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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549**

# FORM 10-Q

**(Mark One)**

**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended March 31, 2018**

**Or**

**o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**Commission file number: 001-36020**

# Onconova Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

| **Delaware** | **22-3627252** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **375 Pheasant Run, Newtown, PA** | **18940** |
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: **(267) 759-3680**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes o No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

| | |
|---|---|
| Large accelerated filer o | Accelerated filer o |
| Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company x |
| | Emerging growth company x |

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. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). o Yes x No

The number of outstanding shares of the registrant's Common Stock, par value $0.01 per share, as of May 7, 2018 was 77,607,812.

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**ONCONOVA THERAPEUTICS, INC.**

**TABLE OF CONTENTS FOR QUARTERLY REPORT ON FORM 10-Q**
**FOR THE QUARTER ENDED MARCH 31, 2018**

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**PART I — FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**Onconova Therapeutics, Inc.**
**Condensed Consolidated Balance Sheets**

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 7,264,000 | $ 4,024,000 |
| Receivables | 477,000 | 59,000 |
| Prepaid expenses and other current assets | 814,000 | 820,000 |
| Total current assets | 8,555,000 | 4,903,000 |
| Property and equipment, net | 48,000 | 64,000 |
| Other non-current assets | 12,000 | 12,000 |
| Total assets | $ 8,615,000 | $ 4,979,000 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,034,000 | $ 6,186,000 |
| Accrued expenses and other current liabilities | 3,063,000 | 3,335,000 |
| Deferred revenue | 455,000 | 455,000 |
| Total current liabilities | 10,552,000 | 9,976,000 |
| Warrant liability | 961,000 | 1,773,000 |
| Deferred revenue, non-current | 3,977,000 | 4,091,000 |
| Total liabilities | 15,490,000 | 15,840,000 |
| Commitments and contingencies | | |
| Stockholders' (deficit) equity: | | |
| Preferred stock, $0.01 par value, 5,000,000 authorized at March 31, 2018 and December 31, 2017, none issued and outstanding at March 31, 2018 and December 31, 2017 | — | — |
| Common stock, $0.01 par value, 100,000,000 and 25,000,000 authorized at March 31, 2018 and December 31, 2017, 19,426,163 and 10,771,163 shares issued and outstanding at March 31, 2018 and December 31, 2017 | 194,000 | 108,000 |
| Additional paid in capital | 359,496,000 | 350,514,000 |
| Accumulated other comprehensive income | 11,000 | 3,000 |
| Accumulated deficit | (367,406,000) | (362,316,000) |
| Total Onconova Therapeutics, Inc. stockholders' (deficit) equity | (7,705,000) | (11,691,000) |
| Non-controlling interest | 830,000 | 830,000 |
| Total stockholders' (deficit) equity | (6,875,000) | (10,861,000) |
| Total liabilities and stockholders' (deficit) equity | $ 8,615,000 | $ 4,979,000 |

See accompanying notes to condensed consolidated financial statements.

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**Onconova Therapeutics, Inc.**
**Condensed Consolidated Statements of Operations (unaudited)**

| | Three months ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Revenue | $ 564,000 | $ 210,000 |
| Operating expenses: | | |
| General and administrative | 1,889,000 | 2,116,000 |
| Research and development | 4,577,000 | 4,886,000 |
| Total operating expenses | 6,466,000 | 7,002,000 |
| Loss from operations | (5,902,000) | (6,792,000) |
| | | |
| Change in fair value of warrant liability | 812,000 | (1,549,000) |
| Net loss | (5,090,000) | (8,341,000) |
| Net loss attributable to non-controlling interest | — | — |
| Net loss attributable to Onconova Therapeutics, Inc. | (5,090,000) | (8,341,000) |
| Net loss per share of common stock, basic and diluted | $ (0.34) | $ (1.23) |
| Basic and diluted weighted average shares outstanding | 15,138,663 | 6,771,383 |

See accompanying notes to condensed consolidated financial statements.



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**Onconova Therapeutics, Inc.**
**Condensed Consolidated Statements of Comprehensive Loss (unaudited)**

| | Three months ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Net loss | $ (5,090,000) | $ (8,341,000) |
| Other comprehensive income (loss), before tax: | | |
| Foreign currency translation adjustments, net | 8,000 | 5,000 |
| Other comprehensive income (loss), net of tax | 8,000 | 5,000 |
| Comprehensive loss | (5,082,000) | (8,336,000) |
| Comprehensive loss attributable to non-controlling interest | — | — |
| Comprehensive loss attributable to Onconova Therapeutics, Inc. | $ (5,082,000) | $ (8,336,000) |

See accompanying notes to condensed consolidated financial statements.



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**Onconova Therapeutics, Inc.**
**Consolidated Statement of Stockholders' (Deficit) Equity (unaudited)**

| | Stockholders' Equity (Deficit) | | | | | | |
|---|---|---|---|---|---|---|---|
| | Common Stock | | Additional Paid in Capital | Accumulated deficit | Accumulated other comprehensive income (loss) | Non-controlling interest | Total |
| | Shares | Amount | | | | | |
| Balance at December 31, 2017 | 10,771,163 | $ 108,000 | $ 350,514,000 | $ (362,316,000) | $ 3,000 | $ 830,000 | $ (10,861,000) |
| Net loss | — | — | — | (5,090,000) | — | — | (5,090,000) |
| Other comprehensive loss | — | — | — | — | 8,000 | — | 8,000 |
| Exercise of stock options | — | — | — | — | — | — | — |
| Stock-based compensation | — | — | 327,000 | — | — | — | 327,000 |
| Issuance of common stock and pre-funded warrants, net | 7,005,000 | 70,000 | 8,655,000 | — | — | — | 8,725,000 |
| Issuance of common stock upon exercise of warrants | 1,650,000 | 16,000 | — | — | — | — | 16,000 |
| Issuance of common stock, net | — | — | — | — | — | — | — |
| Balance at March 31, 2018 | 19,426,163 | $ 194,000 | $ 359,496,000 | $ (367,406,000) | $ 11,000 | $ 830,000 | $ (6,875,000) |

See accompanying notes to condensed consolidated financial statements.



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**Onconova Therapeutics, Inc.**
**Condensed Consolidated Statements of Cash Flows (unaudited)**

| | Three months ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Operating activities: | | |
| Net loss | $ (5,090,000) | $ (8,341,000) |
| Adjustment to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 16,000 | 23,000 |
| Change in fair value of warrant liabilities | (812,000) | 1,549,000 |
| Stock compensation expense | 278,000 | 458,000 |
| Changes in assets and liabilities: | | |
| Receivables | (418,000) | (95,000) |
| Prepaid expenses and other current assets | 6,000 | 740,000 |
| Accounts payable | 848,000 | 84,000 |
| Accrued expenses and other current liabilities | (223,000) | (361,000) |
| Deferred revenue | (114,000) | (113,000) |
| Net cash used in operating activities | (5,509,000) | (6,056,000) |
| | | |
| Investing activities: | | |
| Net cash provided by investing activities | — | — |
| | | |
| Financing activities: | | |
| Proceeds from the sale of common stock and warrants, net of costs | 8,725,000 | 40,000 |
| Proceeds from the exercise of warrants | 16,000 | — |
| Net cash provided by financing activities | 8,741,000 | 40,000 |
| Effect of foreign currency translation on cash | 8,000 | 5,000 |
| Net increase (decrease) in cash and cash equivalents | 3,240,000 | (6,011,000) |
| Cash and cash equivalents at beginning of period | 4,024,000 | 21,400,000 |
| Cash and cash equivalents at end of period | $ 7,264,000 | $ 15,389,000 |

See accompanying notes to condensed consolidated financial statements.



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**Onconova Therapeutics, Inc.**
**Notes to Condensed Consolidated Financial Statements**
**(Unaudited)**

**1. Nature of Business**

**The Company**

Onconova Therapeutics, Inc. (the "Company") was incorporated in the State of Delaware on December 22, 1998 and commenced operations on January 1, 1999. The Company's headquarters are located in Newtown, Pennsylvania. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule product candidates primarily to treat cancer. Using its proprietary chemistry platform, the Company has created an extensive library of targeted anti-cancer agents designed to work against specific cellular pathways that are important to cancer cells. The Company believes that the product candidates in its pipeline have the potential to be efficacious in a variety of cancers. The Company has three clinical-stage product candidates and several preclinical programs. In 2011, the Company entered into a license agreement, as subsequently amended, with SymBio Pharmaceuticals Limited ("SymBio"), which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. On March 2, 2018, the Company entered into a License, Development and Commercialization Agreement with Pint International SA (which, together with its affiliate Pint Pharma GmbH, are collectively referred to as "Pint"). Under the terms of the agreement, the Company granted Pint an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product containing rigosertib in all uses of rigosertib in certain Latin America countries. In 2012, the Company entered into a development and license agreement with Baxter Healthcare SA, the predecessor in interest to Baxalta GmbH (together with its affiliates, "Baxalta"), pursuant to which the Company granted an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in Europe. The Baxalta agreement terminated effective August 30, 2016, at which time the rights the Company licensed to Baxalta reverted to the Company at no cost. The Company has retained development and commercialization rights to rigosertib in the rest of the world, including the United States. During 2012, Onconova Europe GmbH was established as a wholly owned subsidiary of the Company for the purpose of further developing business in Europe. In April 2013, GBO, LLC, a Delaware limited liability company, ("GBO") was formed pursuant to an agreement with GVK Biosciences Private Limited, a private limited company located in India, ("GVK") to collaborate and develop two programs using the Company's technology platform. The two preclinical programs sublicensed to GBO have not been developed to clinical stage as initially hoped, and the Company is in discussions with GVK regarding the future of GBO.

On March 21, 2018, the Company amended its certificate of incorporation to increase the number of authorized shares of common stock par value $0.01 per share from 25,000,000 to 100,000,000.



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**Liquidity**

The Company has incurred recurring operating losses since inception. For the three months ended March 31, 2018, the Company incurred a net loss of $5,090,000 and as of March 31, 2018 the Company had generated an accumulated deficit of $367,406,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. At March 31, 2018, the Company had cash and cash equivalents of $7,264,000. The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy.

From its inception through July 2013, the Company raised capital through the private issuance of preferred stock. On July 30, 2013, the Company completed its initial public offering (the "IPO") of 594,167 shares of Common Stock, at a price of $150.00 per share. The Company received net proceeds of $79,811,000 from the sale, net of underwriting discounts and commissions and other estimated offering expenses. Immediately prior to the consummation of the IPO, all outstanding shares of preferred stock automatically converted into shares of Common Stock at the applicable conversion ratio then in effect. From the IPO through December 31, 2016, the Company closed on several offerings which included Common Stock and warrants. Total net proceeds from these offerings was approximately $24.9 million

On April 26, 2017 the Company closed on an underwritten public offering of 2,476,190 shares of Common Stock. On May 17, 2017, the Company sold an additional 363,580 shares as a result of the underwriter's exercise of its over-allotment option. Net proceeds from these transactions were approximately $5.3 million. (See Note 13)

On November 14, 2017 the Company closed on a registered direct offering to select accredited investors of 920,000 shares of common stock. Net proceeds were approximately $1.1 million. (See Note 13)

On February 12, 2018 the Company closed on an offering of units of common stock and warrants. The Company issued 7,005,000 shares of common stock, pre-funded warrants to purchase 2,942,500 share of common stock, and preferred stock warrants to purchase 1,044,487.5 shares of Series A convertible preferred stock. Each share of Series A convertible preferred stock is convertible into ten shares of common stock. Net proceeds were approximately $8.7 million. (See Note 13)

On May 1, 2018 the Company closed on an offering of units of common stock and warrants. The Company issued 55,411,763 shares of common stock, pre-funded warrants to purchase 12,235,295 shares of common stock, and preferred stock warrants to purchase 1,691,176.450 shares of Series B convertible preferred stock. Each share of Series B convertible preferred stock is convertible into 40 shares of common stock. Net proceeds were approximately $25.6 million. (See Note 13)

The Company has and may continue to delay, scale-back, or eliminate certain of its research and development activities and other aspects of its operations until such time as the Company is successful in securing additional funding. The Company continues to explore various dilutive and non-dilutive sources of funding, including equity financings, strategic alliances, business development and other sources. The future success of the Company is dependent upon its ability to obtain additional funding. There can be no assurance, however, that the Company will be successful in obtaining such funding in sufficient amounts, on terms acceptable to the Company, or at all. The Company currently anticipates that current cash and cash equivalents will be sufficient to meet its anticipated cash requirements into the fourth quarter of 2019.



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**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States ("GAAP") for interim financial information. Certain information and footnotes normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). The financial statements include the consolidated accounts of the Company, its wholly-owned subsidiary, Onconova Europe GmbH, and GBO. All significant intercompany transactions have been eliminated.

**Unaudited Interim Financial Information**

The accompanying condensed consolidated balance sheet as of March 31, 2018, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2018 and 2017, the consolidated statement of stockholders' (deficit) equity for the three months ended March 31, 2018 and the condensed consolidated statements of cash flows for the three months ended March 31, 2018 and 2017 are unaudited. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2018, the results of its operations for the three months ended March 31, 2018 and 2017, and its cash flows for the three months ended March 31, 2018 and 2017. The financial data and other information disclosed in these notes related to the three months ended March 31, 2018 and 2017 are unaudited. The results for the three months ended March 31, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018, any other interim periods, or any future year or period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2017 included in the Company's annual report on Form 10-K filed with the SEC on March 16, 2018.

**Segment Information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment, which is the identification and development of oncology therapeutics.



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**2. Summary of Significant Accounting Policies (Continued)**

**Significant Accounting Policies**

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2017 included in the Company's annual report on Form 10-K filed with the SEC on March 16, 2018. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

**Fair Value Measurements**

The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts. The fair value of the warrant liability is discussed in Note 7, "Fair Value Measurements."

**Revenue Recognition**

The Company recognizes revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), which the Company adopted effective January 1, 2018 using the modified retrospective method. There was no material impact to our financial position and results of operations as a result of the adoption. The Company applies ASC 606 to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. In accordance with ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods and services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract that falls under the scope of ASC 606, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company derives revenue from collaboration and licensing agreements and the sale of products associated with material transfer, collaboration and supply agreements.

*License, Collaboration and Other Revenues*

The Company enters into licensing and collaboration agreements, under which it licenses certain of its product candidates' rights to third parties. The Company recognizes revenue related to these agreements in accordance with ASC 606. The terms of these arrangements typically include payment of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of the licensed product.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligation under each of its agreements, the Company performs the five steps described above. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement of personnel costs, discount rates and probabilities of technical and regulatory success.



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**Onconova Therapeutics, Inc.**
**Notes to Condensed Consolidated Financial Statements (Continued)**
**(Unaudited)**

**2. Summary of Significant Accounting Policies (Continued)**

*Licensing of Intellectual Property:* If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front-fees. The Company evaluates the measure of progress each reporting period, and, if necessary, adjusts the measure of performance and related revenue recognition.

*Milestone Payments*: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensees, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in their period of adjustment.

*Manufacturing supply services.* Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. The Company assesses if these options provide material rights to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded when the customer obtains control of the goods, which is upon shipment.

*Royalties*: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some of all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from its license agreements.



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**2. Summary of Significant Accounting Policies (Continued)**

**Recent Accounting Pronouncements**

In February 2016, the FASB issued guidance which supersedes much of the current guidance for leases. The new standard requires lessees to recognize a right-of-use asset and a lease liability on their balance sheets for all the leases with terms greater than twelve months. Based on certain criteria, leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. For leases with a term of twelve months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. The guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The modified retrospective approach includes a number of optional practical expedients primarily focused on leases that commenced before the effective date of the new guidance, including continuing to account for leases that commence before the effective date in accordance with previous guidance, unless the lease is modified. The Company is evaluating the impact of the adoption of the standard on its consolidated financial statements.



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**2. Summary of Significant Accounting Policies (Continued)**

In March 2016, the FASB issued guidance that addresses the income tax effects of stock-based payments and eliminates the windfall pool concept, as all of the tax effects related to stock-based payments will now be recorded at settlement (or expiration) through the income statement. The new guidance also permits entities to make an accounting policy election for the impact of forfeitures on the recognition of expense for stock-based payment awards. Forfeitures can be estimated or recognized when they occur. The standard was effective for annual periods beginning after December 15, 2016 and interim periods within that reporting period. Early adoption was permitted in any interim or annual period, with any adjustment reflected as of the beginning of the fiscal year of adoption. The Company adopted the new guidance as of January 1, 2017. The adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

In November 2016, the FASB issued guidance requiring that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The guidance is effective for interim and annual periods beginning in 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company adopted this guidance effective December 31, 2017. Restricted Cash was $50,000 at December 31 2017, 2016 and 2015. The adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

**3. Revenue**

The Company's revenue during the three months ended March 31, 2018 and 2017 was from its license and collaboration agreements with SymBio and HanX (See Note 10).

Deferred revenue is as follows:

| | Symbio Upfront Payment |
|---|---|
| Deferred balance at December 31, 2017 | $ 4,546,000 |
| Recognition to revenue | 114,000 |
| Deferred balance at March 31, 2018 | $ 4,432,000 |

See Note 10, “License and Collaboration Agreements,” for a further discussion of the agreements with SymBio and HanX.



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**Onconova Therapeutics, Inc.**
**Notes to Condensed Consolidated Financial Statements (Continued)**
**(Unaudited)**

## 4. Net Loss Per Share of Common Stock

The following potentially dilutive securities outstanding at March 31, 2018 and 2017 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive (reflects the number of common shares as if the dilutive securities had been converted to common stock):

| | March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Warrants | 15,232,146 | 3,525,771 |
| Stock options | 1,118,849 | 891,518 |
| | 16,350,995 | 4,417,289 |

## 5. Warrants

Common Stock warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, *Derivatives and Hedging — Contracts in Entity’s Own Equity* (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Some of the Company’s warrants are classified as liabilities because in certain circumstances they could require cash settlement.

Warrants outstanding and warrant activity (reflects the number of common shares as if the warrants were converted to common stock) for the three months ended March 31, 2018 is as follows:

| Description | Classification | Exercise Price | Expiration Date | Balance Decemeber 31, 2017 | Warrants Issued | Warrants Exercised | Warrants Expired | Balance March 31, 2018 |
|---|---|---|---|---|---|---|---|---|
| Non-tradable warrants | Liability | $ 11.50 | July 2021 | 96,842 | — | — | — | 96,842 |
| Tradable warrants | Liability | $ 4.92 | July 2021 | 3,192,022 | — | — | — | 3,192,022 |
| Non-tradable pre-funded warrants | Equity | $ 0.01 | July 2023 | 5,907 | — | — | — | 5,907 |
| Non-tradable warrants | Equity | $ 0.45 | * | — | 9,947,500 | — | — | 9,947,500 |
| Non-tradable warrants | Equity | $ 1.2625 | * | — | 497,375 | — | — | 497,375 |
| Non-tradable warrants | Equity | $ 0.9400 | March 2021 | — | 75,000 | — | — | 75,000 |
| Non-tradable warrants | Equity | $ 1.4100 | March 2021 | — | 125,000 | — | — | 125,000 |
| Non-tradable pre-funded warrants | Equity | $ 0.01 | none | — | 2,942,500 | (1,650,000) | — | 1,292,500 |
| | | | | 3,294,771 | 13,587,375 | (1,650,000) | — | 15,232,146 |

* These preferred stock warrants expire on the earlier of (A) the one-month anniversary of the date on which the Company publically releases topline results of the INSPIRE Pivotal phase 3 that compare the overall survival (OS) of patients in the rigosertib group vs the Physician’s Choice group, in all patients and in a subgroup of patients with IPSS-R very high risk and (B) December 31, 2019. These preferred stock warrants may be exercised on a cashless basis in certain circumstances specified therein.



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**Onconova Therapeutics, Inc.**
**Notes to Condensed Consolidated Financial Statements (Continued)**
**(Unaudited)**

## 6. Balance Sheet Detail

Prepaid expenses and other current assets:

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Research and development | $ 394,000 | $ 514,000 |
| Manufacturing | 33,000 | 48,000 |
| Insurance | 162,000 | 181,000 |

| | | |
|---|---|---|
| Other | 225,000 | 77,000 |
| | $ 814,000 | $ 820,000 |

Property and equipment:

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Property and equipment | $ 2,228,000 | $ 2,228,000 |
| Accumulated depreciation | (2,180,000) | (2,164,000) |
| | $ 48,000 | $ 64,000 |

Accrued expenses and other current liabilities:

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Research and development | $ 1,884,000 | $ 1,912,000 |
| Employee compensation | 1,055,000 | 1,258,000 |
| Professional fees | 124,000 | 165,000 |
| | $ 3,063,000 | $ 3,335,000 |



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**Onconova Therapeutics, Inc.**
**Notes to Condensed Consolidated Financial Statements (Continued)**
**(Unaudited)**

**7. Fair Value Measurements**

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

On January 5, 2016, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with an institutional investor providing for the issuance and sale by the Company of 193,684 shares of Common Stock, at a purchase price of $9.50 per share and warrants to purchase up to 96,842 shares of Common Stock (the "Warrants") for aggregate gross proceeds of $1,840,000 (see Note 13). The Company has classified the warrants as a liability (see Note 5). The fair value was estimated using the Black-Scholes pricing model.

On July 29, 2016 the Company closed on a Rights Offering, issuing 3,599,786 shares of Common Stock, 3,192,022 Tradable Warrants and 656,400 Pre-Funded Warrants. The Tradable Warrants are exercisable for a period of five years for one share of Common Stock at an exercise price of $4.92 per share. After the one-year anniversary of issuance, the Company may redeem the Tradable Warrants for $0.001 per Tradable Warrant if the volume weighted average price of its Common Stock is above $12.30 for each of 10 consecutive trading days (see Note 13). The Company has classified the Tradable Warrants as a liability (see Note 5). The Tradable Warrants have been listed on the NASDAQ Capital Market since issuance and the Company regularly monitors the trading activity. During the period from issuance on July 29, 2016 through March 31, 2017 the Company determined that trading volume was insufficient to use the NASDAQ Capital Market value to determine the fair value of the warrant liability. The fair value was estimated using the Black-Scholes pricing model. During the quarter ended June 30, 2017, the Company determined that an active and orderly market for the Tradable Warrants had developed and that the NASDAQ Capital Market price was the best indicator of fair value of the warrant liability. Consequently, the Company changed its valuation technique from the Black-Scholes pricing model to the quoted market price, effective April 1, 2017. The change in valuation technique resulted in a reclassification of the liability within the valuation hierarchy form Level 3 to Level 1. The quoted market price was used to determine the fair value at December 31, 2017 and March 31, 2018.

The Company estimated the fair value of the non-tradable warrant liability at March 31, 2018, using the Black-Scholes option pricing model with the following weighted-average assumptions:

| | |
|---|---|
| Risk-free interest rate | 2.39% |
| Expected volatility | 74.07% |
| Expected term | 3.29 years |
| Expected dividend yield | 0% |

Expected volatility is based on the historical volatility of the Company's Common Stock since its IPO in July 2013.



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**7. Fair Value Measurements (Continued)**

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2018 and December 31, 2017:

| | Fair Value Measurement as of: | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | March 31, 2018 | | | | December 31, 2017 | | | |
| | Level 1 | Level 2 | Level 3 | Balance | Level 1 | Level 2 | Level 3 | Balance |
| Tradable warrants liability | $ 957,000 | $ — | $ — | $ 957,000 | $ 1,755,000 | $ — | $ — | $ 1,755,000 |
| Non-tradable warrants liability | — | — | 4,000 | 4,000 | — | — | 18,000 | 18,000 |
| Total | $ 957,000 | $ — | $ 4,000 | $ 961,000 | $ 1,755,000 | $ — | $ 18,000 | $ 1,773,000 |

The following table presents a reconciliation of the Company's liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three months ended March 31, 2018:

| | Warrant Liability |
|---|---|
| Balance at December 31, 2017 | $ 18,000 |
| Issuance of warrants | — |
| Change in fair value upon re-measurement | 14,000 |
| Balance at March 31, 2018 | $ 4,000 |

There were no transfers between Level 1 and Level 2 in any of the periods reported.



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**8. Stock-Based Compensation**

The 2007 Equity Compensation Plan as amended (the "2007 Plan"), amended, restated and renamed the Company's 1999 Stock Based Compensation Plan (the "1999 Plan"), which provided for the granting of incentive and nonqualified stock options and restricted stock to its employees, directors and consultants at the discretion of the board of directors.

The 2013 Equity Compensation Plan (the "2013 Plan"), amended, restated and renamed the 2007 Plan. Under the 2013 Plan, the Company may grant incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, deferred share awards, performance awards and other equity-based awards to employees, directors and consultants. The Company initially reserved 610,783 shares of Common Stock for issuance, subject to adjustment as set forth in the 2013 Plan. The 2013 Plan includes an evergreen provision, pursuant to which the maximum aggregate number of shares that may be issued under the 2013 Plan is increased on the first day of each fiscal year by the lesser of (a) a number of shares equal to four percent (4%) of the issued and outstanding Common Stock of the Company, without duplication, (b) 200,000 shares and (c) such lesser number as determined by the Company's board of directors, subject to specified limitations. At March 31, 2018, there were 33,779 shares available for future issuance.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in the Company's statements of operations and comprehensive loss in either research and development expenses or general and administrative expenses depending on the function performed by the optionee. No net tax benefits related to the stock-based compensation costs have been recognized since the Company's inception. The Company recognized stock-based compensation expense as follows for the three months ended March 31, 2018 and 2017:

| | Three Months ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| General and administrative | $ 158,000 | $ 265,000 |
| Research and development | 120,000 | 193,000 |
| | $ 278,000 | $ 458,000 |



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**8. Stock-Based Compensation (Continued)**

A summary of stock option activity for the three months ended March 31, 2018 is as follows:

| | Shares | Options Outstanding | | | |
|---|---|---|---|---|---|
| | | Number of | Weighted- | Weighted | Aggregate |

| | Available for Grant | Shares | Average Exercise Price | Average Remaining Contractual Term (in years) | Intrinsic Value |
|---|---|---|---|---|---|
| Balance, December 31, 2017 | 57,632 | 894,996 | $ 57.02 | 6.72 | $ 0 |
| Authorized | 200,000 | — | | | |
| Granted | (330,849) | 330,849 | $ 1.41 | | |
| Exercised | — | — | $ — | | |
| Forfeitures | 106,996 | (106,996) | $ 80.97 | | |
| Balance, March 31, 2018 | 33,779 | 1,118,849 | $ 25.00 | 8.03 | $ 0 |
| Vested or expected to vest, March 31, 2018 | | 1,098,389 | $ 42.02 | 7.16 | $ 0 |
| Exercisable at March 31, 2018 | | 624,116 | $ 42.02 | 7.16 | $ 0 |

Information with respect to stock options outstanding and exercisable at March 31, 2018 is as follows:

| Exercise Price | Shares | Exercisable |
|---|---|---|
| $1.09 - $6.50 | 802,214 | 336,045 |
| $14.80 - $15.00 | 29,775 | 19,445 |
| $23.20 - $39.80 | 75,369 | 59,635 |
| $43.40 - $75.30 | 87,343 | 84,843 |
| $132.80 - $151.20 | 118,798 | 118,798 |
| $277.10 - $291.40 | 5,350 | 5,350 |
| | 1,118,849 | 624,116 |

*Options granted after April 23, 2013*

The Company accounts for all stock-based payments made after April 23, 2013 to employees and directors using an option pricing model for estimating fair value. Accordingly, stock-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. Compensation expense is recognized for the portion that is ultimately expected to vest over the period during which the recipient renders the required services to the Company using the straight-line single option method. In accordance with authoritative guidance, the fair value of non-employee stock-based awards is re-measured as the awards vest, and the resulting increase in fair value, if any, is recognized as expense in the period the related services are rendered.



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**Onconova Therapeutics, Inc.**
**Notes to Condensed Consolidated Financial Statements (Continued)**
**(Unaudited)**

**8. Stock-Based Compensation (Continued)**

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes model requires the Company to make certain estimates and assumptions, including estimating the fair value of the Company's Common Stock, assumptions related to the expected price volatility of the Common Stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company's stock.

As of March 31, 2018, there was $1,074,000 of unrecognized compensation expense related to the unvested stock options issued from April 24, 2013 through March 31, 2018, which is expected to be recognized over a weighted-average period of approximately 1.95 years.

The weighted-average assumptions underlying the Black-Scholes calculation of grant date fair value include the following:

| | Three Months ended March 31, 2018 | 2017 |
|---|---|---|
| Risk-free interest rate | 2.60% | 2.07% |
| Expected volatility | 74.13% | 79.38% |
| Expected term | 5.78 years | 6.00 years |
| Expected dividend yield | 0% | 0% |
| Weighted average grant date fair value | $ 0.84 | $ 1.86 |

The weighted-average valuation assumptions were determined as follows:

- Risk-free interest rate: The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- Expected term of options: Due to its lack of sufficient historical data, the Company estimates the expected life of its employee stock options using the "simplified" method, as prescribed in Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.
- Expected stock price volatility: Expected volatility is based on the historical volatility of the Company's Common Stock since its IPO in July 2013.
- Expected annual dividend yield: The Company has never paid, and does not expect to pay, dividends in the foreseeable future. Accordingly, the Company assumed an expected dividend yield of 0.0%.
- Estimated forfeiture rate: The Company's estimated annual forfeiture rate on stock option grants was 4.14% in 2018 and 2017, based on the historical forfeiture experience.

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**Onconova Therapeutics, Inc.**
**Notes to Condensed Consolidated Financial Statements (Continued)**
**(Unaudited)**

**9. Research Agreements**

The Company has entered into various licensing and right-to-sublicense agreements with educational institutions for the exclusive use of patents and patent applications, as well as any patents that may develop from research being conducted by such educational institutions in the field of anticancer therapy, genes and proteins. Results from this research have been licensed to the Company pursuant to these agreements. Under one of these agreements with Temple University ("Temple"), the Company is required to make annual maintenance payments to Temple and royalty payments based upon a percentage of sales generated from any products covered by the licensed patents, with minimum specified royalty payments. As no sales had been generated through March 31, 2018 under the licensed patents, the Company has not incurred any royalty expenses related to this agreement. In addition, the Company is required to pay Temple a percentage of any sublicensing fees received by the Company.



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**Onconova Therapeutics, Inc.**
**Notes to Condensed Consolidated Financial Statements (Continued)**
**(Unaudited)**

**10. License and Collaboration Agreements**

**SymBio Agreement**

In July 2011, the Company entered into a license agreement with SymBio, which has been subsequently amended, granting SymBio an exclusive, royalty-bearing license for the development and commercialization of rigosertib in Japan and Korea. Under the SymBio license agreement, SymBio is obligated to use commercially reasonable efforts to develop and obtain market approval for rigosertib inside the licensed territory and the Company has similar obligations outside of the licensed territory. The Company has also entered into an agreement with SymBio providing for it to supply SymBio with development-stage product. Under the SymBio license agreement, the Company also agreed to supply commercial product to SymBio under specified terms that will be included in a commercial supply agreement to be negotiated prior to the first commercial sale of rigosertib. The supply of development-stage product and the supply of commercial product will be at the Company's cost plus a defined profit margin. Sales of development-stage product have been de minimis. The Company has additionally granted SymBio a right of first negotiation to license or obtain the rights to develop and commercialize compounds having a chemical structure similar to rigosertib in the licensed territory.

Under the terms of the SymBio license agreement, the Company received an upfront payment of $7,500,000 in 2011. The Company is eligible to receive milestone payments of up to an aggregate of $22,000,000 from SymBio upon the achievement of specified development and regulatory milestones for specified indications. Of the regulatory milestones, $5,000,000 is due upon receipt of marketing approval in the United States for rigosertib IV in higher-risk MDS patients, $3,000,000 is due upon receipt of marketing approval in Japan for rigosertib IV in higher-risk MDS patients, $5,000,000 is due upon receipt of marketing approval in the United States for rigosertib oral in lower-risk MDS patients, and $5,000,000 is due upon receipt of marketing approval in Japan for rigosertib oral in lower-risk MDS patients. Furthermore, upon receipt of marketing approval in the United States and Japan for an additional specified indication of rigosertib, which the Company is currently not pursuing, an aggregate of $4,000,000 would be due. In addition to these pre-commercial milestones, the Company is eligible to receive tiered milestone payments based upon annual net sales of rigosertib by SymBio of up to an aggregate of $30,000,000.

Further, under the terms of the SymBio license agreement, SymBio will make royalty payments to the Company at percentage rates ranging from the mid-teens to 20% based on net sales of rigosertib by SymBio.

Royalties will be payable under the SymBio agreement on a country-by-country basis in the licensed territory, until the later of the expiration of marketing exclusivity in those countries, a specified period of time after first commercial sale of rigosertib in such country, or the expiration of all valid claims of the licensed patents covering rigosertib or the manufacture or use of rigosertib in such country. If no valid claim exists covering the composition of matter of rigosertib or the use of or treatment with rigosertib in a particular country before the expiration of the royalty term, and specified competing products achieve a specified market share percentage in such country, SymBio's obligation to pay the Company royalties will continue at a reduced royalty rate until the end of the royalty term. In addition, the applicable royalties payable to the Company may be reduced if SymBio is required to pay royalties to third-parties for licenses to intellectual property rights necessary to develop, use, manufacture or commercialize rigosertib in the licensed territory. The license agreement with SymBio will remain in effect until the expiration of the royalty term. However, the SymBio license agreement may be terminated earlier due to the uncured material breach or bankruptcy of a party, or force majeure. If SymBio terminates the license agreement in these circumstances, its licenses to rigosertib will survive, subject to SymBio's milestone and royalty obligations, which SymBio may elect to defer and offset against any damages that may be determined to be due from the Company. In addition, the Company may terminate the license agreement in the event that SymBio brings a challenge against it in relation to the licensed patents, and SymBio may terminate the license agreement without cause by providing the Company with written notice within a specified period of time in advance of termination.



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**10. License and Collaboration Agreements (Continued)**

The Company assessed the SymBio arrangement in accordance with ASC 606 and determined that its performance obligations under the SymBio agreement include the exclusive, royalty-bearing, sublicensable license to rigosertib, the research and development services to be provided by the Company and its obligation to serve on a joint committee. The Company concluded that the license was not distinct since it was of no benefit to SymBio without the ongoing research and development services and that, as such, the license and the research and development services should be bundled as a single performance obligation. Since the provision of the license and research and development services, are considered a single performance obligation; the $7,500,000 upfront payment is being recognized as revenue ratably through December 2027, the expected period over which the Company expects the research and development services to be performed as the services are performed.

SymBio's purchases of rigosertib as development-stage product or for commercial requirements represent options under the agreement and revenues are therefore recognized when control of the product is transferred, which is typically when shipped. If SymBio orders the supplies from the Company, the Company expects the pricing for this supply to equal its third-party manufacturing cost plus a pre-negotiated percentage, which will not result in a significant incremental discount to market rates.



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Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

**10. License and Collaboration Agreements (Continued)**

**HanX Agreement**

In December 2017, the Company entered into a license and collaboration agreement with HanX Biopharmaceuticals, Inc. ("HanX"), a company focused on development of novel oncology products, for the further development, registration and commercialization of ON 123300 in Greater China. ON 123300 is a preclinical compound which the Company believes has the potential to overcome the limitations of current generation CDK 4/6 inhibitors. The key feature of the collaboration is that HanX will provide all funding required for future Chinese IND enabling studies necessary for filing an IND with the Chinese Food and Drug Administration. The studies would be conducted to meet the Good Laboratory Practice ("GLP") requirements of the FDA such that the Company could simultaneously file an IND with the US FDA. The Company and HanX will oversee the IND enabling studies. The Company will maintain global rights outside of China.

Pursuant to the agreement, the Company received a $450,000 upfront payment on April 11, 2018. If the compound receives regulatory approval and is commercialized, the Company would receive regulatory and commercial milestone payments, as well as royalties on sales in the Greater China territory.

The Company assessed the HanX arrangement for revenue recognition in accordance with ASC 606 and determined that the license was distinct and that control of the license had been transferred during the first quarter of 2018. As such, the Company recognized the $450,000 allocated to the license in the quarter ended March 31, 2018. Accordingly, the revenue is included in the consolidated statement of operations for the period ended March 31, 2018 and the amount receivable from HanX is included in receivables in the balance sheet at March 31, 2018.

**Pint Agreement**

On March 2, 2018, the Company entered into a License, Development and Commercialization Agreement (the "License Agreement") and a Securities Purchase Agreement (the "Securities Purchase Agreement") with Pint.

Under the terms of the License Agreement, the Company granted Pint an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product (the "Product") containing rigosertib in all uses of rigosertib in humans in Latin American countries (the "Territory," including Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, French Guiana, British Guiana, Suriname, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela).

Pint agreed to make an upfront equity investment in the Company's common stock. In addition, the Company could receive up to $41.5 million in additional regulatory, development and sales-based milestone payments, an additional equity investment, as well as tiered, double digit royalties based on net aggregate net sales in the Territory. Pint and the Company have also agreed to enter into a supply agreement providing for Pint purchasing rigosertib and the Product from the Company within 90 days of the FDA approval of an a New Drug Application ("NDA") for the Product.

Pint may terminate the License Agreement in whole (but not in part) at any time upon 45 days' prior written notice. The License Agreement also contains certain provisions for termination by either party in the event of breach of the License Agreement by the other party, subject to a cure period, or bankruptcy of the other party.

Under the terms of the Securities Purchase Agreement Pint agreed to make an upfront equity investment in the Company at a specified premium to the Company's share price. Pursuant to the Securities Purchase Agreement, closing of the upfront equity investment occurred on April 4, 2018 and Pint purchased 816,945 shares of common stock for $1,250,000.



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**10. License and Collaboration Agreements (Continued)**

In addition, under the Securities Purchase Agreement, if the FDA approves the NDA for the Product, Pint will reimburse the Company for certain research and development expenses. Half of the reimbursement amount will be paid in cash, the other half of the amount will be by an equity investment at a premium to the average of the volume weighted average price of common stock for the ten consecutive trading days ended on the day the FDA approves the NDA.

Pursuant to the Securities Purchase Agreement, the common stock purchased by Pint is subject to certain lock-up restrictions and Pint is entitled to certain registration and participation rights.

The Company assessed the Pint arrangement in accordance with ASC 606 and determined that the requirements to recognize revenue were not met as of March 31, 2018.

**11. Preclinical Collaboration**

In December 2012, the Company agreed to form GBO, an entity owned by the Company and GVK. The purpose of GBO is to collaborate on and develop two programs through filing of an investigational new drug application and/or conducting proof of concept studies using the Company's technology platform. If a program failure occurs for one or both programs, the Company may contribute additional assets to GBO to establish a replacement program or programs.

During 2013, GVK made an initial capital contribution of $500,000 in exchange for a 10% interest in GBO, and the Company made an initial capital contribution of a sublicense to all the intellectual property controlled by the Company related to the two specified programs in exchange for a 90% interest. Under the terms of the agreement, GVK may make additional capital contributions. The GVK percentage interest in GBO may change from the initial 10% to up to 50%, depending on the amount of its total capital contributions. During November 2014, GVK made an additional capital contribution of $500,000 which increased its interest in GBO to 17.5%. The Company evaluates its variable interests in GBO on a quarterly basis and has determined that it is the primary beneficiary.

For thirty days following the 15-month anniversary of the commencement of either of the two programs, the Company will have an option to (i) cancel the license and (ii) purchase all rights in and to that program. There are three of these buy-back scenarios depending on the stage of development of the underlying assets. In addition, upon the occurrence of certain events, namely termination of the Company's participation in the programs either with or without a change in control, GVK will be entitled to purchase or obtain the Company's interest in GBO. GVK will have operational control of GBO and the Company will have strategic and scientific control.

The two preclinical programs sublicensed to GBO have not been developed to clinical stage as initially hoped, and the Company is in discussions with GVK regarding the future of GBO. There was no activity in GBO during the three months ended March 31, 2018 and 2017.



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**12. Related-Party Transactions**

The Company has entered into a research agreement, as subsequently amended, with the Mount Sinai School of Medicine ("Mount Sinai"), with which a member of its board of directors and a significant stockholder is affiliated. Mount Sinai is undertaking research on behalf of the Company on the terms set forth in the agreements. Mount Sinai, in connection with the Company, will prepare applications for patents generated from the research. Results from all projects will belong exclusively to Mount Sinai, but the Company will have an exclusive option to license any inventions. Payments to Mount Sinai under this research agreement for the three months ended March 31, 2018 and 2017 were $88,000 and $88,000, respectively. At March 31, 2018 and December 31, 2017, the Company had $614,000 and $526,000, respectively, payable to Mount Sinai under this agreement.

The Company has entered into a consulting agreement with a member of its board of directors, who is also a significant stockholder of the Company. The board member provides consulting services to the Company on the terms set forth in the agreement. Payments to this board member for the three months ended March 31, 2018 and 2017 were $33,000 and $33,000, respectively. At March 31, 2018 and December 31, 2017, the Company had $33,000 and $33,000, respectively, payable under this agreement.



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**13. Securities Registrations and Sales Agreements**

On October 8, 2015, the Company entered into a Purchase Agreement, and a registration rights agreement with Lincoln Park. A registration statement (Form S-1 No. 333-207533), relating to the shares, which was filed with the SEC became effective on November 3, 2015.

Subject to the terms and conditions of the purchase agreement, including the effectiveness of a registration statement covering the resale of the shares, the Company may sell additional shares of its Common Stock, having an aggregate offering price of up to $15,000,000 to Lincoln Park from time to time until December 1, 2018.

Upon execution of the Lincoln Park purchase agreement, Lincoln Park made an initial purchase of 84,676 shares of the Company's Common Stock for $1,500,000. Subject to the terms and conditions of the purchase agreement, including the effectiveness of a registration statement covering the resale of the shares, the Company has the right to sell to and Lincoln Park is obligated to purchase up to an additional $15,000,000 of shares of Common Stock, subject to certain limitations, from time to time until December 1, 2018. The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 10,000 shares of Common Stock on any business day, increasing to up to 25,000 shares depending upon the closing sale price of the Common Stock (such purchases, "Regular Purchases"). However, in no event shall a Regular Purchase be more than $1,000,000. The purchase price of shares of Common Stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a Regular Purchase the closing sale price of the Common Stock is not below the threshold price as set forth in the Purchase Agreement. The Company's sales of shares of Common Stock to Lincoln Park under the Purchase Agreement were limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 4.99% of the then-outstanding shares of the Common Stock, which limit increased to 9.99% on May 1, 2016.

Pursuant to the terms of the Lincoln Park purchase agreement and to comply with the listing rules of the NASDAQ Stock Market, the number of shares issued to Lincoln Park thereunder shall not exceed 19.99% of the Company's shares outstanding on October 8, 2015 unless the approval of the Company's stockholders is obtained. This limitation shall not apply if the average price paid for all shares issued and sold under the purchase agreement is equal to or greater than $15.56. The Company is not required or permitted to issue any shares of Common Stock under the Lincoln Park purchase agreement if such issuance would breach the Company's obligations under the listing rules of the NASDAQ Stock Market.

As consideration for entering into the purchase agreement, the Company issued to Lincoln Park 20,000 shares of Common Stock. Lincoln Park represented to the Company, among other things, that it was an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the "Securities Act"), and the Company sold the securities in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The securities sold may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

The net proceeds to the Company under the Lincoln Park purchase agreement will depend on the frequency and prices at which the Company may sell shares of Common Stock to Lincoln Park. The Company expects that the proceeds received from the initial purchase and any additional proceeds from future sales to Lincoln Park will be used to fund the development of the Company's clinical and preclinical programs, for other research and development activities and for general corporate purposes.



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**Onconova Therapeutics, Inc.**
**Notes to Condensed Consolidated Financial Statements (Continued)**
**(Unaudited)**

**13. Securities Registrations and Sales Agreements (continued)**

In December 2016, the Company entered into a sales agreement (the "Sales Agreement") with FBR Capital Markets & Co. ("FBR") to create an at-the-market equity program ("ATM Program") under which the Company from time to time may offer and sell shares of its common stock through FBR. The Shares to be sold under the Sales Agreement were issued and sold pursuant to the Company's shelf registration statement on Form S-3 (File No 333-199219), previously filed with the SEC on October 8, 2014 and declared effective by the SEC on November 20, 2014. A prospectus supplement related to the Company's ATM Program was filed with the SEC on December 5, 2016. Sales under the Sales Agreement were 12,764 shares for net proceeds of approximately $40,000. The Sales Agreement was terminated effective April 19, 2017.

