UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): **December 18, 2019**

Onconova Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**001-36020**	**22-3627252**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

375 Pheasant Run
Newtown, PA 18940
(267) 759-3680
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Not Applicable
(Former name or former address, if changed since last report)

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

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

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

Emerging growth company ☐

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

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 $.01 per share	ONTX	The Nasdaq Stock Market LLC
Warrants to purchase common stock	ONTXW	The Nasdaq Stock Market LLC

Item 1.01. Entry into a Material Definitive Agreement

Distribution, License and Supply Agreement

On December 18, 2019 (the "Effective Date"), Onconova Therapeutics, Inc. (the "Company") entered into a Distribution, License and Supply Agreement (the "License Agreement") with Specialised Therapeutics Asia Pte. Ltd. ("Licensee"). Under the terms of the License Agreement, the Company granted Licensee (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and manufacture any product (the "Licensed Product") containing rigosertib for Australia and New Zealand (the "Territory") and in human uses (the "Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to commercialize the Licensed Product in the Territory and in the Field.

Licensee has also agreed to obtain from the Company all of Licensee's requirements of the Licensed Products for the Territory, and the Company has agreed to supply Licensee with all of its requirements of the Licensed Products. The Company may, at its discretion, use the services of a contract manufacturer to manufacture and package the Licensed Products.

The Company may be entitled to receive clinical, regulatory and sale-based milestone payments up to $30.4 million. The Company may also be entitled to receive tiered double-digit royalties based on net sales in the Territory.

The License Agreement is for a term of 15 years from the launch on a country by country basis in the Territory and contains customary provisions for termination by either party in the event of breach of the License Agreement by the other party (subject to a cure period), bankruptcy of the other party, or challenges to the patents by any sublicensee or assignee.

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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit
10.1*	Distribution, License and Supply Agreement, dated as of December 18, 2019, by and between Onconova Therapeutics, Inc. and Specialised Therapeutics Asia Pte. Ltd.
99.1	Press release dated December 18, 2019

* Portions of the exhibit have been omitted.

EXHIBIT INDEX

Exhibit No.	Exhibit
10.1*	Distribution, License and Supply Agreement, dated as of December 18, by and between Onconova Therapeutics, Inc. and Specialised Therapeutics Asia Pte. Ltd.
99.1	Press release dated December 18, 2019

* Portions of the exhibit have been omitted.

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.

Dated: December 19, 2019

Onconova Therapeutics, Inc.

By: /s/ Mark Guerin
Name: Mark Guerin
Title: Chief Financial Officer

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

DISTRIBUTION, LICENSE AND SUPPLY AGREEMENT

by and between

Onconova Therapeutics, Inc.

and

Specialised Therapeutics Asia Pte. Ltd.

DATE: December 18, 2019

DISTRIBUTION, LICENSE AND SUPPLY AGREEMENT

THIS AGREEMENT, effective December 18, 2019, by and between **ONCONOVA THERAPEUTICS, INC.**, a corporation formed under the laws of Delaware ("**Licensor**") and **SPECIALISED THERAPEUTICS ASIA PTE. LTD.**, a corporation incorporated under the laws of Singapore ("**Licensee**").

RECITALS

WHEREAS Licensor owns or licenses all right, title and interest in and to certain patents, trademark(s) and Know-How relating to rigosertib;

WHEREAS Licensor is willing to grant to Licensee and Licensee wishes to accept an exclusive license from Licensor to develop and Commercialize the Licensed Products in the Territory;

WHEREAS Licensee wishes to procure the Licensed Products from Licensor and Licensor wishes to supply the Licensed Products to Licensee;

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

1. DEFINITIONS

1.1 **Definitions.** The following terms as used hereinafter in this Agreement shall have the meaning set forth in this Section:

"**Adverse Drug Reaction**" means a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment, or prevention of a disease or the modification of an organic function.

"**Adverse Drug Event**" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

"**Affiliate**" means any corporation, firm, partnership or other entity that directly or indirectly controls, is controlled by or is under common control with a Party, with "control" meaning ownership of greater than fifty percent (50%) of the voting stock or other voting interests in the Party or the right to receive over fifty percent (50%) of the profits or earnings of the Party. Such other relationship as in fact results in actual control over the management, business, and affairs of a Party shall also be deemed to constitute control.

"**Agreement", "hereto", "hereunder", "herein"** and similar expressions mean this Distribution, License and Supply Agreement.

"**Applicable Laws**" means any law, regulation, rule, guidance, order, judgment or decree having the force of law in the Territory.

"**Business Day**" means any day other than (i) Saturday or Sunday or (ii) a day that is a legal holiday in either of Australia or Singapore or Newtown, Pennsylvania or (iii) any other day on which banks in either of Australia or Singapore or Newtown, Pennsylvania, are required to be closed.

"**Calendar Quarter**" means the three (3) month periods ending on March 31, June 30, September 30 and December 31 in each Calendar Year; provided, however, that the first Calendar Quarter shall begin on the Effective Date and end on the last day of the calendar quarter during which the Effective Date occurs.

"**Calendar Year**" means, in respect of any particular year, the one (1) year period beginning on January 1 and ending on December 31; provided, however, that the first Calendar Year shall begin on the Effective Date and end on December 31 of the calendar year during which the Effective Date occurs.

"**Commercial Sale**" means any shipment of the Licensed Products in the Territory following receipt of Regulatory Approval pursuant to an arm's length sale by Licensee or its Affiliates, sublicensees or assignees to a Third Party.

"**Commercialize**" means marketing, using, distributing, promoting, offering for sale, and selling the Licensed Products. For clarity, "Commercialization" shall not include any activities related to clinical research, manufacturing or development of the Licensed Product.

"**Compound**" shall mean rigosertib, having the chemical structure set forth in Schedule 1.1, including any and all salt, free acid/base, solvate, hydrate, pro-drug, stereoisomer, and enantiomer thereof, and polymorphic forms thereof.

"**Cost of Goods**" means, with respect to the Licensed Products, the production cost of such Licensed Products (for the avoidance of doubt, including, without limitation, manufacturing oversight, freight, shipping, insurance and quality assurance) calculated in accordance with internal cost accounting methods consistently applied by Licensor for its other similar pharmaceutical products; provided, that such methods comply with IFRS or U.S. generally accepted accounting principles, as applicable. Cost of Goods shall include direct labor, direct materials (including taxes and duties), but exclude corporate administrative overhead, any costs associated with excess capacity, any royalties or license fees payable to Third Parties and any other indirect costs. Notwithstanding the foregoing, in the event a Licensed Product is manufactured by a Third Party supplier and procured by Licensor, the "Cost of Goods" shall include the costs charged for such Licensed Product by such Third Party supplier to Licensor.

"**Effective Date**" means the date specified in the initial paragraph of this Agreement.

"**Field**" means human use.

"**Force Majeure**" has the meaning set forth in Section 14.6.

"GMP" means good manufacturing practices as required under the rules of the applicable Governmental Authority in the Territory.

"**Governmental Authority**" means any federal, state, provincial, or municipal government body, commission, agency, board, court or tribunal in the Territory and having jurisdiction in the particular circumstances.

"**IFRS**" means, at any time, the International Financial Reporting Standards, promulgated by the International Accounting Standards Board, as amended, supplemented or replaced from time to time.

"**Improvements**" means any new dosage strengths, reformulations, line extensions or other advances in, modifications or improvements to a Licensed Product, as applicable.

"**Inability to Supply**" means either a Long Term Inability to Supply or a Short Term Inability to Supply and means both a Long Term Inability to Supply and a Short Term Inability to Supply collectively.

"**Initial Term**" has the meaning set forth in Section 11.1.

"**Know-How**" means all scientific, technical, manufacturing, marketing, production, sales and other information relating to the Licensed Products that is known to or controlled by Licensor and which is reasonably necessary for the Commercialization of the Licensed Products in accordance with the terms of this Agreement.

"**Launch**" means the date of the first Commercial Sale in each country of the Territory of the applicable Licensed Product.

"**Licensor Indemnified Party**" has the meaning set forth in Section 10.6.

"**Licensor Marks**" means any marks Licensor may adopt for use for the Licensed Products, as listed in Exhibit A.

"**Licensor Patents**" means all patents in the Territory, including patent applications, continuations, divisional patents, re-examined patents, reissued patents, and foreign equivalents thereof, that are owned by or licensed to Licensor which claim inventions reasonably necessary for the Commercialization of the Licensed Products in the Territory, including those listed in Exhibit B.

"**Licensed Products**" means each of any product containing a Compound and all Improvements thereto.

"**Long Term Inability to Supply**" shall mean the inability to supply, including for reason of a non-conformity of the Licensed Products, at least seventy percent (70%) of the volumes of a Licensed Product indicated in the current forecast that exceeds one hundred and twenty (120) days or more than one Short-Term Inability to Supply in a period of twelve (12) months.

"**Licensee Indemnified Party**" has the meaning set forth in Section 10.5.

"**Net Sales**" Net Sales" means, with respect to any period, the gross amount billed or invoiced on sales of the Licensed Product during such period anywhere in the Territory by Licensee or any of its Affiliates or sublicensees or assignees (or permitted distributors) to unaffiliated Third Parties in bona fide arm's length transactions, less the following deductions, in each case to the extent reasonable and customarily provided to unaffiliated entities and actually allowed and taken with respect to such sales:

i. actual credits, price adjustments or allowances for damaged products, returns or rejections of the Licensed Product in accordance with Licensee's returned goods policy;
ii. normal and customary trade, cash and quantity discounts, allowances and credits (other than price discounts granted at the time of invoicing which have already been included in the gross amount invoiced);
iii. chargeback payments, repayments and rebates (or the equivalent thereof) granted to or imposed by group purchasing organizations, managed health care organizations or federal, state/provincial, local and other governments, including any or all of their regulatory authorities, agencies, review boards or tribunals, or trade customers;
iv. sales, value-added (to the extent not refundable in accordance with applicable law), and excise taxes, tariffs and duties, and other taxes directly related to the sale (but not including taxes assessed against the income derived from such sale);
v. outbound freight, shipment and insurance costs incurred by Licensee to sell the Licensed Product to the extent included in the price and separately itemized;
vi. quality and stability costs; and
vii. stocking allowances.

Net Sales shall include (a) any named patient sales following first regulatory approval in Australia, if applicable, and (b) the amount or fair market value of all other consideration received by Licensee or any of its Affiliates or sublicensees or assignees (or permitted distributors) in respect of sales of the Licensed Product, whether such consideration is in cash, payment in kind, exchange, or other form. Net Sales shall not include sales between or among Licensee or any of its Affiliates or sublicensees or assignees (or permitted distributors) unless any such associated party is the end user. Subject to the above, Net Sales shall be calculated in accordance with the standard internal policies and procedures of Licensee, which shall at all times be in accordance with IFRS, consistently applied.

