take the actions set forth in the preceding sentence. If Licensee fails to commence a suit or initiate equitable relief to enforce the applicable Licensor Patents against such Territory Infringement or to settle or otherwise secure the abatement of such Territory Infringement within [***] days after becoming aware of such Territory Infringement, or if a legal proceeding must be commenced earlier than such [***] days to avoid a loss of rights, then no later than [***] days prior to such deadline Licensor may commence a suit or take other action to enforce such Licensor Patents against such Territory Infringement at its own cost and expense. In this case, Licensee will take appropriate reasonable and timely actions to enable Licensor to commence a suit or take the other actions set forth in the preceding sentence.
- (c) <u>Collaboration</u>. Each Party will provide to the enforcing Party reasonable and timely assistance in such enforcement, at such enforcing Party's request and expense, including executing all necessary and proper documents and if required to establish and maintain standing to join such action as a party plaintiff if required by Law to pursue such action, *provided* that the Party so joined as a party plaintiff shall be under no obligation to participate except to the extent that such participation is required as the result of its being a named party to such action or by applicable Laws, and the enforcing Party agrees to fully indemnify, defend and hold harmless the other Party from and against all Claims (including reasonable legal fees and expenses) incurred by the other Party relating thereto. Each Party will additionally use Commercially Reasonable Efforts to have joined to such action as a party plaintiff any Third Party whose joinder is required by law to establish and maintain standing to pursue such action. The enforcing Party will keep the other Party regularly

informed of the status and progress of such enforcement efforts, will reasonably consider the other Party's comments on any such efforts, and will seek consent of the other Party in any material aspects of such enforcement, including determination of litigation strategy, settlement per Section 9.4(d), and filing of material papers to the competent court or other applicable Government Authority, which consent will not be unreasonably withheld, conditioned or delayed by the non-enforcing Party. The non-enforcing Party may obtain separate legal representation in such matter by counsel of its own choice and at its own expense, but such Party will at all times cooperate fully with the enforcing Party, subject to the provisions of Section 9.4(d).

- (d) Settlement. Licensor will not settle any claim, suit or action that it brought in respect of Territory Infringement in any manner that would negatively impact the applicable Licensor Patents or that would limit or restrict the ability of Licensee to Develop, use, make, have made or Commercialize any Compound or Product anywhere in the Territory in the Field, without the prior written consent of Licensee, which consent will not be unreasonably withheld, conditioned or delayed. Nothing in this Article 9 requires Licensee to consent to any settlement that is reasonably anticipated by Licensee to have a substantially adverse impact upon any Licensor Patent in the Territory, or to the Development, manufacture or Commercialization of any Compound or Product in the Territory. Licensee will not settle any claim, suit or action that it brought in respect of Territory Infringement that (i) includes any statement that may be used as an admission of invalidity or unenforceability of any Licensor Patents, or (ii) imposes any material obligations on Licensor or admits fault on behalf of Licensor, in each case without Licensor's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.
- (e) Expenses and Recoveries. The enforcing Party bringing a claim, suit, or action in respect of Territory Infringement will pay for any expenses incurred by such Party as a result of such claim, suit, or action. If such Party recovers all reasonably documented out-of-pocket monetary damages in such claim, suit or action, such recovery will be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation, and any remaining amounts will be retained as follows: (i) if Licensee is the enforcing Party, then [***], and (ii) if Licensor is the enforcing Party, then [***].
- (f) <u>Hatch Waxman Litigation</u>. Notwithstanding anything herein to the contrary, should a Party receive a certification under 21 U.S.C. § 355 (j)(2)(A)(vii)(iv) and 21 C.F.R. § 314.94 (a)(12)(i)(A)(4) with respect to one or more Licensor Patents or Licensee Patents pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417, known as the Hatch-Waxman Act), as amended, or its equivalent in a country other than the US, then such Party shall immediately provide the other Party with a copy of such certification. Licensee shall have [***] Business Days from the date on which it receives or provides a copy of such certification to provide written notice to Licensor ("<u>Paragraph IV Notice</u>") whether Licensee will bring suit, at its expense, within a [***] day period from the date of such certification. Should such [***] Business Day period expire without Licensee providing such Paragraph IV Notice to Licensor or with written notification that Licensee has no intention to bring suit under the Hatch-Waxman Act, then Licensor shall be free to immediately bring suit in its name.

- 9.5 Infringement of Third Party Rights. If a Product made, used, offered for sale or sold by Licensee, its Affiliates or Sublicensees, the Licensor Technology and/or the Licensee Technology becomes the subject of a Third Party's claim or assertion of infringement of a Patent granted by a jurisdiction within the Territory (each such claim or assertion a "Third Party Patent Claim"), Licensee will promptly notify Licensor, or vice versa if the Licensor is notified first. and the Parties will work toward their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties will promptly meet to consider the Third Party Patent Claim and the appropriate course of action. Licensee will defend any such Third Party Patent Claim that pertains solely to Patents that include claims directed to any Product; *provided* that the provisions of Section 9.4 govern the right of Licensee to assert a counterclaim of infringement of any Licensee Patent or any Licensor Patent. Notwithstanding the above, Licensee shall not enter into any settlement of any Third Party Patent Claim that would (a) require [***], or (b) limit or restrict [***], in each case without Licensor's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.
- 9.6 <u>Patent Marking</u>. Licensee and its Affiliates and Sublicensees will mark any Product marketed and sold by Licensee or its Affiliates or Sublicensees hereunder with appropriate patent numbers or indicia; *provided*, *however*, that Licensee will only be required to so mark such Product (a) [***] or (b) as otherwise required by applicable Law.
- 9.7 <u>Packaging; Trademarks</u>. Licensee will have the [***] right to [***] of Product for use in the Territory and may [***] of Products in the Territory and [***].

ARTICLE 10

REPRESENTATIONS AND WARRANTIES; COVENANTS

- 10.1 <u>Licensee Representations, Warranties and Covenants</u>. Licensee represents, warrants and covenants to Licensor, as of the Effective Date, as follows:
- (a) <u>Due Organization</u>. It is a corporation duly organized, validly existing and in good standing under the Laws of the jurisdiction in which it was incorporated. Licensee has sufficient cash on hand to fulfil its obligations pursuant to Article 8.1 and Article 8.10.
 - (b) <u>Power, Authority and Binding Agreement.</u>
 - (i) Licensee has the power and authority to enter into this Agreement and perform its obligations hereunder;
- (ii) Licensee has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and
- (iii) This Agreement has been duly executed and delivered on behalf of Licensee, and constitutes a legal, valid and binding obligation of Licensee that is enforceable against it in accordance with its terms, subject to bankruptcy, insolvency,

reorganization, moratorium or similar Laws affecting or relating to the enforcement of creditors' rights generally, and to general principles of equity.

- (c) <u>No Conflict</u>. The execution and delivery of this Agreement by Licensee and the performance of Licensee's obligations hereunder do not conflict with or violate, or constitute a breach of or default under, (i) any applicable Laws, (ii) Licensee's certificate of incorporation or by-laws, or (iii) any material contract, instrument or understanding, oral or written, to which Licensee is a party or by which it is bound.
- (d) Other Rights. Neither Licensee nor any of its Affiliates is a party to or otherwise bound by any contract or agreement that will result in any other person obtaining any interest in, or that would give to any other person any right to assert any claim in or with respect to, any of Licensee's rights under this Agreement.
- (e) <u>No Violation</u>. Neither Licensee nor any of its Affiliates is under any obligation to any person, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of Licensee's obligations hereunder.
- (f) No Debarment. Neither Licensee nor any of its Affiliates is debarred or suspended or excluded under the FD&C Act or by the analogous Laws of any Regulatory Authority.
- (g) <u>Valid Issuance</u>. The Shares have been duly authorized and, when issued, sold and delivered in accordance with this Agreement for the consideration expressed herein, will be validly issued, fully paid and will be free and clear of all liens, charges and encumbrances of any nature whatsoever except for restrictions on transfer under this Agreement and under applicable federal and state securities laws.
- (h) <u>SEC Filings</u>. Licensee has timely made all filings ("<u>SEC Filings</u>") required to be made by it pursuant to applicable securities laws (including without limitation, all filings required under the Securities Exchange Act of 1934, as amended (the "<u>1934 Act</u>")), and none of such SEC Filings contains any untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.
- 10.2 <u>Licensor Representations, Warranties and Covenants</u>. Licensor represents, warrants and covenants to Licensee, as of the Effective Date, as follows:
- (a) <u>Due Organization</u>. It is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it was incorporated or formed.
 - (b) Power, Authority and Binding Agreement.
- (i) It has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder;
- (ii) It has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and