On April 20, 2017, the Company entered into an underwriting agreement with Laidlaw & Company (UK) Ltd. ("Laidlaw"), with respect to the issuance and sale in an underwritten public offering by the Company of 2,476,190 shares of Common Stock, at a price to the public of $2.10 per share. Pursuant to the underwriting agreement, the Company granted Laidlaw a 45-day option to purchase up to an additional 363,580 shares. The underwriting agreement contained customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and Laidlaw, including for liabilities under the Securities Act of 1933, as amended (the "Securities Act"), other obligations of the parties and termination provisions. The offering closed on April 26, 2017 and the proceeds to the Company, net of expenses, were approximately $4.6 million. On May 12, 2017, Laidlaw exercised their option to purchase 363,580 additional shares. Closing on the additional shares was May 17, 2017 and the proceeds to the Company, net of expenses, were approximately $0.7 million.

On November 9, 2017, the Company entered into a placement agency agreement with Laidlaw relating to the Company's registered direct offering, issuance and sale to select accredited investors of 920,000 shares of the Company's common stock at a price of $1.50 per share on a best efforts basis. These shares are registered under the Securities Act on the Company's Registration Statement on Form S-3 (File No. 333-199219). The offering closed on November 14, 2017. The net proceeds to the Company from the offering, after deducting placement agent fees and other expenses, were approximately $1,082,000. The Company intends to use the net proceeds from this offering to fund the development of its clinical and preclinical programs, for other research and development activities and for general corporate purposes, which may include capital expenditures and funding its working capital needs.

On February 8, 2018, the Company entered into an underwriting agreement (the "February 2018 Underwriting Agreement") with H.C. Wainwright & Co., LLC ("HCW"), relating to the public offering (the "February 2018 Offering") of 5,707,500 shares of the Company's common stock, pre-funded warrants (the "February 2018 Pre-Funded Warrants") to purchase an aggregate of 2,942,500 shares of common stock and preferred stock warrants (the "February 2018 Preferred Stock Warrants") to purchase up to an aggregate of 865,000 shares of the Company's Series A Convertible Preferred Stock, par value $0.01 per share (the "Series A Preferred Stock"). Each share of common stock or February 2018 Pre-Funded Warrant, as applicable, was sold together

with a February 2018 Preferred Stock Warrant to purchase a 0.1 share of Series A Preferred Stock at a combined public offering price of $1.01 per share of common stock or $1.00 per February 2018 Pre-Funded Warrant, as applicable, and accompanying February 2018 Preferred Stock Warrant.

The Company also granted HCW a 30-day option to purchase up to 1,297,500 additional shares of common stock at a purchase price of $1.00 per share and February 2018 Preferred Stock Warrants to purchase up to an aggregate of 129,750 shares of Series A Preferred Stock at a purchase price of $0.01 per February 2018 Preferred Stock Warrant, less the underwriting discounts and commissions. Prior to closing, HCW exercised this option in full to purchase 1,297,500 additional shares of common stock and February 2018 Preferred Stock Warrants to purchase 129,750 shares of Series A convertible preferred stock.

The offering closed on February 12, 2018. Net proceeds from the offering were approximately $8.7 million after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the offering to fund the development of its clinical and preclinical programs, for other research and development activities and for general corporate purposes, which may include capital expenditures and funding its working capital needs.

The February 2018 Pre-Funded Warrants are exercisable immediately at an exercise price of $0.01 per share, may be exercised until they are exercised in full, and may be exercised on a cashless basis in certain circumstances specified therein.



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**13. Securities Registrations and Sales Agreements (continued)**

The February 2018 Preferred Stock Warrants are exercisable immediately at an exercise price of $1.01 per 0.1 share of Series A Preferred Stock and will expire on the earlier of (A) the one-month anniversary of the date on which the Company publically releases topline results of the INSPIRE Pivotal phase 3 that compare the overall survival (OS) of patients in the rigosertib group vs the Physician's Choice group, in all patients and in a subgroup of patients with IPSS-R very high risk and (B) December 31, 2019. The February 2018 Preferred Stock Warrants may be exercised on a cashless basis in certain circumstances specified therein.

Each 0.1 share of Series A Preferred Stock will be convertible into one share of common stock. A holder of Series A Preferred Stock will be prohibited from converting Series A Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the shares of the Company's shares of common stock then issued and outstanding, which may be increased to 9.99% in certain circumstances. Shares of Series A Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to (i) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation of the Series A Preferred Stock, (ii) amend any provision of the Company's certificate of incorporation that would have a materially adverse effect on the rights of the holders of the Series A Preferred Stock, (iii) increase the number of authorized shares of Series A Preferred Stock, or (iv) enter into any agreement with respect to the foregoing. Shares of Series A Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors, and will rank (i) on parity with the Company's common stock on an as-converted basis, (ii) senior to any class or series of the Company's capital stock created thereafter specifically ranking by its terms junior to the Series A Preferred Stock, (iii) on parity to any class or series of the Company's capital stock created thereafter specifically, (iv) ranking by its terms on parity with the Series A Preferred Stock; and (v) junior to any class or series of the Company's capital stock created thereafter specifically ranking by its terms senior to the Series A Preferred Stock.

The exercise price and number of shares of common stock or Series A Preferred Stock issuable upon exercise of the Pre-Funded Warrants or Preferred Stock Warrants, as the case may be, and the conversion price and number of shares of common stock issuable upon the conversion of Series A Preferred Stock, is subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction, as described in the Pre-Funded Warrants, Preferred Stock Warrants and the Certificate of Designation of the Series A Preferred Stock, as applicable. The shares of common stock or Pre-Funded Warrants, as applicable, and the accompanying Preferred Stock Warrants could only be purchased together as a unit in the offering but were issued as separate securities.

HCW acted as sole book-running manager for the offering, which was a firm commitment underwritten public offering pursuant to a registration statement on Form S-1 (Registration No. 333-222374) that was declared effective by the SEC on February 7, 2018. The offering was made only by means of a prospectus forming a part of the effective registration statement. The Company paid HCW a commission equal to 7.0% of the gross proceeds of the offering, a management fee equal to 1.0% of the gross proceeds of the offering and other expenses. As additional compensation, the Company issued warrants to HCW exercisable for 49,737.5 shares of Series A Preferred Stock, which are convertible into 497,375 shares of common stock subject to the terms of the Series A Preferred Stock. These warrants have substantially the same terms as the February 2018 Preferred Stock Warrants except that the exercise price per share is equal to $1.2625 per 0.1 share of Series A Preferred Stock.



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**14. Subsequent Events**

***Securities Offering***

On April 27, 2018, the Company entered into an underwriting agreement with HCW relating to the public offering (the "April 2018 Offering") of 46,588,234 shares of the Company's common stock, pre-funded warrants (the "May 2018 Pre-Funded Warrants") to purchase an aggregate of 12,235,295 shares of common stock and preferred stock warrants (the "May 2018 Preferred Stock Warrants") to purchase up to an aggregate of 1,470,588.225 shares of the Company's Series B Convertible Preferred Stock, par value $0.01 per share (the "Series B Preferred Stock"). Each share of common stock or April 2018 Pre-Funded Warrant, as applicable, was sold together with a May 2018 Preferred Stock Warrant to purchase a 0.025 share of Series B Preferred Stock at a combined public offering price of $0.425 per share of common stock or $0.415 per May 2018 Pre-Funded Warrant, as applicable, and accompanying May 2018 Preferred Stock Warrant.

The Company also granted HCW a 30-day option to purchase up to 8,823,529 additional shares of common stock at a purchase price of $0.415 per share and May 2018 Preferred Stock Warrants to purchase up to an aggregate of 220,588.225 shares of Series B Preferred Stock at a purchase price of $0.01 per May 2018 Preferred Stock Warrant, less the underwriting discounts and commissions. Prior to closing, HCW exercised this option in full to purchase 8,823,529 additional shares of common stock and May 2018 Preferred Stock Warrants to purchase 220,588.225 shares of Series B convertible preferred stock.

The offering closed on May 1, 2018. Net proceeds from the offering were approximately $25.6 million after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the offering to fund the development of its clinical and preclinical programs, for other research and development activities and for general corporate purposes, which may include capital expenditures and funding its working capital needs.

The May 2018 Pre-Funded Warrants are exercisable immediately at an exercise price of $0.01 per share, may be exercised until they are exercised in full, and may be exercised on a cashless basis in certain circumstances specified therein.

The May 2018 Preferred Stock Warrants are exercisable immediately at an exercise price of $0.425 per 0.025 share of Series B Preferred Stock (convertible into one share of Common Stock) and will expire on the 18-month anniversary of the date (the "New Charter Amendment Date") on which the Company publicly announces through the filing of a Current Report on Form 8-K that the New Charter Amendment (defined below) has been filed with the Secretary of State of the State of Delaware. The May 2018 Preferred Stock Warrants may be exercised on a cashless basis in certain circumstances specified therein.

Each 0.025 share of Series B Preferred Stock will be convertible into one share of common stock. The Company does not currently have a sufficient number of authorized shares of common stock to cover the shares issuable upon the conversion of Series B Preferred Stock. As a result, before any shares of Series B Preferred Stock can be converted, the Company needs to receive stockholder approval of an amendment (the "New Charter Amendment") to its Tenth Amended and Restated Certificate of Incorporation, as amended, to sufficiently increase the authorized shares of common stock to cover the conversion of all outstanding shares of Series B Preferred Stock into common stock. The Company intends to seek such approval at a special meeting of stockholders on June 7, 2018. The Series B Preferred Stock is not convertible until the next business day after the Company files the New Charter Amendment with the Secretary of State of the State of Delaware. In addition, a holder of Series B Preferred Stock will be prohibited from converting Series B Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the shares of the Company's shares of common stock then issued and outstanding, which may be increased to 9.99% in certain circumstances. Shares of Series B Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B Preferred Stock will be required to (i) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the Certificate of Designation of the Series B Preferred Stock, (ii) amend any provision of the Company's certificate of incorporation that would have a materially adverse effect on the rights of the holders of the Series B Preferred Stock, (iii) increase the number of authorized shares of Series B Preferred Stock, or (iv) enter into any agreement with respect to the foregoing. Shares of Series B Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors, and will rank (i) on parity with the Company's common stock on an as-converted basis, (ii) senior to any class or series of the Company's capital stock created thereafter specifically ranking by its terms junior to the Series B Preferred Stock, (iii) on parity to any class or series of the Company's capital stock created thereafter specifically, (iv) ranking by its terms on parity with the Series B Preferred Stock; and (v) junior to any class or series of the Company's capital stock created thereafter specifically ranking by its terms senior to the Series B Preferred Stock.



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The exercise price and number of shares of common stock or Series B Preferred Stock issuable upon exercise of the Pre-Funded Warrants or Preferred Stock Warrants, as the case may be, and the conversion price and number of shares of common stock issuable upon the conversion of Series B Preferred Stock, is subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction, as described in the May 2018 Pre-Funded Warrants, May 2018 Preferred Stock Warrants and the Certificate of Designation of the Series B Preferred Stock, as applicable. The shares of common stock or May 2018 Pre-Funded Warrants, as applicable, and the accompanying May 2018 Preferred Stock Warrants could only be purchased together as a unit in the offering but were issued as separate securities.

HCW acted as sole book-running manager for the offering, which was a firm commitment underwritten public offering pursuant to a registration statement on Form S-1 (Registration No. 333-224315) that was declared effective by the SEC on April 26, 2018. The offering was made only by means of a prospectus forming a part of the effective registration statement. The Company paid HCW a commission equal to 8.0% of the gross proceeds of the offering, a management fee equal to 1.0% of the gross proceeds of the offering and other expenses.

In connection with the February 2018 Offering, the Company agreed to certain restrictions (the "Company Lock-Up") set forth in Section 5(j) of the February 2018 Underwriting Agreement. The Company Lock-Up, among other items, prohibited the Company, during a period of one hundred and thirty-five (135) days from February 8, 2018, without the prior written consent of HCW, from offering or selling any Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock. In order to received HCW's waiver of the Company Lock-Up, in connection with the April 2018 Offering, on April 16, 2018, the Company entered into a Lock-Up Waiver Agreement (the "Lock-Up Waiver Agreement") with HCW and certain holders of the February 2018 Preferred Stock Warrants, pursuant to which (i) HCW waived the Company Lock-Up solely with respect to the April 2018 Offering, and (ii) the Company agreed to reduce the exercise price of the February 2018 Preferred Stock Warrants such that the exercise price of the February 2018 Preferred Stock Warrants shall be equal to 105% of the public offering price of common stock sold in the April 2018 Offering (but only to the extent that such public offering price is lower than the current exercise price of the February 2018 Preferred Stock Warrants) and that such repricing shall be effective

concurrently with the closing of the April 2018 Offering. In accordance with the Lock-Up Waiver Agreements, the exercise price of the February 2018 Preferred Stock Warrants was repriced from $1.01 per 0.1 share of Series A Convertible Preferred Stock to $0.44625 per 0.1 share of Series A Convertible Preferred Stock when the April 2018 Offering closed on May 1, 2018.

***Special Meeting of Stockholders on June 7, 2018***

On May 7, 2018, The Company filed with the SEC a preliminary proxy statement on Schedule 14A relating to the Special Meeting of Stockholders the Company intends to hold on June 7, 2018 to seek stockholders' approval of an amendment to the Company's Tenth Amended and Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of capital stock from 105,000,000 shares to 255,000,000 shares in order to increase the number of authorized shares of common stock from 100,000,000 shares to 250,000,000 shares.



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**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with interim unaudited condensed consolidated financial statements contained in Part I, Item 1 of this quarterly report, and the audited consolidated financial statements and notes thereto for the year ended December 31, 2017 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our annual report on Form 10-K filed with the SEC on March 16, 2018. As used in this report, unless the context suggests otherwise, "we," "us," "our," "the Company" or "Onconova" refer to Onconova Therapeutics, Inc. and its consolidated subsidiaries.*

**Cautionary Note Regarding Forward-Looking Statements**

This quarterly report on Form 10-Q includes forward-looking statements. We may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements appear in a number of places throughout this report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, protection of our intellectual property portfolio, the degree of clinical utility of our products, particularly in specific patient populations, our ability to develop commercial and manufacturing functions, expectations regarding clinical trial data, our results of operations, cash needs, financial condition, liquidity, collaborations, partnerships, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this report. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate are consistent with the forward-looking statements contained in this report, they may not be predictive of results or developments in future periods.

Actual results could differ materially from our forward-looking statements due to a number of factors, including risks related to:

- our need for additional financing for our INSPIRE trial and other operations, and our ability to obtain sufficient funds on acceptable terms when needed, and our plans and future needs to scale back operations if adequate financing is not obtained;
- our ability to continue as a going concern;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials, including site initiation and patient enrollment, and regulatory approval of protocols for future clinical trials;
- our ability to enter into, maintain and perform collaboration agreements with other pharmaceutical companies, for funding and commercialization of our clinical product candidates or preclinical compounds, and our ability to achieve certain milestones under those agreements;
- the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;
- our plans and ability to develop, manufacture and commercialize our product candidates;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- recently enacted and future legislation and regulation regarding the healthcare system;
- the success of competing therapies and products that are or become available;
- our ability to maintain the listing of our common stock on a national securities exchange;



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- the potential for third party disputes and litigation; and
- the performance of third parties, including contract research organizations ("CROs") and third-party manufacturers.

Any forward-looking statements that we make in this report speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events. Comparisons of results for

current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

You should also read carefully the factors described in the "Risk Factors" in our most recent annual report on Form 10-K and quarterly reports on Form 10-Q, to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this report and you should not place undue reliance on any forward-looking statements.

**Overview**

We are a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule product candidates primarily to treat cancer. Using our proprietary chemistry platform, we have created a library of targeted agents designed to work against cellular pathways important to cancer cells. We believe that the product candidates in our pipeline have the potential to be efficacious in a variety of cancers. We have one Phase 3 clinical-stage product candidate and two other clinical-stage product candidates (one of which is being developed for treatment of acute radiation syndromes) and several preclinical programs. Substantially all of our current effort is focused on our lead product candidate, rigosertib. Rigosertib is being tested in an intravenous formulation as a single agent, and an oral formulation in combination with azacitidine, in clinical trials for patients with higher-risk myelodysplastic syndromes ("MDS").

In December 2015, we enrolled the first patient into our INSPIRE trial, a randomized controlled Phase 3 clinical trial of intravenous rigosertib ("rigosertib IV") in a population of patients with higher-risk MDS after failure of hypomethylating agent ("HMA") therapy. The primary endpoint of INSPIRE is overall survival. An interim analysis of the trial was performed in January 2018 and we anticipate reporting topline data from the INSPIRE trial in the first half of 2019.

Our net losses were $5.1 million and $8.3 million for the three months ended March 31, 2018 and 2017, respectively. As of March 31, 2018, we had an accumulated deficit of $367.4 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, even if milestones under our license and collaboration agreements may be met. As of March 31, 2018, we had $7.3 million in cash and cash equivalents.

In January 2016, we completed a sale of common stock and warrants for net proceeds of approximately $1.6 million. In July 2016, we completed a rights offering of units of common stock and warrants for net proceeds of $15.8 million. In December 2016, we entered into a sales agreement with FBR Capital Markets & Co. ("FBR") to create an at-the-market equity program under which we from time to time may offer and sell shares of common stock through FBR. Sales under this sales agreement in 2017 were 20,499 shares for net proceeds of approximately $64,000. The sales agreement was terminated effective April 19, 2017. There were no sales of common stock under this program during the year ended December 31, 2016.

In April 2017, we closed on an underwritten public offering of 2,476,190 shares of common stock. In May 2017, we sold an additional 363,580 shares as a result of the underwriter's exercise of its over-allotment option. Net proceeds from these transactions were approximately $5.3 million. In November 2017, we closed on a registered direct offering to select accredited investors of 920,000 shares of common stock. Net proceeds were approximately $1.1 million. In February 2018, we closed on an offering of units of common stock and warrants. We issued 7,005,000 shares of common stock, pre-funded warrants to purchase 2,942,500 share of common stock, and preferred stock warrants to purchase 1,044,487.5 shares of Series A convertible preferred stock. Each share of Series A convertible preferred stock is convertible into ten shares of common stock. Net proceeds were approximately $8.7 million. In May 2018, we closed on an offering of units of common stock and warrants. We issued 55,411,763 shares of common stock, pre-funded warrants to purchase 12,235,295 share of common stock, and preferred stock warrants to purchase 1,691,176.450 shares of Series B convertible preferred stock. Each share of Series B convertible preferred stock is convertible into forty shares of common stock. Net proceeds were approximately $25.6 million.

On March 21, 2018, we amended our certificate of incorporation to increase the number of authorized shares of common stock from 25,000,000 to 100,000,000.

We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials into the fourth quarter of 2019. We do not have a recurring source of revenue to fund our operations and will need to raise additional funds to obtain regulatory approval for our



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drug candidates; therefore, there is substantial doubt about our ability to continue as a going concern.

We are exploring various sources of funding for development and obtaining regulatory approval of rigosertib as well as for our ongoing operations. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, including rigosertib, or grant licenses on terms that are not favorable to us. There can be no assurance, however, that we will be successful in obtaining such financing in sufficient amounts, on terms acceptable to us, or at all. In addition, there can be no assurance that we will obtain approvals necessary to market our products or achieve profitability or sustainable, positive cash flow. If we are unable to successfully raise sufficient additional capital, through future financings or through strategic and collaborative arrangements, we will not have sufficient cash to fund our ongoing trials and operations.

***Rigosertib***

Rigosertib is a small molecule that we believe blocks cellular signaling by targeting RAS effector pathways. This is believed to be mediated by the interaction of rigosertib to the RAS-binding domain ("RBD"), found in many RAS effector proteins, including the Raf and PI3K kinases. We believe this mechanism of action provides a new approach to block the interactions between RAS and its targets containing RBD sites. Rigosertib is currently being tested in clinical trials as a single agent, and in combination with azacitidine, in patients with MDS. We have enrolled more than 1,300 patients in rigosertib clinical trials for MDS and other conditions. We were a party to a license and development agreement with Baxalta (as defined below), which granted Baxalta certain rights to commercialize rigosertib in Europe. The Baxalta agreement was terminated on August 30, 2016, at which time the European rights reverted to us at no cost. We are party to a collaboration agreement with SymBio, which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. We are party to a license agreement with Pint Pharma International SA ("Pint"), which grants Pint certain rights to commercialize rigosertib in certain countries in Latin America. We have retained development and commercialization rights to rigosertib in the rest of the world, including in the United States and Europe,

although we could consider licensing commercialization rights to other territories as we continue to seek additional funding. Previously we were a party to a license and development agreement with Baxalta (as defined below), which granted Baxalta certain rights to commercialize rigosertib in Europe. The Baxalta agreement was terminated on August 30, 2016, at which time the European rights reverted to us at no cost.

The table below summarizes our rigosertib clinical stage programs.

| Disease | Formulation | Indication | Stage | Expected Timelines | Potential Market Opportunity (US)/Benefit | |
|---|---|---|---|---|---|---|
| MDS | Intravenous | HR - following HMA failure<br><br>No approved product following HMA failure | Phase 3 Interim analysis completed | Phase 3 completion 2019 | ~ 5,000 patients | No directly competing FDA approved product in the market |
| | Oral | HR - prior to HMAs<br><br>In combination with AZA | Phase 2 | Phase 3 protocol in 2018 | ~ 18,000 | No oral NCE approved since 2005 |
| | Oral | Lower Risk | Phase 2 | Select patient population in 2018 | > 10,000 | Longer potential duration of treatment |
| RASopathies | Intravenous and oral | JMML/other RAS Pathway diseases | Phase 1 | -NIH CRADA signed<br>-Proof of concept 2019 | Rare disease | Pediatric clinical trial |

*Rigosertib IV for higher-risk MDS*

We are developing an IV version of rigosertib for the treatment of higher-risk MDS following the failure of HMA therapy. In early 2014, we announced topline survival results from our "ONTIME" trial, a multi-center Phase 3 clinical trial of rigosertib IV as a single agent versus best supportive care including low dose Ara-C. The ONTIME trial did not meet its primary endpoint of an improvement in overall survival in the intent-to-treat population, although improvements in median overall survival were observed in various pre-specified and exploratory subgroups of higher-risk MDS patients. As a result, additional clinical work is on-going.



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During 2014 and 2015, we held meetings with the U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA"), and several European national regulatory authorities to discuss and seek guidance on a path for approval of rigosertib IV in higher-risk MDS patients whose disease had failed HMA therapy. After discussions with the FDA and EMA, we refined our patient eligibility criteria by defining what we believe to be a more homogenous patient population. After regulatory feedback, input from key opinion leaders in the U.S. and Europe and based on learnings from the ONTIME study, we designed a new randomized controlled Phase 3 trial, referred to as INSPIRE. The INSPIRE trial is enrolling higher-risk MDS patients under 82 years of age who have progressed on, relapsed, or failed to respond to, previous treatment with HMAs within nine months or nine cycles over the course of one year after initiation of HMA therapy, and had their last dose of HMA within six months prior to enrollment in the trial. Patients are randomized to either rigosertib with best supportive care, or the physician's choice of therapy with best supportive care. The primary endpoint of this study is the sequential analysis of overall survival of all randomized patients in the intent-to-treat ("ITT") population and the International Prognostic Scoring System- Revised (IPSS-R) Very High Risk ("VHR") subgroup. The first patient in the INSPIRE trial was enrolled at the MD Anderson Cancer Center in December 2015, the first patient in Europe was enrolled in March, 2016, and the first patient in Japan was enrolled in July, 2016.

Enrollment for the INSPIRE Phase 3 trial for second-line higher-risk MDS patients is highly selective with stringent entry criteria as outlined above. Currently, the INSPIRE study has opened approximately 175 trial sites in 22 countries across four continents, and has enrolled more than 170 patients. Our partner, SymBio Pharmaceuticals, has opened more than 30 sites in Japan. The selection of countries and trial sites is carefully undertaken to ensure availability of appropriate patients meeting eligibility criteria. Since these criteria are purposely designed to be narrow and selective, extensive site screening and education is integral to our plan. At launch, the INSPIRE trial was expected to enroll 225 patients and the outcome is measured by overall survival.

The INSPIRE trial included a pre-planned interim analysis triggered by 88 events (deaths), which occurred in December 2017. The statistical analysis plan ("SAP") for the INSPIRE trial featured an adaptive trial design, permitting several options following the interim analysis, which included continuation of the trial as planned, discontinuation of the trial for futility or safety, trial expansion using pre-planned sample size re-estimation, and trial continuation for only the pre-defined treatment subgroup of patients classified as VHR based on the IPSS-R.

After review of the interim data, in January 2018 the Independent Data Monitoring Committee ("DMC") recommended continuation of the trial with a one-time expansion in enrollment, using a pre-planned sample size re-estimation, consistent with the SAP. As recommended by the DMC, the expanded INSPIRE study will continue to enroll eligible patients based on the current trial criteria of the overall ITT population and will increase enrollment by adding 135 patients to the original target to reach a total enrollment of 360 patients, with the aim of increasing the power of the trial. Due to the adaptive trial design and the DMC's assessment, the INSPIRE trial will continue to analyze both the ITT and the VHR population for the primary endpoint of overall survival. The design of the trial with the expanded study enrollment will be identical to the current study design and will include the sequential analysis of the overall survival endpoint in the ITT population and if required the pre-specified VHR subgroup. The Company remains blinded to the specific interim analysis results. We anticipate reporting topline data from the INSPIRE trial in the first half of 2019.

*Safety and Tolerability of rigosertib in MDS and other hematologic malignancies*

A comprehensive analysis of rigosertib IV and rigosertib oral safety in patients with Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) was presented in December 2016 at the American Society of Hematology (ASH) Annual Meeting. The most commonly reported treatment-emergent adverse events (TEAEs) in $\geq$ 10% of patients with MDS/AML (n= 335) receiving rigosertib intravenous (IV) monotherapy were fatigue (33%), nausea (33%), diarrhea (27%), constipation (25%), anaemia (24%) and pyrexia (24%). The most common $\geq$ Grade 3 AEs were anaemia (21%), febrile

neutropenia (13%), pneumonia (12%) and thrombocytopenia (11%). The most common serious AEs were febrile neutropenia (10%), pneumonia (9%), and sepsis (7%). The most common AEs leading to discontinuation of IV rigosertib were sepsis and pneumonia (3% each).



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*Rigosertib oral in combination with azacitidine for higher-risk MDS*

We are developing rigosertib oral for use in combination with azacitidine prior to treatment with HMA therapy for higher risk MDS. In December 2016, at the American Society of Hematology (ASH) Annual Meeting, we presented Phase 1/2 data from the initial portion of an ongoing rigosertib oral and azacitidine combination trial in higher-risk MDS. 33 of 40 MDS patients enrolled were evaluable for response at the time of the analysis. The median age of patients was 66, with 73% being male. The IPSS-R distribution was: 7.5% Low, 12.5% Intermediate, 37.5% High, 32.5% Very High and 10% unknown. 76% of patients responded per 2006 International Working Group (IWG) criteria. Responses were as follows:

| | Overall Evaluable (N=33) | No prior HMA (N-20) | Prior HMA (N=13) |
|---|---|---|---|
| Complete remission (CR) | 8(24)% | 7(35)% | 1(8)% |
| Marrow CR + hematologic improvement | 10(30)% | 6(30)% | 4(31)% |
| Marrow CR alone | 6(18)% | 3(15)% | 3(23)% |
| Hematologic improvement alone | 1(3)% | 1(5)% | 0 |
| Stable disease | 8(24)% | 3(15)% | 5(38)% |
| Overall IWG response | 25(76)% | 17(85)% | 8(62)% |
| Clinical benefit response | 19(58)% | 14(70)% | 5(38)% |

The median duration of response was 8 months for CR, 12.3 months for marrow CR.

*Safety/Tolerability of the Combination:*

Based upon a comprehensive analysis of patients receiving oral rigosertib in combination with azacitidine that was presented in 2016, the combination of rigosertib oral and azacitidine was well tolerated. The most common TEAEs in $\geq$ 10% of patients with MDS/AML (n=54) receiving rigosertib oral and azacitidine were nausea (41%), fatigue (39%), diarrhea (37%), constipation (37%) and dysuria (28%). The most common serious AEs were pneumonia (11%) and febrile neutropenia (7%). The most common AEs leading to discontinuation were AML (4%) and pneumonia (4%).

*Next steps for rigosertib oral in combination with azacitidine for higher-risk MDS*

Following an end of Phase 2 meeting with the Food and Drug Administration (FDA) in September 2016, we began development of a Phase 3 protocol. The Phase 3 trial will be designed as a global 1:1 randomized, placebo-controlled trial of rigosertib oral plus azacitidine compared to azacitidine plus oral placebo. Based on the results of the Phase 1/2 Study, full dose of azacitidine will be used in combination with rigosertib oral, as defined in the product insert for azacitidine. The patient population studied in this trial will be first-line (HMA naïve) higher-risk MDS patients. The primary endpoint for assessment of efficacy will be the composite Response Rate of complete remission (CR) + partial remission (PR,) as per the IWG 2006 Response Criteria. The trial will be under the review of a DMC. Formal FDA review may be sought via the Special Protocol Assessment (SPA) mechanism. We will not commence the Phase 3 trial without additional financing.

While the Phase 3 trial is being designed, we have expanded the Phase 1/2 trial cohort by enrolling 45 additional patients. Under a protocol expansion, we are using the expanded cohorts to explore dose optimization by increasing the dose of rigosertib oral to a total of 1120 mg in combination with full dose azacitidine and varying the dose administration scheme of rigosertib oral (560 mg before breakfast and 560 mg after lunch or 840 mg before breakfast and 280 mg after lunch) to identify an optimal dose and schedule. During this expansion, we also instituted risk-mitigation strategies, as further described below, in order to address a prior urinary adverse event of interest, hematuria. After amendments were filed with the regulatory agencies, we started the expansion phase of this trial in the U.S. sites that participated in the initial trial. Since the trial initiation, we have added additional US sites to complete enrollment of the expanded trial. The first patient was enrolled in April 2017 and as of April 2018, complete enrollment of 45 patients was achieved in the expansion trial; and the trial is ongoing.

In March 2018, at the 6th International Bone Marrow Failure Disease Symposium, we presented data on the incidence of hematuria in 37 higher-risk MDS patients receiving rigosertib oral in combination with azacitidine as part of the Phase 1/2 expanded cohort. In the first part of the Phase 1/2 study, prior to the study expansion, of 42 patients studied with oral rigosertib 840 mg total and azacitidine, the incidence of hematuria was 48%. In 37 patients studied with oral rigosertib 1120 mg total and azacitidine in the Phase 1/2 expanded cohort, with the use of risk-mitigating strategies to minimize hematuria, the incidence of hematuria was 11% at the time of the presentation. The study is ongoing. The risk-mitigating strategies employed are as follows:



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| | | | |
|---|---|---|---|
| 2nd RIGO dose must be administered at 3 PM (±1 hour) at least 2 hours after lunch to avoid a nocturnal bladder dwell time | Oral hydration of at least two liters of fluid per day is encouraged | Mandatory bladder emptying prior to bedtime | Urine pH approximately 2 hrs after AM dose. Sodium bicarbonate suggested administration of 650 TID if pH tests < 7.5 |

The comparison of the hematuria results from the two parts of this study are presented below:

**Hematuria Comparison Between Rigosertib Combination Therapy Parts 1 and 2:**

| | |
|---|---|
| All Patients on Combination Part 1 (Rigosertib 840 mg total & Azacitidine) | 42 |
| Patients with hematuria | 20(48)% |
| Patients with grade 1 or 2 hematuria | 17(40)% |
| Patients with grade ≥3 hematuria | 5(12)% |
| | |
| All Patients on Combination Part 2 (Rigosertib 1120 mg total) & Azacitidine) with risk-mitigation strategies | 37 |
| Patients with hematuria | 4(11)% |
| Patients with grade 1 or 2 hematuria | 4(11)% |
| Patients with grade ≥3 hematuria | 0(0)% |

In June 2017, at the Congress of the European Hematology Association Meeting, we updated the data from the Phase 1/2 trial and highlighted results in AML patients included in this study. Response data was presented on eight evaluable patients with AML who were tested with the rigosertib and azacitidine combination. For the eight evaluable patients with AML, the combination was well tolerated and the safety profile was similar to single-agent azacitidine, based on safety information in the azacitidine FDA approved label. Based on the presented results of the combination studies, the authors concluded that continued study in AML was warranted. We will not commence further development of rigosertib oral in combination with azacitidine for AML without additional financing.

Upon completion of our Phase 1/2 study, we will submit the study results to the applicable regulatory authorities. The final results of this study may differ from the results presented above and the applicable regulatory authorities may not agree with our analyses. We will not commence the Phase 3 trial of oral rigosertib in combination with azacitidine for higher-risk MDS or AML without additional financing.

*Rigosertib oral for lower-risk MDS*

We are also developing rigosertib oral as a single agent treatment for lower risk MDS. Higher-risk MDS patients suffer from a shortfall in normal circulating blood cells, or cytopenias, as well as elevated levels of cancer cells, or blasts in their bone marrow and sometimes in their peripheral blood with a significant rate of transformation to acute leukemia. Lower-risk MDS patients suffer mainly from cytopenias, that is low levels of red blood cells, white blood cells or platelets. Thus, lower-risk MDS patients depend on transfusions and growth factors or other therapies to improve their low blood counts; but have a lower rate of acute leukemic transformation.

We have explored single agent rigosertib oral as a treatment for lower-risk MDS in two Phase 2 clinical trials, 09-05 and 09-07. In December 2017, we presented data at the Annual ASH Meeting from the 09-05 Phase 2 trial. This data demonstrated a 44% rate of achieving transfusion independence in the cohort of Lower -risk MDS patients treated with rigosertib oral at a dose of 560 mg BID (1120 mg over 24 hrs). To date, Phase 2 clinical data has indicated that further study of single agent rigosertib oral in transfusion-dependent, lower-risk MDS patients is warranted. Rigosertib has been generally well tolerated, except for urinary side effects at higher dose levels. Future clinical trials will be needed to evaluate dosing and schedule modifications and their impact on efficacy and safety results of rigosertib oral in lower-risk MDS patients.

Data presented from the 09-05 trial also suggested the potential of a genomic methylation assessment of bone marrow cells to prospectively identify lower-risk MDS patients likely to respond to rigosertib oral. We therefore expanded the 09-05 trial by adding an additional cohort of 20 patients to advance the development of this genomic methylation test. To date, a biomarker which would predict response has not been identified. Further testing and development of rigosertib oral for lower-risk MDS will be required. We will not commence further development of rigosertib oral for lower-risk MDS without additional financing.



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*Safety and Tolerability of rigosertib oral in MDS and other hematologic malignancies*

As presented at the December 2016 ASH Annual Meeting, rigosertib oral as a monotherapy was evaluated in four Phase 1 and 2 studies in MDS and other hematologic malignancies. One study is completed and a clinical study report is available. The most common TEAEs in ≥ 10% of patients with MDS/AML (n=168) were pollakiuria (increased urinary frequency) (35%), fatigue (32%), diarrhea (26%), dysuria (29%) and haematuria (24%). The most common ≥ Grade 3 AEs were anaemia (17%), thrombocytopenia (5%), haematuria (4%) and urinary tract infection (4%). The most common serious AE was pneumonia (6%). The most common AEs leading to discontinuation of patients receiving rigosertib oral as monotherapy were dysuria (8%), urinary tract pain (7%), haematuria (5%) and urinary frequency (5%).

In addition to the above described clinical trials, we are continuing the preclinical and chemistry, manufacturing, and control work for IV and rigosertib oral.

*Rare Disease Program in "RASopathies"*

Based on new mechanism of action data published last year, we are initiating a collaborative development program focusing on a group of rare diseases with a well-defined genetic basis in expression or defects involving the Ras Effector Pathways. Since "RASopathies" are rare diseases affecting young children, we are embarking on a multifaceted collaborative program involving patient advocacy, government and academic organizations. The RASopathies are a group of rare diseases which share a well-defined genetic basis in expression or defects involving Ras Effector Pathways. They are usually caused by germline mutations in genes that alter the RAS subfamily and mitogen-activated protein kinases that control signal transduction and are among the most common genetic syndromes. Together, this group of diseases can impact more than 1 in 1000 individuals, according to RASopathiesNet.

In January 2018, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), part of the National Institutes of Health (NIH). Under the terms of the CRADA, the NCI will conduct research, including preclinical laboratory studies and a clinical trial, on rigosertib in pediatric cancer associated RASopathies.

As part of the CRADA, we will provide rigosertib supplies and initial funding towards non-clinical studies. The NCI will fund the majority of the research, including the cost of the clinical trial, which is expected to start in 2018. A clinical trial protocol has been developed and will be reviewed by the Institutional Review Board.

While the NCI will conduct a trial for RASopathy related cancers in pediatric patients, Onconova will focus on initiating a trial as well in Juvenile Myelomonocytic Leukemia (JMML), a well-described RASopathy affecting children which is incurable without an allogenic hematopoietic stem cell transplant.

***Other Programs***

The vast majority of the Company's efforts are now devoted to the advanced stage development of rigosertib for unmet medical needs of MDS patients. Other programs are either paused, inactive or require only minimal internal resources and efforts.

***Bricicliib***

Briciclib, another of our product candidates, is a small molecule targeting an important intracellular regulatory protein, Cyclin D1, which is often found at elevated levels in cancer cells. Cyclin D1 expression is regulated through a process termed cap-dependent translation, which requires the function of eukaryotic initiation factor 4E protein. In vitro evidence indicates briciclib binds to eukaryotic initiation factor 4E protein, blocking cap-dependent translation of Cyclin D1 and other cancer proteins, such as c-MYC, leading to tumor cell death. We have been conducting a Phase 1 multi-site dose-escalation trial of briciclib in patients with advanced solid tumors refractory to current therapies. Safety and efficacy assessments are complete in six of the seven dose-escalation cohorts of patients in this trial. As of December 2015, the Investigational New Drug ("IND") for briciclib is on full clinical hold following a drug product lot testing failure. We will be required to undertake appropriate remedial actions prior to re-initiating the clinical trial and completing the final dose-escalation cohort.



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***Recilisib***

Recilisib is a product candidate being developed in collaboration with the U.S. Department of Defense for acute radiation syndromes. We have completed four Phase 1 trials to evaluate the safety and pharmacokinetics of recilisib in healthy human adult subjects using both subcutaneous and oral formulations. We have also conducted animal studies and clinical trials of recilisib under the FDA's Animal Rule, which permits marketing approval for new medical countermeasures for which conventional human efficacy studies are not feasible or ethical, by relying on evidence from adequate and well-controlled studies in appropriate animal models to support efficacy in humans when the results of those studies establish that the drug is reasonably likely to produce a human clinical benefit. Human safety data, however, is still required. Ongoing studies of recilisib, focusing on animal models and biomarker development to assess the efficacy of recilisib are being conducted by third parties with government funding. We anticipate that any future development of recilisib beyond these ongoing studies would be conducted solely with government funding or by collaboration. Use of government funds to finance the research and development in whole or in part means any future effort to commercialize recilisib will be subject to federal laws and regulations on U.S. government rights in intellectual property. Additionally, we are subject to laws and regulations governing any research contracts, grants, or cooperative agreements under which government funding was provided.

***Preclinical Product Candidates***

In addition to our three clinical-stage product candidates, we have several product candidates that target kinases, cellular metabolism or cell division in preclinical development. We may explore additional collaborations to further the development of these product candidates as we focus internally on our more advanced programs.

Positive preclinical data was announced at the American Association for Cancer Research (AACR) annual meeting, which took place April 1-5, 2017 in Washington, DC, for ON 123300, a first-in-class dual inhibitor of CDK4/6 + ARK5, and for ON 150030, a novel Type 1 inhibitor of FLT3 and Src pathways. We believe our CDK inhibitor is differentiated from other agents in the market (Palbociclib, Ribociclib and Abemaciclig) or in development (such as the compounds being developed by G1 Therapeutics) by its dual inhibition of CDK4/6 + ARK5. We are party to a license and collaboration agreement with HanX Biopharmaceuticals, Inc. ("HanX"), which grants HanX certain rights to commercialize ON 123300 in China. We continue to carry out research to enhance the pre-clinical data package for this compound in an attempt to seek additional partners outside of China for co-development of this novel compound.

In a preclinical Rb+ve xenograft model for breast cancer, ON 123300 activity was shown to be similar to Palbociclib (Pfizer's Ibrance®). Moreover, based on the same preclinical model, ON 123300 may have the potential advantage of reduced neutropenia when compared to Palbociclib. Whereas both compounds resulted in decreased RBC and platelet counts in this preclinical model system, Palbociclib was found to have a more prominent and statistically significant ($P< 0.05$) inhibitory effect on neutrophil counts when compared to ON 123300.

In December 2017, we entered into a license and collaboration agreement with HanX, a company focused on development of novel oncology products, for the further development, registration and commercialization of ON 123300 in Greater China. Under the terms of the agreement, we received an upfront payment, and would receive regulatory and commercial milestone payments, as well as royalties on sales in the Greater China territory. The key feature of the collaboration is that HanX will provide all funding required for Chinese IND enabling studies necessary for filing an IND with the Chinese Food and Drug Administration. The studies would be conducted to meet the Good Laboratory Practice ("GLP") requirements of FDA such that we could simultaneously file an IND with the US FDA. We and HanX will oversee the IND enabling studies. We will maintain global rights outside of China.

In March 2018, Onconova and HanX completed the pre-Investigational New Drug, or pre-IND, consultation with FDA. These discussions provided guidance for the manufacturing of ON 123300 and the pre-clinical development plan for the submission of an IND application.

In April 2018, at the American Association for Cancer Research 2018 Annual Meeting, we announced an advance in pre-clinical development and the presentation of new pre-clinical data for ON 123300. The data from preclinical studies demonstrates that there is a differential metabolism of ON 123300 in male versus female rodents. As a result, the drug exposure is almost 2-3 fold higher in female rats. Based upon preclinical animal liver microsome studies, this differential effect appears to be limited to rodents, and is not observed in preclinical studies with human liver microsomes. Based on the preclinical liver microsome metabolism data from other species, relevant species have been selected along with the dosing strategy to be implemented in GLP toxicological studies to be conducted by HanX.

**Critical Accounting Policies and Significant Judgments and Estimates**

This management's discussion and analysis of our financial condition and results of operations is based on our interim unaudited consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, revenue recognition, deferred revenue and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe there have been no significant changes in our critical accounting policies as discussed in our annual report on Form 10-K filed with the SEC on March 16, 2018, with the exception of the adoption of ASC 606, as described further in the footnotes to the quarterly financial information contained in this filing.





**Results of Operations**

***Comparison of the Three Months Ended March 31, 2018 and 2017***

| | Three Months ended March 31, | | |
|---|---|---|---|
| | 2018 | 2017 | Change |
| Revenue | $ 564,000 | $ 210,000 | $ 354,000 |
| Operating expenses: | | | |
| General and administrative | 1,889,000 | 2,116,000 | 227,000 |
| Research and development | 4,557,000 | 4,886,000 | 309,000 |
| Total operating expenses | 6,466,000 | 7,002,000 | 536,000 |
| Loss from operations | (5.902,000) | (6,792,000) | 890,000 |
| Change in fair value of warrant liability | 812,000 | (1,549,000) | 2,361,000 |
| Other income (expense), net | — | — | — |
| Net loss before income taxes | (5,090,000) | (8,341,000) | (3,251,000) |
| Income taxes | — | — | — |
| Net loss | $ (5,090,000) | $ (8,341,000) | $ 3,251,000 |

*Revenues*

Revenues increased by $0.4 million for the three months ended March 31, 2018 when compared to the same period in 2017 primarily as a result of the recognition of HanX revenue in the 2018 period, partially offset by less clinical supply revenue from SymBio in the 2018 period.

*General and administrative expenses*

General and administrative expenses decreased by $0.2 million, or 11%, to $1.9 million for the three months ended March 31, 2018 from $2.1 million for the three months ended March 31, 2017. The decrease was attributable primarily to a decrease of $0.1 million in professional and consulting fees in the 2018 period, as the 2017 period included costs related to stock offerings which were not completed. The decrease was also caused by lower stock compensation expense in the 2018 period due to fewer options being outstanding and contributing to expense in the 2018 period and the impact of a lower stock price in the 2018 period compared to the 2017 period in stock compensation expense calculations.

*Research and development expenses*

Research and development expenses decreased by $0.3 million, or 6%, to $4.6 million for the three months ended March 31, 2018 from $4.9 million for the three months ended March 31, 2017. This decrease was caused primarily by a $0.7 million decrease in manufacturing cost in the 2018 period due to the timing of drug substance and drug product manufacturing activities and a $0.2 million decrease in consulting expenses in the 2018 period. These decreases were partially offset by a $0.5 million increase in clinical expenses in the 2018 period related to our INSPIRE trial and our 09-08 expansion study, as well as a $0.2 million increase in personnel costs related to higher personnel costs in the 2018 period.