"**NZ Health**" means the New Zealand Ministry of Health and any successor Governmental Authority having substantially the same function.

"**Party**" means either Licensor or Licensee and "**Parties**" means both Licensor and Licensee.

"**PBS**" means The Pharmaceutical Benefits Scheme of the Australian Government Department of Health.

"**PHARMAC**" means the Pharmaceutical Management Agency, the New Zealand government agency that decides which medicines and medical devices are funded in New Zealand.

"**Prices and Payments**" has the meaning set forth in Section 6.

"**Regulatory Approval**" means any and all approvals, marketing authorizations, registrations and licenses (including amendments and supplements thereto) necessary from a Governmental Authority for the Commercialization or manufacture of the Licensed Products in or for the Territory.

"**Regulatory Submissions**" means all applications, filings, dossiers and the like submitted to a Governmental Authority for the purpose of obtaining Regulatory Approval.

"**Renewable Term**" has the meaning set forth in Section 11.1.

"**Sales-Related Payments**" means any sales-related payments received by Licensee or any of its Affiliates or assignees from sublicensing its rights under this Agreement.

"**SDEA**" means the Safety Data Exchange Agreement to be entered into by the Parties within ninety (90) days after the Effective Date.

"**Short Term Inability to Supply**" shall mean the inability to supply, including for reason of a non-conformity of the Licensed Products, at least seventy percent (70%) of the volumes of a Licensed Product indicated in the current forecast that continues for more than sixty (60) days but less than one hundred and twenty (120) days.

"**Specifications**" means the finished product specifications for each Licensed Product as required by the applicable Regulatory Approval and as may be modified from time to time in accordance with Regulatory Approval.

"**Sublicense Revenue**" means (i) any upfront payments and development, regulatory, and sales milestone payments or other payments received by Licensee or any of its Affiliates in connection with any sublicense of its rights (or any option thereto) or assignment of its rights (or any option thereto) under this Agreement and (ii) premiums paid by a Third Party in excess of the fair market value for purchase of Licensee's securities sold in connection with any sublicense or assignment of rights under this Agreement. For the avoidance of doubt, Sublicense Revenue shall not include Royalty Revenue, or any amounts included in Net Sales, but in the case of any non-cash consideration, shall include at the election of Licensee, such non-cash consideration or the fair market value thereof on the date of payment to Licensee.

"**Supply Price**" has the meaning set forth in Section 6.4.

"Term" has the meaning set forth in Section 11.1**.**

"Territory" means Australia and New Zealand.

"**Third Party**" means any person other than the Parties and their Affiliates.

"**TGA**" means Therapeutics Goods Administration of Australian Department of Health and any successor Governmental Authority having substantially the same function.

1.2 **Other Definitional and Agreement References**. References to any agreement, contract, statute, act, or regulation are to that agreement, contract, statute, act, or regulation as amended, modified or supplemented from time to time in accordance with the terms hereof and thereof.

1.3 **Ambiguities**. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

1.4 **Sections and Headings**. The term "Section" refers to the specified Section of this Agreement, unless otherwise specified. Headings and captions of the Sections hereof are for convenience only and are not to be used in the interpretation of this Agreement.

1.5 **U.S. Dollars**. References in this Agreement to "Dollars" or "$" shall mean the legal tender of the United States, unless otherwise noted.

1.6 **Date References**. References from or through any date mean, unless otherwise specified, from and including or through and including, respectively.

1.7 **Gender**. Words of one gender include the other gender.

1.8 **Include, Includes, Including**. Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import.

1.9 **Solidary Obligations**. Unless specified otherwise in this Agreement, the obligations of any Party consisting of more than one person are solidary (joint and several).

1.10 **No Strict Construction**. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

1.11 **Number of Days**. Whenever this Agreement refers to a number of days, unless otherwise specified, such number shall refer to calendar days.

1.12 **Party References**. Reference to any Party includes the successors and permitted assigns of that Party.

1.13 **Singular/Plural**. Words using the singular or plural number also include the plural or singular number, respectively.

2. GRANT OF RIGHTS

2.1 **License**. Subject to the terms of this Agreement, Licensor, on behalf of itself and its Affiliates, hereby grants to Licensee and Licensee hereby accepts (a) a non-exclusive (including with regards to Licensor and its Affiliates), royalty-bearing license (or sub-license) under the Licensor Patents, the Licensor Marks, and Know How to develop and manufacture (subject to Section 8.18(b)) the Licensed Products for the Territory and in the Field and (b) an exclusive (including with regards to Licensor and its Affiliates), royalty-bearing license (or sub-license) under the Licensor Patents, the Licensor Marks, and Know How to Commercialize the Licensed Products in the Territory and in the Field.

2.2 **Sublicensing**. Licensee may sublicense its rights granted hereunder or use sub-distributors or third party service providers to exercise its right or fulfill its obligations hereunder subject to Licensor's prior written consent (not to be unreasonably withheld, conditioned or delayed). All sublicense agreements, distribution or other arrangements or agreements shall be consistent with the terms and conditions of this Agreement, and Licensee assumes full responsibility for any actions taken by any sublicensee, distributor or other party and any of the expenses, costs, or fees incurred by any sublicensee, distributor or other party. Licensee shall provide a written copy of any sublicensing or distribution agreements to the Licensor, which copy may be redacted to remove sensitive information not necessary to confirm the sublicensee's compliance with the terms and conditions set forth herein.

2.3 **No Implied Licenses**. Neither Party grants to the other Party any right or license to use any of its intellectual property, Know-How or other proprietary information, materials or technology, or to practice any of its patent, trademark, or trade dress rights, except as expressly set forth in this Agreement.

2.4 **Restriction on Licensee Sales**. Licensee shall not: (i) knowingly solicit or accept orders for distribution of Licensed Products to a Third Party outside the Territory; (ii) knowingly distribute any Licensed Products for sale or use outside the Territory; or (iii) supply any Third Party that has distributed or offered to distribute Licensed Products outside the Territory after Licensee has actual knowledge that said Third Party has distributed or offered to distribute Licensed Products obtained from Licensee outside of the Territory.

2.5 **Restriction on Licensor Sales.** Licensor shall not: (i) knowingly solicit or accept orders for distribution of Licensed Products to a Third Party for sale or distribution in the Territory; (ii) knowingly distribute any Licensed Products for sale or use in the Territory; or (iii) supply any Third Party that has distributed or offered to distribute Licensed Products in the Territory after Licensor has actual knowledge that said Third Party has distributed or offered to distribute Licensed Products obtained from Licensor in the Territory.

2.6 **Performance by Affiliates**. The Parties agree that their respective rights and obligations may be exercised or performed by any of their Affiliates; provided, however, that each Party shall be fully responsible and liable for the actions of such Affiliates in the performance of such obligations and shall ensure that such Affiliate complies with the terms of this Agreement. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against an Affiliate, for any obligation or performance hereunder prior to proceeding directly against such Party.

3. REGULATORY AND DEVELOPMENT

3.1 **Regulatory Submissions**. Licensee shall be solely responsible, at its expense, for preparing, filing, and managing any Regulatory Submission and for maintaining any Regulatory Approval for the Licensed Products in the Territory. Licensor shall provide required documents to Licensee in making submissions to Governmental Authorities and maintaining such Regulatory Approvals. Unless otherwise required by Applicable Law, any Regulatory Approvals shall be filed, owned and held in the name of Licensee. Licensee shall notify Licensor of all Regulatory Submissions that it submits.

3.2 **Regulatory Correspondence**. Each Party shall promptly (and in any event, within five (5) Business Days of the date of receipt of notice) notify the other Party in writing of, and shall provide the other Party with copies of, any material correspondence received from a Governmental Authority in the Territory. In the event that a Party receives any material regulatory letter requiring a response, the other Party will cooperate fully with the receiving Party in preparing such response and will promptly provide the receiving Party with any data or information required by the Receiving Party in preparing any such response.

3.3 **Other Covenants of Licensee**. In addition to its other obligations, commitments and undertakings set out in this Agreement, Licensee agrees to:

(a) assume all marketing, sales and distribution expenses related to the Commercialization of the Licensed Products in the Territory.

3.4 **Other Covenants of Licensor**. In addition to its other obligations, commitments and undertakings set out in this Agreement, Licensor agrees to:

(a) provide Licensee with all documentation relating to the submissions for Regulatory Approval to the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA) for the Licensed Products within three months of the Effective Date;

(b) provide Licensee with all documentation required for the submission for GMP approval;

(c) provide Licensee with required international pricing for the Licensed Products in the Patented Medicine Prices Review Board recognized countries in order for Licensee to be in compliance with applicable pricing regulations;

(d) where applicable, provide reasonable assistance to Licensee with the Regulatory Submission of the Licensed Products in the Territory;

(e) secure intellectual property protection in the Territory for the Licensed Products;

(f) assume the reasonable costs of intellectual property filings, procurement and maintenance for all intellectual property applications and registrations associated with the Licensed Products in the Territory;

(g) not assign the intellectual property associated with Licensed Products to any Third Party;

(h) promptly provide United States or other international marketing and sales materials used for the Licensed Products

3.5 **Rights of Reference to Regulatory Submissions**.

(a) Licensor hereby grants to Licensee a right of reference to all Regulatory Submissions filed by Licensor for development, manufacture or Commercialization of the Licensed Products solely for the purposes of manufacturing and development activities to obtain Regulatory Approval and Commercialization in the Field in the Territory.

(b) Licensee hereby grants to Licensor a right of reference to all Regulatory Submissions filed by Licensee in the Territory for development, manufacture or Commercialization of the Licensed Products in the Field in the Territory solely for the purposes of manufacturing and development activities to obtain Regulatory Approval and Commercialization outside the Territory.

4. TRADEMARKS

4.1 **Trade-Mark License**. Licensor hereby grants to Licensee, for the Term, an exclusive, royalty-free license to use the Licensor Marks in the Territory and Field in association with the Licensed Products; provided that, Licensee shall be entitled to Commercialize the Licensed Products in the Territory during the Term under its own trademark.

4.2 **Ownership**. Licensee acknowledges that the Licensor Marks are owned by Licensor. The Licensor Marks shall be and remain the sole and exclusive property of Licensor. Licensee shall not contest the ownership of the Licensor Marks or the validity of any registration relating thereto. Licensee agrees, at the request of Licensor, to execute any and all proper documents appropriate to assist Licensor in obtaining and maintaining Licensor's rights in and to the Licensor Marks.

