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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

or

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

Commission File Number 001-36818

TRACON Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**34-2037594**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
8910 University Center Lane, Suite 700, San Diego CA	**92122**
(Address of principal executive offices)	**(Zip Code)**

(858) 550-0780
(Registrant's telephone number, including area code)

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. Yes ☒ 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒

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

The number of outstanding shares of the registrant's common stock as of November 4, 2016 was 13,065,971.

TRACON Pharmaceuticals, Inc.

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PART I FINANCIAL INFORMATION
Item 1. Financial Statements

TRACON Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 29,648	$ 41,373
Short-term investments	5,465	10,783
Prepaid and other assets	1,395	1,150
Total current assets	36,508	53,306
Property and equipment, net	106	173
Other assets	—	43
Total assets	$ 36,614	$ 53,522
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,697	$ 8,281
Accrued compensation and related expenses	1,188	1,163
Current portion of deferred revenue	1,749	3,353
Long-term debt, current portion	3,536	1,378
Total current liabilities	13,170	14,175
Other long-term liabilities	874	905
Long-term debt, less current portion	4,786	7,464
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.001 par value, authorized shares — 10,000,000 at September 30, 2016 and December 31, 2015; issued and outstanding shares—none	—	—
Common stock, $0.001 par value; authorized shares — 200,000,000 at September 30, 2016 and December 31, 2015; issued and outstanding shares — 13,056,253 and 12,175,942 at September 30, 2016 and December 31, 2015, respectively	13	12
Additional paid-in capital	97,055	89,556
Accumulated deficit	(79,284)	(58,590)
Total stockholders' equity	17,784	30,978
Total liabilities and stockholders' equity	$ 36,614	$ 53,522

See accompanying notes.

TRACON Pharmaceuticals, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Collaboration revenue	$ 815	$ 1,180	$ 2,832	$ 6,509
Operating expenses:				
Research and development	4,531	5,885	16,799	15,121
General and administrative	1,881	1,530	5,934	4,019
Total operating expenses	6,412	7,415	22,733	19,140
Loss from operations	(5,597)	(6,235)	(19,901)	(12,631)
Other income (expense):				
Interest expense, net	(287)	(221)	(871)	(701)
Other income (expense), net	13	9	78	(31)
Total other income (expense)	(274)	(212)	(793)	(732)
Net loss	(5,871)	(6,447)	(20,694)	(13,363)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	(31)
Net loss attributable to common stockholders	$ (5,871)	$ (6,447)	$ (20,694)	$ (13,394)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.48)	$ (0.53)	$ (1.70)	$ (1.24)
Weighted-average shares outstanding, basic and diluted	12,227,081	12,117,988	12,200,628	10,761,383

See accompanying notes.

TRACON Pharmaceuticals, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2016	**2015**
Cash flows from operating activities		
Net loss	$ (20,694)	$ (13,363)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,339	1,346
Depreciation and amortization	70	33
Amortization of debt discount	77	78
Amortization of premium/discount on short-term investments	4	2
Noncash interest	403	323
Change in fair value of preferred stock warrant liability	—	65
Deferred rent	(38)	(4)
Deferred revenue	(1,604)	(2,582)
Changes in assets and liabilities:		
Prepaid expenses and other assets	(128)	(1,487)
Accounts payable and accrued expenses	(1,619)	3,779
Accrued compensation and related expenses	25	165
Net cash used in operating activities	(21,165)	(11,645)
Cash flows from investing activities		
Purchase of property and equipment	(3)	(77)
Purchases of available-for-sale short-term investments	(8,802)	(10,505)
Proceeds from the maturity of available-for-sale short-term investments	14,117	—
Net cash provided by (used in) investing activities	5,312	(10,582)
Cash flows from financing activities		
Proceeds from long-term debt	—	8,000
Repayment of long-term debt	(1,000)	(9,930)
Proceeds from sale of common stock, net of offering costs paid in the current period	5,000	36,260
Proceeds from issuance of common stock under equity plans	128	49
Net cash provided by financing activities	4,128	34,379
(Decrease) increase in cash and cash equivalents	(11,725)	12,152
Cash and cash equivalents at beginning of period	41,373	35,000
Cash and cash equivalents at end of period	$ 29,648	$ 47,152

See accompanying notes.

1. Organization and Summary of Significant Accounting Policies

Organization and Business

TRACON Pharmaceuticals, Inc. (formerly Lexington Pharmaceuticals, Inc.) (TRACON or the Company) was incorporated in the state of Delaware on October 28, 2004. TRACON is a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration and fibrotic diseases. The Company's research focuses on antibodies that bind to the endoglin receptor, which is essential to angiogenesis (the process of new blood vessel formation) and a key contributor to fibrosis (tissue scarring).

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, TRACON Pharma Limited, which was formed in September 2015. All significant intercompany accounts and transactions have been eliminated.

Basis of Presentation

As of September 30, 2016, the Company has devoted substantially all of its efforts to product development, raising capital, and building infrastructure and has not realized revenues from its planned principal operations. The Company has incurred operating losses since inception. As of September 30, 2016, the Company had an accumulated deficit of $79.3 million. The Company anticipates that it will continue to incur net losses into the foreseeable future as it: (i) continues the development and commercialization of its product candidates; (ii) works to develop additional product candidates through research and development programs; and (iii) continues to expand its corporate infrastructure. At September 30, 2016, the Company had cash, cash equivalents and short-term investments of $35.1 million. Based on the Company's current business plan, management believes that existing cash, cash equivalents and short-term investments will be sufficient to fund the Company's obligations to the middle of 2017. The Company plans to continue to fund its losses from operations and capital funding needs through cash and investments on hand, as well as future debt and equity financing and potential collaboration arrangements. If the Company is not able to secure adequate additional funding, it may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or delay or reduce the scope of its planned development programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

Unaudited Interim Financial Information

The unaudited condensed consolidated financial statements at September 30, 2016, and for the three and nine months ended September 30, 2016 and 2015, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and with accounting principles generally accepted in the United States (GAAP) applicable to interim financial statements. These unaudited condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company's financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year or future periods. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ materially from those estimates. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2015, included in its Annual Report on Form 10-K filed with the SEC on February 19, 2016.

Use of Estimates

The Company's condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of the Company's condensed consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to revenue recognition and the valuation of equity awards. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less at the date of purchase. Cash and cash equivalents include cash in readily available checking and money market funds, as well as certificates of deposit.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Preferred Stock Warrant Liabilities

Prior to the completion of the Company's initial public offering in February 2015, the Company had outstanding freestanding warrants to purchase shares of its Series A redeemable convertible preferred stock. Since the underlying Series A redeemable convertible preferred stock was classified outside of permanent equity, these preferred stock warrants were classified as liabilities in the December 31, 2014 balance sheet. The Company adjusted the carrying value of such preferred stock warrants to their estimated fair value at each reporting date, with any related increases or decreases in the fair value recorded as an increase or decrease to other income (expense) in the statements of operations. Upon the completion of the Company's initial public offering, the warrants no longer required liability accounting and the then fair value of the warrant liability was reclassified into stockholders' equity.

The Company performed the final remeasurement of the warrant liability as of the initial public offering date and recorded the $65,000 change in fair value into other income (expense) for the nine months ended September 30, 2015.

Revenue Recognition

The Company's revenue is derived from its license agreement with Santen Pharmaceutical Co., Ltd. (Santen) as described in Note 7. The Company recognizes revenue when all four of the following criteria are met: (1) there is persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured. Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue.

The Company evaluates multiple-element arrangements to determine: (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. Deliverables are considered separate units of accounting provided that: (a) the delivered items have value to the customer on a standalone basis and (b) if the arrangement includes a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and substantially in the Company's control. In assessing whether an item has standalone value, the Company considers factors such as the research, manufacturing and commercialization capabilities of the partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the partner can use the other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items and whether there are other vendors that can provide the undelivered elements.

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. The Company uses the following hierarchy of values to estimate the selling price of each deliverable: (1) vendor-specific objective evidence of fair value; (2) third party evidence of selling price; and (3) best estimate of selling price (BESP). The BESP reflects the Company's best estimate of what the selling price would be if the Company regularly sold the deliverable on a standalone basis. In developing the BESP for a unit of accounting, the Company considers applicable market conditions and relevant entity-specific factors, including factors that are contemplated in negotiating an arrangement and estimated costs. The Company validates the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting.

The Company then applies the applicable revenue recognition criteria to each of the separate units of accounting in determining the appropriate period and pattern of recognition. If there is no discernible pattern of performance and/or objectively measurable performance measures do not exist, then the Company recognizes revenue under the arrangement on a straight-line basis over the period the Company expects to complete its performance obligations.

With respect to revenue derived from reimbursement of direct, out-of-pocket expenses for research and development costs associated with collaborations, where the Company acts as a principal with discretion to choose suppliers, bear credit risk, and

perform part of the services required in the transaction, the Company records revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the statements of operations.

Milestones

The Company uses the milestone method of accounting and revenue is recognized when earned, as evidenced by written acknowledgement from the collaborator or other persuasive evidence that the milestone has been achieved and the payment is non-refundable, provided that the milestone event is substantive. A milestone event is defined as an event: (1) that can only be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance; (2) for which there is substantive uncertainty at the inception of the arrangement that the event will be achieved; and (3) that would result in additional payments being due to the Company. Events for which the occurrence is either contingent solely upon the passage of time or the result of a counterparty's performance are not considered to be milestone events. A milestone event is substantive if all of the following conditions are met: (a) the consideration is commensurate with either the Company's performance to achieve the milestone, or the enhancement of the value to the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone; (b) the consideration relates solely to past performance; and (c) the consideration is reasonable relative to all the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

The Company assesses whether a milestone is substantive at the inception of each arrangement. If a milestone is deemed non-substantive, the Company will account for that milestone payment in accordance with the multiple element arrangements guidance and recognize it consistent with the related units of accounting for the arrangement over the related performance period.

Clinical Trial Expense Accruals

As part of the process of preparing the Company's financial statements, the Company is required to estimate expenses resulting from its obligations under contracts with vendors, contract research organizations (CROs), and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

The Company's objective is to reflect the appropriate trial expenses in its financial statements by recording those expenses in the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of completion of trials. During the course of a clinical trial, the Company adjusts the clinical expense recognition if actual results differ from its estimates. The Company makes estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The Company's clinical trial accruals are dependent upon accurate reporting by CROs and other third-party vendors. Although the Company does not expect its estimates to differ materially from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any particular period. For the three and nine months ended September 30, 2016 and 2015, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of employee stock option grants, employee restricted stock unit grants and employee stock purchase plan (ESPP) rights recognized as expense over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures. The Company estimates the fair value of stock option grants and ESPP rights using the Black-Scholes option pricing model.

The Company accounts for stock options granted to non-employees using the fair value approach. These option grants, if any, are subject to periodic revaluation over their vesting terms.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and comprehensive loss were the same for all periods presented.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average shares of common stock outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted-average number of common shares outstanding that are subject to repurchase. The Company has excluded 7,013 and 5,663 weighted-average shares subject to repurchase from the weighted-average number of common shares outstanding for the three and nine months ended September 30, 2016, respectively, and 6,301 and 6,818 weighted-average shares subject to repurchase for the three and nine months ended September 30, 2015, respectively. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Potentially outstanding dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	Nine Months Ended September 30,	
	2016	2015
Warrants to purchase common stock	57,173	53,490
Common stock options and restricted stock units	1,977,988	1,586,677
ESPP shares	3,079	3,931
	2,038,240	1,644,098

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which converges the FASB and the International Accounting Standards Board standard on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2017. The Company has not yet selected a transition method and is currently evaluating the impact that the adoption of ASU 2014-09 will have on its financial statements and related disclosures.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate relevant conditions, events and certain management plans that are known or reasonably knowable that when, considered in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management's plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. The Company is currently evaluating the impact that the adoption of ASU 2014-15 will have on its financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends ASC Topic 718, Compensation – Stock Compensation. ASU 2016-09 includes an update which simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 is effective for public entities for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. The Company is currently evaluating the impact that the adoption of ASU 2016-09 will have on its financial statements and related disclosures.

Recently Adopted Accounting Standards

In April 2015, the FASB issued ASU 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. ASU 2015-03 requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying value of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 was effective for interim and annual periods beginning on January 1, 2016. The Company applied the amended presentation requirements in the first quarter of 2016, which resulted in no change on its financial statements.

2. Short-Term Investments and Fair Value Measurements

At September 30, 2016, short-term investments consisted of certificates of deposit. The Company classifies all investments as available-for-sale, as the sale of such investments may be required prior to maturity to implement management strategies. These investments are carried at amortized cost which approximates fair value, with the unrealized gains and losses reported as a component of other comprehensive income in equity until realized. A decline in the market value of any short-term investment below cost that is determined to be other-than-temporary will result in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. No such impairment charges were recorded for any period presented.

Realized gains and losses from the sale of short-term investments, if any, are determined on a specific identification basis. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense on the consolidated statements of operations. Realized and unrealized gains and losses during the periods presented were immaterial. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method and are included in interest income on the consolidated statements of operations. Interest and dividends on securities classified as available-for-sale are included in interest income on the consolidated statements of operations. At September 30, 2016, the remaining contractual maturities of all available-for-sale investments were less than one year.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. No transfers between levels have occurred during the periods presented.

The fair values of the Company's assets and liabilities, which are measured at fair value on a recurring basis, were determined using the following inputs (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
At September 30, 2016				
Certificates of deposit and money market funds, included in Cash equivalents and Short-term investments	$ 12,055	$ —	$ 12,055	$ —
At December 31, 2015				
Certificates of deposit and money market funds, included in Cash equivalents and Short-term investments	$ 14,996	$ —	$ 14,996	$ —

The carrying amounts of cash and cash equivalents, prepaid and other assets, accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, which is considered a Level 2 input, the Company believes that the fair value of long-term debt approximates its carrying value.

3. Property and Equipment

Property and equipment consist of the following (in thousands):

	September 30, 2016	December 31, 2015
Computer and office equipment	$ 115	$ 112
Furniture and fixtures	19	19
Leasehold improvements	124	99
Construction in process	—	25
	258	255
Less accumulated depreciation and amortization	(152)	(82)
	$ 106	$ 173

Depreciation expense related to property and equipment totaled approximately $23,000 and $15,000 for the three months ended September 30, 2016 and 2015, respectively, and $70,000 and $33,000 for the nine months ended September 30, 2016 and 2015, respectively.

4. Long-Term Debt

Long-term debt and unamortized debt discount balances are as follows (in thousands):

	September 30, 2016	December 31, 2015
Long-term debt	$ 9,000	$ 10,000
Less debt discount, net of current portion	(214)	(536)
Long-term debt, net of debt discount	8,786	9,464
Less current portion of long-term debt	(4,000)	(2,000)
Long-term debt, net of current portion	$ 4,786	$ 7,464
Current portion of long-term debt	$ 4,000	$ 2,000
Current portion of debt discount	(464)	(622)
Current portion of long-term debt, net	$ 3,536	$ 1,378

In May 2015, the Company entered into an Amended and Restated Loan and Security Agreement with Silicon Valley Bank (the 2015 Amended SVB Loan) under which the Company could borrow up to $10.0 million. At December 31, 2015, the Company had borrowed the full $10.0 million available under the 2015 Amended SVB Loan, of which, borrowings of approximately $8.0 million were used to refinance amounts outstanding under the prior loan and security agreements (the SVB loan), which was first entered into in November 2013 (SVB Loan Agreement) and amended and restated in June 2014 (Amended SVB Loan Agreement). In connection with the 2015 Amended SVB Loan, the Company issued warrants to purchase up to 18,415 shares of common stock at an exercise price of $10.86 per share. The warrants are fully exercisable and expire on May 13, 2022. The transaction was accounted for as a debt modification.

The 2015 Amended SVB Loan provides for interest to be paid at a rate of 6.5% per annum. Interest-only payments were due monthly through June 2016. Thereafter, in addition to interest accrued during such period, the monthly payments include an amount equal to the outstanding principal at July 1, 2016 divided by 30 months. At maturity (or earlier prepayment), the Company is also required to make a final payment equal to 8.5% of the original principal amount of the amounts borrowed. The 2015 Amended SVB Loan provides for prepayment fees of 2.0% of the amount prepaid if the prepayment occurs prior to May 13, 2017 and 1.0% of the amount prepaid if the prepayment occurs thereafter.

The fair value of the warrants and the final payment related to the 2015 Amended SVB Loan were recorded as debt discounts and are being amortized to interest expense using the effective interest method over the term of the debt, in addition to the remaining unamortized discounts related to the SVB Loan and the Amended SVB Loan Agreements.

Consistent with the terms of the SVB Loan and the Amended SVB Loan Agreements, the 2015 Amended SVB Loan is collateralized by substantially all of the Company's assets, other than the Company's intellectual property, and contains customary conditions of borrowing, events of default and covenants, including covenants that restrict the Company's ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of the Company's capital stock. Should an event of default occur, including the occurrence of a material adverse change, the Company could be liable for immediate repayment of all obligations under the 2015 Amended SVB Loan.

In connection with the SVB Loan and the Amended SVB Loan, the Company issued warrants to purchase 37,500 shares and 112,500 shares of Series A redeemable convertible preferred stock, respectively, at an exercise price of $2.00 per share. The warrants are fully exercisable and expire on November 14, 2023 and June 4, 2024, respectively. The initial fair value of the warrants as of the November 2013 and June 2014 issuance dates was estimated to be $0.1 million and $0.2 million, respectively, based on the application of the Black-Scholes option pricing model, and these discounts are being amortized to interest expense using the effective interest method over the term of the debt. Upon completion of the Company's initial public offering in February 2015, the warrants became exercisable for an aggregate of 38,758 shares of common stock at an exercise price of $7.74 per share.

Future minimum principal and interest payments under the 2015 Amended SVB Loan, including the final payment, as of September 30, 2016 are as follows (in thousands):

Remaining 2016	$	1,142
2017		4,406
2018		4,993
		10,541
Less interest and final payment		(1,541)
Long-term debt	$	9,000

5. Commitments and Contingencies

License Agreements

The Company has entered into various license agreements pursuant to which the Company acquired licenses to certain intellectual property. The agreements generally required an upfront license fee and, in some cases, reimbursement of patent costs. Additionally, under each agreement, the Company may be required to pay annual maintenance fees, royalties, milestone payments and sublicensing fees. Each of the license agreements is generally cancelable by the Company, given appropriate prior written notice. At September 30, 2016, potential future milestone payments under these agreements totaled an aggregate of approximately $127.0 million.

6. Stockholders' Equity

Initial Public Offering and Related Transactions

In February 2015, the Company completed its initial public offering in which it sold 3,600,000 shares of common stock at an initial public offering price of $10.00 per share. In addition, a concurrent private placement to an existing stockholder was completed in which the Company sold 500,000 shares of common stock, also at $10.00 per share. Proceeds from the initial public offering and concurrent private placement, net of underwriting discounts, commissions and offering costs paid by us of approximately $6.0 million, were approximately $35.0 million.

In addition, in connection with the completion of the Company's initial public offering on February 4, 2015, all of the outstanding shares of redeemable convertible preferred stock were converted into 6,369,567 shares of the Company's common stock; outstanding warrants to purchase 150,000 shares of Series A redeemable convertible preferred stock were converted into warrants to purchase 38,758 shares of the Company's common stock, and the Company's certificate of incorporation was amended and restated to authorize 200,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock.

Redeemable Convertible Preferred Stock

Prior to its automatic conversion in the initial public offering, the Company classified its redeemable convertible preferred stock outside of permanent equity since such stock was contractually redeemable outside of the Company's control. As a result, the carrying value was increased to its redemption value by periodic accretion charges over the estimated redemption period. In the absence of retained earnings, these accretion charges were recorded against additional paid-in capital.

Sales of Common Stock

In September 2016, concurrent with its License and Option Agreement with Janssen Pharmaceutica N.V. (Janssen) and its affiliate, Johnson & Johnson Innovation-JJDC, Inc. (JJDC) (see Note 7), the Company issued and sold 840,022 shares of its common stock at a purchase price of $5.95 per share (determined by the average of the daily volume weighted average closing prices of the common stock as reported on NASDAQ for the five days prior to the date of the purchase) to JJDC for gross proceeds of $5.0 million. The Company also entered into an Investor Rights Agreement, pursuant to which the Company granted JJDC certain rights to require the Company to register the shares for resale under the Securities Act.

The Company issued zero and 9,300 shares of common stock upon the exercise of outstanding stock options during the three and nine months ended September 30, 2016, respectively, and issued 57,512 shares of common stock upon the exercise of outstanding stock options during the year ended December 31, 2015.

Stock-Based Compensation Expense

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Risk-free interest rate	—%	1.8	1.6%	1.7%
Expected volatility	—%	72	78%	73%
Expected term (in years)	—	6.2	6.3	6.2
Expected dividend yield	—%	—%	—%	—%

Stock compensation expense for the Employee Stock Purchase Plan was immaterial for the three and nine months ended September 30, 2016.

The allocation of stock-based compensation is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	$ 85	$ 295	$ 795	$ 677
General and administrative	453	377	1,544	669
	$ 538	$ 672	$ 2,339	$ 1,346

7. Collaborations

Santen

In March 2014, the Company entered into a license agreement with Santen, under which the Company granted Santen an exclusive, worldwide license to certain patents, information and know-how related to TRC105. Under the agreement, Santen is permitted to use, develop, manufacture and commercialize TRC105 products for ophthalmology indications, excluding systemic treatment of ocular tumors. Santen also has the right to grant sublicenses to affiliates and third party collaborators. In the event Santen sublicenses any of its rights under the agreement, Santen will be obligated to pay the Company a portion of any upfront and certain milestone payments received under such sublicense.

Santen has sole responsibility for funding, developing, seeking regulatory approval for and commercializing TRC105 products in the field of ophthalmology. In the event that Santen fails to meet certain commercial diligence obligations, the Company will have the option to co-promote TRC105 products in the field of ophthalmology in the United States with Santen. If the Company exercises this option, the Company will pay Santen a percentage of certain development expenses, and the Company will receive a percentage of profits from sales of the licensed products in the ophthalmology field in the United States, but will not receive royalties on such sales.

In consideration of the rights granted to Santen under the agreement, the Company received a one-time upfront fee of $10.0 million. The license agreement provides for various types of payments, including the upfront payment, payment for various technical and regulatory support, payments for delivery of drug substance, reimbursement of certain development costs, milestone payments, and royalties on net product sales. The Company has identified multiple deliverables, which include at inception: (1) a license to patents, information and know-how related to TRC105, (2) technology transfer, (3) collaboration, including technical and regulatory support provided by the Company, (4) manufacturing and supply obligations, and (5) shared chemistry, manufacturing and controls (CMC) development activities. Deliverables 1 and 2 above were substantially delivered at the inception of the agreement, and deliverables 3 through 5 are expected to be delivered during the estimated 40-month period over which the Company will provide technical and regulatory support to Santen. At inception and through September 30, 2016, the Company has identified one single unit of accounting for all the deliverables under the agreement since the delivered elements do not have standalone value. The Company's technical and regulatory expertise, including manufacturing and CMC activities, in the development of biologic therapeutics, specifically TRC105, is a significant component of Santen's ability to utilize the license and know-how related to TRC105. Given the early stage of development of TRC105 for ophthalmology, the Company is the only party capable of performing the level and type of

technical and regulatory collaboration services required by Santen under the agreement. As a result, the Company has determined that the license, including the ability to sublicense, and know-how related to TRC105 do not have standalone value to a licensee. As such, the Company is recognizing revenue for the fixed or determinable collaboration consideration on a straight-line basis over the estimated 40-month period over which it will deliver its technical and regulatory support.

During the nine months ended September 30, 2016, the expected term over which the Company will provide technical and regulatory support to Santen was extended from 31 to 40 months. The changes in the estimated term increased net loss by $0.8 million, or $0.06 per share, and $1.9 million, or $0.15 per share, for the three and nine months ended September 30, 2016, respectively.

In addition, the Company is eligible to receive up to a total of $155.0 million in milestone payments upon the achievement of certain milestones, of which $20.0 million relates to the initiation of certain development activities, $52.5 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals and $82.5 million relates to commercialization activities and the achievement of specified levels of product sales. The Company has determined that $10.0 million related to the initiation of certain clinical development activities will be based upon its efforts and meet the criteria of substantive milestones and therefore will be recognized as revenue upon achievement of the milestone in accordance with the milestone method of accounting. As of September 30, 2016, the Company had received a $3.0 million milestone payment related to development activities, revenue for which was recognized in the year ended December 31, 2015. The remaining $145.0 million of potential milestone payments are not substantive milestones as they do not require the efforts of the Company.

If TRC105 products are successfully commercialized in the field of ophthalmology, Santen will be required to pay the Company tiered royalties on net sales ranging from high single digits to low teens, depending on the volume of sales, subject to adjustments in certain circumstances. In addition, Santen will reimburse the Company for all royalties due by the Company under certain third party agreements with respect to the use, manufacture or commercialization of TRC105 products in the field of ophthalmology by Santen and its affiliates and sublicensees. Royalties will continue on a country-by-country basis through the later of the expiration of the Company's patent rights applicable to the TRC105 products in a given country or 12 years after the first commercial sale of the first TRC105 product commercially launched in such country.

Santen may unilaterally terminate this agreement in its entirety, or on a country-by-country basis, upon written notice to the Company. Either party may terminate the agreement in the event of the other party's bankruptcy or dissolution or for the other party's material breach of the agreement that remains uncured 90 days (or 30 days with respect to a payment breach) after receiving notice from the non-breaching party. Unless earlier terminated, the agreement continues in effect until the termination of Santen's payment obligations.

In connection with the collaboration with Santen, the Company recognized revenue of $0.8 million and $1.2 million for the three months ended September 30, 2016 and 2015, respectively, and $2.8 million and $6.5 million for the nine months ended September 30, 2016 and 2015, respectively. At September 30, 2016, deferred revenue totaled $1.7 million.

Janssen

In September 2016, the Company entered into a license and option agreement with Janssen (the License and Option Agreement) under which Janssen granted the Company a license to technology and intellectual property to develop, manufacture and commercialize two compounds: a small molecule inhibitor of androgen receptor and androgen receptor mutations (the AR Mutant Program or TRC253) which is intended for the treatment of men with prostate cancer, and an inhibitor of NF-kB inducing kinase (the NIK Program or TRC694, and, together with the AR Mutant Program, the Programs).

With respect to the AR Mutant Program, Janssen maintains an option, which is exercisable until 90 days after the Company demonstrates clinical proof of concept, to regain the rights to the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the AR Mutant Program. If Janssen exercises the option, Janssen will be obligated to pay the Company (i) a one-time option exercise fee of $45.0 million; (ii) regulatory and commercial based milestone payments totaling up to $137.5 million upon achievement of specified events; and (iii) royalties in the low single digits on annual net sales of AR Mutant Program products. If Janssen does not exercise the option, the Company would then have the right to retain worldwide development and commercialization rights to the AR Mutant Program, in which case, the Company would be obligated to pay to Janssen (x) development and regulatory based milestone payments totaling up to $45.0 million upon achievement of specified events, and (y) royalties in the low single digits based on annual net sales of AR Mutant Program products, subject to certain specified reductions.

With respect to the NIK Program, Janssen maintains a right, which is exercisable within 90 days following the date on which the Company demonstrates clinical proof of concept with respect to the NIK Program, to negotiate for a period of six months for a reversion of the related rights in the licensed intellectual property and to obtain an exclusive license to commercialize the compounds

and certain other specified intellectual property developed under the NIK Program. If Janssen does not exercise its right of first negotiation, or, if after exercise of such right, the Company and Janssen are unable to reach an agreement on the terms of a reversion and exclusive license, and, in either case, the Company continues the development of the NIK Program, then the Company would be obligated to pay Janssen (i) development and regulatory based milestone payments totaling up to $60.0 million upon achievement of specified events, and (ii) royalties in the low single digits based on annual net sales of NIK Program products, subject to certain specified reductions.

No consideration was exchanged for these assets on the acquisition date. Given the early preclinical stage of development of these assets and the low likelihood of success of development through regulatory approval, no value has been assigned to these assets in the accompanying balance sheet.

The Company is obligated to use diligent efforts to develop the Programs according to agreed upon development plans, timelines and budgets. For each Program that the Company retains, the Company is further obligated to use commercially reasonable efforts to develop, obtain marketing approval for, and commercialize licensed products. Until the expiration or earlier termination of the development term of the AR Mutant Program or the NIK Program, as applicable, under the License and Option Agreement, subject to specified exceptions, the Company has agreed not to research, develop or commercialize any compounds or products related to the AR Mutant Program or the NIK Program, as applicable, other than pursuant to the collaboration with Janssen.

The License and Option Agreement may be terminated for uncured breach, bankruptcy, or the failure or inability to demonstrate clinical proof of concept with respect to a particular Program during specified timeframes. In addition, the License and Option Agreement will automatically terminate (a) with respect to the AR Mutant Program, upon Janssen exercising its option in respect of the AR Mutant Program and making payment of the option exercise fee to the Company or, if Janssen does not exercise the option, upon the expiration of all payment obligations of the Company to Janssen with respect of the AR Mutant Program, and (b) with respect to the NIK Program, upon the Company and Janssen entering into an exclusive license agreement following Janssen's exercise of its right of first negotiation or, if Janssen's right of first negotiation with respect to the NIK Program expires and the Company and Janssen have not entered into an exclusive license agreement, upon the expiration of all payment obligations of the Company to Janssen with respect of the NIK Program. The Company may also terminate a Program or the Agreement in its entirety without cause, subject to specified conditions.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, timing of future events and future financial performance, includes forward-looking statements that are based upon current beliefs, plans and expectations and involve risks, uncertainties and assumptions. You should review the "Risk Factors" section of this Quarterly Report for a discussion of important factors that could cause our actual results and the timing of selected events to differ materially from those described in or implied by the forward-looking statements contained in this Quarterly Report. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this Report or to reflect actual outcomes.

Overview

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration, or wet AMD, and fibrotic diseases. We are a leader in the field of endoglin biology and are using our expertise to develop antibodies that bind to the endoglin receptor. Endoglin is essential to angiogenesis, the process of new blood vessel formation, and a key contributor to the development of fibrosis, or tissue scarring. Our lead product candidate, TRC105, is an endoglin antibody that is being developed for the treatment of multiple solid tumor types in combination with inhibitors of the vascular endothelial growth factor, or VEGF, pathway. The VEGF pathway regulates vascular development in the embryo, or vasculogenesis, and angiogenesis. TRC105 has been studied in seven completed Phase 2 clinical trials and three completed Phase 1 clinical trials, and is currently being dosed in five Phase 2 clinical trials. Our TRC105 oncology clinical development plan is broad and involves a tiered approach. We are initially focused on two orphan indications, angiosarcoma and gestational trophoblastic neoplasia, or GTN, both of which are tumors that highly express endoglin, the target of TRC105, and therefore may be more responsive to treatment with TRC105. We have seen complete ongoing responses in these tumor types and have initiated dosing in an international multicenter Phase 2 trial in GTN and plan to initiate initial Phase 3 development in angiosarcoma in December 2016 or early 2017. The proposed Phase 3 trial in angiosarcoma was recently reviewed by the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, at an End-of-Phase 2 meeting and protocol assistance meeting, respectively. The feedback from both Agencies was incorporated into the Phase 3 protocol. The protocol has been submitted for Special Protocol Assessment to the FDA and any further comments will also be incorporated. The next tier of development includes ongoing Phase 2 trials in renal cell carcinoma, which is a randomized trial, and hepatocellular carcinoma, that are expected to produce top-line data in 2017, and that, if positive, would also enable Phase 3 development. Additionally, we expect top-line data from a Phase 2 randomized trial in glioblastoma in late 2016 or early 2017. We consider these indications attractive because the endpoints for regulatory approval may be attained more quickly than the endpoints for other indications. We also expect that these initial indications would be for the same lines of treatment for which the companion VEGF inhibitor is approved. Finally, the third tier of development includes large indications including an ongoing Phase 1 trial in lung cancer and a Phase 1/2 trial in breast cancer. Positive data in these larger indications would enable further development.

During September 2016, we entered into a strategic licensing collaboration with Janssen Pharmaceutica N.V. (Janssen) for two novel oncology assets from Janssen's early oncology development portfolio. The agreement grants us the rights to develop TRC253 (formerly JNJ-63576253), a novel small molecule high affinity competitive inhibitor of wild type androgen receptor (AR) and multiple AR mutant receptors which display drug resistance to currently approved treatments, which is intended for the treatment of men with prostate cancer, and TRC694 (formerly JNJ-6420694), a novel, potent, orally bioavailable inhibitor of NF-kB inducing kinase (NIK), which is intended for the treatment of patients with hematologic malignancies, including myeloma.

TRC253 has completed IND-enabling studies and we expect to initiate a Phase 1/2 proof of concept, or POC, clinical study in the first half of 2017. Until 90 days after we complete the initial POC study, Janssen has an exclusive option to reacquire full rights to TRC253 for an upfront payment of $45.0 million to us, and obligations to make regulatory and commercialization milestone payments totaling up to $137.5 million upon achievement of specified events and a low single-digit royalty. If Janssen does not exercise its exclusive option to reacquire the program, we would then retain worldwide development and commercialization rights to the program, in which case we would be obligated to pay Janssen a total of up to $45.0 million in development and regulatory milestones upon achievement of specified events, in addition to a low single digit royalty.

TRC694 is currently in preclinical development and we expect to file an IND application in 2018, following completion of additional preclinical studies. Until 90 days after we complete the initial POC study, Janssen has a right of first negotiation to reacquire the program on terms to be negotiated between the parties. If Janssen does not exercise the negotiation right or the parties cannot agree to terms following negotiations, and if we elect to continue development of TRC694, we would be obligated to make development and regulatory milestone payments to Janssen totaling up to $60.0 million upon the achievement of specified events and a low single-digit royalty.

In addition, Johnson and Johnson Innovation – JJDC, Inc. made a $5.0 million equity investment in TRACON through the purchase of common stock at $5.95 per share (determined by the average of the daily volume weighted average closing prices of the common stock as reported on NASDAQ for the five days prior to the date of the purchase). We expect this funding to offset development expenses for TRC253 and TRC694 for at least the next 12 months.

During October 2016, at the European Society for Medical Oncology (ESMO) 2016 Congress, we reported updated results from a Phase 1b clinical trial combining TRC105 with Inlyta® (axitinib) in patients with advanced or metastatic renal cell carcinoma (RCC). Median progression free survival (PFS) of 11.3 months was observed in all RCC patients in the study, including those patients with clear cell RCC, the most prevalent form of RCC. An objective response rate (ORR) of 29% was also seen in the trial. For comparative purposes, median PFS observed in the large subgroup of VEGFR TKI-refractory patients treated with Inlyta (n=194) in the Inlyta AXIS Phase 3 study in second line clear cell RCC patients (a separate trial) was 4.8 months and ORR was 11.3%.

During October 2016, we announced the successful completion of the End-of-Phase 2 meeting process with both the FDA and the EMA. The FDA and the EMA separately determined the acceptability of the following key aspects of the proposed Phase 3 randomized trial comparing Votrient alone to a combination of Votrient (pazopanib) and TRC105 in angiosarcoma:

- Progression-free survival, or PFS, as the primary end-point; overall survival as a secondary endpoint;
- Adaptive design that allows for sample size reestimation to a maximum of 200 patients as well as enrichment of more responsive patients, based on an interim analysis, that we expect to occur in early 2018; and
- Open label format with independent blinded determination of endpoint.

The trial is designed to provide at least 80% power to determine an improvement in median PFS from 4.0 to 7.3 months using a two-tailed alpha of 0.05.

In June 2016, we presented updated data from the ascending dose portion of a Phase 2 clinical trial of TRC105 with Votrient in patients with advanced soft tissue sarcoma. The combination of TRC105 and Votrient demonstrated encouraging signs of activity in the five angiosarcoma patients enrolled in the first cohort of the Phase 1b/2 trial. All of these patients had radiographic tumor reductions, including two durable complete responses (CRs) by RECIST 1.1, and median PFS for the five angiosarcoma patients was greater than 12.9 months. For comparison, PFS was 3.0 months with no CRs in a previously completed study with single agent Votrient in 30 angiosarcoma patients and there were no complete responses in sarcoma patients treated with Votrient (n=246) in the Votrient PALETTE Phase 3 trial. Signs of clinical or radiologic activity were also observed in three of four patients enrolled in the trial's angiosarcoma expansion cohort and treated initially with TRC105 and Votrient. Endoglin expression on archival tumor tissue across all sarcoma subtypes treated in the study was not associated with improved PFS. Tumor heterogeneity, the long period of time between sampling and treatment, and the effects of tumor evolution resulting from prior treatment(s) may have limited the reliability of the archival tumor tissue used to accurately reflect tumor endoglin status at the time of initiation of TRC105 treatment. We plan to initiate a Phase 3 study in angiosarcoma in December 2016 or early 2017.

During May 2016, we received notice that the EMA granted TRC105 orphan drug designation for the treatment of patients with soft tissue sarcoma, including angiosarcoma. This designation complemented the orphan drug designation for TRC105 in soft tissue sarcoma received from the FDA in January 2016, and provides regulatory and financial incentives to develop and market therapies that treat rare diseases.

Our other product candidates include TRC205, an endoglin antibody that is in preclinical development for the treatment of fibrotic diseases, and TRC102, which is a small molecule that is in clinical development for the treatment of lung cancer and glioblastoma. In March 2014, Santen licensed from us exclusive worldwide rights to develop and commercialize our endoglin antibodies for ophthalmology indications.