*Change in fair value of warrant liability*

The fair value of the warrant liability decreased by $0.8 million for the three months ended March 31, 2018, compared to an increase of $1.5 million for the three months ended March 31, 2017. This change was caused primarily by the decrease in the fair market value of the warrants issued in our rights offering in 2016.





***Financial Condition***

Total assets increased $3.6 million, or approximately 73%, from $5.0 million at December 31, 2017 to $8.6 million at March 31, 2018. The increase in total assets was due primarily to increases in cash, cash equivalents, and receivables. Total liabilities decreased from $15.8 million at December 31, 2017

to $15.5 million at March 31, 2018, a decrease of $0.4 million, primarily as a result of the decrease in the warrant liability since December 31, 2017 and our continuing recognition of revenue related to a combined license and research and development under our SymBio agreement, partially offset by higher accounts payable and accrued expenses. Total stockholders' deficit decreased $4.0million from $10.9 million at December 31, 2017 to $6.9 million at March 31, 2018, primarily due to a net loss of $5.1 million for the three months ended March 31, 2018, partially offset by increases in common stock and additional paid in capital related to stock compensation expense and our sale of securities during the first quarter of 2018.

**Liquidity and Capital Resources**

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of $5.1 million and $8.3 million for the three months ended March 31, 2018 and 2017, respectively. Our operating activities used $5.5 million and $6.1 million of net cash during the three months ended March 31, 2018 and 2017, respectively. At March 31, 2018, we had an accumulated deficit of $367.4 million, a working capital shortfall of $2.0 million, and cash and cash equivalents of $7.3 million.

On April 27, 2018, we entered into the Underwriting Agreement with HCW for an offering of units of common stock and warrants, which closed on May 1, 2018. The Company issued 55,411,763 shares of common stock, pre-funded warrants to purchase 12,235,295 shares of common stock, and preferred stock warrants to purchase 1,691,176.450 shares of Series B convertible preferred stock. Each share of Series B convertible preferred stock is convertible into 40 shares of common stock. Net proceeds were approximately $25.6 million. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the fourth quarter of 2019.

***Cash Flows***

The following table summarizes our cash flows for the three months ended March 31, 2018 and 2017:

| | Three Months ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Net cash (used in) provided by: | | |
| Operating activities | $ (5,509,000) | $ (6,056,000) |
| Investing activities | — | — |
| Financing activities | 8,741,000 | 40,000 |
| Effect of foreign currency translation | 8,000 | 5,000 |
| Net decrease in cash and cash equivalents | $ 3,240,000 | $ (6,011,000) |

*Net cash used in operating activities*

Net cash used in operating activities was $5.5 million for the three months ended March 31, 2018 and consisted primarily of a net loss of $5.1 million, which included $0.8 million of income related to the change in the fair value of the warrant liability and $0.3 million of noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net increase in cash of $0.1 million. Significant changes in operating assets and liabilities included an increase in accounts payable and accrued liabilities of $0.7 million as a result of the timing of receipt and payment of vendor invoices, primarily related to our INSPIRE trial, and an increase in receivables related to our receivable from HanX. Deferred revenue decreased $0.1 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

*Net cash provided by investing activities*

There was no net cash provided by or used in investing activities for the three months ended March 31, 2018 or 2017.

*Net cash provided by financing activities*

Net cash provided by financing activities for the three months ended March 31, 2018 and 2017 was $8.7 million and $40,000 respectively, which resulted from the proceeds received from the sale of our Common Stock during those periods.



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**Operating and Capital Expenditure Requirements**

We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the fourth quarter of 2019. We are exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. If we are unable to obtain additional funding, we may not be able to continue as a going concern and may be forced to curtail all of our activities and, ultimately, potentially cease operations. If we are unable to raise sufficient additional funding, we will not have sufficient cash flows and liquidity to fund our planned business operations, and may be forced to limit many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing to others the development and commercialization of products that we consider valuable and would otherwise likely develop ourselves. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests. The consolidated financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect our net cash expenditures in 2018 to be comparable to 2017. We will incur substantial costs beyond the present and planned clinical trials in order to file a New Drug Application (NDA) for rigosertib. The nature, design, size and cost of further studies will depend in large part on the outcome of preceding studies and discussions with regulators.

For additional risks, please see "Risk Factors" in this 10-Q and previously disclosed in our annual report on Form 10-K filed with the SEC on March 16, 2018.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

As a smaller reporting company, the Company is not required to provide the information otherwise required by this Item.



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**Item 4. Controls and Procedures**

**Managements' Evaluation of our Disclosure Controls and Procedures**

Our management, with the participation of our principal executive and principal financial officers, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of March 31, 2018, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective.

**Changes in Internal Control Over Financial Reporting**

Our management, with the participation of our principal executive and principal financial officers, evaluated any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive and principal financial officers concluded that no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended March 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



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**PART II — OTHER INFORMATION**

**Item 1. Legal Proceedings**

We are not party to any pending material legal proceedings and are not aware of any such proceedings contemplated by governmental authorities.

**Item 1A. Risk Factors**

The following risk factor should be read in conjunction with the "Risk Factors" previously disclosed in our annual report on Form 10-K filed with the SEC on March 16, 2018.

***We are not in compliance with the Nasdaq continued listing requirements. If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could affect the common stock's market price and liquidity and reduce our ability to raise capital.***

On May 7, 2018, the Company received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that the Company has failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2). Nasdaq Listing Rule 5550(a) (2) requires that companies listed on the Nasdaq Capital Market maintain a minimum closing bid price of at least $1.00 per share.

Under Nasdaq Listing Rule 5810(c)(3)(A), the Company has a 180 calendar day grace period, or until November 5, 2018, to regain compliance by meeting the continued listing standard. The continued listing standard will be met if the Company's common stock has a minimum closing bid price of at least $1.00 per share for a minimum of ten consecutive business days during the 180 calendar day grace period.

If the Company is not in compliance by November 5, 2018, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement. In addition, the Company would be required to notify Nasdaq of its intention to cure the minimum bid price deficiency during the second compliance period, by effecting a reverse stock split, if necessary.

If the Company does not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be subject to delisting. At that time, the Company may appeal the Nasdaq Staff's determination to a Hearings Panel.

The Company intends to monitor the closing bid price of the Company's common stock and consider its available options to resolve the noncompliance with the minimum bid price requirement. No determination regarding the Company's response has been made at this time. There can be no assurance that the Company will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria. For example, as of March 31, 2017, June 30, 2017, September 30, 2017, December 31, 2017 and March 31, 2018, the Company's total stockholders' equity was $(2.7) million, $0.4 million, $(6.1) million, $(10.9) million and $(7.3) million, respectively. As a result, the Company did not comply with the Nasdaq's $2.5 million minimum stockholders' equity requirement, nor the alternative compliance standards under Nasdaq Listing Rule 5550(b) for the continued listing of our securities on The Nasdaq Capital Market. As a result of the April 2018 Offering, the Company was able to regain compliance with the minimum stockholders' equity requirement. However, there is no assurance that the Company will be able to maintain compliance. If the

Company's securities are delisted, it could be more difficult to buy or sell the Company's securities and to obtain accurate quotations, and the price of the Company's securities could suffer a material decline. Delisting could also impair the Company's liquidity and ability to raise capital.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

On April 4, 2018, the Company sold 816,945 shares of common stock to Pint for $1,250,000 in connection with the Company's License, Development and Commercialization Agreement with Pint \ and the related Securities Purchase Agreement with Pint. The sale of such shares was not registered under the Securities Act because it was made in a transaction exempt from registration under Section 4(a)(2) of the Securities Act and/or Rule 506 promulgated thereunder.

On March 26, 2018, the Company agreed to issue to World Wide Holdings, LLC d/b/a Invictus Resources ("Invictus"), in connection with that certain Master Services Agreement between the Company and Invictus, warrants for Common Stock. The warrants issuable as of March 26, 2018 are exercisable for (i) 75,000 shares of common stock at a price of $0.94 per share of Common



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Stock and (ii) 125,000 shares of common stock at a price of $1.41 per share of common stock. The sale of such securities to Invictus was not registered under the Securities Act because it was made in a transaction exempt from registration under Section 4(a)(2) of the Securities Act and/or Rule 506 promulgated thereunder.

On February 12, 2018, the Company issued warrants to HCW as additional underwriter compensation in connection with an underwritten offering of securities of the Company. These warrants are exercisable for 49,737.5 shares of Series A Preferred Stock, which are convertible into 497,375 shares of common stock subject to the terms of the Series A Preferred Stock. These warrants have an exercise price of $1.2625 per 0.1 share of Series A Preferred Stock. The sale of such securities to HCW was not registered under the Securities Act because it was made in a transaction exempt from registration under Section 4(a)(2) of the Securities Act and/or Rule 506 promulgated thereunder.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

As disclosed in the Company's Current Report on Form 8-K filed with the SEC on May 15. 2018, the Company's 2018 Annual Meeting of Stockholders is scheduled to be held on June 27, 2018. This date is more than 30 days after the anniversary of the Company's 2017 Annual Meeting of Stockholders. As a result, in accordance with the applicable rules and regulations of the Securities and Exchange Commission (the "SEC") and the Company's Amended and Restated Bylaws, written notice from a stockholder interested in bringing business before the Company's 2018 Annual Meeting of Stockholders or nominating a director candidate for election at the Company's 2018 Annual Meeting of Stockholders (including any notice on Schedule 14N) must be received by no later than 5:00 p.m., Eastern time, on May 25, 2018 at the Company's principal executive offices, 375 Pheasant Run, Newtown, PA 18940. Any such written notice must be directed to the attention of the Company's Secretary and comply with the applicable advance notice provisions of the Company's Amended and Restated Bylaws. Stockholder proposals intended to be considered for inclusion in the Company's proxy materials for the 2018 Annual Meeting of Stockholders must comply with the requirements, including the deadline, set forth above as well as the all applicable rules and regulations promulgated by the SEC under the Exchange Act.



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**Item 6. Exhibits**

| Exhibit Number | Description |
|---|---|
| 3.1 | Certificate of Designation of Series A Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 8, 2018). |
| 3.2 | Certificate of Amendment to Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc., as amended (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 22, 2018) |
| 4.1 | Form of Underwriter Warrant issued as of February 12, 2018 (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 8, 2018). |
| 4.2 | Form of Preferred Stock Warrant issued as of February 12, 2018 (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on February 8, 2018). |
| 4.3 | Form of Pre-Funded Warrant issued as of February 12, 2018 (Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on February 8, 2018). |
| 10.1* | License, Development and Commercialization Agreement, dated as of March 2, 2018, by and between Onconova Therapeutics, Inc. and Pint International SA |
| 10.2 | Securities Purchase Agreement, dated as of March 2, 2018, by and between Onconova Therapeutics, Inc. and Pint Pharma GmbH |
| 31.1 | Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer |
| 31.2 | Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer |
| 32.1 | Section 1350 Certifications of Principal Executive Officer |

| | |
|---|---|
| 32.2 | Section 1350 Certifications of Principal Financial Officer |
| | |
| 101.INS | XBRL Instance |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Labels Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.



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* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.



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**SIGNATURES**

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

**ONCONOVA THERAPEUTICS, INC.**

Dated: May 15, 2018

/s/ RAMESH KUMAR, Ph.D.
Ramesh Kumar, Ph.D.
President and Chief Executive Officer
(*Principal Executive and Principal Operating Officer*)

Dated: May 15, 2018

/s/ MARK GUERIN
Mark Guerin
Chief Financial Officer

(*Principal Financial Officer*)

**Exhibit 10.1**

**EXECUTION VERSION**

**Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "[**]" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Securities and Exchange Commission.**

**LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

DATED AS OF MARCH 2, 2018

by and between

**ONCONOVA THERAPEUTICS, INC.**

and

**PINT PHARMA INTERNATIONAL SA**

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**LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

This License, Development and Commercialization Agreement (this "**Agreement**"), dated as of March 2, 2018 (the "**Effective Date**"), is made by and among Onconova Therapeutics, Inc., a Delaware corporation ("**Onconova**"), and Pint Pharma International SA, a company registered under Swiss laws having its registered office at Route de Chenaux 9, 1091 Bourg-en-Levaux, Switzerland ("**Pint**"). Onconova and Pint are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

**RECITALS**

**WHEREAS**, Onconova has certain rights to patents and other intellectual property related to the Compound (as defined below);

**WHEREAS**, Pint has significant experience in the development and commercialization of pharmaceutical products in the Territory (as defined below);

**WHEREAS**, Pint desires to license from Onconova such intellectual property rights, and to further Develop and Commercialize the Compound and Products in the Territory for use in the Field (all as defined below), and Onconova desires to grant such a license to Pint in accordance with the terms and conditions of this Agreement; and

**WHEREAS**, concurrently with the execution and delivery of this Agreement, the Parties are entering into a securities purchase agreement dated as of the date of this Agreement (the "**Securities Purchase Agreement**"), providing for the issuance to Pint of common stock of Onconova.

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

**ARTICLE 1**
**DEFINITIONS**

As used in this Agreement, the following capitalized terms shall have the meanings set forth in this Article 1 or as otherwise defined elsewhere in this Agreement:

**1.1** "**Affiliate**" means any Person directly or indirectly controlled by, controlling or under common control with, a Party, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") shall be presumed to exist with respect to a Person in the event of the possession, direct or indirect, of (i) the power to direct or cause the direction of the management and policies of such Person (whether through ownership of securities, by contract or otherwise), or (ii) at least fifty percent (50%) of the voting securities or other comparable equity interests. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent

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(50%), and that in such case, such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct or cause the direction of the management and policies of such Person. For the avoidance of doubt, neither of the Parties shall be deemed to be an "Affiliate" of the other.

**1.2** "**Commercialize**", "**Commercializing**" or "**Commercialization**" means all activities directed to the marketing, promotion, selling or offering for sale of a product for an indication, including planning, market research, pre-marketing, advertising, educating, marketing, promoting, importing, exporting, distributing and post-marketing safety surveillance and reporting. For clarity, "Commercialization" shall not include any activities related to clinical research, Manufacturing or Development of the Product.

**1.3** "**Commercially Reasonable Efforts**" means, with respect to a Party's obligation under this Agreement, including to Develop or Commercialize the Product, the level of diligent and sustained efforts to accomplish an objective as a typical company in the pharmaceutical industry would normally use to accomplish a similar objective under similar circumstances. It is understood and agreed that such efforts shall be substantially equivalent to those efforts and resources commonly used by typical companies in the pharmaceutical industry for products owned by them or to which they have rights,

which are at a similar stage in development or product life or have similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products, the patent and other proprietary position of the product(s), the likelihood of regulatory approval given the Regulatory Authority involved, the profitability of the product including amounts payable to licensors of patents or other intellectual property rights, alternative products, other risks associated with the development or commercialization of the product and other relevant factors. Commercially Reasonable Efforts will be determined on a market-by-market and indication-by-indication basis for a particular Product, and it is anticipated that the level of effort may be different for different markets, and may change over time, reflecting among other things changes in the status of the Product(s) and market(s) involved. Payments required to be made to Onconova under this Agreement shall not be considered in evaluating Pint's obligations to use Commercially Reasonable Efforts. In addition, other compounds or products owned, licensed, distributed or sold by a Party shall not be considered in evaluating a Party's obligations to use Commercially Reasonable Efforts.

**1.4** "**Competitive Product**" means any pharmaceutical product that is being researched, developed or commercialized for the same specific indication(s) for which Regulatory Approval has been obtained or is reasonably anticipated to be obtained for Product in the Territory.

**1.5** "**Compound**" means the pharmaceutical compound rigosertib, a diagram of which is attached hereto as Schedule 1.5.

**1.6** "**Control**" means, when used in reference to intellectual property, other intangible property or materials, that a Party owns or has a license or sublicense to such intellectual property, other intangible property or materials, and has the ability to grant a license or sublicense or other right to use such intellectual property, other intangible property or materials, as applicable, as provided for herein, without (i) requiring the consent of a Third Party or (ii) violating the terms of any agreement or other arrangement with any Third Party.

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**1.7** "**Develop**", "**Developing**" or "**Development**" means all activities relating to research, non-clinical, preclinical and clinical, toxicology testing, statistical analysis and reporting, preparation and submission of applications for regulatory approval of the Product, all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining all regulatory approvals for the Product and all other development-related activities that are deemed by the JSC to be Commercially useful.

**1.8** "**Development Activities**" means those Development activities undertaken by or on behalf of Pint or its Affiliates with respect to the Product in the Field in the Territory consistent with the applicable Development Plan.

**1.9** "**Dollar**" means a U.S. dollar, and "$" shall be interpreted accordingly.

**1.10** "**Dossier**" means the Common Technical Document for the Registration of Pharmaceuticals for Human Use, or equivalent.

**1.11** "**FDA**" means the U.S. Food and Drug Administration and any successor Governmental Authority having substantially the same function.

**1.12** "**FD&C Act**" means the U.S. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

**1.13** "**Field**" means all uses of Compound or Product in humans.

**1.14** "**Finished Product**" means Product including primary and secondary packaging and labeling (a) as approved in the country of origin for "named patient" sale in a country within the Territory prior to Regulatory Approval in such country within the Territory, or (b) in Spanish or Portuguese as approved in the country of intended sale within the Territory following Regulatory Approval of Product in such country.

**1.15** "**First Commercial Sale**" means, with respect to the Product, the first sale of the Product in a given country or other regulatory jurisdiction in the Territory by or on behalf of Pint, its Affiliates or sublicensees to a Third Party.

**1.16** "**Good Clinical Practices**" or "**GCP**" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (i) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (ii) U.S. Code of Federal Regulations (C.F.R.) Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (iii) the equivalent Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect of the rights, integrity, and confidentiality of trial subjects.

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**1.17** "**Good Laboratory Practices**" or "**GLP**" means all applicable Good Laboratory Practice standards, including, as applicable, the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and the equivalent Laws in any relevant country, each as may be amended and applicable from time to time.

**1.18** "**Good Manufacturing Practices**" or "**GMP**" means all applicable Good Manufacturing Practice standards including (i) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, 601 and 610, (ii) the principles detailed in the ICH Q7A guidelines and (iii) the equivalent Laws in any relevant country, each as may be amended and applicable from time to time.

**1.19** "**Governmental Authority**" means any multinational, federal, state, local, municipal or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal), in each case, having jurisdiction over the applicable subject matter.

**1.20** "**IND**" means (i) an Investigational New Drug Application as defined in the FD&C Act or (ii) the equivalent application to the equivalent agency in any other regulatory jurisdiction outside the U.S., such as a clinical trial application or a clinical trial exemption, the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

**1.21** "**Invention**" means any invention, discovery, improvement or technology (in each case, whether patentable or otherwise) that is first discovered or conceived as a result of activities under this Agreement during the Term.

**1.22** "**ITT Population"** means the trial eligibility criteria set forth in the protocol for the INSPIRE trial as of the Effective Date as approved by the FDA and EMA.

**1.23** "**Joint Inventions**" means all Inventions developed or invented jointly by, on the one hand, employee(s) of Pint and/or its Affiliates, and/or a Third Party acting on behalf of Pint and/or its Affiliates, and, on the other hand, by employee(s) of Onconova and/or its Affiliates, and/or a Third Party acting on behalf of Onconova and/or its Affiliates.

**1.24** "**JSC**" means the joint steering committee formed by the Parties as described in Section 3.1.

**1.25** "**Know-How**" means any proprietary data, results, material(s), technology, and nonpublic information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports and plans, market research, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, toxicological, preclinical and clinical test data), analytical and quality control data, stability data, other study data and procedures.

**1.26** "**Laws**" means all laws, statutes, rules, regulations, directives, decisions, ordinances, guidelines and other pronouncements of any Governmental Authority.

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**1.27** "**Manufacture**" or "**Manufacturing**" means all activities related to the manufacturing of the Compound and/or Product, or any ingredient thereof, including manufacturing for clinical use or commercial sale, in-process and finished product testing, release of product, quality assurance activities related to manufacturing and release of product and ongoing stability tests and regulatory activities related to any of the foregoing.

**1.28** "**Marketing Authorization Application**" or "**MAA**" means an application to the appropriate Regulatory Authority for approval to sell the Product (but excluding Pricing Approval) in any particular country or regulatory jurisdiction.

**1.29** "**NDA**" means a New Drug Application as defined in the FD&C Act, filed with the FDA to obtain approval to sell the Product in the United States.

**1.30** "**Net Sales**" means the gross amount invoiced by or on behalf of Pint or any of its Affiliates or sublicensees (or permitted distributors) on account of sales of the Product to the first Third Party, less the following deductions specifically and solely related to the Product and actually allowed:

**(a)** customary trade, cash or quantity discounts allowed and taken, to the extent not already reflected in the amount invoiced, but specifically excluding prompt payment and/or cash discounts;

**(b)** excise, sales and value added taxes and customs duties to the extent included in the price (but specifically excluding, for clarity, any income taxes assessed against the income arising from such sale);

**(c)** outbound freight, shipment and insurance costs;

**(d)** amounts actually allowed or credited on returns in accordance with Pint's returned goods policy provided to Onconova, including by reason of rejections, defects return goods allowance, recalls or returns, or because of retroactive price reductions, including rebates or wholesaler chargebacks; and

**(e)** price reductions, rebates or charge-backs, retroactive or otherwise, imposed by, negotiated with or otherwise paid to Governmental Authorities or other payees.

In all cases, deductions taken into account in the computation of Net Sales shall not exceed (on an invoice by invoice basis) in the aggregate fifty percent (50%) of the gross amounts invoiced by or on behalf of Pint or any of its Affiliates or sublicensees for sales of the Product. For clarity, (i) Net Sales shall not be reduced by the amount of any commissions paid to individuals, whether they are associated with independent sales agencies or regularly employed by Pint (or any agent, sublicensee, distributee or designee thereof) or for a cost of collection or any other amount not specifically set forth in (a) through (e) above and (ii) the amount of any discounts, rebates or allowances granted or taken with respect to the total sales to a customer for multiple products of Pint (or any agent, distributee, or designee thereof) shall not be deducted in calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the

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case of any sale of the Product for value other than in an arm's-length transaction exclusively for cash, such as barter or counter-trade, Net Sales shall be determined by referencing Net Sales at which substantially similar quantities of the Product are sold in an arm's-length transaction for cash.

Net Sales shall be accounted for in accordance with International Financial Reporting Standards (IFRS), consistently applied. For purposes of determining Net Sales, the Product shall be deemed to be sold when invoiced. Pint, its Affiliates and sublicensees (and any permitted distributor) will sell the Product as a stand-alone product and will not sell the Product as part of a bundle with other products or offer package deals to customers that include the Product, except to the extent required to obtain sales contracts with government entities, and in such case, the price of the Product relevant for the calculation of Net Sales will be the average price in the preceding calendar quarter of the Product sold separately less the average discount of all products sold as part of the package.

**1.31** "**Onconova Inventions"** means all Inventions developed or invented solely by employee(s) of Onconova and/or its Affiliates, and or a Third Party acting on behalf of Onconova and/or its Affiliates, and not employed by Pint and/or Pint's Affiliates.

**1.32** "**Onconova Know-How**" means all Know-How that (i) is Controlled by Onconova or its Affiliates as of the Effective Date or (ii) comes under the Control of Onconova or its Affiliates during the Term (including Onconova Inventions), in each case of (i) or (ii), which specifically describes, embodies or relates to the Product or its manufacture or use in any formulation or is necessary or useful for the Development, Manufacture or Commercialization of the Product in the Field in the Territory. For clarity, "Onconova Know-How" shall not include the Onconova Patents.

**1.33** "**Onconova Patent**" means any Patent in the Territory that is (i) Controlled by Onconova or its Affiliates as of the Effective Date as set forth on Schedule 1.33 or (ii) a Patent that comes under the Control of Onconova or its Affiliates during the Term, in each case of (i) and (ii), that claims or covers (a) Compound or Product or the manufacture or use thereof or (b) any Onconova Know-How.

**1.34** "**Onconova Technology**" means the Onconova Patents and Onconova Know-How.

**1.35** "**Patents**" means patents and patent applications and all substitutions, divisions, continuations, continuations-in-part, any patent issued with respect to any such patent applications, any reissue, reexamination, utility models or designs, renewal or extension (including any supplemental patent certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts thereof in any country.

**1.36** "**Patent Term Extension**" means any term extensions, supplementary protection certificates, Regulatory Exclusivity and equivalents thereof offering Patent protection beyond the initial term with respect to any issued Patents.

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**1.37** "**Person**" shall mean any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

**1.38** "**Pint Inventions**" means all Inventions developed or invented solely by employee(s) of Pint and/or its Affiliates, and or a Third Party acting on behalf of Pint and/or its Affiliates, and not employed by Onconova and/or Onconova's Affiliates.

**1.39** "**Pint Know-How**" means all Know-How that is (i) Controlled by Pint or its Affiliates as of the Effective Date or (ii) comes under the Control of Pint or its Affiliates during the Term (including Pint Inventions), in each case of (i) or (ii), which specifically describe, embody or relate to the Product or its manufacture or use in any formulation or is necessary or useful for the Manufacturing, Development or Commercialization of the Product in the Field. For clarity, "Pint Know-How" shall not include the Pint Patents.

**1.40** "**Pint Patent**" means any Patent that is (i) Controlled by Pint or its Affiliates as of the Effective Date or (ii) comes under the Control of Pint or its Affiliates during the Term, in each case of (i) or (ii), which claims or covers (a) Compound or Product or the manufacture or use thereof or (b) any Pint Know-How.

**1.41** "**Pint Technology**" means the Pint Know-How and the Pint Patents.

**1.42** "**Pricing Approval**" means the approval, agreement, determination or decision from a Governmental Authority establishing the price or reimbursement for the Product for sale in a given country or regulatory jurisdiction, as required by applicable Law in such country or other regulatory jurisdiction prior to the sale of the Product in such country or regulatory jurisdiction.

**1.43** "**Product**" means any pharmaceutical product containing a Compound.

**1.44** "**Regulatory Approvals**" means all necessary approvals (including INDs, NDAs, MAAs and supplements and amendments thereto and Pricing Approvals), licenses, registrations or authorizations of any Governmental Authority, necessary for the manufacture, distribution, use, promotion and sale of the Product in a given country or regulatory jurisdiction.

**1.45** "**Regulatory Authority**" means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or regulatory jurisdiction, including in the U.S., the FDA.

**1.46** "**Regulatory Data**" means any and all research data, pharmacology data, chemistry, manufacturing and control data, preclinical data, clinical data and all other documentation submitted, or required to be submitted, to Regulatory Authorities in association with regulatory filings for the Product (including any applicable Drug Master Files ("**DMFs**"), Chemistry, Manufacturing and Control ("**CMC**") data, or similar documentation).

**1.47** "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Governmental Authority with respect to the Product other than a Patent right, including rights conferred in the U.S. under the Hatch-Waxman Act or the

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FDA Modernization Act of 1997, or rights similar thereto outside the U.S., including in the European Union, European Commission Regulation (EC) No 726/2004 and European Commission Directive 2001/83/EC (as amended).

**1.48** "**Regulatory Materials**" means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority that are necessary in order to Develop, Manufacture, market, sell or otherwise Commercialize the Product in a particular country or regulatory jurisdiction. Regulatory Materials include INDs, NDAs, MAAs and applications for other Product approvals.

**1.49** "**Royalty Term**" means, on a country-by-country basis, the period of time commencing on the First Commercial Sale of the Product in a country within the Territory and continuing until the latest of (i) the expiration of the last-to-expire Valid Claim of an Onconova Patent in such country, (ii) the expiration of Regulatory Exclusivity for such Product in such country or (iii) ten (10) years from the date of First Commercial Sale of Product within such country.

**1.50** "**Supply Agreement**" means the quality and supply agreement referenced in Section 7.1 hereto.

**1.51** "**Temple License Agreements**" means, collectively, those certain License Agreements, dated as of January 1, 1999, October 1, 1999, November 1, 1999, and October 1, 2000, by and between Onconova and Temple University - Of the Commonwealth System of Higher Education, as each is amended from time to time.

**1.52** "**Territory**" means Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, French Guiana, British Guiana, Suriname, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela.

**1.53** "**Third Party**" means any Person other than Onconova or Pint or their respective Affiliates.

**1.54** "**U.S.**" means the United States of America and its possessions and territories.

**1.55** "**Valid Claim**" means (i) a claim of an issued and unexpired Patent that has not been disclaimed, revoked or held to be invalid or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal can be further taken or (ii) a claim included in a pending patent application whether filed before or after the Effective Date and that has not been (a) canceled, (b) withdrawn from consideration, (c) finally determined to be unallowable by the applicable governmental authority (from which no appeal is or can be taken), or (d) abandoned or disclaimed.

**Interpretation**. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (a) "include", "includes" and "including" are not limiting; (b) "hereof", "hereto", "herein" and "hereunder" and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this

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Agreement; (c) words of one gender include the other gender; (d) references to a contract or other agreement mean such contract or other agreement as from time to time amended, modified or supplemented; (e) references to a Person are also to its permitted successors and assigns; (f) references to an "Article", "Section" or "Schedule" refer to an Article or Section of, or Schedule to, this Agreement, unless expressly stated otherwise; and (g) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the date of this Agreement.

**Additional Definitions.** The following terms have the meanings set forth in the corresponding Sections of this Agreement:

| Term | Section |
|---|---|
| "**Agreement**" | Preamble |
| "**Audited Party**" | 8.11 |
| "**Audit**" | 8.11 |
| "**CMC**" | 1.46 |
| "**CMC Information**" | 5.3(a) |
| "**Commercialization Data**" | 6.7 |
| "**Commercialization Plan**" | 6.2.1(a) |
| "**Confidential Information**" | 12.1 |
| "**Controlling Party**" | 9.4.1(a) |
| "**Development Data**" | 4.5 |
| "**Development Plan**" | 4.2.1 |
| "**Disclosing Party**" | 12.1 |
| "**DMFs**" | 1.46 |
| "**Effective Date**" | Preamble |
| "**Executive Officer**" | 3.4.1 |
| "**Indemnification Claim Notice**" | 11.3.1 |
| "**Indemnified Party**" | 11.3.1 |
| "**Indemnifying Party**" | 11.3.1 |
| "**Indemnitees**" | 11.3.1 |
| "**Infringement Claim**" | 9.4.1 |
| "**Losses**" | 11.1 |
| "**Onconova**" | Preamble |
| "**Party**" or "**Parties**" | Preamble |
| "**Patent Challenge**" | 9.7 |
| "**Pint**" | Preamble |
| "**Receiving Party**" | 12.1 |
| "**Recovery**" | 9.4.2(c)(iv) |
| **"Research and Development Event"** | 8.1.2 |
| "**Research and Development Payment**" | 8.1.2 |
| **"Securities Purchase Agreement"** | Preamble |
| "**Term**" | 13.1 |
| "**Third Party Claim**" | 11.1 |

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## ARTICLE 2
## LICENSES

**2.1** **Grant to Pint.** Subject to the terms and conditions of this Agreement and the applicable terms of the Temple License Agreements, Onconova hereby grants to Pint an exclusive, royalty-bearing license, with the right to sublicense, under the Onconova Technology to Develop and Commercialize (including to make, have made, use, import, export, offer to sell and sell) the Product in the Field in the Territory.

**2.2 Grant to Onconova.**

**2.2.1 General Grant to Onconova.** Subject to the terms and conditions of this Agreement, Pint, together with its Affiliates, hereby grants to Onconova during the Term (i) an exclusive, fully paid-up, royalty-free license, with the right to sublicense, under the Pint Technology to make and have made the Product anywhere in the world for (a) Development, Commercialization or other use outside the Territory or (b) for supply to Pint or its Affiliates or sublicensees in the Territory, and (ii) an exclusive, fully paid-up, royalty-free license, with the right to sublicense, under the Pint Technology to Develop and Commercialize the Product outside the Territory.

**2.2.2 Additional Grant to Onconova.** Pint, together with its Affiliates, hereby grants to Onconova, from and after the end of the Term, a non-exclusive, paid-up, irrevocable, perpetual, worldwide license, with the right to sublicense, under the Pint Technology, to Develop (including obtaining and maintaining regulatory approval), make, use, import, export, offer for sale and sell the Product anywhere in the world.

**2.3 Additional Licensing Provisions.**

**2.3.1 Negative Covenant.** Each Party covenants that it will not use or practice any of the other Party's Patent rights or other intellectual property rights licensed (or sublicensed, as applicable) to it under this Article 2 except for the purposes expressly permitted in the applicable license grant.

**2.3.2 No Implied Licenses; Retained Rights.** Except as explicitly set forth in this Agreement, neither Party grants any license, express or implied, under its intellectual property rights to the other Party, whether by implication, estoppel or otherwise. Without limiting the generality of the foregoing, Onconova hereby expressly retains, on behalf of itself and its Affiliates, licensees and sublicensees, all right, title and interest in and to the Onconova Technology, Development Data and Regulatory Materials with respect to (i) developing (including obtaining and maintaining regulatory approval), making, using, importing, exporting, offering for sale and selling pharmaceutical products containing Compound for sale anywhere in the world (other than the sale of the Product in the Field in the Territory), and (ii) exercising its rights and performing its obligations hereunder, including the Manufacture of the Product for Development and Commercialization in the Field in the Territory. .

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**2.4 Performance by Affiliates, Sublicensees and Subcontractors.**

**2.4.1 Performance by Affiliates.** The Parties recognize that each may perform some or all of its obligations under this Agreement through Affiliates; provided, however, that each Party shall remain responsible for and be guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. 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. Wherever in this Agreement the Parties delegate responsibility to Affiliates, the Parties agree that such entities may not make decisions inconsistent with this Agreement, amend the terms of this Agreement or act contrary to its terms in any way.

**2.4.2 Sublicensees.** Each Party and its respective Affiliates shall be entitled, without the prior consent of the other Party, to grant one or more sublicenses, in full or in part, by a written agreement to Third Parties (with the right to sublicense through multiple tiers); provided, however, that as a condition precedent to and requirement of any such sublicense: (i) any such permitted sublicense shall be consistent with and subject to the terms and conditions of this Agreement and (ii) the sublicensing Party will continue to be responsible for full performance of such Party's obligations under this Agreement and will be responsible for all actions of the sublicensee as if such sublicensee were the sublicensing Party hereunder.

**2.4.3 Subcontractors.** Each Party shall ensure that each of its subcontractors accepts and complies with all of the terms and conditions of this Agreement, and such Party shall guarantee its subcontractors' performance under this Agreement. For the avoidance of doubt, Pint will remain directly responsible for all amounts owed to Onconova under this Agreement, including royalty payments for Net Sales by Pint's permitted subcontractors. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against a subcontractor, for any obligation or performance hereunder prior to proceeding directly against such Party.

**2.5 Exclusivity.** Pint hereby covenants not to research, develop (including submitting any applications for regulatory approval), manufacture or commercialize, during the Term, any Competitive Product, either on its own, with or through any Affiliate, or in collaboration with a Third Party, in each case other than with respect to the Development and Commercialization of the Product in the Field in the Territory pursuant to this Agreement.

**2.6 Restrictive Covenants.**

**2.6.1 Ex-Territory Activities.** Pint hereby covenants and agrees that it shall not (and shall cause its Affiliates, sublicensees and subcontractors not to), either directly or indirectly, market, distribute or sell the Product into countries outside of the Territory. Without limiting the generality of the foregoing, with respect to such countries outside of the Territory, Pint shall not (i) engage in any advertising activities relating to the Product directed to customers located or for use in such countries, or (ii) solicit orders from any prospective purchaser located or for use in such countries. If Pint receives any order from a prospective purchaser located or for use in a country outside of the Territory, Pint shall immediately refer that order to Onconova and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) any Product under such order. If Pint should reasonably know that a customer or distributor, or a

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customer's distributor or customer, is engaged in the sale or distribution of the Product outside of the Territory, then Pint shall (a) within forty-eight (48) hours of gaining knowledge, or a reasonable suspicion, of such activities notify Onconova regarding such activities and provide all information that Onconova may request concerning such activities and (b) take all reasonable steps (including cessation of sales to such customer) necessary to limit such sale or distribution outside the Territory.

**2.6.2 Territory Activities.** Onconova hereby covenants and agrees that it shall not (and shall cause its Affiliates, sublicensees and subcontractors not to), either directly or indirectly, market, distribute or sell the Product into countries within the Territory; provided that, for clarity, Onconova may Manufacture and supply the Product for Development or Commercialization in the Territory in connection with this Agreement. Without limiting the generality of the foregoing, with respect to such countries within the Territory, Onconova shall not (i) engage in any advertising activities relating to the Product directed to customers located or for use in such countries, or (ii) solicit orders from any prospective purchaser located or for use in such

countries. If Onconova receives any order from a prospective purchaser located or for use in a country within the Territory, Onconova shall immediately refer that order to Pint and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) any Product under such order. If Onconova should reasonably know that a customer or distributor, or a customer's distributor or customer, is engaged in the sale or distribution of the Product within the Territory, then Onconova shall (a) within forty-eight (48) hours of gaining knowledge, or a reasonable suspicion, of such activities notify Pint regarding such activities and provide all information that Pint may request concerning such activities and (b) take all reasonable steps (including cessation of sales to such customer) necessary to limit such sale or distribution within the Territory.

## ARTICLE 3
## GOVERNANCE

**3.1 Joint Steering Committee.** The Parties shall establish a joint steering committee (JSC) within thirty (30) days after the Effective Date that will have the responsibility for the overall coordination of the Parties' activities under this Agreement. The role of the JSC shall be:

**(a)** to review and discuss the overall strategy for Developing and Commercializing the Product in the Field in the Territory, including reviewing, coordinating and discussing the overall strategy for seeking Regulatory Approvals (including Pricing Approvals) and obtaining, maintaining and enforcing Patent protection and market and data exclusivity for the Product in the Field in the Territory;

**(b)** to review any amendments or revisions to the Development Plan and the Commercialization Plan;

**(c)** to facilitate the exchange of information between the Parties under this Agreement regarding the strategy for implementing the Development Activities, including sharing Development Data created pursuant to this Agreement, if any, and establishing procedures for the efficient sharing of information and materials necessary or useful for the Parties' Development of the Product in the Field in the Territory;

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**(d)** to review the design of the clinical trial protocols and endpoints of all clinical trials to be conducted with respect to the Product in the Field in the Territory;

**(e)** to discuss Pint's performance against the then-current Development Plan;

**(f)** to resolve any disputes and to consider any other issues brought to its attention by the Parties;

**(g)** to perform such other functions as appropriate to further the purposes of this Agreement, as mutually agreed upon by the Parties in writing.

**3.2 Joint Steering Committee Membership.** Onconova and Pint shall each designate two (2) representatives to serve on the JSC by written notice to the other Party. Either Party may designate substitutes for its representatives if one (1) or more of such Party's designated representatives are unable to be present at a meeting. From time to time each Party may replace its representatives by written notice to the other Party specifying the prior representative(s) and their replacement(s). One of the Onconova representatives shall serve as the chairperson of the JSC. The chairperson shall be responsible for (i) calling meetings, (ii) preparing and issuing minutes of each such meeting within thirty (30) days thereafter, and (iii) preparing and circulating an agenda for the upcoming meeting; provided that the chairperson shall consider including any agenda items proposed by Pint no less than five (5) days prior to the next scheduled JSC meeting.

**3.3 Joint Steering Committee Meetings.** The JSC shall hold at least one (1) meeting per calendar quarter at such times during such calendar quarter as it elects to do so; provided that, notwithstanding the foregoing, the JSC shall hold an initial meeting within ninety (90) days of the Effective Date. Meetings of the JSC shall be effective only if at least one (1) representative of each Party is present or participating. The JSC may meet either (i) in person at either Party's facilities or at such locations as the Parties may otherwise agree or (ii) by audio or video teleconference; provided that no less than one (1) meeting of the JSC during each calendar year shall be conducted in person. Other representatives of each Party involved with the Product may attend meetings as non-voting participants, subject to the confidentiality provisions set forth in Article 12. Additional meetings of the JSC may also be held with the consent of each Party, or as required under this Agreement, and neither Party shall unreasonably withhold its consent to hold such additional meetings. Each Party shall be responsible for all of its own expenses incurred in connection with participating in the JSC meetings.

**3.4 Joint Steering Committee Decisions.**

**3.4.1 Initial Dispute Resolution Procedures.** Subject to the provisions of this Section 3.4, actions to be taken by the JSC shall be taken only following a unanimous vote, with each Party having one (1) vote. If the JSC fails to reach unanimous agreement on a matter before it for decision for a period in excess of thirty (30) days, the matter shall be referred to the Chief Executive Officers of each of the Parties, or a designee from senior management with decision-making authority (the Chief Executive Officer or such designee, the "**Executive Officer**") for resolution. In the event that the Executive Officers are unable to resolve such

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dispute within ten (10) days of such dispute being referred to the Executive Officers, then the provisions of Section 3.4.2 shall apply.

**3.4.2 Subsequent Dispute Resolution Procedures.** To the extent a dispute of the JSC has not been resolved pursuant to Section 3.4.1, the following shall apply:

**(a)** Subject to Section 3.4.2(b), the Pint Executive Officer shall have the final decision-making authority with respect to any dispute involving the Development or Commercialization of the Product in the Field in the Territory.

**(b)** The Onconova Executive Officer shall have the final decision-making authority with respect to any dispute involving the Product which is reasonably likely to adversely affect the safety profile of the Product outside the Territory or outside the Field.

**(c)** Resolution of any other dispute that is the subject of this Section 3.4.2, but not subject to any of the foregoing clause (a) or (b), shall be handled pursuant to Article 15.

**(d)** Notwithstanding the foregoing provisions of this Section 3.4.2, neither Party shall exercise its right to finally resolve a dispute pursuant to the foregoing clause (a) or (b), as applicable, in a manner that excuses such Party from any of its obligations specifically enumerated under this Agreement or in a manner that negates any consent rights or other rights specifically allocated to the other Party under this Agreement. In addition, in resolving a dispute pursuant to the foregoing clauses (a), (b) or (c), each Party shall at all times act in good faith.

**3.4.3 No Limitation on Remedies.** Nothing in this Section 3.4 shall affect the right of a Party to exercise its rights or remedies for a breach of this Agreement by the other Party.

**3.5 Authority.** The JSC shall have only the powers assigned expressly to it in this Article 3 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement. In furtherance thereof, each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated or vested in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Without limiting the generality of the foregoing, the JSC shall have no decision-making authority with respect to any matters related to the (i) Manufacturing of the Product for sale outside the Territory or (ii) the Development, Commercialization or use of the Product outside the Field or outside of the Territory.

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## ARTICLE 4
## DEVELOPMENT

**4.1 Overview.**

**4.1.1 Overview of Development.** During the Term, Pint shall be solely responsible for Developing the Product in the Territory for use in the Field at its sole cost and expense.

**4.1.2 Development Outside the Field or Outside the Territory; Regulatory Approvals Outside the Territory.** The Parties hereby agree and acknowledge that: (i) nothing contained herein shall limit or otherwise restrict the ability of Onconova to (a) Develop the Product outside the Field or outside the Territory or (b) Develop the Product in the Territory for purposes of obtaining Regulatory Approval outside the Territory; and (ii) nothing contained herein shall limit or otherwise restrict the ability of Onconova to obtain or maintain Regulatory Approvals for the Product outside the Field and/or outside the Territory. Without limiting the generality of the foregoing, at all times prior to conducting Development of the Product in the Territory for purposes of obtaining Regulatory Approval outside the Territory, Onconova shall keep Pint reasonably apprised in advance and during such planned activities.

**4.1.3 Compliance.** Pint shall conduct its Development Activities in compliance with all applicable Laws.

**4.2 Development Plan.**

**4.2.1 General.** Pint shall be solely responsible for the creation of a comprehensive development plan (the "**Development Plan**") related to Pint's planned Development of the Product for use in the Field in the Territory. Such Development Plan shall reflect that Pint shall conduct, at its expense, any pre-clinical and clinical trials necessary to receive and maintain Regulatory Approval (including registrations) to Commercialize Product in the Territory; provided that no pre-clinical or clinical trials for Product shall be conducted by or on behalf of Pint without Onconova's prior written consent, which consent shall not be unreasonably withheld. The initial Development Plan for the Product for the first full calendar year of this Agreement (including any additional period from the Effective Date through the end of the initial calendar year) has been circulated by Pint to Onconova.

**4.2.2 Updating and Amending Development Plan; Additional Development Activities.**On or before the end of each calendar year during the Term, Pint shall update the Development Plan, which shall cover the Development Activities to be conducted during the upcoming calendar year, and shall, on at least a quarterly basis, review and update, as appropriate, the then-current Development Plan to reflect any changes, reprioritizations of, or additions to the Development Plan; provided, however, that any disputes with respect thereto shall be resolved pursuant to Section 3.4.