4.3 **No Similar Mark**. Licensee will not, without Licensor's prior written consent, register or use in connection with any product, any trade-mark that is confusingly similar to the Licensor Marks.

5. COMMERCIALIZATION

5.1 **Safety Data Exchange Agreement**. The parties agree to develop and commit to a Safety Data Exchange Agreement ("**SDEA**") that allows them to fulfill their respective regulatory and pharmacovigilance obligations relating to Adverse Drug Event and Adverse Drug Reaction reporting. Such SDEA will be completed within [**] after filing of the first Regulatory Submission in the Territory.

5.2 **Quality Complaint Reporting.** Licensee shall be solely responsible for collecting and responding to any product quality complaint relating to the Licensed Products received from a customer in the Territory and resulting from use in the Field. Licensor shall investigate and provide Licensee, in a timely manner, with reports resulting from such investigations. If Licensor receives a product quality complaint relating to the Licensed Products from a customer in the Territory resulting from use in the Field, it shall investigate and promptly report the investigation results to Licensee, who will be solely responsible for communication and response, if any, to the customer in the Territory. Furthermore, Licensor shall be responsible for investigating and submitting reports to Licensee respecting any product quality complaints related to the manufacturing of the Licensed Products.

5.3 **Other Information**. In addition to the foregoing information to be provided, each Party shall provide to the other Party with any: (i) information relating to the efficacy and/or safety of the Licensed Products, including any recall of the Licensed Products; (ii) complaints from customers, healthcare professionals or competitors in the Territory relating to the Licensed Products; (iii) information relating to any potential liability to any Third Party in the Territory that is reasonably likely to arise for either Party in connection with the manufacture, or Commercialization of the Licensed Products in the Territory; (iv) information relating to any inspections, inquiries, issues raised or actions taken by any Governmental Authority in the Territory; and (v) any other information necessary or reasonably desirable to enable each Party to comply with any Applicable Law in the Territory or elsewhere.

5.4 **Recall**. Licensee shall advise Licensor of any Governmental Authority initiated mandatory recall of Licensed Products in the Territory. Licensee shall not initiate any voluntary recall of Licensed Products in the Territory without prior notice to and consultation with Licensor. Prior to executing any recall of Licensed Products in the Territory, Licensee shall review with Licensor the proposed manner in which the recall is to be carried out. Licensee will give due consideration to any reasonable recommendation from Licensor as to the manner of conducting the recall, provided that it is agreeable to the applicable Governmental Authority. Licensee shall communicate directly with the applicable Governmental Authorities in relation to a Licensed Products recall in the Territory. If any Licensed Products recall in the Territory results from improper handling, shipping or storage of Licensed Products by Licensee, and in no way results from the manufacture, control, handling, shipping or storage of the Licensed Products before receipt by Licensee, the costs associated with the recall shall be paid by Licensee and Licensee shall indemnify Licensor against any Third Party claims in connection with the recall. If the recall results from any cause or issue other than ones for which Licensee is responsible as set forth in the prior sentence and in no way results from the control, handling, shipping or storage of the Licensed Products after receipt by Licensee, all costs and expenses arising from the recall, including any costs associated with replacing recalled Licensed Products, shall be paid for by Licensor and Licensor shall indemnify Licensee against any Third Party Claims in connection therewith.

6. PRICES AND PAYMENTS

6.1 **Event-Based Milestone Payments**.

(a) Licensee will pay Licensor a one-time, non-refundable, non-creditable fee of $50,000 (Fifty Thousand U.S. dollars) within ten (10) Business Days after the Effective Date by wire transfer of immediately available funds into an account designated by Licensor.

(b) Licensee will pay Licensor the following one-time, non-refundable, non-creditable payments by wire transfer of immediately available funds into an account designated by Licensor within thirty (30) days after the end of the Calendar Quarter during which the applicable milestone is achieved; provided that, the achievement of a higher sales milestone event shall trigger the milestone payment for such milestone event as well as for all lower milestone events in the event such lower milestone events had not been previously triggered and paid:

(i) [**] if the Phase III INSPIRE trial successfully meets the primary endpoint of Overall Survival in the intention-to-treat population as set forth in the Statistical Analysis Plan;

(ii) [**] upon PBS reimbursement for intravenous rigosertib for 2nd-line high risk myelodysplastic syndromes;

(iii) [**] upon PHARMAC approval for intravenous rigosertib for 2nd-line high risk myelodysplastic syndromes;

(iv) [**] upon PBS reimbursement for oral rigosertib for 1st-line high risk myelodysplastic syndromes;

(v) [**] upon PHARMAC approval for oral rigosertib for 1st-line high risk myelodysplastic syndromes;

(vi) [**] upon PBS Reimbursement for rigosertib for the first indication for the diagnosis, treatment, or prevention of any disease, other than myelodysplastic syndromes;

(vii) [**] upon PBS Reimbursement for rigosertib for the second indication for the diagnosis, treatment, or prevention of any disease, other than myelodysplastic syndromes;

(viii) [**] upon first attaining [**] in aggregate annual Net Sales of the Licensed Products;

(ix) [**] first attaining [**] in aggregate annual Net Sales of the Licensed Products;

(x) [**] upon first attaining [**] in aggregate annual Net Sales of the Licensed Products;

(xi) [**] upon first attaining [**] in aggregate annual Net Sales of the Licensed Products;

(xii) [**] upon first attaining [**] in aggregate annual Net Sales of the Licensed Products;

(xiii) [**] upon first attaining [**] in aggregate annual Net Sales of the Licensed Products;

(xiv) [**] upon first attaining [**] in aggregate annual Net Sales of the Licensed Products; and

(xv) [**] upon first attaining [**] in aggregate annual Net Sales of the Licensed Products.

The Parties understand and agree that amounts paid by Licensee to Licensor pursuant to this Section 6.1 shall be used to fund and reimburse Licensor for research and development activities of the Licensed Products.

6.2 **Sales-Related Payments.** Licensee will pay to Licensor a non-refundable, non-creditable payment equal to a percentage of aggregate annual Net Sales of the Licensed Products at the following rates, as calculated by multiplying the applicable rate set forth below by the corresponding amount of incremental aggregate Net Sales in all or any portion of the Calendar Year:

(a) A base sales-related payment of [**] on all aggregate annual Net Sales up to [**];

(b) [**] on all aggregate annual Net Sales greater than [**] and up to [**];

(c) [**] on all aggregate annual Net Sales greater than [**] and up to [**];

(d) [**] on all aggregate annual Net Sales greater than [**] and up to [**];

(e) [**] on all aggregate annual Net Sales greater than [**].

Licensee shall calculate all amounts payable to Licensor pursuant to this Section 6.2 with respect to Net Sales at the end of each Calendar Quarter. Licensee shall pay to Licensor the amount due for Net Sales during a given Calendar Quarter within thirty (30) days after the end of such Calendar Quarter. Each payment due to Licensor shall be accompanied by (i) a statement of the amount of gross sales of each Licensed Product in the Territory during the applicable Calendar Quarter, (ii) an itemized calculation of Net Sales (a) in the Territory as a whole and (b) on a country-by-country basis, showing for both (a) and (b) deductions provided for in the definition of "Net Sales" during such Calendar Quarter, and (iii) a calculation of the amount of payment due on such Net Sales for such Calendar Quarter. Without limiting the generality of the foregoing, Licensee shall require its Affiliates and sublicensees and assignees to account for its Net Sales and to provide such reports with respect thereto as if such sales were made by Licensee.

Licensee shall have the sole right to determine if it believes that a license under Third Party patents or Third Party know-how is necessary or useful to develop, manufacture or commercialize the Licensed Products in the Field in the Territory. In the event it makes such determination following the Effective Date, the costs of each such license, to the extent the costs directly relate to the Licensed Products in the Field in the Territory shall be paid by Licensee, subject to deduction from payments to the extent set forth in the paragraph below.

In the event that payments based on a percentage of aggregate sales are payable by Licensee to Licensor with respect to any Licensed Product in any country in the Territory under this Section 6.2, then, subject to the last paragraph of this Section 6.2, Licensee shall have the right to deduct a maximum of [**] of any royalties or other amounts actually paid by Licensee to a Third Party with respect to any license obtained pursuant to the paragraph above with respect to such Licensed Product in any country in the Territory, but only to the extent that the patents or know-how licensed under such other license are necessary for the development, manufacture or commercialization of such Licensed Product in such country in the Field in the Territory, from payments otherwise due and payable by Licensee to Licensor under this Section 6.2 with respect to such Licensed Product in such country in the Field in the Territory, on a Licensed Product-by-Licensed Product and country-by-country basis. In no event shall the payment reductions described in this Section 6.2 reduce the payments payable by Licensee for a Licensed Product in a country in any given Calendar Quarter to less than [**] of the amounts otherwise payable by Licensee for such Licensed Product in such country in such Calendar Quarter. Licensee may carry over and apply any such payment reductions, which are incurred or accrued in a Calendar Quarter and are not deducted in such Calendar Quarter due to the limitation set forth above in this Section 6.2, to any subsequent Calendar Quarter(s) and shall begin applying such reduction to such payments as soon as practicable and continue applying such reduction on a Calendar Quarterly basis thereafter until fully deducted, in all cases subject to the limitation set forth above in this Section 6.2.

6.3 **Supply Price**. Licensee will pay Licensor a supply price equal to Cost of Goods plus [**] of Cost of Goods, plus applicable sales taxes (subject to Section 8.18(a)) (the "**Supply Price**"). The Cost of Goods of the Licensed Products as of the Effective Date are set forth in Exhibit C. Licensor will be entitled to increase the Cost of Goods provided that Licensor consults with Licensee in relation to the reasons for its intended price increase and it delivers to Licensee at least six (6) months advance written notice of a proposed increase in price and is able to demonstrate based on reasonable documentary evidence that the proposed price increase corresponds exclusively to an increase in the prices of raw materials and/or production and/or manufacturing processes that necessitate an increase of the Cost of Goods. Licensor shall be required to promptly, and in any event, no later than three (3) months following realization of any decrease in any COGs, pass such reductions along to Licensee.