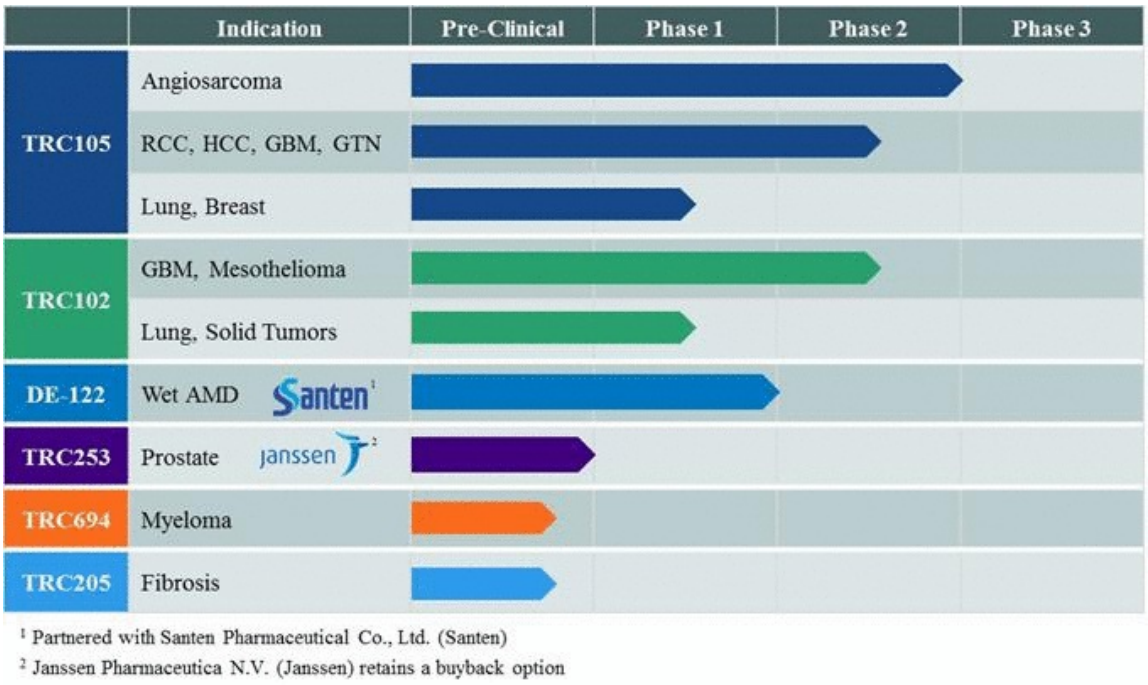
We completed certain preclinical studies of our endoglin antibodies in the first quarter of 2016, including TRC205, in three fibrosis models in mice: a model of chemically-induced liver fibrosis, a model of chemically induced pulmonary fibrosis, and a model of non-alcoholic steatohepatitis, or NASH. In each study, one or more endoglin antibodies achieved the primary endpoint of the study compared to control. In the NASH study, the clinical candidate TRC205 significantly reduced the Non-Alcoholic Fatty Liver Disease (NAFLD) Activity Score versus control, and reduced fibrotic gene expression without significantly reducing the fibrotic area by visual inspection. We will present data from two of these models in November 2016 at the annual meeting of the American Association for the Study of Liver Disease, or AASLD.

TRC102 is a small molecule in clinical development to reverse resistance to specific chemotherapeutics by inhibiting base-excision repair, or BER. In initial clinical trials of more than 100 patients, TRC102 has shown good tolerability and promising anti-tumor activity, in combination with alkylating and antimetabolite chemotherapy in the treatment of lung cancer and glioblastoma.

TRC102 began Phase 2 testing in mesothelioma in combination with the approved chemotherapeutic Alimta in 2015 and began Phase 2 testing in glioblastoma in combination with the approved chemotherapeutic Temodar in 2016. TRC102 is also being studied in three Phase 1 trials: in combination with Alimta and cisplatin in mesothelioma patients, in combination with chemoradiation in lung cancer patients, and in combination with Temodar in ovarian, lung and colorectal cancer patients. All current TR102 trials are sponsored by the National Cancer Institute, or NCI, and are funded by the NCI. We retain global rights to develop and commercialize TRC102 in all indications.

We have collaborated with NCI, which has selected TRC105 and TRC102 for federal funding of clinical development, as well as Case Western. Under these collaborations, NCI has sponsored or is sponsoring nine completed or ongoing clinical trials of TRC105 and TRC102, and Case Western sponsored two clinical trials of TRC102. We anticipate that NCI will complete ongoing Phase 2 clinical trials of TRC105 and may initiate other Phase 2 clinical trials in addition to the Phase 2 clinical trials of TRC105 that we are sponsoring. In addition, we expect that Phase 2 clinical trials of TRC102 will be completed with NCI funding. If merited by Phase 2 data, we expect to fund additional Phase 3 clinical trials of TRC105 in certain indications beyond angiosarcoma and initial Phase 3 clinical trials of TRC102 and, based on NCI's past course of conduct with similarly situated pharmaceutical companies in which it has sponsored pivotal clinical trials following receipt of positive Phase 2 data, we anticipate that NCI will sponsor Phase 3 clinical trials in additional indications.

The following chart summarizes our pipeline of product candidates:



[1] Partnered with Santen Pharmaceutical Co., Ltd. (Santen)

[2] Janssen Pharmaceutica N.V. (Janssen) retains a buyback option

The following table summarizes key information regarding ongoing and planned development of our product candidates:

	Phase	Data Expected
TRC105		
Planned trials:		
Angiosarcoma	Phase 3	Interim analysis first half 2018
Ongoing trials:		
Soft Tissue Sarcoma (including angiosarcoma)	Phase 2	Late 2016
Renal Cell Carcinoma	Randomized Phase 2	Mid 2017
Gestational Trophoblastic Neoplasia (GTN)	Phase 2	Preliminary data second half 2017
Glioblastoma	Randomized Phase 2	Late 2016 or early 2017
Hepatocellular Carcinoma	Phase 2	2017
Breast Cancer	Phase 1/2	2017
Lung Cancer	Phase 1	2017
Wet AMD (Santen) (DE-122)	Phase 1/2	2017
TRC102		
Ongoing trials:		
Mesothelioma	Phase 2	2017
Glioblastoma	Phase 2	2017
Solid tumors or Mesothelioma	Phase 1	2017
Solid tumors (Oral) and Lymphomas	Phase 1	2017
Lung Cancer	Phase 1	2017
TRC253		
Planned trials:		
Prostate Cancer	Phase 1/2	2018

Since our inception in 2004, we have devoted substantially all of our resources to research and development efforts relating to our product candidates, including conducting clinical trials and developing manufacturing capabilities, in-licensing related intellectual property, providing general and administrative support for these operations and protecting our intellectual property. We have not generated any revenue from product sales and, through December 31, 2014, had funded our operations primarily with the aggregate net proceeds of $79.1 million from the private placement of redeemable convertible preferred stock and common stock, a $10.0 million one-time upfront fee received in connection with our collaboration with Santen, and $10.0 million of commercial bank debt under our credit facility with SVB. In February 2015, we completed our initial public offering and a concurrent private placement and raised proceeds, net of underwriting discounts, commissions and offering costs of approximately $6.0 million, totaling approximately $35.0 million. At September 30, 2016, we had cash, cash equivalents and short-term investments totaling $35.1 million.

We have incurred losses from operations in each year since our inception. Our net losses were $24.4 million and $6.8 million for the years ended December 31, 2015 and 2014, respectively. At September 30, 2016, we had an accumulated deficit of $79.3 million.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will increase substantially in connection with our ongoing activities as we:

- continue to conduct clinical trials of our product candidates;
- continue our research and development efforts;
- manufacture preclinical study and clinical trial materials;
- maintain, expand and protect our intellectual property portfolio;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- hire additional staff, including clinical, operational, financial and technical personnel to execute on our business plan; and
- implement operational, financial and management systems.

We do not expect to generate any revenues from product sales until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory

approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to raise substantial additional capital. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our preclinical and clinical development efforts and the timing and nature of the regulatory approval process for our product candidates. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and ability to develop our product candidates.

Collaboration and License Agreements

Santen Pharmaceutical Co., Ltd.

In March 2014, we entered into a license agreement with Santen, under which we granted Santen an exclusive, worldwide license to certain patents, information and know-how related to TRC105, or the TRC105 Technology. Under the agreement, Santen is permitted to use, develop, manufacture and commercialize TRC105 products for ophthalmology indications, excluding systemic treatment of ocular tumors. Santen also has the right to grant sublicenses to affiliates and third party collaborators, provided such sublicenses are consistent with the terms of our agreement. Santen has sole responsibility for funding, developing, seeking regulatory approval for and commercializing TRC105 products in the field of ophthalmology.

In consideration of the rights granted to Santen under the agreement, we received a one-time upfront fee of $10.0 million. In addition, we are eligible to receive up to a total of $155.0 million in milestone payments upon the achievement of certain milestones, of which $20.0 million relates to the initiation of certain development activities, $52.5 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals and $82.5 million relates to commercialization activities and the achievement of specified levels of product sales. As of September 30, 2016, we had received $3.0 million in milestones related to development activities. If TRC105 products are successfully commercialized in the field of ophthalmology, Santen will be required to pay us tiered royalties on net sales ranging from high single digits to low teens, depending on the volume of sales, subject to adjustments in certain circumstances. In addition, Santen will reimburse us for all royalties due by us under certain third party agreements with respect to the use, manufacture or commercialization of TRC105 products in the field of ophthalmology by Santen and its affiliates and sublicensees. Royalties will continue on a country-by-country basis through the later of the expiration of our patent rights applicable to the TRC105 products in a given country or 12 years after the first commercial sale of the first TRC105 product commercially launched in such country.

Janssen Pharmaceutica N.V.

During September 2016, we entered into a strategic licensing collaboration with Janssen for two novel oncology assets from Janssen's early oncology development portfolio. The agreement grants us the rights to develop TRC253 (formerly JNJ-63576253), a novel small molecule high affinity competitive inhibitor of wild type androgen receptor (AR Mutant Program) and multiple AR mutant receptors which display drug resistance to approved treatments, which is intended for the treatment of men with prostate cancer, and TRC694 (formerly JNJ-6420694), a novel, potent, orally bioavailable inhibitor of NF-kB inducing kinase (the NIK Program and, together with the AR Mutant Program, the Programs), which is intended for the treatment of patients with hematologic malignancies, including myeloma.

Janssen maintains an option, which is exercisable until 90 days after we demonstrate clinical proof of concept with respect to the AR Mutant Program, to regain the rights to the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the AR Mutant Program. If Janssen exercises the option, Janssen will be obligated to pay us (i) a one-time option exercise fee of $45.0 million; (ii) regulatory and commercial based milestone payments totaling up to $137.5 million upon achievement of specified events; and (iii) royalties in the low single digits on annual net sales of AR Mutant Program products. If Janssen does not exercise the option, we would then have the right to retain worldwide development and commercialization rights to the AR Mutant Program, in which case, we would be obligated to pay to Janssen (x) development and regulatory based milestone payments totaling up to $45.0 million upon achievement of specified events, and (y) royalties in the low single digits based on annual net sales of AR Mutant Program products, subject to certain specified reductions.

With respect to the NIK Program, Janssen maintains a right, which is exercisable within 90 days following the date on which we demonstrate clinical proof of concept with respect to the NIK Program, to negotiate for a period of six months for a reversion of the related rights in the licensed intellectual property and to obtain an exclusive license to commercialize the compounds and certain other specified intellectual property developed under the NIK Program. If Janssen does not exercise its right of first negotiation, or, if after exercise of such right, Janssen and we are unable to reach an agreement on the terms of a reversion and exclusive license, and, in either case, we continue the development of the NIK Program, then we would be obligated to pay Janssen (i) development and

regulatory based milestone payments totaling up to $60.0 million upon achievement of specified events, and (ii) royalties in the low single digits based on annual net sales of NIK Program products, subject to certain specified reductions.

Financial Operations Overview

Revenue

Our revenue to date has been derived solely from our March 2014 collaboration with Santen. The terms of this arrangement contain multiple deliverables, which include at inception: (1) a license to patents, information and know-how related to TRC105; (2) technology transfer; (3) collaboration, including technical and regulatory support provided by us; (4) manufacturing and supply obligations; and (5) shared CMC development activities. The license agreement provides that we may receive various types of payments, including an upfront payment, payment for various technical and regulatory support, payments for delivery of drug substance, reimbursement of certain development costs, milestone payments, and royalties on net product sales. In accordance with our revenue recognition policy described in detail below, we have identified one single unit of accounting for all the deliverables under the agreement and are recognizing revenue for the fixed or determinable collaboration consideration on a straight-line basis over the estimated development period.

We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing of any future achievement of milestones, whether and when Janssen reacquires rights to the AR Mutant Program and/or NIK Program and the extent to which any of our products are approved and successfully commercialized by us or Santen. If we or Santen fail to develop product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenues, our results of operations and our financial position could be adversely affected.

Research and Development Expenses

Research and development expenses consist of costs associated with the preclinical and clinical development of our product candidates. These costs consist primarily of:

- costs to acquire, develop and manufacture preclinical study and clinical trial materials;
- salaries and employee-related expenses, including stock-based compensation and benefits for personnel in research and development functions;
- costs associated with conducting our preclinical, development and regulatory activities, including fees paid to third party professional consultants, service providers and our scientific advisory board;
- costs incurred under clinical trial agreements with investigative sites;
- payments related to licensed products and technologies; and
- facilities, depreciation and other expenses, including allocated expenses for rent and maintenance of facilities.

Research and development costs, including third party costs reimbursed by Santen as part of our collaboration, are expensed as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received.

The following table summarizes our research and development expenses by product candidate for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands)			
Third-party research and development expenses:				
TRC105	$ 2,944	$ 4,465	$ 11,487	$ 11,345
TRC253 & TRC694	197	-	197	-
TRC102	97	37	395	50
TRC205	29	65	71	208
Total third-party research and development expenses	3,267	4,567	12,150	11,603
Unallocated expenses	1,264	1,318	4,649	3,518
Total research and development expenses	$ 4,531	$ 5,885	$ 16,799	$ 15,121

Unallocated expenses consist of our internal personnel costs, facility costs and scientific advisory board related expenses.

We expect our current level of research and development expenses to continue to increase for the foreseeable future as we continue development of TRC105 in orphan indications, including initiating a Phase 3 clinical trial in angiosarcoma and a Phase 2 clinical trial in GTN, initiate manufacturing activities required for regulatory approval, and begin our development of our licensed compounds TRC253 and TRC694.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

The costs of clinical trials to us may vary significantly based on factors such as:

- the extent to which costs are borne by third parties such as NCI;
- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance and administration, corporate development and administrative support functions, including stock-based compensation expenses and benefits. Other significant general and administrative expenses include insurance, accounting and legal services, expenses associated with obtaining and maintaining patents, the cost of various consultants and occupancy costs.

We anticipate that our general and administrative expenses will remain relatively constant in the near term.

Other Income (Expense)

Other income (expense) primarily consists of interest related to our loan agreements with SVB offset by interest income from our short-term investments and cash equivalents.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on our historical experience and on 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 value of assets and liabilities that are not readily apparent

from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies Involving Management Estimates and Assumptions," included in our Annual Report on Form 10-K for the year ended December 31, 2015.

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which converges the FASB and the International Accounting Standards Board standard on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2017. We have not yet selected a transition method and are currently evaluating the impact that the adoption of ASU 2014-09 will have on our financial statements and related disclosures.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate relevant conditions, events and certain management plans that are known or reasonably knowable that when, considered in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management's plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. We are currently evaluating the impact that the adoption of ASU 2014-15 will have on our financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends ASC Topic 718, Compensation – Stock Compensation. ASU 2016-09 includes an update which simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 is effective for public entities for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. We are currently evaluating the impact that the adoption of ASU 2016-09 will have on our financial statements and related disclosures.

Recently Adopted Accounting Standards

In April 2015, the FASB issued ASU 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. ASU 2015-03 requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying value of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by ASU 2015-03. ASU 2015-03 was effective for interim and annual periods beginning on January 1, 2016. We applied the amended presentation requirements in the first quarter of 2016, which resulted in no change to our financial statements.

Results of Operations

Comparison of the Three Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the three months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		
	2016	2015	Change
	(in thousands)		
Collaboration revenue	$ 815	$ 1,180	$ (365)
Research and development expenses	4,531	5,885	(1,354)
General and administrative expenses	1,881	1,530	351
Other income (expense)	(274)	(212)	(62)

Collaboration revenue. Collaboration revenue, all of which resulted from our collaboration with Santen, was $0.8 million and $1.2 million for the three months ended September 30, 2016 and 2015, respectively. The decrease of $0.4 million was due to a change in the expected term over which we will provide technical and regulatory support to Santen.

Research and development expenses. Research and development expenses were $4.5 million and $5.9 million for the three months ended September 30, 2016 and 2015, respectively. The decrease of $1.4 million was due primarily to decreased TRC105 drug manufacturing expenses, offset by increased clinical study related expenses and expenses associated with acquiring TRC253 and TRC694.

General and administrative expenses. General and administrative expenses were $1.9 million and $1.5 million for the three months ended September 30, 2016 and 2015, respectively. The increase of $0.4 million was due primarily to increased compensation related expenses, including stock-based compensation expenses, due to increased headcount in 2016.

Other income (expense). Other income (expense) was ($0.3) million and ($0.2) million for the three months ended September 30, 2016 and 2015, respectively.

Comparison of the Nine Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,		
	2016	2015	Change
	(in thousands)		
Collaboration revenue	$ 2,832	$ 6,509	$ (3,677)
Research and development expenses	16,799	15,121	1,678
General and administrative expenses	5,934	4,019	1,915
Other income (expense)	(793)	(732)	(61)

Collaboration revenue. Collaboration revenue, all of which resulted from our collaboration with Santen, was $2.8 million and $6.5 million for the nine months ended September 30, 2016 and 2015, respectively. The decrease of $3.7 million was primarily due to the achievement of a development milestone by Santen in June 2015 in connection with our collaboration, which triggered a $3.0 million milestone payment.

Research and development expenses. Research and development expenses were $16.8 million and $15.1 million for the nine months ended September 30, 2016 and 2015, respectively. The increase of $1.7 million was due to increased clinical study related expenses, compensation related expenses, including stock-based compensation expenses, due to increased headcount, as well as increased preclinical expenses for TRC105 and expenses associated with acquiring TRC253 and TRC694, offset by decreased TRC105 drug manufacturing expenses.

General and administrative expenses. General and administrative expenses were $5.9 million and $4.0 million for the nine months ended September 30, 2016 and 2015, respectively. The increase of $1.9 million was due primarily to increased compensation related expenses, including stock-based compensation expenses, due to increased headcount in 2016.

Other income (expense). Other income (expense) was ($0.8) million and ($0.7) million for the nine months ended September 30, 2016 and 2015.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception. As of September 30, 2016, we had an accumulated deficit of $79.3 million, and we expect to continue to incur net losses for the foreseeable future. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may seek to obtain through one or more equity offerings, debt financings, government or other third party funding, and licensing or collaboration arrangements.

Credit Facility with SVB

In May 2015, we entered into an Amended and Restated Loan and Security Agreement with SVB (the 2015 Amended SVB Loan) under which we could borrow up to $10.0 million. At December 31, 2015, we had borrowed the full $10.0 million available, of which, borrowings of approximately $8.0 million were used to refinance amounts outstanding under the prior loan and security agreements. In connection with the 2015 Amended SVB Loan, we issued warrants to purchase up to 18,415 shares of common stock at an exercise price of $10.86 per share. The warrants are fully exercisable and expire on May 13, 2022.

The 2015 Amended SVB Loan provides for interest to be paid at a rate of 6.5% per annum. Interest-only payments were due monthly through June 2016. Thereafter, in addition to interest accrued during such period, the monthly payments include an amount equal to the outstanding principal at July 1, 2016 divided by 30 months. At maturity (or earlier prepayment), we are also required to make a final payment equal to 8.5% of the original principal amount of the amounts borrowed. The 2015 Amended SVB Loan provides for prepayment fees of 2.0% of the amount prepaid if the prepayment occurs prior to May 13, 2017 and 1.0% of the amount prepaid if the prepayment occurs thereafter.

The 2015 Amended SVB Loan is collateralized by substantially all of our assets, other than our intellectual property, and contains customary conditions of borrowing, events of default and covenants, including covenants that restrict our ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of our capital stock. Should an event of default occur, including the occurrence of a material adverse change, we could be required to immediately repay all obligations under the 2015 Amended SVB Loan.

ATM Facility

In February 2016, we entered into an At-the-Market Equity Offering Sales Agreement, or the Sales Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, pursuant to which we may sell from time to time, at our option, up to an aggregate of $25.0 million of our shares of our common stock through Stifel, as sales agent. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made on the Nasdaq Global Market under our effective registration statement on Form S-3, by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the Sales Agreement, we may also sell shares of our common stock through Stifel, on the Nasdaq Global Market or otherwise, at negotiated prices or at prices related to the prevailing market price. Stifel will use its commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We are obligated to pay Stifel an aggregate sales agent commission equal to up to 2.5% of the gross proceeds of the sales price for common stock sold under the Sales Agreement. As of September 30, 2016, no shares of our common stock have been sold under the Sales Agreement and the full $25.0 million of common stock remains available to be sold.

Cash Flows

The following table summarizes our net cash flow activity for each of the periods set forth below:

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (21,165)	$ (11,645)
Investing activities	5,312	(10,582)
Financing activities	4,128	34,379
(Decrease) increase in cash and cash equivalents	$ (11,725)	$ 12,152

Operating activities. Net cash used in operating activities was $21.2 million for the nine months ended September 30, 2016 and was primarily due to our net loss and changes in our working capital, offset by non-cash charges including stock-based compensation. Net cash used in operating activities was $11.6 million for the nine months ended September 30, 2015 and was primarily due to our net loss and changes in our working capital, offset by non-cash charges including stock-based compensation.

Investing activities. Net cash provided by investing activities was $5.3 million for the nine months ended September 30, 2016 and was primarily due to maturities of short-term investments, offset by purchases of these investments. Net cash used in investing activities was $10.6 million for the nine months ended September 30, 2015 and was primarily due to the purchase of short-term investments.

Financing activities. Net cash provided by financing activities was $4.1 million during the nine months ended September 30, 2016 and primarily resulted from $5.0 million in proceeds received from the sale of our common stock to JJDC, offset in part by $1.0 million in repayments under our SVB loan agreement. Net cash provided by financing activities was $34.4 million during the nine months ended September 30, 2015 and resulted from net proceeds received totaling approximately $36.3 million from our initial public offering and concurrent private placement received in the period, offset in part by $1.9 million in net repayments on borrowings under our SVB loan agreement.

Funding Requirements

At September 30, 2016, we had cash, cash equivalents and short-term investments totaling $35.1 million. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our anticipated cash requirements for our planned operations to the middle of 2017, which we expect will allow us to deliver top-line data in TRC105 randomized trials in glioblastoma and renal cell carcinoma. We will need additional funding to complete the development and commercialization of our product candidates, specifically our lead product candidate, TRC105, including to complete our planned Phase 2 trial in GTN and planned Phase 3 trial in angiosarcoma. In addition, we may evaluate in-licensing and acquisition opportunities to gain access to new product candidates that fit with our strategy. Any such transaction, including our strategic licensing transaction with Janssen, will likely increase our future funding requirements.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

- our ability to initiate, and the progress and results of, our planned clinical trials of TRC105;
- Santen's ability and willingness to continue clinical development of DE-122;
- our ability to enter into and maintain our collaborations, including our collaboration with Santen;
- our ability to achieve, and our obligations to make, milestone payments under our collaboration and license agreements;
- the costs and timing of procuring supplies of our product candidates for clinical trials and regulatory submissions;
- the scope, progress, results and costs of preclinical development, and clinical trials of our other product candidates;
- whether and when Janssen reacquires the rights to the AR Mutant Program and/or the NIK Program;
- the costs, timing and outcome of regulatory review of our product candidates;
- the revenue, if any, received from commercial sales of our product candidates for which we or any of our partners, including Santen, may receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval and do not partner for commercialization; and
- the extent to which we acquire or in-license other products and technologies.

Until we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and licensing arrangements.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the applicable rules of the Securities and Exchange Commission (the SEC).

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our cash and cash equivalents consist of cash, money market funds and certificates of deposit. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes. Our long-term debt bears interest at a fixed rate.

Foreign Currency Exchange Risk

We incur significant expenses for manufacturing of clinical trial materials outside the United States based on contractual obligations denominated in currencies other than the U.S. dollar, primarily Pounds Sterling. At the end of each reporting period, these liabilities are converted to U.S. dollars at the then-applicable foreign exchange rate. As a result, our business is affected by fluctuations in exchange rates between the U.S. dollar and foreign currencies. We do not enter into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks. Exchange rate fluctuations may adversely affect our

expenses, results of operations, financial position and cash flows. However, to date, these fluctuations have not been significant. Based on our purchase commitments for our 2016 fiscal year, a movement of 1% in the U.S. dollar to Pounds Sterling exchange rate would not have a material effect on our results of operations or financial condition.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations or financial condition during the periods presented.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit 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 us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of September 30, 2016, the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below with an asterisk (*) next to the title contain changes to the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred losses from operations since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability.*

We are a clinical stage company with limited operating history. All of our product candidates, including our most advanced product candidate, TRC105, will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have incurred losses from operations in each year since our inception, including net losses of $24.4 million and $6.8 million for the years ended December 31, 2015 and 2014, respectively. At September 30, 2016, we had an accumulated deficit of $79.3 million.

We expect to continue to incur substantial and increased expenses as we expand our development activities and advance our clinical programs, particularly with respect to our planned clinical development and manufacturing activities for TRC105.

To become and remain profitable, we or our partners must succeed in developing our product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we or our partners may obtain regulatory approval. We or they may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates or continue our operations.

We will require substantial additional financing to achieve our goals, and failure to obtain additional financing when needed could force us to delay, limit, reduce or terminate our drug development efforts.*

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs, including our planned and future clinical trials of TRC105.

At September 30, 2016, we had cash, cash equivalents and short-term investments totaling $35.1 million. Based upon our current operating plan, we believe that our existing cash will enable us to fund our operating expenses and capital requirements into the middle of 2017. We will need additional funding to complete the development and commercialization of our product candidates, specifically our lead product candidate, TRC105, including for the completion of our planned Phase 2 trial in GTN and planned Phase 3 trial in angiosarcoma. In addition, we recently licensed two early-stage oncology programs from Janssen Pharmaceutica N.V. (Janssen) and are subject to obligations to develop the programs through clinical proof of concept. While we concurrently received a $5.0 million equity investment from an affiliate of Janssen that will help fund the costs of the development activities, we anticipate that we will need additional funds to complete clinical proof of concept for the programs and, to the extent we retain the programs afterwards, to advance the programs through later stages of development.

Regardless of our expectations, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties or we could encounter difficulties obtaining clinical trial material that could increase our development costs more than we expect. In any event, we will require additional capital prior to completing Phase 3 development of, filing for regulatory approval for, or commercializing, TRC105 or any of our other product candidates.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development or commercialization of our product candidates or otherwise significantly curtail, or cease, operations. If we are unable to pursue or forced to delay our planned drug development efforts due to lack of financing, it would have a material adverse effect on our business, operating results and prospects.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

Our loan and security agreement with Silicon Valley Bank, or SVB, contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.

In May 2015, we entered into an amended loan and security agreement with SVB to borrow up to $10.0 million, $8.0 million of which was used to refinance amounts outstanding under prior credit facilities with SVB. The agreement, as amended, contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- convey, sell, lease or otherwise dispose of certain parts of our business or property;
- change the nature of our business;
- liquidate or dissolve;
- enter into certain change in control or acquisition transactions;
- incur or assume certain debt;
- grant certain types of liens on our assets;
- maintain certain collateral accounts;
- pay dividends or make certain distributions to our stockholders;
- make certain investments;
- enter into material transactions with affiliates;
- make or permit certain payments on subordinate debt; and
- become an “investment company” as defined under the Investment Company Act of 1940, as amended.

The restrictive covenants of the agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial.

A breach of any of these covenants could result in an event of default under the agreement. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, which could potentially include negative results in clinical trials, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the agreement occurs. In the case of a continuing event of default under the agreement, SVB could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted SVB a security interest under the

agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the agreement are secured by all of our existing and future assets, excluding intellectual property, which is subject to a negative pledge arrangement.

Risks Related to Clinical Development and Regulatory Approval of Our Product Candidates

We are heavily dependent on the success of our lead product candidate TRC105, which is in a later stage of development than our other product candidates. We cannot give any assurance that TRC105 will successfully complete clinical development or receive regulatory approval, which is necessary before it can be commercialized.

Our business and future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize our lead product candidate TRC105, which is currently in Phase 2 clinical trials for the treatment of multiple solid tumor types. Any delay or setback in the development of any of our product candidates, particularly TRC105, could adversely affect our business and cause our stock price to decline. We cannot assure you that our planned clinical development for TRC105 will be completed in a timely manner, or at all, or that we or our partner Santen or any additional future partners, will be able to obtain approval for TRC105 from the FDA or any foreign regulatory authority.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.*

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. For example, enrollment was closed for two of our Phase 2 clinical trials sponsored by NCI following interim analyses that did not meet the requirements for continuing enrollment. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials. In particular, the positive results observed in the Phase 1 and 2 clinical trials of TRC105 do not ensure that the ongoing or planned clinical trials of TRC105 will demonstrate similar results. In addition, further interim results or the final results from these trials could be negative.

Even if our product candidates demonstrate favorable results in ongoing or planned Phase 1 and 2 clinical trials, many product candidates fail to show desired safety and efficacy traits in late-stage clinical trials despite having progressed through earlier trials. In addition to the inherent safety and efficacy traits of our product candidates, clinical trial failures may result from a multitude of factors including flaws in trial design, manufacture of clinical trial material, dose selection and patient enrollment criteria. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or our partners may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval.

If TRC105 or any other product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be materially harmed. For example, if the results of ongoing or planned clinical trials of TRC105 demonstrate unexpected safety issues or do not achieve the primary efficacy endpoints, as applicable, the prospects for approval of TRC105 as well our stock price would be materially and adversely affected.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of our product candidates. Our ongoing and planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- adverse findings in toxicology studies, including chronic toxicology studies;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in recruiting suitable patients to participate in a trial;

- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers or other third parties to produce and deliver sufficient supply of clinical trial materials.

If initiation or completion of our ongoing or planned clinical trials are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize our product candidates could be materially harmed, which could have a material adverse effect on our business.

Our product candidates may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events, or AEs, caused by our product candidates or other potentially harmful characteristics of our product candidates could cause us, our partners, including NCI or other third party clinical trial sponsors, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval.

Phase 1 or Phase 2 clinical trials of TRC105 and TRC102 conducted to date have generated AEs related to the study drug, some of which have been serious. The most common AEs identified to date and related to TRC105 have been anemia, dilated small vessels in the skin and mucosal membranes (which may result in nosebleeds and bleeding of the gums), headache, fatigue and gastrointestinal and other symptoms during the initial infusion of TRC105. While we have not observed an exacerbation of side effects commonly associated with VEGF inhibitors in clinical trials of TRC105 in combination with a VEGF inhibitor, it is possible that future trials, including larger and lengthier Phase 3 clinical trials, may show this effect due to both drugs acting to inhibit angiogenesis simultaneously. Because our development and regulatory approval strategy for TRC105 is focused on combining TRC105 with VEGF inhibitors, if we encountered safety issues associated with combining TRC105 with VEGF inhibitors, it would be a significant setback for our development program and our ability to obtain regulatory approval for TRC105 may be adversely impacted. The most common AE identified in our clinical trials of TRC102 has been anemia.

Further, if any of our approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.*

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For example, we cannot guarantee that for certain oncology indications where the FDA has traditionally granted approval to therapies that can demonstrate progression-free survival, the agency will not later require us to demonstrate overall survival, which would greatly extend the time and increase the capital required to complete clinical development. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application, or BLA, or a New Drug Application, or NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve our validation methods for detecting TRC105 serum levels and antibodies to TRC105 and assessing TRC105 activity in a biologic release assay; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market TRC105 or our other product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates. For example, we anticipate that if we were to obtain regulatory approval for TRC105 in some or all of the initial oncology indications we are pursuing, we or our partners such as NCI would still need to conduct additional Phase 3 clinical trials in order to obtain approval for additional indications and expand TRC105's market potential. In addition, we believe that TRC105 may be most effective as a treatment of solid tumors, such as angiosarcoma and GTN, that express high levels of endoglin. We previously analyzed endoglin expression on archival tumor tissue across various sarcoma subtypes and did not find a correlation between endoglin expression and response to TRC105 treatment. We believe that this analysis may have limited utility due to tumor heterogeneity, the long period of time between sampling and treatment, and the effects of tumor evolution resulting from prior treatment. If we are unable to establish a correlation between endoglin expression and response to TRC105 treatment in subsequent analyses or to identify additional tumor types that express endoglin, our ability to successfully identify target patient populations for future clinical development or to expand TRC105's market potential may be limited.

We have not previously submitted a BLA or NDA, or any similar drug approval filing to the FDA or any comparable foreign authority for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

We may not receive Fast Track designation for additional product candidates from the FDA, or Fast Track designation may not actually lead to a faster development or regulatory review or approval process.

We received Fast Track designation for TRC105 in renal cell carcinoma in May 2015 and we intend to seek Fast Track designation or other appropriate expedited development options for our eligible product candidates in other indications. Fast track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in

addition to the potential for rolling review once a marketing application is filed. A new drug or biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for the disease or condition. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA will grant it. Despite our receipt of Fast Track designation for TRC105 in renal cell carcinoma, and even if additional product candidates receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may be unsuccessful in our efforts to obtain additional orphan drug designations from the FDA for our product candidates or may not ultimately realize the potential benefits of orphan drug designation.*

We received orphan drug designation for TRC105 in soft tissue sarcoma in 2016 in the US and EU and we intend to seek orphan drug designation for our eligible product candidates in other indications. We have applied for orphan drug designation in gestational trophoblastic neoplasia (GTN) and the FDA has requested additional information to further review our application. The FDA grants orphan designation to drugs that are intended to treat rare diseases with fewer than 200,000 patients in the United States or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Orphan drugs do not require prescription drug user fees with a marketing application, may qualify the drug development sponsor for certain tax credits, and may be eligible for a market exclusivity period of seven years. Despite our receipt of orphan drug designation for TRC105 in soft tissue sarcoma, we cannot guarantee that we will be able to receive orphan drug status from the FDA for any other product candidates or indications. If we are unable to secure orphan drug designation for additional product candidates or indications, our regulatory and commercial prospects may be negatively impacted.

Despite orphan drug exclusivity, the FDA can still approve another drug containing the same active ingredient and used for the same orphan indication if it determines that a subsequent drug is safer, more effective or makes a major contribution to patient care, and orphan exclusivity can be lost if the orphan drug manufacturer is unable to assure that a sufficient quantity of the orphan drug is available to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective. In addition, orphan drug exclusivity does not prevent the FDA from approving competing drugs for the same or similar indication containing a different active ingredient. If orphan drug exclusivity is lost and we were unable to successfully enforce any remaining patents covering our eligible product candidates, we could be subject to generic competition earlier than we anticipate. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as any of our product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as studies or trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we would intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any of our product candidates for which we receive regulatory approvals will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional

elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing, as well as continued compliance with regulatory requirements for current good manufacturing practices, or cGMPs, and current good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of existing approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Risks Related to Our Reliance on Third Parties

We depend in part on NCI and other third party sponsors to advance clinical development of TRC105 and TRC102.*

NCI is currently sponsoring and funding two ongoing clinical trials involving TRC105 and four clinical trials involving TRC102. The University of Alabama, Birmingham Cancer Center, or UAB, is also funding a trial with TRC105 in breast cancer. In addition, Case Western has sponsored and funded two separate clinical trials involving TRC102. The advancement of our product candidates depends in part on the continued sponsorship and funding of clinical trials by these organizations, as our resources and capital would not be sufficient to conduct these trials on our own. None of these third party sponsors are obligated to continue sponsorship or funding of any clinical trials involving our product candidates and could stop their support at any time. If these third party sponsors ceased their support for our product candidates, our ability to advance clinical development of our product candidates could be limited and we may not be able to pursue the number of different indications for our product candidates that are currently being pursued.

Even if these third party sponsors continue to sponsor and fund clinical trials of our product candidates, our reliance on their support subjects us to numerous risks. For example, we have limited control over the design or timing of their clinical trials and limited visibility into their day-to-day activities, including with respect to how they are providing and administering our product candidates. If there is a failure in a clinical trial sponsored by a third party sponsor due to poor design of the trial, errors in the way the clinical trial is executed or any other reason, or if the sponsor fails to comply with applicable regulatory requirements, it could represent a major set-back for the development and approval of our product candidates, even if we were not directly involved in the trial and even if the clinical trial failure was not related to the underlying safety or efficacy of the product candidate. In addition, these third party sponsors could decide to de-prioritize clinical development of our product candidates in relation to other projects, which could adversely affect the timing of further clinical development. We are also subject to various confidentiality obligations with respect to the clinical trials sponsored by third party sponsors, which could prevent us from disclosing current information about the progress or results from these trials until the applicable sponsor publicly discloses such information or permits us to do so. This may make it more difficult to evaluate our business and prospects at any given point in time and could also impair our ability to raise capital on our desired timelines.

We are dependent on our license agreement with Santen to develop and commercialize our endoglin antibodies, including DE-122, in the field of ophthalmology. The failure to maintain our agreement with Santen or the failure of Santen to perform its obligations under the agreement, could negatively impact our business.*

Pursuant to the terms of our license agreement with Santen, we granted Santen an exclusive, worldwide license to certain patents, information and know-how related to our endoglin antibodies, including TRC105, which is referred to by Santen as DE-122, for development and commercialization in ophthalmology indications, excluding systemic treatment of ocular tumors. Consequently, our ability to realize value or generate any revenues from our endoglin antibodies in the field of ophthalmology depends on Santen's willingness and ability to develop and obtain regulatory approvals for and successfully commercialize product candidates using our technology for these indications. We have limited control over the amount and timing of resources that Santen will dedicate to these efforts. In particular, we will not be entitled to receive additional milestone or royalty payments from Santen absent further development and eventual commercialization of endoglin antibodies in ophthalmology indications.

We are subject to a number of other risks associated with our dependence on our license agreement with Santen, including:

- Santen may not comply with applicable regulatory requirements with respect to developing or commercializing products under the license agreement, which could adversely impact development, regulatory approval and eventual commercialization of such products;
- we and Santen could disagree as to future development plans and Santen may delay initiation of clinical trials or stop a future clinical trial;
- there may be disputes between us and Santen, including disagreements regarding the terms of the license agreement, that may result in the delay of or failure to achieve development, regulatory and commercial objectives that would result in milestone or royalty payments to us, the delay or termination of any future development or commercialization of endoglin antibodies using our technology in the field of ophthalmology, and/or costly litigation or arbitration that diverts our management's attention and resources;
- Santen may not provide us with timely and accurate information regarding development progress and activities under the license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our endoglin antibodies, including TRC105, in non-ophthalmology indications;
- business combinations or significant changes in Santen's business strategy may adversely affect Santen's ability or willingness to perform its obligations under the license agreement;
- Santen may not properly maintain or defend our intellectual property rights in the field of ophthalmology or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation; and
- the royalties we are eligible to receive from Santen may be reduced or eliminated based upon Santen's and our ability to maintain or defend our intellectual property rights.