- (iii) This Agreement has been duly executed and delivered on behalf of Licensor, and constitutes a legal, valid and binding obligation of Licensor that is enforceable against it in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting or relating to the enforcement of creditors' rights generally, and to general principles of equity.
- (c) <u>No Conflict</u>. The execution and delivery of this Agreement by Licensor, the performance of Licensor's obligations hereunder, and the grant by Licensor of the licenses and sublicenses granted hereunder do not and will not conflict with or violate, or constitute a breach of or default under, (i) any applicable Laws; (ii) Licensor's certificate of incorporation, by-laws or equivalent organizational documents; or (iii) any material contract to which Licensor is a party or by which it is bound.
- (d) Other Rights. Neither Licensor nor any of its Affiliates is a party to or otherwise bound by any contract or agreement that will result in any other person obtaining any interest in, or that would give to any other person any right to assert any claim in or with respect to, any of Licensor's rights under this Agreement.
- (e) <u>No Violation</u>. Neither Licensor nor any of its Affiliates is under any obligation to any person, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of Licensor's obligations hereunder. Neither Licensor nor any of its Affiliates are bound by any non-competition agreements related to any Compound or Product.
- (f) <u>No Debarment</u>. Neither Licensor nor any of its Affiliates is debarred, suspended or excluded under the FD&C Act or by the analogous Laws of any Regulatory Authority.
- (g) <u>Licensor Patents</u>. Exhibit A and Exhibit B together list all Patents Controlled by Licensor anywhere in the Territory as of the Effective Date that Cover any Compound or Product. Licensor has complied with all Laws in connection with the prosecution and maintenance of the Licensor Patents and regulatory exclusivity, including the duty of candor owed to any patent office or Regulatory Authority pursuant to such Laws. All material renewal and maintenance fees due as of the Effective Date with respect to the prosecution and maintenance of the Licensor Patents have been paid by or for Licensor. The inventors named in the Licensor Patents are all of the true inventors for such Licensor Patents and each of such inventors has assigned to Licensor or its Affiliates (or, in the case of Patents within the Sublicensed Rights, to the Principal Licensor) all of his or her right, title and interest to such Licensor Patents and the inventions described therein, or if assignment is not allowed by applicable Law then issued an exclusive, non-royalty bearing, worldwide license to Licensor or its Affiliates (or, in the case of Patents within the Sublicensed Rights, to the Principal Licensor).
- (h) <u>Title: Encumbrances</u>. Licensor Controls all Licensor Technology and has sufficient legal title, ownership or license rights in the Licensor Technology, free and clear of mortgages, pledges, liens, security interests, options, encumbrances, charges or claims of any kind, to grant the licenses to Licensee as purported to be granted pursuant to this Agreement. Licensor has not granted any rights with respect to any Compound or Product in the Territory to any person or entity other than Licensee.

- (i) <u>Validity</u>. No Third Party has initiated or threatened in writing any legal action asserting that the Licensor Patents are invalid or unenforceable or that such Third Party has any rights thereto. Licensor has received no notice, and to the knowledge of Licensor after reasonable inquiry, the Principal Licensor has received no notice, that any Third Party has taken any action before any patent and trademark office (or similar Governmental Authority), which, if successful, would render any of the Licensor Technology invalid or unenforceable or would otherwise in any way alter ownership rights of the Licensor. Licensor does not have knowledge of any Information which leads it to believe that any issued or pending Patents included in (or associated with) the Licensor Patents are invalid or unenforceable or that the Licensor's ownership rights would be adversely impacted.
- (j) Non-Infringement. To the knowledge of Licensor, (i) no Third Party is infringing or has infringed the Licensor Technology or is misappropriating the Licensor Know-How; and (ii) the Development, manufacture and Commercialization of the Compounds and Products can be carried out in the manner contemplated by this Agreement without infringing any Patent or other intellectual property rights of any Third Party. Licensor has not received, and to the knowledge of Licensor after reasonable inquiry the Principal Licensor has not received, any written notice from any Third Party asserting or alleging that (i) any research, Development or manufacture of any Compound or Product before the Effective Date infringed or misappropriated the intellectual property rights of such Third Party or (ii) the exercise of Licensee's rights as granted under this Agreement infringes or would infringe any Third Party intellectual property rights.
- (k) <u>No Proceedings</u>. To the knowledge of Licensor, there are no pending, alleged or threatened, (i) inter partes reviews, post-grant reviews, interferences, re-examinations or oppositions involving the Licensor Patents that are in or before any patent authority (or other Governmental Authority performing similar functions) or (ii) inventorship challenges involving the Licensor Patents that are in or before any patent or other Governmental Authority.
- (l) <u>No Consents</u>. Licensor possesses all permits, licenses, registrations, authorizations, orders and approvals required to (i) conduct its business as pertains to the Compounds and Products in compliance with Laws, and (ii) enter into and perform its obligations under this Agreement.
- (m) Access to Information. Licensor has allowed, and will continue to allow, Licensee access to all material information in Licensor's possession or control (i) containing [***]; (ii) concerning [***]; (iii) useful to [***]; and (iv) in respect of [***], all of which information (referred to in clauses (i), (ii) and (iii) above) is true and correct in all material respects. Licensor has disclosed to Licensee all material contracts relating to the Licensor Technology or the Development, manufacture or Commercialization of any Compound or Product and is not in material breach or default of any such material contracts.
- (n) <u>Confidentiality Obligations</u>. All current and former employees and paid consultants of Licensor and its Affiliates who are or have been substantively involved in the conception, design, review, evaluation, reduction to practice, or Development of the Licensor Technology, any Compound or any Product have executed written contracts or are otherwise obligated to protect the confidential status and value thereof and to vest in Licensor exclusive ownership, or if prohibited by applicable Law, an exclusive, non-royalty bearing,

worldwide license thereto of the Licensor Technology, any Compound and any Product. No Third Party has any Licensor Know-How in its possession or control which is not subject to continuing obligations of confidentiality owed to Licensor or its Affiliates for at least the duration of the Term.

- (o) Principal License Agreement. Licensor has delivered to Licensee a true, correct and complete copy of the Principal License Agreement and all amendments thereto. The Principal License Agreement is legal, valid, binding, enforceable and in full force and effect in accordance with its terms. No act, omission or event has occurred that constitutes (or with notice or the passage of time or both would constitute) a material breach, violation or default by Licensor (or to the best of Licensor's knowledge, by the Principal Licensor) of or under the Principal License Agreement. Without limiting the generality of the foregoing, Licensor has paid all license fees, sublicense fees, minimum license fees, royalties, milestones and other amounts due and payable by it to the Principal Licensor on or before the Effective Date. Licensor will fully comply with all terms of the Principal License Agreement for the duration of the Term of this Agreement, and should it be notified of any breach or termination, or threatened breach or termination, of the Principal License Agreement by or for the Principal Licensor, it has and will provide immediate notice to Licensee and take all necessary steps to remain in compliance with said Principal License Agreement.
- (p) <u>Safety and Efficacy</u>. Licensor is not aware of any problems, questions or challenges concerning the safety, tolerability or efficacy of any Compound or Product (including any of their ingredients) or of any questions raised by any Regulatory Authority with respect thereto, and Licensor has informed Licensee of all adverse drug reactions and other safety and tolerability matters known to Licensor relating to any Compound or Product or their use.

(q) Regulatory Matters.

- (i) Licensor has provided or made available, when requested by Licensee to conduct its due diligence review, any and all documents and communications in its possession from and to any Governmental Authority, or prepared by any Governmental Authority, related to any Compound or Product, that may bear on the compliance with the requirements of any Governmental Authority, including any notice of inspection, inspection report, warning letter, notice of violation, deficiency letter, or similar communication;
- (ii) Licensor and its Affiliates have conducted all research and Development of the Compound and Products in accordance with Laws and with GLP, GCP and GMP, as applicable;
- (iii) Neither Licensor nor any of its Affiliates has received any oral or written communication (including any warning letter, notice of violation, deficiency letter, untitled letter, or similar notices, or other legal action) from any Governmental Authority, and there is no action pending or to Licensor's knowledge threatened, in each case alleging that Licensor or any of its Affiliates has failed to comply with Laws in connection with the research and Development of any Compound or Product; and
- (iv) To Licensor's knowledge, none of Licensor, any of its Affiliates, or any of their respective officers, employees or agents has made, with respect to

any Compound or Product, an untrue statement of a material fact to any Governmental Authority or failed to disclose a material fact required to be disclosed to such Governmental Authority.