**4.3 Records, Reports and Information.**

**4.3.1 General.** Pint shall maintain current and accurate records of all work conducted by it under the Development Plan and all data and other information resulting from

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such work. Such records shall properly reflect all work done and results achieved in the performance of the Development Activities in good scientific manner appropriate for regulatory purposes. Pint shall document all preclinical studies and clinical trials to be conducted pursuant to the Development Plan in formal written study reports according to applicable national and international (e.g., ICH, GCP and GLP) guidelines. Pint shall provide copies of any such study reports (including copies of all toxicity, pharmacokinetics (PK) and pharmacodynamics (PD) reports to Onconova within ninety (90) days of completion of each report.

**4.3.2 Status Updates in the Territory.** Pint shall provide the JSC with reports detailing its Development Activities under the Development Plan and the results thereof at each JSC meeting.

**4.4 Right to Audit.** Pint shall ensure that Onconova's authorized representatives and, to the extent permitted by applicable Law, any Regulatory Authorities may, during regular business hours and upon reasonable prior written notice, (i) examine and inspect its facilities or, subject to any Third Party confidentiality restrictions and other obligations, the facilities of any subcontractor or any investigator site used by it in the performance of Development of the Product in the Territory hereunder, and (ii) subject to applicable Law and any Third Party confidentiality restrictions and other obligations, inspect all data, documentation and work product relating to the activities performed by it, the subcontractor or investigator site, in each case

generated pursuant to Development of the Product in the Territory hereunder. This right to inspect all data, documentation, and work product relating to the Product in the Field in the Territory may be exercised no more often than one time per year (except for cause audits).

**4.5 Ownership and Transfer of Development Data.** All data (including pre-clinical, clinical, technical, chemical, safety, and scientific data and information), know-how and other results generated by or resulting from or in connection with the conduct of Development Activities, including relevant laboratory notebook information, screening data, Regulatory Data and synthesis schemes, including descriptions in any form, data and other information (collectively, the "**Development Data**"), shall be promptly provided to Onconova, owned jointly by Onconova and Pint, and deemed the Confidential Information of both Parties.

## ARTICLE 5
## REGULATORY

**5.1 Regulatory Filings and Regulatory Approvals.**

**5.1.1 General.** Pint shall be responsible for formulating regulatory strategy for obtaining and maintaining Regulatory Approvals for the sale of the Product in the Field in the Territory. Pint shall be responsible for the preparation of all Regulatory Materials necessary or desirable for obtaining and maintaining such Regulatory Approvals in the Territory (including in connection with package inserts, labeling and packaging for the Product in the Field in the Territory; provided, however, that Onconova shall share with Pint all open files (artwork) related to its own packaging development outside the Territory). Pint shall submit such Regulatory Materials and Regulatory Approval applications to the applicable Government Authorities in the Territory. Onconova shall cooperate with Pint in connection therewith, including providing all such supporting documentation in Onconova's possession and control for Regulatory Materials

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to Pint with sufficient time to allow Pint to review and timely submit such Regulatory Materials in accordance with applicable Law. The provisions of this Section 5.1.1 shall be subject to the provisions of Section5.1.2.

**5.1.2 Pricing Approvals.** To the extent that a given country or regulatory jurisdiction in the Territory requires Pricing Approval for sale of the Product in the Field in such country or regulatory jurisdiction, Pint shall (to the extent permitted by applicable Laws) be solely responsible for obtaining and maintaining Pricing Approvals in all such countries and regulatory jurisdictions in the Territory. Without limiting the foregoing, Pint shall apply for Pricing Approvals in each country or regulatory jurisdiction where Pricing Approvals are required for the sale of the Product in the Field promptly following the receipt of the MAA for the Product in such country or regulatory jurisdiction in the Territory. Pint shall keep Onconova reasonably informed on an ongoing basis through the JSC of Pint's strategy for seeking, and the results it obtains in seeking, such Pricing Approvals in the Territory.

**5.1.3 Ownership of Regulatory Materials and Regulatory Approvals.** All Regulatory Approvals in the Territory for sale of the Product in the Field in the Territory shall be in the name of Pint, and Pint shall own all right, title and interest in all such Regulatory Approvals and all related Regulatory Materials.

**5.1.4 Cost of Regulatory Activities.** All costs and expenses incurred by either Party (or their Affiliates) in connection with the preparation or maintenance of Regulatory Materials and Regulatory Approvals for sale of the Product in the Field in the Territory, including any filing fees shall be borne solely by Pint.

**5.1.5 Reporting and Review.** Pint shall keep Onconova reasonably informed via the JSC in connection with the preparation of all Regulatory Materials, Regulatory Authority review of Regulatory Materials, and Regulatory Approvals, in each case with respect to the Product for sale in the Field in the Territory. Pint shall provide Onconova with all clinical reports with respect to the Product in the Field in the Territory in accordance with Section 4.3.1. Each Party shall provide the other Party, in a timely manner, with copies of all notices, questions, and requests for information in tangible form which it receives from a Regulatory Authority in the Territory with respect to the Product for sale in the Field in the Territory; provided, however that such Party shall have the right to redact any information to the extent not related to the Product for sale in the Field in the Territory. Notwithstanding the foregoing, each Party shall only provide such copies to the extent permitted under any contractual obligations of such Party (provided that each Party shall use Commercially Reasonable Efforts to avoid any such contractual restrictions) and to the extent such information is in such Party's possession and control.

**5.2 Communications.** The Parties shall cooperate in communicating with any Regulatory Authority having jurisdiction in the Territory regarding the Product in the Field in the Territory and each Party shall immediately notify the other in the event that such Party communicates, or intends to communicate, either on its own initiative in accordance with this Agreement or as a result of such a Regulatory Authority initiating contact with such Party. Notwithstanding the foregoing, each Party shall only provide such notification to the extent permitted under any contractual obligations of such Party (provided that each Party shall use

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Commercially Reasonable Efforts to avoid any such contractual restrictions) and to the extent such information is in such Party's possession and control. Notwithstanding the foregoing, except as may be required by Law, (1) Pint shall not, with respect to the Product, communicate with any Regulatory Authority having jurisdiction outside of the Territory regarding the Product without the prior written consent of Onconova, or unless so ordered by such Regulatory Authority, in which case Pint shall immediately notify Onconova of such order; and (2) Onconova shall not, with respect to the Product, communicate with any Regulatory Authority having jurisdiction inside the Territory regarding the Product without the prior written consent of Pint, or unless so ordered by such Regulatory Authority, in which case Onconova shall immediately notify Pint of such order.

**5.3 Rights of Reference to Regulatory Materials.**

**(a)** Onconova hereby grants to Pint a right of reference to all Regulatory Materials filed by Onconova outside the Territory for Development or Commercialization of the Product in the Field outside the Territory solely for the purposes of Development Activities to obtain Regulatory Approval and Commercialization in the Field in the Territory. Within ninety (90) days following FDA Regulatory Approval of Product for sales within the United States, Onconova shall provide to Pint true and complete copies of the documents set forth on Schedule 5.3(a) hereto.

**(b)** Pint hereby grants to Onconova a right of reference to all Regulatory Materials filed by Pint in the Territory for Development or Commercialization of the Product in the Field in the Territory solely for the purposes of Manufacturing and Development Activities to obtain Regulatory Approval and Commercialization outside the Territory.

**5.4 Pharmacovigilance.** Pint shall be responsible for all processing of information related to any adverse events, including any information regarding such adverse events that is received from a Third Party, related to any Product sold by Pint or on behalf of Pint or any of its Affiliates or sublicensees in the Territory and shall also be responsible for all expedited and periodic reporting of such events to the applicable Governmental Authority in the Territory in accordance with applicable Law. Each Party shall provide to the other Party the relevant safety information it receives (either directly or indirectly) for any Product sold by or on behalf of such Party or any of its Affiliates or sublicensees in a timely manner so as to allow the other Party to timely comply with its responsibility to report pharmacovigilance information to the applicable Governmental Authorities in accordance with applicable Law. Without limiting the generality of the foregoing, each Party shall be allowed to utilize any such adverse event report and other information to allow such Party (and its designees) to comply with safety reporting requirements or other applicable Laws with respect to the Product within the Territory with respect to Pint, and outside of the Territory with respect to Onconova. As soon as reasonably practicable following the Effective Date, the pharmacovigilance departments of each of Onconova and Pint shall meet and determine the approach to be taken for the collection, review, assessment, tracking, exchange and filing of information related to adverse events associated with the Product, consistent with the provisions of this Section 5.4 (including establishing and maintaining a global safety database, which shall be maintained by Onconova). Such approach shall be documented in a separate pharmacovigilance agreement between Onconova and Pint, substantially in the form attached hereto as Schedule 5.4. Such agreement will be in accordance with, and enable

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the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to Government Authorities and other applicable Law.

**5.5 Regulatory Authority Communications Received by a Party.**

**5.5.1 General.** Each Party shall inform the other Party within forty-eight (48) hours, or such shorter time as is necessary to comply with the reporting requirements of any applicable Regulatory Authority, of notification of any action by, or notification or other information which it receives (directly or indirectly) from any Regulatory Authority in the Territory which (i) raises any material concerns regarding the safety or efficacy of the Product; (ii) indicates or suggests a potential material liability to Third Parties in connection with the Product; (iii) is reasonably likely to lead to a recall, market withdrawal or field alert with respect to the Product in or outside the Territory; or (iv) relates to expedited and periodic reports of adverse events with respect to the Product in or outside the Territory, and which may have an adverse impact on Regulatory Approval or the continued Commercialization of the Product. Notwithstanding the foregoing, in each case, each Party shall only provide such notification to the extent permitted under any contractual obligations of such Party (provided that each Party shall use Commercially Reasonable Efforts to avoid any such contractual restrictions) and to the extent such information is in such Party's possession and control. Each Party shall also promptly provide the other Party with a copy of all correspondence received from a Regulatory Authority specifically regarding the matters referred to above; provided that each Party shall only provide such copy to the extent permitted under any contractual obligations of such Party (provided that each Party shall use Commercially Reasonable Efforts to avoid any such contractual restrictions) and to the extent such information is in such Party's possession and control.

**5.5.2 Disclosures.** In addition to its obligations under this Agreement, each Party shall disclose to the other Party the following regulatory information:

**(a) Regulatory Actions.** All material information pertaining to actions taken by Regulatory Authorities in the Territory controlled by such Party, in connection with the Product in the Field in or outside the Territory, including any notice, audit notice, notice of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the Product in the Field in or outside the Territory, notice of violation letter (i.e., an untitled letter), warning letter, service of process or other inquiry; provided, however, that a Party shall be entitled to redact those portions thereof to the extent not related to the Product in the Field. Notwithstanding the foregoing, each Party shall only provide such information to the extent permitted under any contractual obligations of such Party (provided that each Party shall use Commercially Reasonable Efforts to avoid any such contractual restrictions) and to the extent such information is in such Party's possession and control.

**(b) Regulatory Non-Compliance.** All information pertaining to notices from Regulatory Authorities in or outside the Territory controlled by such Party of non-compliance with Laws in connection with the Product in or outside the Field in the Territory, including receipt of a warning letter or other notice of alleged non-compliance from any Regulatory Authority relating to the Product in or outside the Field in the Territory; provided, however, that a Party shall be entitled to redact those portions thereof to the extent not related to the Product in the Field. Notwithstanding the foregoing, each Party shall only provide such

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information to the extent permitted under any contractual obligations of such Party (provided that each Party shall use Commercially Reasonable Efforts to avoid any such contractual restrictions) and to the extent such information is in such Party's possession and control.

**5.6 Recall, Withdrawal or Field Alert of Product.**

**5.6.1 Notification and Determination.** In the event that any Governmental Authority threatens or initiates any action to remove the Product from the market in the Field in or outside the Territory (in whole or in part), the Party receiving notice thereof shall notify the other Party of such communication immediately, but in no event later than three (3) business days, after receipt thereof. Notwithstanding the foregoing, each Party shall only provide such notice to the extent permitted under any contractual obligations of such Party (provided that each Party shall use Commercially Reasonable Efforts to avoid any such contractual restrictions) and to the extent such information is in such Party's possession and control. Notwithstanding the foregoing, in all cases Pint, as the holder of the IND or MAA for the Product in the Territory, shall determine whether to initiate any recall, withdrawal or field alert of the Product in the Territory, including the scope of such recall or withdrawal (e.g., a full or partial recall, or a temporary or permanent recall) or field alert; provided, however that before Pint initiates a recall, withdrawal or field alert, the Parties shall promptly meet and discuss in good faith the reasons therefor, provided that such discussions shall not delay any action that Pint reasonably believes has to be taken in relation to any recall, withdrawal or field alert. In the event of any such recall, withdrawal or field alert, Pint, as the holder of the IND or MAA for the Product in the Territory, shall determine the necessary actions to be taken, and as distributor of the Product in the Territory hereunder, shall implement such action, with reasonable assistance from Onconova, to conduct such recall, withdrawal or field alert. Without limiting the foregoing, Onconova shall have the right to propose that a Product recall, withdrawal or

field alert should be initiated by Onconova, but Pint, as holder of the IND or MAA for the Product, shall make the final decision as to whether or not the recall, withdrawal or field alert should be initiated.

## ARTICLE 6
## COMMERCIALIZATION

**6.1 Commercialization in the Field in the Territory.** During the Term, Pint shall be solely responsible for Commercializing the Product in the Territory for use in the Field, which Commercialization shall be in accordance with the Commercialization Plan and this Agreement, with the goal of maximizing the commercial potential of the Product in the Field in the Territory. Pint shall be responsible for all expenses (including pre-marketing and other Commercialization expenses) incurred in connection with the Commercialization of the Product in the Territory for use in the Field.

**6.2 Pint's Performance.**

**6.2.1 Commercialization Plan.**

**(a)** On an annual basis no later than September 30th of each year (except with respect to the initial plan, which shall be prepared and circulated to the JSC no later than six (6) months prior to First Commercial Sale of Product in the Territory), Pint shall create

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and submit to the JSC for its review the commercialization plan for the following calendar year (each, a "**Commercialization Plan**"). From time to time during a given calendar year, Pint may propose written updates to the Commercialization Plan for review by the JSC.Pint shall conduct all Commercialization of the Product in the Territory in accordance with the Commercialization Plan.

**(b)** Each annual Commercialization Plan shall include, at a minimum, and set forth on a country-by-country basis, among other things, the following items in connection with the Commercialization of the Product in the Territory for use in the Field:

**(i)** a description of the short- and long-term vision for the Product and Product positioning; a situation analysis; and a description of critical issues, strategic imperatives and tactics by strategic imperative with timelines and budget, all of the foregoing from each of the following perspectives: marketing, sales, and reimbursement;

**(ii)** a summary of the minimum level of sales efforts to be dedicated to the promotion of the Product, including detailing information;

**(iii)** a description of any promotional materials and campaigns, including publication plans to be used in connection with the promotion of the Product in the Field; and

**(iv)** a detailed budget for the Commercialization activities for the applicable period.

**6.2.2 Specific Commercialization Obligations.** Without limiting the generality of the provisions of Section 6.1, in connection with the Commercialization of the Product in the Territory for use in the Field by Pint hereunder, during the Term, Pint shall be responsible for (and each Commercialization Plan shall reflect that):

**(a)** Pint shall be solely responsible for (i) receiving, accepting and filling orders for the Product in the Field in the Territory, (ii) handling all returns of the Product in the Field in the Territory, (iii) controlling invoicing, order processing and collection of accounts receivable for the sales of the Product in the Field in the Territory, (iv) booking and recording sales of the Product in the Field in the Territory in its books of account and (v) distributing and managing inventory of the Product in the Field in the Territory, in each case in accordance with International Financial Reporting Standards (IFRS), consistently applied, to the extent applicable.

**(b)** Pint shall use Commercially Reasonable Efforts to (i) obtain and maintain Regulatory Approvals for the Product for Commercialization in at least three of the following four countries within the Territory: Argentina, Brazil, Colombia and Mexico, and (ii) Commercialize the Product in such countries in the Territory where Regulatory Approvals have been obtained.

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**6.3 Reports.** Pint shall update the JSC on a country-by-country basis at each meeting regarding its significant Commercialization activities involving the Product. Pint shall present written reports to the JSC at least quarterly, summarizing its significant Commercialization activities with respect to the Product pursuant to this Agreement. Such reports submitted by Pint shall cover the subject matter at a level of detail reasonably sufficient to enable Onconova to determine Pint's compliance with its diligence obligations pursuant to this Article 6.

**6.4 Compliance.** Pint shall comply with all applicable Laws, including the U.S. Foreign Corrupt Practices Act, as well as all applicable Regulatory Approvals for the Product. In addition, Pint shall not use in any capacity relating to the Product, any Person who has been debarred pursuant to Section 306 of the FD&C Act (or similar Law outside of the U.S.), or who is the subject of a conviction described in such section, and Pint shall inform Onconova in writing immediately if it or any Person who is performing services for Pint hereunder is debarred or is the subject of a conviction described in Section 306 (or similar Law outside of the U.S.), or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to the Pint's knowledge, is threatened, relating to the debarment of Pint or any Person used in any capacity by Pint relating to the Product.

**6.5 Use of Subcontractors.** Pint shall not have the right, without Onconova's prior written consent (which may be withheld at Onconova's sole discretion, but which is hereby granted as of the Effective Date with respect to the subcontractors set forth on Schedule 6.5 hereto), to distribute or detail the Product in the Territory in the Field directly or indirectly through any Third Party(ies). Any proposal by Pint to use a Third Party to distribute or detail the Product is subject to prior consultation with Onconova.

**6.6 Promotional Materials.**

**6.6.1 Creation of Promotional Materials.** Pint will create and develop promotional materials for the Territory in accordance with the Commercialization Plan, the Regulatory Approvals and applicable Laws. To the extent Pint includes any Onconova trademarks in the promotional materials, Pint shall comply with Onconova's then-current guidelines for trademark usage, a copy of which shall be provided to Pint from time to time.

**6.6.2 Inclusion of Logos on Packaging and Promotional Materials.** To the extent permitted or required by applicable Law and subject to obtaining necessary Regulatory Authority approvals, with respect to Product to be sold by Pint or on behalf of Pint or any of its Affiliates in the Territory, the Onconova housemark and the Pint housemark shall be given equal prominence on all package inserts utilized by Pint; provided, however, in the event that applicable Law prevents the foregoing, Onconova shall still be identified on all package inserts for the Product. Pint hereby grants to Onconova a non-exclusive, royalty-free, sublicensable right and license during the Term to utilize the Pint housemark (including all trademarks, names and logos) in order to perform any activities to be performed by or on behalf of Onconova hereunder, and Onconova hereby grants to Pint a non-exclusive, royalty-free right and license during the Term to utilize the Onconova housemark (including all trademarks, names and logos) in order to perform the Commercialization activities required to be performed by Pint hereunder in accordance with the terms of this Agreement. Each Party shall only use the housemark of the other Party with the necessary trademark designations, and each Party shall use the other Party's

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housemarks in a manner that does not derogate from such Party's rights in its trademarks, names and logos. Each Party will take no action that will interfere with or diminish the other's rights in its respective trademarks, names and logos, and if a Party reasonably believes that the use of its trademarks, names and logos by the other Party hereunder is interfering with or diminishing its rights, such Party shall notify the other Party thereof in writing and such other Party shall promptly cease use of such trademarks, names or logos in such manner. Each Party agrees that all use of the other Party's trademarks, names and logos will inure to the benefit of such other Party, including all goodwill in connection therewith.

**6.7 Product Trademarks and Product Trade Dress.**

**6.7.1 Generally.** Onconova shall, at its own expense, register Product-specific trademarks in each country within the Territory. In the alternative, at Onconova's request, Pint shall register such trademarks in each country within the Territory in Onconova's name, and, in such case, Onconova shall promptly reimburse Pint for all expenses associated therewith. Pint shall Commercialize the Product in the Field in the Territory consistent with (a) any trademark (and logo) or trade dress as Onconova may determine and notify Pint of prior to the First Commercial Sale in the Territory, or such other trademark or trade dress as the Parties mutually agree upon. All uses of the Product trademarks and trade dress to identify and/or in connection with the Commercialization of the Product in the Field in the Territory shall be reviewed by the JSC, shall be in accordance with the Commercialization Plan, Regulatory Approvals and all applicable Laws and shall be subject to the approval of Onconova in its reasonable discretion. The Product trademarks and trade dress under which the Product is marketed or sold (other than Pint's corporate trademarks or trade names) shall be used by Pint only pursuant to the terms of this Agreement to identify and in connection with the Commercialization of the Product, and shall not be used by Pint to identify or in connection with the marketing of any other products.

**6.7.2 Trademark Acknowledgments.** Each Party acknowledges the sole ownership by the other Party and validity of all trademarks, trade dress, logos and slogans owned by the other Party and used or intended to be used in connection with the Commercialization of the Product for the Field in the Territory. Each Party agrees that it will not at any time during or after the Term assert or claim any interest in, or do anything which may adversely affect the validity or enforceability of, any copyright, trademark, trade dress, logo or slogan owned by the other Party and used or intended to be used on or in connection with the marketing or sale of the Product. Neither Party will register, seek to register or cause to be registered any copyrights, trademarks, trade dress, logos or slogans owned by the other Party and used or intended to be used on or in connection with the marketing or sale of the Product or any variation thereof, under any applicable Law providing for registration of copyrights, trademarks, service marks, trade names or fictitious names (including as an Internet domain name) or similar Laws, without the other Party's prior written consent (in its sole discretion).

**6.8 Commercialization Data.** Pint shall own all marketing and sales data and information resulting from its Commercialization of the Product in the Field in the Territory during the Term (the "**Commercialization Data**").

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## ARTICLE 7
## SUPPLY

**7.1 General.** For so long as Onconova complies with the terms of the Parties' supply and quality agreement ("Supply Agreement") and is able to meet Pint's requirements of Compound and Product, Pint shall purchase all of its requirements of Compound and Product exclusively from Onconova pursuant to the terms of this Article 7. All Product supplied by Onconova to Pint shall be Finished Product. The Parties shall enter into a Supply Agreement within ninety (90) days after FDA approval of an NDA for Product.

**7.2 Price.** Onconova shall supply sufficient quantities of Product to Pint to satisfy all Regulatory Authority requests and Development requirements within the Territory, invoiced at a price equal to Onconova's fully-burdened cost, except with respect to Product intended for such use in Argentina or Brazil, the invoice shall be at a price equal to fifty percent (50%) of Onconova's fully-burdened cost. Product supplied by Onconova to Pint or its designee for Pint's or its Affiliates', sublicensees' or subcontractors' commercial or other revenue-generating sales within the Territory shall be invoiced at a price equal to Onconova's fully-burdened cost plus ten percent (10%), and the foregoing agreed pricing shall be set forth in the Parties' Supply Agreement.

## ARTICLE 8
## PAYMENTS

**8.1 Upfront Equity Issuance; Research and Development Payment.**

**8.1.1 Upfront Equity Issuance.** Pint shall purchase shares of common stock of Onconova pursuant to the terms of the Securities Purchase Agreement ("SPA") entered into by the Parties concurrent with execution and delivery of this Agreement. In the event that initial closing under the SPA does not occur by the Initial Closing Date (as defined therein), in lieu of the purchase of shares thereunder, Pint shall on the Initial Closing Date make a cash payment to Onconova in the amount of $324,074 (the "Alternative Initial Cash Payment"). Upon Pint's payment of the Alternative Initial Cash Payment as provided herein, this Agreement shall not be terminated or terminable due to the failure of Pint to purchase the Initial Closing Shares or the Alternative Initial Closing Shares pursuant to the SPA, or the termination of the SPA in accordance of Section 7.1(b) thereof.

**8.1.2 Reimbursement of Research and Development Expenses.** Upon the approval of an NDA for Product by the FDA (the "Research and Development Event"), Pint shall pay to Onconova two million five hundred thousand Dollars ($2,500,000) by wire transfer of immediately available funds into an account designated in writing by Onconova within thirty (30) days after Onconova provides written notice of the achievement of such approval (the "**Research and Development Payment**") ; provided, however, that the Research and Development Payment shall be one million two hundred fifty thousand Dollars ($1,250,000) if such NDA approval by the FDA for Product is for use only with a population of patients narrower than the ITT Population. One-half of the Research and Development Payment (the "Cash Half" of the Research and Development Payment) shall be made in consideration of, and as reimbursement for, the research and Development activities performed by or on behalf of

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Onconova with respect to the Product prior to such approval, and one-half of the Research and Development Payment (the "Securities Purchase Half") shall be in consideration of the sale by Onconova to Pint of Common Stock of Onconova as set forth in the SPA. In the event that the SPA is terminated in accordance with Section 7.1(b) thereof, then in lieu of the Securities Purchase Half of the Research and Development Payment, Pint instead shall make a cash payment (the "Alternative Securities Purchase Half") to Onconova in an amount equal to twenty-five percent (25%) multiplied by the average of the daily VWAPs (as defined in the SPA) for the Common Stock for each of the ten (10) consecutive Trading Days (as defined in the SPA) ending on (and including) the Trading Day immediately prior to the date the Research and Development Event is reached, and further multiplied by the number of Research and Development Event Shares (as defined in the SPA) calculated in accordance with the SPA. For the avoidance of doubt, relevant SPA sections referenced in this Section 8.1.2 shall be used for purposes of computation under this Section 8.1.2 regardless of whether the SPA is terminated at the time of such calculation. In the event that at the time for payment of the Alternative Securities Purchase Half no VWAPs (as defined in the SPA) are available for purposes of calculating the Alternative Securities Purchase Half in the manner described in the immediately preceding sentence, then the Alternative Securities Purchase Half shall be $250,000 in the event that the NDA approval is for Product use with the entire ITT Population, or shall be $125,000 in the event that the NDA approval is for Product use with a population of patients narrower than the entire ITT Population. To the extent Pint pays the Alternative Securities Purchase Half in accordance with this Section 8.1.2, (a) Pint shall still also pay Onconova the Cash Half of the Research and Development Payment in full, and (b) this Agreement shall not be terminated or terminable due to the failure of Pint to purchase the Research and Development Event Shares pursuant to the SPA. Such Research and Development Payment shall be non-refundable and non-creditable against any other payments due hereunder.

**8.2 Development Milestone Payments.** Pint shall pay to Onconova the milestone payments described in this Section 8.2 upon achievement (first occurrence) of the corresponding milestone event. Pint shall promptly notify Onconova in writing, but in no event later than thirty (30) days after, of the achievement of each such milestone event achieved by it or any Affiliate or sublicensee. Pint shall pay the applicable milestone payment by wire transfer of immediately available funds into an account designated by Onconova within thirty (30) days after the achievement (first occurrence) of the applicable milestone event. Each such payment is non-refundable and non-creditable against any other payments due hereunder.

| Milestone Event | Milestone Payment |
|---|---|
| 1. Receipt of a complete Dossier for a Product prepared by or on behalf of Onconova or any of its Affiliates or licensees for submission outside of the Territory. The Dossier shall be compliant according to requirements for the country or region outside of the Territory for which it has been or is being submitted. | $ [**] |

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|---|---|
| 2. Receipt of the first approval of an MAA in the Territory for Product. | $[**]; provided that the milestone payment shall be $[**] if such MAA approval is use with a population of patients narrower than the ITT Population |

**8.3 Sales Milestone Payments**. Pint shall pay to Onconova the milestone payments described in this Section 8.3 upon achievement (first occurrence) of the corresponding milestone event. Pint shall promptly notify Onconova in writing, but in no event later than ten (10) days after, of the achievement of each such milestone event achieved by it or any Affiliate or sublicensee. Pint shall pay the applicable milestone payment by wire transfer of immediately available funds into an account designated by Onconova within thirty (30) days after receipt by Pint of an invoice from Onconova for same following Pint's notification to Onconova of the achievement of an applicable milestone. Each such payment is non-refundable and non-creditable against any other payments due hereunder. 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.

| Milestone Event | Milestone Payment |
|---|---|
| 1. The first 12 consecutive month period in which the aggregate annual Net Sales of all Products in the Territory equals or exceeds $10,000,000 | $ [**] |
| 2. The first 12 consecutive month period in which the aggregate annual Net Sales of all Products in the Territory equals or exceeds $25,000,000 | $ [**] |
| 3. The first 12 consecutive month period in which the aggregate annual Net Sales of all Products in the Territory equals or exceeds $40,000,000 | $ [**] |
| 4. The first 12 consecutive month period in which the aggregate annual Net Sales of all Products in the Territory equals or exceeds $50,000,000 | $ [**] |
| 5. The first 12 consecutive month period in which the aggregate annual Net Sales of all Products in the Territory equals or exceeds $100,000,000 | $ [**] |

**8.4 Royalties.**

**8.4.1 Royalty Rates for Product.** As further consideration for the rights granted to Pint hereunder and subject to the terms and conditions set forth in this Agreement, during the Royalty Term, Pint shall pay to Onconova a tiered royalty on aggregate annual Net

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Sales of all Products in the Territory at the applicable rate set forth below with respect to all Net Sales in all or any portion of the calendar year:

| Annual Net Sales of Product | Royalty Rate |
|---|---|
| For that portion of aggregate annual Net Sales less than or equal to $30,000,000 | [**]% |
| For that portion of aggregate annual Net Sales greater than $30,000,000 | [**]% |

**8.4.2 Reduction of Royalty Due to No Valid Claims.** On a country-by-country basis, and a Product-by Product basis, in the event that, and in such case from and after the date on which, a Product is Commercialized in a country in the Territory and is not covered by a Valid Claim of an Onconova Patent that covers the Product or its manufacture or use in such country, the royalty rate set forth in Section 8.4.1 with respect to such country shall be reduced by [**] percent ([**]%). In the event certain Net Sales are subject to the royalty reduction set forth in this Section 8.4.2, Licensee shall calculate the royalty rates as follows: Licensee shall allocate the applicable reductions to a portion of the Net Sales during a particular calendar quarter to the relevant Net Sales tier set forth in Section 8.4.1 equal to the proportion of Net Sales eligible for such reduction compared to total Net Sales. For example, if the total Net Sales for a calendar quarter are $80 million, and $20 million of such Net Sales are eligible for royalty reduction under this Section 8.4.2 (meaning 25% of total Net Sales for such calendar quarter are eligible for reduction), then the reduced royalty rates shall apply to 25% of the Net Sales in each applicable royalty tier, and the full royalty rates shall apply to the remaining 75% of Net Sales in each applicable royalty tier.

**8.4.3** In the event that, subject to Section 8.6.1, Pint obtains a license under, or other rights to, patent rights or know-how or other intellectual property from any Third Party(ies) necessary in order to Develop or Commercialize Product in the form being Developed outside of the Territory by Onconova as of the Effective Date in the Field and in the Territory, [**] percent ([**]%) of any and all payments (including royalties and any payments for obtaining such right or license) actually paid under such Third Party licenses by Pint or its Affiliates for a calendar quarter shall be creditable against the royalty payments due to Onconova by Pint with respect to the sale of such Product within such calendar quarter. At the request of Pint, Onconova shall cooperate with Pint in obtaining any such Third party licenses.

**8.4.4** Notwithstanding the foregoing, in no event will the reductions allowable by Section 8.4.2 and 8.4.3 together cause royalties payable to Onconova in a given calendar quarter to be reduced to less than [**] percent ([**]%) of the applicable royalties set forth in Section 8.4.1.

**8.5 Royalty Payments and Reports.** Pint shall calculate all amounts payable to Onconova pursuant to Section 8.4 with respect to Net Sales at the end of each calendar quarter, which amounts shall be converted to Dollars at such time in accordance with Section 8.8. Pint shall pay to Onconova the royalty amount due for Net Sales during a given calendar quarter

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within thirty (30) days after the end of such calendar quarter. Each payment of royalties due to Onconova shall be accompanied by (i) a statement of the amount of gross sales of each Product in the Territory during the applicable calendar quarter (including such amounts expressed in local currency and as converted to Dollars), (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 royalty payment due on such Net Sales for such calendar quarter. Without limiting the generality of the foregoing, Pint shall require its Affiliates and sublicensees to account for its Net Sales and to provide such reports with respect thereto as if such sales were made by Pint.

**8.6 Third Party Licenses.**

**8.6.1** If Pint or any of its Affiliates or sublicensees desires to obtain a license, covenant not to sue or similar rights under any Third Party Patents or other Third Party intellectual property necessary or useful Development, Manufacture or Commercialization of a Product for sale in the Field, then prior to the earlier of commencing negotiations with, or entering into any agreement with, any such Third Party with respect to any such license, covenant or right, Pint shall promptly notify Onconova in writing. Onconova, itself or through any of its Affiliates or licensees, shall have the first right to in-license or otherwise obtain such rights on a worldwide or country-by-country basis, in Onconova's sole discretion. In the event Onconova elects not to in-license or otherwise obtain such rights in the Territory, Pint or its Affiliates or sublicensees may in-license or otherwise acquire rights under such Third Party Patents or other Third Party intellectual property, but only with respect to the Licensed Territory. In the event Pint enters into any license or covenant not to sue or similar rights to any Third Party Patents or other Third Party intellectual property necessary or useful for the Development, Manufacture or Commercialization of a Product, Pint shall include in any such license or covenant not to sue or similar rights the right to sublicense or otherwise transfer rights to Onconova pursuant to Section 2.2.

**8.7 Taxes and Withholding.** Any income or other taxes which a paying Party is required by Law to pay or withhold on behalf of a receiving Party with respect to any payments payable to a receiving Party under this Agreement shall be deducted from the amount of such payments due, and paid or withheld, as appropriate, by the paying Party on behalf of the receiving Party. Any such tax required by applicable Law to be paid or withheld shall be an expense of, and borne solely by, the receiving Party. The paying Party shall furnish the receiving Party with reasonable evidence of such payment or amount withheld, in electronic or written form, as soon as practicable after such payment is made or such amount is withheld. The Parties will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax laws or under any other applicable Law in connection with the making of any required tax payment or withholding payment, or in connection with any claim to a refund of or credit for any such payment.

**8.8 Currency Conversion.** All payments to a Party hereunder shall be made in Dollars. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar

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equivalents, calculated using the average for the applicable currency conversion as published by *The Wall Street Journal, Eastern Edition*, for the three (3) months preceding the date on which such calculation is made.

**8.9 General Payment Procedures.** With the exception of the Upfront Payment payable pursuant to Section 8.1.1, the Research and Development Payment payable pursuant to Section 8.1.2, the milestone payments payable pursuant to Sections 8.2 and 8.3, royalties payable pursuant to Section 8.5 or other amounts expressly payable in certain time frames set forth herein, the receiving Party shall invoice the paying Party for all amounts due

to such receiving Party under this Agreement, and such payments shall be made within sixty (60) days following the receipt by the paying Party of an invoice from the receiving Party specifying the amount due.

**8.10 Late Payments.** Without limiting any other rights or remedies available to a Party hereunder, if such Party does not receive payment of any amount due to it on or before the due date, the other Party shall pay to such Party interest on any such amounts from and after the date such payments are due under this Agreement at a rate of one and one-half percent (1.5%) per month or the maximum applicable legal rate, if less, calculated on the total number of days' payment is delinquent.

**8.11 Records; Audits.** Pint, its Affiliates and sublicensees 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 royalties and other amounts payable to Onconova hereunder (including records of Net Sales) and any other records reasonably required to be maintained with respect to Pint's obligations under this Agreement, in each case for a minimum period of four (4) years or such longer period as required by applicable Law. Onconova shall have a right to request an audit of Pint, its Affiliates or sublicensees (the "**Audited Party**") in order to confirm the accuracy of any of the foregoing (an "**Audit**"); provided, however, that Onconova shall only have the right to request such Audit one time during any given calendar year. Upon the written request by Onconova to Audit the Audited Party, Onconova 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 Onconova; 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 Pint'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 Pint shall be paid to Onconova within ten (10) business days of notification of the results of such inspection. Any

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overpayments made by Pint shall be refunded by Onconova within ten (10) business days of notification of the results of such inspection. The cost of the accountants shall be the responsibility of Onconova 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 Pint and Pint shall reimburse Onconova for any Onconova costs incurred for the Audit.

## ARTICLE 9
## INTELLECTUAL PROPERTY MATTERS

**9.1 Ownership of Intellectual Property.**

**9.1.1 General.** Subject to the provisions of this Section 9.1.1 and except as expressly set forth otherwise in this Agreement, as between the Parties: (i) Onconova shall solely own any Onconova Patents and Onconova Know-How, and (ii) Pint shall solely own any Pint Patents and Pint Know-How. The Parties shall jointly own Joint Inventions and, with respect to Joint Inventions, the Parties shall reasonably cooperate with respect to the filing, prosecution and maintenance of any Patents arising therefrom. Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, license, assign and otherwise exploit the Joint Inventions and Patents arising therefrom without the duty of accounting or seeking consent from the other Party. Each Party shall promptly disclose to the other Party all Inventions, as applicable, made by it during the Term. The determination of inventorship for Inventions for the purpose of allocating proprietary rights therein, shall, for purposes of this Agreement, be made in accordance with applicable Laws relating to inventorship set forth in the patent Laws of the United States (Title 35, United States Code).

**9.1.2 Employees.** Each Party will require all of its and its Affiliates' employees to assign all Inventions that are developed, made or conceived by such employees according to the ownership principles described in Section 9.1.1. Each Party will require any agents or independent contractors performing an activity pursuant to this Agreement to assign all Inventions that are developed, made or conceived by such agents or independent contractors to Onconova and/or Pint according to the ownership principles described in Section 9.1.1.

**9.2 Disclosures; Disputes Regarding Inventions.** Each Party shall, before filing a new patent application (including provisionals and continuations-in-part) claiming an Invention to be assigned pursuant to Section 9.1.1, promptly disclose such Invention to the other Party and shall provide the other Party with a copy of the proposed patent application at least ten (10) business days before filing such application or such shorter time as may be required to preserve Patent rights, including the avoidance of a statutory bar. If the non-filing Party believes that the filing Party's proposed patent application discloses Confidential Information of the non-filing Party, the non-filing Party shall so notify the filing Party within such ten (10) business days after receipt thereof, and the filing Party shall amend its proposed application to comply with the confidentiality provisions of this Agreement.

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**9.3 Patent Filings.**

**9.3.1 Onconova Responsibilities.** Onconova shall have the first right to prepare, file, prosecute and maintain (i) Patents claiming or covering Inventions and (ii) all other Onconova Patents. For clarity, the obligations in this Section 9.3.1 are subject to Pint's obligations pursuant to Section 9.1.1. If, during the Term, Onconova intends to allow any Onconova Patent in the Territory to which Pint has a license under this Agreement to expire or intends to otherwise abandon any such Onconova Patent, Onconova shall notify Pint of such intention at least thirty (30) days prior to the date upon which such Onconova Patent shall expire or be abandoned and Pint shall thereupon have the right, but not the obligation, to assume responsibility for the preparation, filing, prosecution or maintenance thereof in the Territory at its sole cost and expense.

**9.3.2 Pint Responsibilities.** Pint shall have the first right to prepare, file, prosecute and maintain Pint Patents. Pint shall keep Onconova informed of the status of each such Patent and shall give reasonable consideration to any suggestions or recommendations of Onconova concerning the preparation, filing, prosecution and maintenance thereof. The Parties shall cooperate reasonably in the prosecution of such Pint Patents under this

Section 9.3.2 and shall share all material information relating thereto promptly after receipt of such information. If, during the Term, Pint intends to allow any Pint Patent to which Onconova has a license under this Agreement to expire or intends to otherwise abandon any Pint Patent, Pint shall notify Onconova of such intention at least thirty (30) days prior to the date upon which such Pint Patent shall expire or be abandoned, and Onconova shall thereupon have the right, but not the obligation, to assume responsibility for the preparation, filing, prosecution or maintenance thereof at its sole cost and expense.

**9.3.3 Cooperation.** The Parties agree to cooperate in the preparation, filing, prosecution and maintenance of all Patents under this Section 9.3, including cooperating with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or maintain such Patents.

**9.3.4 Patent Expenses.** Any expenses incurred by a Party in connection with the preparation, filing, prosecution and maintenance of any Onconova Patents or Pint Patents, as applicable, shall be borne by the Party incurring such expenses; provided, however, that Pint will be responsible for all such expenses with respect to Onconova Patents in the Territory.

**9.4 Defense and Enforcement of Patents.**

**9.4.1 Infringement of Third Party Patents.** Onconova and Pint shall each promptly notify the other in writing if either Party, or any of their respective Affiliates, shall be individually named as a defendant in a legal proceeding by a Third Party alleging infringement of a patent or other intellectual property right of such Third Party as a result of the Manufacturing, Development, use or Commercialization of the Product hereunder for sale in the Field in the Territory (each, an "**Infringement Claim**").

**(a)** In the event that such Infringement Claim is brought solely against Pint but is not in connection with Onconova Know-How or an Onconova Patent, then Pint shall have the first right to assume sole control of the defense of any such Infringement Claim and Pint shall be deemed to be the "**Controlling Party**" for purposes of such Infringement Claim. In the

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event that such Infringement Claim is brought (i) against Onconova or both of Pint and Onconova in respect of the Product, (ii) relates to the Manufacture of the Product for sale outside the Territory or (iii) is brought against either or both of Pint and Onconova in connection with Onconova Know-How or an Onconova Patent, then Onconova (or its designee) shall have the first right, but not the obligation, to assume sole control of the defense of any such Infringement Claim and Onconova shall be deemed to be the "**Controlling Party**".

**(b)** If the Controlling Party wishes to assume sole control of the defense of any such Infringement Claim, the Controlling Party may do so upon written notice to the other Party and in such event (i) the Controlling Party will have the exclusive right, at its cost, to hire, fire and direct an attorney to represent both it and the other Party with respect to such Infringement Claims; and (ii) the Controlling Party will have the exclusive right to settle any Infringement Claim without the consent of the other Party, unless such settlement shall have a material adverse impact upon the other Party.

**(c)** If the Controlling Party does not exercise its right to control the defense of such Infringement Claim within ten (10) days, then the Parties shall jointly control the defense of any such Infringement Claim, and in such event, (i) each Party shall have the right but not the obligation, at its sole cost and expense, to retain its own counsel to participate in any such Infringement Claim, and (ii) neither Party may settle such Infringement Claim without the consent of the other Party; provided, however, that, notwithstanding the foregoing, in no event shall Pint have any right to control the defense of, either by itself or jointly, or settle, any Infringement Claim relating to the Manufacture of the Product.

**(d)** If a Party shall become engaged in or participate in any suit described in this Section 9.4.1, the other Party shall cooperate, and shall cause its and its Affiliates' employees to cooperate, with such Party in all reasonable respects in connection therewith.

**9.4.2 Prosecution of Infringers.**

**(a) Notice.** If either Party (i) receives notice of any patent nullity actions, any declaratory judgment actions or any alleged or threatened infringement of patents or patent applications or misappropriation of intellectual property comprising the Onconova Patents, Onconova Inventions, Onconova Know-How, Pint Patents, Pint Inventions or Pint Know-How or (ii) learns that a Third Party is infringing or allegedly infringing any Patent within the Onconova Patents or the Pint Patents, or if any Third Party claims that any such Patent is invalid or unenforceable, in each case, with respect to the Field in the Territory, it will promptly notify the other Party thereof, including providing evidence of infringement or the claim of invalidity or unenforceability reasonably available to such Party. The Parties will cooperate and use reasonable efforts to stop such alleged infringement or to address such claim without litigation.

**(b) Enforcement of Onconova Patents and Pint Patents.**

**(i)** Pint will have the first right (but not the obligation) to take the appropriate steps to enforce or defend any Patent within the Pint Patents against infringement

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by a Third Party in the Field in the Territory. Pint may take steps including the initiation, prosecution and control of any suit, action, proceeding or other legal action by counsel of its own choice. Pint shall bear the costs of such enforcement. Notwithstanding the foregoing, Onconova will have the right, at its own expense, to be represented in any such action by counsel of its own choice.

**(ii)** If, pursuant to Section 9.4.2(b)(i), Pint fails to take the appropriate steps to enforce or defend any Patent within the Pint Patents that have not been assigned pursuant to Section 9.1.1 but that relate to the Product within one hundred eighty (180) days of the date one Party has provided notice to the other Party pursuant to Section 9.4.2(a) of such infringement or claim, then Onconova will have the right (but not the obligation), at its own expense, to bring any such suit, action or proceeding by counsel of its own choice and Pint will have the right, at its own expense, to be represented in any such action by counsel of its own choice.

**(iii)** Onconova will have the first right (but not the obligation) to take the appropriate steps to enforce any Onconova Patent against infringement by a Third Party in the Field in the Territory, including the initiation, prosecution and control of any suit, proceeding or other legal

action by counsel of its own choice. Each of Onconova and Pint will bear the costs of such enforcement equally. Notwithstanding the foregoing, Pint will have the right, at its own expense, to be represented in any such action by counsel of its own choice.