6.4 **Records; Audits**. Licensee, its Affiliates, sublicensees and assignees shall keep full, true and accurate records and books of account containing all particulars that may be necessary for the purpose of confirming the accuracy of, and calculating, as applicable, all sales-related payments and other amounts payable to Licensor hereunder (including records of Net Sales) and any other records reasonably required to be maintained with respect to Licensee's obligations under this Agreement, in each case for a minimum period of four (4) years or such longer period as required by Applicable Laws. Licensor shall have a right to request an audit of Licensee, its Affiliates or sublicensees or assignees (the "**Audited Party**") in order to confirm the accuracy of any of the foregoing (an "**Audit**"); provided, however, that Licensor shall only have the right to request such Audit one time during any given Calendar Year. Upon the written request by Licensor to Audit the Audited Party, Licensor shall have the right to engage an independent, internationally recognized accounting firm that is reasonably acceptable to the Audited Party to perform a review as is reasonably necessary to enable such accounting firm to calculate or otherwise confirm the accuracy of any of the foregoing for the Calendar Year(s) requested by Licensor; provided that (i) such accountants shall be given access to, and shall be permitted to examine and copy such books and records of the Audited Party upon five (5) business days' prior written notice to the Audited Party, and at all reasonable times on such business days, (ii) prior to any such examination taking place, such accountants shall enter into a confidentiality agreement with the Audited Party reasonably acceptable to the Audited Party in order to keep all information and data contained in such books and records strictly confidential and shall not disclose such information or copies of such books and records to any third person including the auditing Party, but shall only use the same for the purpose of the reviews and/or calculations which they need to perform in order to determine any amounts being reviewed, and (iii) such accountants shall use reasonable efforts to minimize any disruption to Audited Party's business. The accountants shall deliver a copy of their findings to each of the Parties within ten (10) business days of the completion of the review, and, in the absence of fraud or manifest error, the findings of such accountant shall be final and binding on each of the Parties. Any underpayments by Licensee shall be paid to Licensor within ten (10) business days of notification of the results of such inspection. Any overpayments made by Licensee shall be refunded by Licensor within ten (10) business days of notification of the results of such inspection. The cost of the accountants shall be the responsibility of Licensor unless the accountants' calculation shows that the actual royalties payable, and/or any such other amount audited hereunder to be different, by more than five percent (5%), than the amounts as previously calculated by the Audited Party, in which event the cost shall be the responsibility of Licensee and Licensee shall reimburse Licensor for any Licensor costs incurred for the Audit.

7. CONFIDENTIALITY

7.1 Both Licensor and Licensee agree that, subject to the limitations set forth in Section 7.3 hereof, all information disclosed to the other party, whether in oral, written or graphic form, shall be deemed "Confidential Information" of the disclosing party. In particular, “Confidential Information” means any scientific, technical, trade or business information, intellectual property, data or materials possessed by a Party which is treated by such Party as confidential or proprietary, including information pertaining to strains, cells, antibodies, organisms, chemical compounds, products, formulations, technologies, techniques, methodologies, algorithms, computer programs, computer security systems and processes, assay systems, procedures, tests, data, documentation, reports, sources of supply, know-how, patent positioning, results, applications, documents, processes, compositions, inventions, trade secrets, protocols, regulatory information, relationships with employees and consultants, business plans, business developments, research, development, process development, manufacturing, commercialization, and marketing, and any other confidential information about or belonging to a Party’s affiliates, suppliers, licensors, licensees, partners, collaborators, customers or others, and is provided by one Party (the “Discloser”) to the other Party (the “Recipient”) under this Agreement.

7.2 Each Party agrees that, except in connection with the performance of its obligations under this Agreement or the exercise of its rights or licenses under this Agreement, it will not otherwise use in any way for its own account or the account of any Third Party, nor disclose or transfer to any Third Party, any Confidential Information revealed to it by the other Party; provided, however, that Confidential Information may be disclosed pursuant to a regulation, law, court order or rule of any applicable securities exchange, but only to the minimum extent required to comply with such regulation, order, or rule and with advance written notice to the Discloser; and provided further that a Recipient may disclose Confidential Information to its subsidiaries, affiliates, professional advisors, consultants, agents provided that they are under confidentiality and use limitations consistent with those in this Agreement and such Party will be liable for breaches of the restrictions set forth in this Agreement by all such persons. Each Party will take commercially reasonable efforts to protect the confidentiality of the other Party’s Confidential Information, such precaution not to be less than the precautions each Party takes to protect the confidentiality of its own Confidential Information of the same kind.

7.3 Both Licensor and Licensee agree that, notwithstanding the above, the obligations of confidentiality shall not be deemed to apply to:

(a) Information which at the time of disclosure is or thereafter becomes generally known or available to the public, through no wrongful act or failure to act on the part of the receiving party.

(b) Information that was known by or in the possession of the Recipient at the time of receiving such information from the Discloser as evidenced by written records.

(c) Information obtained by the receiving party from a third party source who is not breaching a commitment of confidentiality to the Discloser by revealing such information to the Recipient.

(d) Information that is the subject of a granted written permission to disclose that is issued by the Discloser to the Recipient.

(e) Information that is independently developed by the Recipient, outside the scope of any Project under this Agreement, without the use of and/or reference to the Discloser's Confidential Information.

(f) Information that is required to be disclosed pursuant to the law, but only to the extent required to be disclosed; provided, however, the Discloser notifies the Recipient in writing and gives the Recipient reasonable time to comment on the same prior to disclosure.

7.4 During the Term and for a period of five (5) years thereafter, each party shall maintain all Confidential Information in trust and confidence and shall not disclose any Confidential Information to any Third Party or use any such information for any unauthorized purpose, other than as authorized in Section 7.3 hereof or as necessary to accomplish the purpose of this Agreement subject to an appropriate binder of confidentiality as set forth in Section 7.5 hereof. Each party may use such Confidential Information only to the extent required to accomplish the purposes of this Agreement. Confidential Information shall not be used for any purpose or in any manner that is not consistent with this Agreement or that would constitute a violation of any laws or regulations including, without limitation, the export control laws of the United States. Each party hereby agrees that it will not in any way attempt to obtain, either directly or indirectly, any information regarding any Confidential Information from any third party who has been employed by, provided consulting services to, or received in confidence information from, the other party.

7.5 Both parties shall make diligent efforts to ensure that all employees, consultants, agents, subcontractors and manufacturing contractors who may have access to Confidential Information of the other party, and any other Third Parties who might have access to Confidential Information, will use such information in a manner consistent with the terms of this Agreement and will be bound by the terms set forth in this Section 7. No Confidential Information shall be disclosed to any employees, subcontractors, agents or consultants who do not have a need to receive such information.

7.6 To the extent either party discloses Confidential Information of the other party to an employee, consultant, subcontractor, or other third-party (collectively "Agents") or permits an Agent to have access to such Confidential Information, such party shall assign to the other party any claims it may have against the Agent as a result of the Agent further disclosing or misusing such Confidential Information.

7.7 To the extent that either Party reasonably determines that it is required to make a filing or any other public disclosure with respect to this Agreement or the terms or existence hereof to comply with the requirements, rules, laws or regulations of any applicable stock exchange, NASDAQ or any governmental or regulatory authority or body (the "Requesting Body"), including, without limitation, the U.S. Securities and Exchange Commission (collectively, the "Disclosure Obligations"), such Party shall promptly inform the other Party thereof and shall use reasonable efforts to maintain the confidentiality of the other Party's Confidential Information and terms of this Agreement in any such filing or disclosure. Prior to making any such filing of a copy of this Agreement, the Parties shall mutually agree on the provisions of this Agreement for which the Parties shall seek confidential treatment, it being understood that if one Party determines to seek confidential treatment for a provision for which the other Party does not, then the Parties will use reasonable efforts in connection with such filing to seek the confidential treatment of any such provision. The Parties shall cooperate, each at its own expense, in such filing, including without limitation such confidential treatment request, and shall execute all documents reasonably required in connection therewith. The Parties will reasonably cooperate in responding promptly to any comments received from the Requesting Body with respect to such filing in an effort to achieve confidential treatment of such redacted form; provided that a Party shall be relieved of such obligation to seek confidential treatment for a provision requested by the other Party if such treatment is not achieved after the second round of responses to comments from the Requesting Body.

7.8 Except as expressly provided in this Section 7, each Party agrees not to disclose any terms of this Agreement to any third party without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed). Each party (the "Providing Party") may, however, provide a copy of this Agreement or otherwise disclose its terms in connections with any financing transaction, provided that the person or entity to whom a copy of this Agreement is provided or to whom the terms of this Agreement are disclosed is bound to the Providing Party by reasonable confidentiality obligations no less stringent than those set forth herein, and provided further that the Providing Party is responsible for breaches or confidentiality hereunder by such person or entity to whom a copy of this Agreement is provided or to whom the terms of this Agreement are disclosed. Notwithstanding the foregoing and subject to Section 7.7, the Parties may issue a mutually agreed upon press release announcing the execution of this Agreement and describing the relationship of the Parties under the Agreement. In addition, each Party may disclose to Third Parties the information disclosed in such press release without the need for further approval by the other Party, and Licensor may disclose to third parties (via press releases or otherwise) the achievement of any material milestones in connection with this Agreement without prior approval by Licensee.

7.9 The Receiving Party shall notify the Disclosing Party promptly upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information, and will cooperate with the Disclosing Party in any reasonably requested fashion to assist the Disclosing Party to regain possession of such Confidential Information and to prevent its further unauthorized use or disclosure.

7.10 Licensee shall submit copies of each proposed academic, scientific, medical and other publication that contains or refers to the Licensed Product to Licensor for review and comment at least thirty (30) days prior to submission for publication. At the request of Licensor, Licensee shall remove, redact or otherwise modify the proposed publication or presentation to remove any Confidential Information of Licensor.

8. MANUFACTURE AND SUPPLY

8.1 **Manufacture by Licensor**. During the Term, Licensee agrees to obtain from Licensor all Licensee's requirements of the Licensed Products for the Territory. Licensor agrees to supply Licensee with all of its requirements of Licensed Products as set forth in each order submitted by Licensee. Licensor may, at its discretion, use the services of a contract manufacturer to manufacture and package the Licensed Products. Licensed Products supplied to Licensee shall be finished and packaged Licensed Products.

8.2 **Forecasts**. Starting on a date to be agreed upon by the Parties, Licensee will submit to Licensor a rolling forecast for the subsequent twelve (12) months, on a monthly basis. The first three (3) months of each forecast shall be binding on Licensee, and Licensee shall submit orders for requirements equivalent to the binding portion of the forecast, and subsequent monthly forecasts may not change the forecasts for such binding months without the prior written consent of Licensor. The remaining nine (9) months monthly forecasts will not be binding on Licensee, but shall represent Licensee's good faith projected requirements for Licensed Product, provided however, Licensor's suppliers may order a reasonable amount of materials required for the manufacturing of Licensed Product based on the full twelve (12) months of any such forecast taking into account factors such as the inventory of Licensed Product materials currently on hand and the lead time for such materials.