(r) <u>Investment Representations</u>.

- (i) Licensor is purchasing the Shares for its own account, for investment purposes only and not with a view to resale or distribution.
- (ii) Licensor is a corporation with total assets exceeding \$5,000,000 and an Accredited Investor as such term is defined under the Securities Act of 1933, as amended (the "1933 Act") and the regulations promulgated thereunder.
- (iii) Licensor understands and acknowledges that none of the Shares have been registered under the 1933 Act, or under any state securities or "blue sky" laws of any state of the United States, and, unless so registered, may not be offered or sold in the United States or, directly or indirectly, to U.S. Persons, as that term is defined in Regulation S under the 1933 Act, except in accordance with the provisions of Regulation S, pursuant to an effective registration statement under the 1933 Act, or pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the 1933 Act and in each case only in accordance with any applicable state and provincial securities laws.
- (iv) Immediately following the issuance of the Shares, Licensor (together with its Affiliates and the members of any "group" (within the meaning of Rule 13d-5(b) under the 1934 Act) in which it or its Affiliates is a member) will not directly or indirectly "beneficially own" (as defined in Rule 13d-3 under the 1934 Act), or have the right to acquire (including by virtue of beneficially owning securities exercisable for Licensee's common stock) any voting securities of Licensee other than the Shares.
- (v) Licensor has (i) reviewed Licensee's SEC Filings, including its most recently filed annual report on Form 10-K and all subsequent filings, (ii) received all the information that it has requested and that it considers necessary or appropriate for deciding whether to enter into this Agreement and to acquire the Shares, and (iii) has had an opportunity to ask questions and receive answers from Licensee regarding the terms and conditions of the offering of the Shares and the merits and risks of investing in the Shares.
- (vi) Licensor acknowledges that it is able to fend for itself, can bear the economic risk of its investment and has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of the investment in the Shares.
- (vii) Licensor is not buying the Shares as a result of any advertisement, article, notice, or other form of general solicitation or general advertising (within the meaning of Regulation D under the 1933 Act) regarding the Shares.
- (viii) Licensor is not engaged in the business of a broker-dealer, is not a registered broker dealer under the 1934 Act, and is not a member of the Financial Industry Regulatory Authority, Inc.

- (ix) Licensor's principal executive office, place of business [***] is in the Republic of Korea.
- (x) Licensor has not, directly or indirectly, nor has any person acting on behalf of or pursuant to any understanding with it, at any time since the [***] day immediately prior to the Effective Date, engaged in any transactions in the securities of Licensee (including any short sales as defined in Rule 200 promulgated under Regulation SHO under the 1934 Act and all types of direct and indirect stock pledges, forward sale contracts, options, puts, calls, swaps and similar arrangements) or made any bids with any broker or dealer to purchase Licensee's common stock.
- (xi) No person will have, as a result of the transactions contemplated by this Agreement, any valid right, interest or claim against or upon Licensee for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of Licensor.
- (s) <u>Assets and Revenues</u>. Licensor does not have more than \$184 million in either annual net sales or total assets for purposes of Section 18a(a)(2)(B)(ii) of the HSR Act. For purposes of this <u>Section 10.2(s)</u>, the term "Licensor" shall include Licensor's "ultimate parent entity" (as such term is defined in 16 C.F.R. § 801.1(a)(3)) and all entities included within Licensor's ultimate parent entity.

10.3 Covenants.

- (a) <u>No Debarment</u>. In the course of its activities pursuant to this Agreement, neither Party will use any employee, consultant or contractor:
- (i) who has been debarred, excluded or suspended under Section 306(a) or 306(b) of the FD&C Act, or other applicable provision(s) of U.S. Law, or pursuant to the analogous Laws of any Regulatory Authority;
- (ii) who, to such Party's knowledge, has been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S. C. §§ 1320a-7(a), 1320a-7(b)(l)-(3), or other applicable provision(s) of U.S. Law, or otherwise pursuant to the analogous Laws of any Regulatory Authority, or is proposed for exclusion, or the subject of exclusion or debarment or suspension proceedings by a Regulatory Authority, during the employee's or consultant's employment or contract term with such Party; or
- (iii) who is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or who has been indicted or convicted of a criminal offense that falls within the scope of 42 U.S. C. §1320a-7 or other relevant U.S. Laws but has not yet been excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by a Regulatory Authority from participation, or otherwise ineligible to participate, in any procurement or non-procurement programs.

Each Party will notify the other Party promptly, but in no event later than five (5) Business Days, upon becoming aware that any of its employees or consultants has been excluded,

debarred, suspended or is otherwise ineligible, or is the subject of exclusion, debarment or suspension proceedings by any Regulatory Authority.

- (b) <u>Compliance</u>. Each Party and its Affiliates will comply in all material respects with all applicable Laws in the Development, manufacture and Commercialization of any Compound and any Products and the performance of its obligations under this Agreement, including where applicable the statutes, regulations and written directives of the FDA, the Korea FDA, the EMA and any other Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Foreign Corrupt Practices Act of 1977, and Korea's Pharmaceutical Affairs Act, Korea's Improper Solicitation and Graft Act of 2016, and Articles 129-133 of Korea's Criminal Act, Korea's Act on Prevention of Corruption, and other anticorruption statutes, each as may be amended from time to time and each to the extent applicable.
- (c) <u>Third Party Confidentiality</u>. Licensor will maintain the confidentiality of the Licensor Know-How and will ensure that no Third Party has any Licensor Know-How in its possession or Control which is not subject to continuing obligations of confidentiality owed to Licensor or its Affiliates for at least [***].
- (d) Transfer Restrictions. Licensor will not, during the period beginning on the Effective Date and continuing to and including the date one hundred eighty (180) calendar days after date of acquisition by Licensor of the Shares from Licensee (as determined pursuant to Rule 144(d)(1) promulgated under the 1933 Act), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any Shares, (2) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the Shares, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of the Shares, in cash or otherwise, or (3) publicly disclose the intention to do any of the foregoing. Licensor acknowledges and agrees that the foregoing precludes the undersigned from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (whether by the undersigned or any other person) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any Shares, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of Shares, in cash or otherwise. Notwithstanding the foregoing, Licensor may [***].

(e) <u>Principal License Agreement</u>.

(i) Licensor shall satisfy all of its obligations under, and take all actions necessary to maintain in full force and effect, the Principal License Agreement. For the avoidance of doubt, Licensor (and not Licensee) shall be responsible for all of the financial and other obligations of Licensor to the Principal Licensor under the Principal License Agreement, including all financial obligations arising from the sale of Products by Licensee and other Selling Parties.

- (ii) Licensor shall not, in whole or in part, assign, amend, waive, terminate, modify or otherwise alter the Principal License Agreement without the prior written consent of Licensee, which consent may be granted or withheld in Licensee's sole discretion.
- (iii) Licensor shall provide Licensee with prompt (i.e., within [***] Business Days) written notice of any claim or notice by either Licensor or the Principal Licensor of (A) any act, omission or event that constitutes (or with notice or the passage of time or both would constitute) a material breach, violation or default of or under the Principal License Agreement, (B) any actual or potential change or modification to any license granted to Licensor by the Principal Licensor under the Principal License Agreement, which change or modification would adversely affect the Sublicensed Rights, or (C) any attempt by the Principal Licensor to terminate the Principal License Agreement for any reason. For the avoidance of doubt, any termination, reduction in scope, or conversion from exclusive to non-exclusive, whether in whole or in part, or other diminution of rights from Principal Licensor to Licensor would adversely affect the Sublicensed Rights.
- (iv) Licensee shall have a right to stand instead of Licensor in relation to curing any breach by Licensor of the Principal License Agreement, or to prevent the early termination of the Principal License Agreement. Licensor shall involve Licensee in Licensor's attempt to remedy breach or prevent early termination and if Licensor is unable to fulfill its obligations, allow in a timely manner for Licensee to stand in its place to ensure compliance with the Principal License Agreement and forgo any early termination of that. Any expenditures and payments that Licensee may have to pay to the Principal Licensor in Licensor's stead pursuant to Section 10.3(e) shall be reimbursed, with interest, to Licensee by Licensor in a timely manner but no less than [***] days after Licensee's payment to the Principal Licensor for Licensor's benefit. [***]
- 10.4 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 11