**(iv)** If, pursuant to Section 9.4.2(b) Onconova fails to take the appropriate steps to enforce any Onconova Patent in the Territory within one hundred eighty (180) days of the date one Party has provided notice to the other Party pursuant to Section 9.4.2(a) of such infringement or claim, then Pint will have the right (but not the obligation), at its own expense, to bring any such suit, action or proceeding in the Territory by counsel of its own choice, and Onconova will have the right, at its own expense, to be represented in any such action by counsel of its own choice; provided, however, that notwithstanding the foregoing, in no event shall Pint have any right to bring any such suit, action or proceeding with respect to any matter involving the Manufacture of the Product.

**(c) Cooperation; Damages.**

**(i)** If one Party brings any suit, action or proceeding under Section 9.4.2(b), the other Party agrees to be joined as party plaintiff if necessary to prosecute the suit, action or proceeding and to give the first Party reasonable authority to file and prosecute the suit, action or proceeding; provided, however, that neither Party will be required to transfer any right, title or interest in or to any property to the other Party or any other party to confer standing on a Party hereunder.

**(ii)** The Party not pursuing the suit, action or proceeding hereunder will provide reasonable assistance to the other Party, subject to the other Party's reimbursement of any out-of-pocket expenses incurred by the non-enforcing or defending Party in providing such assistance.

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**(iii)** Pint shall not settle any claim, suit or action that it brought under Section 9.4.2 involving Onconova Patents without the prior written consent of Onconova in its sole discretion.

**(iv)** Any settlements, damages or other monetary awards (a "**Recovery**") recovered pursuant to a suit, action or proceeding brought pursuant to Section 9.4.2(b) will be allocated first to the costs and expenses of the Party taking such action, and second, to the costs and expenses (if any) of the other Party, with any remaining amounts (if any) to be allocated as follows: (i) if Pint is the enforcing Party, to the extent that such Recovery is a payment for lost sales of the Product in the Field in the Territory, any such Recovery shall be payable eighty percent (80%) to Pint and twenty percent (20%) to Onconova, and all other Recoveries shall be payable ninety percent (90%) to Onconova and ten percent (10%) to Pint, and (ii) if Onconova is the enforcing Party, to the extent that such Recovery is a payment for lost sales of the Product in the Field in the Territory, all Recoveries shall be payable fifty percent (50%) to Onconova and fifty percent (50%) to Pint and all other Recoveries shall be payable ninety percent (90%) to Onconova and ten percent (10%) to Pint.

**(d) Infringement of Onconova Patents Outside of the Territory or Outside the Field.** For clarity, with respect to any and all infringement of any Onconova Patent anywhere outside of the Territory or outside the Field, Onconova (or its designee) shall have the sole and exclusive right to bring an appropriate suit or other action against any Person engaged in such infringement of any such Onconova Patents, in its sole discretion and Pint shall have no rights with respect thereto.

**9.5 Patent Term Extensions.** Onconova and Pint shall cooperate in good faith in gaining Patent Term Extensions wherever applicable to the Onconova Patents and Pint Patents in the Territory. However, Onconova shall have the sole discretion in determining for which Onconova Patent(s) to seek Patent Term Extensions for any particular compound, protein, composition, article, product, process or use.

**9.6 Patent Marking.** Pint shall mark the Product marketed and sold by Pint (or its Affiliate or distributor) hereunder with appropriate patent numbers or indicia at Onconova's request.

**9.7 Consequences of Patent Challenge.** Onconova will be permitted to terminate this Agreement upon written notice to Pint, effective upon receipt, if Pint or any of its Affiliates, directly or indirectly, (i) initiate or request an interference or opposition proceeding with respect to any Onconova Patent, (ii) make, file or maintain any claim, demand, lawsuit or cause of action to challenge the validity or enforceability of any Onconova Patent, or (iii) oppose any extension of, or the grant of a supplementary protection certificate with respect to, any Onconova Patent.

## ARTICLE 10
## REPRESENTATIONS, WARRANTIES AND COVENANTS

**10.1 Mutual Representations and Warranties.** Each Party hereby represents and warrants (as applicable) to the other Party, as of the Effective Date, that:

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**10.1.1 Corporate Existence and Power.** It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

**10.1.2 Authority and Binding Agreement.** (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder, and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, except as enforcement may be affected by bankruptcy, insolvency or other similar laws and by general principles of equity.

**10.1.3 No Conflicts.** The execution, delivery and performance of this Agreement by it does not violate any Laws of any Governmental Authority having jurisdiction over it.

**10.1.4 All Consents and Approvals Obtained.** Except with respect to Regulatory Approvals for the Development, Manufacturing or Commercialization of the Product or as otherwise described in this Agreement, (i) all necessary consents, approvals and authorizations of, and (ii) all notices to, and filings by such Party with, all Governmental Authorities and other persons or entities required to be obtained or provided by such Party as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained and provided, except for those approvals, if any, not required at the time of execution of this Agreement.

**10.2 Additional Representations and Warranties of Onconova.** Onconova hereby represents and warrants to Pint, as of the Effective Date, that:

**10.2.1** Onconova has not filed and to Onconova's knowledge no other third party has filed any Marketing Authorization Applications with a Governmental Authority in the Territory for the sale of the Product in the Field in the Territory;

**10.2.2** Neither Onconova nor its Affiliates, nor, to Onconova's knowledge, its subcontractors, has received any notice in writing or otherwise has knowledge of any facts which have led Onconova to believe that any of Onconova's Regulatory Filings relating to the Product are not currently in good standing with the FDA;

**10.2.3** Neither Onconova nor, to the knowledge of Onconova, its subcontractors, has received written notice of any proceedings pending before or threatened by any Regulatory Authority with respect to the Product or any facility where the Product is Manufactured;

**10.2.4** To the knowledge of Onconova, no claim or demand of any Person has been asserted in writing to Onconova that challenges the rights of Onconova to use or license any of the Onconova Technology in the Territory;

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**10.2.5** Schedule 1.33 sets forth all of the Patents Controlled by Onconova as of the Effective Date that relate to Compound and/or Product and Onconova Controls all of the patents and patent applications listed on Schedule 1.33; and

**10.2.6** There are no claims, judgments or settlements against or owed by Onconova, nor any pending reissue, reexamination, interference, opposition or similar proceedings, with respect to the Onconova Patent Rights or Onconova Know-How, and Onconova has not received written notice as of the Effective Date of any threatened claims or litigation or any reissue, reexamination, interference, opposition or similar proceedings seeking to invalidate or otherwise challenge the Onconova Patent Rights or Onconova Know-How.

**10.2.7** all issued Patents within the Onconova Patent Rights are in full force and effect, and, to Onconova's knowledge, exist and are not invalid or unenforceable, in whole or in part;

**10.2.8** it has the full right, power and authority to grant the licenses granted hereunder;

**10.2.9** it (and its Affiliates) has not prior to the Effective Date (i) assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Onconova Patent Rights or Onconova Know-How in the Field in the Territory, or (ii) otherwise granted any rights to any Third Parties that would conflict with the rights granted to Pint hereunder;

**10.2.10** to Onconova's knowledge, it is the sole and exclusive owner of the Onconova Patent Rights and Onconova Know-How, all of which are free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has or shall have any claim of ownership whatsoever with respect to same;

**10.2.11** to Onconova's knowledge, the exercise of the license granted to Pint under the Onconova Patent Rights and Onconova Know-How, for the Development and Commercialization of Product in the form being Developed outside of the Territory by Onconova as of the Effective Date will not interfere with or infringe any intellectual property rights owned or possessed by any Third Party;

**10.2.12** there are no claims, judgments or settlements against or owed by Onconova (or any of its Affiliates) relating to the Onconova Patent Rights and Onconova Know-How and no pending or, to Onconova's knowledge, threatened claims or litigation relating to the Onconova Patent Rights and Onconova Know-How;

**10.2.13** Onconova has disclosed or otherwise made available to Pint all reasonably relevant and material information in Onconova's possession regarding (i) the Compounds and/or Products and/or (ii) the Onconova Patent Rights licensed under this Agreement, including (a) any licenses and material agreements related to the Onconova Patent Rights, Onconova Know-How, Compound and/or Product in the Field in the Territory and (b) safety or efficacy information related to the Compound and/or Products;

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**10.2.14** neither it nor any of its Affiliates has received any written notification from a Third Party that the research, development, manufacture, use, sale or import of Compound or Product in the form being Developed outside of the Territory by Onconova as of the Effective Date infringes or misappropriates the Patent Rights or know-how owned or controlled by such Third Party, and Onconova has no knowledge that a Third Party has any basis for any such claim;

**10.2.15** Onconova has complied with all existing country-specific laws and regulations involving inventor remuneration associated with the Onconova Patent Rights;

**10.2.16** Onconova has disclosed or otherwise made available to Pint all material correspondences to/from any Regulatory Authority in Onconova's possession, in each case related to the Compound or Products, to the extent such correspondence is relevant to the potential commercial, scientific or strategic value or attractiveness of the Compound or Products;

**10.2.17** Onconova has obtained all necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by it as of the Effective Date, as applicable, in connection with the execution, delivery and performance of this Agreement;

**10.2.18** To Onconova's knowledge, all research and development (including non-clinical studies and clinical trials) related to the Compound and/or Products prior to the Effective Date has been conducted in accordance with all Applicable Laws;

**10.2.19** except for the Temple License Agreements, there are no agreements (including any licenses), written or oral, granting any licenses or other rights to (or from) Onconova (or any of its Affiliates) relating to the Compound or Products or the Onconova Know-How or Onconova Patent Rights in the Territory;

**10.2.20** with respect to each Temple License Agreement, (i) it is in full force and effect; (ii) neither Onconova nor any of its Affiliates is in breach thereof; (iii) neither Onconova nor any of its Affiliates has received any notice of breach or notice of threatened breach thereof; and (iv) neither Onconova nor any of its Affiliates has received any notice from Temple of intent to reduce the scope of the field thereof or render any of the licenses thereunder non-exclusive, and no event, act or omission has occurred which could give rise to the right of Temple to reduce the scope of the field thereof or render any of the licenses thereunder non-exclusive; and

**10.2.21** to Onconova's knowledge, all information and data provided by or on behalf of Onconova to Pint on or before the Effective Date in contemplation of this Agreement was and is true and accurate and complete in all material respects, and to Onconova's knowledge, Onconova has not disclosed, failed to disclose, or cause to be disclosed, any information or data that would reasonably be expected to cause the information and data that has been disclosed to be misleading in any material respect.

**10.3 Additional Representations and Warranties of Pint.** Pint hereby represents and warrants to Onconova, as of the Effective Date, that:

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**10.3.1** Pint is solvent and has the ability to pay and perform all of its obligations as and when such obligations become due, including payment obligations and other obligations under this Agreement;

**10.4 Mutual Covenants.** Each Party hereby covenants to the other Party that:

**10.4.1** All employees of such Party or its Affiliates or Third Party subcontractors working under this Agreement will be under appropriate confidentiality provisions at least as protective as those contained in this Agreement and, to the extent permitted under Law, have agreed to a present assignment of all right, title and interest in and to their inventions and discoveries, whether or not patentable, to such Party as the sole owner thereof;

**10.4.2** To its knowledge, such Party will not (i) employ or use, nor hire or use any contractor or consultant that employs or uses, any individual or entity, including a clinical investigator, institution or institutional review board, debarred or disqualified by the FDA (or subject to a similar sanction by any Regulatory Authority outside the United States) or (ii) employ any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding by any Regulatory Authority outside the United States), in each of subclauses (i) and (ii) in the conduct of its activities under this Agreement; and

**10.4.3** Neither Party nor any of its Affiliates shall, during the Term, grant any right or license to any Third Party relating to any of the intellectual property rights it owns or Controls which would conflict with any of the rights or licenses granted to the other Party hereunder; and such Party and its Affiliates shall perform its activities pursuant to this Agreement in compliance (and shall ensure compliance by any of its subcontractors) in all material respects with all Laws including GLPs, GMPs and GCPs as applicable and with respect to the Development, Manufacturing and Commercialization activities contemplated hereunder.

**10.5 Disclaimer.** Pint understands that the Product is the subject of ongoing clinical research and development and that Onconova cannot ensure the safety or usefulness of the Product or that the Product will receive Regulatory Approvals. In addition, Onconova makes no warranties except as set forth in this Article 10 concerning the Onconova Technology or otherwise.

**10.6 No Other Representations or Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

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## ARTICLE 11
## INDEMNIFICATION

**11.1 Indemnification by Onconova.** Onconova hereby agrees to indemnify, defend and hold Pint, its Affiliates, and their respective directors, officers, agents and employees harmless from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") arising in connection with any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions by a Third Party (each, a "**Third Party Claim**") resulting or otherwise arising from (i) any breach by Onconova of any of its representations, warranties, covenants or obligations pursuant to this Agreement, (ii) the negligence or willful misconduct by Onconova or its Affiliates or their respective officers, directors, employees, agents, consultants or sublicensees in performing any obligations under this Agreement, or (iii) any matter related to the Development, handling, storage, use, packaging and labeling, or Commercialization of the Product outside the Territory (including, for clarity, any product liability Losses resulting therefrom) by Onconova or its Affiliates or their respective officers, directors, employees, agents, consultants or sublicensees; in each case, except to the extent that such Losses are subject to indemnification by Pint pursuant to Section 11.2.

**11.2 Indemnification by Pint.** Pint hereby agrees to indemnify, defend and hold Onconova, its Affiliates, and their respective directors, agents and employees harmless from and against any and all Losses arising in connection with any and all Third Party Claims resulting or otherwise arising from (i) any breach by Pint of any of its representations, warranties, covenants or obligations pursuant to this Agreement, (ii) the negligence or willful misconduct by Pint or its Affiliates or their respective officers, directors, employees, agents, consultants or sublicensees in performing any obligations under this

Agreement, or (iii) any matter related to the Development, handling, storage, use, packaging and labeling, or Commercialization of the Product hereunder (including, for clarity, any product liability Losses resulting therefrom) by Pint or its Affiliates or their respective officers, directors, employees, agents, consultants or sublicensees; in each case, except to the extent that such Losses are subject to indemnification by Onconova pursuant to Section 11.1.

**11.3 Indemnification Procedures.**

**11.3.1 Notice of Claim.** All indemnification claims in respect of any indemnitee seeking indemnity under Section 11.1 or 11.2, as applicable (collectively, the "**Indemnitees**" and each, an "**Indemnitee**") will be made solely by the corresponding Party (the "**Indemnified Party**"). The Indemnified Party will give the indemnifying Party (the "**Indemnifying Party**") prompt written notice (an "**Indemnification Claim Notice**") of any Losses and any legal proceeding initiated by a Third Party against the Indemnified Party as to which the Indemnified Party intends to make a request for indemnification under Section 11.1 or 11.2, as applicable, but in no event will the Indemnifying Party be liable for any Losses that result from any delay in providing such notice which materially prejudices the defense of such proceeding. Each Indemnification Claim Notice shall contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). Together with the Indemnification Claim Notice, the Indemnified Party will furnish promptly to

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the Indemnifying Party copies of all notices and documents (including court papers) received by any Indemnitee in connection with the Third Party Claim.

**11.3.2 Control of Defense.** At its option, the Indemnifying Party may assume the defense of any Third Party Claim subject to indemnification as provided for in Section 11.1 or 11.2, as applicable, by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party's receipt of an Indemnification Claim Notice. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel it selects, and such Indemnifying Party shall thereafter continue to defend such Third Party Claim in good faith. Should the Indemnifying Party assume the defense of a Third Party Claim (and continue to defend such Third Party Claim in good faith), the Indemnifying Party will not be liable to the Indemnified Party or any other Indemnitee for any legal expenses subsequently incurred by such Indemnified Party or other Indemnitee in connection with the analysis, defense or settlement of the Third Party Claim, unless the Indemnifying Party has failed to assume the defense and employ counsel in accordance with this Section 11.3.

**11.3.3 Right to Participate in Defense.** Without limiting Section 11.3.2, any Indemnitee will be entitled to participate in the defense of a Third Party Claim for which it has sought indemnification hereunder and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnitee's own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing, or (ii) the Indemnifying Party has failed to assume the defense (or continue to defend such Third Party Claim in good faith) and employ counsel in accordance with this Section 11.3, in which case the Indemnified Party will be allowed to control the defense.

**11.3.4 Settlement.** With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnitee becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnitee in any manner, and as to which the Indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnitee hereunder, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its reasonable discretion, will deem appropriate (provided, however, that such terms shall include a complete and unconditional release of the Indemnified Party from all liability with respect thereto), and will transfer to the Indemnified Party all amounts which said Indemnified Party will be liable to pay prior to the time of the entry of judgment. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 11.3.2, the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, provided it obtains the prior written consent of the Indemnified Party (which consent will be at the Indemnified Party's reasonable discretion). The Indemnifying Party that has assumed the defense of (and continues to defend) the Third Party Claim in accordance with Section 11.3.2 will not be liable for any settlement or other disposition of a Loss by an Indemnitee that is reached without the written consent of such Indemnifying Party. No Indemnitee will admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without first

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offering to the Indemnifying Party the opportunity to assume the defense of the Third Party Claim in accordance with Section 11.3.2.

**11.3.5 Cooperation.** If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party will, and will cause each other Indemnitee to, cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection with such Third Party Claim. Such cooperation will include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket expenses incurred in connection with such cooperation.

**11.4 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 11. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 OR 11.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 12.

**11.5 Insurance.** Each Party shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which the Product is being clinically tested in human subjects or commercially distributed or sold by such Party pursuant to this Agreement. 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.

**ARTICLE 12**
**CONFIDENTIALITY**

**12.1 Confidential Information.** As used in this Agreement, the term "**Confidential Information**" means all information, whether it be written or oral, including all production schedules, lines of products, volumes of business, processes, new product developments, product designs, formulae, technical information, laboratory data, clinical data, patent information, know-how, trade secrets, financial and strategic information, marketing and promotional information and data, and other material relating to any products, projects or processes of one Party (the "**Disclosing Party**") that is provided to, or otherwise obtained by, the other Party (the

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"**Receiving Party**") in connection with this Agreement (including information exchanged prior to the date hereof in connection with the transactions set forth in this Agreement, including any information disclosed by either Party pursuant to that certain Confidential Disclosure Agreement between the Parties dated March 24, 2017). Notwithstanding the foregoing sentence, Confidential Information shall not include any information or materials that:

**(a)** were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party, to the extent such Receiving Party has documentary evidence to that effect;

**(b)** were generally available to the public or otherwise part of the public domain at the time of disclosure thereof to the Receiving Party;

**(c)** became generally available to the public or otherwise part of the public domain after disclosure or development thereof, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement;

**(d)** were disclosed to a Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or

**(e)** were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party, to the extent such Receiving Party has documentary evidence to that effect.

**12.2 Confidentiality Obligations.** Each of Pint and Onconova shall keep all Confidential Information received from or on behalf of the other Party with the same degree of care with which it maintains the confidentiality of its own Confidential Information, but in all cases no less than a reasonable degree of care. Neither Party shall use such Confidential Information for any purpose other than in performance of this Agreement or disclose the same to any other Person other than to such of its and its Affiliates' directors, managers, employees, independent contractors, agents or consultants who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement; provided, however, that a Receiving Party shall advise any of its and its Affiliates' directors, managers, employees, independent contractors, agents or consultants who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and the Receiving Party shall ensure (including, in the case of a Third Party, by means of a written agreement with such Third Party having terms at least as protective as those contained in this Article 12) that all such directors, managers, employees, independent contractors, agents or consultants comply with such obligations. Upon termination of this Agreement, the Receiving Party shall return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the possession of the Receiving Party or its directors, managers, employees, independent contractors, agents or consultants, except that the Receiving Party may keep one copy of the Confidential Information in the legal department files of the Receiving Party, solely for archival purposes. Such archival copy shall be deemed to be the property of the Disclosing Party, and shall continue to be subject

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to the provisions of this Article 12. It is understood that receipt of Confidential Information under this Agreement will not limit the Receiving Party from assigning its employees to any particular job or task in any way it may choose, subject to the terms and conditions of this Agreement.

**12.3 Permitted Disclosure and Use.** Notwithstanding Section 12.2, (i) either Party may disclose Confidential Information belonging to the other Party only to the extent such disclosure is reasonably necessary to: (a) comply with or enforce any of the provisions of this Agreement; and (b) comply with applicable Law; (ii) either Party may disclose Confidential Information belonging to the other Party related to a Product only to the extent such disclosure is reasonably necessary to obtain or maintain regulatory approval of a Product, as applicable, to the extent such disclosure is made to a Governmental Authority; and (iii) each Party may disclose Development Data (A) as reasonably necessary for filing or prosecuting Patents as permitted by this Agreement, or (B) to actual and potential licensees employees, consultants and sublicensees bound by a written agreement with such Party having terms at least as protective as those contained in this Article 12. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 12.3, such Party shall give reasonable advance written notice of such disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure confidential treatment of such information, including seeking a protective order or other appropriate remedy.

**12.4 Notification.** 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.

**12.5 Publicity; Filing of this Agreement.** The press release to be issued in connection with the transactions is set forth on Schedule 12.5. Except as otherwise provided in this Section 12.5, each Party shall maintain the confidentiality of all provisions of this Agreement, and without the prior written consent of the other Party, which consent shall not be unreasonably withheld, neither Party nor its respective Affiliates shall make any press release or other public announcement of or otherwise disclose the provisions of this Agreement to any Third Party, except for: (i) disclosure to those of its directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, advisors and agents whose duties reasonably require them to have access to this Agreement, provided that such directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, advisors and agents are required to maintain the confidentiality of this Agreement, (ii) disclosures required by Nasdaq regulation or any listing agreement with a national securities exchange, in which case the disclosing Party shall provide the nondisclosing Party with at least forty eight (48) hours' notice unless otherwise not practicable, but in any event no later than the time the disclosure required by such Nasdaq regulation or listing agreement is made, (iii) disclosures as may be required by Law, in which case the disclosing Party shall provide the nondisclosing Party with prompt advance notice of such

disclosure and cooperate with the nondisclosing Party to seek a protective order or other appropriate remedy, including a request for confidential treatment in the case of a filing with the Securities and Exchange Commission, (iv) the report on Form 8-K, which may be filed by Onconova or an Affiliate of Onconova setting forth the press

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release referred to above, and/or this Agreement in redacted form, (v) disclosures that are consistent with or complementary to those described in clause (iv) but which do not contain any Confidential Information of the other Party; and (vi) other disclosures for which consent has previously been given. A Party may publicly disclose without regard to the preceding requirements of this Section 12.5 any information that was previously publicly disclosed pursuant to this Section 12.5.

**12.6 Publication.** Pint shall submit copies of each proposed academic, scientific, medical and other publication or presentation that contains or refers to the Onconova Patents, Onconova Know-How or otherwise relates to the Product or any research or Development Activities under this Agreement to Onconova for review and comment at least thirty (30) days prior to submission for publication or other disclosure. At Onconova's request, Pint shall remove, redact or otherwise modify the proposed publication or presentation to remove any Confidential Information of Onconova. Upon request by Onconova in writing, Pint will grant Onconova an additional period of time, not to exceed an additional ninety (90) days, in order to allow patent applications to be filed to protect the potential patentability of any data, information or material described therein. In addition, in the event that the document includes data, information or material generated by Onconova's scientists, and professional standards for authorship would be consistent with including Onconova's scientists as co-authors of the document, the names of such scientists will be included as co-authors.

**12.7 Use of Names.** Except as otherwise set forth in this Agreement, neither Party shall use the name of the other Party in relation to this transaction in any public announcement, press release or other public document without the written consent of such other Party, which consent shall not be unreasonably withheld; provided, however, that subject to Section 12.5, either Party may use the name of the other Party in any document filed with any regulatory agency or Governmental Authority, including the FDA, CFDA and the Securities and Exchange Commission.

**12.8 Survival.** The obligations and prohibitions contained in this Article 12 as they apply to Confidential Information shall survive the expiration or termination of this Agreement for a period of seven (7) years.

## ARTICLE 13
## TERM AND TERMINATION

**13.1 Term.** This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect until the expiration of all royalty payment obligations under this Agreement (the "**Term**").

**13.2 Termination for Breach.** Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in the event that the other Party shall have materially breached or defaulted in the performance of any of its obligations. The non-terminating Party shall have thirty (30) days (ten (10) days in the event of non-payment) after written notice thereof was provided to the non-terminating Party by the terminating Party to remedy such default. Any such termination shall become effective at the end of such thirty (30)-day period (ten (10)-day period for non-payment) unless the non-terminating Party has cured any

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such breach or default prior to the expiration of such thirty (30)-day period (ten (10)-day period for non-payment).

**13.3 Termination as a Result of Bankruptcy.** Each Party shall have the right to terminate this Agreement upon written notice as a result of the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided that such termination shall be effective only if such proceeding is not dismissed within ninety (90) days after the filing thereof.

**13.4 Termination for Convenience by Pint**. Pint may terminate this Agreement in whole (but not in part) at any time upon forty-five (45) days' prior written notice to Onconova.

## ARTICLE 14
## EFFECTS OF TERMINATION

**14.1 Termination by Onconova.** Without limiting any other legal or equitable remedies that a Party may have, if this Agreement is terminated by Onconova pursuant to Section 13.2 or 13.3 or by Pint pursuant to Section 13.4, then the following provisions shall apply.

**14.1.1 Termination of Licenses.** All rights and licenses granted to Pint hereunder shall immediately terminate and be of no further force and effect and Pint shall cease Developing and Commercializing the Product (except as otherwise set forth in Section 14.1.4).

**14.1.2 Assignments.** Pint will promptly, in each case within sixty (60) days after receipt of Onconova's request, at Onconova's reasonable expense:

**(a)** assign to Onconova all of Pint's right, title and interest in and to any agreements (or portions thereof) between Pint and Third Parties that relate to the Development or Commercialization of the Product in any country for which such termination is effective;

**(b)** assign and does hereby to Onconova all of Pint's right, title and interest in and to any (i) promotional materials and (ii) copyrights and trademarks, any registrations and design patents for the foregoing and any internet domain name registrations for such trademarks and slogans, all to the extent solely related to the Product in any country for which such termination is effective; provided, however, in the event Onconova exercises such right to have assigned such promotional materials, Pint shall grant, and hereby does grant, a royalty-free right and license to any housemarks, trademarks, names and logos of Pint (not otherwise transferred pursuant to this clause (b)) contained therein for a period of eighteen (18) months in order use such promotional materials in connection with the Commercialization of the Product;

**(c)** assign to Onconova, the management and continued performance of any clinical trials for the Product ongoing hereunder as of the effective date of such termination in any country for which such termination is effective;

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**(d)** transfer and assign and does hereby transfer and assign to Onconova all of, if any, Pint's right, title and interest in and to any and all regulatory filings, Regulatory Approvals and other Regulatory Materials for the Product in any country for which such termination is effective;

**(e)** transfer and assign and does hereby transfer and assign to Onconova all of Pint's right, title and interest in and to any and all Commercialization Data Controlled by Pint for the Product in any country for which such termination is effective;

**(f)** provide copies of any other books, records, documents and instruments Controlled by Pint to the extent related to the Product;

**(g)** grant, and hereby does grant to Onconova and its Affiliates, and Onconova and its Affiliates will automatically have, an exclusive, fully paid-up license, with the right to grant sublicenses through multiple tiers, under any and all intellectual property rights (including any applicable trademarks) Controlled by Pint and its Affiliates and sublicensees covering or relating to Product or its manufacture or use in any formulation, to make, have made, use, offer to sell, sell, import and otherwise exploit Product in the Territory;

provided, however, that to the extent that any agreement or other asset described in this Section 14.1.2 is not assignable by Pint, then such agreement or other asset will not be assigned, and upon the request of Onconova, Pint will take such steps as may be necessary to allow Onconova to obtain and to enjoy the benefits of such agreement or other asset, without additional payment therefor, in the form of a license or other right to the extent Pint has the right and ability to do so. For purposes of clarity, Onconova shall have the right to request that Pint take any or all of the foregoing actions in whole or in part, or with respect to all or any portion of the assets set forth in the foregoing provisions.

**14.1.3 Disclosure and Delivery.** Pint will promptly transfer to Onconova copies of any physical embodiment of any Pint Know-How, to the extent then used in connection with the Development or Commercialization of the Product; such transfer shall be effected by the delivery of documents, to the extent such Pint Know-How is embodied in documents, and to the extent that Pint Know-How is not fully embodied in documents, Pint shall make its employees and agents who have knowledge of such Pint Know-How in addition to that embodied in documents available to Onconova for interviews, demonstrations and training to effect such transfer in a manner sufficient to enable Onconova to practice such Pint Know-How. At Onconova's request and expense, Pint shall cooperate with Onconova (and/or its designees) to provide reasonable assistance to the extent necessary or reasonably useful to allow Onconova to continue to Develop and/or Commercialize Product, either itself or through one or more Third Parties, in the Territory.

**14.1.4 Disposition of Inventory.** Onconova shall have the option, exercisable within thirty (30) days following the effective date of such termination, to purchase any inventory of the Product affected by such termination at the price for which such Product was sold to Pint by Onconova hereunder. Onconova may exercise such option by written notice to Pint during such thirty (30)-day period; provided, however in the event Onconova exercises such right to purchase such inventory, Pint shall grant, and hereby does grant, a royalty-free right and

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license to any housemarks, trademarks, names and logos of Pint contained therein for a period of eighteen (18) months in order to sell such inventory. Upon such exercise, the Parties will establish mutually agreeable payment and delivery terms for the sale of such inventory. If Onconova does not exercise such option during such thirty (30)-day period, or if Onconova provides Pint with written notice of its intention not to exercise such option, then Pint and its Affiliates will be entitled, during the period ending on the last day of the eighteenth (18th) full month following the effective date of such termination, to sell any inventory of Product affected by such termination that remains on hand as of the effective date of the termination, so long as Pint pays to Onconova the royalties and other amounts payable hereunder (including milestones) applicable to said subsequent sales, with respect to sales in the Territory, as applicable, in accordance with the terms and conditions set forth in this Agreement.

**14.1.5 Disposition of Commercialization-Related Materials.** Pint will promptly deliver to Onconova in electronic, sortable form (i) a list identifying all wholesalers and other distributors involved in the Commercialization of the Product in the Territory as well as any customer lists related to the Commercialization of the Product in the Territory and (ii) all promotional materials as well as any items bearing the Product trademark and/or any trademarks or housemarks otherwise associated with the Product or Onconova.

**14.2 Termination by Pint.** Without limiting any other legal or equitable remedies that Pint may have, if this Agreement is terminated by Pint in accordance with Section 13.3 or if this Agreement is terminated by Pint in accordance with Section 13.2 and Onconova is the breaching Party, then all rights and licenses granted by one Party to the other hereunder shall immediately terminate and be of no further force and effect, and Pint shall cease Developing and Commercializing all Products.

**14.3 Pint Alternative to Termination for Onconova Breach.** In any instance in which Pint would have the right to terminate this Agreement pursuant to Section 13.2 for an uncured Onconova breach, Pint in the alternative and at its sole discretion may elect to not terminate this Agreement but instead terminate the license grants to Onconova under Section 2.2, terminate the JSC, and, if Onconova's uncured breach is failure by Onconova to supply Compound or Product pursuant to the Supply Agreement, terminate its obligation under Article 7 to purchase Product exclusively from Onconova.

**14.4 Bankruptcy Code**. If this Agreement is terminated by Pint pursuant to Section 13.3 due to Onconova's bankruptcy, all licenses and rights granted under or pursuant to this Agreement to Pint shall be considered to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the "Code"), licenses of rights to "intellectual property" as defined in the Code. The Parties agree that Pint, as an exclusive licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code.

**14.5 Expiration of the Royalty Term.** On a country-by-country basis, upon the expiration of the Royalty Term for each country within the Territory, the license set forth in Section 2.1 shall become a fully paid-up, perpetual license.

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

effective date of such termination. Such termination will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

**14.7 Survival.** Notwithstanding anything to the contrary contained herein, all provisions, which by their nature would be reasonably expected to survive expiration of termination of this Agreement, shall so survive, including: Articles 1, 8 (but only with respect to payments due related to the Research and Development Payment, sales made or milestones achieved prior to termination, as well as Sections 8.7, 8.10 and 8.11), 11, 12, 14, 15 and 16 and Sections 2.1 (solely to the extent the license set forth therein has become fully paid-up and perpetual pursuant to Section 14.5), 2.2.2, 2.4.2 (solely with respect to the license granted to Onconova pursuant to Section 2.2.2), 4.5, 5.3(a) (solely to the extent the license grant to Pint under Section 2.1 has become fully paid-up and perpetual pursuant to Section 14.5), 5.3(b), and 9.1. Except as set forth in this Article 14 or otherwise expressly set forth herein, upon termination or expiration of this Agreement all other rights and obligations of the Parties shall cease.

## ARTICLE 15
## DISPUTE RESOLUTION

**15.1 Disputes.** The Parties recognize that, from time to time during the Term, disputes may arise as to certain matters which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 15 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement (other than a dispute addressed in Section 3.4).

**15.2 Executive Officers.** With respect to all disputes arising between the Parties and not from the JSC, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within thirty (30) days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Executive Officers of each Party for attempted resolution by good-faith negotiations within thirty (30) days after such notice is received.

**15.3 Venue.** If the Executive Officers are not able to resolve such dispute referred to them under Section 15.2 within such thirty (30)-day period, then the Parties shall have right to pursue any legal or equitable remedy available to it under Law; provided that any litigation arising under this Agreement shall be brought in a state or federal court located in the State of Delaware. Each Party hereby agrees to the exclusive jurisdiction of such forum and waives any objections as to the personal jurisdiction or venue of such forum. Notwithstanding anything herein to the contrary, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights covering the manufacture, use or sale of any Product or of any trademark rights relating to any Product shall be submitted to a court of competent jurisdiction in the Territory in which such patent or trademark rights were granted or arose.

**15.4 Injunctive Relief.** Nothing herein may prevent either Party from seeking a preliminary injunction or temporary restraining order so as to prevent any Confidential Information from being disclosed in violation of this Agreement.

## ARTICLE 16
## MISCELLANEOUS

**16.1 Entire Agreement; Amendment.** This Agreement and the Securities Purchase Agreement, including the Schedules hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidential Disclosure Agreement between the Parties dated March 24, 2017 (which shall remain effective prior to the Effective Date). There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized representative of each Party.

**16.2 Force Majeure.** A Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party makes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of force majeure affecting such Party.

**16.3 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 16.3, and shall be deemed to have been given for all purposes (i) when delivered, if hand-delivered or sent by facsimile on a business day, (ii) on the next business day if sent by a reputable international overnight courier service, or (iii) five (5) business days after mailing, if mailed by first-class certified or registered airmail, postage prepaid, return receipt requested. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below:

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|---|---|
| If to Onconova: | Onconova Therapeutics, Inc.<br>375 Pheasant Run<br>Newton, Pennsylvania 18940<br>Attn: Chief Executive Officer<br>Fax: 267-759-3681 |
| If to Pint: | Pint Pharma GmbH |

Wipplingerstrasse 34 Top 112 — 119
Vienna (Austria)
Attention: CEO
Email: david.munoz@pint-pharma.com
With a copy to: Legal Counsel
Email: legal@pint-pharma.com

**16.4 No Strict Construction; Interpretation.** This Agreement has been prepared jointly and shall not be strictly construed against either Party. 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. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

**16.5 Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that either Party may make such an assignment without the other Party's consent to (i) Affiliates and (ii) a successor to substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.5 shall be null, void and of no legal effect.

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

**16.7 Severability.** If any one or more of the provisions of this Agreement are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, such provision or provisions shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good-faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**16.8 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

**16.9 Independent Contractors.** Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

**16.10 English Language; Governing Law.** This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding,

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the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of Delaware, without giving effect to any choice of law principles that would require the application of the laws of a different country.

**16.11 Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[*Signature Page Follows*]

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**IN WITNESS WHEREOF,** the Parties have executed this Agreement by their duly authorized representatives as of the Effective Date.

| **PINT PHARMA INTERNATIONAL SA** | | **ONCONOVA THERAPEUTICS, INC.** | |
|---|---|---|---|
| By: | /s/ David Munoz | By: | /s/ Ramesh Kumar |
| Name: | David Munoz | Name: | Ramesh Kumar |
| Title: | CEO | Title: | Chief Executive Officer |

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SCHEDULE 1.33

Onconova Patent

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|---|---|---|
| **Composition Of Matter** | **WO2003072062, filed February 28, 2003 (US Provisional 60/360,697, filed February28, 2002)** | **Amino-Substituted (E)-2,6-Dialkoxystyryl 4-substituted-benzylsulfones for Treating Proliferative Disorders (1910)** |
| | Reddy, Reddy & Bell | |

| | | |
|---|---|---|
| **Rigosertib Non-aqueous Formulation** | **Granted in MX (CoM) Expiration Date of February 27, 2023**<br>**US Serial No. 15/688,320, filed April 13, 2017.**<br>**Filed in PCT, US, AR, BO, PY, UY & TW** | **Formulations with Enhanced Stability and Bioavailability for Administration of (E)-2,6-Dialkoxystyryl 4-Substituted Benzylsulfones** |
| | Maniar | |
| | **Pending** | |

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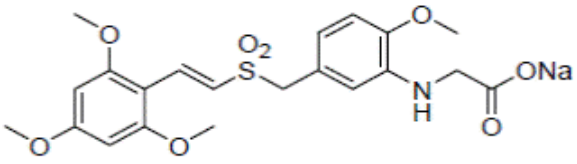
SCHEDULE 1.5




**Rigosertib**

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SCHEDULE 5.3(a)

The following **Required Documents** are to be provided by Onconova to Pint for use by Pint in obtaining Regulatory Approvals, including Marketing Authorizations, for Product.

All Required Documents will be delivered in the then-existing form in Onconova's possession. All modifications that Pint determines is appropriate for obtaining Regulatory Approval, including Marketing Authorization, for Product in each country within the Territory, including translations and modifications for country-specific requirements, shall be Pint's responsibility at Pint's expense.

**1** The **FDA dossier** covering Onconova's New Drug Application as used to obtain Marketing Authorization for Product in the United States (the "**FDA Dossier**"), appropriately certified by Onconova, including any supporting and related materials or correspondence in Onconova's possession, which Pint reasonably determines may be necessary or useful in obtaining any Regulatory Approval for Product in the Territory.

1.1 Pint will cooperate with Onconova to maintain the confidentiality of sensitive sections of the FDA Dossier but Onconova will not withhold from any Regulatory Authority in the Territory any portion of the FDA Dossier, including restricted portions, that Pint determines are required to achieve Marketing Authorization for a Product from such Regulatory Authority. Pint will need to obtain all CMC Data, including but not limited to Confidential Information of Onconova, relating to the composition, formulae, manufacturing or testing methods for the Product as contained in the FDA Approval, or in any certificate of analysis or certificate of manufacture relating to Product.

**2** A "**Certificate of a Pharmaceutical Product — Approved Drug Product**," to be obtained by Onconova from the FDA's Center for Drug Evaluation and Research. A separate Certificate will be required for each country in the Territory. Unless otherwise determined by Pint, such Certificate for Brazil will not be required until requested by Brazil's Regulatory Authority (ANVISA).

**3** **Appropriate evidence of cGMP compliance**, as received by Onconova from the FDA (assuming manufacturing is done in US) or Onconova's manufacturer, and the most recent Establishment Inspection Report, if provided to Onconova by its manufacturer.

**4** **New Pharmaceutical Product (New Drug) Letters**: separate letters from Onconova to the appropriate regulatory official in each country in the Territory as to the studies carried out in respect of Product to ensure safety and to support the intended use of Product, that such studies have been finalized and that any revision to the Risk Management Plan submitted to the FDA and the documents associated with the results obtained by pharmacovigilance programs with respect to Product shall be made available to the country's Regulatory Authority through Pint or its Affiliates or legal representatives.

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**5** **Additional Documents, if Requested**. Any additional documents in Onconova's possession or readily producible by Onconova that Pint reasonably determines are required by any Regulatory Authority in any country in the Territory, (with Onconova having reasonable time, not to exceed 30 days from notice from Pint that such documents are required, to provide such additional documents). Examples might include:

5.1 **Product Cover Letter.** A product cover letter, prepared by the appropriate officer at Onconova for delivery to the requesting Regulatory Authority, providing information available to Onconova and required to register Product in the requesting country (an example of such a letter will be provided to Onconova).

5.2 **Technical Responsibility for the Dossier Letter.** A letter prepared by the appropriate officer at Onconova certifying to the requesting Regulatory Authority that all the technical information in the attached dossier has been reviewed and fulfils the regulatory and quality requirements as stipulated by US FDA**.**

6 **Powers of Attorney** from Onconova to Pint (and its designated Affiliates) authorizing Pint to obtain Marketing Authorization for Product, to register, market and distribute Product and to use the licensed patents and trademarks, directed to each country in the Territory, and each to the extent required by the applicable Regulatory Authority in order for Pint or its designated Affiliate to obtain Marketing Authorization for Product. One Power of Attorney will be required for each country.

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SCHEDULE 5.4

**SAFETY DATA EXCHANGE AGREEMENT**

**Between**

Product Owner (hereinafter "COMPANY ")

**And**

Pint- Pharma Gesellschaft m.b.H, Wipplingerstraße 34 Top 112 A-1010 Vienna, AUSTRIA (hereinafter referred to as "PINT")

This is a safety data exchange agreement by and between COMPANY and PINT on behalf of PINT's affilites due to a framework agreement for Licency and Suppy/Distribution dated DDMMMYYYY COMPANY and PINT may be referred to herein individually as a "Party" or collectively as the "Parties."

**WHEREAS**

COMPANY is the YYY of the PRODUCT and has granted the rights to PINT to authorise and/or and distribute the PRODUCT in XXXXXX, (hereinafter referred to as "The TERRITORIES").

PINT is the MAH and Distribution partner for the product(s) listed in Appendix 1.

This agreement sets out the safety data exchange procedures agreed upon between COMPANY and PINT, in order to guarantee that all safety data concerning the PRODUCT are handled and, reported to the relevant Regulatory Authorities in the TERRITORIES and European Authorities/EMA in accordance with applicable laws and regulations.

It applies in its integrity to all affiliates and/or sub-licensed partners of COMPANY and/or consultancy companies appointed by PINT.

Any amendment or modification to this Agreement will only be made in writing and will only be valid when signed by both parties. The only exceptions to this rule are changes to Appendix 2 (Contact Persons), which shall be valid immediately after a written notification is acknowledged.

Definitions and abbreviations related to this agreement are reported in the glossary (Appendix 4).

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CONTENTS

## 1 RESPONSIBILITIES

Should PINT become aware of any relevant safety-related information regarding the PRODUCT it will promptly forward this information to COMPANY.

Contact details are provided in Appendix 2. Each party shall be responsible for keeping the contact details up-to-date and for the timely notification of any changes to the other party.

## 2 PHARMACOVIGILANCE SYSTEM

COMPANY is responsible for setting up a global system, which ensures that all safety-related information concerning the PRODUCT is properly collected, evaluated and communicated in accordance with applicable laws and regulations duly described.

Further on COMPANY is responsible for having the service of a QPPV who is appointed to the national competent authority by COMPANY or PINT if required by local law and regulations.

In its function as the MAH PINT is responsible for setting up a local system, which ensures that all safety-related information concerning the PRODUCT is properly collected, evaluated and communicated in accordance with applicable local laws and regulations duly described.

Further on PINT if required by local law and regulations is responsible for having the service of local Pharmacovigilance reposible person who is appointed to the national competent authority by PINT if applicable.

## 3 SAFETY-RELATED TERMINOLOGY

Both parties are responsible to use the most current version of the Medicinal Dictionary for Regulatory Activities (MedDRA) in the performance of its obligations under this agreement and to keep MedDRA version updated. New versions should be implemented within two months of release. The number of the MedDRA version used to code report data should be included in all reports.

## 4 PHARMACOVIGILANCE ACTIVITIES

### 4.1 General considerations

PINT will maintain in place a mechanism and, if relevant, appropriate contractual arrangements, to ensure that all suspected adverse drug reactions (ADRs) it receives regarding the PRODUCT in the TERRITORIES, are adequately captured, documented and transmitted to COMPANY as per the procedures described in this agreement.

PINT will adequately document through its internal procedures the collection, investigation, handling, transmission and archiving of suspected ADRs concerning the PRODUCT.

Each party is responsible for keeping current with local regulations in its Territories and with EMA provisions. Each party is responsible for promptly notifying the other party in case of regulatory changes having an impact on the terms of this agreement, or pertaining to the PRODUCT.

### 4.2 Assessment of individual case reports (ICSRs)

PINT will document any medical assessment of a case report received from the reporter and provide it to COMPANY. PINT as the MAH and distribution partner in the TERRITORIES will be responsible for the first assessment of all cases originating in the TERRITORIES, in terms of MedDRA coding, seriousness, relatedness, and expectedness.