8.3 **Orders**. Licensee shall order Licensed Products from Licensor by submitting purchase orders to Licensor. Such purchase order shall specify, at a minimum, the desired delivery date, unit quantity (such unit quantity shall be greater than or equal to the minimum order quantities specified in Exhibit C for the applicable Licensed Product), place of delivery and an order number. Licensee shall order Licensed Products with [**] lead time between the time when an order for Licensed Products is submitted to Licensor until the Licensed Products is delivered to Licensee. Licensor shall not be obligated to deliver quantities of Licensed Product ordered in excess of the binding portion of the forecast, but shall use commercially reasonable efforts to deliver any such excess ordered.

8.4 **Delivery Terms**. Licensed Products will, at Licensee's direction, be shipped directly to Licensee or to a Third Party in the Territory as designated by Licensee. The terms for delivery of orders of Licensed Products shall be DDP (Incoterms 2010). Title to the Licensed Products shall transfer to Licensee or its designee upon pickup by Licensee.

8.5 **Packaging and Labeling**. Licensee shall determine the artwork and design for the packaging and labelling in the Territory in consultation with Licensor. Licensee shall be entitled to have its trade-marks displayed on the packaging for the Licensed Products. Licensee shall be responsible for the costs associated with the development of Licensee's artwork for the packaging and labeling of the Licensed Products for Launch and for any changes thereto made at Licensee's request or for any special packaging required by Licensee or a Governmental Authority. All Licensed Products shall also include the language "distributed by Specialised Therapeutics."

8.6 **Specifications**. Licensed Products manufactured and supplied to Licensee hereunder shall conform to the Specifications which may be changed from time to time upon mutual agreement, or as required by any Governmental Authority.

8.7 **GMP**. All manufacture and quality control operations by Licensor or its designee shall be in compliance with GMP.

8.8 **Shelf Life**. All Licensed Products supplied by Licensor hereunder shall have not less than [**] of its shelf life remaining upon delivery to Licensee but in any event never less than [**] remaining shelf life upon delivery to Licensee.

8.9 **Quality and Pharmacovigilance Agreements**. The Parties shall enter into separate quality agreement and pharmacovigilance agreements regarding supply of Licensed Products by Licensor to Licensee, incorporating provisions that are standard in the pharmaceutical field within [**] of the Effective Date.

8.10 **Changes**.

(a) A Party shall promptly notify the other Party in writing of all proposed changes, whether voluntary or involuntary, including those arising from a request from a Governmental Authority, concerning the quality of Licensed Products and/or documentation or other items for such changes relating to the quality of the Licensed Products. The Parties shall negotiate in good faith towards an appropriate response to a Governmental Authority in respect of each proposed change in the quality of the Licensed Products including any costs associated with implementing said changes. Licensor shall notify Licensee of any proposed change in manufacturing facility or manufacturing procedures.

(b) Licensor shall ensure that any changes in manufacturing sites shall be done in accordance with TGA and NZ Health requirements and will prepare the documents required for the supplemental regulatory filings. Licensor shall provide these documents to Licensee for review, approval and submission to TGA and NZ Health. Prior to TGA and NZ Health approval of the new manufacturing site, Licensor shall continue to manufacture inventory for Licensee from the previous approved sites, until the new manufacturing site has been approved by both TGA and NZ Health. The parties will work together in good faith to minimize the number of changes that occur.

8.11 **Minor Changes**. Minor changes in the procedures for manufacture or quality control that do not require approval from a Governmental Authority or that will not affect Regulatory Approvals will be communicated by Licensor to Licensee in an annual review.

8.12 **Release to Licensee**. Licensor, or its designee, shall only release for shipment to Licensee, finished batches of Licensed Products that have been examined by Licensor for compliance with the Specifications. Licensor is responsible for conducting, or having conducted, all required stability and release testing to ensure that the finished batches of Licensed Products are in compliance with the Specifications.

8.13 **Quality Audit**. During normal working hours and upon reasonable notice, Licensee shall be entitled to inspect areas within Licensor’s or its contract manufacturer’s establishment where Licensed Products are manufactured or stored, and to inspect the manufacturing, packaging, and quality control records relating to the Licensed Products.

8.14 **Government Inspections.** Licensor shall make its internal practices, and its manufacturing, packaging, and quality control records relating to the Licensed Products available to Governmental Authorities and will allow access to all facilities used for manufacturing the Licensed Products to the applicable Governmental Authorities for the purposes of determining Licensor's compliance with Applicable Laws. Licensor agrees to advise Licensee immediately of any proposed or announced visit or inspection, and as soon as possible but in any case within three (3) Business Days after any unannounced visit or inspection, by a Governmental Authority in the Territory relating to the Licensed Products. Licensor shall provide Licensee with a reasonable description in writing of each such visit or inspection promptly thereafter, and with copies of any letters, reports or other documents issued by any such Governmental Authorities that relate to the Licensed Products.

8.15 **Defects**. Any claim by Licensee regarding an apparent failure of the Licensed Products to comply with the Specifications must be made in writing with full particulars within thirty (30) days after receipt of the Licensed Products by Licensee. In the case of latent defects, such defects shall be reported to Licensor within thirty (30) days of Licensee discovering the defect. In case of a justifiable claim for defect because of a failure of the Licensed Products to conform to the Specifications, Licensor or its designee shall, without charge, promptly replace the defective portion with supplies that are in compliance with such Specifications. Licensor shall assume all costs associated with transportation of replacement Licensed Products. Licensee shall follow any reasonable instructions to return to Licensor or dispose of, in either event at Licensor's expense, any quantities of Licensed Products as aforesaid that are not in compliance with the Specifications.

8.16 **Independent Lab**. If Licensor does not agree with Licensee that the Licensed Products rejected by Licensee fails to conform to the Specifications, the matter will be submitted for analysis to an independent laboratory agreed between the Parties. The decision of such independent laboratory following its analysis of the Licensed Products shall be final. The cost of the analysis, as well as the costs associated with reasonable shipping, handling, and storage of any Licensed Products under dispute as to compliance with the Specifications, shall be borne by the Party who was in error.

8.17 **Short Shipment.** If Licensee determines that there is a shortage in the quantity of any shipment of Licensed Products (from quantities specified in the relevant bill of lading or other shipping documents), and it is determined that discrepancy existed at the time it was delivered to Licensee from Licensor, Licensee shall notify Licensor in writing as soon as reasonably possible, and Licensor shall make up the shortage within thirty (30) days of such notification at no additional cost to Licensee.

8.18 **Failure**. In the event of any Short Term Inability to Supply or Long Term Inability to Supply, Licensee shall have available to it, in addition to the remedies available to Licensor from the Third Party supplier of the Licensed Product, the following remedies:

(a) In the event of any Short Term Inability to Supply, the Supply Price of the applicable Licensed Product for Licensee’s next [**] purchase orders shall be the Cost of Goods with no markup, plus applicable sales taxes.

(b) In the event of a Long Term Inability to Supply or two (2) Short Term Inability to Supply events within a [**] period, Licensee shall be entitled to all of the rights and recourses set forth in Section 8.18. In addition, Licensee shall be entitled by notice in writing to terminate the supply arrangements contemplated in this Agreement, in which event:

(i) Licensee shall be entitled to purchase the Licensed Products from a Third Party. For greater certainty, Licensor shall grant to a Third Party designated by the Licensee the non-exclusive license to use all relevant intellectual property for or in respect of the manufacture of the Licensed Products for commercialization in the Territory.

(ii) Licensor shall provide such assistance as is required by Licensee acting reasonably, from time to time to assist in sourcing the Licensed Products from a third party.

8.19 Without limiting the generality of the foregoing, Licensor shall enter into a technology transfer agreement with a Third Party manufacturer selected by Licensee under which Licensor shall transfer to the selected manufacturer all technical information necessary to manufacture the Licensed Products and supply the Licensed Products in the Territory.

8.20 **Shortfall**. In the event of an interruption or shortfall in supply of Licensed Products, for whatever reason, that exceeds [**] in duration, such that not all purchase orders for Licensed Products hereunder can be met, then Licensor shall immediately notify Licensee and shall allocate a prorated share of its available sources and supplies among Licensee and Licensor's other partners (distributors, licensees, agents) and internal needs, based on the respective forecasted commercial supply requirements of each of the parties for that allocation period. In any case, the Parties will discuss and agree in good faith on acceptable delivery dates and measures to mitigate the effects of the interruption or shortfall. Licensor shall use commercially reasonable efforts to eliminate, cure or overcome such shortage and to resume performance of its obligations hereunder as soon as reasonably possible.

8.21 **Capacity and Supply**. Licensor will maintain sufficient manufacturing time in its production schedule to provide consistent availability of Licensed Products to meet Licensee's firm orders. Licensor shall maintain or cause its contract manufacturer to maintain sufficient volumes of Licensed Products to meet [**] worth of Licensee's [**] rolling forecast.

8.22 **GMP**. All manufacture and quality control operations by Licensor or its designee shall be in compliance with GMP. Licensor shall ensure at all times that it has a back-up supplier that has GMP compliance and is approved by TGA and NZ Health and is capable of supplying (and verifiable from time to time by Licensee) Product to Licensee.

8.23 **Payment Method**. All payment due to Licensor hereunder will be paid in U.S. Dollars by wire transfer to an account designated by Licensor.

8.24 **Currency Conversion**. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than U.S. dollars), any amounts expressed in a currency other than U.S. dollars (where the relevant threshold or amount is expressed in U.S. dollars) shall be converted into the relevant currency using the month end exchange rate reported by the [Bank of America] which is in effect at the close of business at the end of the last Business Day for the relevant month for converting such other currency into U.S. dollars.

8.25 **Record Retention**. Licensor will maintain complete and accurate books, records, and accounts used for the determination of expenses, deductions, credits, or other relevant factors in connection with the calculation of Cost of Goods, in sufficient detail to confirm the accuracy of any payments required under this Agreement, which books, records, and accounts will be retained until three (3) years after the end of the period to which such books, records, and accounts pertain.

8.26 **Audit**. During the Term of this Agreement and for three (3) years thereafter, Licensee will have the right to have an independent certified public accounting firm of internationally recognized standing access during normal business hours, and upon reasonable prior written notice, to such of the records of Licensor as may be reasonably necessary to verify the accuracy of Cost of Goods for any Calendar Quarter. The accounting firm will disclose to the Parties only whether the Cost of Goods reported by Licensor is correct or incorrect and the specific details concerning any discrepancies. The auditing Party will bear all costs of such audit, unless the audit reveals a discrepancy in the auditing Party's favor of more than five percent (5%), in which case the other Party will bear the cost of the audit. Each Party will treat all information subject to review under this Section 6 as Confidential Information and will cause its accounting firm to enter into a reasonably acceptable confidentiality agreement obligating such firm to maintain all such financial information in confidence pursuant to such confidentiality agreement.