INDEMNIFICATION

11.1 <u>Indemnification by Licensor</u>. Licensor will, at its sole expense, defend, indemnify, and hold harmless Licensee and its Affiliates and their respective officers, directors, shareholders or owners, employees, and agents (the "<u>Licensee Indemnitees</u>") from and against any and all Third Party claims, suits, proceedings, damages, losses, liabilities, taxes, costs, expenses (including court costs and reasonable attorneys' fees and expenses) and recoveries (collectively, "<u>Claims</u>") to the extent that such Claims arise out of, are based on, or result from (a) the research, Development, manufacture, use, testing or Commercialization of

any Compound or Product by or on behalf of Licensor or its Affiliates or its or their sublicensees (other than Licensee and its Affiliates), (b) the breach of any of Licensor's obligations under this Agreement or the Principal License Agreement, including Licensor's representations and warranties, covenants and agreements, or (c) the willful misconduct or negligent acts of Licensor, its Affiliates, or the officers, directors, employees, or agents of Licensor or its Affiliates. The foregoing indemnity obligation will not apply (i) to the extent that (x) the Licensee Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Licensor's defense of the relevant Claims is prejudiced by such failure or (y) such Claims arise out of or result from the gross negligence or willful misconduct of Licensee or its Affiliates, or any related breach by Licensee of its representations, warranties or covenants or any other obligation of Licensee hereunder; or (ii) to Claims for which Licensee has an obligation to indemnify Licensor pursuant to Section 11.2, as to which Claims each Party will indemnify the other to the extent of its respective liability for such Claims.

- 11.2 <u>Indemnification by Licensee</u>. Licensee will, at its sole expense, defend, indemnify, and hold harmless Licensor and its Affiliates and their respective officers, directors, shareholders or owners, employees, and agents (the "<u>Licensor Indemnitees</u>") from and against any and all Third Party Claims to the extent that such Claims arise out of, are based on, or result from (a) research, Development, manufacture, use, testing or Commercialization of any Compound or Product by or on behalf of Licensee or its Affiliates or its or their Sublicensees, (b) the breach of any of Licensee's obligations under this Agreement, including Licensee's representations and warranties, covenants and agreements or (c) the willful misconduct or negligent acts of Licensee, its Affiliates, or the officers, directors, employees, or agents of Licensee or its Affiliates. The foregoing indemnity obligation will not apply (i) to the extent that (x) the Licensor Indemnitees fail to comply with the indemnification procedures set forth in <u>Section 11.3</u> and Licensee's defense of the relevant Claims is prejudiced by such failure or (y) such Claims arise out of or result from the gross negligence or willful misconduct of Licensor or its Affiliates, or any related breach by Licensor of its representations, warranties or covenants hereunder; or (ii) to Claims for which Licensor has an obligation to indemnify Licensee pursuant to <u>Section 11.1</u>, as to which Claims each Party will indemnify the other to the extent of its respective liability for such Claims.
- 11.3 <u>Indemnification Procedures</u>. The Party claiming indemnity under this <u>ARTICLE 11</u> (the "<u>Indemnified Party</u>") will give written notice to the Party from whom indemnity is being sought (the "<u>Indemnifying Party</u>") promptly after learning of a Claim. The Indemnified Party will provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided*, *however*, the Indemnifying Party may assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party will not settle any Claim without the prior written consent of the Indemnified Party will not settle or compromise any such Claim without the prior written consent of the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or

enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this ARTICLE 11.

- 11.4 <u>Limitation of Liability</u>. EXCEPT (A) IN THE EVENT OF THE FRAUD OF A PARTY OR OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER <u>ARTICLE 12</u>, (B) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS <u>ARTICLE 11</u> OR (C) IN CONNECTION WITH ANY MISREPRESENTATION, BREACH OR INACCURACY OF ANY REPRESENTATION MADE BY A PARTY, NEITHER PARTY NOR ANY OF ITS AFFILIATES OR SUBLICENSEES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE, REMOTE, EXEMPLARY OR SPECULATIVE DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS, ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES OR THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY.
- 11.5 <u>Insurance</u>. Licensee, [***], shall maintain clinical trials and product liability insurance in an amount consistent with industry standards for a company of similar standing during the term of this Agreement and [***].

ARTICLE 12

CONFIDENTIALITY

- 12.1 <u>Confidentiality</u>. Each Party agrees that, during the Term and, subject to <u>Section 12.5</u>, for a period of [***] years thereafter, it and its Affiliates will keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder or thereunder) any Confidential Information furnished to it or its Affiliate by or on behalf of the other Party or its Affiliate pursuant to this Agreement, except to the extent expressly authorized by this Agreement or as otherwise agreed to in writing by the Parties. The foregoing confidentiality and non-use obligations do not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:
- (a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party or its Affiliate;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party or its Affiliate;

- (c) 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 or its Affiliate in breach of this Agreement;
- (d) was disclosed to the receiving Party or its Affiliate by a Third Party who had a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party or its Affiliate; or
- (e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application or use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.
- 12.2 <u>Authorized Disclosure</u>. Notwithstanding the obligations set forth in <u>Section 12.1</u>, a Party or its Affiliate may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:
- (a) such disclosure is reasonably necessary (i) for the filing or prosecuting of Patent rights as contemplated by this Agreement; (ii) to comply with the requirements of Regulatory Authorities and applicable Laws with respect to obtaining and maintaining Regulatory Approval(s) of Product; or (iii) for prosecuting or defending litigation or taking other appropriate enforcement actions as contemplated by this Agreement;
- (b) such disclosure is reasonably necessary to its officers, directors, employees, agents, consultants, contractors, licensees, sublicensees, advisors (including financial advisors), attorneys, accountants, lenders, insurers or licensors on a need-to-know basis for the sole purpose of performing its due diligence, similar investigations, obligations or exercising its rights under this Agreement; *provided* that in each case, the disclosees are bound by obligations of confidentiality and non-use no less stringent than those contained in this Agreement;
- (c) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, Sublicensee or other financial or commercial partner for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; *provided* that in each case, the disclosees are bound by reasonable written obligations of confidentiality and non-use; or
- (d) such disclosure is reasonably necessary to comply with Laws, including regulations promulgated by applicable securities exchanges or guidances or pursuant to the listing rules of any applicable securities exchanges on which the such Party's securities are traded, and to be traded, court orders, administrative subpoenas or other orders by a Government Authority.

Notwithstanding the foregoing, if a Party or its Affiliate is required to make a disclosure of the other Party's Confidential Information pursuant to <u>Section 12.2(a)</u> or <u>12.2(d)</u>, such Party will promptly notify in writing the other Party of such required disclosure and, upon the other Party's request, such Party and its Affiliates will use reasonable and timely efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

12.3 <u>Publications</u>. Licensee and its Affiliates shall be free to publish and present, and to authorize its Sublicensees to publish and present, the results of any preclinical study or Clinical Study or other Development activities with respect to a Compound or Product conducted by or on behalf of Licensee or its Affiliates or Sublicensees, [***]. Licensor shall not publish or present any Licensor Know-How without [***].