The license agreement is subject to early termination, including through Santen's right to terminate without cause upon advance notice to us. If the agreement is terminated early, we may not be able to find another collaborator for the commercialization and further development of our endoglin antibodies for ophthalmology indications on acceptable terms, or at all, and we may otherwise be unable to pursue continued development on our own for these indications.

To the extent we enter into additional agreements for the development and commercialization of our product candidates we would likely be similarly dependent on the performance of those third parties and subject to similar risks. For example, if Janssen exercises its option to reacquire rights to the AR mutant program that we are developing, we would be entitled to receive a pre-negotiated up-front fee from Janssen, but we would be dependent on Janssen to further develop the program in order to receive any further value in the form of milestone payments or royalties.

We may not be successful in establishing and maintaining additional collaborations, which could adversely affect our ability to develop and commercialize our product candidates.

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into additional out-licensing and collaboration agreements, including potentially with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as having the requisite potential to demonstrate safety and efficacy and as being economically valuable in light of the terms that we are seeking and other available products for licensing by other companies. Due to our existing license agreement with Santen, we may find it more difficult to secure additional collaborations for our endoglin antibodies if major biotechnology or pharmaceutical companies would

prefer to have exclusive control over development for all indications. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any inability or delay in entering into new collaboration agreements related to our product candidates, in particular in foreign countries where we do not have and do not intend to establish significant capabilities, could delay the development and commercialization of our product candidates and reduce their market potential.

We rely on third parties to conduct preclinical studies and clinical trials of our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We do not have our own capabilities to perform preclinical testing of our product candidates, and therefore rely entirely on third party contractors and laboratories to conduct these studies for us. In addition, while we intend to continue designing, monitoring and managing our domestic Phase 1 and Phase 2 clinical trials of our product candidates using our clinical operations and regulatory team, we still depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials at their sites under agreements with us. In addition, we expect that we will need to rely on third party contract research organizations, or CROs, to assist in monitoring, managing and otherwise carrying out any portion of our Phase 2 clinical trials, or any future Phase 3 clinical trials, that we sponsor at sites outside the United States. We will compete with many other companies for the resources of these third party contractors, laboratories, investigators, collaborators and CROs, and the initiation and completion of our preclinical studies and Phase 2 or future Phase 3 clinical trials may be delayed if we encounter difficulties in engaging these third parties or need to change service providers during a study or trial.

We control only certain aspects of the activities conducted for us by the third parties on which we currently rely and on which we will rely in the future for our preclinical studies and clinical trials. Nevertheless, we are responsible for ensuring that each of our clinical trials and certain of our preclinical studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. With respect to clinical trials, we and these third parties are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with product candidates produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state health care laws, including, among others, fraud and abuse, false claims, privacy and security, and physician payment transparency laws. Any third parties conducting our preclinical studies and clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical development programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our preclinical studies and clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines.

We rely on third party manufacturers to make our product candidates, and any failure by a third party manufacturer may delay or impair our ability to complete clinical trials or commercialize our product candidates.

Manufacturing drugs and biologics is complicated and is tightly regulated by regulatory authorities, including the FDA and foreign equivalents. We currently rely on third party manufacturers to supply us, as well as other parties conducting studies and trials of our product candidates, such as NCI, Case Western and Santen, with drug substance for preclinical and clinical trials. We also expect to continue to rely on third party manufacturers for any drug substance required for commercial supply, and do not intend to build our own manufacturing capability. Moreover, the market for contract manufacturing services for drug products, including biologics such as TRC105 and small molecules such as TRC253 and TRC694, is highly cyclical, with periods of relatively abundant

capacity alternating with periods in which there is little available capacity. If any need we have for contract manufacturing services increases during a period of industry-wide tight capacity, we may not be able to access the required capacity on a timely basis or on commercially viable terms, which could result in delays in initiating or completing clinical trials or our ability to apply for or receive regulatory approvals. In addition, we contract with fill and finishing providers with the appropriate expertise, facilities and scale to meet our needs.

Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is time consuming and subject to potential difficulties and delays. For example, we rely on Lonza Sales AG, or Lonza, to manufacture TRC105 drug substance for our on-going and planned clinical trials and separately license from Lonza its proprietary cell line and other methods of producing TRC105 drug substance. While we have the right to transfer the manufacture of TRC105 drug substance to additional or alternate suppliers and to sublicense Lonza's TRC105 manufacturing technology to such other suppliers, we may encounter delays in any such transfer due to the time and effort required for another party to understand and successfully implement Lonza's proprietary process. We are currently optimizing the process and transferring the manufacturing of TRC105 drug substance to a separate Lonza facility in order to meet cGMP regulatory requirements and scale production for commercial quantities. This new process and transfer may result in setbacks in replicating the current manufacturing process at a new facility and in scaling up production. In particular, for biologics, it is not uncommon to experience setbacks and delays in scaling up production in a reliable and contamination-free manner, which may delay our ability to obtain regulatory approval or may result in higher costs to manufacture commercial drug product than we currently expect. In addition, we do not have any long-term supply agreements for the manufacture of our product candidates and cannot guarantee that Lonza or any other third party manufacturer would be willing to continue supplying drug product for clinical trials or commercial sale at a reasonable cost or at all.

The facilities used by our current or future third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA or an NDA to the FDA. While we work closely with our third party manufacturers on the manufacturing process for our product candidates, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our third party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both drug substances and finished drug products. If our third party manufacturers cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or other third party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies which could do harm to our business and affect our ability to be profitable. In particular, our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. Additionally, we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Any disclosure or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in our market.

The patent position of biotechnology companies is generally uncertain because it involves complex legal and factual considerations in a legal framework that is constantly evolving. The standards applied by the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. There is a substantial amount of prior art in the biotechnology and pharmaceutical fields, including scientific publications, patents and patent applications. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for

our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If patent applications we hold or have in-licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us. Several patent applications covering our product candidates have been filed recently. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidate that we may develop. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate.

For applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the claims of our applications and patents. As of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to "first- to-file" from "first-to-invent" is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear, what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. Furthermore, due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all our product candidates or methods involving these product candidates in the parent patent application.

In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords is limited. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic and biosimilar products.

Any loss of patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products.

We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely impact our business and operations.*

As of October 26, 2016, we are the exclusive licensee of seven issued U.S. patents and four pending U.S. patent applications and ten issued non-U.S patents and four pending non-U.S. patent applications relating to "Anti-Endoglin Monoclonal Antibodies and their use in Antiangiogenic Therapy," "Method For Increasing the Efficacy of Anti-Tumor Agents by Anti-Endoglin Antibody," "Methoxyamine Potentiation of Temozolomide Anti-Cancer Activity," "Methoxyamine Combinations in the Treatment of Cancer," "Alkylating Agent Combinations in the Treatment of Cancer" and "Combination Therapy of Cancer with Anti-Endoglin Antibodies and Anti-VEGF Agents." We are also the exclusive licensee of pending applications, which have not yet published, related to the product candidates TRC253 and TRC694.

As a licensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our

licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

Third party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination and review proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we and our partners are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates, that we failed to identify. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our product candidates or methods of use of our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use or manufacture of our product candidates.

The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also, in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

If any third party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we or our partner obtain a license. These licenses may not be available on acceptable terms, if at all. Even if we or our partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we or our partner could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our partner are unable to enter into licenses on acceptable terms.

Parties making claims against us or our partner may obtain injunctive or other equitable relief, which could effectively block our or our partner's ability to further develop and commercialize one or more of our product candidates. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Third parties may submit applications for patent term extensions in the United States and/or supplementary protection certificates in the European Union member states seeking to extend certain patent protection which, if approved, may interfere with or delay the launch of one or more of our products.

We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages.

During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

We may become involved in lawsuits to protect or enforce our inventions, patents or other intellectual property or the patent of our licensors, which could be expensive and time consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. In addition, one or more of our third party collaborators may have submitted, or may in the future submit, a patent application to the USPTO without naming a lawful inventor that developed the subject matter in whole or in part while under an obligation to execute an assignment of rights to us. As a result, we may be required to file infringement or inventorship claims to stop third party infringement, unauthorized use, or to correct inventorship. This can be expensive, particularly for a company of our size, and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation or other proceedings brought at the USPTO or any foreign patent authority may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or collaborators, to prevent misappropriation of our trade secrets, confidential information or proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

We have in-licensed a portion of our intellectual property, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.*

We are a party to a number of license agreements that are important to our business, and we may enter into additional license agreements in the future. Our product candidate TRC105 is protected by patents exclusively in-licensed from Roswell Park Cancer Institute. Our product candidate TRC102 is protected by patents exclusively licensed from Case Western. Our product candidates TRC253 and TRC694 and associated intellectual property have been licensed from Janssen.

Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment or diligence obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our and our partner's ability to utilize the affected intellectual property in our drug development efforts, and our ability to enter into collaboration or marketing agreements for a product candidate, may be adversely affected.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our development processes that involve proprietary know-how or information that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business.

Risks Related to Commercialization of Our Product Candidates

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors and others in the medical community.

The use of endoglin antibodies as a means of inhibiting angiogenesis, including in combination with VEGF inhibitors for the treatment of cancer, is a recent clinical development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, third party payors and others in the medical community. Factors that will influence whether our product candidates are accepted in the market include:

- the clinical indications for which our product candidates are approved, if any;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by governmental and commercial third party payors;
- the willingness of patients to pay out-of-pocket in the absence of coverage by governmental and commercial third party payors;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, we expect that in oncology indications, TRC105 will be most effective as a combination treatment with VEGF inhibitors. If VEGF inhibitors become associated with presently unknown safety concerns, are withdrawn from the market or otherwise fall out of favor as cancer treatments among physicians, patients, hospitals, cancer treatment centers or others in the medical community, the market potential for TRC105 would likely be significantly harmed.

If, for any of these or other reasons, our product candidates fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

We face competition both in the United States and internationally, including from major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, other pharmaceutical and biotechnology companies, including Pfizer, Inc. and Acceleron Pharma Inc., have active programs to develop therapies targeting proteins in the endoglin pathway that would compete directly with certain of our product candidates, including TRC105. Many other companies are developing other cancer therapies that, if successful, could change the standard of care for cancer patients and relegate anti-angiogenesis therapy to a last-line or niche role or make it obsolete.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

Under the terms of our license agreement with Case Western, we obtained an exclusive, worldwide license to certain patents, know-how and other intellectual property controlled by Case Western related to TRC102. Despite our exclusive license, Case Western retained the right to grant non-exclusive licenses to third parties in the same field of use as our exclusive license as a means to settle any intellectual property disputes Case Western may have in the future with such third parties. While Case Western has not made us aware of any present intent to exercise this right, there can be no guarantee that Case Western will not do so in the future or that it would not grant such an non-exclusive license to a competitor of ours seeking to develop and commercialize a product that is identical to TRC102 in the same field of use that we are pursuing. If this were to occur, and we did not have other intellectual property outside of the Case Western license agreement to prevent competitive products for the same indications, we may face competition much earlier than we currently anticipate and the value of TRC102 may decline substantially.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from "biosimilars" due to the changing regulatory environment. In the United States, the Biologics Price Competition and Innovation Act created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or "biosimilar," to or "interchangeable" with an FDA-approved biological product. This new pathway could allow competitors to reference data from biological products already approved after 12 years from the time of approval. Future FDA standards or criteria for determining biosimilarity and interchangeability, and FDA discretion to determine the nature and extent of product characterization, non-clinical testing and clinical testing on a product-by-product basis, may further facilitate the approval of biosimilar products and their ability to compete with our product candidates. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Any such event or further changes in the law could decrease the period for which we have exclusivity and consequently negatively impact our business and competitive position. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired.

Finally, as a result of the expiration or successful challenge of our patent rights, we could face litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third party payors. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and other third party payors, such as commercial health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third party payor may depend upon a number of factors, including, but not limited to, the third party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Obtaining coverage and reimbursement approval of a product from a government or other third party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data to each payor separately for the use of our products, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of coverage and adequate reimbursement from third party payors for our product candidates.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

Third party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, was enacted. The Affordable Care Act and its implementing regulations, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, including our product candidates, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain market acceptance in the medical community;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although we intend to establish a specialty sales and marketing organization to promote or co-promote TRC105 and/or TRC102 in North America, if approved in oncology indications, we currently have no such organization or capabilities, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, we must build sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services.

In addition, we do not intend to establish our own sales and marketing organizations outside the United States and will therefore depend on third parties to commercialize our product candidates outside of the United States. Any third parties upon which we rely for commercializing our product candidates may not dedicate sufficient resources to the commercialization effort or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective third party arrangements to enable the sale of our product candidates in territories outside of the United States, or if our potential future partners do not successfully commercialize our product candidates in these territories, our ability to generate revenue from product sales will be adversely affected.

If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all, when we are otherwise ready and able to commercially launch a product candidate. If we do not have sufficient funds, we will not be able to bring any product candidates to market or generate product revenue, including in the United States.

We and any partners that we may engage will be competing with many companies that currently have extensive and well-funded marketing and sales operations to commercialize alternative therapies. If we, alone or with commercialization partners, are unable to compete successfully against these established companies, the commercial success of any approved products will be limited.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If TRC105 or other product candidates are approved for commercialization, we expect that we or our partners will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If we or our partners outside of the Unites States are unable to successfully manage these risks associated with international operations, the market potential for our product candidates outside the Unites States will be limited and our results of operations may be harmed.

Risks Related to Our Business and Industry

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.*

We do not have internal new drug discovery capabilities or a technology platform with which to develop novel product candidates. Unless we develop or acquire these capabilities or a technology platform, our only means of expanding our product pipeline will be to acquire or in-license product candidates that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring or licensing promising product candidates requires substantial technical, financial and human resources. Efforts to do so may not result in the actual development, acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. With respect to TRC253, Janssen has an option to reacquire the intellectual property rights to the program on pre-negotiated terms until a certain period of time following the completion of clinical proof of concept. If Janssen exercises this right, while we would be entitled to receive an up-front payment and would have the opportunity to receive future milestone and royalty payments from Janssen, we would have no further rights to develop, commercialize or realize value from TRC253. In addition, Janssen has an option to negotiate with us to reacquire rights to TRC694 following the completion of clinical proof of concept, which may or may not result in an out-license of the product candidate back to

Janssen. If we are unable to retain existing product candidates and add additional product candidates to our pipeline, our long-term business and prospects will be limited.

If we fail to attract and keep senior management and key clinical operations and regulatory personnel, we may be unable to successfully develop our product candidates and execute our business strategy.

We are highly dependent on members of our senior management, including Charles Theuer, M.D., Ph.D., our President and Chief Executive Officer. Our clinical development strategy and ability to directly manage or oversee our on-going and planned clinical trials are also dependent on the members of our clinical operations and regulatory team. The loss of the services of any of these persons could impede the development of our product candidates and our ability to execute our business strategy. We may be particularly impacted by the unexpected loss of employees due to our small employee base and limited ability to quickly shift responsibilities to other employees in our organization. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining other qualified employees for our business, including scientific, quality assurance and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense, particularly in the San Diego, California area, and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our development and strategic objectives.

Our employees, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate:

- FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA;
- manufacturing standards;
- federal and state fraud and abuse laws and other healthcare laws;
- laws governing the conduct of business abroad; or
- laws that require the reporting of true and accurate financial information or data.

Additionally, these parties may fail to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with additional third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with partners, consultants, suppliers and other third parties. Future growth will impose significant added responsibilities on members of our management, including having to divert a disproportionate amount of its attention away from day-to-day operating activities to implement and manage future growth. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and,

if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

We are subject to extensive federal and state regulation, and our failure to comply with these laws could harm our business.

Although we do not currently have any products on the market, we are subject to healthcare regulation and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal anti-kickback statute, which applies to our business activities, including our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or in return for the purchase or recommendation of any good, facility item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other governmental healthcare programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which created federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes certain regulatory and contractual requirements on covered entities and their business associates regarding the privacy, security and transmission of individually identifiable health information;
- federal "sunshine" requirements imposed by the Affordable Care Act, on certain drug manufacturers regarding any transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by such physicians and their immediate family members; and
- state or foreign law equivalents of each of the above federal laws that may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

It is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened certain of these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them to have committed a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, administrative, civil and/or criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We currently carry product liability insurance covering our clinical trials with limits we believe are customary for other companies in our field and stage of development. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

If our third party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States and abroad governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability, including through obligations to indemnify our third party manufacturers, or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our development and production efforts or those of our third party manufacturers, which could harm our business, prospects, financial condition or results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2015, we had federal and California net operating loss carryforwards, or NOLs, of approximately $42.9 million and $22.9 million, respectively, which expire in various years beginning in 2030, if not utilized. As of December 31, 2015, we had federal and California research and development tax credit carryforwards of approximately $1.7 million and $0.7 million, respectively. The federal research and development tax credit carryforwards expire in various years beginning in 2031, if not utilized. The California research and development credit will carry forward indefinitely under current law. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We believe we have experienced certain ownership changes in the past and have reduced our deferred tax assets related to NOLs and research and development tax credit carryforwards accordingly. In the event that it is determined that we have in the past experienced additional ownership changes, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we

earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our current or future contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, third parties that are also sponsoring clinical trials involving our product candidates, such as NCI and Case Western, could experience similar events relating to their computer systems, which could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. In addition, NCI may be affected by government shutdowns or withdrawn funding, which may lead to suspension or termination of ongoing NCI-sponsored clinical development of our product candidates. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. In addition, our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of our third party manufacturers, including Lonza, are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters are located in San Diego, California near major earthquake faults and fire zones. The ultimate impact on us and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Risks Related to Our Common Stock

The market price of our common stock may be highly volatile, and our stockholders may not be able to resell their shares at a desired market price and could lose all or part of their investment.

Prior to our initial public offering which was completed in 2015, there was no public market for our common stock. We cannot assure you that an active, liquid trading market for our shares will develop or persist. Our stockholders may not be able to sell their shares quickly or at a recently reported market price if trading in our common stock is not active. The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in clinical trials;
- inability to obtain additional funding;
- any delay in filing a BLA or an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that BLA or NDA;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our product candidates;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;

- announcements of significant acquisitions, collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future, in particular any sales by significant stockholders or our affiliates; and
- trading volume of our common stock.

In addition, the stock market in general, and the Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.*

As of September 30, 2016, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially owned approximately 50% of our voting stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.*

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this Quarterly Report and our other periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

We completed our initial public offering on February 4, 2015. As a newly public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. For example, as a public company, we are now subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. We have incurred and will continue to incur costs associated with the preparation and filing of these reports. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC, and the Nasdaq Global Market have imposed various other requirements on public companies, and we have incurred and will continue to incur costs associated with compliance with such requirements. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we incur substantial costs to maintain our current levels of such coverage.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Additionally, our credit agreement with SVB contains covenants that restrict our ability to pay dividends. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES

Recent Sales of Unregistered Securities

Set forth below is information regarding securities issued by us during the three months ended September 30, 2016 that were not registered under the Securities Act of 1933, as amended, or Securities Act. Also included is the information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

Between July 1 and September 30, 2016 we issued 12,335 shares of common stock upon execution of a consulting agreement. No underwriters were involved in the foregoing issuance of securities. The shares of common stock are subject to forfeiture on a pro-rata basis if the consulting agreement and related consulting obligation is terminated within one year of the agreement. The securities described above were issued in reliance on the exemptions from registration provided by Section 4(2) of the Securities Act and/or Rule 506 of Regulation D promulgated under the Securities Act. The purchaser in this transaction represented to us in connection with its purchase that it was acquiring the securities for investment and not for distribution and that it could bear the risks of the investment. The purchaser received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from registration.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation, as currently in effect.
3.2(1)	Amended and Restated Bylaws, as currently in effect.
4.1(2)	Form of Common Stock Certificate of the Registrant.
4.2(2)	Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated September 19, 2014.
4.3	Investor Agreement By and Between Johnson & Johnson Innovation-JJDC, Inc. and TRACON Pharmaceuticals, Inc., dated September 27, 2016.
10.1*	License and Option Agreement By and Between Janssen Pharmaceutica N.V. and TRACON Pharmaceuticals, Inc., dated September 27, 2016.
10.2	Stock Purchase Agreement By and Between Johnson & Johnson-JJDC, Inc. and TRACON Pharmaceuticals, Inc., dated September 27, 2016.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label 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 SEC.

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on February 4, 2015.

(2) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-201280), as amended.

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.

TRACON Pharmaceuticals, Inc.

Date: November 8, 2016

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer
(principal executive officer)

Date: November 8, 2016

/s/ Patricia L. Bitar, C.P.A.
Patricia L. Bitar, C.P.A.
Chief Financial Officer
(principal financial and accounting officer)

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31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label 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 SEC.

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on February 4, 2015.

(2) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-201280), as amended.

Exhibit 4.3

INVESTOR AGREEMENT

By and Between

JOHNSON & JOHNSON INNOVATION-JJDC, INC.

AND

TRACON PHARMACEUTICALS, INC.

Dated as of September 27, 2016

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INVESTOR AGREEMENT

THIS INVESTOR AGREEMENT (this "**Agreement**") is made as of September 27, 2016, by and among Johnson & Johnson Innovation-JJDC, Inc., a New Jersey corporation ("**Investor**"), with its principal place of business at 410 George Street, New Brunswick, New Jersey 08901 and TRACON Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), with its principal place of business at 8910 University Center Lane, Suite 700, San Diego, California 92122.

WHEREAS, the Stock Purchase Agreement, dated as of the date hereof, by and between the Investor and the Company (the "**Purchase Agreement**") provides for the issuance and sale by the Company to the Investor, and the purchase by the Investor, of a number of shares (such shares, the "**Purchased Shares**") of the Company's common stock, par value $0.001 per share (the "**Common Stock**"); and

WHEREAS, as a condition to consummating the transactions contemplated by the Purchase Agreement, the Investor and the Company have agreed upon certain rights and restrictions as set forth herein with respect to the Purchased Shares and other securities of the Company beneficially owned by the Investor and its Affiliates, and it is a condition to the closing under the Purchase Agreement that this Agreement be executed and delivered by the Investor and the Company.

NOW, THEREFORE, in consideration of the promises and mutual agreements hereinafter set forth, and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Definitions. As used in this Agreement, the following terms shall have the following meanings:

(a) "**Affiliate**" shall mean, with respect to any Person, another Person that controls, is controlled by or is under common control with such Person; provided that with respect to the Investor, "Affiliate" shall mean only the Investor's subsidiaries that are wholly-owned directly or indirectly, by the Investor and any Person that wholly-owns, directly or indirectly, the Investor; provided further, that with respect to the Investor, the term "Affiliate" shall not include any employee benefit plan of the Investor. 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 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 Investor 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 Investor or any of its Affiliates.

(b) "**Agreement**" shall have the meaning set forth in the Preamble to this Agreement, including all Exhibits attached hereto.

(c) "**Beneficial owner**," "**beneficially owns**," "**beneficial ownership**" and terms of similar import used in this Agreement shall, with respect to a Person, have the meaning set forth in Rule 13d-3 under the Exchange Act (i) assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents beneficially owned by such Person and (ii) determined without regard for the number of days in which such Person has the right to acquire such beneficial ownership.

(d) "**Business Day**" shall mean a weekday on which banking institutions in the United States are generally open for business.

(e) "**Change of Control**" shall occur if: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of the Company, or if the percentage ownership of such person or entity in the voting securities of the Company is increased through stock redemption, cancellation or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than fifty percent (50%) of the total voting power of all of the then outstanding voting securities of the Company; (b) a merger, consolidation, recapitalization, or reorganization of the Company is consummated, other than any such transaction, which would result in stockholders or equity holders of the Company immediately prior to such transaction, owning at least fifty percent (50%) of the outstanding securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the stockholders or equity holders of the Company approve a plan of complete liquidation of the Company, or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets, other than pursuant to the transaction described above or to an Affiliate; (d) individuals who, as of the date hereof, constitute the Board of Directors of the Company (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the Board of Directors of the Company (provided, however, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election by the Company's shareholders, was recommended or approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board of Directors of the Company); or (e) the sale or transfer to a Third Party of all or substantially all of the Company's assets taken as a whole is effected.

(f) "**Closing Date**" shall have the meaning set forth in the Purchase Agreement.

(g) "**Common Stock**" shall have the meaning set forth in the Preamble to this Agreement.

(h) "**Common Stock Equivalents**" shall mean any options, warrants or other securities or rights convertible into or exercisable or exchangeable for, whether directly or

following conversion into or exercise or exchange for other options, warrants or other securities or rights, shares of Common Stock or any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of, or voting or other rights of, the Common Stock.

(i) "**Company**" shall have the meaning set forth in the Preamble to this Agreement.

(j) "**Demand Request**" shall have the meaning set forth in Section 2.1.

(k) "**Disposition**" or "**Dispose of**" shall mean any (i) pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Common Stock, or any Common Stock Equivalents, including, without limitation, any "short sale" or similar arrangement, or (ii) swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

(l) "**Exchange Act**" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC promulgated thereunder.

(m) "**Filing Date**" shall mean (i) with respect to any Registration Statement to be filed on Form S-1 (or any applicable successor form), sixty (60) days after receipt by the Company of a Demand Request for such Registration Statement and (ii) with respect to any Registration Statement to be filed on Form S-3 (or any applicable successor form), fifteen (15) Business Days after receipt by the Company of a Demand Request for such Registration Statement.

(n) "**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.

(o) "**Holders**" shall mean (but, in each case, only to the extent such Person holds Registrable Securities) the Investor and any Permitted Transferee thereof, if any, in accordance with Section 2.13.

(p) "**Initiating Holders**" shall have the meaning set forth in Section 2.4.

(q) "**Interference**" shall have the meaning set forth in Section 2.6.

(r) "**Investor**" shall have the meaning set forth in the Preamble to this Agreement.

(s) "**Law**" or "**Laws**" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

(t) "**License Agreement**" shall mean that certain License and Option Agreement, of even date herewith, between an Affiliate of the Investor and the Company.

(u) "**Lock-Up Securities**" shall have the meaning set forth in Section 4.1.

(v) "**Lock-Up Term**" shall mean the period from and after the date of this Agreement until the occurrence of any event set forth in Section 5.3.

(w) "**Modified Clause**" shall have the meaning set forth in Section 6.7.

(x) "**Permitted Transferee**" shall mean (i) a controlled Affiliate of the Investor that is wholly owned, directly or indirectly, by the Investor, or (ii) a controlling Affiliate of the Investor (or any controlled Affiliate of such controlling Affiliate) that wholly owns, directly or indirectly, the Investor, or the acquiring Person in the case of a Change of Control of the Investor; it being understood that for purposes of this definition "wholly owned" shall mean an Affiliate in which the Investor owns, or an Affiliate that owns, as applicable, directly or indirectly, at least ninety-nine percent (99%) of the outstanding capital stock of such Affiliate or the Investor, as applicable.

(y) "**Person**" shall mean any individual, limited liability company, partnership, firm, corporation, association, 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.

(z) "**Prospectus**" shall mean the prospectus forming a part of any Registration Statement, as supplemented by any and all prospectus supplements and as amended by any and all amendments (including post-effective amendments) and including all material incorporated by reference or explicitly deemed to be incorporated by reference in such prospectus.

(aa) "**Purchase Agreement**" shall have the meaning set forth in the Preamble to this Agreement, and shall include all Exhibits attached thereto.

(bb) "**Purchased Shares**" shall have the meaning set forth in the Preamble to this Agreement, and shall be adjusted for (i) any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the Purchased Shares.

(cc) "**registers**," "**registered**," and "**registration**" refer to a registration effected by preparing and filing a Registration Statement or similar document in compliance with the Securities Act, and the declaration or ordering of effectiveness of such Registration Statement or document by the SEC.

(dd) "**Registrable Securities**" shall mean (i) the Purchased Shares, together with any shares of Common Stock issued in respect thereof as a result of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security

that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the shares of Common Stock described in clause (i) of this definition, excluding in all cases, however, (A) any Registrable Securities if and after they have been transferred to a Permitted Transferee in a transaction in connection with which registration rights granted hereunder are not assigned, (B) any Registrable Securities sold to or through a broker or dealer or underwriter in a public distribution or a public securities transaction, or (C) any Registrable Securities eligible for resale pursuant to Rule 144(b)(1) under the Securities Act.

(ee) "**Registration Expenses**" shall mean all expenses incurred by the Company in connection with any Required Registration pursuant to Section 2.1 or Company's compliance with Section 2.8, including, without limitation, all registration and filing fees, fees and expenses of the Company to comply with securities or blue sky Laws (including reasonable fees and disbursements of counsel to the Company in connection with blue sky qualifications) or any Registrable Securities), expenses of printing (i) certificates for any Registrable Securities in a form eligible for deposit with the Depository Trust Company or (ii) Prospectuses if the printing of Prospectuses is reasonably requested by Holders, messenger and delivery expenses, fees and disbursements of counsel for the Company and its independent certified public accountants (including the expenses of any management review, cold comfort letters or any special audits required by or incident to such performance and compliance), Securities Act liability insurance (if the Company elects to obtain such insurance), the reasonable fees and expenses of any special experts retained by the Company in connection with such registration, fees and expenses of other Persons retained by the Company and the reasonable fees and expenses (such fees and expenses not to exceed $25,000) of one (1) counsel for the Holders of Registrable Securities in each Required Registration, selected by the Holders of a majority of the Registrable Securities to be included in such Required Registration, related to the preparation, filing and effectiveness of the related Registration Statement. In addition, the Company will pay its internal expenses (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), the expense of any annual audit and the fees and expenses incurred in connection with the listing of the Purchased Shares to be registered on each securities exchange, if any, on which the Common Stock is then listed or the quotation of the Purchased Shares to be registered on any national securities exchange on which the Common Stock is then quoted.

(ff) "**Registration Notice**" shall have the meaning set forth in Section 2.3(a).

(gg) "**Registration Notice Period**" shall have the meaning set forth in Section 2.3(a).

(hh) "**Registration Rights Term**" shall mean the period from and after the expiration of the Lock-Up Term until the occurrence of any event set forth in Section 5.1.

(ii) "**Registration Statement**" shall mean any registration statement filed by the Company under the Securities Act pursuant to the provisions of this Agreement that covers the resale of any of the Registrable Securities, including the related Prospectus, all amendments and supplements to such registration statement (including post-effective amendments), and all exhibits and all materials incorporated by reference or explicitly deemed to be incorporated by reference in such Registration Statement.

(jj) "**Required Period**" with respect to a Required Registration shall mean the earlier of (i) the date on which all Registrable Securities covered by such Required Registration are sold pursuant thereto and (ii) ninety (90) days following the first day of effectiveness of the Registration Statement for such Required Registration, in each case subject to extension as set forth herein; provided, however, that in no event will the Required Period expire prior to the expiration of the applicable period referred to in Section 4(3) of the Securities Act and Rule 174 promulgated thereunder; provided, further, however, that (i) such ninety (90) day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Stock (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such ninety (90) day period shall be extended, if necessary, to keep the Registration Statement effective until the earlier of (A) such time as all such Registrable Securities registered on such Registration Statement are sold, (B) all such Registrable Securities on such Registration Statement no longer qualify as Registrable Securities, or (C) three (3) years after the effective date of such Registration Statement.

(kk) "**Required Registration**" shall have the meaning set forth in Section 2.1.

(ll) "**SEC**" shall mean the United States Securities and Exchange Commission.

(mm) "**Securities Act**" shall mean the Securities Act of 1933, as amended, and the rules and regulations of the SEC promulgated thereunder.

(nn) "**Selling Expenses**" shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities pursuant to this Agreement.

(oo) "**Shares of Then Outstanding Common Stock**" shall mean, at the time of determination, the issued and outstanding shares of Common Stock at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend or reclassification of Common Stock distributable (without any further action by the Company's board of directors or stockholders), on a pro rata basis, to all holders of Common Stock.

(pp) "**Shelf Registration Statement**" shall have the meaning set forth in Section 2.1.

(qq) "**Standstill Parties**" shall have the meaning set forth in Section 3.1.

(rr) "**Standstill Term**" shall mean the period from and after the date of this Agreement until the occurrence of any event set forth in Section 5.2.

(ss) "**Third Party**" shall mean any Person (other than a Governmental Authority) other than the Investor, the Company or any of their respective Affiliates.

(tt) "**Underwritten Offering**" shall mean a registered offering in which Registrable Securities are sold to an underwriter for reoffering to the public.

(uu) "**Violation**" shall have the meaning set forth in Section 2.11(a).

2. Registration Rights.

2.1. Required Registration. If, during the Registration Rights Term (or prior to the Registration Rights Term in the event the filing of a Registration Statement will not occur or be required to occur until the Registration Rights Term has begun), the Company receives from any Holder or Holders holding a majority of the then-outstanding Registrable Securities a written request or requests (each, a "**Demand Request**") that the Company file a Registration Statement under the Securities Act to effect the registration (a "**Required Registration**") of Registrable Securities for resale, the Company shall use reasonable efforts to file a Registration Statement covering such Holders' Registrable Securities for resale as soon as practicable (and by the applicable Filing Date) and shall use reasonable efforts to, as soon as practicable thereafter, effect the registration of the Registrable Securities to permit or facilitate the sale and distribution (including by way of an Underwritten Offering; a delayed or continuous offering or a shelf registration statement (a "**Shelf Registration Statement**") pursuant to Rule 415 of the Securities Act; or other customary means reasonable requested by the applicable Holders) of all or such portion of such Holder's or Holders' Registrable Securities as are specified in such Demand Request, subject however, to the conditions and limitations set forth herein; provided, however, that the Company shall not be obligated to effect any registration of Registrable Securities upon receipt of a Demand Request pursuant to this Section 2.1 if:

(a) the Company has already completed two (2) Required Registrations;

(b) a Registration Statement registering all Registrable Securities subject to such Demand Request is already effective or was previously declared effective and kept effective for the Required Period;

(c) the Company furnishes to the Holders a certificate signed by an authorized officer of the Company stating that (i) within sixty (60) days of receipt of the Demand Request under this Section 2.1, the Company expects to file a registration statement for the public offering of securities for the account of the Company (other than a registration of securities (x) issuable pursuant to an employee stock option, stock purchase or similar plan, (y) issuable pursuant to a merger, exchange offer or a transaction of the type specified in Rule 145(a) under the Securities Act or (z) in which the only securities being registered are securities issuable upon conversion of debt securities which are also being registered), provided, that the Company is actively employing good faith efforts to cause such registration statement to become effective, or (ii) the Company is engaged in a material transaction or has an undisclosed material corporate development, in either case, which would be required to be disclosed in the Registration Statement, and in the good faith judgment of the Company's Chief Executive Officer, such disclosure would be materially detrimental to the Company and its stockholders at such time (in which case, the Company shall disclose the matter as promptly as practicable after such conditions no longer exist and thereafter file the Registration Statement, and each Holder agrees not to disclose any information about such material transaction to Third Parties until such disclosure has occurred or such information has entered the public domain other than through breach of any confidentiality obligation by such Holder); provided, however, that the Company

shall have the right to defer the filing of the Registration Statement pursuant to this subsection for a period of more than ninety (90) days in the aggregate during any twelve-month period;

(d) the Company has, within the twelve (12) month period preceding the date of the Demand Request, already effected one (1) Required Registration for any Holder pursuant to this Section 2.1;

(e) the Company is prohibited from filing a Registration Statement because of contractual obligations owed to an underwriter participating in an offering of securities by the Company; provided, however, that the Company shall have the right to defer the filing of the Registration Statement pursuant to this subsection for no more than the lesser of ninety (90) days from the date of the Demand Request or the Business Day after the date such contractual prohibition lapses; or

(f) at any time during the period between the Company's receipt of the Demand Request and the completion of the Required Registration, any Holder is in breach of or has failed to cause its Affiliates to comply with the obligations and restrictions of Sections 3 or 4 of this Agreement, the Company has provided notice of such breach to a Holder and such breach or failure is ongoing and has not been remedied; it being understood that (i) a one-time, inadvertent and de minimis breach of Section 4 shall not be deemed to be a breach of the obligations and restrictions under Section 4 for purposes of this Section 2.1(d) and (ii) an inadvertent and de minimis breach of Section 3.1(a) hereof, or an inadvertent breach of Section 3.1(g) hereof arising solely from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (f) of Section 3.1, shall not be deemed to be a breach of the obligations and restrictions under Section 3.1 for purposes of this Section 2.1(d).

2.2. [Reserved].

2.3. [Reserved].

2.4. [Reserved].

2.5. Revocation of Required Registration. With respect to one (1) Required Registration only, the Holders of at least a majority of the Registrable Securities to be included in a Registration Statement with respect to such Required Registration may, at any time prior to the effective date of such Registration Statement, on behalf of all Holders of all Registrable Securities requested to be included therein, revoke the request to have Registrable Securities included therein and revoke the request for such Required Registration by providing a written notice to the Company, in which case such Required Registration that has been revoked will be deemed not to have been effected and will not count as a Required Registration for purposes of Section 2.1 (i) if, and only if, the Holders of Registrable Securities which had requested inclusion of Registrable Securities in such Required Registration promptly reimburse the Company for all Registration Expenses incurred by the Company in connection with such Required Registration. Notwithstanding the foregoing sentence, the parties agree and acknowledge that the Holders of a majority of the Registrable Securities requested to be included in such Required Registration, may revoke any Required Registration (without any obligation to reimburse the Company for

Registration Expenses incurred in connection therewith) if such revocation is based on (i) a material adverse change in circumstances with respect to the Company and its subsidiaries, taken as a whole, caused by an act or failure to act by the Company or any of its subsidiaries and not known to any Holder at the time the Required Registration was first made or (ii) the Company's failure to comply in any material respect with its obligations hereunder and any such revocation based on an event described in (i) or (ii) shall be exercisable at any time prior to the effective date of the applicable Registration Statement and shall not be counted as the one (1) revocation of a Required Registration permitted by the first sentence of this Section 2.5.