8.27 **Payment of Additional Amounts**. If, based on the results of any audit under Section 8.26, payments are owed by one Party to the other under this Agreement, then the Party having such obligation will make such payment promptly after the accounting firm's written report is delivered by courier or registered mail to both Parties.

9. INTELLECTUAL PROPERTY

9.1 **Patent Prosecution:** Licensor shall not abandon prosecution or maintenance of any or all patents or patent applications exclusively related to the Licensed Product in the Territory without notifying Licensee in a timely manner of Licensor's intention and reason therefore and providing Licensee with reasonable opportunity to comment upon such abandonment and to assume responsibility for prosecution or maintenance of such patent rights. In the event that Licensor abandons prosecution or maintenance of any or all patents or patent applications exclusively related to the Licensed Product in the Territory, Licensee may assume prosecution and filing responsibility for such patent rights in the Territory, and thereafter such patent rights will be owned solely and exclusively by Licensee. The Parties shall mutually agree on any patent term extension decisions and shall work together to make decisions related to patent term extension intended to maximize the potential of the Licensed Product.

9.2 **Notification of Third Party Infringement**. Each Party shall promptly disclose to the other in writing within ten (10) Business Days, any actual, alleged, or threatened Third Party infringement or misappropriation in the Territory of any Licensor Patent and any actual, alleged or threatened infringement or passing off of the Licensor Mark, of which such Party becomes aware.

9.3 **Response to Third Party Infringement**. Licensor shall have the first right, but not any obligation, to respond to any actual or threatened infringement of a Licensor Patent, the Licensor Mark or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods, or like offenses in the Territory relating to the Licensed Products. If Licensor elects to respond to any actual or threatened infringement by initiating a proceeding, Licensor shall use legal counsel of its choice at its expense and shall have full control over the conduct of such proceeding. Licensor may settle or compromise any such proceeding without the consent of Licensee; provided, however, that if such settlement affects Licensee's rights under this Agreement, or Licensee's ability to Commercialize the Licensed Products within the Territory, or otherwise requires Licensee to admit wrongdoing, fault, or liability, Licensor will not settle or compromise any such proceeding without the consent of Licensee, such consent not to be unreasonably withheld, conditioned, or delayed. If Licensor elects not to respond to any actual or threatened infringement of an Licensor Patent, the Licensor Mark or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods, or like offenses in the Territory relating to the Licensed Products, then Licensee shall have the right, but not the obligation, to take action, at its sole expense, in which case Licensee shall have full control over the conduct of such proceeding and Licensee may settle or compromise any such proceeding without the consent of Licensor; provided, however, that if such settlement affects Licensor's intellectual property rights or its rights under this Agreement, or Licensor's ability to Commercialize the Licensed Products outside the Territory, or otherwise requires Licensor to admit wrongdoing, fault, or liability, Licensee will not settle or compromise any such proceeding without the consent of Licensor, such consent not to be unreasonably withheld, conditioned, or delayed. Licensee shall be solely responsible for any legal costs or damages awards made in any proceeding that is initiated by Licensee in the event that Licensor elects not to respond to any actual or threatened infringement.

9.4 **Cooperation**. Each Party shall cooperate reasonably, at its expense, in any enforcement effort initiated by the other Party. Neither the Parties nor their Affiliates shall contest any joinder in any proceeding sought to be brought by the other Party if such joinder is required by Applicable Law.

9.5 **Recovery**. Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any monetary award recovered from a Third Party in connection with any proceeding initiated to protect, maintain, defend, or enforce any intellectual property in the Territory or recovered from a Third Party in connection with any proceeding initiated for infringement or misappropriation of intellectual property shall first be used to reimburse the Parties for any out-of-pocket legal expenses relating to such proceeding and the balance being retained by the Party that brought and controlled such litigation.

9.6 **Infringement of Third Party IP**. If either Party becomes aware that its activities performed hereunder may constitute actual or alleged infringement or misappropriation of the intellectual property rights of a Third Party, it shall promptly notify the other Party and the Parties shall discuss a strategy to defend or mitigate against any actual or alleged infringement.

10. REPRESENTATION AND WARRANTIES

10.1 **Licensor Covenants, Representations and Warranties**. Licensor covenants, represents and warrants (as the case may be) to Licensee that:

(a) Licensor is a corporation duly organized, validly existing and in good standing under the laws of Delaware;

(b) Licensor has provided Licensee with all Licensor Patents and intellectual property rights necessary or useful for Licensee to perform its obligations under this Agreement in the Territory;

(c) Licensor has informed Licensee about all information in its possession or control concerning the safety and efficacy of the Licensed Products, and any side effects, injury, toxicity or sensitivity reactions and incidents associated with all uses, studies, investigations or tests involving the Licensed Products (animal or human) throughout the world;

(d) As of the Effective Date, Licensor is not aware of any facts that would reasonably lead it to conclude that the Licensed Products will be unable to receive Regulatory Approval other than those which has already been disclosed to Licensee;

(e) Licensed Products shall be manufactured in accordance with the Specifications therefor and shall be manufactured, packaged, stored and shipped in accordance with all laws and regulations applicable to the Territory and to the country in which the Licensed Products are manufactured, including GMP;

(f) all of the Licensor Patents and intellectual property licensed hereunder are valid and enforceable and are owned or validly licensed by Licensor and Licensor has not received any notice alleging the contrary;

(g) Licensor has taken all necessary actions to authorize the execution, delivery and performance of this Agreement;

(h) Upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of Licensor, enforceable against Licensor in accordance with its terms, except to the extent enforceability is limited by bankruptcy, insolvency or similar laws affecting creditors' rights and remedies or equitable principles;

(i) The performance of Licensor's obligations under this Agreement will not conflict with its organizational documents, as amended, or result in a breach of any material agreements or contracts to which it is a party;

(j) Licensor has not entered into, and will not during the term of this Agreement, enter into any agreements or contracts that would conflict with its obligations under this Agreement;

(k) Licensor has not received any notice that the manufacture, sale, or use of the Licensed Products in the Territory infringes upon any intellectual property rights of any Third Parties in the Territory;

(l) To the knowledge of Licensor, there are no activities being carried out by Third Parties in the Territory that would constitute infringement or misappropriation of the Licensor Patents or the Licensor Mark;

(m) Licensor has obtained all consents, licenses, authorizations and sublicenses necessary to grant the rights to the Licensee hereunder and such rights will continue to be enforceable during the Term

10.2 **Licensee Representations and Warranties**. Licensee covenants, represents and warrants to Licensor (as the case may be) as follows:

(a) Licensee is a corporation duly organized, validly existing and in good standing, under the laws of Singapore.

(b) Licensee has the legal right, authority, and power to enter into this Agreement.

(c) Licensee has taken all necessary action to authorize the execution, delivery, and performance of this Agreement.

(d) Upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of Licensee, enforceable against Licensee in accordance with its terms, except to the extent enforceability is limited by bankruptcy, insolvency or similar laws affecting creditors' rights and remedies or equitable principles.

(e) The performance of Licensee's obligations under this Agreement will not conflict with its organizational documents or result in a breach of any material agreements or contracts to which any is a party.

(f) Licensee has not and will not, during the term of this Agreement, enter into any material agreements or contracts that would be inconsistent with its obligations under this Agreement.

(g) Neither Licensee nor its Affiliates will initiate a proceeding to challenge the validity or enforceability of any Licensor Patent or the Licensor Marks, or directly or indirectly assist any Third Party with respect to any such proceeding.

10.3 **WARRANTY DISCLAIMER**. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE LICENSED PRODUCTS OR ANY TECHNOLOGY OR ANY LICENSE GRANTED BY EITHER PARTY HEREUNDER.

10.4 **LIMITATIONS OF LIABILITY**. WITHOUT LIMITING THE PARTIES' OBLIGATIONS REGARDING INDEMNIFICATION, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR TO ANY THIRD PARTY WHO MAY BENEFIT FROM ANY PROVISION OF THIS AGREEMENT FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER.

10.5 **Indemnification by Licensor**. Licensor hereby agrees to defend, indemnify, and hold Licensee, its Affiliates and their respective officers, directors, employees and agents, (each a "**Licensee Indemnified Party**") harmless from and against any Third Party's claims for loss, damage, or liability, including reasonable attorneys' fees and expenses) (collectively, "**Losses**") resulting from: (i) any breach of this Agreement or any warranty or covenant provided in this Agreement by Licensor or an Affiliate of Licensor; (ii) any violation of Applicable Law by Licensor or its Affiliates; and (iii) any negligent act or omission or willful misconduct of Licensor or its Affiliates; (iv) any claim that the sale by Licensee or its Affiliates, of the Licensed Products infringes on intellectual property rights in the Territory of any other person which exists as of the Effective Date; (v) any damage to property, personal injury or death arising in any way from the Licensed Product, except to the extent that damage, personal injury or death arises out of the act or omission of Licensee; and (vi) any claim arising from any use, within the approved labelling, made by any person of any of the Licensed Products; in all cases, except to the extent such Third Party's claim for loss, damage or liability is the result of: (i) any breach of this Agreement by Licensee or a Licensee Indemnified Party, (ii) any violation of Applicable Law by Licensee or a Licensee Indemnified Party, or (iii) any negligent act or omission or willful misconduct of Licensee or a Licensee Indemnified Party. Notwithstanding anything to the contrary, this Section 10.5 does not apply to the matters referred to in the final two paragraphs in Section 6.2.

10.6 **Indemnification by Licensee**. Licensee hereby agrees to defend, indemnify, and hold Licensor, its Affiliates and their respective officers, directors, employees and agents, (each a "**Licensor Indemnified Party**") harmless from and against any Third Party's claims for Losses resulting from: (i) any breach of this Agreement or any warranty or covenant provided in this Agreement by Licensee or an Affiliate of Licensee; (ii) any violation of Applicable Law by Licensee or its Affiliates; and (iii) any negligent act or omission or willful misconduct of Licensee or its Affiliates; in all cases, except to the extent such Third Party's claim for loss, damage or liability is the result of: (i) any breach of this Agreement by Licensor or an Licensor Indemnified Party, (ii) any violation of Applicable Law by Licensor or an Licensor Indemnified Party, or (iii) any negligent act or omission or willful misconduct of Licensor or an Licensor Indemnified Party.