12.4 Publicity; Terms of Agreement.

- (a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this <u>Section 12.4</u>.
- (b) The Parties will each make a public announcement of the execution of this Agreement, to be mutually agreed press releases by the Parties, which will be issued within four (4) Business Days after the Effective Date, as agreed by the Parties, in their respective countries of incorporation. In addition, Licensee will file a Current Report on Form 8-K with the SEC.
- After release of such press release and filing of Licensee's Current Report on Form 8-K, if either Party or its Affiliate desires to make a public announcement concerning the material terms of this Agreement, such Party will give reasonable prior advance written notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided), such approval not to be unreasonably withheld. A Party commenting on such a proposed announcement will provide its comments, if any, within [***] Business Days after receiving the announcement for review, or such shorter period as may be reasonably required in order for the proposing Party to comply with any applicable deadline for making such announcement (as such deadline is communicated by the proposing Party to the commenting Party). For the avoidance of doubt, within [***] days from the Effective Date, both Parties shall not disclose additional information regarding material terms other than the level of detail disclosed in the press release attached hereto as Exhibit G, without other Party's prior written consent, except to the extent such disclosure is required by applicable Laws (including SEC regulations). In addition, where required by Laws, including regulations promulgated by applicable securities exchanges, such Party or its Affiliate may make a press release (or SEC or other regulatory filing) announcing the achievement of each milestone under this Agreement as it is achieved, the achievements of Regulatory Approvals in the Territory as they occur, or any other material event with respect to this Agreement or the Parties' performance thereof, subject only to the review procedure set forth in the preceding sentence. In relation to the other Party's review of such an announcement, such other Party may make specific, reasonable comments on such proposed press release (or SEC or other regulatory filing) within the prescribed time for commentary, but will not withhold, condition, or delay its consent to disclosure of the information that the relevant milestone or Regulatory Approval has been achieved or material event has occurred. Neither Party nor their Affiliates are required to seek the permission of the other Party to repeat or summarize any information regarding the terms of this Agreement that has already been substantially publicly disclosed by such Party or its Affiliate, or by the other Party or its Affiliate, in accordance with this Section 12.4, if such information remains accurate as of such time. Notwithstanding the foregoing, [***].

- (d) The Parties acknowledge that either or both Parties may be obligated to file under Laws a copy of this Agreement with the U.S. Securities and Exchange Commission ("SEC") or any recognized stock exchange on which the Licensor's securities are traded, to be traded, or other Governmental Authorities. Each Party will make such a required filing and will request confidential treatment of the commercial terms and sensitive technical or other competitively sensitive terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show the provisions for which such Party intends to seek confidential treatment and will reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed. The reviewing Party shall respond with any comments hereunder within [***] Business Days of receipt, unless a shorter deadline is required for the disclosing Party to comply with applicable reporting Laws.
- 12.5 <u>Return of Confidential Information</u>. Except as otherwise set forth in this Agreement, upon termination of this Agreement, the receiving Party will promptly return all of the disclosing Party's Confidential Information, including all reproductions and copies thereof in any medium, except that the receiving Party may retain one (1) copy for only archival purpose as may be required by law, its standard document retention policies, or to demonstrate its compliance with this Agreement.
- 12.6 <u>Unauthorized Use</u>. If either Party becomes aware or has knowledge of any unauthorized use or disclosure of the other Party's Confidential Information, it will promptly notify the other Party in writing of such unauthorized use or disclosure.
- 12.7 <u>Exclusive Property</u>. All Confidential Information is the sole and exclusive property of the disclosing Party and the permitted use thereof by the receiving Party for purposes of its performance hereunder will not be deemed a license or other right of the receiving Party to use any such Confidential Information for any other purpose.

ARTICLE 13

TERM AND TERMINATION

13.1 <u>Term</u>. This Agreement becomes effective on the Effective Date, and, unless sooner terminated as specifically provided in this Agreement, continues in effect on a Product-by-Product and country-by-country basis until the expiration of all payment obligations hereunder (the "<u>Term</u>").

13.2 <u>Termination</u>.

(a) <u>Default Notice / Breach.</u> Each Party (the "<u>Non-Breaching Party</u>") may terminate this Agreement, on a country-by-country basis, a Program-by-Program basis, or in its entirety, immediately upon written notice to the other Party (the "<u>Breaching Party</u>") if the Breaching Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail (a "<u>Default Notice</u>"), fails to cure such material breach within [***] days (the "<u>Cure Period</u>") after delivery of the Default Notice (or within [***] days after delivery of the Default Notice if such material

breach is solely based on the Breaching Party's failure to pay any amounts due hereunder). If the Breaching Party disputes in good faith the basis for termination and, on or before the end of the Cure Period, either Party has referred the matter to arbitration pursuant to Section 14.1, then the Cure Period will be tolled and this Agreement will not terminate unless and until the chief executive officer of Licensor and the chief executive officer of Licensee resolve the dispute or the arbitrators issue a final, binding, nonappealable ruling or award upholding such basis for termination (or unless and until the Breaching Party is no longer disputing such basis in good faith, if earlier). If the arbitrators issue a final, binding, nonappealable ruling or award upholding such basis for termination, then the Cure Period will resume, and the Breaching Party will have the remainder of the Cure Period to cure the material breach. If the material breach is so cured within the remainder of the Cure Period, then this Agreement will remain in full force and effect; otherwise, this Agreement will terminate as specified in the Default Notice. If the arbitrators issue a final binding nonappealable ruling rejecting such basis for termination, then this Agreement will remain in full force and effect. Notwithstanding the foregoing, if Licensee is the Breaching Party and the material breach is of Licensee's obligations to use Commercially Reasonable Efforts in Developing (including obtaining Regulatory Approval) or Commercializing Products with respect to only one Program, then this Agreement may be terminated only with respect to such Program and not in its entirety.

- (b) <u>Insolvency</u>. Each Party shall have the right to terminate this Agreement upon written notice to the other Party: (a) if the other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (b) if a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against the other Party and such petition is not dismissed within [***] days after filing; (c) if the other Party shall make or execute an assignment of substantially all of its assets for the benefit of creditors; or (d) substantially all of the assets of the other Party are seized or attached and not released within [***] days thereafter. In any event when one Party first becomes aware of the likely occurrence of any Insolvency event in regard to itself, it shall promptly so notify the other Party in sufficient time to give the other Party sufficient notice to protect its interests under this Agreement.
- (c) <u>Unilateral Termination by Licensee Upon Written Notice</u>. Notwithstanding any other provision of this Agreement, Licensee may at any time terminate this Agreement in its sole discretion, on a country-by-country basis, a Program-by-Program basis, or in its entirety, upon [***] days' prior written notice to Licensor.
- (d) <u>Termination by Licensor for Licensee's Abandonment</u>. At any point in time prior to the achievement of [***], if Licensee has [***], itself or through one or more Affiliates or Third Parties, any and all [***] activities with respect to the Series A Compound or Series A Product for [***], then, provided that such [***], Licensor may provide written notice to Licensee of its intent to terminate this Agreement [***]. For avoidance of doubt, this Agreement may be terminated only with respect to [***] and not in its entirety.

13.3 Consequences of Terminations.

(a) <u>Accrued Obligation.</u> Termination of this Agreement for any reason shall not release any Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such

termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

- (b) <u>License.</u> Upon any termination of this Agreement pursuant to [***], all rights and licenses granted to Licensee by Licensor with respect to [***] shall immediately terminate. Notwithstanding the foregoing, upon termination of this Agreement pursuant to [***], all rights and licenses granted to Licensee by Licensor in [***] shall terminate.
 - (c) Upon any termination of this Agreement for any reason except termination by Licensee pursuant to [***]:
- (i) Assignment of [***]. Licensee shall promptly assign and transfer to Licensor [***], and shall take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under such [***] to Licensor. Licensee shall cause each of its Affiliates and all Sublicensees [***] to transfer any such [***] to Licensor if this Agreement terminates. If applicable laws, rules or regulations prevents or delays the transfer of [***] to Licensor, Licensee shall [***]. Within [***] days after the effective date of such termination, Licensee shall provide to Licensor copies of all such [***]. Licensor shall be free to use and disclose such [***] and other items in connection with the exercise of its rights and licenses relating to [***].
- (ii) <u>License</u>. Licensee shall grant, and hereby does grant, to Licensor, effective upon the effective date of such termination: (A) [***], and (B) [***], in each case under the preceding sub-clauses (A) and (B) solely to the extent reasonably necessary or useful for Licensor to [***].
- (iii) [***] Consideration. In consideration for the assignments, rights and licenses granted to Licensor pursuant to this Section 13.3, Licensor shall pay to Licensee a royalty on [***]. The Parties shall negotiate in good faith commercially reasonable [***] terms. For purposes of the foregoing, the definition of [***] in this Agreement shall be applied mutatis mutandis to [***]. Notwithstanding the terms of this Section 13.2(c), if any such [***] is subject to payment obligations to a Third Party, Licensee shall promptly disclose such obligations to Licensor in writing and such [***].
- (iv) <u>Trademark</u>. Licensee hereby assigns and shall cause to be assigned to Licensor all rights in and to any and all trademarks used in connection with [***]. It is understood that such assignment shall not include Licensee's name or trademark for Licensee's (or its Affiliates') company itself. Notwithstanding the foregoing, in the event of termination in one or more, but not all, countries, if Licensee will continue to use any such trademarks in countries as to which this Agreement has not been terminated, then in lieu of the foregoing assignment, Licensee hereby grants to Licensor an exclusive license to use such trademarks in connection with [***].
- (v) <u>Development</u>. If there are any ongoing clinical trials with respect to [***] at the time of notice of termination, at Licensor's request, Licensee agrees to [***]. Licensor [***] the costs of such transition except in the case of a termination for Default Notice / Breach of this Agreement pursuant to [***], in which case Licensee, the Breaching Party, [***] such costs.