2.6. Effective Required Registrations. A Required Registration will not be deemed to be effected for purposes of Section 2.1(a) if the Registration Statement for such Required Registration has (a) not been declared effective by the SEC or (b) become effective in accordance with the Securities Act and the rules and regulations thereunder and not been kept effective for the Required Period. In addition, if after such Registration Statement has been declared or becomes effective, (i) the offering of Registrable Securities pursuant to such Registration Statement is interfered with by any stop order, injunction, or other order or requirement of the SEC or other governmental agency or court such that the continued offer and sale of Registrable Securities being offered pursuant to such Registration Statement would violate applicable Law and such stop order, injunction or other order or requirement of the SEC or other governmental agency or court does not result from any act or omission of any Holder whose Registrable Securities are registered pursuant to such Registration Statement (an "**Interference**") and (ii) any such Interference is not cured within ninety (90) days thereof, such Required Registration will be deemed not to have been effected and will not count as a Required Registration. In the event such Interference occurs and is cured, the Required Period relating to such Registration Statement will be extended by the number of days of such Interference, including the date such Interference is cured.

2.7. Continuous Effectiveness of Registration Statement. The Company will use reasonable efforts to cause each Registration Statement filed pursuant to this Section 2 to be declared effective by the SEC or to become effective under the Securities Act as promptly as practicable and to keep each such Registration Statement that has been declared or becomes effective continuously effective for the Required Period.

2.8. Obligations of the Company. Whenever required under Section 2.1 to effect the registration of any Registrable Securities, the Company shall, as promptly as practicable:

(a) prepare and file with the SEC a Registration Statement with respect to such Registrable Securities sought to be included therein; provided that at least five (5) Business Days prior to filing any Registration Statement or Prospectus or any amendments or supplements thereto, the Company shall furnish to the Holders of the Registrable Securities covered by such Registration Statement, their counsel and any managing underwriter copies of all such documents proposed to be filed, and any such Holder shall have the opportunity to comment on any information pertaining solely to such Holder and its plan of distribution that is contained therein and the Company shall make the corrections reasonably requested by such Holder or the managing underwriter with respect to such information prior to filing any such Registration Statement or amendment;

(b) prepare and file with the SEC such amendments and post-effective amendments to any Registration Statement and any Prospectus used in connection therewith as may be necessary to keep such Registration Statement effective for the Required Period, and cause the Prospectus to be supplemented by any required prospectus supplement, and as so supplemented to be filed pursuant to Rule 424 under the Securities Act, to comply with the provisions of the Securities Act with respect to the disposition of all Registrable Securities covered by such registration statement for the Required Period; provided that at least five (5) Business Days prior to filing any such amendments and post-effective amendments or supplements thereto that modify any information pertaining solely to such Holder and its plan of distribution, the Company shall furnish to the Holders of the Registrable Securities covered by such Registration Statement, their counsel and the managing underwriter copies of all such documents proposed to be filed, and any such Holder or managing underwriter shall have the opportunity to comment on any information pertaining solely to such Holder and its plan of distribution that is contained therein and the Company shall make the corrections reasonably requested by such Holder and the managing underwriter with respect to such information prior to filing any such amendment, post-effective amendment or supplement to any such Registration Statement;

(c) furnish to the Holders of Registrable Securities covered by such Registration Statement and any managing underwriter such numbers of copies of such Registration Statement, each amendment and supplement thereto, the Prospectus included in such Registration Statement (including each preliminary prospectus or free writing prospectus prepared by the Company) in conformity with the requirements of the Securities Act, and such other documents as they may reasonably request in order to facilitate the disposition of Registrable Securities owned by them;

(d) notify the Holders of Registrable Securities covered by such Registration Statement, promptly after the Company shall have received notice thereof, of the time when such Registration Statement becomes or is declared effective or when any amendment or supplement or any Prospectus forming a part of such Registration Statement has been filed, other than reports or schedules filed with the SEC which are automatically incorporated by reference in such Registration Statement or Prospectus;

(e) notify the Holders of Registrable Securities covered by such Registration Statement promptly of any request by the SEC for the amending or supplementing of such Registration Statement or Prospectus or for additional information pertaining to the offer of Registrable Securities under such Registration Statement and promptly deliver to such Holders copies of any such comments received from the SEC;

(f) notify the Holders promptly of any stop order suspending the effectiveness of such Registration Statement or Prospectus or the initiation of any proceedings for that purpose, and use reasonable efforts to obtain the withdrawal of any such order or the termination of such proceedings;

(g) use reasonable efforts to register and qualify the Registrable Securities covered by such Registration Statement under such other securities or blue sky Laws of such jurisdictions within the United States as shall be reasonably requested by the Holders, use

reasonable efforts to keep each such registration or qualification effective, including through new filings, or amendments or renewals, during the Required Period, and notify the Holders of Registrable Securities covered by such Registration Statement of the receipt of any written notification with respect to any suspension of any such registration or qualification; provided, however, that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(h) promptly notify each Holder of Registrable Securities covered by such Registration Statement at any time when a Prospectus relating thereto is required to be delivered under the Securities Act of the happening of any event as a result of which the Prospectus included in such Registration Statement or any offering memorandum or other document includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein not misleading in the circumstances then existing. Upon receiving such notice, each Holder of Registrable Securities covered by such Registration Statement shall immediately cease any offer or sales of such Registrable Securities under such Registration Statement as well as any further delivery of the Prospectus related thereto until such time as the Company notifies such Holder that the Registration Statement and Prospectus have been supplemented or amended so as to not contain any untrue statement of material fact or omit to state any fact necessary to make the statements therein not misleading. After delivering a notice pursuant to this paragraph, the Company agrees to promptly prepare a supplement or amendment to such Prospectus or file any other required document so that, as thereafter delivered to the purchasers of such Registrable Securities, such Prospectus will not contain an untrue statement of material fact or omit to state any fact necessary to make the statements therein not misleading; provided, however, that if the Company's Chief Executive Officer determines in good faith that the public disclosure of certain information necessary to so amend or supplement the Prospectus would be materially detrimental to the Company and its stockholders at such time, then the Company may delay the preparation and filing of such supplement or amendment until the earlier of the time such conditions no longer exist and 60 days following the delivery of the original notice pursuant to this paragraph;

(i) permit any Holder of Registrable Securities covered by such Registration Statement, which Holder in its reasonable judgment would be deemed to be an underwriter with respect to an Underwritten Offering pursuant to which such Registrable Securities are being offered, or to be a controlling Person of the Company, to reasonably participate in the preparation of such Registration Statement and to require the insertion therein of information to the extent concerning such Holder, furnished to the Company in writing, which in the reasonable judgment of such Holder and its counsel should be included;

(j) use reasonable efforts to comply with all applicable rules and regulations of the SEC relating to such registration and make generally available to its security holders earning statements satisfying the provisions of Section 11(a) of the Securities Act, provided that the Company will be deemed to have complied with this Section 2.8(j) with respect to such earning statements if it has satisfied the provisions of Rule 158 under the Securities Act;

(k) if requested by a managing underwriter or any selling Holder, promptly incorporate in a prospectus supplement or post-effective amendment such information the managing underwriter or any selling Holder reasonably requests to be included therein, with respect to the Registrable Securities being sold by such selling Holder, including, without limitation, the purchase price being paid therefor by the underwriters and with respect to any terms of the Underwritten Offering of Registrable Securities to be sold in such offering, and promptly make all required filings of such prospectus supplement or post-effective amendment;

(l) cause the Registrable Securities covered by such Registration Statement to be listed on each securities exchange, if any, on which the Common Stock is then listed; and

(m) reasonably cooperate with each selling Holder and each underwriter participating in the disposition of such Registrable Securities and their respective counsel in connection with filings required to be made with the Financial Industry Regulatory Authority, Inc., if any.

2.9. Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself and the Registrable Securities held by it as shall be reasonably necessary to effect the registration of such Holder's Registrable Securities.

2.10. Expenses. Except as specifically provided herein, all Registration Expenses shall be borne by the Company. Each Holder shall bear its own Selling Expenses incurred in connection with any registration or sale of Registrable Securities hereunder.

2.11. Indemnification. In the event any Registrable Securities are included in a Registration Statement under this Agreement:

(a) The Company shall indemnify and hold harmless each Holder including Registrable Securities in any such Registration Statement, any underwriter (as defined in the Securities Act) for such Holder and each Person, if any, who controls such Holder or underwriter within the meaning of Section 15 of the Securities Act or Section 20 of Exchange Act and the officers, directors, owners, agents and employees of such controlling Persons, against any and all losses, claims, damages or liabilities (joint or several) to which they may become subject under any securities Laws including, without limitation, the Securities Act, the Exchange Act, or any other statute or common law of the United States or any other country or political subdivision thereof, or otherwise, including the amount paid in settlement of any litigation commenced or threatened (including any amounts paid pursuant to or in settlement of claims made under the indemnification or contribution provisions of any underwriting or similar agreement entered into by such Holder in connection with any offering or sale of securities covered by this Agreement), and shall promptly reimburse them, as and when incurred, for any reasonable legal or other expenses incurred by them in connection with investigating any claims and defending any actions, insofar as any such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (each, a "**Violation**"): (i) any untrue statement or alleged untrue statement of a

material fact contained in or incorporated by reference into such Registration Statement, including any preliminary prospectus or final prospectus contained therein or any free writing prospectus authorized by the Company or any amendments or supplements thereto, or in any offering memorandum or other offering document authorized by the Company relating to the offering and sale of such securities, (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading or (iii) any violation or alleged violation by the Company (or any of its agents or Affiliates, excluding any Holder) of the Securities Act, the Exchange Act, any state securities Law or any rule or regulation promulgated thereunder; provided, however, the Company shall not be liable in any such case for any such loss, claim, damage, liability or action to the extent that it (A) arises out of or is based upon a Violation which occurs in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder; or (B) is caused by such Holder's disposition of Registrable Securities during any period which such Holder is obligated to discontinue any disposition of Registrable Securities as a result of Section 2.8(h) or any stop order suspending the effectiveness of any registration statement or prospectus with respect to Registrable Securities of which such Holder has received written notice, but only following receipt of such notice. The Company shall pay, as incurred, any legal or other expenses reasonably incurred by any Person entitled to be indemnified pursuant to this Section 2.11(a), in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the indemnity agreement contained in this Section 2.11(a) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without consent of the Company, which consent shall not be unreasonably withheld.

(b) Each Holder including Registrable Securities in a registration statement shall indemnify and hold harmless the Company, each of its directors, each of its officers, each Person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act and the officers, directors, owners, agents and employees of such controlling Persons, any underwriter, any other Holder selling securities in such registration statement and any controlling Person of any such underwriter or other Holder, against any losses, claims, damages or liabilities (joint or several) to which any of the foregoing Persons may become subject, under liabilities (or actions in respect thereto) which arise out of or are based upon any Violation, in each case to the extent (and only to the extent) that such Violation: (i) arises out of or is based upon a Violation which occurs in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder; or (ii) is caused by such Holder's disposition of Registrable Securities during any period which such Holder is obligated to discontinue any disposition of Registrable Securities as a result of Section 2.8(h) or any stop order suspending the effectiveness of any registration statement or prospectus with respect to Registrable Securities of which such Holder has received written notice. Each such Holder shall pay, as incurred, any legal or other expenses reasonably incurred by any Person entitled to be indemnified pursuant to this Section 2.11(b), in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the indemnity agreement contained in this Section 2.11(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without consent of the Holder, which consent shall not be unreasonably withheld.

(c) Promptly after receipt by an indemnified party under this Section 2.11 of notice of the commencement of any action (including any action by a Governmental Authority), such indemnified party shall, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.11, deliver to the indemnifying party a written notice of the commencement thereof and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain its own counsel, with reasonable fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or reasonably likely differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such indemnifying party of any liability to the indemnified party under this Section 2.11, but the omission so to deliver written notice to the indemnifying party shall not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.11.

(d) In order to provide for just and equitable contribution to joint liability in any case in which a claim for indemnification is made pursuant to this Section 2.11 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Section 2.11 provided for indemnification in such case, the Company and each Holder of Registrable Securities shall contribute to the aggregate losses, claims, damages or liabilities to which they may be subject (after contribution from others) in proportion to the relative fault of the Company, on the one hand, and such Holder, severally, on the other hand; provided, however, that in any such case, no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; provided, further, however, that in no event shall any contribution under this Section 2.11(d) on the part of any Holder exceed the net proceeds received by such Holder from the sale of Registrable Securities giving rise to such contribution obligation, except in the case of willful misconduct or fraud by such Holder.

(e) The obligations of the Company and the Holders under this Section 2.11 shall survive the completion of any offering of Registrable Securities in a registration statement under this Agreement and otherwise.

2.12. SEC Reports. With a view to making available to the Holders the benefits of Rule 144 under the Securities Act and any other rule or regulation of the SEC that may at any time permit a Holder to sell Registrable Securities of the Company to the public without registration or pursuant to a registration on Form S-3, for so long as any Holder owns Purchased Shares, the Company agrees to:

(a) make and keep available adequate current public information, as those terms are understood and defined in Rule 144 under the Securities Act;

(b) use its reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act; and

(c) furnish to any Holder, forthwith upon request (i) a written statement by the Company that it has complied with the reporting requirements of Rule 144, (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other information as may be reasonably requested by any Holder to comply with any rule or regulation of the SEC (exclusive of Rule 144A under the Securities Act) which permits the selling of any Purchased Shares without registration or pursuant to Form S-3.

2.13. Assignment of Registration Rights. The rights to cause the Company to register any Registrable Securities pursuant to this Agreement may be assigned in whole or in part (but only subject to all restrictions and obligations set forth in this Agreement) by a Holder to a Permitted Transferee which acquires at least 1,000,000 Registrable Securities (subject to adjustment in the event of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization) from such Holder; provided, however, (a) such Holder shall, within five (5) days prior to such transfer, furnish to the Company written notice of the name and address of such Permitted Transferee, details of its status as a Permitted Transferee and details of the Registrable Securities with respect to which such registration rights are being assigned, (b) the Permitted Transferee, prior to or simultaneously with such transfer or assignment, shall agree in writing to be subject to and bound by all restrictions and obligations set forth in this Agreement and (c) in the case of a partial assignment, the Investor shall continue to be bound by all restrictions and obligations set forth in this Agreement.

3. Restrictions on Beneficial Ownership.

3.1. Standstill. During the Standstill Term neither the Investor nor any of its Affiliates (collectively, the "**Standstill Parties**") shall (and the Investor shall cause its Affiliates not to), except as expressly approved or invited in writing by the Company:

(a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Common Stock and/or Common Stock Equivalents, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Common Stock and/or Common Stock Equivalents; provided, however, that notwithstanding the provisions of this Section 3.1(a), if the number of shares constituting Shares of Then Outstanding Common Stock is reduced or if the aggregate ownership of the Standstill Parties is increased as a result of (i) the participation in any offering by the Company of any securities or (ii) a repurchase by the Company of Shares of Then Outstanding Common Stock, a stock split, a stock dividend or a recapitalization of the Company, the Standstill Parties shall not be required to dispose of any of their holdings of Shares of Then Outstanding Common Stock even though such action resulted in the Standstill Parties' beneficial ownership increasing;

(b) directly or indirectly, seek to have called any meeting of the stockholders of the Company, propose or nominate for election to the Company's Board of Directors any person whose nomination has not been approved by a majority of the Company's

Board of Directors or cause to be voted any Shares of Then Outstanding Common Stock in favor of such person for election to the Company's Board of Directors;

(c) directly or indirectly, solicit proxies or consents or become a "participant" in a "solicitation" (as such terms are defined in Regulation 14A under the Exchange Act) without the prior written consent of, or in opposition to the recommendation of, the Company's Board of Directors with respect to any matter, or seek to advise or influence any Person, with respect to voting of any Shares of Then Outstanding Common Stock of the Company;

(d) deposit any Shares of Then Outstanding Common Stock in a voting trust or subject any Shares of Then Outstanding Common Stock to any arrangement or agreement with respect to the voting of such Shares of Then Outstanding Common Stock;

(e) publicly propose (i) any merger, consolidation, business combination, tender or exchange offer, purchase of the Company's assets or businesses, or similar transaction involving the Company or (ii) any recapitalization, restructuring, liquidation or other extraordinary transaction with respect to the Company;

(f) act in concert with any Third Party to take any action in clauses (a) through (e) above, or form, join or in any way participate in a "partnership, limited partnership, syndicate, or other group" within the meaning of Section 13(d)(3) of the Exchange Act; or

(g) enter into discussions, negotiations, arrangements or agreements with any Third Party relating to the foregoing actions referred to in (a) through (e) above; provided, however, that (A) nothing contained in this Section 3.1 shall prohibit the Investor from making confidential, non-public proposals to, or entering into confidential, non-public discussions, negotiations, arrangements or agreements with, the Company and with Third Parties with the express prior authorization of the Company (provided that no such proposals, discussions, negotiations, arrangements or agreements would reasonably be expected to require the Company or any Third Party to be required to publicly disclose the same), which the Investor or any Affiliate may request in a confidential, non-public manner, regarding a transaction or matter of the type described in the foregoing clauses (a) through (f); (B) nothing in the foregoing clause (b) shall prohibit the Investor from inquiring of the Company's Nominating and Corporate Governance Committee (and not pursuant to the advance notice provisions set forth in the Company's bylaws), in a confidential, non-public manner, whether the Company would be interested in receiving potential director candidates for consideration by the Company's Nominating and Corporate Governance Committee, which candidates the Investor believes would be in the best interest of the Company and its stockholders; and (C) nothing contained in this Section 3.1 prohibits the Investor or its Affiliates from acquiring a company or business that owns Shares of Then Outstanding Common Stock and/or Common Stock Equivalents provided that any such securities of the Company so acquired will be subject to the provisions of this Section 3.

4. Restrictions on Dispositions.

4.1. Lock-Up. During the Lock-Up Term, without the prior approval of the Company, the Investor shall not, and shall cause its Affiliates not to, Dispose of (x) any of the Purchased Shares, together with any shares of Common Stock issued in respect thereof as a result of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization, and (y) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the shares of Common Stock described in clause (x) of this sentence (collectively, the "**Lock-Up Securities**"); provided, however, that the foregoing shall not prohibit the Investor from (A) transferring Lock-Up Securities to a Permitted Transferee, provided that any Lock-Up Securities so transferred will be subject to the provisions of this Section 4, or (B) Disposing of any Lock-Up Securities in order to reduce the beneficial ownership of the Standstill Parties to 19.9%, or such lesser percentage as advised in good faith and in writing by the Investor's certified public accountants that would be necessary pursuant to applicable accounting rules and guidelines so as to not require the Investor to include in its financial statements its portion of the Company's financial results, of the Shares of Then Outstanding Common Stock.

4.2. Certain Tender Offers. Notwithstanding any other provision of this Section 4, this Section 4 shall not prohibit or restrict any Disposition of Shares of Then Outstanding Common Stock and/or Common Stock Equivalents by the Standstill Parties into (a) a tender offer by a Third Party which is not opposed by the Company's Board of Directors (but only after the Company's filing of a Schedule 14D-9, or any amendment thereto, with the SEC disclosing the recommendation of the Company's Board of Directors with respect to such tender offer) or (b) an issuer tender offer by the Company.

5. Termination of Certain Rights and Obligations.

5.1. Termination of Registration Rights Term. Except for Section 2.11, which shall survive until the expiration of any applicable statutes of limitation, Section 2 shall terminate automatically and have no further force or effect upon the earliest to occur of:

(a) the third (3rd) anniversary of the expiration of the Lock-Up Term;

(b) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act;

(c) the date on which the then-outstanding Registrable Securities constitute less than 1% of the Shares of Then Outstanding Common Stock; and

(d) a liquidation or dissolution of the Company.

5.2. Termination of Standstill Term. Section 3 shall terminate automatically and have no further force or effect, upon the earliest to occur of:

(a) the date twelve (12) months after the Closing Date;

(b) provided that none of the Standstill Parties has materially violated Section 3.1, the date on which a Third Party publicly announces a tender, exchange or other offer for the Company's Common Stock or proposal that, if consummated, would result in a Change of Control of the Company;

(c) the date that the Company enters into a letter of intent relating to a Change of Control of the Company, publicly announces its intent to do so or publicly announces that it is pursuing a transaction that would reasonably be expected to result in a Change of Control of the Company;

(d) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act; and

(e) a liquidation or dissolution of the Company;

provided, however, that if Section 3 terminates due to clauses (b) or (c) above and such agreement, tender, exchange or other offer, as applicable, is abandoned and no other similar transaction by a Third Party has been publicly announced and not abandoned or terminated, the restrictions contained in Section 3 shall again be applicable until otherwise terminated pursuant to this Section 5.2.

5.3. Termination of Lock-Up Term. Section 4 shall terminate automatically and have no further force or effect upon the earliest to occur of:

(a) the date twelve (12) months after the Closing Date;

(b) the expiration or earlier valid termination of the License Agreement;

(c) immediately prior to the consummation of a Change of Control of the Company;

(d) the later of the date that is 6 months after the Closing Date and the date on which the Investor and any Permitted Transferees together beneficially own less than five percent (5%) of the Shares of Then Outstanding Common Stock; provided that the Holder does not make any public filing or announcement regarding a transfer of Lock-Up Securities except as required by Law;

(e) a liquidation or dissolution of the Company; and

(f) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act.

5.4. Effect of Termination. No termination pursuant to any of Sections 5.1, 5.2 or 5.3 shall relieve any of the parties (or the Permitted Transferee, if any) for liability for breach of or default under any of their respective obligations or restrictions under any terminated provision of this Agreement, which breach or default arose out of events or circumstances occurring or existing prior to the date of such termination.

6. Miscellaneous.

6.1. Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 6.3 or in such other manner as may be permitted by law, shall be valid and sufficient thereof.

6.2. Waiver. Waiver by a party of a breach hereunder by another party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

6.3. Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit A attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission or electronic mail, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile or electronic mail (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Any party may change its address by giving notice to the other parties in the manner provided above.

6.4. Entire Agreement. This Agreement and the Purchase Agreement contain the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.

6.5. Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the parties hereto.

6.6. Headings; Section References. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

6.7. Construction. Whenever required by the context, any pronoun used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns, pronouns, and verbs shall include the plural and vice versa. Reference to any agreement, document, or instrument means such agreement, document, or instrument as amended or otherwise modified from time to time in accordance with the terms thereof and, if applicable, hereof. A reference to any party hereto includes such party's permitted assignees and/or the respective successors in title to substantially the whole of such party's undertaking. All references to "Sections" and "Exhibits" contained in this Agreement are, unless specifically indicated otherwise, references to sections or exhibits of or to this Agreement. The recitals and exhibits to this Agreement form part of the operative provisions of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the recitals and exhibits to this Agreement. As used in this Agreement, the following terms shall have the meanings indicated: (a) "day" means a calendar day; (b) "U.S." or "United States" means the United States of America; (c) "dollar" or "$" means lawful currency of the United States; (d) "including" or "include" means "including without limitation"; and (e) references in this Agreement to specific laws includes the succeeding law, section, or provision corresponding thereto and the rules and regulations promulgated thereunder.

6.8. Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("**Modified Clause**"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

6.9. Assignment. Except for an assignment of this Agreement by the Investor to a Permitted Transferee, neither this Agreement nor any rights or duties of a party hereto may be assigned by such party, in whole or in part, without (a) the prior written consent of the Company in the case of any assignment by the Investor; or (b) the prior written consent of the Investor in the case of an assignment by the Company; provided that the Company may assign this Agreement to a successor in connection with a Change of Control of the Company which results in the Registrable Securities being exchanged for securities of such successor.

6.10. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

6.11. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile transmission or electronic mail and any counterpart so delivered shall be deemed to have been duly and validly delivered and be effective for all purposes.

6.12. Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party other than any Affiliate of the Investor. No Third Party with the exception of any Affiliate of the Investor 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.

6.13. No Strict Construction. This Agreement has been prepared jointly and will not be construed against any party.

6.14. Remedies. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

6.15. Specific Performance. The Company and the Investor hereby acknowledge and agree that the rights of the parties hereunder are special, unique and of extraordinary character and that if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or the Investor, as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged party at law or in equity, such damaged party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

6.16. No Conflicting Agreements. The Investor hereby represents and warrants to the Company that it is not, as of the date of this Agreement, a party to, and agrees it shall not, on or after the date of this Agreement, enter into any agreement that conflicts with the rights granted to the Company in this Agreement. The Company hereby represents and warrants to each Holder that it is not, as of the date of this Agreement, a party to, and agrees that it shall not, on or after the date of this Agreement, enter into any agreement or approve any amendment to its Organizational Documents (as defined in the Purchase Agreement) that conflicts with the rights granted to the Holders in this Agreement. The Company further represents and warrants that the rights granted to the Holders hereunder do not in any way conflict with the rights granted to any other holder of the Company's securities under any other agreements.

6.17. Use of Proceeds. The Company shall use the proceeds from the sale of the Shares for research and development and other working capital purposes and shall not use such proceeds for the redemption of any shares of Common Stock or for the payment of any dividends on shares of Common Stock.

6.18. Publicity. The parties hereto agree that the provisions of Section 10.6 of the Purchase Agreement shall be applicable to the parties to this Agreement with respect to any public disclosures regarding the proposed transactions contemplated by the Purchase Agreement or regarding the parties hereto or their Affiliates (it being understood that the provisions of Section 10.6 of the Purchase Agreement shall be read to apply to disclosures of information relating to this Agreement and the transactions contemplated hereby).

6.19. Limitation of Liability. OTHER THAN UNDER SECTION 2.11 HEREOF OR BASED ON INTENTIONAL BREACHES HEREUNDER, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES) IN CONNECTION WITH THIS AGREEMENT FOR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

JOHNSON & JOHNSON INNOVATION-JJDC, INC.

By: /s/ Marian T Nakada
Name: Marian T Nakada
Title: VP Venture Investments

TRACON PHARMACEUTICALS, INC.

By: /s/ Charles Theuer
Name: Charles Theuer
Title: CEO

EXHIBIT A

NOTICES

(a) If to the Investor:

Johnson & Johnson Innovation--JJDC, Inc.
255 Main Street 7th floor
Cambridge, MA 02142
Attention: Marian T. Nakada, Ph.D
Facsimile: (732) 247-5309

with a copy to:

Johnson & Johnson Law Department
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Attention: Steven Rosenberg & Scott Orchard
Facsimile: (732) 524-5334

with a copy to (which shall not constitute notice pursuant to Section 6.3):

Dechert LLP
1095 Avenue of the Americas
New York, NY 10036
Attention: Kristopher Brown & Tony Chan
Facsimile: (212) 698-3599

(b) If to the Company:

TRACON Pharmaceuticals, Inc.
8910 University Center Lane, Suite 700
San Diego, CA 92122
Attention: Charles Theuer & Patricia Bitar

with a copy to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Attention: Sean Clayton & Kay Chandler

Exhibit 10.1

*****Text Omitted and Filed Separately with
the Securities and Exchange Commission.
Confidential Treatment Requested Under
17 C.F.R. Sections 200.80(b)(4) and 240.24b-2.**

LICENSE AND OPTION AGREEMENT

BY AND BETWEEN

JANSSEN PHARMACEUTICA N.V.

AND

TRACON PHARMACEUTICALS, INC.

LICENSE AND OPTION AGREEMENT

This LICENSE AND OPTION AGREEMENT (this "**Agreement**") is made and effective as of September 27, 2016 (the "**Effective Date**"), by and between Janssen Pharmaceutica N.V. ("**Janssen**") and TRACON Pharmaceuticals, Inc., a Delaware corporation ("**Licensee**"). Each of Janssen and Licensee is sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Janssen has developed certain technology and owns certain intellectual property rights relating to certain preclinical development Programs (as defined below) conducted by Janssen and its Affiliates prior to the Effective Date;

WHEREAS, Licensee desires to obtain, and Janssen desires to grant to Licensee, an exclusive, worldwide license under such Janssen technology and intellectual property rights to develop, manufacture and commercialize Licensed Compounds (as defined below) and Licensed Products (as defined below) with respect to each Program;

WHEREAS, the license granted to Licensee with respect to the AR Mutant Program (as defined below) shall be subject to Janssen's exclusive option to obtain a reversion of the rights granted by Janssen to Licensee with respect to the AR Mutant Program and an exclusive license under any technology and intellectual property rights developed by Licensee in the course of conducting the AR Mutant Program, on the terms and conditions set forth in this Agreement; and

WHEREAS, the license granted to Licensee with respect to the NIK Program (as defined below) shall be subject to Janssen's right to negotiate with Licensee to obtain a reversion of the rights granted by Janssen to Licensee with respect to the NIK Program and an exclusive license under any technology and intellectual property rights developed by Licensee in the course of conducting the NIK Program, on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the various promises and covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

Article 1
DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, will have the meaning set forth below or, if not listed below, the meaning designated where first used in this Agreement.

1.1. "**Acquirer**" means any Third Party that is a party to any Change of Control transaction and any of such Third Party's Affiliates.

1.2. "**Affiliate**" means, with respect to any Party, any corporation or other business entity that directly or indirectly controls, is controlled by, or is under common control with such Party at the time at which the determination of affiliation is being made. For the purposes of this definition,

the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to any Party, means the possession of at least 50% of the voting stock or other ownership interest of the other corporation or entity, or the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint at least 50% of the members of the governing body of the corporation or other entity through the ownership of the outstanding voting securities or by contract or otherwise.

1.3. "**Antitrust Laws**" means any federal, state or foreign law, regulation or decree, including the HSR Act, designed to prohibit, restrict or regulate actions for the purpose or effect of monopolization or restraint of trade.

1.4. "**Applicable Law**" means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any governmental authority, including the FFDCA, Prescription Drug Marketing Act of 1987 (21 U.S.C. §§331, 333, 353, 381), the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335(a) et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder.

1.5. "**AR Competing Product**" means a therapeutic product, an active pharmaceutical ingredient of which […***…].

1.6. "**AR Mutant Compound**" means any compound that is (a) (i) described as a composition-of-matter as of the Effective Date in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) set forth on Schedule AR Mutant Program Patents of the Schedule Letter or (ii) described after the Effective Date in a claim of such a Patent Right filed within […***…], or (b) described in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) Controlled by a Party which also describes as a composition-of-matter a compound described in (a) above as of the […***…]. AR Mutant Compound includes the compound specifically set forth on Schedule AR Mutant Compound of the Schedule Letter.

1.7. "**AR Mutant Data Package**" means: (a) the AR Mutant POC Trial Data; (b) the full tables, figures and listings from any other Clinical Trial of any AR Mutant Product conducted by or on behalf of Licensee; (c) the data and results of all other Development activities conducted by or on behalf of Licensee with respect to any AR Mutant Compound or AR Mutant Product; and (d) an IP Disclosure Document for the AR Mutant Program.

1.8. "**AR Mutant License Agreement**" means the license agreement that would become effective upon Janssen's exercise of the Option in accordance with Section 3.3.1, which is attached hereto as Exhibit A.

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1.9. "**AR Mutant Pre-Phase III Activities**" means the activities with respect to the AR Mutant Program described on Schedule AR Mutant Pre-Phase III Activities of the Schedule Letter.

1.10. "**AR Mutant POC Trial**" means the first Clinical Trial of the AR Mutant Product containing the AR Mutant Compound set forth on Schedule AR Mutant Compound of the Schedule Letter as the only active ingredient that satisfies the following criteria: (a) such Clinical Trial has […***…]; and (b) such Clinical Trial has […***…]. For purposes of this definition, […***…] means that […***…].

1.11. "**AR Mutant POC Trial Data**" means full tables, figures and listings from the AR Mutant POC Trial.

1.12. "**AR Mutant Product**" means any pharmaceutical product in any dosage form containing an AR Mutant Compound.

1.13. "**AR Mutant Program**" means the conduct of Development, Manufacturing and Commercialization activities with respect to AR Mutant Compounds and AR Mutant Products.

1.14. "**AR Mutant Program Know-How**" means any Know-How Controlled by Janssen or any of its Affiliates on the Effective Date or during the Term (other than Janssen-Owned Development Program Know-How) that is necessary to make, have made, use, have used, import, have imported, sell, have sold, offer for sale or have offered for sale any AR Mutant Compound or AR Mutant Product, including the Know-How contained in or embodied by the items described on Schedule AR Mutant Program Know-How of the Schedule Letter; *provided, however,* that with regard to Know-How regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Know-How that is applied to or used to make any AR Mutant Product as such AR Mutant Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Know-How is excluded. For clarification, AR Mutant Program Know-How does not include any Know-How with respect to any active ingredient(s) in any Combination Product other than an AR Mutant Compound.

1.15. "**AR Mutant Program Patents**" means any Patent Rights Controlled by Janssen or any of its Affiliates on the Effective Date or during the Term (other than Development Program Patents) that Cover any AR Mutant Compound or AR Mutant Product, including the Patent Rights set forth on Schedule AR Mutant Program Patents of the Schedule Letter and all Patent Rights arising therefrom; *provided, however,* that with regard to Patent Rights regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Patent Rights that are applied to or used to make any AR Mutant Product as such AR Mutant Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Patent Rights are excluded. AR Mutant Program Patents does not include any Patent Rights with respect to any active ingredient(s) in any Combination Product other than an AR Mutant Compound or the Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter.

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1.16. "**Calendar Quarter**" means each of the successive three (3) month periods beginning on January 1, April 1, July 1 and October 1 of a given Calendar Year; *provided*, *however*, that the first Calendar Quarter and the last Calendar Quarter of the applicable period (such as the Royalty Term) may be partial quarters as applicable under the relevant Calendar Year.

1.17. "**Calendar Year**" means the twelve (12) month period beginning on January 1 and ending on December 31; *provided*, *however*, that the first Calendar Year and the last Calendar Year of the applicable period (such as the Royalty Term) may be partial years as the case may be.

1.18. "**Change of Control**" means, with respect to a Party: (a) that any Third Party acquires directly or indirectly the beneficial ownership of any voting securities of such Party, or if the percentage ownership of such person or entity in the voting securities of such Party is increased through stock redemption, cancellation or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of outstanding voting securities representing more than fifty percent (50%) of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization or reorganization of such Party is consummated, other than any such transaction in which stockholders or equity holders of such Party immediately prior to such transaction beneficially own, directly or indirectly, at least fifty percent (50%) of the voting securities of the surviving entity (or its parent entity) immediately following such transaction; (c) that the stockholders or equity holders of such Party approve a plan of complete liquidation of such Party; (d) that individuals who, as of the Effective Date, constitute the Board of Directors of such Party (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the Board of Directors of such Party (*provided*, *however*, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election by such Party's stockholders, was recommended or approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board of Directors of such Party); or (e) the sale or disposition to a Third Party of all or substantially all of such Party's assets taken as a whole.

1.19. "**Clinical Trial**" means any Phase I Clinical Trial, Phase II Clinical Trial, Phase II/III Clinical Trial or Phase III Clinical Trial.

1.20. "**Combination Product**" means: (a) any Licensed Product that contains a Licensed Compound and one or more other active pharmaceutical ingredient(s), where such Licensed Compound and other active pharmaceutical ingredient(s) are co-formulated into a single product; or (b) any combination, package or bundle of a Licensed Product with one or more other pharmaceutical products that are not Licensed Products sold together for a single invoiced price.

1.21. "**Commercialization**" means any activities directed to marketing, promoting, educating, informing, distributing, importing, offering to sell and/or selling a pharmaceutical product. When used as a verb, "**Commercialize**" means to engage in Commercialization activities.

1.22. "**Commercially Reasonable Efforts**" means: (a) with respect to Licensee's performance of Development activities with respect to a Program during the Development Term, the carrying out of such activities using reasonable, good faith efforts and resources (including, at a minimum, allocating time, effort, equipment and skilled personnel to perform the activities set forth in the Development Plans on a timely basis); (b) with respect to the Development, seeking and obtaining Marketing Approval, Manufacture or Commercialization of a Licensed Product in a country by or on behalf of Licensee during the License Term, those reasonable, good faith efforts normally used by biopharmaceutical companies of similar size and stage of development under similar circumstances for similar products or product candidates owned or controlled by such company, or to which such company has similar rights, which product or product candidate is of similar market potential in such country and is at a similar stage in its development or product life, taking into account (with respect to those efforts described in this clause (b) only) all Relevant Factors; or (c) with respect to the efforts to be expended by either Party with respect to any objective or activity other than those described in clause (a) or (b) of this Section 1.22, those reasonable, good faith efforts to accomplish such objective or perform such activity as such Party would normally use to accomplish a similar objective under similar circumstances.

1.23. "**Competing Product**" means (a) with respect to the AR Mutant Program, an AR Competing Product; and (b) with respect to the NIK Program, a NIK Competing Product.

1.24. "**Confidential Information**" means: (a) all non-public or proprietary information (including Know-How) that is disclosed by a Party (or any of its Affiliates) to the other Party (or any of its Affiliates) pursuant to or in connection with this Agreement; and (b) all other non-public or proprietary information (including Know-How) that is expressly deemed in this Agreement to be Confidential Information, whether or not disclosed by a Party (or any of its Affiliates) to the other Party (or any of its Affiliates), in each case ((a) or (b)), without regard as to whether any of the foregoing is marked "confidential" or "proprietary," or in oral, written, graphic or electronic form.

1.25. "**Control**" or "**Controlled**" means, with respect to any Know-How, Patent Right or other intellectual property right, possession by a Party (whether by ownership or license or otherwise, but without taking into account any rights granted pursuant to this Agreement), directly or through an Affiliate of such Party, of the ability to transfer, or grant a license or sublicense under, such right as provided for herein without violating the terms of any contract with any Third Party that exists on the Effective Date or other binding arrangement with any Third Party that exists on the Effective Date, or, subject to Section 2.5, any contract or other binding arrangement with any Third Party that exists after the Effective Date with regard to any Know-How, Patent Right or other intellectual property right licensed to or acquired by a Party from a Third Party after the Effective Date; *provided*, *however*, that any Know-How, Patent Right or other intellectual property right that is owned or licensed by an Acquirer of a Party or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of such Party prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control) shall not be deemed to be Controlled by such Party for purposes of this Agreement, except to the extent, and only to the extent that, such Know-How, Patent Right or other intellectual property right is either (a) actually used by such Party, the Acquirer or any of their respective Affiliates in the performance of Development, Manufacturing or Commercialization activities with respect to any Licensed Compound or Licensed Product following the

consummation of the Change of Control of such Party, or (b) made, conceived or reduced to practice by the Acquirer or any such Affiliates through the use of any Licensed Technology, Development Program Know-How, Development Program Patents or Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter following the consummation of the Change of Control of such Party.

1.26. "**Cover**", "**Covering**" and "**Covered**" means, with respect to a Patent Right and an invention, that, in the absence of ownership of or a license under such Patent Right, the practice of such invention (e.g., with respect to a Patent Right in the U.S., the manufacture, use, sale, offer for sale or importation of such invention) would infringe a Valid Claim of such Patent Right (in the case of a pending patent application, if the claims of such patent application as then existing were issued).