10.7 **Indemnification Procedure**. If an indemnified party intends to claim indemnification under this Section 10, such party shall promptly notify the other party of any loss, claim, damage, liability or action in respect of which the indemnified party intends to claim such indemnification, and the indemnifying party shall have a first opportunity to assume the sole defense thereof (provided that such claim solely seeks monetary damages and for which the indemnifying party agrees, as between the indemnifying party and the indemnified party, the indemnifying party shall be solely responsible for payment of Losses related to such Third Party claim), with counsel selected by the indemnifying party and approved by the indemnified party acting reasonably; provided, however, that an indemnified party shall have the right to retain its own counsel and participate fully in the defense, with the fees and expenses to be paid by the indemnified party. The failure or delay to deliver notice to the indemnifying party, within a reasonable time after the commencement of any such proceeding, if irreparably prejudicial to the indemnifying party's ability to defend such proceeding, shall relieve the indemnifying party of any and all liability to the indemnified party under this Section 10. The indemnified party shall cooperate fully with the indemnifying party and their legal representatives in the investigation of any loss, claim, damage, or liability covered by this indemnification, and shall mitigate such loss and damages. Any amount payable in order to satisfy an indemnity hereunder shall be paid as soon as reasonably possible after the indemnified party has incurred an indemnified expense and notified the indemnifying party thereof.

10.8 **Compliance with Law**. Each Party shall comply, and shall require their Affiliates and permitted sublicensees to comply, with all Applicable Laws relative to their obligations hereunder.

10.9 **Insurance**. The Parties shall maintain insurance, including product liability insurance, that is adequate to cover their obligations hereunder and that is consistent with normal business practices of prudent corporations engaged in the same or a similar business. The Parties acknowledge and agree that such insurance shall not be construed to create a limit with respect to their indemnification obligations. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, nonrenewal or material change in such insurance or self-insurance which materially adversely affects the rights of the other Party hereunder.

11. TERM AND TERMINATION

11.1 **Term**. This Agreement will take effect from the Effective Date and, unless earlier terminated in accordance with the terms herein, will continue in full force and effect for fifteen (15) years from the Launch on a country by country basis in the Territory (the "**Initial Term**"). This Agreement shall automatically renew for successive fifteen (15) year periods (each a "**Renewal Term**" and, together with the Initial Term, the "**Term**") unless, at least one (1) year prior to the expiry of the Initial Term or Renewal Term, either Party provides the other with written notice of its intention not to renew the Agreement at the end of the applicable period.

11.2 **Termination for Breach**. Either Party may terminate this Agreement by written notice to the other Party with immediate effect in the following cases:

(a) In the event of a petition in bankruptcy or insolvency of the other Party, or in case of the filing by the other Party of any petition or answer seeking reorganization, readjustment, or rearrangement of its business under any law or any government regulation relating to bankruptcy or insolvency, or in case of the institution by the other Party of any proceedings for the liquidation or winding up of its business, or for the termination of its corporate charter.

(b) If the other Party is otherwise in material default or breach of this Agreement and such default or breach is not cured within (i) sixty (60) days after written notice thereof is delivered to the defaulting or breaching Party (thirty (30) days in the case of Licensee's failure to pay any amounts due hereunder), or (ii) in the case of a breach that cannot be cured within sixty (60) days, within a reasonable period not exceeding one hundred twenty (120) days after written notice thereof is delivered to the defaulting or breaching Party.

(c) If Licensee or any Affiliate, sublicensee or assignee institutes any challenge to any Licensor Patents, then Licensor shall be entitled to terminate this Agreement with immediate effect.

11.3 **Effect of Termination**. Upon expiry or termination of this Agreement, all licenses and rights granted by Licensor hereunder shall terminate and Licensee undertakes to:

(a) except as provided for in Section 11.5, cease any Commercialization of the Licensed Products in the Territory; and

(b) within thirty (30) days or expiry or termination, start to transfer title to all current and pending Regulatory Approvals for the Licensed Products to Licensor and assist Licensor, at Licensor's cost, in submitting appropriate documents to transfer the Regulatory Approvals for the Licensed Products to Licensor or its designee.

11.4 **Survival**. In the event of the termination of this Agreement for any reason, the following provisions of this Agreement shall survive: **Articles 1, 7, 11, 12 and 14, and Sections 6.4, 8.6-8.15, 8.25, 8.26, 9.3-9.6, and 10.4-10.8** and any other terms which, by their nature, require or contemplate performance by the Parties after expiry or termination. In any event, termination of this Agreement shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such termination.

11.5 **Sell-Off of Inventory**. Upon termination of this Agreement, Licensee shall be entitled to sell off any inventory of the Licensed Products existing on the date such termination is effective.

12. DISPUTE RESOLUTION

12.1 **Arbitration**. Except as otherwise expressly provided herein, any dispute or claim arising out of or relating to this Agreement, or to the breach, termination, or validity of this Agreement, will be resolved as follows: each Party shall discuss the matter and make reasonable efforts to attempt to resolve the dispute. If the Parties are unable to resolve, the dispute a CEO or President of each Party will meet within thirty days (30) of a request to attempt to resolve such dispute being made by a Party. If the CEOs or Presidents cannot resolve the dispute through good faith negotiations within sixty (60) days after a Party requests such meeting, then the Parties shall resort to binding arbitration before a single arbitrator using the arbitration procedures set forth under the simplified rules of the International Chamber of Commerce in New York. The decision of the arbitrator shall be final and not subject to appeal and the arbitrator may apportion the costs of the arbitration, including the reasonable fees and disbursements of the parties, between or among the parties in such manner as the arbitrator considers reasonable. All matters in relation to the arbitration shall be kept confidential to the full extent permitted by law, and no individual shall be appointed as an arbitrator unless he or she agrees in writing to be bound by this provision.

12.2 **Irreparable Harm**. Notwithstanding anything to the contrary in Section 12.1, if either Party in its sole judgment, acting reasonably, believes that any such dispute could cause it irreparable harm, such Party (i) will be entitled to seek equitable relief in order to avoid such irreparable harm and (ii) will not be required to follow the procedures set forth in Section 12.1.

13. **Named Patient Sales**. Notwithstanding anything to the contrary in this Agreement, all named patient sales will be sales of Licensor, unless negotiated otherwise pursuant to a separate agreement, until first regulatory approval in Australia. The Parties will discuss in good faith the administration of any named patient program prior to the first regulatory approval in Australia. Following the first regulatory approval in Australia, all named patient sales shall be deemed Net Sales under this Agreement.

14. OTHER PROVISIONS

14.1 **Withholding Tax**. The upfront payment, milestones and sales-related payments payable by Licensee to Licensor pursuant to this Agreement (each, a "**Payment**") shall be paid free and clear of any and all taxes (which, for clarity, shall be the responsibility of Licensee), except for any withholding taxes required by Applicable Law. Except as provided in this Section 14, Licensor shall be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from Payments and remitted by Licensee) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Licensee shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if Licensor is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to Licensee or the appropriate governmental authority (with the assistance of Licensee to the extent that this is reasonably required and is requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Licensee of its obligation to withhold such tax and Licensee shall apply the reduced rate of withholding or dispense with withholding, as the case may be; provided, that Licensee has received evidence of Licensor's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorisation at least fifteen (15) Business Days prior to the time that the Payments are due). If, in accordance with the foregoing, Licensee withholds any amount, it shall pay to Licensor the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to Licensor proof of such payment within ten (10) Business Days following such payment.

14.2 **Further Assurances**. Upon request by either Party and at such Party's expense, the other Party shall do such further acts and execute such additional agreements and instruments as may be reasonably necessary to give effect to the purposes of this Agreement.

14.3 **Independent status**. Each Party shall act as an independent contractor and shall not bind nor attempt to bind the other Party to any contract, nor any performance of obligations outside of the license agreement. Nothing contained or done under the Agreement shall be interpreted as constituting either Party the agent of the other in any sense of the term whatsoever or in the relationship of partners or joint venturers.

14.4 **Assignment**. Except in connection with the acquisition of a Party or the sale of all or substantially all of the assets of such Party to which this Agreement relates (provided that the assignee agrees in writing to assume all of the assigning Party's obligations under this Agreement), this Agreement may not be, directly or indirectly, assigned or transferred, in whole or in part, by a Party to a Third Party without the prior written consent of the other Party. The rights and obligations contained herein shall enure to the benefit of each Party's successors and permitted assigns, and shall be binding on and enforceable against the relevant Party's successors and permitted assigns. Any reference in this Agreement to any Party shall be construed accordingly. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.4 shall be null, void and of no legal effect. Notwithstanding anything to the contrary in this Section 14.4, Licensor shall be entitled to enter into financing and sales transactions with Third Parties regarding the assignment, pledging, and collateralization (including grants of liens, encumbrances and other charges) of the right to receive all amounts under this Agreement in connection with Licensor's interest in any Licensed Product.

Binding Effect - Subject to the provisions of Article 14.4 herein, this Agreement shall inure to the benefit of, and be binding upon, the respective successors of the Parties.

14.5 **Compliance with law**. Each Party shall comply with, and shall not be in violation of any valid applicable international, national, provincial or local statutes, laws, ordinances, rules, regulations, or other governmental orders of the Territory.

14.6 **Force Majeure**. No Party shall be responsible for a failure or delay in performance of any of the obligations hereunder due wars, insurrections, strikes, acts of God, power outages, storms, or actions of regulatory agencies (such events being defined as "**Force Majeure**"), provided that the Party seeking relief from its obligations advises the other Party forthwith of the Force Majeure. A Party whose performance of obligations has been delayed by force majeure shall use commercially reasonable efforts to overcome the effect of the Force Majeure as soon as possible. The other Party will have no right to demand indemnity for damage or assert a breach against such Party, provided, however, that if the event of Force Majeure preventing performance shall continue for more than six (6) months and such underlying cause would not also prevent other parties from performing such obligations, then the Party not subject to the event of Force Majeure may terminate this Agreement with a written notice to the other without any liability hereunder, except the obligation to make payments due to such date.