- (vi) <u>Commercialization</u>. If this Agreement is terminated after achieving the Regulatory Approval of Product(s) [***], Licensee shall have the right, for a period of up to [***] months following such termination, to sell stocks of Product(s) on hand at the time of such termination. In addition, if reasonably requested by Licensor, Licensee agrees to continue to distribute existing stocks of Product(s) for which Regulatory Approval has been obtained prior to such termination at [***] cost, in accordance with, and subject to, the terms and conditions of this Agreement, for a period requested by Licensor, not to exceed [***] months from the effective date of such termination (the "<u>Wind-down Period</u>"), but in no event shall Licensor have the right to [***]. Within [***] days after the expiration of the Wind-down Period, Licensee shall notify Licensor of any quantity of Product(s) remaining in Licensee's inventory and Licensor shall have the option, upon notice to Licensee, to repurchase any such quantities of Product(s) from Licensee at a price equal to [***].
- (vii) <u>Sublicense</u>. Licensee's Sublicenses shall, [***]. In the event Licensor does not [***], then such Sublicenses shall be deemed to [***], and such Sublicenses shall be considered [***], provided that [***].
- (viii) <u>Transition Assistance</u>. Licensee agrees to fully cooperate with Licensor and its designee(s) to facilitate a smooth, orderly and prompt transition of [***]. Without limiting the foregoing [***].
- 13.4 <u>Survival.</u> Termination or expiration of this Agreement will not affect rights or obligations of the Parties under this Agreement that have accrued before the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions will survive any expiration or termination of this Agreement: <u>ARTICLE 1</u> (Definitions), <u>Section 3.1</u> (Exclusivity Covenant), <u>Section 8.7</u> (Records), <u>Section 8.8</u> (Audits), <u>Section 8.9</u> (Taxes), <u>Section 10.3(d)</u> (Transfer Restrictions), <u>ARTICLE 11</u> (Indemnification), <u>ARTICLE 12</u> (Confidentiality), <u>ARTICLE 13</u> (Term and Termination), <u>ARTICLE 14</u> (Dispute Resolution), and <u>ARTICLE 15</u> (Miscellaneous).

ARTICLE 14

DISPUTE RESOLUTION

14.1 <u>Arbitration</u>. In the event of any disputes, controversies or differences between the Parties arising out of, in relation to, or in connection with this Agreement, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the validity, construction, interpretation, enforceability, breach, performance, application, or termination of this Agreement ("<u>Dispute</u>"), then upon the written request of either Party, the Parties agree to meet and discuss in good faith an amicable resolution thereof, which good faith efforts include at least one (1) meeting between the most senior executive officer of Licensor and the chief executive officer of Licensee. If the Dispute is not resolved within [***] days following the written request for amicable resolution, then either Party may initiate arbitration under this <u>Section 14.1</u>. Any Dispute that the Parties do not resolve through amicable resolution will be settled by final, binding and conclusive arbitration administered by JAMS, Inc., the alternative dispute resolution company formerly known as Judicial Arbitration and Mediation Services, Inc., pursuant to its Comprehensive Arbitration Rules and Procedures then in effect (the "<u>JAMS Rules</u>"), except as otherwise provided. The number of the arbitrators will be three, with each Party selecting one arbitrator and those two arbitrators selected by the Parties

then selecting the third arbitrator. The arbitration will be conducted in New York, New York, U.S. The language of the arbitration will be in English. Judgment on the award may be entered in any court having jurisdiction and the Parties may file in a court of appropriate jurisdiction to enforce an arbitral award issued hereunder. Except as may be required by applicable Laws, neither Party may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both Parties.

- 14.2 <u>Equitable Relief.</u> Notwithstanding <u>Section 14.1</u>, each Party acknowledges that its breach of <u>ARTICLE 12</u> may cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated by damages in an action at law. By reason thereof, each Party agrees that the other Party may, in addition to any other remedies it may have under this Agreement or otherwise, seek preliminary and permanent injunctive and other equitable relief from any state or federal court of competent jurisdiction in New York, New York, U.S. to prevent or curtail any actual or threatened breach of <u>ARTICLE 12</u> that is reasonably likely to cause it irreparable harm. In addition, notwithstanding <u>Section 14.1</u>, to the fullest extent provided by Law, either Party may bring an action in any court of competent jurisdiction for injunctive relief (or any other provisional remedy) to protect a Party's rights or enforce a Party's obligations under this Agreement pending final resolution of any claims related thereto pursuant to the dispute resolution procedure set forth in <u>Section 14.1</u>.
- 14.3 <u>Governing Law.</u> This Agreement and all disputes arising out of or related to this Agreement or any breach hereof are governed by and construed under the Laws of the State of New York, U.S. without giving effect to any choice of law principles that would require the application of the Laws of a different state or country.
- 14.4 <u>Patent and Trademark Disputes</u>. Notwithstanding <u>Section 14.1</u>, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent or trademark rights outside the U.S. covering the Development, manufacture, use, import, export, offer for sale or sale or Commercialization of Product will be submitted to a court of competent jurisdiction in the country in which such Patent or trademark rights were granted or arose.

ARTICLE 15

MISCELLANEOUS

15.1 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, together with the Development Plan and any other documents delivered pursuant hereto or thereto, and any subsequent amendments of the same, set forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and their Affiliates with respect to the subject matter hereof and supersede, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to the subject matter of this Agreement other than as are set forth in this Agreement and the other documents referred to in the preceding sentence. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

- 15.2 Force Majeure. Both Parties will be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides written notice of the prevention to the other Party. Such excuse will continue for so long as the condition constituting force majeure continues and the non-performing Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure includes conditions beyond the reasonable control of the Parties, regardless of whether it could be anticipated or not, including an act of God, war, civil commotion, terrorist or criminal act, epidemic, pandemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, and storm or like natural catastrophe, or as otherwise defined or allowed pursuant to Governing Law. The Parties agree the effects of [***] may be invoked as a Force Majeure for the purposes of this Agreement [***]. The non-performing Party shall promptly notify in writing the other Party stating such Force Majeure, anticipated duration, and any action being taken to avoid or minimize its effects and shall promptly undertake commercially reasonable efforts necessary to cure such Force Majeure. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than [***] days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement to mitigate the delays caused by such force majeure.
- 15.3 <u>Notices</u>. Any notice required or permitted to be given under this Agreement will be in writing, will specifically refer to this Agreement, and will be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this <u>Section 15.3</u>, and will be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by email with non-automated confirmed read receipt or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Licensor: Voronoi Inc.