1.27. "**Data Package**" means: (a) with respect to the AR Mutant Program, an AR Mutant Data Package; and (b) with respect to the NIK Program, a NIK Data Package.

1.28. "**Development**" means all research and non-clinical and clinical drug development activities and processes, including toxicology, pharmacology, project management and other non-clinical efforts, formulation development, delivery system development, statistical analysis, manufacturing development, the performance of Clinical Trials (including the manufacturing of products for use in clinical trials), or other activities reasonably necessary in order to obtain and maintain, Marketing Approval of a pharmaceutical product. When used as a verb, "**Develop**" means to engage in Development activities.

1.29. "**Development Program Know-How**" means, with respect to a Program, any Know-How that is generated (or, in the case of an invention, reduced to practice) by a Party's, or its Affiliates' or Third Party Subcontractors', employees or agents in performing any Development activities with Licensed Compounds or Licensed Products with respect to such Program during the applicable Development Term, *provided* that Third Party Subcontractor Reserved Technology shall be excluded to the extent not assigned or licensed to a Party.

1.30. "**Development Program Invention**" means, with respect to a Program, any Development Program Know-How with respect to such Program that is an invention.

1.31. "**Development Term**" means: (a) with respect to the AR Mutant Program, the period beginning on the Effective Date and ending upon the expiration of the Option in accordance with Section 3.3.2, unless terminated earlier pursuant to Section 3.3.1, 11.2, 11.3 or 11.4; and (b) with respect to the NIK Program, the period beginning on the Effective Date and ending upon the expiration of the ROFN Period, unless terminated earlier pursuant to Section 3.4.1(d), 11.2, 11.3 or 11.4.

1.32. "**Drug Approval Application**" means: (a) a new drug application submitted to the FDA pursuant to Section 505(b) of the FFDCA, 21 U.S.C. § 355(b) (an "**NDA**"); or (b) an application for authorization to market and/or sell a drug product submitted to a Regulatory Authority in any country or jurisdiction other than the U.S., in each case ((a) and (b)), including all amendments and supplements thereto.

1.33. "**EMA**" means the European Medicines Agency or any successor agency for the EU with responsibilities comparable to those of the European Medicines Agency.

1.34. "**EPO**" means the European Patent Organization, or any successor entity with responsibilities comparable to those of the European Patent Organization.

1.35. "**EU**" means the countries of the European Economic Area, as it is constituted on the Effective Date and as it may be modified from time to time after the Effective Date.

1.36. "**Executive Officers**" means the Chief Executive Officer of Licensee and the Global Head, Oncology Therapeutic Area of Janssen Research & Development LLC, an Affiliate of Janssen.

1.37. "**FDA**" means the United States Food and Drug Administration or any successor agency in the United States with responsibilities comparable to those of the United States Food and Drug Administration.

1.38. "**FFDCA**" means the U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.), as amended from time to time.

1.39. "**Field**" means all uses.

1.40. "**First Commercial Sale**" means, with respect to a given Licensed Product and a given country, the first arm's-length commercial sale of such Licensed Product to a Third Party in the Field in such country after the receipt of Marketing Approval for such Licensed Product in such country. Sales for Clinical Trial purposes, early access or compassionate use programs, or similar uses, shall not constitute a First Commercial Sale. In addition, sales of a Licensed Product by and between Licensee and its Affiliates, distributors and (sub)licensees, or between the Parties (or their respective Affiliates, distributors or (sub)licensees), shall not constitute a First Commercial Sale.

1.41. "**FTE**" means the equivalent of work devoted to or in direct support of the AR Mutant Pre-Phase III Activities by qualified employees, contractors or consultants of Licensee or its Affiliates, as measured in accordance with Licensee's normal time allocation practices, *provided* that, such employees, contractors or consultants must be scientific or technical personnel with […***…], but shall not include personnel performing administrative and corporate functions (including human resources, finance, legal and investor relations).

1.42. "**FTE Costs**" means, with respect to any period, the FTE Rate multiplied by the FTE hours expended during such period.

1.43. "**FTE Rate**" means a rate of […***…] per FTE hour per Calendar Year (pro-rated for the period beginning on the Effective Date and ending on the last day of the first Calendar Year of the Term).

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1.44. "**Governmental Authority**" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any nation, state, province, county, city or other political subdivision thereof or (c) any supranational body.

1.45. "**HSR Act**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

1.46. "**IND**" means (a) an Investigational New Drug application as defined in the FFDCA and applicable regulations promulgated thereunder by the FDA; (b) a clinical trial authorization application for a product filed with a Regulatory Authority in any other regulatory jurisdiction outside the U.S., the filing of which (in the case of (a) or (b)) is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction; or (c) documentation issued by a Regulatory Authority that permits the conduct of clinical testing of a product in humans in such jurisdiction.

1.47. "**Indication**" means a discrete clinically recognized form of a disease. For purposes of this Agreement, treatment of different subpopulations within a population of patients having a disease shall not be treated as separate Indications (e.g., front-line treatment, second-line or relapsed refractory treatment and maintenance treatment of prostate cancer shall not be treated as separate Indications) and treatment of different signs or symptoms of the same disease shall not be treated as separate Indications; *provided*, *however*, that front-line treatment, second-line or relapsed refractory treatment and maintenance treatment of prostate cancer shall be treated as separate Indications with respect to the AR Mutant Program only.

1.48. "**Internal Research**" means research that is controlled by Janssen, whether conducted internally by Janssen or any of its Affiliates or by Third Party contractors on behalf of Janssen or any of its Affiliates, where Janssen or its Affiliate owns the data or intellectual property generated in such research, including research employing standards (i) to initially identify active compounds against a target or (ii) to validate activity of test compounds in animal models. For the avoidance of doubt, and notwithstanding the foregoing, Internal Research specifically excludes any GLP-compliant or other IND-enabling preclinical study and clinical trials and any research conducted by academic collaborators.

1.49. "**IP Disclosure Document**" means (a) with respect to the AR Mutant Program, a document in the form attached to the AR Mutant License Agreement describing the Licensee Program Know-How, Licensee Program Patents, Licensee-Owned Development Program Know-How, Licensee-Owned Development Program Patents and Joint Development Program Patents applicable to the AR Mutant Program as of such date; and (b) with respect to the NIK Program, a document substantially similar to the document described in clause (a) describing the Licensee Program Know-How, Licensee Program Patents, Licensee-Owned Development Program Know-How, Licensee-Owned Development Program Patents and Joint Development Program Patents applicable to the NIK Program as of such date.

1.50. "**Janssen AR Mutant Activities**" means the activities with respect to the AR Mutant Program described on Schedule Janssen AR Mutant Activities of the Schedule Letter.

1.51. "**Janssen License Agreements**" means the agreements set forth on Schedule Janssen License Agreements of the Schedule Letter.

1.52. "**Janssen Program Know-How**" means: (a) with respect to the AR Mutant Program, the AR Mutant Program Know-How; and (b) with respect to the NIK Program, the NIK Program Know-How.

1.53. "**Janssen Program Patents**" means: (a) with respect to the AR Mutant Program, the AR Mutant Program Patents; and (b) with respect to the NIK Program, the NIK Program Patents.

1.54. "**Know-How**" means any non-public or proprietary information, inventions, discoveries, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, trade secrets, technology, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies, Regulatory Documentation, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority or patent office, data (including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions), devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.

1.55. "**Licensed Compound**" means any AR Mutant Compound or NIK Compound.

1.56. "**Licensed Product**" means any AR Mutant Product or NIK Product.

1.57. "**Licensed Technology**" means, with respect to a Program: (a) the Janssen Program Know-How; (b) the Janssen-Owned Development Program Know-How; (c) the Janssen Program Patents; (d) the Janssen-Owned Development Program Patents; and (e) Janssen's interest in the Joint Development Program Patents, in each case ((a) through (e)), with respect to such Program.

1.58. "**Licensee NIK Program Technology**" means: (a) the Licensee Program Know-How; *provided, however,* that with regard to Know-How regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Know-How that is applied to or used to make any AR Mutant Product as such AR Mutant Product exists as of the effective date of the Janssen NIK License Agreement is included, and any other formulation or Manufacturing method Know-How is excluded; (b) the Licensee-Owned Development Program Know-How; (c) the Licensee Program Patents; *provided, however,* that with regard to Patent Rights regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Patent Rights that are applied to such Licensed Product as such Licensed Product exists as of the effective date of the Janssen NIK License Agreement are included, and any other formulation or Manufacturing method Patent Rights are excluded; (d) the Licensee-Owned Development Program Patents; and (e) Licensee's interest in the Joint Development Program Patents, in each case ((a) through (e)), only with respect to the NIK Program.

1.59. "**Licensee Program Know-How**" means, with respect to a Program, any Know-How Controlled by Licensee or any of its Affiliates on the Effective Date or during the Term (other than Licensee-Owned Development Program Know-How) that is necessary to make, have made, use, have used, import, have imported, sell, have sold, offer for sale or have offered for sale Licensed Compounds and Licensed Products only with respect to such Program. For clarification, Licensee Program Know-How does not include any Know-How with respect to any active ingredient(s) in any Combination Product other than a Licensed Compound.

1.60. "**Licensee Program Patents**" means, with respect to a Program, any Patent Rights Controlled by Licensee or any of its Affiliates on the Effective Date or during the Term (other than Development Program Patents) that Cover a Licensed Compound or Licensed Product with respect to such Program. For clarification, Licensee Program Patents does not include any Patent Rights with respect to any active ingredient(s) in any Combination Product other than a Licensed Compound.

1.61. "**Major European Countries**" means France, Germany, Italy, Spain and the United Kingdom.

1.62. "**Manufacturing**" means any activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a pharmaceutical product. When used as a verb, "**Manufacture**" means to engage in Manufacturing activities.

1.63. "**Marketing Approval**" means the approval of the applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical product for an Indication in the Field in a country, including any and all approvals that may be required in such country for pricing and reimbursement. For clarity, as of the Effective Date, no pricing and reimbursement approvals are required to market or sell a pharmaceutical product in the United States.

1.64. "**Net Sales**" means the gross amounts invoiced on sales of a Licensed Product by Licensee, or any of its Affiliates or sublicensees, to a Third Party purchaser in an arm's-length transaction, less the following customary and commercially reasonable deductions, determined in accordance with US generally accepted accounting principles and internal policies and actually taken, paid, accrued, allocated, or allowed based on good faith estimates:

(a) trade, cash and/or quantity discounts, allowances, deductions, fees and credits, excluding commissions for commercialization;

(b) excise taxes, use taxes, tariffs, sales taxes and customs duties and/or other government charges or fees imposed on the sale of Licensed Product (including VAT, but only to the extent that such VAT taxes are not reimbursable or refundable), specifically excluding, for clarity, any income taxes assessed against the income arising from such sale;

(c) compulsory or negotiated payments and cash rebates or other expenditures to governmental authorities (or designated beneficiaries thereof) in the context of any national or local health insurance programs or similar programs, including pay-for-

performance agreements, risk sharing agreements and government-levied fees as a result of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148;

(d) rebates, chargebacks, administrative fees and discounts (or equivalent thereof) to managed health care organizations, group purchasing organizations, insurers, pharmacy benefit managers (or equivalent thereof), specialty pharmacy providers, governmental authorities, or their agencies or purchasers, reimbursers, or trade customers, as well as amounts owed to patients through co-pay assistance cards or similar forms of rebate to the extent the latter are directly related to the prescribing of Licensed Product;

(e) outbound freight, shipment, insurance and other distribution costs to the extent included in the invoiced price and separately itemized on the invoice;

(f) retroactive price reductions, credits or allowances actually granted upon claims, rejections or returns of Licensed Product, including for recalls or damaged or expired goods, billing errors and reserves for returns; and

(g) any invoiced amounts that are not collected by the selling party or its Affiliates, including bad debts.

All of the aforementioned deductions shall only be allowable to the extent they are commercially reasonable and shall be determined, on a country-by-country basis, as incurred in the ordinary course of business in type and amount verifiable based on Licensee's and its Affiliates' reporting system. All such discounts, allowances, credits, rebates, and other deductions shall be fairly and equitably allocated to Licensed Product and other products of Licensee and its Affiliates and sublicensees such that Licensed Product does not bear a disproportionate portion of such deductions.

For clarity, (x) sales of a Licensed Product by and between Licensee and any of its Affiliates or (sub)licensees shall not be considered sales to unaffiliated Third Parties and shall be excluded from Net Sales calculations for all purposes as long as such Licensed Product is subsequently resold to an unaffiliated Third Party and (y) only a single sales transaction with respect to a particular unit of Licensed Product, made at the time Licensee or any of its Affiliates or (sub)licensees sells such unit of Licensed Product to an unaffiliated Third Party purchaser in arms-length transaction, will qualify as the basis for determining the Net Sales amount for such unit of Licensed Product.

Notwithstanding the foregoing, the following sales of a Licensed Product shall be excluded from Net Sales calculations for all purposes: (i) transfer or dispositions of reasonable quantities of samples of such Licensed Product at no cost for promotional or educational purposes; (ii) transfers or dispositions of reasonable and customary quantities of such Licensed Product as free samples or donations, or for patient assistance, testing marketing programs or other similar programs at no cost; and (iii) use or sale of such Licensed Product for clinical study or other scientific testing purposes, early access programs (such as to provide patients with such Licensed Product prior to Regulatory Approval pursuant to treatment INDs or protocols, named patient programs or compassionate use programs) or any similar use.

In the event a Licensed Product is sold as part of a Combination Product in a country, the Net Sales with respect to the Combination Product in such country shall be determined by multiplying the Net Sales amount for the Combination Product during the applicable reporting period, calculated as set forth above, by the fraction A/(A+B), where A is the weighted average sale price (by sales volume) of the Licensed Product when sold separately, and B is the weighted average sales price of the other active ingredient(s) or product(s) in the Combination Product when sold separately, in each case in the same dosage and dosage form and in the same country as the Combination Product during the applicable reporting period. If the other active ingredient(s) or product(s) in the Combination Product is not sold separately during the applicable reporting period in a country, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by a fraction A/C where A is the weighted average sale price (by sales volume) of the Licensed Product in such country when sold separately, and C is the weighted average sale price (by Sales volume) of the Combination Product in such country. If neither sales of the Licensed Product sold separately nor sales of the other active ingredient(s) or product(s) sold separately occurred during the applicable reporting period, then the respective average sales prices during the most recent reporting period in which sales of both occurred in the same country as the Combination Product. In the event that the weighted average sale price (by sales volume) of the Licensed Product is not available in a given country for any reporting period, then the average sales prices (weighted by sales volume) of the respective products described above (in the same dosage and dosage form as the Combination Product) in a proxy country to be agreed upon by both Parties will be used (such agreement not be unreasonably withheld, delayed or conditioned), and if the Parties cannot agree upon such proxy country, or no such comparable sales figures are available in an appropriate proxy country, Net Sales for the applicable Combination Product shall be allocated based on the relative value contributed by each component (such relative value to be agreed upon by the Parties or, if the Parties cannot agree, to be determined by the dispute resolution procedures set forth in Article 12).

1.65. "**NIK Competing Product**" means a therapeutic product, an active pharmaceutical ingredient of which […***…].

1.66. "**NIK Compound**" means any compound (a) (i) described as a composition-of-matter as of the Effective Date in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) set forth on Schedule NIK Program Patents of the Schedule Letter, or (ii) described after the Effective Date in a claim of such a Patent Right filed within […***…], or (b) described in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) Controlled by a Party which also describes as a composition-of-matter a compound described in (a) above as of the […***…].

1.67. "**NIK Data Package**" means: (a) the NIK POC Trial Data; (b) the full tables, figures and listings from any other Clinical Trial of any NIK Product conducted by or on behalf of Licensee; (c) the data and results of all other Development activities conducted by or on behalf of Licensee with respect to any NIK Compound or NIK Product; and (d) an IP Disclosure Document for the NIK Program.

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1.68. "**NIK POC Trial**" means the first Clinical Trial of a NIK Product that has […***…].

1.69. "**NIK POC Trial Data**" means the full tables, figures and listings from the NIK POC Trial.

1.70. "**NIK Product**" means any pharmaceutical product in any dosage form containing a NIK Compound.

1.71. "**NIK Program**" means the conduct of Development, Manufacturing and Commercialization activities with respect to NIK Compounds and NIK Products.

1.72. "**NIK Program Know-How**" means the Know-How Controlled by Janssen or any of its Affiliates on the Effective Date or during the Term (other than Janssen-Owned Development Program Know-How) that is necessary to make, have made, use, have used, import, have imported, sell, have sold, offer for sale or have offered for sale any NIK Compound or NIK Product, including the Know-How contained in or embodied by the items described on Schedule NIK Program Know-How of the Schedule Letter; *provided, however,* that with regard to Know-How regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Know-How that is applied to or used to make any NIK Product as such NIK Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Know-How is excluded. For clarification, NIK Program Know-How does not include any Know-How with respect to any active ingredient(s) in any Combination Product other than a NIK Compound.

1.73. "**NIK Program Patents**" means any Patent Rights Controlled by Janssen or any of its Affiliates on the Effective Date or during the Term (other than Development Program Patents) that Cover any NIK Compound or NIK Product, including the Patent Rights set forth on Schedule NIK Program Patents of the Schedule Letter and all Patent Rights arising therefrom; *provided, however,* that with regard to Patent Rights regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Patent Rights that are applied to or used to make any NIK Product as such NIK Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Patent Rights are excluded. For clarification, NIK Program Patents does not include any Patent Rights with respect to any active ingredient(s) in any Combination Product other than a NIK Compound.

1.74. "**Nondisclosure Agreement"** means the Confidential Disclosure Agreement between the Parties dated January 25, 2016.

1.75. "**Patent Costs**" means any out-of-pocket costs and expenses incurred by a Party or its Affiliates in prosecuting any Patent Rights.

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1.76. "**Patent Rights**" means any and all (a) patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) any other form of government-issued right substantially similar to any of the foregoing, and (f) all United States and foreign counterparts of any of the foregoing.

1.77. "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.

1.78. "**Phase I Clinical Trial**" means, in reference to a clinical trial of a Licensed Product, that such trial would satisfy the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a) or a Phase I study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).

1.79. "**Phase II Clinical Trial**" means, in reference to a clinical trial of a Licensed Product, that such trial would satisfy the requirements for a Phase 2 study as defined in 21 C.F.R. § 312.21(b) or a Phase II study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).

1.80. "**Phase II/III Clinical Trial**" means a Phase II Clinical Trial involving a sufficient number of subjects that, prior to commencement of the trial or at any other defined point in the trial, satisfies both of the following ((a) and (b)):

(a) such trial is designed to (i) establish that the applicable Licensed Product is safe and efficacious for its intended use, and (ii) define and determine warnings, precautions, and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed, which trial is intended to support Marketing Approval of such Product or a similar clinical study prescribed by the FDA; and

(b) such trial is or becomes a registration trial sufficient for filing an application for a Marketing Approval for such Licensed Product in the U.S., as evidenced by (i) an agreement with or statement from the FDA on a Special Protocol Assessment or equivalent, or (ii) other guidance or minutes issued by the FDA, for such registration trial.

1.81. "**Phase III Clinical Trial**" means, in reference to a clinical trial of a Licensed Product, that such trial is would satisfy the requirements for a Phase 3 study as defined in 21 C.F.R. § 312.21(c) or a Phase III study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).

1.82. "**POC Trial**" means (a) with respect to the AR Mutant Program, the AR Mutant POC Trial and (b) with respect to the NIK Program, the NIK POC Trial.

1.83. "**POC Trial Notice**" means, with respect to a Program, a notice from Licensee to Janssen providing the Data Package with respect to such Program.

1.84. "**Program**" means either of the AR Mutant Program or NIK Program.

1.85. "**Program-Related Information**" means, with respect to a Program: (a) the Development Plan for such Program; (b) the Program Records generated during the course of conducting such Program; (c) the Development reports delivered by Licensee to Janssen with respect to such Program pursuant to Section 2.2.5; (d) the Data Package(s), interim data packages and additional information delivered by Licensee to Janssen with respect to such Program pursuant to Section 3.2; and (e) non-public Development Program Know-How and Development Program Patents with respect to such Program, including non-public Licensee-Owned Development Program Know-How disclosed by Licensee to Janssen during meetings between the Parties pursuant to Section 2.2.5 and non-public Janssen-Owned Development Program Know-How disclosed by Janssen to Licensee during meetings between the Parties pursuant to Section 2.2.5.

1.86. "**Regulatory Authority**" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing and sale of a pharmaceutical product in a country, such as the FDA in the United States or EMA in the EU.

1.87. "**Regulatory Approval**" means any and all approvals (including Marketing Approvals), licenses (including import licenses), registrations or authorizations of any national, regional, state or local Regulatory Authority, department, bureau, commission, council or other governmental entity, that are necessary or useful to Development, Manufacture or Commercialize a pharmaceutical product in any country or jurisdiction in the Territory for one or more uses.

1.88. "**Regulatory Documentation**" means, with respect to a Program: (a) all applications for Regulatory Approval of any Licensed Compound or Licensed Product with respect to such Program; (b) all Regulatory Approvals for any Licensed Compound or Licensed Product with respect to such Program, including INDs, Drug Approval Applications and Marketing Approvals; (c) all supporting documents created for, referenced in, submitted to or received from an applicable Regulatory Authority relating to any of the applications or Regulatory Approvals described in clauses (a) or (b), including drug master files (or any equivalent thereof outside the U.S.), annual reports, regulatory drug lists, advertising and promotion documents shared with Regulatory Authorities, adverse event files, complaint files and Manufacturing records; and (d) all correspondence made to, made with or received from any Regulatory Authority (including written and electronic mail correspondence and minutes from meetings, discussions or conferences (whether in person or by audio conference or videoconference)).

1.89. "**Regulatory Exclusivity Period**" means, with respect to a given Licensed Product and given country, a period of exclusivity (other than patent exclusivity), granted or afforded by Applicable Laws or by a Regulatory Authority in such country, that confers exclusive marketing rights with respect to such Licensed Product in such country and prevents the initial market entry of a generic product with respect to such Licensed Product. In the event that such exclusivity is not available with respect to a Licensed Product in a country, the Regulatory Exclusivity Period for such Licensed Product in such country shall be deemed to expire upon the First Commercial Sale of such Licensed Product in such country

1.90. "**Relevant Factors**" means all relevant scientific, technical, operational, commercial, economic and other factors that may affect the development, Marketing Approval, manufacture or commercialization of a product, including (as applicable): actual and potential issues of safety, efficacy and/or stability; expected and actual product profile (including product modality, category and mechanism of action); stage of development or life cycle status; actual and projected development, Marketing Approval, manufacturing, and commercialization costs, timelines and budgets; any issues regarding the ability to manufacture or have manufactured the Licensed Product; the likelihood of obtaining Marketing Approvals (including satisfactory reimbursement or pricing approvals); the timing of such approvals; labeling or anticipated labeling; the then-current competitive environment and the likely competitive environment at the time of projected entry into the market, including the expected and actual competitiveness of alternative products sold by Third Parties in the market; past performance of the product or similar products; present and future market potential; existing or projected pricing, sales, reimbursement and profitability; and expected and actual proprietary position, strength and duration of patent protection and anticipated regulatory or other exclusivity.

1.91. "**ROFN Exercise Deadline**" means the date that is […***…] after the POC Trial Notice Date with respect to the NIK Program (which shall terminate early upon termination of this Agreement in its entirety pursuant to Section 11.2, 11.3 or 11.4 or termination of this Agreement with respect to the NIK Program pursuant to Section 11.2, 11.3 or 11.4); *provided*, *however*, […***…].

1.92. "**ROFN Period**" means the period commencing on the Effective Date and ending on the ROFN Exercise Deadline or, if Janssen exercises the Right of First Negotiation pursuant to Section 3.4.1 on or before the ROFN Exercise Deadline, the expiration of the Negotiation Period.

1.93. "**Royalty Term**" means, with respect to a given Licensed Product and a given country, the period beginning on the date of First Commercial Sale of such Licensed Product in such country and ending on the later of: (a) […***…] the date of First Commercial Sale of such Licensed Product in such country; (b) the expiration […***…]; or (c) […***…].

1.94. "**Schedule Letter**" means the letter dated as of the Effective Date between Janssen and Licensee delivering copies of certain schedules.

1.95. "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon).

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1.96. "**Territory**" means worldwide.

1.97. "**Third Party**" means any Person other than a Party or any of its Affiliates.

1.98. "**Third Party NIK Program Agreement**" means a Third Party Program Agreement with respect to the NIK Program.

1.99. "**Third Party Program Agreement**" means, with respect to a Program, an agreement (other than a Permitted Subcontract) between Licensee or any of its Affiliates, on the one hand, and a Third Party, on the other hand, to collaborate with, grant a license or sublicense to or otherwise authorize such Third Party, or grant such Third Party any rights, to Develop, Manufacture or Commercialize any Licensed Compound or Licensed Product with respect to such Program.

1.100. "**Third Party Subcontractor Reserved Technology**" means results of the activities undertaken and other intellectual property made, invented or generated by a Third Party Subcontractor's employees or agents with respect to a Program pursuant to a Permitted Subcontract solely to the extent that they are either improvements to such Third Party Subcontractor's intellectual property or generally applicable Development or Manufacturing technology, and in either case not specific to any Licensed Compound or Licensed Product.

1.101. "**Trademark**" means any word, name, symbol, color, designation, or device or any combination thereof, whether registered or unregistered, including any trademark, trade dress, service mark, service name, brand mark, trade name, brand name, logo or business symbol.

1.102. "**Valid Claim**" means: (a) a claim of any issued and unexpired patent that (i) has not been dedicated to the public, disclaimed, revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or a decision of a court or governmental agency of competent jurisdiction that can be appealed, but with respect to which an appeal has not taken within the time allowed for appeal, and (ii) has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (b) a claim of any pending patent application that (i) has not been cancelled, withdrawn or abandoned, without being re-filed in another application in the applicable jurisdiction, (ii) has not been finally rejected by an administrative agency or other governmental action from which no appeal can be taken and (iii) has not been pending or filed more than […***…] from the earliest possible priority date for such patent application.

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1.103. **Additional Definitions.** Each of the following definitions are found in the body of this Agreement as indicated:

Defined Term	**Section**
Acquired Compound	2.3.2(b)
Acquired Product	2.3.2(b)
Action	7.4.2
Additional NIK Program Information	3.4.1(c)
Agreement	Preamble
Anti-Corruption Laws	9.5.4
AR Mutant Development Plan	2.2.2(a)
AR Mutant Schedule Information	3.2.1
Audited Site	9.5.5
Bankruptcy Code	11.4.2
Breaching Party	11.3.1
CAPA	9.5.5
CPR Mediation Procedure	12.2.1
CPR Rules	12.3.1
CREATE Act	7.3.5
Cure Period	11.3.1
Development Program Patent	7.2.1
Development Plan	2.2.2(b)
Development Term Acquirer Activities	2.3.2
Disclosing Party	8.1.1
Dispute	12.1
Effective Date	Preamble
Existing Janssen Program Know-How	9.2.49.2.1
Existing Janssen Program Patents	13.9
Force Majeure Event	
GCP	9.5.5
GLP	9.5.5
GMP	9.5.5
Indemnified Party	10.2
Indemnifying Party	10.2
Insolvency Event	11.4.1
IRB	9.5.5
Janssen	Preamble
Janssen Indemnified Party	10.1.1
Janssen NIK License Agreement	3.4.1(b)
Janssen-Owned Development Program Know-How	7.2.1
Janssen-Owned Development Program Patent	7.2.1
Janssen Personnel	9.2
Joint Development Program Patent	7.2.1
Knowledge	9.2
License Term	4.1
Licensee	Preamble

Licensee Indemnified Party	10.1.2
Licensee Party	11.4.2
Licensee-Owned Development Program Know-How	7.2.1
Licensee-Owned Development Program Patent	7.2.1
Licensor Party	11.4.2
Losses	10.1.1
Milestone Event	6.1.2
Milestone Payment	6.1.2
Missing Information Notice	3.2.2
NDA	1.32
Negotiation Period	3.4.1(b)
NIK Development Plan	2.2.2(b)
Option	3.1
Option Exercise Effective Date	3.3.1
Option Exercise Fee	3.3.1
Option Period	3.3.1
Other Invention	7.2.2
Other Patent	7.2.2
Party/Parties	Preamble
Patent Representative	7.1
Patent Term Extension	7.6
Permitted Liens	9.2
Permitted Subcontract	2.2.3(e)
POC Trial Notice Date	3.2.2
Post-Development Term Acquirer Activities	5.5.2
Product Infringement	7.4.2
Program Records	2.2.4(a)
Protocol	12.3.6
Receiving Party	8.1.1
Restricted Contract	2.1.3
Restricted Third Party NIK Program Agreement	3.4.1(c)
Right of First Negotiation (or ROFN)	3.4.1
ROFN Exercise Notice	3.4.1(b)
Royalty Records	6.5
Subcontracting Party	2.2.3(e)
Supply Agreement	2.1.6
Tail Period	3.4.1(c)
Term	11.1
Terminated Program	11.6.1
Terminating Party	11.3.1
Third Party Claim	10.1.1
Third Party Consent	2.1.3
Third Party Offer Notice	2.4
Third Party Subcontractor	2.2.3(e)
Transferred Assets	2.1.3
Transferred Contracts	2.1.3(b)

Transferred Contract Effective Date	2.1.3(b)
Transferred Materials	2.1.3(a)
Transition Period	2.1.5(a)
Transition Plan	2.1.5(a)

Article 2
LICENSE GRANTS AND DEVELOPMENT ACTIVITIES DURING DEVELOPMENT TERM

2.1. **Development Term License Grants; Transfer of Programs**.

2.1.1. **License Grants to Licensee**.

(a) *AR Mutant Program License*. Subject to the terms and conditions of this Agreement (including Section 2.1.2), during the Development Term with respect to the AR Mutant Program, Janssen hereby grants to Licensee:

(1) an exclusive (subject to Section 2.1.2), non-transferable (except to the extent permitted under Section 13.6), non-sublicensable license under the Licensed Technology with respect to the AR Mutant Program to make, have made, use, have used, import and have imported the AR Mutant Compounds and AR Mutant Products in the Field in the Territory, solely for the purpose of conducting: (i) the AR Mutant POC Trial; (ii) the AR Mutant Pre-Phase III Activities; and (iii) and any other Development activities, including Manufacturing activities, with respect to the AR Mutant Compounds and AR Mutant Products that are reasonably necessary to conduct and complete the AR Mutant POC Trial or the AR Mutant Pre-Phase III Activities or to generate and deliver to Janssen a complete AR Mutant Data Package (including the AR Mutant POC Trial Data); and

(2) an exclusive (subject to Section 2.1.2) non-transferable (except to the extent permitted under Section 13.6), non-sublicensable license under the Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter to make, have made, use, have used, import and have imported companion diagnostic products solely for use with AR Mutant Compounds and AR Mutant Products in the Field in the Territory for the purpose of conducting: (i) the AR Mutant POC Trial; (ii) the AR Mutant Pre-Phase III Activities; and (iii) and any other Development activities, including Manufacturing activities, with respect to the companion diagnostic products that are reasonably necessary to conduct and complete the AR Mutant POC Trial or the AR Mutant Pre-Phase III Activities or to generate and deliver to Janssen a complete AR Mutant Data Package (including the AR Mutant POC Trial Data).

(b) *NIK Program License*. Subject to the terms and conditions of this Agreement (including Section 2.1.2), during the Development Term with respect to the NIK Program, Janssen hereby grants to Licensee an exclusive (subject to Section 2.1.2), non-transferable (except to the extent permitted under Section 13.6), non-sublicensable license under the Licensed Technology with respect to the NIK Program to make, have made, use, have used, import and have imported the NIK Compounds and NIK Products in the Territory, solely for the purpose of conducting the NIK POC Trial and any other Development activities, including Manufacturing activities, with respect to the NIK Compounds and NIK Products that are reasonably necessary to conduct and complete the NIK POC Trial or to generate and deliver to Janssen a complete NIK Data Package (including the NIK POC Trial Data).

(c) *NIK Program Covenant*. Licensee covenants and agrees not to exercise any of its rights under Section 2.1.1(b) to make, have made, use, have used, import and have imported the NIK Compounds and NIK Products for any […***…] Indication unless and until the License Term of the NIK Program begins.

2.1.2. **Janssen Retained Rights**. Licensee acknowledges and agrees that:

(a) Janssen and its Affiliates (i) retain the right to use the Licensed Technology and the Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter to make, have made, use, have used, import and have imported Licensed Compounds and Licensed Products solely to conduct Internal Research with Licensed Compounds or Licensed Products and (ii) shall not be obligated to remove any Licensed Compound from its compound libraries that are used for Internal Research; and

(b) Janssen and its Affiliates may use for any purpose (other than those purposes for which Licensee is granted an exclusive license pursuant to Section 2.1.1 or 5.2) […***…]; *provided, however,* that the foregoing is not intended to grant, and shall not be deemed to grant, […***…].

2.1.3. **Assignment of Transferred Assets.** Subject to the terms and conditions of this Agreement, Janssen, on behalf of itself and its Affiliates, hereby irrevocably sells, conveys, transfers and assigns to Licensee all of Janssen's and its Affiliates' right, title and interest in, to and under the following assets (collectively, the "**Transferred Assets**"):

(a) the assays and materials listed on Schedule Transferred Materials of the Schedule Letter (the "**Transferred Materials**");

(b) the contracts, agreements and commitments that will be listed on Schedule Transferred Contracts of the Schedule Letter by written agreement of the Parties during the Transition Period (collectively, the "**Transferred Contracts**"); *provided* that assignment of such Transferred Contracts and any

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other provisions of this Agreement applicable to such Transferred Contracts shall not become effective, and the Transferred Contracts shall not be Transferred Assets, without limitation of the last paragraph of this Section 2.1.3 unless and until the date that the Parties agree in writing to the Schedule Transferred Contracts (the "**Transferred Contract Effective Date**"); and

(c) all claims, counterclaims, defenses, causes of action, rights under express or implied warranties, rights of recovery, rights of set-off, rights of subrogation and all other rights of any kind against any Third Party, solely to the extent relating to any Assumed Liabilities or Transferred Assets.

Notwithstanding anything in this Agreement to the contrary, this Agreement shall not constitute an agreement to assign or transfer any Transferred Contract that is not assignable or transferable without the consent of any Third Party (each, a "**Restricted Contract**"), to the extent that such consent has not been obtained prior to the Effective Date (each, a "**Third Party Consent**"). Janssen shall use, during the Transition Period, Commercially Reasonable Efforts to obtain, and Licensee shall use Commercially Reasonable Efforts to assist and cooperate with Janssen to obtain, all Third Party Consents; *provided*, *however*, that none of Janssen, Licensee or any of their respective Affiliates shall be required to pay money to any Third Party, commence any litigation or offer or grant any accommodation (financial or otherwise) to any Third Party to obtain any Third Party Consent. During the period beginning on the Effective Date and ending on the earlier of (a) the date on which […***…] and (b) the […***…], Janssen shall (i) use Commercially Reasonable Efforts to provide Licensee with the benefits of such Restricted Contract (or benefits substantially comparable to the benefits of such Restricted Contract), *provided* that Licensee performs the obligations of Janssen under such Restricted Contract, and (ii) upon the request of, for the benefit of and at the expense of Licensee, enforce any rights of Janssen arising under such Restricted Contract against any Person, including the right to seek any available remedies or to terminate such Restricted Contract. Janssen provides no assurances to Licensee that any Third Party Consent will be granted. Subject to Janssen's compliance with this Section 2.1.3, the Parties acknowledge and agree that (x) neither Janssen nor any of its Affiliates shall be obligated to obtain any Third Party Consent and (y) neither Janssen's failure to obtain any Third Party Consent, nor any default, termination, lawsuit, action, claim, proceeding or investigation commenced or threatened by or on behalf of any Person arising from Janssen's failure to obtain any Third Party Consent, shall be deemed to be a breach of any representation, warranty or covenant of Janssen contained in this Agreement.

2.1.4. **Assumption of Assumed Liabilities.** Subject to the terms and conditions of this Agreement, Janssen hereby conveys, assigns and transfers to Licensee and its successors and assignees, forever, and Licensee hereby assumes, and agrees to satisfy, perform and otherwise discharge when due, all liabilities arising from or relating to the Transferred Contracts arising on or after the Transferred Contract Effective Date, but excluding all liabilities resulting from any breach of or non-compliance with any Transferred Contract by Janssen or any of its Affiliates prior to the Transferred Contract Effective Date (the "**Assumed Liabilities**"). All risk of loss with respect to the Transferred Assets (whether

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or not covered by insurance) shall pass to Licensee on the Effective Date or, if later with respect to any Transferred Asset, the date that such Transferred Asset is actually transferred to Licensee pursuant to the Transition Plan . Licensee does not assume any liabilities with respect to the Transferred Assets other than the Assumed Liabilities.

2.1.5. **Transition.** In order to effect a prompt and orderly transition of each Program from Janssen to Licensee, and to facilitate the transfer of the Janssen Program Know-How and Transferred Assets from Janssen to Licensee:

(a) the Parties shall comply with the provisions of the transition plan for each Program attached as Schedule Transition Plan of the Schedule Letter (the "**Transition Plan**") during the period beginning on the Effective Date and ending […***…] thereafter (the "**Transition Period**");

(b) Janssen shall use Commercially Reasonable Efforts to (i) deliver physical embodiments of the Janssen Program Know-How identified on Schedule AR Mutant Program Know-How or Schedule NIK Program Know-How of the Schedule Letter and the Transferred Assets to Licensee prior to the end of the Transition Period, *provided* that Janssen shall determine in its discretion whether to provide originals or copies of any documentation included within the Janssen Program Know-How, and (ii) respond to Licensee's requests for additional information, documents, files or assistance with respect to the items described in clause (i) during the Transition Period;

(c) each Party shall appoint one individual to have primary responsibility and oversight for, and to serve as the primary point of contact regarding, the transition and transfer activities for each Program contemplated by this Section 2.1.5 and the Transition Plan; and

(d) each Party shall bear its own costs in performing its obligations under this Section 2.1.5 and the Transition Plan.