COMPANY in its function as the licensor and responsible for the global safety of the product and will supplement all ICSR received by PINT with its own medical assessment.

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Both parties agree that all spontaneous reports notified by healthcare professionals, patients or consumers are considered suspected adverse reactions, even if the relationship is unknown or unstated, unless the reporter specifically states that the events are unrelated or that a causal relationship with the PRODUCT can be excluded.

4.3 Reporting Responsibilities

As MAH PINT in accordance with local applicable laws and regulations, is responsible for the submission of individual case safety reports (ICSRs) and other safety relevant information to the Regulatory Authorities in the TERRITORIES within local legal timelines and will provide COMPANY with proof of submission within 24h after submission.

As the MAH will be responsible for writing and submitting PSURs and safety related information regarding the PRODUCT in the TERRITITORY, COMPANY will provide available PSURS or other required reports and support PINT in satisfying specific local submission requirements.

If required by local laws or regulations, PINT will notify the Regulatory Authority in the TERRITORIES of the arrangements of this agreement at the time of signature or when any change to it has been signed. If so, a copy of the notification to the Regulatory Authority will be provided to COMPANY.

**5 SAFETY DATA EXCHANGE**

5.1 Clinical Studies

This agreement does not include any provisions for the conduct of clinical trials within the scope of European directive 2001/20/EC and Regulation EU No 536/2014.

Should the Parties agree to conduct any clinical studies or otherwise to generate additional clinical data or to perform any analyses of additional clinical data, the terms of this agreement will be supplemented for accordingly.

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5.2 Post-Marketing

**5.2.1** General Considerations

PINT will forward to COMPANY any suspected ADRs concerning the PRODUCT, occurring in the TERRITORIES.

Any exchange of information under this agreement will be performed between the persons identified in Appendix 2.

PINT agrees to respond promptly to requests made by the COMPANY for further information regarding any Adverse Reactions.

**5.2.2** Timelines

*Responsibilities of PINT*

All ADR reports which PINT becomes aware of, associated with the marketed PRODUCT and occurring in the TERRITORIES, will be transmitted to COMPANY within 2 (two) working days but not later than 3 calendar days from Day zero on a CIOMS I form, in English (Appendix 3).

*Responsibilities of COMPANY*

All ADR reports received from PINT will be supplemented with a medical assessment and re-transmitted within 10 calendar days after receipt.

COMPANY in its function as the licensor retains the right to upgrade any non-serious AE to serious.

In summary, the timelines for ADR exchange between the Parties are as follows:

| Report | Timeline | Format | Method of exchange |
|---|---|---|---|
| **From PINT to COMPANY** | | | |
| ADR | 2 working (but not later than 3 calendar days) | CIOMS I in English | e-mail |

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| Report | Timeline | Format | Method of exchange |
|---|---|---|---|
| **From COMPANY to PINT** | | | |

| | | | |
|---|---|---|---|
| ADR | 10 calendar days | CIOMS I in English | e-mail |

COMPANY agrees to provide to PINT the information, reports and details relating to any Adverse Reactions and complaints which COMPANY receives in regard to sales outside the TERRITORIES insofar as they are relevant to PINT (in accordance with the EU directive).

COMPANY agrees to report to PINT within 7 calendar days, about any kind of accumulation of at least 5 unusual (such as “Unexpected adverse event” or “Unlisted adverse event” or) ADRs (including non-serious) or 5 cases of inefficacy that were received by COMPANY following to changes in the Product formulation.

**5.2.3** Case Transmission Compliance Monitoring

PINT will be responsible for the documented monitoring of compliance with regard to timely ICSR transmission to COMPANY. For any non-compliance the relevant reasons should be tracked and PINT should provide COMPANY with the following information:

- Brief description of non-compliance
- Root cause
- Description of corrective/preventive action
- Planned completion date
- Person responsible for CAPA implementation

**5.2.4** Non-Valid cases

All reports of suspected adverse reactions should be validated before reporting them to the Regulatory Authorities to make sure that the minimum criteria for reporting are included in the reports (see Appendix 4). Only valid ICSRs should be reported to Regulatory Authorities/EMA.

Nonetheless, non-valid cases should be sent to COMPANY by PINT within 8 (eight) calendar days for use in on-going safety evaluation activities.

PINT is expected to exercise due diligence in following up the case to collect the missing data elements.

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Receipt of missing minimum information: When missing minimum information has been obtained about a non-valid ICSR, the validated case should be managed as a Follow-up of the initial non-valid case (see 5.2.5).

**5.2.5** Follow-up

PINT will follow-up all reports of suspected ADRs originating in its TERRITORIES missing minimum information (non-valid cases) or important information and/or upon request by the other party, in order to adequately document each case.

On request by COMPANY, PINT will provide COMPANY with all necessary assistance to obtain additional information on ADR reports.

The follow-up information will be managed in accordance with the timelines set forth in 5.2.2.

**5.2.6** Literature searches

COMPANY is responsible for searching for case reports and safety information associated with the PRODUCT in the international scientific literature (PubMED).

PINT is responsible for screening the local literature in the TERRITORIES in order to check for suspected ADRs and safety information useful for the PRODUCT benefit — risk analysis.

PINT will search for suspected ADRs and safety information associated with the PRODUCT in local journals that are not indexed in international databases. If an article containing a suspected ADR is found, relevant safety information from an article has to be reported in English in a CIOMS I form according to the timelines described in 5.2.2.

**5.2.7** Pregnancy and breastfeeding

PINT will ensure that mechanisms are in place, so as to ensure that data relevant to pregnancies and breast feeding are properly collected, investigated and reported.

Reports, whether or not associated with an ADR, where the embryo or foetus may have been exposed to the PRODUCT (either through maternal exposure or transmission of a medicinal product via semen following paternal exposure) should be reported according to the timelines described in 5.2.2.

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Any information of breast-fed infants exposed to the PRODUCT (with or without the occurance of an ADR) will be sent to COMPANY by PINT, according to the timelines described in 5.2.2.

PINT will monitor pregnancy cases, providing COMPANY with follow-up information regarding the Pregnancy outcome. In particular, a follow-up will be requested by PINT within 30 days after the expected date of childbirth. Pregnancy outcome should be forwarded to COMPANY within 2 working days but

not later than 3 calendar days of knowledge. When two cases concern respectively mother and child, the appropriate cross-references should be made in each case.

**5.2.8** Overdose, abuse, misuse, lack of efficacy, off-label use, medication error, occupational exposure

Reports of overdose, abuse, misuse, lack of efficacy, off-label use, medication error and occupational exposure will be reported as follows:

- if associated with an ADR, the report will be exchanged according to the timelines described in 5.2.2
- if not associated with an ADR the report will be exchanged according to the timelines described in 5.2.2

**5.2.9** Reports from non-Health Care Professionals

PINT will send COMPANY reports received from non-health care professionals according to the timelines set forth in 5.2.2 and 5.2.4.

PINT will ensure reasonable attempts to get all reports received from non-Health Care Professionals confirmed by a medically-qualified person.

If a consumer provides medical documentations (e.g. laboratory or other test data) supporting the occurrence of the suspected adverse reaction, or indicating that an identifiable healthcare professional suspects a reasonable possibility of causal relationship between a medicinal product and the reported adverse event, the spontaneous report is considered as confirmed by a healthcare professional.

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**5.2.10** Reports from internet and digital media

PINT should regularly screen internet or digital media under their respective management or responsibility, for potential reports of suspected adverse reactions. Any identified ADR should be exchanged based on the timelines described in 5.2.2. and 5.2.4.

**5.2.11** Reporting via Pharmaceutical Representatives

PINT is responsible for ensuring that pharmaceutical representatives promoting the PRODUCT receive adequate training with regard to the collection and transmission of ADR reports.

Should a pharmaceutical representative become aware of a suspected ADR during a visit, he/she should contact immediately the PV responsible person at PINT with relevant information.

PINT should have a process is place to ensure that the Pharmaceutical Representatives are aware of and have access to the last approved SmPC of the PRODUCT. In case of safety variations with a significant impact on the safety of patients, Pharmaceutical Representatives should be promptly informed in order to communicate information regarding these safety variations to Health Care Professionals during the course of visits, highlighting new safety information as necessary.

**5.2.12** Product Complaints

According to the timelines set forth in 5.2.2 PINT will send to COMPANY suspected adverse reactions associated with:

- any PRODUCT complaint
- a suspected or confirmed falsified medicinal product

**5.2.13** Acknowledgement of receipt

For each exchange of case reports, COMPANY will notify the sending party by email, of the receipt of the email message or fax.

If PINT does not receive an acknowledgement within 2 (two) working days, it must investigate the reason and resend the report or agree further action with the other party.

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**5.2.14** Reconciliation

In the first week of each month, PINT will provide COMPANY with a list of all suspected ADRs associated with the PRODUCT, occurred in the TERRITORIES by email or fax if required.

If no cases associated with the PRODUCT have occurred in the TERRITORIES, PINT will send a notification informing COMPANY that no local cases have been received if required.

**5.2.15** Medical Enquiries

Medical enquiries received by PINT should be evaluated for whether they contain any ADRs and, if so, the suspected ADRs should be transmitted to COMPANY in accordance with the format and the time lines set forth in 5.2.2.

For medical enquiries from the TERRITORIES which cannot be handled locally, it will be the responsibility of COMPANY in providing the answers.

The response will be provided by COMPANY to PINT as soon as possible, depending on the complexity of the answer. PINT will then be responsible for forwarding such an answer to the inquirer.

**5.2.16** Claims for compensation/Civil actions

Claims for compensation/Civil actions received by PINT should be evaluated for whether they contain any ADRs and, if so, the suspected ADRs should be reported to COMPANY in accordance with the format and the timelines set forth in 5.2.2.

5.3 Aggregate Reports

PINT will support COMPANY by providing the relevant information for the preparation of PSURs and other pharmacovigilance documentation. COMPANY will prepare the Periodic Safety Update Reports (PSURs) for the PRODUCT, according to the relevant periodicity. For PRODUCT Renewals, COMPANY will prepare the "Addendum to the Clinical overview".

After DLP and upon request by COMPANY, PINT will provide COMPANY with all the information needed to complete the concerned reports (sales data, last updated SmPC and any relevant Regulatory information associated with the PRODUCT) for the PRODUCT in the TERRITORIES

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during a specified period, in time for preparation and submission to Regulatory Authorities, but no later than 20 calendar days from the DLP or from COMPANY's request, whichever is earlier.

Upon a specific request issued by the Regulatory Authorities in the TERRITORIES for the preparation of additional reports, PINT will forward the request to COMPANY as soon as possible, but no later than 5 (five) calendar days from notification.

COMPANY will prepare and provide the requested documentation assumed that the deadline for the response is acceptable. Timeframes should be agreed in writing between the Parties.

PINT, in accordance with local applicable laws and regulations, is responsible for the submission of Periodic Safety Update Reports/MA Renewals and additional reports on the PRODUCT in the TERRITORIES and provide to COMPANY the proof of submission within 24h after submission.

5.4 Signal detection

COMPANY will be responsible for the global signal detection and risk/benefit assessment for the PRODUCT by reviewing the worldwide safety information of the PRODUCT obtained from any source and by analysing the impact of a detected potential safety signal on the established safety profile of the PRODUCT. COMPANY agrees to report to PINT within 7 calendar days, about any kind of safety signal, this specifically includes but not limited to any deviation of the ADRs frequency of the product (comparing the frequency of the specific ADR as it is mentioned in the company SPC to the actual accumulation of the ADR frequency as it is recorded in the company safety data base).

5.5 Risk Management Plan

COMPANY is responsible for the preparation and updating (routine and safety-related updates) of the Risk Management Plan for the PRODUCT, if required.

After DLP and upon request by COMPANY, PINT will provide COMPANY with all the information needed to complete the report for the PRODUCT in the TERRITORIES during a specified period, in time for its preparation and submission to Regulatory Authorities, not later than 15 (fifteen) calendar days from COMPANY's request.

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5.6 Regulatory Authority Actions

Each party will promptly inform the other party of any proposed/requested action issued by Regulatory Authorities that might affect the risk/benefit balance of the PRODUCT, within 2 (two) working days of receipt of such information.

Particularly, but not only, with regard to:

- marketing authorisation withdrawal or suspension for safety reasons
- failure to obtain marketing authorisation renewal
- clinical trial suspension/withdrawal for safety reasons
- dosage/formulation modification for safety reasons
- changes in target population or indications for safety reasons
- changes to the safety section of the SmPC or local labelling

COMPANY agrees to report to PINT within 7 calendar days, about any safety (present or potential) prohibitions, restrictions or warnings that were set or published by any of "Recognized Health Authorities" regarding the Product, its marketing or its usage specifications.

COMPANY agrees to report to PINT within 7 calendar days, about any ADR related announcements or publication made by COMPANY or by Health Authority that was made within the borders of "Recognized Health Authorities" and was addressed to the medical staff or to the general public regarding the Product, its marketing or its usage specifications.

COMPANY agrees to report to PINT about any change in the formulation of the Product, including formulation change of type II, and formulation change not of type II. Within this report COMPANY also agrees to provide information regarding the nature of the formulation change and any possible safety consequences that this change may have on the target population of the Product. This section will not be construed as modifying the provisions of the Main agreement with regard to formulation changes.

5.7 Regulatory Authority Enquiries

PINT will immediately inform COMPANY of any enquiries received from the Regulatory Authority in the TERRITORIES within 2 (two) working days. COMPANY will assist PINT ,

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if necessary, in preparing the answer and PINT will forward this information to its Regulatory Authority within the required deadline and will provide COMPANY with proof of submission.

5.8 SmPC changes related to safety information

- *Initiated by COMPANY or by any regulatory authority outside the TERRITORIES*

COMPANY will notify PINT of any changes to the Summary of Product Characteristics (SmPC) initiated by COMPANY or by any regulatory authority outside the TERRITORIES.

PINT will implement the SmPC change in the TERRITORIES.

- *Requested by Regulatory Authority in PINT 's TERRITORIES*

PINT will notify COMPANY within one (1) calendar week of any regulatory requirement in the TERRITORIES resulting in a change of the SmPC of the PRODUCT.

Upon request by PINT,COMPANY will provide its support in implementing the Regulatory Authority's request and/or in initiating other actions as identified by PINT

**6 CONTRACTS with Third Parties**

PINT will notify COMPANY of any new or updated PV contracts with third parties.

**7 RECORD MANAGEMENT**

7.1 Record Keeping

Each party will collect, prepare and maintain complete, updated, accurate, organised and legible documentation in a manner acceptable for submission to or review by Regulatory Authorities and in full compliance with this agreement. Applicable data protection laws will be followed by each party.

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7.2 Record Retention

PINT will retain original safety documentation for the time of the life cycle of the drug and additionally ten years.

The whole documentation will be retained in a secure area reasonably protected from fire, theft and accidental destruction.

PINT will make the whole documentation available upon request to COMPANY for review, copying and audit/inspection at all times provided reasonably advanced notice is given.

**8 QUALITY SYSTEM**

8.1 Pharmacovigilance Audits

PINT will permit COMPANY and its QPPV or an independent auditor appointed by COMPANY to have access to its records. Audits will be announced at least two months in advance and will be conducted during ordinary business hours. The independent auditor will set up an appropriate confidentiality agreement with PINT.

PINT will keep accurate records with sufficient detail to enable COMPANY its designee to monitor compliance with this agreement.

8.2 Training

PINT will be responsible that all individuals involved in the performance of pharmacovigilance activities concerning the PRODUCT are properly trained with regard to pharmacovigilance tasks, and on the procedures covered by this agreement, to ensure that provisions of this agreement are met.

Adequate training should also be considered for those staff members to whom no specific pharmacovigilance tasks and responsibilities have been assigned but whose activities may have an impact on the pharmacovigilance system or the conduct of pharmacovigilance activities.

There should be a process in place within PINT to document training activities (training plan, records and materials), to verify that training results in the appropriate levels of understanding and conduct of pharmacovigilance activities for the assigned tasks and responsibilities and to identify unmet training needs.

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8.3 SOPs

Both parties will ensure to have Procedures System in place covering all the Pharmacovigilance processes covered in this agreement.

8.4 Archiving

Each party will ensure that Pharmacovigilance related documentation (electronic and/or hardcopy versions) is maintained and protected from conditions that could cause its accidental damage and loss. A process should be in place to ensure the appropriate archiving, maintenance, retention, retrieval of documents, whether in paper or electronic format.

**9 INSPECTIONS BY REGULATORY AUTHORITIES**

PINT will notify COMPANY within 2 (two) working days of any announced pharmacovigilance inspection of its facilities by the Regulatory Authority.

COMPANY will provide PINT with all reasonable co-operation in the conduct of Regulatory Authority's inspections.

PINT shall inform COMPANY in writing of any findings by Regulatory Authorities (including all deficiencies of the pharmacovigilance system) that may impact upon the reliability, completeness or reporting of the safety information that they are obliged to exchange under the terms of this agreement.

Both COMPANY and PINT agree to take remedial actions in a timely manner to correct any deviations or omissions that are under their own responsibilities, which have been identified by the Regulatory Authority.

COMPANY will cooperate in good faith to address any shortcomings so as to ensure that PINT can fulfil its own pharmacovigilance obligations and requirements under the terms of this agreement.

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**10 CHANGES IN THE REGULATORY ENVIRONMENT**

In case of any changes in the regulatory environment insofar as they relate to Pharmacovigilance obligations (for example any changes in the regulatory status of the PRODUCT, any additional Pharmacovigilance obligations regarding the PRODUCT in the TERRITORIES, etc.) COMPANY and PINT will agree in good faith and in a timely manner on any required modifications to this agreement, so as to enable COMPANY and/or PINT to comply with all applicable Pharmacovigilance obligations regarding the PRODUCT.

**11 DATA PRIVACY**

Both COMPANY and PINT will at all times abide by the applicable laws and regulations aimed at protecting the information related to private individuals (Privacy Laws) and will take all steps necessary and perform all obligations as required by applicable Privacy Laws.

**12 CONFIDENTIALITY**

PINT acknowledges that any information supplied to it by COMPANY under this agreement concerning COMPANY and/or COMPANY's business partners and/or the PRODUCT is confidential. PINT undertakes to keep secret any such confidential information until such information enters the public domain through no fault of PINT. PINT will not, without COMPANY's prior written consent, disclose confidential information to any third party (other than to extent reasonably necessary to obtain and/or maintain the Marketing Authorisation of the PRODUCT), nor use confidential information for any purpose other than the fulfilment of its obligations under the terms of this agreement.

PINT will take all steps necessary to prevent any of the confidential information disclosed hereunder becoming known to unauthorised third parties and in particular (but without limitation) will ensure that each of its employees to whom any such information is disclosed is made aware prior to such disclosure of the restrictions herein contained and that such employees observe such restrictions.

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**13 BREACH**

Upon receipt of a notice of a breach of any provision of this present agreement, the defaulting party agreement will immediately take all appropriate measure to ensure the non-recurrence thereof, without prejudice to any of the non-defaulting parties under the relevant agreement.

**14 TERM AND TERMINATION**

This agreement will enter into force on the date of the last signature hereto and will remain valid as long as at least one party is under an obligation to report safety data with regards to the relevant PRODUCT to a relevant Health Authority or any change is requested by one of the parties.

**15 ENTIRE AGREEMENT**

This agreement, the annexes and any other documents and agreements referred to herein, set forth the entire agreement of the parties with reference to the safety data exchange procedures, and supersede any prior oral or written agreement between the parties hereto referred to the mentioned issue.

## 16 GOVERNING LAW /JURISDICTION

This agreement will be ruled and interpreted according to the laws of all disputes arising out of or in connection with this agreement, if not amicably settled, will be submitted to the Courts of Vienna.

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## 17 SIGNATURE PAGE

**COMPANY**

Name:

Signature:
Place: Date:

Name:
Title:
Signature:
Place: Date:

**PINT**

Name: Dr. Stefan Zohmann
Title: Qualified Person for Pharmacovigilance

Signature:
Place: Vienna Date:

Name: Dr. Erich Travniczek
Title: Industrial Manager

Signature:
Place: Vienna Date:

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## APPENDIX 1

### PRODUCTS COVERED BY THIS SDEA

**The following PRODUCTS and TERRITORIES are subject to this pharmacovigilance agreement**

| COMPANY function | Local XXXX MAH/Licensee | Active ingredient | Product | Territories |
|---|---|---|---|---|
| Licensor | | | | |

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## APPENDIX 2

### CONTACT PERSONS

| COMPANY | XXXX |
|---|---|
| QPPV<br>Dr. Stefan Zohmann<br>DREHM Pharma GmbH<br>Hietzinger Hauptstrasse 37/2<br>1130 Wien, Austria<br>Phone: +43 1 879 52 45 12<br>Fax: +43 1 879 52 45 3<br>Mobile: +43 650 879 6 879<br>Mobile (24h): +43 650 711 50 97<br>E-Mail: zohmann@drehm.at | |
| 1st Deputy QPPV<br>Dr. Alexandra Slawik<br>DREHM Pharma GmbH<br>Hietzinger Hauptstrasse 37/2<br>1130 Wien, Austria<br>Phone: +43 1 879 52 45 18 | |

Fax: +43 1 879 52 45 3
Mobile: +43 699 132 89 898
E-Mail: slawik@drehm.at

2nd Deputy QPPV —
Dr. Tina Kreiner
DREHM Pharma GmbH
Hietzinger Hauptstrasse 37/2
1130 Wien, Austria
Phone: +43 1 879 52 45 29
Fax: +43 1 879 52 45 3
Mobile: +43 664 52 168 72
E-Mail: kreiner@drehm.at

**Contact details for safety information exchanges:**
pv@drehm.at
pv@pint-pharma.com

Each party shall notify the other party in writing of any changes in its safety contacts.

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**APPENDIX 3**

CIOMS FORM

| SUSPECT ADVERSE REACTION REPORT | |
|---|---|

## I. REACTION INFORMATION

| 1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH Day | Month | Year | 2a. AGE Years | 3. SEX | 4-6 REACTION ONSET Day | Month | Year | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | ☐ PATIENT DIED<br>☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION<br>☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY<br>☐ LIFE THREATENING |
| 7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) | | | | | | | | | | |

## II. SUSPECT DRUG(S) INFORMATION

| 14. SUSPECT DRUG(S) (include generic name) | | 20 DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA |
|---|---|---|
| 15. DAILY DOSE(S) | 16. ROUTE(S) OF ADMINISTRATION | 21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA |
| 17. INDICATION(S) FOR USE | | |
| 18. THERAPY DATES (from/to) | 19. THERAPY DURATION | |

## III. CONCOMITANT DRUG(S) AND HISTORY

| 22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) |
|---|
| 23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.) |

## IV. MANUFACTURER INFORMATION

| 24a. NAME AND ADDRESS OF MANUFACTURER | |
|---|---|
| | 24b. MFR CONTROL NO. |
| 24c. DATE RECEIVED BY MANUFACTURER | 24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL |
| DATE OF THIS REPORT | 25a. REPORT TYPE ☐ INITIAL ☐ FOLLOWUP |

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**APPENDIX 4**

**GLOSSARY**

*DEFINITIONS*

The definitions and standards listed below (in accordance with Guideline on good pharmacovigilance practices, GVP Annex I) should be used to ensure compliance with regulatory reporting requirements and in communications between the parties:

In particular, for a more immediate reference to the items of this agreement the most relevant are reported hereinafter.

· **Abuse of a medicinal product**

Persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects [DIR 2001/83/EC Art 1(16)].

- **Adverse event (AE); synonym: Adverse experience**

  Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment [Dir 2001/20/EC Art 2(m)].

  An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

- **Adverse reaction; synonyms: Adverse drug reaction (ADR), Suspected adverse (drug) reaction, Adverse effect, Undesirable effect**

  An adverse reaction is a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility.

  This includes adverse reactions which arise from:

  - the use of a medicinal product within the terms of the marketing authorisation;
  - the use outside the terms of the marketing authorisation, including overdose, off-label use, misuse, abuse and medication errors;

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  - occupational exposure.

- **Causality**

  The definition of an adverse reaction implies at least a reasonable possibility of a causal relationship between a suspected medicinal product and an adverse event. An adverse reaction, in contrast to an adverse event, is characterised by the fact that a causal relationship between a medicinal product and an occurrence is suspected. For regulatory reporting purposes, if an event is spontaneously reported, even if the relationship is unknown or unstated, it meets the definition of an adverse reaction. Therefore all spontaneous reports notified by healthcare professionals, patients or consumers are considered suspected adverse reactions, since they convey the suspicions of the primary sources, unless the reporters specifically state that they believe the events to be unrelated or that a causal relationship can be excluded.

- **CIOMS form:** The internationally recognized standard form to exchange case report information as established by the Council for International Organizations of Medical Sciences.

- **Day:** In this agreement the expression “day” has to be intended as “calendar day”, not business day, unless otherwise specified.

- **Day 0 (Day zero):** The clock for the reporting of a valid ICSR starts as soon as the information containing the minimum reporting criteria has been brought to the attention of the national or regional pharmacovigilance centre of a competent authority or of any personnel of the marketing authorisation holder, including medical representatives and contractors. This date should be considered as day zero. In practice this is the first business day the receiver becomes aware of the information. For ICSRs described in the scientific and medical literature, the clock starts (day zero) with awareness of a publication containing the minimum information for reporting. When additional significant information is received for a previously reported case, the reporting time clock starts again for the submission of a follow-up report from the date of receipt of the relevant follow-up information.

- **Falsified Medicinal Products**

  Any medicinal product with a false representation of:

  a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

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  b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

  c) its history, including the records and documents relating to the distribution channels used.

  This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.

- **Healthcare Professional (see also non- Healthcare Professional)**

  a healthcare professional is defined as a medically-qualified person such as a physician, dentist, pharmacist, nurse, coroner or as otherwise specified by local regulations

- **Individual case safety report (ICSR); synonym: Adverse (drug) reaction report**

  Format and content for the reporting of one or several suspected adverse reactions to a medicinal product that occur in a single patient at a specific point of time.

- **Marketing Authorisation**: An authorization granted by the relevant regulatory authorities allowing the marketing of the PRODUCT in the TERRITORIES.

- **Medicinal product**

A medicinal product is characterised by any substance or combination of substances,

- presented as having properties for treating or preventing disease in human beings; or
- which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis [DIR Art 1].

- **Medically Qualified Person (see Healthcare Professional)**

- **Medication error**

Medication error refers to any unintentional error in the prescribing, dispensing, or

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administration of a medicinal product while in the control of the healthcare professional,

patient or consumer.

- **Minimum Criteria for reporting**

- One or more identifiable reporter (primary source), characterised by qualification (e.g. physician, pharmacist, other healthcare professional, lawyer, consumer or other non-healthcare professional) name, initials or address. All parties providing case information or approached for case information should be identifiable, not only the initial reporter.
- One single identifiable patient characterised by initials, patient identification number, date of birth, age, age group or gender. The information should be as complete as possible.
- One or more suspected substance/medicinal product
- One or more suspected adverse reaction.

- **Misuse of a medicinal product**

Situations where the medicinal product is intentionally and inappropriately used not in accordance with the authorised product information.

- **Non-Healthcare Professional (see also Healthcare Professional)**

A consumer is defined as a person who is not a healthcare professional such as a patient, lawyer, friend, relative of a patient or carer.

Medical documentations (e.g. laboratory or other test data) provided by a consumer that support the occurrence of the suspected adverse reaction, or which indicate that an identifiable healthcare professional suspects a reasonable possibility of causal relationship between a medicinal product and the reported adverse event, are sufficient to consider the spontaneous report as confirmed by a healthcare professional.

- **Occupational exposure to a medicinal product**

For the purpose of reporting cases of suspected adverse reactions, an exposure to a medicinal product as a result of one's professional or non-professional occupation.

- **Off-label use**

Situations where a medicinal product is intentionally used for a medical purpose not in accordance with the authorised product information.

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- **Overdose**

Administration of a quantity of a medicinal product given per administration or cumulatively which is above the maximum recommended dose according to the authorised product information. Clinical judgement should always be applied.

- **Primary source**

The primary source of the information on a suspected adverse reaction(s) is the person who reports the facts. Several primary sources, such as healthcare professionals and/or a consumer, may provide information on the same case. In this situation, all the primary sources' details, including the qualifications, should be provided in the case report, with the "Primary source(s)" section repeated as necessary.

- **Periodic safety update report (PSUR)**

Format and content for providing an evaluation of the risk-benefit balance of a medicinal product for submission by the marketing authorisation holder at defined time points during the post-authorisation phase.

- **Pregnancy Report**:

A report of pregnancy in a patient or trial subject to whom a Medicinal Product has been administered or a report of a pregnancy where the father is a patient or a trial subject to whom a Medicinal Product has been administered.

· **Product:**

Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;

· **Product Complaints:**

Any complaints or reports concerning a potential defect or any other quality related issue in the manufacture, release or transportation of one or more batches of the PRODUCT that may represent a safety hazard for the patients to a batch of the PRODUCT.

· **Periodic Safety Update Report (PSUR):**

Reports summarizing available safety data for a Medicinal Product which must be submitted in accordance with applicable laws and regulations.

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· **Qualified Person for Pharmacovigilance**:

The qualified person responsible for pharmacovigilance appointed by a Marketing Authorisation Holder pursuant to European Directive 2001/83 Article 103 (as amended) and/or Regulation 726/2004 Article 23 (as amended) and/or national laws.

· **Regulatory Authorities:**

Bodies in the TERRITORIES or a part of the TERRITORIES, including the EMA and/or the FDA, as applicable, having the power to approve the marketing of pharmaceutical products, regulate and review submitted clinical data and those that conduct inspections. These bodies are sometimes also referred to as competent authorities.

· **Spontaneous report, synonym: Spontaneous notification**

An unsolicited communication by a healthcare professional or consumer to a company, regulatory authority or other organisation that describes one or more adverse reactions in a patient who was given one or more medicinal products and that does not derive from a study or any organised data collection scheme. In this context, an adverse reaction refers to a suspected adverse reaction.

· **Serious adverse reaction**

An adverse reaction which results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.

Life-threatening in this context refers to a reaction in which the patient was at risk of death at the time of the reaction; it does not refer to a reaction that hypothetically might have caused death if more severe.

Medical and scientific judgement should be exercised in deciding whether other situations should be considered serious reactions, such as important medical events that might not be immediately life threatening or result in death or hospitalisation but might jeopardise the patient or might require intervention to prevent one of the other outcomes listed above. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalisation or development of dependency or abuse.

Any suspected transmission via a medicinal product of an infectious agent is also considered a serious adverse reaction.

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· **Signal**

Information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action [IR Art 19(1)].

For the purpose of monitoring data in the EudraVigilance database, only signals related to an adverse reaction shall be considered [IR Art 19(1)].

· **Unexpected adverse reaction**

An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics [DIR 2001/83/EC Art 1(13)]4.

This includes class-related reactions which are mentioned in the summary of product characteristics (SmPC) but which are not specifically described as occurring with this product. For products authorised nationally, the relevant SmPC is that authorised by the Regulatory Authority in the Member State to whom the reaction is being reported. For centrally authorised products, the relevant SmPC is the SmPC authorised by the European Commission. During the time period between a CHMP opinion in favour of granting a marketing authorisation and the Commission decision granting the marketing authorisation, the relevant SmPC is the SmPC annexed to the CHMP opinion.

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*ABBREVIATIONS*

| | |
|---|---|
| **ADR** | Adverse Drug Reaction |
| **AE** | Adverse Event |
| **CIOMS** | Council for International Organizations of Medical Sciences |
| **DLP** | Data Lock Point |
| **EMA** | European Medicine Agency |
| **ICSR** | Individual Case Safety Report |
| **MAH** | Marketing Authorisation Holder |
| **MedDRA** | Medicinal Dictionary for Regulatory Activities |
| **PSMF** | Pharmacovigilance System Master File |
| **PSUR** | Periodic Safety Update Report |
| **QPPV** | Qualified Person for Pharmacovigilance |
| **SAE** | Serious Adverse Event |
| **SmPC** | Summary of Product Characteristics |

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SCHEDULE 6.5: Approved Subcontractors

LABORATORIOS IMPERIALES, S.A. DE C.V.

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SCHEDULE 12.5: Agreed Press Release

**Onconova Therapeutics Announces License Agreement with Pint Pharma to Commercialize Rigosertib for Treatment of Myelodysplastic Syndromes in Latin America**

- Pint Pharma to Make Upfront Investment in Onconova
- Onconova also Eligible to Receive up to $42.75 Million in Regulatory and Sales Milestones

**NEWTOWN, PA, MARCH 5, 2018 —** Onconova Therapeutics, Inc. (NASDAQ: ONTX), a Phase 3-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, with a primary focus on myelodysplastic syndromes (MDS), today announced that they have entered into a license agreement with Pint Pharma to commercialize rigosertib, a novel targeted anti-cancer compound currently in a Phase 3 study for the treatment of MDS, a group of rare hematologic malignancies. Pint Pharma is a European-based pharmaceutical company focused on the development, registration and commercialization of specialty-based treatments for the Latin American market.

Under the terms of the agreement, Onconova has granted to Pint Pharma an exclusive license to commercialize rigosertib in Latin America. In exchange for these rights, Pint will make investment totaling up to $2.5 million by purchasing shares at a premium to market. In addition, Pint Pharma will make additional regulatory, development and sales-based milestone payments to Onconova of up to $42.75 million and pay double digit tiered royalties on net sales in Latin America. Onconova will supply the finished product for sale in the licensed territories. Pint Pharma will also support Onconova's clinical trial initiatives in the territory.

"Following the recently announced promising interim analysis of our Phase 3 INSPIRE trial, we remain dedicated to advancing IV rigosertib towards commercialization in order to address the needs of MDS patients who fail hypomethylating agents (HMAs). Since HMAs are used globally, we are seeking regional partnerships to help prepare for the commercialization of rigosertib worldwide. We are delighted to partner with Pint Pharma, which has a wide footprint in South and Central America, and view this license agreement as further validation of the potential of rigosertib for the treatment of MDS. We also look forward to working with the clinicians and experts at Pint Pharma to advance clinical trials for IV and oral rigosertib in important centers in their territory," said Dr. Ramesh Kumar, President and CEO of Onconova Therapeutics, Inc.

"We are excited about the opportunity to provide this therapy to patients in our region; we hope that rigosertib will become a reality in clinical oncological practice and deliver a new option to patients and specialists," said David Munoz, Chief Executive Officer of Pint Pharma. "Rigosertib is highly complementary to our comprehensive hematology oncology portfolio, and will further strengthen our mission to enable the Latin American population with life-altering conditions to live better lives by providing early and efficient access to innovative technologies."

Rigosertib is currently being evaluated in a Phase 3 INSPIRE clinical trial in patients who have failed or relapsed after receiving current therapeutic options, with top-line data expected in 2019. Rigosertib is also being evaluated in an expanded Phase 2 combination study with Azacitidine in MDS patients. Onconova recently signed a research collaboration agreement with the National Cancer Institute to study rigosertib in rare pediatric diseases. Rigosertib has been granted orphan drug designation for MDS in the United States and Europe. Onconova is partnered with SymBio Pharmaceuticals, Tokyo, for commercialization of rigosertib in Japan and Korea.

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**About Pint Pharma**

PINT PHARMA INTERNATIONAL SA is a company registered under Swiss laws, having its registered office at Route de Chenaux 9, 1091 Bourg-en-Levaux, Switzerland, and is devoted to the development, registration, and commercialization of specialty based treatments. Pint Pharma benefits from leaders with extensive experience in the pharmaceutical sector and who are based strategically throughout Latin America and Europe. Pint Pharma has a long track

record of developing strong relationships with global pharmaceutical and healthcare companies. Pint Pharma strives to be the first Pan-Latin American provider of innovative and high value-added treatments within Rare Diseases, Specialty Care, and Oncology.

**About Onconova Therapeutics, Inc.**

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company focused on discovering and developing novel small molecule drug candidates to treat cancer, with a primary focus on Myelodysplastic Syndromes (MDS). Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule agent, which the Company believes blocks cellular signaling by targeting RAS effector pathways. 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. Onconova has three product candidates in the clinical stage and several pre-clinical programs. 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. For more information, please visit http://www.onconova.com.

**About IV Rigosertib**

The intravenous form of rigosertib has been employed in Phase 1, 2, and 3 clinical trials involving more than 800 patients, and is currently being evaluated in a randomized Phase 3 international INSPIRE trial for patients with higher-risk MDS, after failure of hypomethylating agent, or HMA, therapy.

**About INSPIRE**

The **IN**ternational **S**tudy of **P**hase III **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 and derives from the findings of the ONTIME Phase 3 trial. INSPIRE is a multi-center, randomized controlled study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, failed to respond to, or relapsed after previous treatment with an HMA within the first 9 months or 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. Following interim analysis in early 2018, the independent Data Monitoring Committee recommended that the trial continue with an expansion in enrollment to 360 patients based on a pre-planned sample size re-estimation. Patients are randomized at a 2:1 ratio into two treatment arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is

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overall survival. 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 Oral Rigosertib**

The oral form of rigosertib was developed to provide more convenient dosing for use where the duration of treatment may extend to multiple years. This dosage form may also support many combination therapy modalities. To date, 368 patients have been treated with the oral formulation of rigosertib. Initial studies with single-agent oral rigosertib were conducted in hematological malignancies, lower-risk MDS, and solid tumors. Combination therapy of oral rigosertib with azacitidine and chemoradiotherapy has also been explored. Currently, oral rigosertib is being developed as a combination therapy together with azacitidine for patients with higher-risk MDS who require HMA therapy. A Phase 1/2 trial of the combination therapy has been fully enrolled and the preliminary results were presented in 2016. This novel combination is the subject of an issued US patent with earliest expiration in 2028.

**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 Therapeutics, Inc.'s expectations regarding the INSPIRE Trial and the transactions contemplated by the licensing agreement. 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. 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. 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, the need for additional financing and current plans and future needs to scale back operations if adequate financing is not obtained, 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.

**General Contact**

http://www.onconova.com/contact/

**Investor Relations Contact**

Katja Buhrer, Affinity Growth Advisors on behalf of Onconova Therapeutics
Katja.Buhrer@affinitygrowth.com / (212) 661-7004

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**Exhibit 10.2**

**Execution Version**

**SECURITIES PURCHASE AGREEMENT**

**By and Between**

**ONCONOVA THERAPEUTICS, INC.**

**and**

**PINT PHARMA GMBH**

**Dated as of March 2, 2018**

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**ONCONOVA THERAPEUTICS, INC.**

**SECURITIES PURCHASE AGREEMENT**

THIS SECURITIES PURCHASE AGREEMENT (the "**Agreement**") is made and entered into as of March 2, 2018 (the "**Signing Date**"), by and between Onconova Therapeutics, Inc., a Delaware corporation (the "**Company**"), and Pint Pharma GmbH, with its registered office located at Wipplingerstrasse 34, Top 112 - 119, AT-1010 Vienna (the "**Purchaser**").

WHEREAS, the Company and the Purchaser are entering into that certain License, Development and Commercialization Agreement of even date herewith (the "**Collaboration Agreement**");

WHEREAS, the obligations of the Company in the Collaboration Agreement are conditioned upon the execution and delivery of this Agreement, pursuant to which the Purchaser will (i) purchase from the Company a number of shares of the Company's common stock, par value $0.01 per share (the "**Common Stock**"), on the Initial Closing Date (as defined herein), as provided for herein, and (ii) if the Research and Development Event is reached under the Collaboration Agreement, purchase the Research and Development Event Shares for an amount equal to, and in satisfaction of, 50% of the Research and Development Payment (in each case, as defined herein) on the terms and conditions set forth herein; and

WHEREAS, the Purchaser desires to purchase, and the Company desires to sell, in reliance upon the exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended, as promulgated by the United States Securities and Exchange Commission (the "**SEC**") under the Securities Act the Securities Act of 1933, as amended, the shares of Common Stock contemplated herein on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual promises, representations, warranties, and covenants hereinafter set forth and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

**1.** **Definitions**. When used in this Agreement, the following terms shall have the respective meanings specified below:

"**Action**" shall mean any action, cause or action, suit, prosecution, investigation, litigation, arbitration, hearing, order, claim, complaint or other proceeding (whether civil, criminal, administrative, investigative or informal) by or before any Governmental Authority or arbitrator.

"**Affiliate**" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or

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shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. For the purposes of this Agreement, in no event shall the Purchaser or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Purchaser or any of its Affiliates.

"**Applicable Price Per Share**" shall mean the Initial Closing Price Per Share with respect to the Initial Closing and the Research and Development Event Price Per Share with respect to the Subsequent Closing.

"**Board of Directors**" means the board of directors of the Company.

"**Business Day**" shall mean any day except Saturday, Sunday and any day on which banking institutions in New York, New York, generally are closed as a result of federal, state or local holiday.

"**Closing**" shall mean the Initial Closing, Alternative Initial Share Closing and the Subsequent Closing, as applicable.

"**Code**" shall mean the United States Internal Revenue Code of 1986, as amended.

"**Consent**" shall mean any approval, authorization, consent, license, franchise, Order, registration, notification, permit, certification, clearance, waiver or other confirmation of or by a Governmental Authority or other Person.

"**Contract**" shall mean, with respect to any Person, any written or oral agreement, contract, commitment, indenture, note, bond, loan, license, sublicense, lease, sublease, undertaking, statement of work or other arrangement to which such Person is a party or by which any of its properties or assets are subject.

"**Exchange Act**" shall mean the U.S. Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"**Excluded Shares**" has the meaning set forth in Section 2.4(b).

"**Governmental Authority**" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.

**"Health Care Laws"** has the meaning set forth in Section 3.29.

"**Indebtedness**" shall mean, with respect to any Person at any applicable time of determination, without duplication, (a) all liabilities and obligations for borrowed money, (b) all liabilities and obligations evidenced by bonds, debentures, notes or other similar instruments or debt securities, (c) all liabilities and obligations under or in respect of swaps, hedges or similar instruments, (d) all liabilities and obligations in respect of letters of credit and similar instruments,

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(e) all liabilities and obligations (contingent or otherwise) arising from or in respect of (i) deferred compensation arrangements, (ii) pension plans, or (iii) amounts payable as a result of the consummation of the transactions contemplated hereby (regardless of whether any additional event, in addition to the consummation of the transactions contemplated hereby, is required to give rise to such liabilities and obligations), (f) all guaranties in connection with any of the foregoing, and (g) all accrued interest, prepayment premiums, fees, penalties, expenses or other amounts payable in respect of any of the foregoing.

"**Initial Closing**" has the meaning set forth in Section 2.1.

"**Initial Closing Date**" has the meaning set forth in Section 2.1.

"**Initial Closing Price Per Share**" shall mean a price per share of Common Stock equal to 135% of the average of the daily VWAPs for the Common Stock for each of the ten (10) consecutive Trading Days ending on (and including) the Trading Day immediately prior to the Signing Date; provided, however, that to the extent VWAP for the Common Stock is not available for a certain Trading Day (the "VWAP Unavailable Date") during the ten consecutive Trading Days, the VWAP for the Trading Day immediately preceding the VWAP Unavailable Date shall be used as the VWAP for the VWAP Unavailable Date.

"**Initial Closing Shares**" has the meaning set forth in Section 2.1.

"**Knowledge**" shall mean knowledge after reasonable investigation of the directors and officers of the Company, as such term is defined in Exchange Act Rule 16a-1(f).

"**Law**" or "**Laws**" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and ordinances of any Governmental Authority, including Health Care Laws.

"**Leased Real Property**" shall mean all leasehold or subleasehold estates and all other rights to use or occupy any land, buildings, structures, improvements, fixtures or other interest in real property held by the Company pursuant to any Lease.

"**Leases**" shall mean all leases, subleases, licenses, concessions and other Contracts pursuant to which the Company holds any Leased Real Property as tenant, sublease, licensee or concessionaire (including the rights to all security deposits and other amounts and instruments deposited by or on behalf of the Company thereunder) and all material amendments, extensions, renewals, guaranties and other agreements with respect thereto.

"**Liens**" shall mean a lien, charge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

"**Material Adverse Effect**" shall mean any change, event or occurrence (each, an "**Effect**") that, individually or when taken together with all other Effects, is materially adverse to the business, financial condition, assets, liabilities, or results of operations (as disclosed in the most recent Company SEC Documents) of the Company and its Subsidiaries, taken as a whole, or on the performance by the Company of its obligations under the Transaction Agreements.

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"**Material Contract**" shall mean any Contract entered into by the Company that is required to be disclosed as an exhibit to any filing made by the Company pursuant to the Exchange Act.

"**Nasdaq**" shall mean The Nasdaq Stock Market LLC.

"**Order**" shall mean any assessment, award, decision, injunction, judgment, order, ruling, verdict or writ entered, issued, made, or rendered by any court, administrative agency, or other Governmental Authority or by any arbitrator.