S 18th fl, Songdogwahak-ro 32, IT Center Yeonsu-gu, Incheon, Korea, 21984

Attn: [***] Email: [***]

With a copy to (which will not constitute notice):

Voronoi Inc.
S 18th fl, Songdogwahak-ro 32, IT Center
Yeonsu-gu, Incheon, Korea, 21984

Attn: [***] Email: [***] If to Licensee:

Brickell Biotech, Inc. 5777 Central Avenue Boulder, CO 80301

Attn: Aron Aizenstat, Senior Director, Corporate Development

Email: [***]

With copies to (which will not constitute notice):

Brickell Biotech, Inc. 5777 Central Avenue Boulder, CO 80301

Attn: David McAvoy, General Counsel

Email: [***]

and

Faegre Drinker Biddle & Reath LLP 2200 Wells Fargo Center, 90 S. 7th Street Minneapolis, MN 55402 Attn: Jonathan Zimmerman

Email: [***]

15.4 No Strict Construction; Interpretation; Headings. The language in this Agreement is to be construed in all cases according to its fair and reasonable meaning to effect the purpose of the Agreement. Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any gender applies to all genders. The word "or" is used in the disjunctive sense and the word "and" is used in the conjunctive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes", whether or not followed by "without limitation" or "including, but not limited to," or words of similar import, shall be construed to mean in each case including, without limitation" or "including, but not limited to" in some instances but not others. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Laws will be construed as referring to such Laws as from time to time enacted, repealed or amended, (iii) any reference to any person will be construed to include the person's successors and permitted assigns, (iv) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (v) any reference to the words "mutually agree" or "mutual written agreement" will not impose any obligation on either Party to agree to any terms relating thereto or to engage in

discussions relating to such terms except as such Party may determine in such Party's sole discretion, (vi) all references to Sections, Exhibits or Schedules will be construed to refer to Sections, Exhibits and Schedules to this Agreement, (vii) the word "days" means calendar days unless otherwise specified, and (viii) the words "copy" and "copies" and words of similar import when used in this Agreement include, to the extent available, electronic copies, files or databases containing the information, files, items, documents or materials to which such words apply. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

- 15.5 <u>Assignment</u>. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party's consent to its Affiliates or to a Third Party successor or transferee to all or substantially all of the assets of such Party to which this Agreement relates (such Third Party, an "<u>Acquiror</u>"), whether in a merger, sale of stock, sale of assets or other transaction. Any successor or assignee of rights or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights or obligations; *provided* that in the case of an assignment to an Affiliate, the assigning Party shall remain primarily liable for performance under this Agreement. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this <u>Section 15.5</u> is null, void and of no legal effect.
- 15.6 <u>Performance by Affiliates</u>. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement is a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.
- 15.7 <u>Further Assurances and Actions</u>. Each Party, upon the request of the other Party, whether before or after the Effective Date and without further consideration, will do, execute, acknowledge, and deliver or cause to be done, executed, acknowledged or delivered all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney, instruments and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement, and to do all such other acts, as may be necessary or appropriate to carry out the purposes and intent of this Agreement. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings in a timely manner and to take such other actions as may be reasonably necessary to consummate or implement expeditiously the transactions contemplated by this Agreement.

- 15.8 <u>Severability</u>. Each of the provisions contained in this Agreement will be severable, and the unenforceability of one will not affect the enforceability of any others or of the remainder of this Agreement. If any one or more of the provisions of this Agreement, or the application thereof in any circumstances, is held to be invalid, illegal, or unenforceable in any respect for any reason, the Parties will negotiate in good faith with a view to the substitution therefor of a suitable and equitable solution to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid provision; *provided*, *however*, that the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions of this Agreement will not be in any way impaired thereby, it being intended that all of the rights and privileges of the Parties hereto will be enforceable to the fullest extent permitted by Law.
- 15.9 No Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver, delay or the failure of any Party to enforce or exercise any term, condition or part of this Agreement at any time or in any one or more instances will not be deemed to be or construed as a waiver of the same or any other term, condition or part, nor will it forfeit any rights, power or privilege to future enforcement thereof. No single or partial exercise of any right, power or privilege will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. No waiver that may be given by a Party will be applicable except in the specific instance for which it is given. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.
- 15.10 Relationship of the Parties. Neither Party will have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party will have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Licensor's legal relationship to Licensee under this Agreement will be that of independent contractor and nothing in this Agreement gives either Party the power or authority to act for, bind, or commit the other Party in any way. This Agreement is not a partnership agreement. Nothing in this Agreement will be construed to establish a relationship of partners, principal and agent or joint venturers between the Parties or their respective employees, Affiliates or sublicensees. Nothing contained in this Agreement shall be construed to create a "separate entity" or "business entity" within the meaning of the U.S. Internal Revenue Code or the regulations thereunder and any foreign equivalents thereto. Neither Licensee nor Licensor will make any statements, representations, or commitments of any kind, or to take any action that is binding on the other, without the prior written consent of the other Party to do so.
- 15.11 English Language. This Agreement was prepared in the English language, which language governs the interpretation of, and any dispute regarding, the terms of this Agreement.

- 15.12 <u>Counterparts</u>. This Agreement may be executed in one or more counterparts, each of which is an original, but all of which together constitute one and the same instrument.
- 15.13 <u>Schedules and Exhibits</u>. The disclosure of any matter in any Section of or on any Schedule or Exhibit to this Agreement will only be deemed to be a disclosure for the Section or subsection of this Agreement to which it corresponds in number, unless the applicability of such Schedule or Exhibit to any other Section is readily apparent. The disclosure of any matter in any Schedule or Exhibit to this Agreement will expressly not be deemed to (a) constitute an admission by either Party hereto, or (b) imply that any such matter is material for purposes of this Agreement.
- 15.14 <u>Expenses</u>. Each of the Parties will bear its own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement and, except as set forth in this Agreement, the performance of the obligations contemplated hereby and thereby.
- 15.15 Section 365(n). The Parties acknowledge and agree that the licenses granted by the Parties pursuant to Article 2 and all other rights granted under or pursuant to this Agreement are, for purposes of Section 365(n), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code (or analogous foreign provisions), and that this Agreement is an executory contract governed by Section 365(n) if a bankruptcy proceeding is commenced involving either Party (as licensor hereunder). Licensee, as the licensee of such rights under Article 2, retains and may fully exercise all of its rights and elections under the Bankruptcy Code. The foregoing provisions of this Section 15.15 are without prejudice to any rights the Parties may have arising under the Bankruptcy Code or other applicable Laws.

[Remainder of this page intentionally left blank]

VORONOI INC.	BRICKELL BIOTECH, INC.
By: /s/ [***]	By: /s/ Robert Brown
Name: [***]	Name: Robert Brown
Title: [***]	Title: Chief Executive Officer
SIGNATURE PAGE TO LICEN	NSE AND DEVELOPMENT AGREEMENT

In Witness Whereof, the Parties hereto have caused this Agreement to be executed by their duly authorized officers as of the Effective

EXHIBIT A

LICENSOR SERIES A PATENTS

No.	Patent Application No.	Filing Date	Applicant	
[***]	[***]	[***]	[***]	
[***]	[***]	[***]	[***]	

EXHIBIT B

LICENSOR SERIES B PATENTS

No.	Patent Application No.	Filing Date	Applicant
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

EXHIBIT C

PRINCIPAL LICENSE AGREEMENT

[***]

EXHIBIT D

CHEMICAL STRUCTURE OF VRN024219

[***]

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EXHIBIT E

DESCRIPTION OF [***] PLATFORM

[***]

EXHIBIT F

MATERIALS TO BE TRANSFERRED TO LICENSEE

[***]

[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
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[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]



Brickell Biotech Acquires Exclusive Rights to Phase 1-Ready DYRK1A Inhibitor Program and Novel Platform Targeting Autoimmune and Inflammatory Diseases

Expect to initiate Phase 1 clinical study of lead DYRK1A inhibitor program, BBI-02, a potential first-in-class oral treatment for autoimmune and inflammatory diseases, in 2022

Acquisition includes rights to platform of DYRK1A inhibitors with potential to create next generation kinase inhibitors (NCEs) targeting neuroinflammatory and other autoimmune diseases

Newly appointed Chief Medical Officer to lead the development strategy for DYRK1A inhibitor pipeline

Management to host investor call today at 8:30 AM ET

BOULDER, CO — September 1, 2021 — Brickell Biotech, Inc. ("Brickell" or the "Company") (Nasdaq: BBI), a clinical-stage pharmaceutical company striving to transform patient lives by developing innovative and differentiated prescription therapeutics for the treatment of dermatologic, autoimmune and other debilitating diseases, today announced it has entered into a definitive agreement with Voronoi Inc., a platform-based drug discovery company in South Korea dedicated to developing new kinase inhibitors, that grants Brickell exclusive, worldwide rights to research, develop and commercialize novel therapeutics generated from a proprietary DYRK1A inhibitor platform. These novel DYRK1A inhibitors aim to restore immune balance in patients whose immune system has become dysregulated, thus offering large potential across a wide array of autoimmune and inflammatory diseases.