After expiration of the Transition Period, except as required elsewhere in this Agreement, Janssen will have no further obligation to provide any additional information, documents, electronic files or support to Licensee in connection with the Programs; *provided, however,* that following the Transition Period, if (i) either Party identifies any assets that were not transferred prior to the end of the Transition Period but that, pursuant to the provisions of this Agreement, were Transferred Assets that were required to be transferred, Janssen and its Affiliates shall, at no additional cost to Licensee, promptly take all actions to transfer such Transferred Assets to Licensee, (ii) if Janssen discovers any Janssen Program Know-How that existed on the Effective Date but was omitted from the Schedule AR Mutant Program Know-How or Schedule NIK Program Know-How of the Schedule Letter, Janssen and its Affiliates shall, at no additional cost to Licensee, promptly take all actions to transfer a copy of such Janssen Program Know-How to Licensee and (iii) Janssen and its Affiliates shall provide reasonable support to Licensee and its Affiliates after the Transition Period to the extent reasonably necessary to allow

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Licensee and its Affiliates to respond to requirements or requests of any Regulatory Authority or other governmental authority with respect to Licensed Compounds or Licensed Products.

2.1.6. **Supply and Quality Assurance Agreements.** Beginning on the Effective Date, the Parties will work together in good faith to negotiate and enter into an agreement within […***…] after the Effective Date for the supply of […***…] for use in conducting activities under the Programs on the terms specified in the Schedule Supply Terms of the Schedule Letter and other terms mutually agreed by the Parties and a related quality assurance agreement on terms mutually agreed by the Parties (collectively, the "**Supply Agreement**").

2.2. **Conduct of Development Activities**. The following provisions of this Section 2.2 shall apply during the Development Term for each Program.

2.2.1. **General.** Subject to the transfer of the Janssen Program Know-How and Transferred Assets to Licensee in accordance with Sections 2.1.3 and 2.1.5 and entry into and performance of the Supply Agreements, Licensee will conduct each Program in accordance with this Article 2; *provided*, *however*, that Janssen will conduct the Janssen AR Mutant Activities in accordance with the AR Mutant Development Plan. Each Party will carry out its responsibilities set forth in each Development Plan in accordance with the terms and conditions of this Agreement, in good scientific manner and in compliance with all applicable Laws.

2.2.2. **Development Plans**.

(a) Licensee shall prepare and deliver to Janssen within […***…] after the Effective Date a written development plan for the AR Mutant Program describing the activities to be performed to up to and including the conduct and completion of the AR Mutant POC Trial and the AR Mutant Pre-Phase III Activities, the deliverables for such activities, target dates and estimated timelines for completion of such activities and a budget for such activities (the "**AR Mutant Development Plan**"). The Development Plan for the AR Mutant Program shall at all times contain […***…]. Janssen shall review the initial AR Mutant Development Plan within […***…] following receipt thereof and may provide comments on such AR Mutant Development Plan, which Licensee shall consider in good faith. Any portion of the initial AR Mutant Development Plan describing a Janssen AR Mutant Activity that is not set forth on Schedule Janssen AR Mutant Activities, or setting forth a target date or timeline for any Janssen AR Mutant Activity, will not become effective unless and until approved in writing by Janssen.

(b) Licensee shall prepare and deliver to Janssen within […***…] after the Effective Date a written development plan for the NIK Program describing the activities to be performed to up to and including the conduct and completion of the NIK POC Trial, the deliverables for such activities, target dates and estimated

timelines for completion of such activities and a budget for such activities (the "**NIK Development Plan**" and the AR Mutant Development Plan or the NIK Development Plan, a "**Development Plan**"). The Development Plan for the NIK Program shall at all times contain: […***…]. Janssen shall review the initial NIK Development Plan within […***…] following receipt thereof and may provide comments on such NIK Development Plan, which Licensee shall consider in good faith.

(c) Subject to Section 2.2.2(a) or 2.2.2(b), as applicable, and Section 2.2.2(e), each Development Plan may be amended from time to time by Licensee, *provided* that no such amendment shall take effect until (i) Licensee provides Janssen with notice of and a copy of the proposed amendment, (ii) Licensee provides Janssen with […***…] to review and provide comments on such amendment and (iii) Licensee considers in good faith any comments made by Janssen; and *provided further* that no such amendment relating to a Janssen AR Mutant Activity shall take effect unless and until approved in writing by Janssen. For clarity, the approval of Janssen is not required to amend any Development Plan except as described in the immediately preceding sentence.

(d) Prior to the commencement of any of the […***…], Licensee shall amend the AR Mutant Development Plan to include a budget for such activities and submit such amendment to Janssen for review pursuant to Section 2.2.2(c).

(e) The Development Plan for a Program shall not contain any Development activities relating to […***…], and Licensee shall not conduct any such activities during the Development Term of such Program.

2.2.3. **Conduct of Programs**.

(a) *Licensee Diligence*. Licensee shall conduct the activities set forth in each Development Plan (and all regulatory matters relating to such activities), other than the Janssen AR Mutant Activities, and shall use Commercially Reasonable Efforts to conduct such activities in accordance with the timelines and budget set forth in such Development Plan. Without limiting the foregoing, Licensee shall use Commercially Reasonable Efforts to:

(1) […***…].

(2) […***…]

(3) […***…]

(4) […***…]

(5) […***…]

It is acknowledged that there may be delays in achievement of such events based upon delays by Janssen in performing its obligations under Sections 2.1.3, 2.1.5 or 2.2.3(b) or the Supply Agreement or actions of any Regulatory Authority, and any delay in achievement of such events for such reason shall not be a breach of this Section 2.2.3(a). It is further acknowledged that, due to timing of activities with respect to a given Program, […***…] provided that […***…]. During […***…], Licensee shall not be obligated to conduct, nor shall Licensee conduct, any Development activities with respect to the applicable Program other than […***…].

(b) *Janssen Diligence*. Janssen shall conduct the Janssen AR Mutant Activities, and shall use Commercially Reasonable Efforts to conduct such activities in accordance with the timelines set forth in the AR Mutant Development Plan.

(c) *Responsibilities*. Licensee shall be solely responsible for all aspects of conducting the Development activities set forth in the Development Plans, including Manufacturing clinical supplies of Licensed Compounds and Licensed Products necessary to conduct the Programs, except that Janssen shall be solely responsible for all aspects of conducting the Janssen AR Mutant Activities. Janssen may provide, through its review of reports delivered by Licensee, and participation in meetings with Licensee, pursuant to Section 2.2.5, such input as it deems appropriate with respect to Licensee's conduct of the Programs, which input Licensee shall consider in good faith.

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(d) *Costs*. Licensee shall conduct each Program at its sole cost and expense, except that Janssen shall conduct the Janssen AR Mutant Activities at its sole cost and expense. In addition, Licensee shall […***…].

(e) *Subcontracting*.

(1) Each Party may subcontract the performance of any Development activities, including Manufacturing activities, conducted pursuant to the Programs to any of its Affiliates or any Third Party, *provided* that such Party shall oversee the performance by its Affiliates and Third Party Subcontractors in a manner that would be reasonably expected to result in their timely completion and shall remain responsible for the performance of such activities in accordance with this Agreement.

(2) With respect to any activities to be subcontracted to a Third Party (a "**Third Party Subcontractor**") by Licensee, or by Janssen pursuant to a subcontracting agreement with a Third Party that is first entered into after the Effective Date: (A) each such arrangement will be set forth in a written contract with such Third Party Subcontractor; and (B) all such contracts shall be consistent with and expressly made subject to the terms and conditions of this Agreement and shall include (i) restrictions on the use and disclosure of Confidential Information of the other Party and (ii) an assignment to the applicable Party entering into such contract (the "**Subcontracting Party**") of all rights to any and all results of the activities undertaken and other intellectual property made, invented or generated by such Third Party Subcontractor with respect to the applicable Program, except as otherwise provided in Section 2.2.3(e)(3).

(3) Any assignment of intellectual property rights described in clause (B)(ii) of Section 2.2.3(e)(2) may exclude any Third Party Subcontractor Reserved Technology rights that are not necessary to make, have made, use, have used, import, have imported, sell, have sold, offer for sale or have offered for sale any Licensed Compound or Licensed Product. If the Subcontracting Party expects that any Third Party Subcontractor Reserved Technology rights […***…], then, before entering into such subcontract, the Subcontracting Party (A) shall […***…], (B) shall […***…] and (C) shall […***…]. If the proposed subcontract […***…].

(4) A Subcontracting Party will notify the other Party of the engagement or retention of any Third Party Subcontractor to conduct any Program activities and, upon the request of such other Party, provide such other Party with a copy of the relevant contract (which may be redacted with respect to financial terms) to ensure compliance with the provisions of this Section 2.2.3(e). A contract between a Party and a Third Party Subcontractor that satisfies the requirements set forth in this Section 2.2.3(e) is referred to in this Agreement as a "**Permitted Subcontract.**"

2.2.4. **Records; Data Requirements**.

(a) Each Party shall prepare and maintain, and shall cause its Affiliates and Third Party Subcontractors to prepare and maintain, complete and accurate written records, accounts, notes, reports and data with respect to the Development activities conducted by or on behalf of such Party during the Development Term with respect to a Program, including all Development Program Know-How (the "**Program Records**"), in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in conformity with Applicable Law and such Party's standard practices, which Program Records shall reflect all work done and results achieved in connection with the Programs. Each Party shall retain, and cause its Affiliates and Third Party Subcontractors to retain, the Program Records for at least […***…] or such longer period as may be required by Applicable Law.

(b) Each Party shall comply with Janssen's data policies set forth on Exhibit B with regarding to Program Records.

2.2.5. **Reports**. Licensee shall submit a reasonably detailed written summary of the status of each Program […***…], updating Janssen on its progress with respect to the conduct of such Program, including any regulatory filings made during such […***…]. Licensee shall make its employees and consultants available for an in-person or telephonic meeting with Janssen at least once every […***…] to discuss its progress with respect to the conduct of the Programs.

2.2.6. **No Branding Activities**. During the Development Term of a Program, Licensee shall not use or file for protection of any Trademarks or trade names for a Licensed Product with respect to such Program.

2.3. **Development Term Exclusivity**.

2.3.1. **Licensee Exclusivity**. During the Development Term with respect to a Program, neither Licensee nor any of its Affiliates shall: (i) […***…].

2.3.2. […***…]

2.3.3. **Exceptions**. Notwithstanding the foregoing:

(a) Section 2.3.1 does not prohibit Licensee and its Affiliates that are subject to Section 2.3.1, alone or through work conducted in collaboration with an Affiliate or Third Party, from conducting research and non-clinical development (or licensing or otherwise granting rights to an Affiliate or a Third Party to conduct research and non-clinical development) of compounds (other than Licensed Compounds) that (i) […***…] or (ii) […***…].

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(b) Section 2.3.2 does not prohibit Janssen and its Affiliates, alone or through work conducted in collaboration with an Affiliate or Third Party, from conducting research and non-clinical development (or licensing or otherwise granting rights to an Affiliate or a Third Party to conduct research and non-clinical development) of compounds (other than Licensed Compounds) that […***…].

(c) This Section 2.3 shall not apply to the Acquirer of a Party or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of such Party prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control), *provided* that, if the Acquirer or such Affiliate conducts any activities described in Section 2.3.1 or 2.3.2 as applicable, during the Development Term (the "**Development Term Acquirer Activities**"), such Acquirer or Affiliate shall use reasonable good faith efforts to segregate such Development Term Acquirer Activities from activities conducted with respect to the Licensed Compounds and Licensed Products pursuant to this Agreement, including by (x) not permitting personnel who perform the Development Term Acquirer Activities to have access to Program-Related Information or other Confidential Information of the other Party (including Know-How and proprietary Development or Commercialization plans or other business information); and (y) not permitting personnel who perform activities conducted with respect to the Licensed Compounds and Licensed Products pursuant to this Agreement to perform Development Term Acquirer Activities (*provided* that the foregoing shall not apply to senior management and regulatory, chemistry-manufacturing-controls, patent, legal and other similar personnel).

(d) Neither Party shall be limited or prohibited by Section 2.3 from negotiating and completing a Change of Control, or taking any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party relating to, or engage in discussions with any Third Party relating to, a Change of Control.

2.4. **No Third Party Program Agreements**. During the Development Term with respect to a Program, neither Licensee nor any of its Affiliates shall (i) enter into a Third Party Program Agreement with respect to such Program or (ii) take any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party or engage in discussions with any Third Party relating to a Third Party Program Agreement with respect to such Program. Notwithstanding anything to the contrary herein, Licensee shall not be limited or prohibited from negotiating and completing any Change of Control, or taking any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party or engage in discussions with any Third Party relating to a Change of Control. If, during the Development Term with respect to a Program, Licensee receives any inquiry, proposal or offer by or from any Third Party relating to a potential Third Party Program Agreement, Licensee shall notify Janssen in writing (a "**Third Party Offer Notice**") as soon as reasonably practicable of the existence of such inquiry, proposal or offer by or from a Third Party, but shall not be required to disclose the identity of the Third Party or any terms of any

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Third Party inquiry, proposal or offer. For clarity, such Third Party Offer Notice shall have no effect on the Option or Right of First Negotiation with respect to the applicable Program.

2.5. **Third Party Contracts**. If any Know-How, Patent Right or other intellectual property right would first become Controlled by a Party after the Effective Date through a license from a Third Party, and […***…], such licensee Party shall first notify the other Party of […***…], and such Know-How, Patent Right or other intellectual property right shall not be deemed to be Controlled by such licensee Party for purposes of this Agreement, except to the extent, and only to the extent that, […***…], and to acknowledge that its sublicense under such license is subject to the terms and conditions of the license agreement with the Third Party.

Article 3
OPTION AND RIGHT OF FIRST NEGOTIATION

3.1. **Grant of Option.** Subject to the terms and conditions of this Agreement, Licensee hereby grants, on behalf of itself and its Affiliates, to Janssen an exclusive option, exercisable at Janssen's sole discretion in accordance with Section 3.3.1 at any time during the Option Period, to (i) terminate the licenses and related rights granted by Janssen to Licensee pursuant to this Agreement with respect to the AR Mutant Program, (ii) obtain an exclusive license under the Licensed Technology (as defined in the AR Mutant License Agreement) to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale the AR Mutant Compounds and AR Mutant Products on the terms and conditions set forth in the AR Mutant License Agreement and (iii) obtain the other rights set forth in the AR Mutant License Agreement (the "**Option**").

3.2. **Delivery of POC Trial Notice and Data Package**.

3.2.1. **Delivery. [**…***…], Licensee shall deliver a POC Trial Notice and Data Package for the applicable Program to Janssen. If such POC Trial Notice and Data Package relates to the AR Mutant Program, Licensee shall concurrently deliver to Janssen the draft TRACON Schedule Letter (as defined in the AR Mutant License Agreement) to be delivered with respect to the AR Mutant License Agreement, including any anticipated exceptions to the representations and warranties of Licensee with regard to Licensed Technology (as defined in the AR Mutant License Agreement) to be made in the AR Mutant License Agreement, and copies of any contracts referenced in such schedules ("**AR Mutant Schedule Information**"). The Parties shall review, discuss and finalize the TRACON Schedule Letter (as defined in the AR Mutant License Agreement) to be delivered with respect to the AR Mutant License Agreement before the AR Mutant License Agreement becomes effective pursuant to Section 3.3.1 in accordance with the procedures set forth on Exhibit C.

3.2.2. **Missing Information**. Janssen shall have […***…] following receipt of a Data Package to notify Licensee in writing if Janssen in good faith believes that any information that is required by the definition of AR Mutant Data Package or NIK Data Package, as applicable, is missing from the Data Package (a "**Missing Information Notice**"), which Missing Information Notice shall identify with reasonable detail such

information that Janssen believes is missing. If Janssen delivers a Missing Information Notice to Licensee, Licensee shall deliver the missing information identified in such Missing Information Notice as soon as practicable and the Data Package will be deemed complete on the date on which all such missing information has been received by Janssen. If Janssen does not deliver a Missing Information Notice to Licensee, the initial Data Package will be deemed complete on the date it was received by Janssen. For purposes of this Agreement, "**POC Trial Notice Date**" means the date upon which Janssen has received a POC Trial Notice and complete Data Package with respect to a Program in accordance with this Section 3.2.2. For the avoidance of doubt, this Section 3.2.2 does not require Licensee to generate new information or to perform any additional activity not contemplated by the applicable Development Plan, except to the extent necessary to generate the information that is required to be included in the applicable Data Package.

3.2.3. **Updates and Additional Information**. During the […***…] period following the POC Trial Notice Date, Licensee shall: (a) promptly update such Data Package if any new data or information becomes available with respect to the applicable Program; (b) upon Janssen's reasonable request, provide (i) any available patent, regulatory or CMC information in Licensee's Control regarding any Licensed Compound or Licensed Product, (ii) any […***…] and (iii) […***…], in each case ((i), (ii) and (iii)) with respect to such Program; and (c) upon Janssen's reasonable request, afford to Janssen and its representatives reasonable access during normal business hours to Licensee's personnel to discuss such Data Package. If such Data Package relates to the AR Mutant Program, during such period, Licensee shall also provide any update to the AR Mutant Schedule Information.

3.2.4. **Interim Data Packages**. From time to time during the Development Term but no more frequently than […***…], Janssen may request, and Licensee shall deliver as soon as reasonably practicable, an interim data package with respect to a Program before delivery of a Data Package with respect to such Program pursuant to Section 3.2.1. Such interim data package will include the same information as a complete Data Package for such Program, but only to the extent such information exists and is available as of the date of Janssen's request. If the requested interim data package relates to the AR Mutant Program, Licensee shall concurrently deliver to Janssen the AR Mutant Schedule Information, but only to the extent such information exists and is available as of the date of Janssen's request. For clarity, such interim data package shall not constitute a Data Package or modify the Parties' rights and obligations under this Section 3.2 or under Section 3.3 or Section 3.4 unless (a) Janssen exercises the Option pursuant to Section 3.3 at any time prior to first availability of the AR Mutant POC Trial Data, in which case the interim data package last delivered with respect to the AR Mutant Program shall constitute the Data Package with respect to the AR Mutant Program, or (b) Janssen exercises the Right of First Negotiation pursuant to Section 3.4 at any time prior to first availability of the NIK POC Trial Data, in which case the interim Data Package last delivered with respect to the NIK Program shall constitute the Data Package with respect to the NIK Program.

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3.3. **Exercise and Expiration of Option**.

3.3.1. **Option Exercise**. To exercise the Option, Janssen shall provide Licensee written notice of Janssen's exercise of the Option at any time during the period commencing on […***…] and ending […***…] after the POC Trial Notice Date with respect to the AR Mutant Program (which shall terminate early upon termination of this Agreement in its entirety pursuant to Section 11.2, 11.3 or 11.4 or termination of this Agreement with respect to the AR Mutant Program pursuant to Section 11.2, 11.3 or 11.4); *provided*, *however*, […***…] (the "**Option Period**"). If Janssen provides written notice of exercise of the Option on or prior to the expiration of the Option Period, the Option shall be deemed to be exercised on the date such exercise notice is deemed given in accordance with Section 13.11. Following Janssen's exercise of the Option pursuant to this Section 3.3.1, Licensee shall invoice Janssen for, and Janssen shall pay to Licensee within […***…] after receipt of such invoice (a) a one-time, non-creditable, non-refundable Option exercise fee of $45,000,000 (the "**Option Exercise Fee**") and (b) […***…]. Effective upon Licensee's receipt of the Option Exercise Fee and the amounts described in clause (b) (the "**Option Exercise Effective Date**"): (i) the Development Term of the AR Mutant Program shall terminate, (ii) this Agreement shall expire and be of no further force and effect with respect to the AR Mutant Program (for clarity, the AR Mutant Program shall not be a Terminated Program), and (iii) the AR Mutant License Agreement shall automatically, with no further action by either Party, go into full force and effect. Upon Janssen's request, each Party shall execute and deliver to the other Party the AR Mutant License Agreement; *provided*, *however*, that any delay or failure to execute or deliver the AR Mutant License Agreement shall not affect whether or when the AR Mutant License Agreement went into full force and effect pursuant to this Section 3.3.1. Notwithstanding the foregoing, (x) Licensee shall complete in a timely manner after the Option Exercise Effective Date any […***…] that were not completed before the Option Exercise Effective Date and (y) Janssen shall […***…] within […***…] after receipt of invoice from Licensee.

3.3.2. **Option Expiration**. If (i) Janssen does not exercise the Option in accordance with Section 3.3.1 on or prior to the expiration of the Option Period, then upon the day immediately after the last day of the Option Period or (ii) Janssen does not make the payments to Licensee required by Section 3.3.1 within […***…] after receipt of invoice from Licensee, then upon the day immediately after the last day of such […***…] period, in either case without any further action on the part of either Party: (a) the Option shall expire and be of no further force or effect; (b) the Development Term of the AR Mutant Program shall terminate; (c) Article 4, Article 5 (other than Sections 5.2 and 5.3) and Article 6, and Sections 7.4.2, 7.6, 7.7, 7.8, 11.5 and 11.6.4 shall become effective with respect to the AR Mutant Program; and (d) Sections 2.1.1(a), 2.1.2, 2.2, 2.3, 2.4, 3.1, 3.2, 3.3.1, 8.1.2, 9.5.1, 11.2 and 11.6.1 shall terminate and be of no further force or effect with respect to the AR Mutant Program.

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3.3.3. **Merger Control Law Compliance**.

(a) As promptly as practicable following the POC Trial Notice Date, Janssen and Licensee shall reasonably cooperate to determine whether any filing or notification is necessary or advisable under any applicable Antitrust Law (a) with respect to the AR Mutant Program, if Janssen were either to exercise or not exercise the Option and (b) with respect to the NIK Program, if the Parties were or were not to enter into a Janssen NIK License Agreement.

(b) If the Parties determine that such a filing or notification under any applicable Antitrust Law is necessary or advisable, then each Party shall make or cause to be made such notifications and filings as promptly as practicable (but in any event within […***…]) after (i) with respect to the AR Mutant Program, Janssen exercises the Option, and (ii) with respect to the NIK Program, the Parties enter into a NIK Program License Agreement.

(c) Each Party shall be responsible for its own costs and expenses associated with such notifications and filings. If Janssen exercises the Option or ROFN, Janssen shall pay any applicable premerger filing fee under the HSR Act with respect to the relevant Program. Each Party shall use Commercially Reasonable Efforts to obtain the expiration or termination of the applicable waiting period under the HSR Act, and to obtain the termination or expiration of any other applicable waiting periods or any necessary approvals or consents under any other applicable Antitrust Law, at the earliest possible date after the date of filing.

(d) If Janssen exercises the Option, the Option Exercise Effective Date shall be deemed to be delayed until the date on which the last waiting period under any applicable Antitrust Law has expired or been terminated or on which the last approval or consent under such Antitrust Law is granted.

(e) Notwithstanding anything to the contrary in this Section 3.3.3, this Section 3.3.3 does not require that either Party (i) offer, negotiate, commit to or effect, by consent decree, hold separate order, trust or otherwise, the sale, divestiture, license or other disposition of any capital stock, assets, rights, products or businesses of Janssen, Licensee or their respective Affiliates, (ii) agree to any restrictions on the activities of Janssen, Licensee or their respective Affiliates, or (iii) pay any material amount or take any other action to prevent, effect the dissolution of, vacate, or lift any decree, order, judgment, injunction, temporary restraining order, or other order in any suit or proceeding that would otherwise have the effect of preventing or delaying any of the transactions contemplated by exercise of the Option or entry into a Janssen NIK License Agreement.

3.4. **NIK Program Right of First Negotiation**.

3.4.1. **Grant of ROFN**. Subject to the terms and conditions of this Agreement, Licensee hereby grants, on behalf of itself and its Affiliates, to Janssen an exclusive right of first

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negotiation with respect to the NIK Program on the terms set forth in this Section 3.4.1 (the "**Right of First Negotiation**" or "**ROFN**").

(a) Janssen may in its sole discretion elect to exercise its Right of First Negotiation by written notice of exercise delivered to Licensee at any time on or before the ROFN Exercise Deadline.

(b) To exercise the Right of First Negotiation, Janssen shall give Licensee written notice of such exercise no later than the ROFN Exercise Deadline (the "**ROFN Exercise Notice**"). Upon Janssen's timely exercise of the ROFN in accordance with this Section 3.4, Janssen and Licensee shall negotiate in good faith on an exclusive basis for up to […***…] from the date the ROFN Exercise Notice is deemed given in accordance with Section 13.11 (the **"Negotiation Period"**) a separate written agreement pursuant to which Licensee would grant Janssen exclusive (even as to Licensee) license under the Licensee NIK Program Technology to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale NIK Compounds and NIK Products in the Field in the Territory on commercially reasonable terms (a **"Janssen NIK License Agreement"**). The Negotiation Period may be extended by mutual agreement of Janssen and Licensee, such agreement to be given, withheld or conditioned by a Party in its sole discretion.

(c) In the event that Janssen exercises its Right of First Negotiation but the Parties do not enter into a Janssen NIK License Agreement within the Negotiation Period, Licensee may thereafter negotiate with Third Parties to enter into a Third Party NIK Program Agreement, take any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party or engage in discussions with any Third Party relating to a Third Party NIK Program Agreement, and enter into a Third Party NIK Program Agreement without further obligation to Janssen under this Section 3.4.1; *provided, however,* that during the […***…] period immediately following the last day of the Negotiation Period (the "**Tail Period**"), Licensee may enter into a Third Party NIK Program Agreement only if the following conditions are satisfied: (i) Licensee has not provided to the applicable Third Party any material information regarding the NIK Program other than the information provided by Licensee to Janssen pursuant to Section 3.2 before or during the Negotiation Period (the "**Additional NIK Program Information**"); and (ii) […***…]; and Licensee may not enter into any Third Party NIK Program Agreement that does not satisfy either condition set forth in clause (i) or (ii) (a "**Restricted Third Party NIK Program Agreement**"), unless Licensee complies with the remainder of this Section 3.4.1(c). Prior to entering into a Restricted Third Party NIK Program Agreement, Licensee shall provide Janssen with a written notice of Licensee's intent to enter into such agreement, which notice shall include any Additional NIK Program Information and […***…]. Janssen shall have […***…] following receipt of such notice to propose an offer of […***…]. If Janssen proposes such an offer within such […***…] period, then the Parties shall negotiate in good faith and

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seek to enter into a Janssen NIK License Agreement on such terms proposed by Janssen for […***…] after Janssen proposes such offer. If (x) Janssen does not propose such an offer within such […***…] period or (y) the Parties do not enter into a Janssen NIK License Agreement within […***…] after Janssen proposes such an offer, then Licensee shall have no further obligations to Janssen under this Section 3.4. For purposes of this Section 3.4.1(c), […***…].

(d) If the Parties enter into a Janssen NIK License Agreement, immediately prior to the effective date of such Janssen NIK License Agreement: (i) the Development Term of the NIK Program shall terminate; and (ii) this Agreement shall expire and be of no further force and effect with respect to the NIK Program (for clarity, the NIK Program shall not be a Terminated Program).

3.4.2. **No Effect on Other Janssen Rights or Licensee Obligations**. For clarity, the provisions of this Section 3.4 are not intended to (a) prohibit or restrict Janssen from making proposals and offers to Licensee at any time (including after the ROFN Period) relating to a potential Janssen NIK License Agreement; (b) modify any of Licensee's obligations under the other applicable provisions of this Agreement (including Sections 2.3 and 2.4); or (c) obligate either Party to enter into any Janssen NIK License Agreement.

3.4.3. **ROFN Expiration**.

(a) If Janssen does not exercise the ROFN in accordance with Section 3.4.1 on or prior to the ROFN Exercise Deadline, then upon the day immediately after the ROFN Exercise Deadline, without any further action on the part of either Party: (i) the ROFN shall expire and be of no further force or effect; (ii) the Development Term of the NIK Program shall terminate; (iii) Article 4, Article 5 (other than Sections 5.2 and 5.3) and Article 6, and Sections 7.4.2, 7.6, 7.7, 7.8, 11.5 and 11.6.4 shall become effective with respect to the NIK Program; and (iv) Sections 2.1.1(b), 2.1.2, 2.2, 2.3, 2.4, 3.1, 3.2, 3.3.1, 8.1.2, 9.5.1, 11.2 and 11.6.1 shall terminate and be of no further force or effect with respect to the NIK Program.

(b) If Janssen exercises the ROFN in accordance with Section 3.4.1 on or prior to the ROFN Exercise Deadline, but the Parties do not execute a Janssen NIK License Agreement on or prior to the expiration of the Negotiation Period, then upon the day immediately after the last day of the Negotiation Period, without any further action on the part of either Party: (i) the ROFN shall expire and be of no further force or effect, *provided* that Section 3.4.1(c) shall survive for the time period set forth therein; (ii) the Development Term of the NIK Program shall terminate; (iii) Article 4, Article 5 (other than Sections 5.2 and 5.3) and Article 6, and Sections 7.4.2, 7.6, 7.7, 7.8, 11.5 and 11.6.4 shall become effective with respect to the NIK Program; and (iv) Sections 2.1.1(b), 2.1.2, 2.2, 2.3, 2.4, 3.1, 3.2, 3.3.1, 8.1.2, 9.5.1, 11.2 and 11.6.1 shall terminate and be of no further force or effect with respect to the NIK Program.

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Article 4
ACTIVITIES AFTER DEVELOPMENT TERM

4.1. **General**.

4.1.1. With respect to the AR Mutant Program, the provisions of this Article 4 shall apply to the AR Mutant Program, and Licensed Compounds and Licensed Products with respect to the AR Mutant Program, during the License Term of the AR Mutant Program if, and only if, the Option expires in accordance with Section 3.3.2. With respect to the AR Mutant Program, the "**License Term**" means the period beginning immediately after the date of expiration of the Option in accordance with Section 3.3.2 and ending on the expiration of the Term with respect to the AR Mutant Program, unless terminated earlier in accordance with Article 11.

4.1.2. With respect to the NIK Program, the provisions of this Article 4 shall apply to the NIK Program, and Licensed Compounds and Licensed Products with respect to the NIK Program, during the License Term of the NIK Program if, and only if, the ROFN expires in accordance with Section 3.4.3. With respect to the NIK Program, the "**License Term**" means the period beginning immediately after the last day of the ROFN Period and ending on the expiration of the Term with respect to the NIK Program, unless terminated earlier in accordance with Article 11.

4.2. **Development**.

4.2.1. **General**. Licensee shall have the sole right and responsibility, at its sole cost and expense, to Develop Licensed Compounds and Licensed Products in the Field in the Territory, and for all regulatory matters relating to such activities. Licensee will conduct such Development activities in accordance with the terms and conditions of this Agreement, in good scientific manner and in compliance with all Applicable Laws.

4.2.2. **Diligence**. Licensee shall use Commercially Reasonable Efforts to […***…].

4.2.3. **Records**. Licensee shall prepare and maintain, and shall cause its Affiliates, sublicensees and Third Party Subcontractors to prepare and maintain, complete and accurate Program Records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in conformity with Applicable Law and Licensee's standard practices, which Program Records shall reflect all work done and results achieved in connection with the Programs. Licensee shall retain, and cause its Affiliates, sublicensees and Third Party Subcontractors to retain, the Program Records for at least […***…] or such longer period as may be required by Applicable Law. In addition, Licensee shall comply with Janssen's data policies set forth on Exhibit B with respect to the Program Records.

4.2.4. **Reports**. Licensee shall provide Janssen with a written summary of its progress with respect to the Development of Licensed Compounds and Licensed Products in the Field in the Territory […***…], including the […***…]. Upon Janssen's reasonable

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request, Licensee shall be available for an in-person or telephonic meeting to discuss its progress on the Development of the Licensed Compounds and Licensed Products with Janssen.

4.3. **Manufacturing**. Licensee shall have the sole right and responsibility, at its sole cost and expense, to Manufacture clinical and commercial supplies of Licensed Compounds and Licensed Products. Licensee will conduct such Manufacturing activities in accordance with the terms and conditions of this Agreement and in compliance with all Applicable Laws.

4.4. **Commercialization**.

4.4.1. **General**. Licensee shall have the sole right and responsibility, at its sole cost and expense, to Commercialize Licensed Compounds and Licensed Products in the Field in the Territory. Licensee will conduct such Commercialization activities in accordance with the terms and conditions of this Agreement and in compliance with all Applicable Laws.

4.4.2. **Diligence**. Licensee shall use Commercially Reasonable Efforts to Commercialize […***…].

Article 5
LICENSE GRANTS

5.1. **General**.

5.1.1. With respect to the AR Mutant Program, the provisions of this Article 5 (other than Sections 5.2 and 5.3) shall apply to the AR Mutant Program, and Licensed Compounds and Licensed Products with respect to the AR Mutant Program, during the License Term of the AR Mutant Program if, and only if, the Option expires in accordance with Section 3.3.2. Sections 5.2 and 5.3 shall apply to the AR Mutant Program during the Term of the AR Mutant Program.

5.1.2. With respect to the NIK Program, the provisions of this Article 5 (other than Sections 5.2 and 5.3) shall apply to the NIK Program, and Licensed Compounds and Licensed Products with respect to the NIK Program, during the License Term of the NIK Program if, and only if, the ROFN expires in accordance with Section 3.4.3. Sections 5.2 and 5.3 shall apply to the NIK Program during the Term of the NIK Program.

5.2. **License Grant**. Subject to the terms and conditions of this Agreement (including Section 5.3), during the Term with respect to a Program, Janssen hereby grants to Licensee an exclusive (subject to Section 5.3), royalty-bearing, non-transferable (except to the extent permitted under Section 13.6), sublicensable through multiple tiers of sublicense (subject to Section 5.4) license under the Licensed Technology with respect to such Program to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale Licensed Compounds and Licensed Products with respect to such Program in the Field in the Territory. Subject to the terms and conditions of this Agreement (including Section 5.3),

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during the Term with respect to the AR Mutant Program, Janssen hereby grants to Licensee an exclusive (subject to Section 5.3), royalty-free, non-transferable (except to the extent permitted under Section 13.6), sublicensable through multiple tiers of sublicense (subject to Section 5.4) license under the Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale companion diagnostic products solely for use with AR Mutant Compounds and AR Mutant Products Developed or Commercialized by Licensee pursuant to this Agreement in the Field in the Territory. Licensee covenants and agrees not to exercise any of its rights under this Section 5.2 with respect to a Program unless and until the License Term of such Program begins; *provided* that this provision shall not limit Licensee's ability to exercise its rights under and in accordance with Article 2.

5.3. **Janssen Retained Rights**. Licensee acknowledges and agrees that:

5.3.1. Janssen and its Affiliates (i) retain the right to use the Licensed Technology and the Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter to make, have made, use, have used, import and have imported Licensed Compounds and Licensed Products solely to conduct Internal Research with Licensed Compounds or Licensed Products and (ii) shall not be obligated to remove any Licensed Compound from its compound libraries that are used for Internal Research; and

5.3.2. Janssen and its Affiliates may use for any purpose (other than those purposes for which Licensee is granted an exclusive license pursuant to Section 2.1.1 or Section 5.2) any information in non-tangible and non-recorded (whether in written, electronic, visual or other media) form which may be retained in the unaided memory of any personnel of Janssen or its Affiliates who had access to the Licensed Compounds, Licensed Products, Licensed Technology and the Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter prior to the Effective Date; *provided, however,* that the foregoing is not intended to grant, and shall not be deemed to grant, any right to disclose such information to any Third Party.

5.4. **Sublicensing**. During the Development Term of a Program, Licensee may not sublicense to any Third Party or any of its Affiliates any of the rights granted to it by Janssen under Section 5.2 with respect to such Program. During the License Term of a Program, Licensee may sublicense to any Third Party or any of its Affiliates the rights granted to it by Janssen under Section 5.2 with respect to such Program. Any such sublicense shall (i) be in writing, and (ii) be subject to, and consistent with, the terms of this Agreement. Licensee shall provide Janssen with a true and complete copy of each such sublicense and all amendments thereto within […***…] after execution thereof. Licensee shall remain responsible to Janssen for the performance of the financial and other obligations of its sublicensees.

5.5. **License Term Exclusivity**.

5.5.1. During the period beginning on the first day of the License Term with respect to a Program and ending […***…] after such day, neither Licensee nor any of its Affiliates shall: […***…].

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5.5.2. Notwithstanding the foregoing:

(a) Section 5.5.1 does not prohibit Licensee and its Affiliates that are subject to Section 5.5.1, alone or through work conducted in collaboration with an Affiliate or Third Party, from conducting research and non-clinical development (or licensing or otherwise granting rights to an Affiliate or a Third Party to conduct research and non-clinical development) of compounds (other than Licensed Compounds) that (i) […***…].

(b) Section 5.5.1 shall not apply to the Acquirer of a Party or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of such Party prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control), *provided* that, if the Acquirer or such Affiliate conducts any activities described in Section 5.5.1 during the period described in Section 5.5.1 (the "**Post-Development Term Acquirer Activities**"), such Acquirer or Affiliate shall use reasonable good faith efforts to segregate such Post-Development Term Acquirer Activities from activities conducted with respect to the Licensed Compounds and Licensed Products pursuant to this Agreement, including by (x) not permitting personnel who perform the Post-Development Term Acquirer Activities to have access to Program-Related Information or other Confidential Information of the other Party (including Know-How and proprietary Development or Commercialization plans or other business information); and (y) not permitting personnel who perform activities conducted with respect to the Licensed Compounds and Licensed Products pursuant to this Agreement to perform Post-Development Term Acquirer Activities (*provided* that the foregoing shall not apply to senior management and regulatory, chemistry-manufacturing-controls, patent, legal and other similar personnel).

(c) Licensee shall not be limited or prohibited by Section 5.5.1 from negotiating and completing a Change of Control, or taking any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party relating to, or engage in discussions with any Third Party relating to, a Change of Control.

Article 6
FINANCIAL TERMS

6.1. **General**.

6.1.1. With respect to the AR Mutant Program, the provisions of this Article 6 shall apply to the AR Mutant Program, and Licensed Compounds and Licensed Products with respect to the AR Mutant Program, during the License Term for such Program if, and only if, the Option expires in accordance with Section 3.3.2.

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6.1.2. With respect to the NIK Program, the provisions of this Article 6 shall apply to the NIK Program, and Licensed Compounds and Licensed Products with respect to the NIK Program, during the License Term of the NIK Program if, and only if, the ROFN expires in accordance with Section 3.4.3.

6.2. **Milestones.** Licensee will notify Janssen in writing within […***…] after the first achievement by Licensee or any of its Affiliates or sublicensees of any of the milestone events set forth in the table below with respect to a Program (each, a "**Milestone Event**"). In consideration of the licenses and rights granted to Licensee under this Agreement, Licensee shall pay to Janssen the applicable milestone payment set forth in the table below (each, a "**Milestone Payment**") within […***…] after receipt of an invoice from Janssen with respect to achievement of each Milestone Event. Each Milestone Payment shall be made only once, and shall be non-refundable and non-creditable.