14.7 **Notices and Amendments**. Any notice or other communication required or permitted to be given hereunder shall be in writing and shall be given by facsimile or other means of electronic communication or by hand delivery as hereinafter provided. Any such notice, if sent by fax or other means of electronic communication, shall be deemed to have been received on the day of sending, or if delivered by hand shall be deemed to have been received at the time it is delivered to the applicable address noted below. Notices of change of address shall also be governed by this Section 14.7. Notices and other communications shall be addressed as follows:

(a) In the case of Licensor:

Onconova Therapeutics, Inc.
375 Pheasant Run
Newton, Pennsylvania 18940
Attn: Chief Executive Officer
Fax: 267-759-3681

with a copy to:

Onconova Therapeutics, Inc.
375 Pheasant Run
Newton, Pennsylvania 18940
Attn: Legal Department
email: legal@onconova.us

(b) In the case of Licensee:

Specialised Therapeutics Asia Pte. Ltd.
50 Raffles Place #32-01
Singapore Land Tower
Singapore 048623
Attention: Chief Executive Officer
Fax: [**]

E-mail: [**]

14.8 **Complete Agreement**. This Agreement together with the SDEA, and the quality agreement and pharmacovigilance agreement, embodies all of the understandings and obligations between the Parties with respect to the Licensed Products and supersedes any prior or contemporaneous agreements and understandings, whether written or oral, between the Parties with respect to the subject matter hereof. Any amendments or supplements to this Agreement shall not be valid unless executed in writing by duly authorized officers of both parties.

14.9 **Waiver**. No failure to exercise and no delay in exercising any right or remedy hereunder shall operate as a waiver thereof. Any waiver granted hereunder shall only be applicable the specific acts covered thereby and shall not apply to any subsequent events, acts, or circumstances.

14.10 **Severability**. In the event any portion of this Agreement shall be held illegal, void or ineffective, the remaining portion hereof shall remain in full force and effect. If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to conform with such statute or rule of law.

14.11 **Governing Law**. This Agreement all disputes arising out of or relating to this Agreement, or the performance, enforcement, breach or termination hereof or thereof, and any remedies relating thereto, shall be construed, governed by and interpreted in accordance with the laws of the State of New York without giving effect to any choice of law principles that would require the application of the laws of a different state or country.

14.12 **Public Announcements**. Neither Party shall originate any publicity, news release, or public announcements relating to this Agreement (including, without limitation, its existence, its subject matter, the Parties' performance, any amendment hereto, or performance hereunder), whether to the public or press, stockholders, or otherwise, without the prior written consent of the other Party, save only such announcements that are required by law or the rules of any relevant stock exchange to be made or that are otherwise agreed to by the Parties. If a Party decides to make an announcement, whether required by law or otherwise, it shall give the other Party reasonable notice of the text of the announcement so that the other Party shall have an opportunity to comment upon the announcement. To the extent that the receiving Party reasonably requests the deletion of any information in any such announcement, the disclosing Party shall delete such information unless, in the opinion of the disclosing Party's legal counsel, such information is required by law or the rules of any relevant stock exchange to be disclosed. The timing and content of the initial press release relating to this Agreement, if any, including its existence, the subject matter to which it relates and the transactions contemplated herein will, except as otherwise required by law or any stock exchange rules, be determined jointly by the Parties. To the extent that either Party reasonably determines that it is required to make a filing or any other public disclosure with respect to this Agreement or the terms or existence hereof to comply with the requirements, rules, laws or regulations of any applicable stock exchange, NASDAQ or any governmental or Regulatory Authority or body (the "*Requesting Body*"), including, without limitation, the U.S. Securities and Exchange Commission (collectively, the "*Disclosure Obligations*"), such Party shall promptly inform the other Party thereof and shall use reasonable efforts to maintain the confidentiality of the other Party's Confidential Information in any such filing or disclosure. Prior to making any such filing of a copy of this Agreement, the Parties shall mutually agree on the provisions of this Agreement for which the Parties shall seek confidential treatment, it being understood that if one Party determines to seek confidential treatment for a provision for which the other Party does not, then the Parties will use reasonable efforts in connection with such filing to seek the confidential treatment of any such provision. The Parties shall cooperate, each at its own expense, in such filing, including without limitation such confidential treatment request, and shall execute all documents reasonably required in connection therewith. The Parties will reasonably cooperate in responding promptly to any comments received from the Requesting Body with respect to such filing in an effort to achieve confidential treatment of such redacted form; provided that a Party shall be relieved of such obligation to seek confidential treatment for a provision requested by the other Party if such treatment is not achieved after the second round of responses to comments from the Requesting Body.

14.13 **Counterparts**. This Agreement may be executed in any number of counterparts, each of which shall be considered one and the same Agreement and shall become effective when a counterpart hereof has been signed by each of the Parties and delivered to the other Party.

14.14 **Time of Essence**. Time shall be of the essence of this Agreement and of each provision hereof.

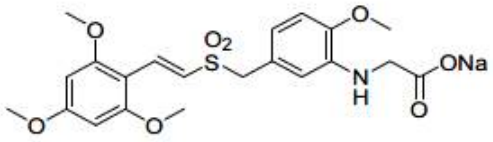
[*Signature page follows*]

IN WITNESS WHEREOF, the parties have signed this Agreement.

ONCONOVA THERAPEUTICS, INC.		**SPECIALISED THERAPEUTICS ASIA PTE. LTD.**	
By:	/s/ Steven M. Fruchtman, M.D.	By:	/s/ Carlo A. Montagner
Name:	Steven M. Fruchtman, M.D.	Name:	Carlo A. Montagner
Title:	President and CEO	Title:	CEO

Signature Page – Distribution, License and Supply Agreement

Schedule 1: Compound



Rigosertib

Exhibit A: Licensor Marks

None as of the Effective Date

Exhibit 99.1

Onconova Therapeutics Announces Exclusive License Agreement with Specialised Therapeutics for Rigosertib in Australia and New Zealand

- **Specialised Therapeutics receives exclusive license to commercialize rigosertib in Australia and New Zealand**
- **Onconova to be eligible to receive up to US $30.4 million in clinical, regulatory, and sales-based milestones and tiered double-digit royalties**

NEWTOWN, PA., Dec 18, 2019 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX) ("Onconova"), a Phase 3-stage biopharmaceutical company discovering and developing novel products to treat cancer, with a focus on myelodysplastic syndromes (MDS), today announced it has entered into a Distribution, License, and Supply Agreement whereby Specialised Therapeutics Asia ("STA") shall have the exclusive rights to commercialize rigosertib in Australia and New Zealand. In addition, Onconova may be entitled to receive clinical, regulatory, and sales-based milestone payments up to US $30.4 million and tiered double-digit royalties on net sales.

"We are pleased to partner with Specialised Therapeutics Asia, which has a strong track record of commercializing new products in oncology and hematology across Australia and New Zealand," said Dr. Steven Fruchtman, President and Chief Executive Officer of Onconova. "We look forward to working together and, pending a successful readout of the ongoing INSPIRE Trial, potentially providing rigosertib as a new therapeutic option for patients diagnosed with MDS."

STA Chief Executive Officer, Mr. Carlo Montagner, said that "patients with high-risk MDS have limited treatment options following currently available first-line treatment. There is no currently approved treatment following failure of standard chemotherapy with hypomethylating agents. Patients are left with the option of entering clinical trials, if available, or supportive care," he said. "If approved, rigosertib would address an unmet medical need and may be a valuable inclusion to the STA therapeutic portfolio. We are delighted to enter into this collaboration with Onconova and look forward to the results of the ongoing phase 3 INSPIRE Trial of intravenous (IV) rigosertib."

About Myelodysplastic Syndromes

MDS is a group of blood disorders that affect bone marrow function, whereby the bone marrow cells appear dysplastic and their capacity to produce cells is defective. As a result, patients with MDS have low blood cell counts and require frequent blood transfusions. In approximately one-third of patients, higher-risk MDS can progress to acute myelogenous leukemia (AML).

About Rigosertib

Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule. A key publication in a preclinical model described rigosertib's ability to block cellular signaling by targeting RAS effector pathways (Divakar, S.K., et al., 2016: "A Small Molecule RAS-Mimetic Disrupts RAS Association with Effector Proteins to Block Signaling." Cell 165, 643). Onconova is currently in the clinical development stage with oral and IV rigosertib, including clinical trials studying single agent IV rigosertib in second-line higher-risk MDS patients (pivotal Phase 3 INSPIRE Trial) and oral rigosertib plus azacitidine in first-line and refractory higher-risk MDS patients (Phase 2). Patents covering oral and injectable rigosertib have been issued in the US and are expected to provide coverage until at least 2037.

About the INSPIRE Phase 3 Clinical Trial

The clinical trial **IN**ternational **S**tudy of **P**hase 3 **I**V **R**igos**E**rtib, or **INSPIRE**, was finalized following guidance received from the U.S. Food and Drug Administration and European Medicines Agency. INSPIRE is a global, multi-center, randomized, controlled study to assess the efficacy and safety of IV rigosertib in higher-risk MDS (HR-MDS) patients who had progressed on, failed to respond to, or relapsed after previous treatment with a hypomethylating agent (HMA) within nine cycles over the course of one year after initiation of HMA treatment. This time-frame optimizes the opportunity to respond to treatment with an HMA prior to declaring treatment failure, as per NCCN Guidelines. Patients are randomized at a 2:1 ratio into two study arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival. The trial continued beyond the pre-specified interim analysis and is nearing its conclusion. Full details of the INSPIRE trial, such as inclusion and exclusion criteria, as well as secondary endpoints, can be found on clinicaltrials.gov (NCT02562443).

About Onconova Therapeutics, Inc.

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company discovering and developing novel small molecule drug candidates to treat cancer, with a focus on Myelodysplastic Syndromes (MDS). Using a proprietary chemistry platform, Onconova has created a pipeline of targeted agents designed to work against specific cellular pathways that are important in cancer cells. Advanced clinical trials with the Company's lead compound, rigosertib, are aimed at what the Company believes are unmet medical needs of patients with MDS. Onconova has conducted trials with two other research compounds and has a pre-clinical program with a CDK4/6 and Ark5 inhibitor, ON 123300.

For more information, please visit http://www.onconova.com.

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients throughout South East Asia, as well as in Australia and New Zealand. STA and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care.

Additional information can be found at www.stbiopharma.com

Onconova Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and involve risks and uncertainties. These statements relate to Onconova expectations regarding its products, its collaboration with Specialised Therapeutics, the INSPIRE Trial and Onconova's other development plans. Onconova has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes. Although Onconova believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including Onconova's ability to continue as a going concern, its ability to maintains its Nasdaq listing, the need for additional financing, the success and timing of Onconova's clinical trials and regulatory approval of protocols, and those discussed under the heading "Risk Factors" in Onconova's most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q. Any forward-looking statements contained in this release speak only as of its date. Onconova undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

CONTACT:

Onconova Therapeutics, Inc.
Avi Oler
267-759-3680
http://www.onconova.com/contact/