"**Permitted Liens**" shall mean (a) mechanics', materialman's, workmens', repairmens', warehousemen's, supplier's, vendor's, carrier's and other similar Liens arising or incurred in the ordinary course of business by operation of Law securing amounts that are not yet due and payable, (b) Liens for Taxes, assessments and other charges of Governmental Authorities not yet due and payable, (c) Liens arising under original purchase price conditional sales

Contracts and equipment leases with third parties, (d) pledges or deposits to secure obligations under workers or unemployment compensation Laws or to secure other statutory obligations, (e) easements, covenants, conditions and restrictions of record affecting title to the Leased Real Property which do not or would not materially impair the use or occupancy of any Leased Real Property in the operation of the business conducted thereon as of the date of this Agreement, and (f) any zoning, or other governmentally established restrictions of encumbrances.

"**Person**" shall mean any individual, partnership, limited liability company, firm, corporation, trust, unincorporated organization, government or any department or agency thereof or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

"**Reduced Shares**" has the meaning set forth in Section 2.4(b).

"**Research and Development Event**" has the meaning ascribed to it in the Collaboration Agreement.

"**Research and Development Payment**" has the meaning ascribed to it in the Collaboration Agreement.

"**Research and Development Event Price Per Share**" shall mean a price per share of Common Stock equal to 125% of the average of the daily VWAPs for the Common Stock for each of the ten (10) consecutive Trading Days ending on (and including) the Trading Day immediately prior the date the Research and Development Event is reached.

**"Research and Development Event Purchase Price**" shall mean an amount of United States dollars equal to 50% of the Research and Development Payment.

"**Research and Development Event Shares**" shall mean a number of shares of Common Stock equal to amount obtained by dividing the Research and Development Event Purchase Price by the Research and Development Event Price Per Share.

"**Shares**" shall mean the Initial Closing Shares, the Alternative Initial Closing Shares and the Research and Development Event Shares.

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"**Securities Act**" shall mean the U.S. Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"**Strategic Lock-Up Period**" has the meaning set forth in Section 5.1.2(d).

"**Subsidiaries"** has the meaning set forth in Section 3.2.

"**Subsequent Closing**" has the meaning set forth in Section 2.4(a).

"**Subsequent Closing Date**" has the meaning set forth in Section 2.4(a).

"**Third Party**" shall mean any Person (other than a Governmental Authority) other than the Purchaser, the Company or any Affiliate of the Purchaser or the Company.

"**Trading Day**" shall mean a day on which the Trading Market is open for trading.

"**Trading Market**" shall mean The Nasdaq Capital Market, or any another exchange or over-the-counter quotation market on which Common Stock is principally listed or quoted on the relevant date.

"**Transaction Agreements**" shall mean this Agreement and the Collaboration Agreement.

"**Transfer Agent**" shall mean Wells Fargo Bank, N.A., or any successor transfer agent of the Company.

"**VWAP**" means, with respect to the Common Stock on any Trading Day, the per share volume-weighted average price as displayed under the heading Bloomberg VWAP on the page applicable to such security (or, if Bloomberg ceases to publish such price, any successor service reasonably chosen by the Company) in respect of the period from the open of trading on the relevant Trading Day until the close of trading on such Trading Day (or, if such volume-weighted average price is unavailable, the market price of one share of such security on such Trading Day determined, using a volume-weighted average method, by a nationally recognized investment banking firm (unaffiliated with the Company) retained for such purpose by the Company).

**2. <u>Closing, Delivery and Payment.</u>**

**2.1 Initial Closing**. Subject to the terms and conditions of the Transaction Agreements, and in reliance on the representations, warranties, covenants and other agreements set forth therein, at the initial closing (the "**Initial Closing**"), the Company hereby agrees to sell to the Purchaser, free and clear of all Liens, and the Purchaser agrees to purchase, a number of shares of Common Stock (the "**Initial Closing Shares**") equal to the lesser of (i) 5% of the Company's total outstanding shares of Common Stock as of the date hereof and (ii) the amount of shares of Common Stock obtained by dividing an aggregate purchase price of One Million Two Hundred Fifty Thousand Dollars ($1,250,000) (the "**Aggregate Purchase Price**") by the Initial Closing Price Per Share. The Initial Closing shall take place remotely via the exchange of documents and signatures at 10:00 a.m., Eastern time, on (i) the later of (A) thirty (30) calendar days from the Signing Date and (B) the date on which the Company files its Certificate of Amendment (the "**Charter Amendment**") to the Company's Tenth Amended and Restated

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Certificate of Incorporation, as amended, to increase the Company's authorized shares of common stock (a form of the Charter Amendment is set forth in Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on February 28, 2018) with the Secretary of State of the State of Delaware, or (ii) at such other date and time as the Company and Purchaser shall mutually agree (which date and time are designated as the "**Initial Closing Date**"). Notwithstanding the foregoing, if the Initial Closing does not occur by May 1, 2018, in lieu of purchasing the Initial Closing Shares at the

Initial Closing Price Per Share, the Purchaser will pay the Company the Alternative Initial Cash Payment (as defined in the Collaboration Agreement) (the "**Alternative Initial Closing**"). Following any Alternative Initial Closing, in the event that the Company, prior to December 31, 2018, has sufficient authorized capital to issue and sell to the Purchaser 816,945 shares of Common Stock, then the Purchaser agrees to purchase, and the Company agrees to sell to the Purchaser, 816,945 shares of Common Stock (the "**Alternative Initial Closing Shares**") for an aggregate purchase price (the "**Alternative Initial Closing Aggregate Purchase Price**") of $925,926 (the "**Alternative Initial Share Closing**"). Purchaser shall make such purchase as soon as reasonably practical following notice from Company of the availability of such shares, with the date of such purchase being known as the "**Alternative Initial Shares Closing Date**."

**2.2 Delivery and Payment**. At the Initial Closing or Alternative Initial Share Closing, subject to the terms and conditions hereof, the Company will instruct the Transfer Agent to deliver to the Purchaser, via book entry to the applicable balance account registered in the name of the Purchaser or certificates in the name of the Purchaser, at the Purchaser's sole election, the Initial Closing Shares or Alternative Initial Closing Shares, against payment of the Aggregate Purchase Price in U.S. dollars by wire transfer of immediately available funds to the order of the Company.

**2.3 Deliveries at Closing**.

**(a) Deliveries by the Company**. At each Closing, the Company shall deliver or cause to be delivered to the Purchaser the following items:

**(i)** a legal opinion of Morgan, Lewis & Bockius LLP, the Company's counsel, dated as of the Initial Closing Date, Alternative Initial Shares Closing Date or Subsequent Closing Date, as applicable, in the form reasonably acceptable to the Purchaser;

**(ii)** (i) a copy of the Company's irrevocable instructions to the Transfer Agent instructing the Transfer Agent to (A) if physical certificates are to be delivered to the Purchaser, deliver, on an expedited basis, one or more stock certificates or (B) if physical certificates are not to be delivered to the Purchaser, make a book-entry record in accordance with the Transfer Agent Instructions, in each case free and clear of all restrictive and other legends (except as expressly provided in Section 5.1 hereof) and evidencing the evidencing the Initial Closing Shares, Alternative Initial Closing Shares or Research and Development Event Shares, as applicable, registered in the name of the Purchaser;

**(iii)** a certificate, dated as of the Initial Closing Date, Alternative Initial Shares Closing Date or Subsequent Closing Date, as applicable, signed by an authorized

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executive officer of the Company, confirming that the conditions to such Closing set forth in Section 6.1 have been satisfied;

**(iv)** a certificate of the Company's Secretary certifying as to (A) the Company's certificate of incorporation and bylaws and (B) the resolutions of the Board of Directors approving this Agreement and the transactions contemplated hereby;

**(v)** evidence of the filing of a Listing of Additional Shares notification to The Nasdaq Stock Market LLC as it relates to the Initial Closing Shares, Alternative Initial Closing Shares or Research and Development Event Shares, as applicable; and

**(vi)** all such other documents, certificates and instruments as the Purchaser may reasonably request in order to give effect to the transactions contemplated hereby and by the other Transaction Agreements.

**(b) Deliveries by the Purchaser**. At each Closing, the Purchaser shall deliver or cause to be delivered to the Company the Aggregate Purchase Price for the Initial Closing Shares, or Alternative Initial Closing Aggregate Purchase Price for the Alternative Initial Closing Shares if applicable, or the Research and Development Event Purchase Price for the applicable Research and Development Event Shares, by wire transfer of immediately available funds to one or more accounts designated by the Company, such designation to be made no later than one (1) Business Days prior to the Closing Date.

**2.4 Research and Development Event Shares; Subsequent Closing**

**(a)** If pursuant to the terms of the Collaboration Agreement, the Research and Development Event is reached, concurrently with and as partial consideration for the Research and Development Payment, the Purchaser agrees to purchase, subject to the terms and conditions of the Transaction Agreements, and in reliance on the representations, warranties, covenants and other agreements hereinafter therein, at a subsequent closing (the "**Subsequent Closing**"), and the Company hereby agrees to sell to the Purchaser, free and clear of all Liens, the Research and Development Event Shares for the Research and Development Event Purchase Price. The Subsequent Closing shall take place remotely via the exchange of documents and signatures at 10:00 a.m., Eastern time, on: (i) the date the Research and Development Payment is made if all of all of the conditions set forth in Section 6 hereof have been satisfied or waived (other than those conditions that by their terms are to be satisfied at the Initial Closing, but subject to the satisfaction or waiver of such conditions); or (ii) at such other date and time as the Company and Purchaser shall mutually agree (which date and time are designated as the "**Subsequent Closing Date**").

**(b)** The parties agree that the aggregate number of shares to be issued by the Company under this Agreement shall not exceed the lesser of (i) 3,787,337 shares of Common Stock and (ii) such number of Shares that would require the Company to obtain prior shareholder approval under The Nasdaq Marketplace Rules (except to the extent that the stockholders of the Company have previously approved any issuance of Shares in excess of that limit). If the purchase of all or any portion of the Shares would cause the number of shares of outstanding Common Stock issued hereunder to exceed 3,787,337 shares of Common Stock or such amount as the Company may not issue without shareholder approval under The Nasdaq

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Marketplace Rules, the number of such Shares so purchased shall be reduced to the lesser of (i) 3,787,337 shares of Common Stock and (ii) such amount as the Company is permitted to issue without shareholder approval under The Nasdaq Marketplace Rules (the number of shares of Common Stock so purchased the "**Reduced Shares**" and the number of shares of Common Stock so reduced the "**Excluded Shares**"). If the number of Shares to be issued under this Agreement is reduced as a result of the provisions of this Section 2.4(b), at the applicable Closing, the Purchaser shall (i) make a cash payment to the

Company in an amount equal to the Excluded Shares multiplied by the Applicable Price Per Share and (ii) purchase the applicable Reduced Shares for a price equal to the Reduced Shares multiplied by the Applicable Price Per Share

**(c)** In addition to the items to be delivered pursuant to Section 2.3(a), as applicable, the Company shall deliver or cause to be delivered at the Subsequent Closing a certificate, signed by an authorized executive officer of the Company, representing and warranting to the Purchaser as to the capitalization of the Company as of the Subsequent Closing Date, consistent with the representation in Section 3.3.

**3. Representations and Warranties of the Company**. The Company hereby represents and warrants to the Purchaser on the date hereof, the Initial Closing Date, the Alternative Shares Closing Date and the Subsequent Closing Date, if applicable, that, except as set forth in the Company SEC Documents (as defined herein), and only to the extent such Company SEC Documents are specifically referenced in such representation or warranty, the following:

**3.1 Organization, Good Standing and Qualification**. The Company is an entity duly incorporated, validly existing and in good standing under the laws of the State of Delaware, with the requisite corporate power and authority to own or lease and use its properties and assets, to execute and deliver the Transaction Agreements, to carry out the provisions of the Transaction Agreements, to issue and sell the Shares and to carry on its business as presently conducted and as proposed to be conducted as described in the Company SEC Documents. Each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing (to the extent such concept exists in the relevant jurisdiction) under the Laws of the jurisdiction of its incorporation or organization, as applicable, and has all requisite power and authority to carry on its business to own and use its properties. Neither the Company nor any of its Subsidiaries is in violation or default in any material respect of any of the provisions of its respective articles of association, charter, certificate of incorporation, bylaws, limited partnership agreement or other organizational or constitutive documents. Each of the Company and its Subsidiaries is duly qualified to do business as a foreign entity and is in good standing (to the extent such concept exists in the relevant jurisdiction) in each jurisdiction in which the conduct of its business or its ownership or leasing of property makes such qualification necessary, except to the extent any failure to so qualify has not had and would not reasonably be expected to have a Material Adverse Effect. The Company does not own or control, directly or indirectly any corporations, partnerships, limited liability partnerships, limited liability companies, associations or other entities.

**3.2 Subsidiaries**. The Company has disclosed all of its subsidiaries required to be disclosed pursuant to Item 601(b)(21) of Regulation S-K in an exhibit to its SEC Documents (the "**Subsidiaries**"). The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding

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shares of capital stock or other equity interests of each Subsidiary are validly issued and are fully paid and, if applicable in the relevant jurisdiction, non-assessable, and free of preemptive and similar rights to subscribe for or purchase securities.

**3.3 Capitalization**.

**(a)** The authorized capital of the Company consists of 25,000,000 shares of Common Stock, 18,946,163 of which are issued and outstanding, and 5,000,000 shares of preferred stock, par value $0.01 per share, none of which are issued and outstanding. (i) Under the Company's 2013 Equity Compensation Plan, as of February 28, 2018, 1,118,849 shares of Common Stock are issuable upon the exercise of outstanding options with a weighted average exercise price of approximately $24.93 per share and (ii) 3,294,771 shares of Common Stock are issuable upon the exercise of outstanding warrants as of February 28, 2018 with a weighted average exercise price of approximately $5.10 per share. (iii) 1,778,406 shares of Common Stock are issuable upon exercise of outstanding prefunded warrants as of February 28, 2018 with a weighted average exercise price of $0.01 per share, and (iv) 10,444,875 shares of Common Stock are issuable upon the exercise of outstanding preferred stock warrants to purchase 1,044,487.5 shares of Series A Convertible Preferred Stock followed by conversion into shares of Common Stock (such conversion are subject to the approval and filing of the Charter Amendment) as of February 28, 2018 with a weighted average exercise price of $10.10 per share of Common Stock.

**(b)** Except as set forth above and in the Company SEC Documents filed prior to the Signing Date, other than the shares of Common Stock reserved for issuance under the Plan, and the shares the Company may also issue to Lincoln Park Capital Fund, LLC ("**Lincoln Park**") pursuant to the purchase agreement the Company and Lincoln Park entered into on October 8, 2015, there are no outstanding options, rights (including conversion or preemptive rights and rights of first refusal), proxy or shareholder agreements, or agreements of any kind for the purchase or acquisition from the Company or any of its Subsidiaries of any of its securities, including the Shares. No Person is entitled to preemptive rights, rights of first refusal, rights of participation or similar rights with respect to any securities of the Company or any of its Subsidiaries, including with respect to the issuance of Shares contemplated hereby. Except as set forth in the Company SEC Documents filed prior to the Signing Date, there are no voting agreements, registration rights agreements or other agreements of any kind among the Company or any of its Subsidiaries and any other Person relating to the securities of the Company or any of its Subsidiaries, including the Shares.

**(c)** All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued and are fully paid and were issued in compliance with all applicable Laws concerning the issuance of securities. The Shares have been duly and validly authorized and, when issued and paid for pursuant to this Agreement, (i) will be validly issued, fully paid and non-assessable, (ii) will not be subject to pre-emptive rights, and (iii) will be free and clear of all Liens.

**(d)** Neither the Company nor any of its Subsidiaries owns or holds the right to acquire any stock, partnership, interest, joint venture interest or other equity ownership interest in any Person.

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**3.4 Authorization; Binding Obligations**. Subject to stockholders' approval of the Charter Amendment and the Company's filing of the Charter Amendment with the Secretary of State of the State of Delaware, all corporate action on the part of the Company, its directors and stockholders necessary for the authorization of the Transaction Agreements, the performance of all obligations of the Company hereunder and thereunder at the Initial Closing, Alternative Initial Closing or the Subsequent Closing and the authorization, sale, issuance and delivery of the Shares pursuant hereto has been taken, including the approval by the board of directors of the Company of a resolution to issue the Shares, a sufficient amount has been reserved from its authorized share capital to provide for the issuance of the Shares, and no action is required on the part of the Company, its board of directors, or its shareholders prior to the Initial Closing for the consummation of the transactions contemplated by the Transaction Agreements. Each of the Transaction Agreements has been duly executed and delivered by the Company and constitutes valid and binding obligations of the Company enforceable in accordance with their terms, except

(a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application affecting enforcement of creditors' rights, (b) general principles of equity that restrict the availability of equitable remedies and (c) to the extent that the enforceability of indemnification provisions may be limited by applicable Laws.

**3.5 Company SEC Documents; Financial Statements; NASDAQ; Indebtedness**.

**(a)** The Company has timely filed and submitted all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein), and any required amendments to any of the foregoing, with the SEC pursuant to the Exchange Act and the Securities Act for the 12 full calendar months preceding the date hereof (collectively, the "**Company SEC Documents**"). As of their respective filing or submission dates, as applicable, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act and Exchange Act applicable to such Company SEC Documents, and no Company SEC Documents when filed, declared effective or mailed, as applicable, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. As of the date hereof, there are no outstanding or unresolved comments in comment letters from the SEC staff with respect to any of the Company SEC Documents and none of the Company SEC Documents is the subject of ongoing SEC review or outstanding investigation. The Company has never been an issuer subject to Rule 144(i) under the Securities Act and none of the Company's Subsidiaries is subject to the periodic reporting requirements of the Exchange Act.

**(b)** The financial statements of the Company included in the Company SEC Documents when filed complied as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto, have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("**U.S. GAAP**"), except as may be otherwise specified in such financial statements or the notes thereto (and except that unaudited financial statements may not contain all footnotes required by U.S. GAAP), and fairly present in all material respects the financial position of the Company as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal,

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year-end audit adjustments. Except (i) as set forth in the Company SEC Documents filed prior to the Signing Date or (ii) for liabilities incurred in the ordinary course of business subsequent to the date of the most recent balance sheet contained in the Company SEC Documents filed prior to the Signing Date, the Company has no liabilities, whether absolute or accrued, contingent or otherwise, other than those that would not, individually or in the aggregate, be material to the Company and its Subsidiaries taken as a whole. Neither the Company nor any of its Subsidiaries has or is subject to any "Off-Balance Sheet Arrangement" (as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated under the Securities Act).

**(c)** The Common Stock is listed on The Nasdaq Capital Market, and the Company has taken no action designed to, or which would reasonably be expected to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from The Nasdaq Capital Market. Other than as disclosed in the Company SEC Documents, neither the Company nor any of its Subsidiaries has received any notification regarding the termination of such listing by the SEC or Nasdaq, and the Company has no Knowledge that the SEC or Nasdaq is contemplating terminating such listing or registration.

**(d)** As of the date hereof, (i) no events have occurred that are required to be disclosed on an item to Form 8-K that have not been so disclosed in a Company SEC Document and (ii) other than as disclosed in the Company SEC Documents filed prior to the Signing Date, the Company does not have any outstanding Indebtedness.

**3.6 Obligations to Related Parties**. Except as disclosed in the Company SEC Documents filed prior to the Signing Date, there are no obligations of the Company to members of the Board of Directors, executives, stockholders, Affiliates, or employees of the Company other than (a) for payment of salary for services rendered, (b) reimbursement for reasonable expenses incurred on behalf of the Company, and (c) for other standard employee benefits made generally available to all employees (including equity award agreements outstanding under any equity incentive plan approved by the Board of Directors). Except as disclosed in the Company SEC Documents filed prior to the Signing Date, none of the members of the Board of Directors, Affiliates, executives, employees or, to the Company's Knowledge, stockholders of the Company or any members of their immediate families, is indebted to the Company or has any direct or indirect ownership interest in any firm or corporation with which the Company is affiliated or with which the Company has a business relationship, or any firm or corporation that competes with the Company, other than passive investments in publicly-traded companies (representing less than three percent (3%) of such company) which may compete with the Company and investments by venture capital funds or similar institutional investors with which members of the Board of Directors may be affiliated. Except as disclosed in the Company SEC Documents, no member of the Board of Directors, executive, Affiliate or, to the Company's Knowledge, stockholder, or any member of their immediate families, is, directly or indirectly, (i) interested in any Material Contract with the Company (other than such contracts as relate to any such person's ownership of Common Stock or other securities of the Company) or (ii) party to a transaction with the Company required to be disclosed in the Company SEC Documents under Item 404 of Regulation S-K that is not so disclosed.

**3.7 Compliance with Other Instruments**. Neither the Company nor any of its Subsidiaries is in violation or default of any term of its articles of association, charter, certificate

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of incorporation, bylaws, limited partnership agreement, or other organizational or constitutive documents, or of any provision of any mortgage, indenture, contract, lease, agreement, instrument or Contract to which it is party or by which it is bound or of any Order, except for such violations or defaults as would not reasonably be expected to have a Material Adverse Effect. The execution, delivery, and performance of and compliance with the Transaction Agreements, and the issuance and sale of the Shares pursuant hereto, will not, with or without the passage of time or giving of notice, (i) conflict with or result in a violation in any material respect of the articles of association, charter, certificate of incorporation, bylaws, limited partnership agreement, or other organizational or constitutive documents of the Company or any of its Subsidiaries, (ii) result in any violation of any Law or Order to which the Company, any of its Subsidiaries or any of their respective assets is subject, (iii) (A) conflict with or result in a breach, violation of, or constitute a default under, (B) give any third party the right to modify, terminate or accelerate, or cause any modification, termination or acceleration of, any obligation under, or (C) require Consent under, any Contract to which the Company or any of its Subsidiaries is a party, or (iv) result in the creation of any Lien upon any of the Company's or any Subsidiary's assets or capital stock, except in the case of any of clauses (ii), (iii) and (iv) above, as would not reasonably be expected to have a Material Adverse Effect. Neither the execution, delivery or performance of any Transaction Agreement by the Company, nor the consummation by it

of the obligations and transactions contemplated hereby and thereby (including the issuance of the Shares) requires any Consent, other than (i) filings required under applicable U.S. federal and state securities Laws and (ii) the notification of the issuance and sale of the Shares to Nasdaq.

**3.8 Litigation**. There is no Action pending or, to the Company's Knowledge, threatened, against the Company or any of its Subsidiaries or which the Company or any of its Subsidiaries intends to initiate. There is no Order in effect against the Company or any of its Subsidiaries. There are no Actions that would be required to be disclosed in the Company SEC Documents under Item 103 of Regulation S-K that are not so disclosed.

**3.9 Compliance with Laws; Permits**. The Company and its Subsidiaries are not, and since January 1, 2015 have not been, in violation in any material respect of any applicable Law (including any Health Care Law) in respect of the conduct of its business or the ownership of its properties. No Consents are required to be filed in connection with the execution and delivery of this Agreement or the issuance of the Shares, except such as have been duly and validly obtained or filed. The Company and each of its Subsidiaries has all franchises, permits, licenses and any similar authority necessary for the conduct of its business as now being conducted by it, except for those the lack of which would reasonably be expected to have a Material Adverse Effect, and the Company believes it can obtain, without undue burden or expense, any similar authority for the conduct of its business as currently planned to be conducted, the lack of which would reasonably be expected to have a Material Adverse Effect.

**3.10 No General Solicitation; Private Placement**. Neither the Company nor any Person acting on the Company's behalf has, directly or indirectly, made any offer or sale of any security or solicitation of any offer to buy any security under circumstances that would (i) eliminate the availability of the exemption from registration under the Securities Act in connection with the offer and sale by the Company of the Shares as contemplated hereby or (ii) cause the offering of the Shares pursuant to the Transaction Agreements to be integrated with prior offerings by the Company for purposes of any applicable law, regulation or stockholder approval provisions,

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including, without limitation, under the rules and regulations of any Trading Market. The sale and issuance of the Shares hereunder does not contravene the rules and regulations of any Trading Market on which Common Stock is listed or quoted. Assuming the accuracy of the representations and warranties of the Investors set forth in Section 4, the offer, sale and issuance of the Shares will be exempt from the registration requirements of the Securities Act, and will have been registered or qualified (or are exempt from registration and qualification) under the registration, permit or qualification requirements of all applicable state securities Laws.

**3.11 Investment Company**. The Company is not, and after giving effect to the transactions contemplated by the Transaction Agreements will not be, an "investment company" or a company "controlled" by an "investment company," within the meaning of the Investment Company Act of 1940, as amended.

**3.12 Sarbanes-Oxley; Internal Accounting Controls**. The Company is in compliance with all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and all applicable rules and regulations promulgated by the SEC thereunder that are effective as of the date hereof. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "**JOBS Act**"), and has taken advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. The Company has taken the exemption from auditor attestation on the effectiveness of its internal controls over financial reporting as permitted under the JOBS Act. The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with U.S. GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company has established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and designed such disclosure controls and procedures to provide reasonable assurance that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

**3.13 Absence of Changes.** Except as set forth in the Company SEC Documents filed prior to the Signing Date, since the date of the latest audited financial statement included in the Company SEC Documents, (a) the Company and each of its Subsidiaries has conducted its business operations in the ordinary course of business consistent with past practice, (b) neither the Company nor any of its Subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company and its Subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its Subsidiaries taken as a whole and (c) there has not occurred any event, change, development, circumstance or condition that, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.

**3.14 Tax Matters**. The Company and its Subsidiaries have filed all United States federal income tax returns that have been required to be filed and has paid all taxes shown

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thereon or otherwise assessed, which are due and payable, except assessments against which appeals have been or will be promptly taken and as to which adequate reserves have been provided. The Company and its Subsidiaries have filed all other material tax returns that are required to have been filed by them pursuant to applicable state, local or foreign law, and has paid all taxes shown thereon or otherwise assessed, which are due and payable, except assessments against which appeals have been or will be promptly taken and as to which adequate reserves have been provided. Neither the Company nor its Subsidiaries have a material tax deficiency that has been or, to the Company's knowledge, might be asserted or threatened against it.

**3.15 Property**. The Company and its Subsidiaries do not own any real property. Except as would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Effect, (a) the Company and each of its Subsidiary has the right to use or occupy the Leased Real Property under valid and binding leases and (b) the Company and each of its Subsidiary has good and valid title to, or a valid license to use or leasehold interest in, all of their respective material tangible assets, free and clear of all Liens (other than Permitted Liens).

**3.16 Employee Benefits Matters**. No "**prohibited transaction**" (as defined in Section 406 of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("**ERISA**"), or Section 4975 of the Code or "accumulated funding deficiency" (as defined in Section 302 of ERISA) or any of the events set forth in Section 4043(b) of ERISA (other than events with respect to which the thirty (30)-day notice requirement under Section 4043 of ERISA has been waived) has occurred or could reasonably be expected to occur

with respect to any employee benefit plan of the Company or any Subsidiary which could, singularly or in the aggregate, have a Material Adverse Effect. Each employee benefit plan of the Company and its Subsidiaries is in compliance in all material respects with applicable law, including ERISA and the Code. Neither the Company and nor any Subsidiary has incurred, nor do the Company or any Subsidiary reasonably be expected to incur, liability under Title IV of ERISA with respect to the termination of, or withdrawal from, any pension plan (as defined in ERISA). Each pension plan for which the Company and any Subsidiary would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified, and nothing has occurred, whether by action or by failure to act, which could, singularly or in the aggregate, cause the loss of such qualification.

**3.17 Labor Matters**. No labor disturbance by the employees of the Company or any Subsidiary exists or, to the Knowledge of the Company, is imminent, and the Company has no Knowledge of any existing or imminent labor disturbance by the employees of any of its or its Subsidiaries' principal suppliers, manufacturers, customers or contractors, that could reasonably be expected, singularly or in the aggregate, to have a Material Adverse Effect. The Company has no Knowledge that any key employee or significant group of employees of the Company or any Subsidiary plans to terminate employment with the Company or any Subsidiary

**3.18 Intellectual Property**. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the Company SEC Documents and which the failure to so have would have a Material Adverse Effect (collectively, the "**Intellectual Property Rights**"). None of, and neither the

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Company nor any Subsidiary has received a notice (written or otherwise) that any of, the patents, trademarks or copyrights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned within seven (7) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included or incorporated in the Company SEC Documents, a written notice of a claim or otherwise has any knowledge that the manufacture, use or sale of any of the Company's existing products, products in development, or services violate, infringe, or will when marketed violate or infringe upon the rights of any Person, except as would not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

**3.19 Environmental Matters**. The Company and its Subsidiaries (a) are in material compliance with any and all applicable federal, state, local and foreign laws, rules, regulations, decisions and orders relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "**Environmental Laws**"), (b) have received and are in compliance with all permits, licenses or other approvals required of it under applicable Environmental Laws to conduct its business, and (c) have not received notice of any actual or potential liability for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants regulated under any Environmental Laws, except in each case as would not, singularly or in the aggregate, have a Material Adverse Effect.

**3.20 Brokers and Finders**. Except as disclosed in Schedule 3.20, no Person will have, as a result of the transactions contemplated by the Transaction Agreements, any right, interest or claim against or upon the Company for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Company. The Company agrees to indemnify the Purchaser for any claims, losses or expenses incurred by the Purchaser as a result of the representation in this Section 3.20 being untrue.

**3.21 Insurance**. Each of the Company and each Subsidiary carries, or is covered by, insurance provided by recognized, financially sound and reputable institutions with policies in such amounts and covering such risks as is adequate, in the judgment of management, for the conduct of its business. The Company has no reason to believe that it or any Subsidiary will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not result in a Material Adverse Effect.

**3.22 Contracts**. Except as would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect, the Company is not in violation, default or breach under any of its Material Contracts. All Material Contracts have been filed with the Company SEC Documents.

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**3.23 Application of Takeover Protections**. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation or the Laws of the State of Delaware that is or could become applicable to the Purchaser as a result of the Purchaser and the Company fulfilling their obligations or exercising their rights under this Agreement, including without limitation as a result of the Company's issuance of the Shares and the Purchaser's ownership of the Shares.

**3.24 Anti-Corruption and Anti-Bribery Laws**. Neither the Company, nor, any of its officers, directors or employees, nor to the Company's Knowledge its agents, representatives, consultants, or other persons associated with or acting for or on behalf of the Company, has, directly or indirectly, in connection with the operation of their business: (a) made, offered or promised to make or offer any payment, loan or transfer of anything of value, including any reward, advantage or benefit of any kind, to or for the benefit of any government official, candidate for public office, political party or political campaign, for the purpose of (i) influencing any act or decision of such government official, candidate, party or campaign, (ii) inducing such government official, candidate, party or campaign to do or omit to do any act in violation of a lawful duty, (iii) obtaining or retaining business for or with any person, (iv) expediting or securing the performance of official acts of a routine nature, or (v) otherwise securing any improper advantage, in each case, in violation of any applicable anticorruption or anti-bribery Law, (b) paid, offered or promised to pay or offer any bribe, payoff, influence payment, kickback, unlawful rebate, or other similar unlawful payment of any nature, (c) made, offered or promised to make or offer any unlawful contributions, gifts, entertainment or other unlawful expenditures, (d) established or maintained any unlawful fund of corporate monies or other properties, (e) created or caused the creation of any false or inaccurate books and records of the Company related to any of the foregoing, or (f) otherwise violated any provision of the Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-l, et seq., or any other applicable anti-corruption or anti-bribery Law. For purposes of this provision, "government official" includes any officer or employee of a government or any department, agency or instrumentality thereof (including wholly or partially owned enterprises or institutions), or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency or instrumentality, or for or on behalf of any such public international organization.

**3.25 Economic Sanctions**. None of the Company or its directors, officers, employees or to the Company's Knowledge its agents (i) is a person with whom transactions are prohibited or limited under any applicable economic sanctions Laws or (ii) within the last five (5) years has done business in or with any Person that is the target of sanctions administered or enforced by the United States, including by the Office of Foreign Assets Control of the U.S. Treasury Department, the United Nations Security Council, the European Union, Her Majesty's Treasury or any other relevant sanctions authority. Within the past five (5) years, the Company has not made any voluntary disclosures to applicable Governmental Authorities under applicable economic sanctions Laws or applicable export control Laws and, to the Knowledge of the Company, the Company has not been the subject of any governmental investigation or inquiry regarding the compliance of the Company with such Laws, nor has the Company been assessed any fine or penalty in regard to compliance with such Laws. The Company will not directly or indirectly use the proceeds of the offering of the Shares contemplated hereby, or lend, contribute

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or otherwise make available such proceeds to any Subsidiary, joint venture partner or other person or entity for the purpose of financing the activities of any person currently subject to any sanctions administered or enforced by such authorities.

**3.26 Accountants**. The Company's independent registered public accounting firm is Ernst & Young LLP. To the Company's Knowledge, such accounting firm is a registered public accounting firm as required by the Exchange Act.

**3.27 Money Laundering**. The operations of the Company are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "**Money Laundering Laws**"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the Company's Knowledge, threatened.

**3.28 FDA.** The preclinical and clinical studies conducted by or, to the Company's knowledge, on behalf of the Company that are described in, or the results of which are referred to in, the Company's SEC Documents were and, if still pending, are being conducted in all material respects in accordance with applicable local, state and federal laws, rules and regulations, including, but not limited to, the Federal Food, Drug and Cosmetic Act and its applicable implementing regulations; each description of the results of such studies contained in the Company's SEC Documents is accurate in all material respects and fairly presents the data derived from such studies, and the Company is not aware of any other studies the results of which the Company believes reasonably call into question the study results described or referred to in the Company's SEC Documents; and except as disclosed in the Company's SEC Documents, neither the Company nor any Subsidiary has received any written notices or other written correspondence from the Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency having jurisdiction over the Company or any of its properties (collectively, the "**Regulatory Agencies**") requiring the termination, suspension or material adverse modification of any clinical trials that are described or referred to in the Company's SEC Documents; and the Company and the Subsidiaries have each operated and currently are in compliance with all applicable rules and regulations of the Regulatory Agencies except where the failure to be in compliance would not be expected reasonably to have a Material Adverse Effect.

**3.29 Health Care Laws**. The Company and the Subsidiaries are, and since January 1, 2013 have been, in compliance with all applicable Health Care Laws except where failure to be in compliance would not be expected reasonably to have a Material Adverse Effect. For purposes of this Agreement, "Health Care Laws" means: (i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), and the regulations promulgated thereunder; (ii) all applicable federal, state, local and foreign health care related fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the U.S. Civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the Federal False Statements Law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. §§ 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"), the Civil Monetary Penalties

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Law (42 U.S.C. § 1320a-7a), the exclusion laws (42 U.S.C. § 1320a-7), the Medicare statute (Title XVIII of the Social Security Act), and the Medicaid statute (Title XIX of the Social Security Act) and the regulations promulgated pursuant to such statutes; (iii) HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), and the regulations promulgated thereunder; (iv) the U.S. Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), and the regulations promulgated thereunder; and (v) any and all other applicable health care laws and regulation applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, advertising, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product under development by the Company. Neither the Company nor the Subsidiaries has received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority alleging that any product operation or activity is in material violation of any Health Care Laws, and, to the Company's knowledge, no such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action is threatened. Neither the Company nor the Subsidiaries is a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority. Additionally, none of the Company or its Subsidiaries or any of their respective officers or directors or, to the Company's knowledge, any of their respective employees has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion. The Company and the Subsidiaries have filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by the Health Care Laws, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission), except in each case, as would not reasonably be expected to have a Material Adverse Effect.

**4. <u>Representations and Warranties of the Purchaser</u>**. The Purchaser hereby represents and warrants to the Company as follows:

**4.1 Organization; Good Standing**. The Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization. The Purchaser has all requisite power and authority to enter into the Transaction Agreements, to purchase the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements.

**4.2 Requisite Power and Authority**. The Purchaser has all necessary power and authority to execute and deliver the Transaction Agreements and to carry out their provisions. All action on the Purchaser's part required for the lawful execution and delivery of the Transaction Agreements has been taken. Upon their execution and delivery, the Transaction Agreements will be valid and binding obligations of the Purchaser, enforceable in accordance with their terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application affecting enforcement of creditors' rights, (b) as limited by general principles of equity that restrict the availability of equitable remedies, and (c) to the extent that the enforceability of indemnification provisions may be limited by applicable Laws.

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**4.3 No Conflicts**. The execution, delivery and performance of the Transaction Agreements and compliance with the provisions thereof by the Purchaser do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Purchaser or any of its assets, are bound, or (c) violate or conflict with any of the provisions of the Purchaser's organizational documents, except as would not impair or adversely affect the ability of the Purchaser to consummate the transactions contemplated pursuant to the Transaction Agreements and perform its obligations under the Transaction Agreements and except, in the case of subsections (a) and (b) as would not have a material adverse effect on the Purchaser.

**4.4 No Governmental Authority or Third Party Consents**. No Consent is required to be obtained by the Purchaser in connection with the authorization, execution and delivery of any of the Transaction Agreements or with the subscription for the Shares.

**4.5 No Public Sale or Distribution**. The Purchaser is acquiring the Shares in the ordinary course of business for its own account and not with a view towards, or for resale in connection with, the public sale or distribution thereof, except pursuant to sales registered under the Securities Act or under an exemption from such registration and in compliance with applicable federal and state securities laws, and the Purchaser does not have a present arrangement to effect any distribution of the Shares to or through any Person; provided, however, that the Purchaser reserves the right to dispose of the Shares at any time in accordance with or pursuant to a registration statement or an exemption under the Securities Act.

**4.6 Investor Status**. At the time the Purchaser was offered the Shares, it was, and at the date hereof it is, an "accredited investor" as defined in Rule 501(a) in Regulation D or a "qualified institutional buyer" as defined in Rule 144A(a) under the Securities Act. The Purchaser is not a registered broker dealer registered under Section 15(a) of the Exchange Act, or a member of the Financial Regulatory Authority, Inc. ("**FINRA**") or an entity engaged in the business of being a broker dealer. The Purchaser is not affiliated with any broker dealer registered under Section 15(a) of the Exchange Act, or a member of FINRA or an entity engaged in the business of being a broker dealer.

**4.7 No General Solicitation**. The Purchaser is not purchasing the Shares as a result of any advertisement, article, notice or other communication regarding the Shares published in any newspaper, magazine or similar media, broadcast over television or radio, disseminated over the Internet or presented at any seminar or any other general solicitation or general advertisement.

**4.8 Experience of the Purchaser**. The Purchaser, either alone or together with its representatives has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such investment. The Purchaser understands that it must bear the economic risk of this investment in the Shares indefinitely, and is able to bear such risk and is able to afford a complete loss of such investment

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**4.9 Access to Information**. The Purchaser acknowledges that it has reviewed the Company SEC Documents and all other materials the Purchaser deemed necessary for the purpose of making an investment decision with respect to the Shares, and has been afforded: (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the Company's business, management and financial affairs and terms and conditions of the offering of the Shares and the merits and risks of investing in the Shares; (ii) access to information (including material non-public information) about the Company and its Subsidiaries and their respective financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment. The Purchaser has evaluated the risks of investing in the Shares, understands there are substantial risks of loss incidental to the investment and has determined that it is a suitable investment for the Purchaser

**4.10 No Governmental Review**. The Purchaser understands that no United States federal or state agency or any other government or governmental agency has passed on or made any recommendation or endorsement of the Shares or the fairness or suitability of the investment in the Shares nor have such authorities passed upon or endorsed the merits of the offering of the Shares.

**4.11 Prohibited Transactions; Confidentiality**. Neither the Purchaser, directly or indirectly, and no Person acting on behalf of or pursuant to any understanding with the Purchaser, has engaged in any purchases or sales in the securities, including derivatives, of the Company (including, without limitation, any Short Sales (a "**Prohibited Transaction**") involving any of the Company's securities) since the time that the Purchaser was first contacted by the Company regarding an investment in the Company. The Purchaser covenants that neither it nor any Person acting on its behalf or pursuant to any understanding with the Purchaser will engage, directly or indirectly, in any Prohibited Transactions in the securities of the Company (including Short Sales) prior to the time the transactions contemplated by this Agreement are publicly disclosed. "**Short Sales**" include, without limitation, all "short sales" as defined in Rule 200 promulgated under Regulation SHO under the Exchange Act and all types of direct and indirect stock pledges, forward sale contracts, options, puts, calls, short sales, swaps, derivatives and similar arrangements (including on a total return basis), and sales and other transactions through non-U.S. broker-dealers or foreign regulated brokers. The Purchaser has maintained the confidentiality of all disclosures made to it in connection with the transaction contemplates by the Transaction Agreements (including the existence and terms of the Transaction Agreements).

**4.12 Restricted Securities**. The Purchasers understand that the Shares are characterized as "restricted securities" under the U.S. federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances.

**4.13 No Legal, Tax or Investment Advice**. The Purchaser understands that nothing in this Agreement or any other materials presented by or on behalf of the Company to the Purchaser in connection with the purchase of the Shares constitutes legal, tax or investment advice.

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The Purchaser has consulted such legal, tax and investment advisors as it, in its sole discretion, has deemed necessary or appropriate in connection with its purchase of the Shares.

**5. Covenants and Agreements**.

**5.1 Transfer Restrictions**.

**5.1.1 Restricted Security Transfer Restrictions.**

**(a)** The Purchaser covenants that the Shares will only be disposed of pursuant to an effective registration statement under, and in compliance with the requirements of, the Securities Act or pursuant to an available exemption from the registration requirements of the Securities Act, and in compliance with any applicable state securities laws. In connection with any transfer of Shares, other than pursuant to an effective registration statement or to Rule 144 (or an analogous successor thereto), the Company may require the transferor to provide to the Company an opinion of counsel selected by the transferor, the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration under the Securities Act.

**(b)** The Purchaser agrees that certificates initially representing the Shares shall bear a restrictive legend (and, with respect to Shares held in book-entry form, the Transfer Agent will record such a legend or other notation on the share register of the Company) in substantially the following form:

> THESE SECURITIES HAVE NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR ANY APPLICABLE STATE SECURITIES LAWS AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT. THESE SECURITIES MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT WITH A REGISTERED BROKER-DEALER OR OTHER LOAN WITH A FINANCIAL INSTITUTION THAT IS AN "ACCREDITED INVESTOR" AS DEFINED IN RULE 501(a) UNDER THE SECURITIES ACT OR OTHER LOAN SECURED BY SUCH SECURITIES

**(c)** Removal of Legends. The restrictive legend set forth in Section 5.1.1(b) above shall be removed and the Company shall issue a certificate without such restrictive legend or any other restrictive legend to the holder of the applicable Shares upon which it is stamped or issue to such holder by electronic delivery at the applicable balance account at the Transfer Agent in accordance with the Transfer Agent Instructions, at such time as Shares are being transferred, (i) if a registration statement covering the resale of the Shares is effective under the Securities Act, (ii) at the request of the holder (regardless of whether such Shares are then being resold), if the Shares are eligible for sale under Rule 144 (or an analogous successor thereto),

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or (iii) if the holder provides the Company with a legal opinion (and the documents upon which the legal opinion is based) to the effect that the legend is not required under applicable requirements of the Securities Act (including controlling judicial interpretations and pronouncements issued by the Staff of the SEC) as contemplated by the last sentence of Section 5.1.1(a) hereof. In connection with the legend removal event related to any Shares contemplated by the foregoing sentence, the Company will no later than two (2) Trading Days following the delivery by the Purchaser to the Company or the Transfer Agent (if delivery is made to the Transfer Agent a copy shall be contemporaneously delivered to the Company) of (i) a legended certificate representing such Shares (and, in the case of a requested transfer, endorsed or with stock powers attached, signatures guaranteed, and otherwise in form necessary to affect transfer), and (ii) an opinion of counsel only to the extent required by the last sentence of Section 5.1.1(a) hereof, direct the Transfer Agent to deliver to such Purchaser a certificate representing such Shares that is free from all restrictive and other legends. Notwithstanding the foregoing, the Company shall direct the Transfer Agent to remove the transfer restrictions and legends applicable to the Shares and deliver to the Purchaser certificates representing the Shares free from all restrictive legends or other transfer restrictions upon: (y) the written request of the Purchaser, within two (2) Trading Days of such request, at such time as the Shares may be transferred without the requirement that the Company be in compliance with the public information requirements and without volume or manner-of-sale restrictions under Rule 144 (or an analogous successor thereto) or (z) if the holder provides the Company with a legal opinion (and the documents upon which the legal opinion is based) to the effect that the legend is not required under applicable requirements of the Securities Act (including controlling judicial interpretations and pronouncements issued by the Staff of the SEC) as contemplated by the last sentence of Section 5.1.1(a) hereof. Certificates for Shares free from all restrictive legends may be transmitted by the Transfer Agent to the Purchaser by crediting the account of the Purchaser's primary broker with the Transfer Agent as directed by the Purchaser. The Company may not make any notation on its records or give instructions to the Transfer Agent that enlarge the restrictions on transfer set forth in this Section 5.1.1.