6.2.1. With respect to the AR Mutant Program:

Milestone Event	Milestone Payment
A. […***…]	$[…***…]
B. […***…]	$[…***…]

[…***…]

6.2.2. With respect to the NIK Program:

Milestone Event	Milestone Payment
C. […***…]	$[…***…]
D. […***…]	$[…***…]
E. […***…]	$[…***…]

[…***…]

6.3. **Royalties**.

6.3.1. **Royalty Rates**.

(a) In consideration of the licenses and rights granted to Licensee under this Agreement with respect to the AR Mutant Program, Licensee shall pay to Janssen a royalty of […***…] on Net Sales of each AR Mutant Product in each country during the Royalty Term for such AR Mutant Product in such country.

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(b) In consideration of the licenses and rights granted to Licensee under this Agreement with respect to the NIK Program, Licensee shall pay to Janssen a royalty of […***…] on Net Sales of each NIK Product in each country during the Royalty Term for such NIK Product in such country.

6.3.2. **Royalty Reductions**.

(a) Licensee shall be responsible for the payment of any amounts that become due to any Third Party(ies) under any Janssen License Agreement as a result of Licensee's activities with respect to the Licensed Compounds or Licensed Products under this Agreement during the applicable License Term, only to the extent […***…]. In the event Janssen makes any such payment to a Third Party, Licensee shall reimburse Janssen for such amount.

(b) If Licensee or its Affiliate or sublicensee is required or reasonably deems it necessary to obtain a license from a Third Party under any intellectual property rights of such Third Party that […***…], Licensee shall have the right to deduct, from the royalties due to Janssen pursuant to Section 6.3.1 with respect to a Licensed Product containing such Licensed Compound during a Calendar Quarter, […***…] of the […***…] payments made by Licensee or its Affiliate or sublicensee to such Third Party(ies) in exchange for such license with respect to such Licensed Compound during such Calendar Quarter, *provided* that if any agreement with such Third Party includes rights to additional compounds or products other than such Licensed Compound, any such payment that is not triggered by sales of such Licensed Product containing such Licensed Compound shall be equitably allocated by Licensee in good faith among all compounds and products under such agreement. Licensee shall provide documentation of such allocation to Janssen and any dispute regarding such allocation shall be subject to resolution under Article 12.

(c) On a country-by-country and Licensed Product-by-Licensed Product basis, the royalties due to Janssen pursuant to Section 6.3.1 shall be reduced during the Royalty Term for such Licensed Product in such country to […***…] of the amount otherwise payable from and after the date that: (i) […***…].

(d) Notwithstanding the foregoing, in no event shall the total deductions under Sections 6.3.2(b) and 6.3.2(c) reduce the royalties payable to Janssen under Section 6.3.1 with respect to a given Licensed Product in a given country in any Calendar Quarter by more than […***…].

6.3.3. **Royalty Reports and Payments.** Commencing with the First Commercial Sale of a Licensed Product by Licensee or its Affiliates or sublicensees, Licensee shall provide written reports to Janssen within […***…] after the end of each Calendar Quarter, stating in each such report, by Licensed Product and by country, the aggregate Net Sales in U.S. Dollars of Licensed Products sold during such Calendar Quarter by Licensee and its Affiliates and sublicensees. Such report shall also include: (a) the calculation of the

royalty payments due to Janssen on such Net Sales; and (b) the exchange rates used in calculating the payments due Janssen, which exchange rates shall comply with Section 6.4.2. Simultaneously with the delivery of each such report, Licensee shall pay to Janssen the total royalties, if any, due to Janssen for the Calendar Quarter that is the subject of such report. If no royalties are due with respect to a particular Calendar Quarter, Licensee shall so report.

6.4. **Payment Terms**.

6.4.1. **Payments**. All payments due under this Agreement shall be made in U.S. Dollars by wire transfer in immediately available funds to an account designated by the receiving Party or by other mutually acceptable means.

6.4.2. **Currency Conversion.** The rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars of Net Sales invoiced in other currencies shall be consistent with Licensee's internal accounting practices used to prepare its audited financial statements.

6.4.3. **Late Payments.** If a Party does not receive payment of any amount due to it under this Agreement on or before the due date, such payment shall bear interest at a rate per annum equal to […***…] in excess of overnight LIBOR or a comparable reference interbank rate per currency or the maximum rate allowable by Applicable Law, whichever is lower.

6.5. **Records; Inspection**. Licensee shall keep (and cause its Affiliates and sublicensees to keep) complete, true and accurate books of account and records for the purpose of determining the royalties payable by Licensee to Janssen under Section 6.3 (the "**Royalty Records**"), which Royalty Records shall be retained for at least […***…] following the end of the Calendar Year to which they pertain. Licensee shall, and shall cause its Affiliates and sublicensees to, make the Royalty Records available for inspection by an independent public accounting firm of national prominence selected by Janssen, and reasonably acceptable to Licensee, during normal business hours, as may be reasonably necessary for the sole purpose of verifying the royalty reports and payments delivered by Licensee pursuant to Section 6.3 during the preceding […***…] full Calendar Years. The records for a given Calendar Year shall be subject to audit no more than one time. Such independent public accounting firm shall execute a reasonable confidentiality agreement with Licensee prior to commencing any such inspection. Such inspections shall be made no more than once each Calendar Year at reasonable times and on reasonable notice. Janssen shall bear the costs and expenses of any inspection conducted under this Section 6.5 unless such inspection reveals an underpayment in royalties payable pursuant to Section 6.3 of more than […***…] of the amount payable for the period covered by such inspection, in which case Licensee shall bear the costs and expenses of such inspection. If such inspection reveals an overpayment by Licensee pursuant to Section 6.3, then Licensee shall deduct the amount of such overpayment from any payment that subsequently becomes due and payable by Licensee under this Agreement or, if no payment is anticipated to be due and payable by Licensee in the following Calendar Quarter, Licensee shall invoice Janssen for the amount of the underpayment and Janssen shall pay such invoice within […***…] after receipt thereof. If such inspection

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reveals an underpayment by Licensee pursuant to Section 6.3, then Janssen shall invoice Licensee for the amount of the underpayment and Licensee shall pay such invoice within […***…] after receipt thereof.

6.6. **Withholding Taxes**.

6.6.1. Licensee will make all payments to Janssen under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.

6.6.2. Any Tax required to be withheld on amounts payable under this Agreement will be paid by Licensee on behalf of Janssen to the appropriate governmental authority, and Licensee will furnish Janssen with proof of payment of such Tax. Any such Tax required to be withheld will be an expense of and borne by Janssen.

6.6.3. Licensee and Janssen will cooperate with respect to all documentation required by any taxing authority or reasonably requested by Licensee to secure a reduction in the rate of applicable withholding Taxes. On the date of execution of this Agreement, Janssen will deliver to Licensee an accurate and complete Internal Revenue Service Form W-8BEN-E certifying that Janssen is entitled to the applicable benefits under the Income Tax Treaty between the Kingdom of Belgium and the United States.

Article 7
INTELLECTUAL PROPERTY

7.1. **Reporting of Development Program Inventions.** Each Party shall designate a patent attorney or agent as its contact to coordinate with the other Party the filing, prosecution and maintenance of Patent Rights as provided in this Article (the "**Patent Representative**"). Each Party shall promptly report to the other Party's Patent Representative any material Development Program Invention.

7.2. **Ownership.**

7.2.1. **Development Program Inventions and other Development Program Know-How.** Ownership in the Territory of Development Program Inventions and Patent Rights filed after the Effective Date claiming one or more Development Program Inventions (each, a "**Development Program Patent**") shall be allocated in accordance with inventorship as determined pursuant to principles of United States patent law as follows:

(a) each Development Program Invention invented solely by one or more employees or agents of Janssen (or its Affiliates or Third Party Subcontractors) and each Development Program Patent to the extent claiming one or more of such Development Program Inventions shall be owned solely by Janssen;

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(b) each Development Program Invention invented solely by one or more employees or agents of Licensee (or its Affiliates or Third Party Subcontractors) and each Development Program Patent to the extent claiming one or more of such Development Program Inventions shall be owned solely by Licensee; and

(c) each Development Program Invention invented jointly by one or more employees or agents of Janssen (or its Affiliates or Third Party Subcontractors) and one or more employees or agents of Licensee (or its Affiliates or Third Party Subcontractors) and each Development Program Patent to the extent claiming one or more of such Development Program Inventions shall be owned jointly by the Parties.

For purposes of this Agreement: (w) Development Program Know-How which is the basis for a Development Program Invention upon the filing of a Development Program Patent therefor will be the Confidential Information of the owner(s) of such Development Program Patent; (x) each Development Program Patent that is owned solely by Janssen pursuant to this Section 7.2.1 shall be referred to as a "**Janssen-Owned Development Program Patent**;" (y) each Development Program Patent that is owned solely by Licensee pursuant to this Section 7.2.1 shall be referred to as a "**Licensee-Owned Development Program Patent**," and (z) each Development Program Patent that is owned jointly by the Parties pursuant to this Section 7.2.1 shall be referred to as a "**Joint Development Program Patent**." Any Development Program Know-How generated by Janssen's or its Affiliates' or Third Party Subcontractors' employees or agents that is not otherwise allocated pursuant to Section 7.2.1(a), (b) or (c) will be the Confidential Information of Janssen ("**Janssen-Owned Development Program Know-How**"). Any Development Program Know-How generated by Licensee's or its Affiliates' or Third Party Subcontractors' employees or agents that is not otherwise allocated pursuant to Section 7.2.1(a), (b) or (c) will be the Confidential Information of Licensee ("**Licensee-Owned Development Program Know-How**").

7.2.2. **Other Inventions.** Ownership of any invention arising from any activities with respect to Licensed Compounds and/or Licensed Products conducted by a Party's or its Affiliates' or Third Party Subcontractors' employees or agents as contemplated by this Agreement (but excluding any Third Party Subcontractor Reserved Technology to the extent not assigned or licensed to a Party as contemplated by Section 2.2.3(e)), other than a Development Program Invention (each an "**Other Invention**"), and Patent Rights filed after the Effective Date claiming one or more Other Inventions, other than a Development Program Patent (each, an "**Other Patent**") shall follow inventorship as determined pursuant to principles of United States patent law. Accordingly, (a) all Other Inventions invented solely by one or more employees or agents of a Party (or its Affiliates or Third Party Subcontractors) and Other Patents to the extent claiming such Other Inventions shall be owned solely by such Party and (b) all Other Inventions invented jointly by one or more employees or agents of one Party (or its Affiliates or Third Party Subcontractors) and by one or more employees or agents of the other Party (or its Affiliates or Third Party Subcontractors) and Other Patents to the extent claiming such Other Inventions shall be owned jointly by the Parties. For clarity, if any

Development Program Patent includes any claim Covering any Other Invention, such Patent Right shall remain a Development Program Patent subject to the terms hereof. Other Inventions and Other Patents solely owned by Janssen and Janssen's interest in Other Inventions and Other Patents jointly owned by Janssen and Licensee shall be included in AR Mutant Program Know-How, AR Mutant Program Patents, NIK Program Know-How or NIK Program Patents, as applicable. Other Inventions and Other Patents solely owned by Licensee and Licensee's interest in Other Inventions and Other Patents jointly owned by Janssen and Licensee shall be included in Licensee Program Know-How or Licensee Program Patents, as applicable.

7.2.3. **Confirmatory Assignments; Inventor Compensation.** Each Party shall take all reasonable actions requested by the other Party responsible for prosecuting any Development Program Patent to perfect or separately document the other Party's ownership interest rights in such Development Program Patent as provided for in this Agreement, including by causing its and its applicable Affiliates' and Third Party Subcontractors' employees and agents to execute appropriate assignment documents, and the requesting Party shall not be required to pay any remuneration to the other Party or its Affiliates or Third Party Subcontractors, or any of their employees, or agents, for the execution of any assignments or other papers pursuant to this Section. For clarity, each Party (directly or through its applicable Affiliate or Third Party Subcontractor) shall be solely responsible for any compensation due to its and its Affiliates' and Third Party Subcontractors' employees and agents in connection with the assignment of their respective rights to any Development Program Inventions and associated Development Program Patents pursuant to this Agreement or the exploitation of any Party or its Affiliates or Third Party sublicensees hereunder of any such Development Program Inventions or associated Development Program Patents with respect to Licensed Compounds or Licensed Products, including any required by operation of Applicable Law on account of any Commercialization of any such Development Program Inventions with respect to Licensed Compounds or Licensed Products hereunder.

7.2.4. **Right to Practice Jointly Owned Technology**. Except to the extent either Party is restricted by the express terms of this Agreement, with respect to any Development Program Inventions, Development Program Patents, Other Inventions and Other Patents that are owned jointly by the Parties pursuant to Section 7.2.1 or 7.2.2, each Party shall have the right to practice and exploit such Development Program Inventions, Development Program Patents, Other Inventions and Other Patents, with full rights to sublicense in the Territory, and without the duty of accounting to or any duty to seek consent from the other Party, and upon the reasonable request of either Party, the other Party shall execute documents that evidence or confirm the requesting Party's right to engage in such activities.

7.3. **Prosecution of Patent Rights.**

7.3.1. **Communications.** Each Party shall use reasonable efforts to handle all communications between the Parties under this Section 7.3 through their Patent Representatives and keep such communications in strict confidence to protect their attorney-client privileged status.

7.3.2. **Reporting of Filings.** A Party planning on filing any priority-establishing or original (in each case, with respect to any claims or new matter described in the patent specification) patent application within the Development Program Patents hereunder shall use reasonable efforts to provide to the other Party with reasonable advance time prior to proposed prosecution filing in a patent office (such as a draft application or response to an official action), provide the other Party an opportunity to comment thereon through its Patent Representative, and give good faith consideration to the other Party's comments. Each Party shall provide to the other, promptly after filing, a copy of each priority-establishing or original (whether provisional or non-provisional) patent application within the Development Program Patents as filed in the patent office and each other substantive prosecution filing (including any other patent application filed within the Development Program Patents).

7.3.3. **Prosecution Responsibility and Coordination.**

(a) *Janssen Program Patents and Janssen-Owned Development Program Patents During the Development Term*. With respect to the Janssen Program Patents and Janssen-Owned Development Program Patents, during the Development Term for a Program:

(1) Janssen shall be primarily responsible, through outside patent counsel mutually acceptable to the Parties and engaged by both Parties, to prosecute AR Mutant Program Patents and Janssen-Owned Development Program Patents with respect to the AR Program, *provided* that Janssen shall: (i) consider the reasonable suggestions of Licensee's Patent Representative as to selection of country patent offices in the Territory for filing or validating applications to form a family of related such Patent Rights and as to the abandonment of any such Patent Rights; and (ii) consider in good faith any reasonable comments of Licensee as provided by its designated Patent Representative in prosecuting any such Patent Rights, including with respect to the filing of any continuation, divisional or other continuing applications.

(2) Licensee shall be primarily responsible, through outside patent counsel mutually acceptable to the Parties and engaged by both Parties, to prosecute NIK Program Patents and Janssen-Owned Development Program Patents with respect to the NIK Program, *provided* that Licensee shall: (i) consider the reasonable suggestions of Janssen's Patent Representative as to selection of country patent offices in the Territory for filing or validating applications to form a family of related such Patent Rights and as to the abandonment of any such Patent Rights; and (ii) consider in good faith any reasonable comments of Janssen as provided by its designated Patent Representative in prosecuting any such Patent Rights, including with respect to the filing of any continuation, divisional or other continuing applications.

(b) *Janssen Program Patents and Janssen-Owned Development Program Patents During the License Term*. With respect to the Janssen Program Patents and Janssen-Owned Development Program Patents, during the License Term for a Program, Licensee shall be primarily responsible, through outside patent counsel mutually acceptable to the Parties and engaged by both Parties, to prosecute such Patent Rights with respect to a Program, *provided* that Licensee shall: (i) consider the reasonable suggestions of Janssen's Patent Representative as to selection of country patent offices in the Territory for filing or validating applications to form a family of related such Patent Rights and as to the abandonment of any such Patent Rights; and (ii) consider in good faith any reasonable comments of Janssen as provided by its designated Patent Representative in prosecuting any such Patent Rights, including with respect to the filing of any continuation, divisional or other continuing applications.

(c) *Duties Imposed by Law*. Sections (a) and (b) of this Section 7.3.3 notwithstanding, it will not be a breach of this Agreement that a Party, in good faith, does not execute a document or withholds or revokes consent to an action in the course of filing, prosecuting or maintaining a Patent Right hereunder that such Party reasonably believes to violate a duty imposed by law on such Party as the owner of such a Patent Right.

(d) *Prosecution Costs for Janssen Program Patents and Janssen-Owned Development Program Patents.* Subject to Section 7.3.3(h), Janssen shall be solely responsible for (i) all Patent Costs incurred in prosecuting any Janssen Program Patents on or before the Effective Date and (ii) all Patent Costs incurred by or on behalf of Janssen in prosecuting any Janssen Program Patents or Janssen-Owned Development Program Patents with respect to the AR Mutant Program during the Development Term with respect to the AR Mutant Program. Subject to Section 7.3.3(h), Licensee shall be solely responsible for all Patent Costs incurred in prosecuting (x) any Janssen Program Patents or Janssen-Owned Development Program Patents with respect to the NIK Program during the Development Term with respect to the NIK Program and (y) any Janssen Program Patents or Janssen-Owned Development Program Patents with respect to a Program during the License Term with respect to such Program.

(e) *Janssen Covenant.* Janssen and its Affiliates will not […***…],

(f) *Licensee Program Patents, Licensee-Owned Development Program Patents, Joint Development Program Patents and Jointly Owned Other Patents.* Licensee shall be primarily responsible, through outside patent counsel mutually selected and engaged by the Parties, for prosecuting any Licensee Program Patents, Licensee-Owned Development Program Patents, Joint Development Program Patents and jointly owned Other Patents during the Term with respect to the applicable Program, *provided* that Licensee shall: (i) consider the reasonable suggestions of Janssen's Patent Representative as to selection of country patent offices in the Territory for filing or validating applications to form a family of

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related such Patent Rights and as to the abandonment of any such Patent Rights; and (ii) consider in good faith any reasonable comments of Janssen in prosecuting any such Patent Rights, including with respect to the filing of any continuation, divisional, or other continuing applications. After the Term with respect to the applicable Program, responsibility for prosecuting any Joint Development Program Patents and jointly owned Other Patents and the Patent Costs incurred in such prosecution shall be subject to mutual written agreement of the Parties.

(g) *Prosecution Costs for Licensee Program Patents, Licensee-Owned Development Program Patents, Joint Development Program Patents and Jointly Owned Other Patents.* Subject to Section 7.3.3(h), Licensee shall be responsible for all Patent Costs incurred by or on behalf of Licensee in prosecuting any Licensee Program Patents, Licensee-Owned Development Program Patents, Joint Development Program Patents or jointly owned Other Patents during the Term with respect to the applicable Program.

(h) *Step-In Rights*. If the applicable Party prosecuting a Patent Right hereunder intends in its discretion to abandon or not maintain (so as to permit to lapse) any Janssen Program Patent, Licensee Program Patent, Development Program Patent or jointly owned Other Patent in any jurisdiction in the Territory, then the prosecuting Party shall provide the other Party with written notice of such intent within a period of time reasonably necessary to allow the other Party to determine its interest in such Patent Right (which notice from the prosecuting Party shall be given no later than […***…] prior to any final deadline for any pending action or response that may be due with respect to such Patent Right with the applicable patent office). If the other Party provides written notice to the prosecuting Party expressing its interest in preserving such Patent Right, the prosecuting Party shall cooperate with the other Party in providing the other Party the right to prosecute such Patent Right in such jurisdiction. The Party assuming the right to prosecute a Patent Right under this Section shall be responsible for all Patent Costs incurred by such Party in prosecuting such Patent Right. Notwithstanding the foregoing, if Licensee determines that it does not want to prosecute any Janssen Program Patent or Janssen-Owned Development Program Patent for which it is responsible pursuant to this Section 7.3.3, Licensee shall so notify Janssen and, following the date that such notice is given, the applicable Patent Right shall no longer be a Janssen Program Patent or Janssen-Owned Development Program Patent, as applicable, for purposes of this Agreement (and, if such Patent Right was set forth on Schedule NIK Program Patents, such Patent Right shall be deemed to be removed from Schedule NIK Program Patents).

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7.3.4. **Prosecution Cooperation.** Each Party shall, at its own expense, provide all reasonable assistance requested by the other Party for prosecuting any Janssen Program Patents, Licensee Program Patents, Development Program Patents or jointly owned Other Patents consistent with the terms hereof, including with respect to the timely completion of filings of prosecution papers, compliance with Applicable Laws and recording of assignments to reflect ownership consistent with the terms hereof. A Party prosecuting any Janssen Program Patents, Licensee Program Patents or Development Program Patents hereunder shall use reasonable efforts to provide the other Party with copies of all material prosecution papers as filed in or received from any patent offices. The Party prosecuting any Janssen Program Patents, Licensee Program Patents, Development Program Patents or jointly owned Other Patents hereunder shall, on an annual basis during the Term, provide the other Party with a report identifying the status of any such Patent Rights; *provided*, *however*, that for Joint Development Program Patents or jointly owned Other Patents, the Parties shall cooperate to jointly prepare such status report.

7.3.5. **CREATE Act.** The Parties acknowledge that, during the course of the Development Term with respect to a Program, Development Program Patents with respect to such Program may be generated with different assigning entities which, during the course of U.S. patent prosecution, may benefit from use of the CREATE Act of 2004 (70 Fed. Reg. 177(54259-54267) as amended by the Leahy-Smith America Invents Act of 2011 (35 U.S.C. §§102(b)(2)(c) and 102(c)) (the "**CREATE Act**"). For the purposes of the benefit of the CREATE Act, the Parties deem this Agreement and/or the written memorialization of transactions contemplated hereunder, such as pertaining to the Development pursuant to a Program, to constitute a qualifying written Joint Research Agreement and agree that, if deemed necessary to effectuate the use of the CREATE Act, appropriate patent applications may be amended to include the names of the Parties. The Parties also acknowledge that a terminal disclaimer submitted during patent prosecution under the CREATE Act, if likewise deemed necessary, may include a provision pursuant to Applicable Law that the assigning entity of a second-filed patent application in prosecution waives the right to separately enforce a first-filed patent application made in the course of the Development pursuant to a Program, and a patent issuing on the second-filed application will not be enforceable if separately litigated. For clarity, a Party submitting a terminal disclaimer under the CREATE Act shall provide a copy of such terminal disclaimer to the other Party's Patent Representative.

7.4. **Patent Enforcement.**

7.4.1. **Notice.**

(a) Each Party shall notify the other promptly of any apparent, threatened, or actual infringement by a Third Party of any Janssen Program Patent, Licensee Program Patent Development Program Patent or jointly owned Other Patent, or misappropriation of any Janssen Program Know-How, Licensee Program Know-How, Development Program Know-How or jointly owned Other Patent, of which the Party becomes aware. The notifying Party shall promptly furnish the other with all known details or evidence of such infringement or misappropriation.

(b) Each Party shall promptly notify the other of any Third Party communications pertaining to any Janssen Program Patent, Licensee Program Patent, Development Program Patent or jointly owned Other Patent that the Party receives pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 or similar such notice, including notices pursuant to §§ 101 and 103 of such act from Persons who have filed an abbreviated NDA (ANDA) or a paper NDA.

7.4.2. **Enforcement Actions.** During the License Term with respect to a Program, Licensee shall have the initial right, at its expense and in its own name (or in the name of Janssen as may be required under Applicable Law), for bringing any infringement suit or other enforcement action (an "**Action**") on account of any Third Party infringement of any Janssen Program Patent, Licensee Program Patent, Development Program Patent or any jointly owned Other Patent with respect to such Program based on any alleged making, using, selling, offering for sale, importing or other exploitation of any product that is competitive with a Licensed Product with respect to such Program in the infringement of any such Patent Rights, or based on misappropriation of any Janssen Program Know-How, Licensee Program Know-How or Development Program Know-How with respect to such Program providing any Regulatory Exclusivity for any such Licensed Product (each a "**Product Infringement**"), by counsel of its own choice, and Janssen will cooperate with Licensee as Licensee may reasonably request in connection with any such Action, including by becoming a party to such Action at Licensee's cost, *provided* that Licensee shall reimburse Janssen for its out-of-pocket costs reasonably incurred in connection with rendering such assistance. If Licensee declines to initiate such an Action against any unabated Product Infringement, it shall so notify Janssen, who shall thereafter have the right (but not the obligation), at Janssen's expense and in its own name, to initiate such Action on account of any Third Party infringement of any Janssen Program Patent, Janssen-Owned Development Program Patent or Joint Development Program Patent by counsel of its choice, and Licensee shall cooperate with Janssen as Janssen may reasonably request, including by becoming a party to such action at Janssen's cost, and Janssen shall reimburse Licensee for its out-of-pocket costs reasonably incurred in connection with rendering such assistance. A settlement or consent judgment or other voluntary final disposition of an Action brought by a Party under this Section may be entered into without the consent of the other Party, *provided* that such settlement, consent judgment, or other disposition does not admit the invalidity or unenforceability of any Patent Rights Controlled by the other Party and, *provided further* that any rights granted to a Third Party to continue any activity upon which such Action was based in such settlement, consent judgment, or other disposition shall be limited to the Third Party's product or activity that was the subject of the Action. Damages recovered and any other amounts awarded in any Actions for Product Infringement under this Section shall be allocated to the Party who brought the Action, after reimbursement of each Party's actual expenses incurred in such Actions as provided hereunder, *provided* that Licensee shall pay to Janssen: (a) as to damage amounts recovered by Licensee due to a Product Infringement in the form of lost profits or reasonable royalties assessed on account of the Third Party's sales of infringing product, an amount equal to the royalty that would be payable pursuant to this Agreement on the imputed amount of Net Sales of the relevant Licensed Product(s) in the country(ies)

where such Product Infringement occurred; and (b) as to damage amounts recovered by Licensee due to a Product Infringement other than in the form of lost profits or reasonable royalties assessed on account of the Third Party's sales of infringing product, an amount equal to the royalty that would be payable pursuant to this Agreement on such damage amounts treated as Net Sales of the relevant Licensed Product(s) in the country(ies) where such Product Infringement occurred.

7.4.3. **Other Enforcement Actions.** Janssen acknowledges that the outcome of any Action on account of any Third Party infringement, other than a Product Infringement, of any Janssen Program Patent or Development Program Patent licensed to Licensee under this Agreement may detrimentally impact the scope, validity, or enforceability of such Patent Right with respect to potential Product Infringements. Accordingly, during the License Term with respect to a Program, the Parties shall reasonably cooperate with each other with respect to any Action on account of any Third Party infringement of any Janssen Program Patent or Development Program Patent licensed to Licensee under this Agreement, other than Product Infringements. For clarity, Janssen will not be required to enforce any Janssen Program Patent against any Third Party infringement.

7.5. **Third Party Patent Rights.** Each Party shall promptly inform the other Party, orally through the Patent Representatives, in the event such Party becomes aware of any Third Party's Patent Rights that may pertain to any Development, Manufacturing or Commercialization activities of Licensee related to a Licensed Compound or Licensed Product.

7.6. **Patent Term Extensions.** During the License Term with respect to a Program, upon Licensee's written request (which shall be by a written notice identifying the date of the applicable Marketing Approval of a Licensed Product with respect to such Program and the deadline for filing a patent term extension, supplemental protection certificate or their equivalent (each a "**Patent Term Extension**")), the Party prosecuting a relevant Patent Right shall use reasonable efforts, in each country or jurisdiction where Marketing Approval for any such Licensed Product has been obtained, and if the Applicable Law of such country or jurisdiction permits application for a Patent Term Extension, to apply, at the reasonable direction of Licensee's Patent Representative, for a Patent Term Extension for a patent within the Janssen Program Patents or Janssen-Owned Development Program Patents including a Valid Claim Covering such Licensed Product, which patent (if any) shall be selected at Licensee's reasonable judgment after considering the opinion of Licensee's patent counsel regarding its eligibility for a Patent Term Extension. Licensee shall have the right to: (a) identify in any list of patents in a Drug Approval Application for a Licensed Product with respect to such Program the applicable Janssen Program Patent(s), Licensee Program Patent(s) and Development Program Patent(s), as Licensee reasonably believes is appropriate; (b) for clarity, commence an Action for any Product Infringement of any such Janssen Program Patent(s) or Janssen-Owned Development Program Patent(s) under Applicable Law as permitted under Section 7.4.2; and (c) subject to specific limitations of this Agreement, exercise any rights that may be exercisable by a patent owner, including applying for a Patent Term Extension, of any Janssen Program Patent(s) or Janssen-Owned Development Program Patent(s) pertaining to an approved Licensed Product with respect to such Program licensed to Licensee and Commercialized by Licensee during the License Term with respect to such Program. Janssen agrees to cooperate with Licensee and its Affiliate and Third Party sublicensees of Licensed Products, as applicable, upon Licensee's reasonable request

in the exercise of the authorizations under this Section, and Janssen shall execute such documents and take such additional action as Licensee may reasonably request in connection therewith, *provided* that Licensee shall reimburse Janssen all reasonable out-of-pocket costs incurred by Janssen in taking such action.

7.7. **Product Trademarks.** During the License Term with respect to a Program, Licensee shall have (directly and through its Affiliates and Third Party sublicensees Commercializing Licensed Products with respect to such Program) the right to brand, at its discretion, Licensed Products with respect to such Program using Trademarks and trade names selected at its discretion and to file for, obtain, and maintain at its discretion and cost Trademarks for such Licensed Products in its own name.

7.8. **Correction of Licensed Patents without Patent Challenge.** During the License Term with respect to a Program, if a Party becomes aware of any good-faith error in any Janssen Program Patent or Development Program Patent that would render the only issued claim(s) therein Covering any marketed Licensed Product with respect to such Program invalid, such Party shall inform the other Party (orally through the Parties' Patent Representatives) and the applicable Party prosecuting such Patent Right shall, subject to this Article 7, use Commercially Reasonable Efforts to correct such error by reissue or reexamination (if such error is so correctable under Applicable Law).

Article 8
CONFIDENTIALITY; PUBLICITY

8.1. **Nondisclosure**.

8.1.1. Each Party agrees that, during the Term and for a period of five (5) years thereafter, the Party (the "**Receiving Party**") receiving Confidential Information of the other Party (the "**Disclosing Party**") shall: (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential or proprietary information of similar kind and value (but no less than reasonable efforts); (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted in Sections 8.3 and 8.4; and (c) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this Article 8 shall not create or imply any rights or licenses not expressly granted under this Agreement).

8.1.2. Notwithstanding the foregoing, during the Development Term with respect to a Program, all Program-Related Information relating to such Program shall be deemed to be Confidential Information of each Party and each Party shall: (a) maintain in confidence all Program-Related Information relating to such Program using not less than the efforts such Party uses to maintain in confidence its own confidential or proprietary information of similar kind and value (but no less than reasonable efforts); (b) not disclose any Program-Related Information relating to such Program to any Third Party without the prior written consent of the other Party, except for disclosures expressly permitted in Sections 8.3 and 8.4; and (c) not use any Program-Related Information

relating to such Program for any purpose except those permitted by this Agreement (it being understood that this Article 8 shall not create or imply any rights or licenses not expressly granted under this Agreement), in each case ((a), (b) and (c)), regardless of which Party is the Disclosing Party and which Party is the Receiving Party with respect to such Program-Related Information. In addition, during the Development Term with respect to a Program, neither Party shall grant any right to any Third Party with respect to any Development Program Know-How relating to such Program, other than to the extent permitted under Section 2.2.3(e). During the License Term with respect to a Program, any information embodied or contained in the Transferred Assets and Program-Related Information relating to such Program (which, for clarity, does not include any Janssen Program Know-How), other than Janssen-Owned Development Program Know-How, shall be deemed to be Confidential Information of Licensee for the purposes of this Article 8 and Licensee shall be deemed the Disclosing Party and Janssen shall be deemed the Receiving Party with respect to such information.

8.2. **Exceptions.** The obligations in Section 8.1 shall not apply to the extent of any portion of the Confidential Information that the Receiving Party can show by competent evidence:

(a) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party under this Agreement;

(b) is known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, in each case, to the Disclosing Party, prior to disclosure to the Receiving Party or any of its Affiliates by the Disclosing Party (*provided* that this exception shall not apply to any Program-Related Information during the Development Term);

(c) is subsequently disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party that, to the Receiving Party's knowledge, is not bound by a similar duty of confidentiality or restriction on its use, in each case, to the Disclosing Party;

(d) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its Affiliates in violation of this Agreement, generally known or available, either before or after it is disclosed to the Receiving Party by the Disclosing Party; or

(e) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the use of or reference to the Confidential Information of the Disclosing Party.

8.3. **Authorized Disclosure.** The Receiving Party may disclose Confidential Information of the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances, or to the extent permissible under the other applicable provisions of this Agreement:

(a) filing, prosecuting, maintaining, enforcing or defending Patent Rights as permitted by this Agreement;

(b) as reasonably required in generating Regulatory Documentation and obtaining Regulatory Approvals as permitted by this Agreement;

(c) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;

(d) subject to Section 8.4, complying with Applicable Law or court or administrative orders;

(e) complying with any obligation under this Agreement;

(f) in communications with existing investors or bona fide prospective investors, consultants and advisors of the Receiving Party in connection with equity financing transactions or bona fide prospective equity financing transactions with the foregoing, in each case on a "need-to-know" basis and under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided*, *however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Third Party who receives Confidential Information pursuant to this Section 8.3(f); *provided further, however,* that, […***…];

(g) to its Affiliates, (sub)licensees or prospective (sub)licensees, subcontractors or prospective subcontractors, consultants, agents and advisors on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided*, *however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person who receives Confidential Information pursuant to this Section 8.3(g); and *provided, further, however* that, during the Development Term of a Program, this Section 8.3(g) does not apply to the disclosure by Licensee of any Confidential Information with respect to such Program to any prospective (sub)licensee; or

(h) by either Party to one or more Third Parties regarding an actual or potential Change of Control of such Party, each of whom prior to disclosure must be bound under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided*, *however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person who receives Confidential Information pursuant to this Section 8.3(h); and *provided*, *further*, *however* that, […***…].

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If and whenever any Confidential Information is disclosed in accordance with this Section 8.3, such disclosure shall not cause any such information to cease to be Confidential Information for purposes of this Agreement, except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing: (x) in the event a Party intends to make a disclosure of the other Party's Confidential Information pursuant to Section 8.3(c) or Section 8.3(d), it will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure; and (y) in the event Licensee intends to make a disclosure of Janssen's Confidential Information relating to a Program during the Development Term of such Program pursuant to Section 8.3(f), 8.3(g) or 8.3(h), it will give reasonable advance notice of such disclosure to Janssen (which shall not include the name of the party accessing Janssen Confidential Information or the nature of the transaction being contemplated).

8.4. **Terms of this Agreement**. The Parties acknowledge and agree that this Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of each Party. In addition to the disclosures permitted under Section 8.3, either Party may disclose the terms of this Agreement and other information relating to this Agreement or the transactions contemplated by this Agreement to the extent required, in the reasonable opinion of such Party's counsel, to comply with the rules and regulations promulgated by the United States Securities and Exchange Commission or the Nasdaq Stock Market or similar security regulatory authorities or stock market in other countries. If a Party intends to disclose this Agreement or any of its terms or other such information in accordance with this Section 8.4, such Party will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure and seek confidential treatment of portions of this Agreement or such terms or information, as may be reasonably requested by the other Party.

8.5. **Public Announcements.** Except as required to comply with Applicable Law or as permitted by Section 8.3 or 8.4, each Party agrees not to issue any press release or other public statement disclosing the execution of this Agreement or any other information relating to this Agreement or the transactions contemplated by this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. In the event that a Party intends to issue such a press release or other public statement as required to comply with Applicable Law, such Party will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure.

8.6. **Prior Non-Disclosure Agreement.** As of the Effective Date, the terms of this Article 8 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement, including the Nondisclosure Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

8.7. **Equitable Relief.** Given the nature of the Confidential Information and the competitive damage that may result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 8. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 8.

8.8. **Scientific Publications.** Licensee may make oral or written publications (such as any abstracts, manuscripts, posters, slide presentations or other materials) of any activities or results relating to a Program, *provided* that (a) during the Development Term, Janssen shall first have the right to review and comment on a draft of any such material proposed for publication by Licensee, including for purposes of ensuring that none of its Confidential Information is disclosed without its permission and (b) Licensee may not include any Confidential Information of Janssen in such publication without Janssen's prior written consent. Licensee shall deliver a complete draft to Janssen at least […***…] ([…***…] days in the case of abstracts) prior to submitting the material to a publisher or initiating any other release. Janssen shall review any such material and give its comments to Licensee within […***…] ([…***…] in the case of abstracts) after the delivery of such draft to Janssen. Licensee shall comply with Janssen's request to: delete from any such proposed publication material prior to its submission or release any references to Janssen or any of its Confidential Information; or delay any submission or release for a period of up to an additional […***…] days to permit Licensee to prepare and file, or have prepared and filed, any patent applications for any Development Program Inventions as contemplated hereunder. For the avoidance of doubt, this Section 8.8 shall not apply to public disclosures required by Applicable Laws or the rules of the United States Securities and Exchange Commission or the Nasdaq Stock Market or similar security regulatory authorities or stock market in other countries, as applicable, which are governed by Sections 8.4 and 8.5.

Article 9
REPRESENTATIONS AND WARRANTIES

9.1. **Mutual Representations and Warranties.** Each Party represents, warrants and covenants to the other Party that, as of the Effective Date:

9.1.1. it is duly organized and validly existing under the laws of its state or country of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions of this Agreement;

9.1.2. this Agreement has been duly executed by it and constitutes a legal, valid and binding obligation of it, enforceable in accordance with its terms;

9.1.3. the execution, delivery and performance of this Agreement by it does not conflict with any material agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and

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9.1.4. it has not granted, and shall not grant during the Term, any right to any Third Party that would conflict with the rights granted to the other Party under this Agreement (including by granting a license after the Effective Date to a Third Party under any intellectual property that is Controlled by the granting Party on the Effective Date that would conflict with the rights to such intellectual property granted to the other Party under this Agreement).