"Recent studies linking DYRK1A to central pathways of inflammation, such as T_H17/T_{REG} differentiation, point to it being an important new druggable target in autoimmune diseases like atopic dermatitis and rheumatoid arthritis. Additional potential applications include type 1 diabetes, given DYRK1A also controls islet beta cell proliferation, as well as precision medicine strategies," states Dr. Bernard Khor, MD, PhD, Principal Investigator and Assistant Member at the Benaroya Research Institute for Translational Medicine and Affiliated Assistant Professor at the University of Washington. "Based on the promising preclinical efficacy data generated to date with Brickell's novel DYRK1A inhibitor programs, this platform has the potential to offer first-in-class, new and potent therapies for many different types of autoimmunity and inflammation."

The initial lead program that Brickell will be advancing is BBI-02, a Phase 1-ready, highly selective and orally bioavailable DYRK1A inhibitor that has demonstrated compelling results in various preclinical models, including of atopic dermatitis and rheumatoid arthritis. In these models, BBI-02 showed encouraging decreases in disease severity and reduction of pro-inflammatory cytokines compared to current standard-of-care agents, such as JAK inhibitors and anti-TNF biologics. Notably, many current therapies for autoimmune disorders are broadly immunosuppressant, which may lead to severe side effects, such as increased infection risk. In contrast, preclinical data have shown BBI-02 to drive regulatory T-cell differentiation while dampening pro-inflammatory T_H17 cells and MyD88/IRAK4-related signaling pathways. Unlike many existing therapies, as well as those currently being investigated, BBI-02 has the ability to target both the adaptive and innate immune imbalance simultaneously, ultimately resulting in the potential restoration of immune homeostasis that would represent a paradigm shift in the treatment of certain autoimmune and inflammatory diseases.

"Today marks a pivotal day in the Company's evolution, as we strengthen our position in dermatology while simultaneously broadening our strategic focus by expanding our pipeline with a Phase 1-ready DYRK1A inhibitor and cutting-edge platform. As we build out our long-term growth strategy, we believe this platform has the potential to create first-in-class therapeutics for the treatment of a wide array of autoimmune and neuroinflammatory disorders," commented Robert Brown, Chief Executive Officer of Brickell. "We also announced today the appointment of a seasoned clinical executive and expert in immunologic disease, Dr. Monica Luchi, as our Chief Medical Officer to lead the development strategy of this exciting pipeline of DYRK1A inhibitors. With her guidance and the completion of this acquisition, we intend to progress BBI-02 into a Phase 1 clinical study in 2022. In addition, over the course of the next year, our team expects to conduct formulation development activities for BBI-03, a topically applied preclinical DYRK1A inhibitor, and to select and initiate development of a lead next generation DYRK1A inhibitor for the potential treatment of neuroinflammatory diseases. Ultimately, this acquisition allows us to enter an innovative emerging field of restoring immune balance with a novel and differentiated approach that we believe will enable Brickell to help improve millions of patient lives while building substantial value for our shareholders," concluded Mr. Brown.

"We are excited to announce the partnering of our novel DYRK1A inhibitor platform with Brickell," said Daekwon Kim, Chief Executive Officer of Voronoi. "We have the utmost confidence in the Brickell team's broad clinical development and partnering experience. This is evidenced by Brickell's advancement of sofpironium bromide in primary axillary hyperhidrosis from early preclinical through Phase 3 studies in the U.S., and the commercial launch in Japan via their current partnership with Kaken Pharmaceutical. Building on the significant investment we've made in the DYRK1A inhibitor programs to-date, we believe Brickell is the right company to maximize the global value of this platform in autoimmune and neuroinflammatory diseases, while we focus on the development of our other core kinase inhibitor programs in the field of precision oncology."

Transaction Terms

Under the terms of the license agreement, in exchange for an exclusive, worldwide license to develop and commercialize compounds from Voronoi's DYRK1A inhibitor platform, Brickell will make a one-time payment to Voronoi of \$2.5 million in cash and \$2.5 million in shares of Brickell common stock. The number of shares to be issued to Voronoi is based on a price of \$0.89 per share, representing a premium of 35% to the trailing 10-day volume weighted average trading price. In addition, Brickell will pay Voronoi success-based development, regulatory and sales milestone payments of up to \$211.0 million with respect to BBI-02 and BBI-03. For the first next generation product arising from the DYRK1A inhibitor platform, Brickell will pay Voronoi success-based development, regulatory and sales milestone payments of up to \$107.5 million. Brickell will also pay Voronoi tiered royalty payments ranging from low single digits up to 10% of net sales of products arising from the DYRK1A inhibitor platform. Brickell will be responsible for all future development activities and expenses related to the DYRK1A inhibitor platform. RM Global Partners LLC served as an advisor to Brickell on this transaction.

Conference Call and Webcast Information

Brickell's management will host a conference call today at 8:30 a.m. ET to discuss the license agreement with Voronoi Inc. and the Company's strategic expansion. The dial-in number for the conference call is 1-877-705-6003 for domestic participants and 1-201-493-6725 for international participants, with Conference ID #13722799. A live webcast of the conference call can be accessed at https://www.brickellbio.com. A replay will be available on this website shortly after conclusion of the event for approximately 90 days.

About Brickell

Brickell Biotech, Inc. is a clinical-stage pharmaceutical company striving to transform patient lives by developing innovative and differentiated prescription therapeutics for the treatment of dermatologic, autoimmune and other debilitating diseases. Brickell's pipeline combines a potential best-in-class, late clinical-stage program for hyperhidrosis with a novel, cutting-edge platform and development stage candidates with broad potential in autoimmune and neuroinflammatory disorders. Brickell's executive management team and board of directors bring extensive experience in product development and global commercialization, having served in leadership roles at large global pharmaceutical companies and biotechs that have developed and/or launched successful products, including several that were first-in-class and/or achieved iconic status, such as Cialis®, Taltz®, Gemzar®, Prozac®, Cymbalta® and Juvederm®. Brickell's strategy is to leverage this experience to in-license, acquire, develop and commercialize innovative and differentiated pharmaceutical products that Brickell believes can meaningfully benefit patients who are suffering from chronic debilitating diseases that are underserved by available therapies. For more information, visit https://www.brickellbio.com.

About Voronoi

Voronoi Inc., located in Bio-Cluster in Incheon, South Korea, is a company with global competitiveness in the field of precision medicine targeted treatments. Voronoi has dramatically shortened the development timeline by combining proprietary artificial intelligence (AI) into the entire process of new drug development. The Company has eleven pipelines and is currently negotiating out-licensing arrangements with a number of domestic and overseas pharmaceutical companies regarding these core pipelines, of which the Brickell deal is one such priority. Voronoi has recently been recognized for its technology and business development capabilities through the recent out-licensing of an innovative non-small cell lung cancer investigational treatment to ORIC Pharmaceutical, a Nasdaq-listed company, and global partnership with inno.N for its selective rearranged during transfection (RET) anti-cancer therapy, For more information, visit https://voronoi.io/ko/

Cautionary Note Regarding Forward-Looking Statements

Any statements made in this press release relating to future financial, business and/or research and clinical performance, conditions, plans, prospects, trends, or strategies and other such matters, including without limitation, the anticipated timing,

scope, design and/or results of ongoing and future pre-clinical and clinical trials, intellectual property rights, including the validity, term and enforceability of such, the expected timing and/or results of regulatory approvals and size and prospects for commercializing any of Brickell's product candidates, or research collaborations with its partners, including in Japan, Korea, the United States or any other country, are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "would," "should," "might," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "look forward" and similar expressions and their variants, as they relate to Brickell, Kaken, Voronoi, or any of Brickell's partners, may identify forward-looking statements. Brickell cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time, often quickly and in unanticipated ways. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including without limitation, research results and data that do not meet targets or expectations, ability to obtain adequate financing to advance product development, ability to maintain and enforce intellectual property rights, potential delays for any reason in product development and clinical trial enrollment, regulatory changes, supply chain disruptions, unanticipated demands on cash resources, any disruption to its business caused by the current COVID-19 pandemic, interruptions, disruption or inability by Kaken or Voronoi to supply and commercialize research material and/or the product in Japan or Korea, as applicable, or obtain or retain adequate pricing or reimbursement, the outcome of Brickell's ongoing U.S. Phase 3 pivotal program on sofpironium br

Further information on the factors and risks that could cause actual results to differ from any forward-looking statements are contained in Brickell's filings with the United States Securities and Exchange Commission (SEC), which are available at https://www.sec.gov (or at https://www.brickellbio.com). The forward-looking statements represent the estimates of Brickell as of the date hereof only, and Brickell specifically disclaims any duty or obligation to update forward-looking statements.

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