**(d)** Acknowledgement. The Purchaser acknowledges its responsibilities under the Securities Act and accordingly will not sell or otherwise transfer the Shares or any interest therein without complying with the requirements of the Securities Act and any other applicable securities laws.).

**5.1.2 Market Standoff; Transfer Restrictions.**

**(a)** So long as the Purchaser's investment in the Shares is equal to or exceeds ten percent (10%) of the Company's then issued and outstanding Common Stock, the Purchaser hereby agrees to execute and promptly deliver to the Company a customary lock-up agreement restricting the disposition of the Shares as may be requested by the Company, or the managing underwriter(s) or placement agent(s), as the case may be, in connection with a public offering or private placement of the Company's Common Stock; provided, that the Purchaser shall be in no way obligated to sign such a lock-up agreement unless, in connection with such financing, (i) the Company agrees in writing with the Purchaser not commence another public offering or private placement until any lock-up agreement executed by the Purchaser pursuant to this Section 5.1.1(a) is no longer effective, (ii) all of the Company's executive

officers and directors and beneficial owners of ten (10%) or more of the Common Stock have first signed a lock-up agreement, and (iii) no such lock-up agreement signed by any of the executive officers, directors

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or beneficial owners of ten (10%) or more of the Common Stock contains terms more favorable to the locked-up party than the lock-up agreement proposed to be signed by the Purchaser. The Company shall deliver the form of requested lock-up agreement to the Purchaser at least five (5) Trading Days prior to the closing of such financing event, but in no event sooner than the date that the Company, or the managing underwriter(s) or placement agent(s), as the case may be, solicit indications of interest from potential investors in such financing event. In no event shall such lock-up agreement restrict the Purchaser for a period longer than ninety (90) days after the date of the final prospectus (if the financing event is a public offering) or the date of the purchase agreement (if the financing event is a private placement), as the case may be. Any such lock-up agreement shall be drafted to terminate upon the earlier of (i)(A) the date the proposed financing is abandoned or (B) the date the underwriting agreement or the purchase agreement related to the financing event, as the case may be, is terminated and (ii) thirty (30) calendar days from the date such lock-up agreement was executed in the event the underwriting agreement or purchase agreement related to the financing, as the case may be, is not executed. Notwithstanding the foregoing, following the expiration of the Strategic Lock-Up Period (as defined below), the Purchaser shall neither be restricted from selling shares pursuant to a lock-up signed pursuant to this Section 5.1.2(a) for a period that exceeds 90 days during any 360-day period nor shall a restricted period contained within a lock-up proposed to be executed by the Purchaser pursuant to this Section 5.1.2(a) be less than thirty (30) consecutive days in duration.

**(b)** The Purchaser acknowledges that the Company shall impose stop-transfer instructions with respect to the Shares subject to the restriction set forth in Section 5.1.2(a) until the end of such "lock-up" period.

**(c)** The Company acknowledges and agrees that, unless the Purchaser is required to sign a lock-up agreement pursuant to Section 5.1.2(a), the Company will not disclose its plans to conduct a financing event to the Purchaser that would, absent the Purchaser's consent, cause the Purchaser to be in possession of material non-public information that would require the Purchaser to refrain from trading in the Common Stock. If the Purchaser is required to sign a lock-up agreement pursuant to Section 5.1.2(a) and receives any notice from the Company regarding the Company's plans to conduct a financing event as described in Section 5.1.2(a) above, the Purchaser agrees to treat such notice of the proposed financing event as material non-public information and refrain from trading in the Common Stock until the financing event is abandoned or completed and disclosed; provided, that, absent an agreement to the contrary with the Purchaser, within thirty (30) calendar days of such notice, the Company shall either inform the Purchaser in writing that it is no longer in possession of such material non-public information or cleanse the Purchaser of such material non-public information via publicly disclose of the material non-public information.

**(d)** Except as otherwise permitted in this Agreement, until the 365th day following the Initial Closing Date or, if the Alternative Initial Cash Payment (as defined in the Collaboration Agreement) is made by the Purchase, the date of such payment, the Purchaser will not transfer any of the Shares purchased hereunder for value without the Company's consent (such 365-day period, the "**Strategic Lock-Up Period**"); provided, that the restrictions set forth in this Section 5.1.2(d) shall in no way prohibit transfers of the Company's securities by the Purchaser (i) to any affiliate of the Purchaser, including to a corporation, member, partner, trust or other business entity that is a direct or indirect affiliate of the Purchaser, or to an investment fund or other entity that manages or directly or indirectly controls the Purchaser, (ii) as part of a distribution, transfer

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or distribution by the Purchaser to its stockholders, members, partners, beneficiaries (or the estates thereof) or its other equity holders, but, in either case (i) or (ii), only if the transferee agrees in writing to be bound to transfer restrictions consistent with this Section 5.1.2(d), (iii) to the Company, (iv) by operation of law, including pursuant to orders of a court or regulatory agency, or (v) pursuant to a tender offer made to all holders of Common Stock or bona fide merger, consolidation or transaction whereby all or substantially all of the Common Stock is acquired by a third-party (including, without limitation, the entering into of any lock-up, voting or similar agreement pursuant to which the undersigned may agree to transfer, sell, tender or otherwise dispose of shares of Common Stock or other such securities in connection with such transaction, or vote any shares of Common Stock or other securities in favor of any such transaction).

**5.2 Furnishing of Information**. Until the date that the Purchaser may no longer holds Registrable Securities, the Company covenants to use its reasonable best efforts to (i) file in a timely manner all reports and other documents required, if any, to be filed by it under the Securities Act and the Exchange Act and the rules and regulations adopted thereunder and (ii) make available information necessary to comply with Rule 144 with respect to resales of the Shares under the Securities Act, at all times, to the extent required from time to time to enable the Purchaser to resell Shares without registration under the Securities Act within the limitation of the exemptions provided by (A) Rule 144 (if available with respect to resales of the Shares), as such rule may be amended from time to time or (B) any other rules or regulations now existing or hereafter adopted by the SEC. The Company further covenants that it will take such further action as any holder of Shares may reasonably request to satisfy the provisions of this Section 5.2.

**5.3 Reservation of Shares**. The Company shall maintain a reserve from its duly authorized shares of Common Stock for issuance pursuant to this Agreement in such amounts as may then be required to fulfill its obligation under this Agreement.

**5.4 Nasdaq Matters**. The Company shall (a) take all actions which are necessary, including providing appropriate notice to Nasdaq of the transactions contemplated by this Agreement, for the Shares purchased at each Closing to remain listed on The Nasdaq Capital Market and (b) comply with all listing, reporting, filing, and other obligations under the rules of Nasdaq and of the SEC. Prior to the Alternative Shares Closing Date, Subsequent Closing Date or the earlier termination of this Agreement in accordance with its terms, the Company shall not voluntarily delist from The Nasdaq Capital Market or amend its certificate of incorporation or bylaws in a manner that is adverse to the Purchaser's rights under the Transaction Agreements. If, prior to the Alternative Shares Closing Date or Subsequent Closing Date, the Common Stock is delisted from The Nasdaq Capital Market, the Company shall use commercially reasonable efforts to regain such listing as promptly as possible.

**5.5 Form D; Blue Sky Filings**. The Company agrees to timely file a Form D with respect to the Shares as required under Regulation D and to provide a copy thereof, promptly upon request of the Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Shares for, sale to the Purchaser under applicable securities or "blue sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of the Purchaser.

**5.6 Further Assurances**. Subject to the terms and conditions of this Agreement, each of the Company and the Purchaser agrees to use its reasonable best efforts to

take, or cause to be taken, all actions, and to do, or cause to be done, and assist the other party hereto in doing, all things reasonably necessary, proper or advisable to obtain satisfaction of the conditions precedent to the consummation of the transactions contemplated at the Initial Closing , Alternative Initial Closing and the Subsequent Closing, if applicable: (a) obtaining all necessary Consents and the making of all filings and the taking of all steps as may be necessary to obtain Consent from, or to avoid an Action by, any Governmental Authority, (b) the defending of any Actions challenging this Agreement or any other Transaction Agreements or the consummation of the transactions contemplated hereby or thereby, including seeking to have any stay or temporary restraining order entered by any court or other Governmental Authority vacated or reversed, and (c) the execution and delivery of any additional instruments necessary to consummate the transactions contemplated by, and to fully carry out the purposes of, this Agreement and the other Transaction Agreements.

**5.7 Non-Public Information**. Except as contemplated by the Collaboration Agreement, the Company covenants and agrees that neither it, nor any other Person acting on its behalf will provide Purchaser or its agents or counsel with any information that constitutes material non-public information, unless prior thereto Purchaser shall have entered into a written agreement with the Company regarding the confidentiality and use of such information. The Company understands and confirms that Purchaser will be relying on the foregoing covenant in effecting transactions in securities of the Company.

**5.8 Securities Law Disclosure; Publicity**. No public release or announcement concerning the transactions contemplated hereby or by any other Transaction Agreement, including the public filing of any Transaction Agreement pursuant to applicable securities Laws, shall be issued by the Company or the Purchaser without the prior consent of the Company (in the case of a release or announcement by the Purchaser) or the Purchaser (in the case of a release or announcement by the Company) (which consents shall not be unreasonably withheld, conditioned or delayed), except for any such public filing, release or announcement as may be required by securities Law or other applicable Law or the applicable rules or regulations of any securities exchange or securities market, in which case the Company or the Purchaser, as the case may be, shall allow the Purchaser or the Company, as applicable, reasonable time to comment on such public filing, release or announcement in advance of such filing or issuance and the disclosing party shall consider the other party's comments in good faith. Following the execution and delivery of this Agreement, the Company shall issue a press release substantially in the form attached to the Collaboration Agreement as Exhibit A.

**5.9 Integration**. The Purchaser acknowledges that the Company may issue additional shares of Common Stock after the date hereof; *provided*, *however*, that the Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in the Securities Act) that would be integrated with the offer or sale of the Shares to be issued to the Purchaser hereunder (i) in a manner that would require the registration under the Securities Act of the sale of the Shares or (ii) for purposes of the rules and regulations of the Trading Market.

**5.10 Use of Proceeds**. The net proceeds received by the Company from each Closing shall be used for general corporate purposes at the direction of the Board of Directors.

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**5.11 Notification**. After achievement of the Research and Development Event and prior to the Subsequent Closing Date, the Company shall promptly deliver to the Purchaser a written notice of any event or development that would, or could reasonably be expected to, result in any condition to the Subsequent Closing set forth in Section 6.1, not to be satisfied.

**5.12 Registration Rights**. The Company covenants and agrees as follows:

**(a)** If the Purchaser holds Registrable Securities (as defined below) upon the expiration of the Strategic Lock-Up Period (the "**Initial Registration Deadline**") or the day that is ten (10) calendar days following the Subsequent Closing Date (the "**Subsequent Registration Deadline,**" and the Initial Registration Deadline and Subsequent Registration Deadline, each a "**Registration Deadline**") or, in either case, such earlier time as the Company in its sole discretion may agree in writing, or such later time as the Purchaser in its sole discretion may agree in writing, then the Company shall file a registration statement to register the resale of the applicable Unregistered Registrable Securities (as defined below) on a registration statement on Form S-3 (or such other form appropriate for such purpose if the Company does not meet the eligibility requirements for use of Form S-3) (a "**Resale Registration Statement**") under the Securities Act and use reasonable best efforts to have such registration statement declared effective and maintain the effectiveness of such registration statement for a period ending on the date the Purchaser no longer holds Registrable Securities (as defined below).

**(b)** The Company shall take reasonable best efforts to register all Unregistered Registrable Securities on Form S-3 if such form is available for use by the Company, provided that if Registrable Securities are registered for resale on Form S-1, the Company shall maintain the effectiveness of such registration statement then in effect until such time as a registration statement on Form S-3 registering the resale of the Registrable Securities has been declared effective by the SEC.

**(c)** The Company shall use reasonable best efforts to have each Resale Registration Statement declared effective by the SEC as soon as practicable following a Filing Deadline, but in no event shall a Resale Registration Statement covering Unregistered Registrable Securities be declared effective by the SEC later than the earlier of (i) ten (10) Business Days after the SEC informs the Company that no review of such Resale Registration Statement will be made or that the SEC has no further comments on such Resale Registration Statement and (ii) the forty-fifth ($45^{th}$) day after an applicable Registration Deadline (or the ninetieth ($80^{th}$) day if the SEC reviews such Resale Registration Statement). The Company shall notify the Purchaser by facsimile or e-mail as promptly as practicable, and in any event, within forty-eight (48) hours, after any Resale Registration Statement is declared effective and shall simultaneously provide the Purchaser with access to a copy of any related prospectus to be used in connection with the sale or other disposition of the securities covered thereby.

**(d)** All expenses, other than Selling Expenses (as defined below), incurred in connection with registrations, filings or qualifications pursuant to this Section 5.12, including all registration, filing and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; and the reasonable fees and disbursements, shall be borne and paid by the Company. All Selling Expenses shall be borne by the Purchaser; or if there are other selling shareholders with shares being registered pursuant to such registration statement,

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then pro rata by the selling shareholders based on the number of shares sold by such selling shareholder in the offering.

**(e)** For the purposes of this Section 5.12,

**(i)** "**Losses**" means any loss, damage, claim or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, claim or liability.

**(ii)** "**Registrable Securities**" means, at any time, the Initial Closing Shares, Alternative Initial Closing Shares and Research and Development Event Shares held by Purchaser including, without limitation, any Common Stock paid, issued or distributed in respect of any such Initial Closing Shares, Alternative Initial Closing Shares and Research and Development Event Shares by way of stock dividend, stock split or distribution, or in connection with a combination of shares, recapitalization, reorganization, merger or consolidation, or otherwise, but excluding Common Stock acquired in the open market before or after the date hereof; provided, however, that the Initial Closing Shares, Alternative Initial Closing Shares and Research and Development Event Shares will not be "Registrable Securities" (A) after such Shares have been sold pursuant to an effective registration statement or in compliance with Rule 144 or (B) when certificates evidencing all of the Shares issuable to the Purchaser under this Agreement have been so issued and the remaining Initial Closing Shares, Alternative Initial Closing Shares and Research and Development Event Shares then held by the Purchaser have been reissued to the Purchaser without restrictive legends and are then free from any other restrictions on transfer (including the possible subsequent designation of such securities as "control" securities as a result of the Subsequent Closing). For the avoidance of doubt, the Company acknowledges and agrees that, even if the legends are removed from the Initial Closing Shares, the Initial Closing Shares shall continue to be "Registrable Securities" if such securities are determined to be "control" securities following the Purchaser's acquisition of the Research and Development Event Shares.

**(iii)** "**Selling Expenses**" means the fees and disbursements of counsel for the Purchaser.

**(iv)** "**Unregistered Registrable Securities**" means any and all Registrable Securities outstanding at a Registration Deadline that have not been registered for resale pursuant to a then-effective registration statement filed with the Commission.

**(f)** **Indemnification**.

**(i)** To the extent permitted by law, the Company will indemnify and hold harmless the Purchaser, and the partners, members, officers and directors of the Purchaser and each Person, if any, who controls the Purchaser (collectively, "**Purchaser Indemnified Parties**"), against any Losses, arising out of and is based upon: (A) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company registering the resale of the Registrable Securities, including any preliminary prospectus or final prospectus contained therein, documents and filings incorporated by reference therein or any amendments or supplements thereto or (B) an omission or alleged omission to state in such registration statement a material fact required to be stated therein, or necessary to make the

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statements therein not misleading; provided, however, that the Company shall not be liable for any Losses arising out of or based upon any untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with written information furnished to the Company by the Purchaser for use in any registration statement of the Company registering the resale of the Registrable Securities, including any preliminary prospectus or final prospectus contained therein, documents and filings incorporated by reference therein and any amendments or supplements thereto, provided, however, that the Company acknowledges and agrees that the only such written information furnished to the Company by the Purchaser for use in any such registration statement of the Company is the Purchaser's information included in its beneficial ownership footnote and the amount of the Company's securities beneficially owned by the Purchaser (but excluding percentages) (collectively, the "**Purchaser Information**").

**(ii)** To the extent permitted by law, the Purchaser will indemnify and hold harmless the Company, its directors, officers, agents and employees and each person who "controls" the Company (collectively, "**Company Indemnified Parties**"), against any Losses, arising out of and is based upon: (A) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company registering the resale of the Registrable Securities, including any preliminary prospectus or final prospectus contained therein, documents and filings incorporated by reference therein and any amendments or supplements thereto or (B) an omission or alleged omission to state in such registration statement a material fact required to be stated therein, or necessary to make the statements therein not misleading; but only to the extent that such untrue statements or omissions or alleged untrue statements or omissions are based solely upon Purchaser Information. In no event shall the liability of the Purchaser hereunder be in excess of the public offering price of all such Registrable Securities offered and sold by the Purchaser pursuant to such registration statement.

**(iii)** A Person from who indemnity is sought hereunder (an "**Indemnifying Party**") will pay to a Person entitled to indemnity hereunder (an "Indemnified Party") any legal or other reasonable and documented expenses incurred thereby in connection with investigating or defending any claim or proceeding from which Losses may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Section 5.12(f) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Indemnifying Party, which consent shall not be unreasonably withheld.

**(g)** Promptly after receipt by the Indemnified Party under this Section 5.12 of notice of the commencement of any action (including any governmental action) for which an Indemnified Party may be entitled to indemnification hereunder, the Indemnified Party will, if a claim in respect thereof is to be made against the Indemnifying Party under this Section 5.12, give the Indemnifying Party notice of the commencement thereof. The Indemnifying Party shall have the right to participate in such action and, to the extent the Indemnifying Party so desires, and to assume the defense thereof with counsel mutually satisfactory to the Indemnified Parties; provided, however, that the Indemnified Parties shall have the right to retain one separate counsel for all such Indemnified Parties, with the reasonable and documented fees and expenses to be paid by the Indemnifying Party, if representation of the Indemnified Parties by the counsel retained by the Company would be inappropriate due to actual or potential conflict of interest between the Indemnified Parties and the Indemnifying Party. The failure to give notice to the Indemnifying

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Party within a reasonable time of the commencement of any such action shall relieve the Indemnifying Party of any liability to the Indemnified Parties under this Section 5.12, only to the extent that such failure materially prejudices the Indemnifying Party ability to defend such action. The failure to give notice to the Indemnifying Party will not relieve it of any liability that it may have to the Indemnified Party otherwise than under this Section 5.12.

**(h)** To provide for just and equitable contribution to joint liability under the Securities Act in any case in which contribution under the Securities Act may be required on the part of the Indemnified Parties, then such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party and each Indemnified Party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the Indemnifying Party and each Indemnified Party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the Indemnifying Party or by a Indemnified Party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case (x) the Purchaser will not be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by the Purchaser pursuant to such registration statement, and (y) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation.

**(i)** The parties acknowledge that the provisions of Sections 5.12(e), (f), (g) and (h) hereof may be superseded by indemnification and contribution provisions included in an underwriting agreement, placement agency agreement or similar document that is executed by the Company and the Purchaser in connection with a public offering or private placement of securities, as the case may be.

**5.13 Participation in Future Financing**.

**(a)** Until such time as the Purchaser no longer holds Registrable Securities, upon any issuance of Common Stock, or securities convertible or exchangeable into Common Stock, by the Company in a private placement (as defined by the SEC) to institutional investors, including at least one such institutional investor that is not an Affiliate of the Company, for cash consideration (a "**Subsequent Financing**"), the Company agrees at least four (4) Trading Days prior to the closing of the Subsequent Financing, to deliver to the Purchaser written notice of its intention to effect a Subsequent Financing (the "**Subsequent Financing Notice**"). The Subsequent Financing Notice shall describe in reasonable detail the proposed terms of such Subsequent Financing, the amount of proceeds intended to be raised thereunder and the Person or Persons through or with whom such Subsequent Financing is proposed to be effected. Upon receipt of the Subsequent Financing Notice, the Company and the Purchaser shall in good faith negotiate the Purchaser's participation in the Subsequent Financing and the Company shall allow the Purchaser to participate up to the Purchaser's Pro-Rata Share (as defined below) on the same terms, conditions and price provided for in the Subsequent Financing. For purposes of this Agreement, the Purchaser's "**Pro-Rata Share**" shall be equal to the number of Common Stock deemed to be

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beneficially owned by the Purchaser immediately prior to the date of the Subsequent Financing Notice (based upon documentation or written representation reasonably satisfactory to the Company), divided by the total number of Common Stock outstanding (including any Common Stock issuable upon conversion or exercise of outstanding Common Share Equivalents deemed to be beneficially owned by the Purchaser and included in the numerator of its pre-Subsequent Financing Notice beneficial ownership calculation) immediately prior to the closing of the Subsequent Financing.

**(b)** If the Purchaser desires to participate in such Subsequent Financing, the Purchaser must provide written notice to the Company, by not later than 5:30 p.m. (New York City time) on the second (2nd) Trading Day after the Purchaser has received the Subsequent Financing Notice (the "**Participation Deadline**"), that the Purchaser is willing to participate in the Subsequent Financing and stating the amount of the Purchaser's elected participation, but in no event shall such amount of Common Stock that would cause the Purchaser to exceed its Pro-Rata Share. If the Company receives no such notice from the Purchaser as of the Participation Deadline, the Purchaser shall be deemed to have notified the Company that it does not elect to participate in the Subsequent Financing.

**(c)** If, by the thirtieth ($30^{th}$) day following delivery of the Subsequent Financing Notice, no public disclosure regarding a transaction with respect to the Subsequent Financing has been made, such Subsequent Financing shall be deemed to have been abandoned and the Purchaser shall not be in possession of any material, non-public information with respect to the Company, unless the Company advises the Purchaser that the Subsequent Financing has not been abandoned. The Company understands and confirms that the Purchaser may rely on this Section 5.13(c) when effecting transactions in securities of the Company.

**6. <u>Conditions to Closing</u>**.

**6.1 Conditions to Purchaser's Obligations at the Closing**. The Purchaser's obligation to purchase the Shares at the Initial Closing, the Alternative Initial Closing and the Subsequent Closing, if applicable, is subject to the satisfaction, at or prior to the Initial Closing Date, the Alternative Initial Shares Closing Date and the Subsequent Closing Date, if applicable, of the following conditions (unless waived in writing by the Purchaser):

**(a)** Representations and Warranties. The representations and warranties made by the Company in Section 3 hereof shall be true and correct in all material respects as of the date hereof and as of the Initial Closing Date, the Alternative Initial Closing Date and the Subsequent Closing Date, if applicable, as if made on such date, as applicable, except to the extent such representation and warranty is (i) specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date or (ii) already qualified by materiality, in which case it shall be true and correct as of such dates.

**(b)** Performance of Obligations. The Company shall have performed and complied with all agreements and conditions herein required to be performed or complied with by the Company on or before the Initial Closing Date, Alternative Initial Closing Date and the Subsequent Closing Date, if applicable.

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**(c)** Legal Investment. The sale and issuance of the Shares shall be legally permitted by all Laws to which the Purchaser and the Company are subject.

**(d)** No Orders. No Order shall be in effect preventing the consummation of the transactions contemplated by the Transaction Agreements.

**(e)** Closing Deliverables. The Company shall deliver or cause to be delivered to the Purchaser all items listed in Section 2.3(a).

**(f)** Collaboration Agreement. The Company shall have executed the Collaboration Agreement, the only remaining condition to the effectiveness of the Collaboration Agreement shall be the Initial Closing or payment of the Alternative Initial Cash Payment, the Effective Date (as such term is defined in the Collaboration Agreement) of the Collaboration Agreement shall have occurred, no breach by the Company of any term of or obligation under the Collaboration Agreement shall have occurred and be continuing, and the Collaboration Agreement shall not have been terminated in accordance with its terms. Solely with regard to the Subsequent Closing, if applicable, the Research and Development Event shall have been reached and the cash portion of the Research and Development Payment shall have been made or is being made concurrent with such Subsequent Closing.

**(g)** Consents, Permits, and Waivers. All Consents necessary or appropriate for consummation of the transactions contemplated by the Transaction Agreements shall have been obtained, including the approval of the Board of Directors.

**(h)** Material Adverse Effect. No Material Adverse Effect shall have occurred and be continuing.

**(i)** The Company's Nasdaq Listing. The Company's Common Stock shall continue to be listed on the Nasdaq Capital Market.

**6.2 Conditions to Company's Obligations at the Closing**. The Company's obligation to issue and sell Shares at the Initial Closing, the Alternative Initial Shares Closing and the Subsequent Closing, if applicable, is subject to the satisfaction, on or prior to the Initial Closing Date, Alternative Initial Closing Date and the Subsequent Closing Date, if applicable, of the following conditions (unless waived in writing by the Company):

**(a)** Representations and Warranties. The representations and warranties in Section 4 made by the Purchaser shall be true and correct in all material respect as of the Initial Closing Date, Alternative Initial Closing Date and the Subsequent Closing Date, if applicable.

**(b)** Performance of Obligations. The Purchaser shall have performed and complied with all agreements and conditions herein required to be performed or complied with by the Purchaser on or before the Initial Closing Date, Alternative Initial Closing Date and the Subsequent Closing Date, if applicable.

**(c)** Legal Investment. The sale and issuance of the Shares shall be legally permitted by all Laws to which the Purchaser and the Company are subject.

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**(d)** No Orders. No Order shall be in effect preventing the consummation of the transactions contemplated by the Transaction Agreements.

**(e)** Closing Deliverables. The Purchaser shall deliver or cause to be delivered to the Company all items listed in Section 2.3(b).

**(f)** Collaboration Agreement. The Purchaser shall have executed the Collaboration Agreement, the only remaining condition to the effectiveness of the Collaboration Agreement shall be the Initial Closing or payment of the Alternative Initial Cash Payment, the Effective Date (as such term is defined in the Collaboration Agreement) of the Collaboration Agreement shall have occurred, no breach by the Purchaser of any term of or obligation under the Collaboration Agreement shall have occurred and be continuing, and the Collaboration Agreement shall not have been terminated in accordance with its terms. Solely with regard to the Subsequent Closing, if applicable, the Research and Development Event shall have been reached and the cash portion of the Research and Development Payment shall have been made or is being made concurrent with such Subsequent Closing.

**(g)** Consents, Permits, and Waivers. All Consents necessary or appropriate for consummation of the transactions contemplated by the Transaction Agreements shall have been obtained.

**7. Miscellaneous**.

**7.1 Termination**. This Agreement and the obligations of the parties hereunder:

**(a)** may be terminated by the Company and the Purchaser, by providing mutual written consent to terminate;

**(b)** will terminate automatically, if the Initial Closing does not occur and, by the close of business on December 31, 2018, the Company has not filed the Charter Amendment with the Secretary of State of the State of Delaware;

**(c)** may be terminated by the Company if (i) any of the representations and warranties of the Purchaser contained in Section 4 of this Agreement shall fail to be true and correct or (ii) there shall be a breach by the Purchaser of any covenant of the Purchaser in this Agreement that, in either case, (A) would result in the failure of a condition set forth in Section 6.2, and (B) which is not curable or, if curable, is not cured upon the occurrence of the twentieth ($20^{th}$) calendar day after written notice thereof is given by the Company to the Purchaser;

**(d)** may be terminated by the Purchaser if (i) any of the representations and warranties of the Company contained in Section 3 of this Agreement shall fail to be true and correct or (ii) there shall be a breach by the Company of any covenant of the Company in this Agreement that, in either case, (A) would result in the failure of a condition set forth in Section 6.1, and (B) which is not curable or, if curable, is not cured upon the occurrence of the twentieth ($20^{th}$) calendar day after written notice thereof is given by the Purchaser to the Company;

**(e)** may be terminated by the Company or the Purchaser, upon notice to the other, if there shall be any Law that makes consummation of the transactions contemplated by

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this Agreement illegal or otherwise prohibited, or a Governmental Authority of competent jurisdiction has issued an Order permanently enjoining or otherwise prohibiting or restraining the consummation of the transactions contemplated by this Agreement, and such Order has become final and non-appealable; provided, however, that the right to terminate this Agreement pursuant to this Section 7.1(e) shall not be available to any party whose breach of any provision of this Agreement results in or causes such Order or who is not in compliance with its obligations under Section 5; and

**(f)** will terminate automatically, upon termination of the Collaboration Agreement.

**(g)** In the event of termination of this Agreement pursuant to Section 7.1 by either Purchaser or the Company, this Agreement will become void and have no further force or effect, without any liability or obligation of the Purchaser, other than (i) as set forth in this Section 7, which will survive any termination of this Agreement, and (ii) with respect to the covenants and agreements set forth in Section 5 hereof, which shall terminate in accordance with their terms.

**7.2 Governing Law; Waiver of Jury Trial**. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. The parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement. EACH OF THE PARTIES TO THIS AGREEMENT HEREBY AGREES THAT JURISDICTION AND VENUE IN ANY SUIT, ACTION OR PROCEEDING BROUGHT BY ANY PARTY ARISING OUT OF OR RELATING TO THIS AGREEMENT (INCLUDING ANY SUIT, ACTION OR PROCEEDING SEEKING EQUITABLE RELIEF) SHALL PROPERLY AND EXCLUSIVELY LIE IN THE STATE AND FEDERAL COURTS LOCATED IN THE STATE OF NEW YORK (THE "**CHOSEN COURTS**"). EACH PARTY HERETO FURTHER AGREES NOT TO BRING ANY SUCH SUIT, ACTION OR PROCEEDING IN ANY COURT OTHER THAN THE CHOSEN COURTS PURSUANT TO THE FOREGOING SENTENCE (OTHER THAN UPON APPEAL). BY EXECUTION AND DELIVERY OF THIS AGREEMENT, EACH PARTY IRREVOCABLY SUBMITS TO THE JURISDICTION OF THE CHOSEN COURTS FOR ITSELF AND IN RESPECT OF ITS PROPERTY WITH RESPECT TO SUCH SUIT, ACTION OR PROCEEDING. THE PARTIES HERETO IRREVOCABLY AGREE THAT VENUE WOULD BE PROPER IN EACH OF THE CHOSEN COURTS, AND HEREBY WAIVE ANY OBJECTION THAT ANY SUCH CHOSEN COURT IS AN IMPROPER OR INCONVENIENT FORUM FOR THE RESOLUTION OF SUCH SUIT, ACTION OR PROCEEDING. TO THE EXTENT NOT PROHIBITED BY APPLICABLE LAW WHICH CANNOT BE WAIVED, EACH PARTY HERETO HEREBY WAIVES AND COVENANTS THAT IT WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT OR OTHERWISE) ANY RIGHT TO TRIAL BY JURY IN ANY FORUM IN RESPECT OF ANY ISSUE OR ACTION, CLAIM, CAUSE OF ACTION OR SUIT (IN CONTRACT, TORT OR OTHERWISE) INQUIRY, PROCEEDING OR INVESTIGATION ARISING OUT OF OR BASED UPON THIS AGREEMENT OR THE SUBJECT MATTER HEREOF OR IN ANY WAY CONNECTED WITH OR RELATED OR INCIDENTAL TO THE TRANSACTIONS CONTEMPLATED

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HEREBY, IN EACH CASE WHETHER NOW EXISTING OR HEREAFTER ARISING. EACH PARTY HERETO ACKNOWLEDGES THAT IT HAS BEEN INFORMED BY THE OTHER PARTIES HERETO THAT THIS SECTION 7.2 CONSTITUTES A MATERIAL INDUCEMENT UPON WHICH THEY ARE RELYING AND WILL RELY IN ENTERING INTO THIS AGREEMENT. ANY PARTY HERETO MAY FILE AN ORIGINAL COUNTERPART OR A COPY OF THIS SECTION 7.2 WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF EACH SUCH PARTY TO THE WAIVER OF ITS RIGHT TO TRIAL BY JURY.

**7.3 Survival**. The representations, warranties, covenants and agreements made herein shall survive the Initial Closing, the Alternative Initial Shares Closingand the Subsequent Closing, if applicable.

**7.4 Successors and Assigns**. Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon the parties hereto and their respective successors, assigns, heirs, executors and administrators and shall inure to the benefit of and be enforceable by each person who shall be a holder of the Shares from time to time; provided, however, that prior to the receipt by the Company of adequate written notice of the transfer of any Shares specifying the full name and address of the transferee, the Company may deem and treat the person listed as the holder of such Shares in its records as the absolute owner and holder of such Shares for all purposes. This Agreement may not be assigned by any party hereto without the consent of the other party, provided, that the Purchaser may assign its rights and obligations hereunder in whole or in part to any Affiliate of the Purchaser or to any successor of the Purchaser as a result of a change of control of the Purchaser, provided that in the case of such assignment the Purchaser shall not be relieved of its obligations hereunder, or to any transferee to whom Shares are properly transferred after the Initial Closing, the Alternative Initial Shares Closing or the Subsequent Closing, if applicable, pursuant to the terms of the Transaction Agreements.

**7.5 Entire Agreement**. This Agreement, the exhibits and schedules hereto, the other Transaction Agreements, and the other documents delivered pursuant hereto constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof and no party shall be liable for or bound to any other in any manner by any oral or written representations, warranties, covenants and agreements except as specifically set forth herein and therein.

**7.6 Severability**. In the event one or more of the provisions of this Agreement should, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein. Upon such determination that any provision of this Agreement, or the application of any such provision, is invalid, illegal, void or unenforceable, the Company and the Purchaser shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Company and the Purchaser as closely as possible to the fullest extent permitted by Law in an acceptable manner to the end that the transactions contemplated hereby and the other Transaction Agreements are fulfilled to the greatest extent possible.

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**7.7 Amendment**. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the Purchaser and the Company. Any amendment effected in accordance with this Section 7.7 shall be binding upon each holder of Shares purchased under this Agreement at the time outstanding, each future holder of all such Shares, and the Company, and any amendment not effected in accordance with this Section 7.7 shall be void and of no effect.

**7.8 Waivers; Delays or Omissions**. It is agreed that no delay or omission to exercise any right, power or remedy accruing to any party, upon any breach, default or noncompliance by another party under this Agreement, shall impair any such right, power or remedy, nor shall it be construed to be a waiver of any such breach, default or noncompliance, or any acquiescence therein, or of or in any similar breach, default or noncompliance

thereafter occurring. It is further agreed that any Consent of any kind or character on any party's part of any breach, default or noncompliance under this Agreement or any waiver on such party's part of any provisions or conditions of the Agreement must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement, by Law, or otherwise afforded to any party, shall be cumulative and not alternative. Any waiver effected in accordance with this Section 7.8 shall be binding upon each holder of Shares purchased under this Agreement at the time outstanding, each future holder of all such Shares, and the Company, and any waiver not effected in accordance with this Section 7.8 shall be void and of no effect.

**7.9 Notices**. All notices and other communications under this Agreement must be in writing and are deemed duly delivered when (a) delivered if delivered personally or by nationally recognized overnight courier service (costs prepaid), (b) sent by facsimile with confirmation of transmission by the transmitting equipment (or, the first Business Day following such transmission if the date of transmission is not a Business Day) or (c) received or rejected by the addressee, if sent by United States of America certified or registered mail, return receipt requested; in each case to the following addresses or facsimile numbers and marked to the attention of the individual (by name or title) designated below (or to such other address, facsimile number or individual as a party may designate by notice to the other parties):

If to the Company:

Onconova Therapeutics, Inc.
375 Pheasant Run
Newtown, PA 18940,
Attention: Ramesh Kumar. Chief Executive Officer

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

Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103
Attention: Joanne Soslow

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If to the Purchaser:

Pint Pharma GmbH
c/o Pint Pharma GmbH
Wipplingerstrasse 34 Top 112 — 119
Vienna (Austria)
Attention: Chief Executive Officer

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

Latham & Watkins LLP
555 Eleventh Street, NW
Suite 1000
Washington, D.C. 20004-1304
Attention: Brandon J. Bortner

**7.10 Expenses**. Each party shall pay all costs and expenses that it incurs with respect to the negotiation, execution, delivery and performance of this Agreement.

**7.11 Replacement of Share**s. If any certificate or instrument evidencing any Shares is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Shares

**7.12 Titles and Subtitles**. The titles of the sections and subsections of the Agreement are for convenience of reference only and are not to be considered in construing this Agreement.

**7.13 Counterparts**. This Agreement may be executed in any number of counterparts (including via facsimile, PDF or other electronic signature), each of which shall be an original, but all of which together shall constitute one instrument.

**7.14 Pronouns**. All pronouns contained herein, and any variations thereof, shall be deemed to refer to the masculine, feminine or neutral, singular or plural, as to the identity of the parties hereto may require. The words "include," "includes" and "including" will be deemed to be followed by the phrase "without limitation". The meanings given to terms defined herein will be equally applicable to both the singular and plural forms of such terms. All references to "dollars" or "$" will be deemed references to the lawful money of the United States of America. All exhibits attached hereto and all other attachments hereto are hereby incorporated herein by reference and made a part hereof.

**7.15 Third-Party Beneficiaries**. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.

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**7.16 No Strict Construction**. This Agreement has been prepared jointly and will not be construed against either party. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto, and no presumption or burden of proof shall arise favoring or disfavoring any party hereto by virtue of the authorship of any provisions of this Agreement.

[*Signature Page to Follow*]

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IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date set forth in the first paragraph hereof.

**Company:**

**ONCONOVA THERAPEUTICS, INC.**

By: /s/ Ramesh Kumar
Name: Ramesh Kumar
Title: Chief Executive Officer

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IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date set forth in the first paragraph hereof.

**Purchaser:**

**PINT PHARMA GmbH**

By: /s/ David R. Munoz Guzman
Name: David R Munoz Guzman
Title: Chief Executive Officer

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Schedule 3.20

Onconova Therapeutics, Inc. (the "Company") has agreed to pay compensation to Lucas Advisors LLC d/b/a KYBORA Emerging Markets ("KYBORA") pursuant to the agreement between the Company and KYBORA, dated as of February 24, 2017.

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Exhibit A

Form of Press Release

**Onconova Therapeutics Announces License Agreement with Pint Pharma to Commercialize Rigosertib for Treatment of Myelodysplastic Syndromes in Latin America**

- Pint Pharma to Make Upfront Investment in Onconova
- Onconova also Eligible to Receive up to $42.75 Million in Regulatory and Sales Milestones

**NEWTOWN, PA, MARCH 5, 2018 —** Onconova Therapeutics, Inc. (NASDAQ: ONTX), a Phase 3-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, with a primary focus on myelodysplastic syndromes (MDS), today announced that they have entered into a license agreement with Pint Pharma to commercialize rigosertib, a novel targeted anti-cancer compound currently in a Phase 3 study for the treatment of MDS, a group of rare hematologic malignancies. Pint Pharma is a European-based pharmaceutical company focused on the development, registration and commercialization of specialty-based treatments for the Latin American market.

Under the terms of the agreement, Onconova has granted to Pint Pharma an exclusive license to commercialize rigosertib in Latin America. In exchange for these rights, Pint will make investment totaling up to $2.5 million by purchasing shares at a premium to market. In addition, Pint Pharma will make additional regulatory, development and sales-based milestone payments to Onconova of up to $42.75 million and pay double digit tiered royalties on net sales in Latin America. Onconova will supply the finished product for sale in the licensed territories. Pint Pharma will also support Onconova's clinical trial initiatives in the territory.

"Following the recently announced promising interim analysis of our Phase 3 INSPIRE trial, we remain dedicated to advancing IV rigosertib towards commercialization in order to address the needs of MDS patients who fail hypomethylating agents (HMAs). Since HMAs are used globally, we are seeking regional partnerships to help prepare for the commercialization of rigosertib worldwide. We are delighted to partner with Pint Pharma, which has a wide footprint in South and Central America, and view this license agreement as further validation of the potential of rigosertib for the treatment of MDS. We also look forward to working with the clinicians and experts at Pint Pharma to advance clinical trials for IV and oral rigosertib in important centers in their territory," said Dr. Ramesh Kumar, President and CEO of Onconova Therapeutics, Inc.

"We are excited about the opportunity to provide this therapy to patients in our region; we hope that rigosertib will become a reality in clinical oncological practice and deliver a new option to patients and specialists," said David Munoz, Chief Executive Officer of Pint Pharma. "Rigosertib is highly

complementary to our comprehensive hematology oncology portfolio, and will further strengthen our mission to enable the Latin American population with life-altering conditions to live better lives by providing early and efficient access to innovative technologies."

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Rigosertib is currently being evaluated in a Phase 3 INSPIRE clinical trial in patients who have failed or relapsed after receiving current therapeutic options, with top-line data expected in 2019. Rigosertib is also being evaluated in an expanded Phase 2 combination study with Azacitidine in MDS patients. Onconova recently signed a research collaboration agreement with the National Cancer Institute to study rigosertib in rare pediatric diseases. Rigosertib has been granted orphan drug designation for MDS in the United States and Europe. Onconova is partnered with SymBio Pharmaceuticals, Tokyo, for commercialization of rigosertib in Japan and Korea.

**About Pint Pharma**

PINT PHARMA INTERNATIONAL SA is a company registered under Swiss laws, having its registered office at Route de Chenaux 9, 1091 Bourg-en-Levaux, Switzerland, and is devoted to the development, registration, and commercialization of specialty based treatments. Pint Pharma benefits from leaders with extensive experience in the pharmaceutical sector and who are based strategically throughout Latin America and Europe. Pint Pharma has a long track record of developing strong relationships with global pharmaceutical and healthcare companies. Pint Pharma strives to be the first Pan-Latin American provider of innovative and high value-added treatments within Rare Diseases, Specialty Care, and Oncology.

About Onconova Therapeutics, Inc.

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company focused on discovering and developing novel small molecule drug candidates to treat cancer, with a primary focus on Myelodysplastic Syndromes (MDS). Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule agent, which the Company believes blocks cellular signaling by targeting RAS effector pathways. 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. Onconova has three product candidates in the clinical stage and several pre-clinical programs. 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. For more information, please visit http://www.onconova.com.

About IV Rigosertib

The intravenous form of rigosertib has been employed in Phase 1, 2, and 3 clinical trials involving more than 800 patients, and is currently being evaluated in a randomized Phase 3 international INSPIRE trial for patients with higher-risk MDS, after failure of hypomethylating agent, or HMA, therapy.

About INSPIRE

The **IN**ternational **S**tudy of **P**hase III **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 and derives from the findings of the ONTIME Phase 3 trial. INSPIRE is a multi-center, randomized controlled study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, failed to respond to, or relapsed after previous treatment with an

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HMA within the first 9 months or 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. Following interim analysis in early 2018, the independent Data Monitoring Committee recommended that the trial continue with an expansion in enrollment to 360 patients based on a pre-planned sample size re-estimation. Patients are randomized at a 2:1 ratio into two treatment arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival. 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 Oral Rigosertib**

The oral form of rigosertib was developed to provide more convenient dosing for use where the duration of treatment may extend to multiple years. This dosage form may also support many combination therapy modalities. To date, 368 patients have been treated with the oral formulation of rigosertib. Initial studies with single-agent oral rigosertib were conducted in hematological malignancies, lower-risk MDS, and solid tumors. Combination therapy of oral rigosertib with azacitidine and chemoradiotherapy has also been explored. Currently, oral rigosertib is being developed as a combination therapy together with azacitidine for patients with higher-risk MDS who require HMA therapy. A Phase 1/2 trial of the combination therapy has been fully enrolled and the preliminary results were presented in 2016. This novel combination is the subject of an issued US patent with earliest expiration in 2028.

**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 Therapeutics, Inc.'s expectations regarding the INSPIRE Trial and the transactions contemplated by the licensing agreement. 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. 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. 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, the need for additional financing and current plans and future needs to scale back operations if adequate financing is not obtained, 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.

**General Contact**

http://www.onconova.com/contact/
**Investor Relations Contact**

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**Exhibit 31.1**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Ramesh Kumar, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Onconova Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 15, 2018

/s/ Ramesh Kumar, Ph.D.
Ramesh Kumar, Ph.D.
President and Chief Executive Officer
*(Principal Executive and Principal Operating Officer)*

**Exhibit 31.2**

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mark Guerin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Onconova Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 15, 2018

/s/ Mark Guerin
Mark Guerin
Chief Financial Officer
*(Principal Financial Officer)*

**Exhibit 32.1**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**
**PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Onconova Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ramesh Kumar, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 15, 2018

/s/ Ramesh Kumar, Ph.D
Ramesh Kumar, Ph.D.
President and Chief Executive Officer (*Principal Executive and Principal Operating Officer* )

*The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.*

**Exhibit 32.2**

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER**
**PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Onconova Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Guerin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 15, 2018

/s/ Mark Guerin
Mark Guerin
Chief Financial Officer
*(Principal Financial Officer)*

*The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.*