9.2. **Additional Representations and Warranties of Janssen.** Janssen represents and warrants to Licensee that, as of the Effective Date (or with respect to Transferred Contracts, as of the Transferred Contract Effective Date):

9.2.1. Schedule AR Mutant Program Patents, Schedule AR Mutant Diagnostic Patent and Schedule NIK Program Patents list all Patent Rights existing as of the Effective Date that are owned or licensed by Janssen or any of its Affiliates and include any claim Covering any AR Mutant Compound or AR Mutant Product (as it exists on the Effective Date) or any NIK Compound or NIK Product (as it exists on the Effective Date), as applicable, or its formulation, Manufacture or use (the "**Existing Janssen Program Patents**");

9.2.2. Schedule AR Mutant Program Patents and Schedule NIK Program Patents identify any Janssen License Agreement pursuant to which any Existing Janssen Program Patents are licensed to Janssen or any of its Affiliates;

9.2.3. Janssen or its Affiliate are the sole and exclusive owners or exclusive licensees of the Existing Janssen Program Patents (as specified in Schedule AR Mutant Program Patents, Schedule AR Mutant Diagnostic Patent and Schedule NIK Program Patents) and is listed (or is in the process of becoming listed) in the records of the appropriate governmental authorities as the sole and exclusive owner of record, if applicable, for each registration, grant and application included in such Patent Rights, except as otherwise noted therein; and Janssen is entitled to grant the licenses under such Patent Rights specified herein;

9.2.4. to the Knowledge of Janssen, Janssen has the right to use and disclose and to enable Licensee to use and disclose (in each case under appropriate conditions of confidentiality) the Janssen Program Know-How set forth on Schedule AR Mutant Program Know-How and Schedule NIK Program Know-How (the "**Existing Janssen Program Know-How**") to the extent that Licensee is granted the right to use and disclose such Existing Janssen Program Know-How pursuant to this Agreement;

9.2.5. to the Knowledge of Janssen, neither Janssen nor any of its Affiliates owns or licenses, with the right to sublicense, any Know-How or Patent Rights used by Janssen and its Affiliates in the conduct of the Programs within the thirty-six (36) months prior to the Effective Date, other than the Existing Janssen Program Know-How and Existing Janssen Program Patents;

9.2.6. neither Janssen nor any of its Affiliates is subject to any royalty or other payment obligation to any Third Party with respect to the practice, or the grant of rights to

Licensee to practice, any of the Existing Janssen Program Know-How and Existing Janssen Program Patents with respect to the Licensed Compounds or Licensed Products under this Agreement, other than those set forth in the Janssen License Agreements as specifically described on Schedule Janssen License Agreements;

9.2.7. neither Janssen nor any of its Affiliates has received written notice of any claim or threatened claim by any Third Party, and to the Knowledge of Janssen, Janssen is not otherwise aware, that (i) any Third Party has any rights to any of the Existing Janssen Program Know-How or Existing Janssen Program Patents, (ii) any of the Existing Janssen Program Patents (to the extent representing issued Patent Rights) are invalid or unenforceable, or (iii) any research, Development or Manufacture of any Licensed Compound or Licensed Product by or on behalf of Janssen or its Affiliate prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

9.2.8. there are no pending actions, claims, investigations, suits or proceedings against Janssen or any of its Affiliates, at law or in equity, or before or by any Regulatory Authority, and neither Janssen nor any of its Affiliates has received any written notice regarding any pending or threatened actions, claims, investigations, suits or proceedings against Janssen or any of its Affiliates, at law or in equity, or before or by any Regulatory Authority, in either case with respect to the Existing Janssen Program Know-How or Existing Janssen Program Patents, and no Existing Janssen Program Patent is the subject of any interference, opposition, cancellation or other protest proceeding;

9.2.9. to the Knowledge of Janssen, there is no actual infringement of any Existing Janssen Program Patents by any Third Party;

9.2.10. neither Janssen nor any of its Affiliates, nor its or their employees, officers, directors, or agents, has been debarred by the FDA, is the subject of a conviction described in 21 U.S.C. 335a, or is subject to any similar sanction;

9.2.11. Janssen and its Affiliates have conducted Development activities with respect to each Program in material compliance with Applicable Law and regulatory standards, including as applicable those relating to GLP, GCP, pharmacovigilance and safety reporting, and requirements for the protection of human subjects;

9.2.12. Janssen owns good and valid title to and has the right to transfer (or cause to be transferred), the Transferred Assets as provided for herein, free and clear of all liens and other encumbrances, except for Permitted Liens;

9.2.13. Janssen has made available to Licensee true and complete copies of each Transferred Contract;

9.2.14. each Transferred Contract is in effect and is valid and binding on Janssen or its Affiliate, enforceable in accordance with its terms, and neither Janssen nor any of its Affiliates, nor to the Knowledge of Janssen any other party thereto, is in material breach of, or material default under, any Transferred Contract, and no event has occurred that,

with the giving of notice or lapse of time or both, would constitute a material breach or material default by Janssen or any of its Affiliates thereunder or result in the payment of any damages or penalties or result in the creation of any lien or encumbrance with respect thereto; and

9.2.15. neither Janssen nor any of its Affiliates has received any written notice from a Third Party at any time during the past three (3) years regarding any actual, alleged or potential material breach or default under any of the Transferred Contracts or stating that such Third Party intends to terminate, cancel or make any material change to any Transferred Contract.

As used in this Section 9.2: (a) "**Knowledge**" means the actual knowledge of the Janssen Personnel after reasonable inquiry of individuals responsible for operational activities with respect to the applicable Program; (b) "**Janssen Personnel**" means the individuals whose names are set forth on Schedule Janssen Personnel; and (c) "**Permitted Liens**" means (i) liens for taxes not yet due, payable, delinquent or subject to penalties for nonpayment, or which are being contested in good faith in the ordinary course of business by appropriate proceedings or (ii) mechanics', materialmens', carriers', workmens', warehousemens', repairmens', landlords' or other like liens and security obligations that are incurred in the ordinary course of business and are not delinquent.

9.3. **Additional Representations and Warranties of Licensee.** Licensee represents and warrants to Janssen that, as of the Effective Date, neither Licensee nor any of its Affiliates, nor its or their employees, officers, directors, or agents, has been debarred by the FDA, is the subject of a conviction described in 21 U.S.C. 335a, or is subject to any similar sanction.

9.4. **Disclaimer of Warranties; Limitations.**

9.4.1. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY NOR ANY OF ITS AFFILIATES MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE PROGRAMS, LICENSED COMPOUNDS, LICENSED PRODUCTS, TRANSFERRED ASSETS, LICENSED TECHNOLOGY OR OTHER PATENT RIGHTS THAT ARE LICENSED OR TRANSFERRED TO THE OTHER PARTY OR SUBJECT TO ANY OPTION OR RIGHT TO LICENSE UNDER THIS AGREEMENT, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT ANY OF THE DEVELOPMENT, MANUFACTURING OR COMMERCIALIZATION EFFORTS WITH REGARD TO ANY LICENSED COMPOUND OR LICENSED PRODUCT WILL BE SUCCESSFUL.

9.4.2. Subject to Sections 2.3, 2.4, 5.5 and 11.6.1(h), each Party acknowledges that (a) the other Party and its Affiliates may have present or future initiatives or opportunities, including initiatives or opportunities with Third Parties, involving similar products, programs, technologies or processes that may compete with products, programs,

technologies or processes covered by this Agreement; (b) nothing in this Agreement will be construed as a representation, warranty, covenant or inference that the other Party or its Affiliates will not itself develop, manufacture or market or enter into business relationships with one or more Third Parties to develop, manufacture or market products, programs, technologies or processes that are similar to or that may compete with any product, program, technology or process covered by this Agreement (including those in the Field); and (c) the other Party or any of its Affiliates may, in their sole discretion, decide to acquire, research, develop and/or market devices, drugs or other products which may compete with any Licensed Product or continue such activity in which they currently are engaged; *provided* that, in each case of clauses (a), (b) and (c), in no event shall a Party or its Affiliates use Confidential Information of the other Party in breach of this Agreement, and in no event may Janssen or its Affiliates practice or use, or grant any Third Party the right to practice or use, any Licensed Technology in conflict with the licenses granted hereunder.

9.5. **Additional Representations, Warranties and Covenants**.

9.5.1. **Assignments**. Each Party shall ensure that each individual employee or agent performing activities under a Program on behalf of such Party or its Affiliate during the Development Term of such Program shall have entered into an agreement with such Party or its Affiliate prior to the performance of any work thereunder by such employee or agent providing for the assignment to such Party or its Affiliate of all inventions and discoveries, whether or not patentable, made or arising in the course of the performance of such activities.

9.5.2. **Healthcare Compliance**.

(a) **Anti-Kickback and Stark Compliance**. Each Party represents and warrants to the other Party as of the Effective Date, and covenants to such other Party, that the Party making such representation and warranty and its Affiliates that are or have been involved in a Program is in compliance and will continue to comply with all applicable state and federal laws, rules and regulations, including the federal anti-kickback statute (42 U.S.C. § 1320a-7b), the related safe harbor regulations, and the Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. § 1395nn) in connection with its activities under this Agreement and, in the case of Janssen, has complied with the foregoing in connection with its activities with respect to a Program prior to the Effective Date. No part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business.

(b) **Exclusion from Federal Health Care Programs**. Each Party shall conduct activities pursuant to this Agreement, and Janssen and its Affiliates have conducted activities with respect to a Program prior to the Effective Date, in accordance with applicable state and federal laws and any applicable regulations regarding Medicare, Medicaid, and other third party-payer programs, if any. Each Party represents and warrants to the other Party, as of the Effective Date, that (1)

it is not excluded from, and has not been convicted of any crime or engaged in any conduct that could result in exclusion from, participation in any state or federal healthcare program, as defined in 42 U.S.C. §1320a-7b(f), for the provision of items or services for which payment may be made by a federal healthcare program; (2) it has not contracted with any employee, contractor, agent, or vendor to perform work under this Agreement who is excluded from participation in any state or federal healthcare program, and in the case of Janssen, did not contract with any employee, contractor, agent, or vendor to perform work under a Program prior to the Effective Date who was excluded from participation in any state or federal healthcare program; and (3) it is not subject to a final adverse action, as defined in 42 U.S.C.§ 1320a-7a(e) and 42 U.S.C. § 1320a-7a(g), and has no adverse action pending or threatened against it. Each Party shall notify the other Party of any final adverse action, discovery of contract with an excluded entity or individual, or exclusion within thirty (30) days of such action.

9.5.3. **No Debarred Individuals**. Each Party agrees that it shall not engage, in any capacity in connection with this Agreement, any person who has been debarred by FDA, is the subject of a conviction described in 21 U.S.C. 335a, or is subject to any similar sanction, and in the case of Janssen, Janssen represents and warrants to Licensee that neither Janssen nor any of its Affiliates engaged any such person in connection with a Program prior to the Effective Date. Each Party shall promptly inform the other Party in writing if such Party or any person performing activities under this Agreement on such Party's behalf is debarred or is the subject of a conviction described in 21 U.S.C. 335a, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or threatened relating to the debarment of conviction of such Party or any such person performing activities in connection with this Agreement on such Party's behalf. Upon written request from the other Party, a Party shall, within ten (10) days, provide written confirmation that it has complied with the foregoing obligation.

9.5.4. **Anti-Corruption Laws**. Neither a Party nor any of its Affiliates shall perform any actions in connection with this Agreement that are prohibited by local and other anti-corruption laws (collectively "**Anti-Corruption Laws**") that may be applicable to such Party, and in the case of Janssen, Janssen represents and warrants to Licensee that neither Janssen nor any of its Affiliates has performed any actions in connection with a Program prior to the Effective Date that are prohibited by Anti-Corruption Laws that were applicable to Janssen or its Affiliates. Without limiting the foregoing, neither Party nor any of its Affiliates shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other Third Party related to the transactions contemplated by this Agreement in a manner that would violate Anti-Corruption Laws.

9.5.5. **Development Compliance Matters**. With respect to each Program, the provisions of this Section 9.5.5 shall apply during the Development Term and License Term of such Program.

(a) **Responsibility for Development**. Licensee shall be solely responsible for the activities of clinical development related to Licensed Products in the Territory under the terms of this Agreement (other than the Janssen AR Mutant Activities), including any post-marketing surveillance studies or Clinical Trials eventually required by Regulatory Authorities or any studies voluntarily undertaken by Licensee.

(b) **IRB**. Licensee shall be responsible for obtaining any necessary approvals from institutional review boards (each, an "**IRB**") including, where applicable, obtaining approval of all Clinical Trial protocols, informed consents, investigator brochures, subject recruitment materials or plans, authorization of disclosure of confidential subject information, and any alterations to or waivers of the same, prior to commencement of any study. Licensee shall not modify the protocol or the informed consent without the prior written agreement of the IRB.

(c) **Informed Consent and Patient Authorization**. Licensee shall be responsible for obtaining (i) an informed consent document, which shall have been approved by the IRB, signed by or on behalf of each human study subject prior to the subject's participation in the Clinical Trial; and (ii) a HIPAA patient authorization signed by or on behalf of each human study subject, as described in 45 C.F.R. Part 164.

(d) **INDs**. Licensee shall be responsible for obtaining and maintaining any IND or comparable regulatory filing in other jurisdictions required for the Clinical Trial.

(e) **Study Conduct**. Licensee shall conduct Clinical Trials in compliance with Applicable Law and regulatory standards, including, as applicable, those relating to Good Laboratory Practices ("**GLP**"), Good Clinical Practices ("**GCP**"), pharmacovigilance and safety reporting, and requirements for the protection of human subjects.

(f) **Clinical Study Registration and Results Reporting**. Licensee shall be responsible for registering Clinical Trials in the appropriate clinical study registry and reporting Clinical Trial results as required under Applicable Law.

(g) **Subcontracting**. To the extent that Licensee enters into arrangements with any Third Party involved in conducting or supporting a Clinical Trial, including clinical investigators, study sites, or a contract research organization, any such arrangements shall be made in writing and consistent with this Agreement.

(h) **Audits**. With respect to any facility or site at which Licensee conducts Clinical Trials or other Development activities or Manufacturing activities

pursuant to this Agreement, and subject to the terms of any agreement between Licensee and any applicable Third Party Subcontractor with respect to any facility or site of such Third Party Subcontractor, Janssen shall have the right, at its own expense, upon reasonable written notice to Licensee, and during normal business hours, to inspect such site and facility of Licensee or to accompany Licensee to inspect any Third Party Subcontractor site and any records relating thereto once per year and also for cause, to verify Licensee's compliance with Applicable Law in carrying out its obligations under this Agreement, including those relating to GLP, GCP, Good Manufacturing Practices ("**GMP**"), pharmacovigilance and safety reporting, and requirements for the protection of human subjects. In the event that any such facility or site is found to be non-compliant with GLP, GCP, GMP, pharmacovigilance and safety reporting, or requirements for the protection of human subjects during such an audit, and such non-compliance relates to or impacts any Licensed Product, Licensee shall submit to Janssen proposed Corrective and Preventative Actions ("**CAPA**") within thirty (30) days after Janssen provides notice of such non-compliance. Janssen shall have the right during the License Term, to review and comment on such CAPA, which comments Licensee shall consider in good faith. Licensee shall use Commercially Reasonable Efforts to implement such CAPA promptly after review and comment by Janssen.

(i) **Audits by Regulatory Authorities**. Licensee shall cooperate in good faith with respect to Regulatory Authority inspections of any site or facility where Clinical Trials or other Development activities or Manufacturing activities are conducted pursuant to this Agreement by Licensee or on its behalf, whether such site or facility is Licensee's, an Affiliate's, or a subcontractor's (each, an "**Audited Site**"). Licensee shall inform Janssen as promptly as practicable and in any event within forty-eight (48) hours of receiving notice of such a Regulatory Authority audit and shall provide daily updates regarding the audit status. In the event that any Audited Site is found to be non-compliant with one or more of GLP, GCP, GMP, current standards for pharmacovigilance and safety reporting, or requirements related to the protection of human subjects, and such non-compliance relates to or impacts any Licensed Product, Licensee shall submit to Janssen proposed CAPA within thirty (30) days after Licensee, its Affiliate, or its subcontractor receives notification of such non-compliance from the relevant Regulatory Authority. Janssen shall have the right during the License Term, to review and comment on such CAPA, which comments Licensee shall consider in good faith. Licensee shall use Commercially Reasonable Efforts to implement such CAPA promptly after review and comment by Janssen.

9.5.6. **Amendment to Janssen License Agreements**. Janssen may not amend any Janssen License Agreement in any manner that would adversely affect any rights granted to Licensee hereunder, including to increase any amount payable by Janssen for which Licensee would be responsible pursuant to Section 6.3.2(a), except with Licensee's prior written consent.

Article 10
INDEMNIFICATION AND INSURANCE

10.1. **Indemnification.**

10.1.1. **Indemnification by Licensee.** Subject to Section 10.2, Licensee shall defend, indemnify and hold harmless Janssen and any of its Affiliates, and each of its and their directors, officers, employees and agents (each, a "**Janssen Indemnified Party**") from and against any and all damages, losses, liabilities, judgments, fines, amounts paid in settlement, costs and expenses (including the reasonable costs and expenses of attorneys and other professionals) (collectively, "**Losses**") incurred by any Janssen Indemnified Party resulting from any claim, action or proceeding brought or initiated by a Third Party ("**Third Party Claim**") against a Janssen Indemnified Party, to the extent that such Losses arise out of or relate to, directly or indirectly:

(a) the Assumed Liabilities;

(b) the breach by Licensee of any of its representations, warranties or covenants set forth herein;

(c) the negligence, recklessness or wrongful intentional acts or omissions of any Licensee Indemnified Party; or

(d) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Licensee or any of its Affiliates on or after the Effective Date and during the Term (or any post-termination or post-expiration period pursuant to Section 11.6) with respect to the applicable Program;

except, in each case ((a) through (d)), to the extent such Losses arise directly or indirectly from (i) the breach by Janssen of any of its representations, warranties, or covenants set forth herein, (ii) the negligence, recklessness or wrongful intentional acts or omissions of any Janssen Indemnified Party, (iii) the Janssen AR Mutant Activities, or (iv) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Janssen or any of its Affiliates prior to the Effective Date or during any post-termination or post-expiration period pursuant to Section 11.6 with respect to the applicable Program.

10.1.2. **Indemnification by Janssen.** Subject to Section 10.2, Janssen shall defend, indemnify and hold harmless Licensee and any of their Affiliates, and each of its and their directors, officers, employees and agents (each, a "**Licensee Indemnified Party**"), from and against any and all Losses incurred by any Licensee Indemnified Party resulting from any Third Party Claim against a Janssen Indemnified Party, to the extent that such Losses arise out of or relate to, directly or indirectly:

(a) all liabilities arising from or relating to the Transferred Assets arising prior to the Effective Date, or after the Effective Date to the extent of any breach of or

non-compliance with any Transferred Contract by Janssen or any of its Affiliates prior to the Effective Date;

(b) the breach by Janssen of any of its representations, warranties or covenants set forth herein; and

(c) the negligence, recklessness or wrongful intentional acts or omissions of any Janssen Indemnified Party;

(d) the Janssen AR Mutant Activities; or

(e) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Janssen or any of its Affiliates prior to the Effective Date or during any post-termination or post-expiration period pursuant to Section 11.6 with respect to the applicable Program;

except, in each case ((a) through (d)), to the extent such Losses arise directly or indirectly from (i) the breach by Licensee of any of its representations, warranties, or covenants set forth herein, (ii) the negligence, recklessness or wrongful intentional acts or omissions of any Licensee Indemnified Party, or (iii) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Licensee or any of its Affiliates on or after to the Effective Date and during the Term (or any post-termination or post-expiration period pursuant to Section 11.6) with respect to the applicable Program.

10.2. **Conditions to Indemnification.** If either a Janssen Indemnified Party or a Licensee Indemnified Party (each, an "**Indemnified Party**") intends to seek indemnification under Section 10.1, the Indemnified Party must: (a) give the other Party (the "**Indemnifying Party**") reasonably prompt written notice of any Loss with respect to which such Indemnified Party intends to seek indemnification; (b) reasonably cooperate with the Indemnifying Party at the Indemnifying Party's request and expense, in the defense or settlement of the claim; and (c) give the Indemnifying Party the right to control the defense or settlement of the claim, *provided* that the Indemnifying Party will not enter into any settlement that adversely affects the Indemnified Party's rights or obligations without the Indemnified Party's prior express written consent, which will not be unreasonably withheld, conditioned or delayed. The Indemnified Party may participate in the defense or settlement of any such claim at its own expense with counsel of its choosing. Notwithstanding the foregoing, any failure of the Indemnified Party to comply with the provisions of clause (a) of this Section 10.2 will not relieve the Indemnifying Party of any defense or indemnity obligations under this Agreement except to the extent that the Indemnifying Party is prejudiced by such failure.

10.3. **Limitations of Liability.** EXCEPT TO THE EXTENT INCLUDED IN LOSSES RESULTING FROM A THIRD PARTY CLAIM FOR WHICH ONE PARTY IS OBLIGATED TO INDEMNIFY THE OTHER PARTY (OR AN INDEMNI FIED PARTY OF SUCH OTHER PARTY) PURSUANT TO THIS ARTICLE 10 OR ANY BREACH OF ARTICLE 8 (CONFIDENTIALITY), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES OR SUBLICENSEES) IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

10.4. **Insurance.** Licensee shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated, at all times during which any Licensed Product is being tested by or on behalf of Licensee, during the period of commercialization of any Licensed Product and for at least […***…] thereafter. At a minimum, Licensee shall be insured for […***…] to cover its obligations under this Agreement. Janssen shall be named as an additional insured under Licensee's product liability and general liability insurance policies. It is understood that such insurance shall not be construed to create a limit of Licensee's liability with respect to its indemnification obligations under this Article 10. Licensee shall provide Janssen with written evidence of such insurance upon request and shall provide Janssen with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance which materially adversely affects the rights of Janssen hereunder.

Article 11
TERM AND TERMINATION

11.1. **Term.** The term of this Agreement (the "**Term**") will commence on the Effective Date and, unless this Agreement is terminated earlier in accordance with this Article 11:

(a) with respect to the AR Mutant Program: (i) if the Option is exercised by Janssen in accordance with Section 3.3.1, this Agreement will expire with respect to the AR Mutant Program on the Option Exercise Effective Date; and (ii) if the Option is not exercised by Janssen in accordance with Section 3.3.1, this Agreement will expire with respect to the AR Mutant Program upon expiration of all of the payment obligations under Article 6 with respect to all AR Mutant Products in all countries; *provided* that, on an AR Mutant Product-by-AR Mutant Product and country-by-country basis, upon expiration of all of the payment obligations under Article 6 with respect to a given AR Mutant Product in a given country, the licenses granted herein with respect to such AR Mutant Product in such country shall survive on a fully-paid, royalty-free, non-exclusive, irrevocable and perpetual basis; and

***Confidential Treatment Requested

(b) with respect to the NIK Program: (i) if Janssen and Licensee enter into a Janssen NIK License Agreement in accordance with Section 3.4 or otherwise, this Agreement will expire with respect to the NIK Program upon the effective date of such Janssen NIK License Agreement; and (ii) if the ROFN expires in accordance with Section 3.4.3 and Janssen and Licensee have not entered into a Janssen NIK License Agreement prior to such expiration, this Agreement will expire with respect to the NIK Program upon expiration of all of the payment obligations under Article 6 with respect to all NIK Products in all countries; *provided* that, on a NIK Product-by-NIK Product and country-by-country basis, upon expiration of all of the payment obligations under Article 6 with respect to a given NIK Product in a given country, the licenses granted herein with respect to such NIK Product in such country shall survive on a fully-paid, royalty-free, non-exclusive, irrevocable and perpetual basis.

11.2. **Termination during Development Term.** The following provisions of this Section 11.2 shall apply during the Development Term with respect to each Program.

11.2.1. **Termination for Safety or Technical Reasons.** If Licensee reasonably determines, based upon the results of activities conducted pursuant to the applicable Development Plan for a Program, that (a) it is not feasible for material safety reasons to continue Development with respect to a Program and desires to terminate this Agreement with respect to such Program, or (b) after […***…], it is not feasible for material technical reasons to continue Development with respect to the NIK Program and desires to terminate this Agreement with respect to the NIK Program, in either case of clause (a) or (b), Licensee may so notify Janssen in writing, which notice shall include a reasonably detailed explanation for Licensee's determination, and, if requested by Janssen, the Parties shall meet to discuss such determination within thirty (30) days following such notice. The Agreement shall terminate with respect to such Program on the date of such notice or upon the date of such meeting between the Parties held within thirty (30) days following such notice.

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11.2.2. **Termination for Licensee Material Breach**. Janssen may terminate this Agreement with respect to a Program during the Development Term of such Program if Licensee has materially breached (i) its covenant under Section 2.1.1(c), (ii) any of its obligations under Section 2.2.3(a) with respect to such Program, (iii) its covenant under Section 2.3.1 with respect to such Program, (iv) its covenant under Section 2.4 with respect to such Program or (v) its covenant under Section 5.2 during the Development Term with respect to such Program, in any case of clause (i), (ii), (iii), (iv) or (v), by providing written notice of such material breach to Licensee describing such alleged material breach in reasonable detail. Any termination of this Agreement pursuant to this Section 11.2.2 shall become effective sixty (60) days after such notice is given unless Licensee cures such breach prior to such date (or, in the case of clause (ii) only, if such breach is not reasonably able to be cured within sixty (60) days after notice of termination is given pursuant to this Section 11.2.2, such termination shall not become effective until the earlier of the date such breach is cured or one hundred twenty (120) days after notice of termination is given pursuant to this Section 11.2.2, *provided* that (a) Licensee notifies Janssen of its plan for curing such breach within sixty (60) days after such notice is given, (b) Licensee commences such plan during such sixty (60) day period and (c) Licensee uses diligent efforts to perform such plan and cure such breach as soon as reasonably practicable).

11.3. **Termination for Breach.**

11.3.1. A Party (the "**Terminating Party**") may terminate this Agreement (a) with respect to a Program in the event the other Party (the "**Breaching Party**") has materially breached this Agreement only with respect to such Program or (b) in its entirety in the Breaching Party has materially breached this Agreement (other than a material breach only with respect to one Program, in which case clause (a) of this Section 11.3.1 shall apply), and, in either case of clause (a) or (b), such material breach has not been cured within sixty (60) days after written notice of such breach is given by the Terminating Party to the Breaching Party (the "**Cure Period**"). This Section 11.3.1 shall not apply to any alleged material breach of Section 2.1.1(c), 2.2.3(a), 2.3.1, 2.4 or 5.2 by Licensee during the Development Term, which is instead subject to Section 11.2.2. The written notice describing the alleged material breach shall provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement with respect to a Program or in its entirety pursuant to this Section 11.3.1 shall become effective at the end of the Cure Period unless the Breaching Party has cured any such material breach prior to the expiration of such Cure Period (or, if such breach (other than a breach of payment obligations) is not reasonably able to be cured within the Cure Period, such termination shall not become effective until the earlier of the date such breach is cured or one hundred and twenty (120) days after notice of termination is given pursuant to this Section 11.3.1, *provided* that (i) the Breaching Party notifies the other Party of its plan for curing such breach during the Cure Period, (ii) the Breaching Party commences such plan during the Cure Period and (iii) the Breaching Party uses diligent efforts to perform such plan and cure such breach as soon as reasonably practicable). The right of either Party to terminate this Agreement with respect to a Program or in its entirety as provided in this Section 11.3.1 shall not be affected

in any way by such Party's waiver of or failure to take action with respect to any previous breach under this Agreement.

11.3.2. If the Parties reasonably and in good faith disagree as to whether there has been a material breach or a cure thereof, the Party that disputes whether there has been a material breach or a cure may contest the allegation in accordance with Article 12. Notwithstanding anything to the contrary contained in Section 11.3.1, the Cure Period for any material breach that is the subject of a Dispute will run from the date that written notice was first given to the Breaching Party by the Terminating Party through the resolution of such Dispute pursuant to Article 12 and for 10 days thereafter, and no termination pursuant to Section 11.3.1 shall become effective during such period. During the pendency of such Dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder; *provided* that the Parties' performance of their respective obligations and exercise of their respective rights hereunder that specify a date by which such obligations must be performed or such rights must be exercised shall be tolled through the resolution of such Dispute pursuant to Article 12 and for 10 days thereafter.

11.4. **Termination for Bankruptcy.**

11.4.1. A Party may terminate this Agreement in its entirety upon providing written notice to the other Party on or after the time that such other Party makes a general assignment for the benefit of creditors, files a voluntary petition in bankruptcy, consents to an order for relief in connection with an involuntary petition in bankruptcy filed against such Party (or an involuntary petition in bankruptcy filed against such Party remains un-dismissed or un-stayed for a period of more than sixty (60) days), petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above (each, an "**Insolvency Event**").

11.4.2. All rights and licenses now or hereafter granted under or pursuant to any Section of this Agreement are rights to "intellectual property" (as defined in Section 101(35A) of Title 11 of the United States Code, as amended (such Title 11, the "**Bankruptcy Code**")). In the event this Agreement is rejected under Section 365 of the Bankruptcy Code by or on behalf of a Party (including by any receiver, trustee or similar officer appointed with respect to such Party), such Party (the "**Licensor Party**") hereby grants to the other Party (the "**Licensee Party**"), subject to the Licensee Party's obligations under Sections 365(n)(2)(A) and (B), a right of access and to obtain possession of and to benefit from embodiments of intellectual property pursuant to Section 365(n) of the Bankruptcy Code (including Program-Related Information and Know-How Controlled by the Licensor Party with respect to Licensed Compounds or Licensed Products and Regulatory Documentation with respect to Licensed Products, all of which constitute embodiments of intellectual property pursuant to Section 365(n) of the Bankruptcy Code) to the extent related to the Licensee Party's exercise of its license rights to any Licensed Compound or Licensed Product or otherwise related to any rights or licenses granted to the Licensee Party under or pursuant to any Section of this Agreement. The Licensor Party agrees not to interfere with the Licensee Party's exercise under the Bankruptcy Code of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement.

11.5. **Termination Without Cause After Development Term**. During the License Term with respect to a Program, Licensee shall have the right to terminate this Agreement with respect to such Program (but not the Agreement in its entirety) without cause by providing Janssen sixty (60) days' prior written notice of such termination. After the end of the Development Terms of both Programs, Licensee shall have the right to terminate this Agreement in its entirety without cause by providing Janssen sixty (60) days' prior written notice of such termination.

11.6. **Effects of Termination or Expiration.**

11.6.1. **Effects of Termination during Development Term**. If this Agreement is terminated with respect to only one Program (the "**Terminated Program**") or in its entirety pursuant to Section 11.2, then the provisions of this Section 11.6.1 shall apply with respect to the Terminated Program or, if this Agreement is terminated in its entirety, with respect to both of the Programs.

(a) The Development Term with respect to the Terminated Program shall end on the date of such termination.

(b) The licenses and other rights granted to Licensee under this Agreement with respect to the Terminated Program, other than those that expressly survive termination of this Agreement, shall terminate on the effective date of termination.

(c) If Licensee is conducting any Development activity with respect to the terminated Program immediately prior to the effective date of termination, then Janssen shall notify Licensee within […***…] after the notice of termination (i) with regard to any Clinical Trial, whether Janssen elects to have Licensee complete such activity (which may involve wind-down of such activity) or transfer such activity to Janssen and (ii) with regard to any other Development activity, whether Janssen elects to have Licensee transfer such activity to Janssen.

(1) With regard to any Clinical Trial, if Janssen notifies Licensee of its election to have Licensee complete such activity (or fails to provide notice within such […***…] period), then Licensee shall complete or wind-down such activity at its sole cost and expense.

(2) If Janssen notifies Licensee of its election to have Licensee transfer such activity to Janssen, then Licensee shall use Commercially Reasonable Efforts to transfer, and Janssen shall use Commercially Reasonable Efforts to assume, such activity as promptly as practicable (and, in any event, within […***…]) after the effective date of termination. Licensee shall bear the costs of such activity incurred by Licensee until the completion of such transfer, and Janssen shall bear the costs of such activity after the completion of such transfer.

(d) Licensee shall, within […***…] after the effective date of termination and at Licensee's expense, return or destroy, at Janssen's election, all Janssen Program Know-How and other Confidential Information of Janssen that is solely related to the Terminated Program (*provided* that (i) Licensee may keep one copy of such Confidential Information subject to an ongoing obligation of confidentiality for archival purposes only, (ii) it is acknowledged that, with regard to any such Confidential Information disclosed to subcontractors, consultants, agents, advisors and other Third Parties as permitted by Section 8.3, Licensee's use of Commercially Reasonable Efforts to return or destroy such Confidential Information shall satisfy its obligation under this Section 11.6.1(d) and (iii) Licensee may retain and continue to use Janssen Program Know-How and other Confidential Information of Janssen to practice any licenses and other rights granted to Licensee under this Agreement with respect to such Program that expressly survive expiration of this Agreement as to such Program).

(e) Licensee shall, and hereby does, assign to Janssen, as of the effective date of termination, all of its right, title and interest in, to and under all of Licensee's ownership interest in any Development Program Know-How and Development Program Patents with respect to the Terminated Program, and Licensee shall transfer all such Development Program Know-How owned solely by Licensee to Janssen promptly after the effective date of termination (to the extent that such Know-How has not previously been transferred to Janssen).

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(f) Licensee shall, and hereby does, assign to Janssen, as of the effective date of termination, all of its right, title and interest in, to and under all of Licensee's ownership interest in any Regulatory Documentation, including any Regulatory Approvals, with respect to the Terminated Program, and Licensee shall transfer all such Regulatory Documentation to Janssen promptly after the effective date of termination.

(g) Licensee shall, and hereby does, grant to Janssen, as of the effective date of termination, an exclusive, perpetual, royalty-free, freely sublicensable, transferable license under any Licensee Program Know-How and Licensee Program Patents to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale Licensed Compounds and Licensed Products with respect to such Terminated Program in the Field in the Territory.

(h) During the period beginning on the effective date of termination with respect to a Program and ending […***…] thereafter, neither Licensee nor any of its Affiliates shall: […***…]. Notwithstanding the foregoing:

(1) Section 11.6.1(h) does not prohibit Licensee and its Affiliates that are subject to Section 11.6.1(h), alone or through work conducted in collaboration with an Affiliate or Third Party, from conducting research and non-clinical development (or licensing or otherwise granting rights to an Affiliate or a Third Party to conduct research and non-clinical development) of compounds (other than Licensed Compounds) that (i) […***…].

(2) Section 11.6.1(h) shall not apply to the Acquirer of a Party or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of such Party prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control).

(3) Licensee shall not be limited or prohibited by Section 11.6.1(h) from negotiating and completing a Change of Control, or taking any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party relating to, or engage in discussions with any Third Party relating to, a Change of Control.

(i) Licensee shall assign to Janssen any Third Party agreements to which Licensee or any of its Affiliates are a party (including any Transferred Contracts) that solely relate to the Terminated Program, solely to the extent that such agreements are assignable without cost to Licensee (or Janssen agrees to bear such costs) and Janssen assumes all liabilities under such agreements that arise following the effective date of such assignment (other than due to a breach or violation of such agreement by Licensee or its Affiliate that occurred prior to the effective date of such assignment).

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(j) At Janssen's request, Licensee shall assign and transfer to Janssen any inventory of Licensed Compounds or Licensed Products with respect to the Terminated Program then in Licensee's or its Affiliate's possession or control subject to Janssen's reimbursement of Licensee's reasonable costs incurred in acquiring such inventory and with respect to shipping thereof.

(k) At Janssen's request, Licensee shall assign and transfer to Janssen any Transferred Assets (other than Transferred Contracts) then in Licensee's or its Affiliate's possession or control that solely relate to the Terminated Program at no cost to Janssen.

(l) For clarity, Janssen shall not be obligated to pay the Option Exercise Fee or to reimburse the out-of-pocket expenses incurred by Licensee or any of its Affiliates in the performance of the […***…] (if applicable) with respect to the Terminated Program.

(m) Licensee shall take such other actions, and execute any instruments, assignments and documents, as reasonably requested by Janssen as may be necessary to effect the foregoing provisions of this Section 11.6.1.

11.6.2. **Effects of Termination for Breach.** If this Agreement is terminated by Janssen pursuant to Section 11.3 with respect to a Terminated Program or in its entirety, then the following provisions shall apply to such Terminated Program or to both Programs, as applicable: Sections 11.6.1(a) (if any Development Term is then in effect), 11.6.1(b), 11.6.1(c), 11.6.1(d), 11.6.1(e), 11.6.1(f), 11.6.1(g), 11.6.1(h), 11.6.1(i), 11.6.1(j), 11.6.1(k), 11.6.1(l) and 11.6.1(m) shall apply. If this Agreement is terminated by Licensee pursuant to Section 11.3 with respect to a Terminated Program or in its entirety, then the following provisions shall apply to such Terminated Program or to both Programs, as applicable: Sections 11.6.1(a) (if any Development Term is then in effect), 11.6.1(b), 11.6.1(c) (but […***…] shall determine whether to complete or transfer such activity and […***…] shall bear the costs of any completion or transfer of activities), 11.6.1(d), and 11.6.1(l).

11.6.3. **Effects of Termination for Bankruptcy.** If this Agreement is terminated by Janssen pursuant to Section 11.4, then the provisions of Sections 11.6.1(a) (if any Development Term is then in effect), 11.6.1(b), 11.6.1(c), 11.6.1(d), 11.6.1(e), 11.6.1(f), 11.6.1(g), 11.6.1(h), 11.6.1(i), 11.6.1(j), 11.6.1(k), 11.6.1(l) and 11.6.1(m) shall apply. If this Agreement is terminated by Licensee pursuant to Section 11.4, then the provisions of Sections 11.6.1(a) (if any Development Term is then in effect), 11.6.1(b), 11.6.1(c), 11.6.1(d), and 11.6.1(l) shall apply.

11.6.4. **Effects of Termination Without Cause.** If this Agreement is terminated by Licensee pursuant to Section 11.5 with respect to a Terminated Program or in its entirety, then the following provisions shall apply to such Terminated Program or to both Programs, as applicable: Sections 11.6.1(b), 11.6.1(c), 11.6.1(d), 11.6.1(e), 11.6.1(f), 11.6.1(g), 11.6.1(h), 11.6.1(i), 11.6.1(j), 11.6.1(k), 11.6.1(l) and 11.6.1(m).

11.6.5. **Licensee Confidential Information.** Janssen shall, within thirty (30) days after the effective date of expiration or termination of this Agreement with respect to a Program or in its entirety, and at Janssen's expense, return or destroy, at Licensee's election, all Confidential Information of Licensee that is solely related to such Program(s) (*provided* that (i) Janssen may keep one copy of such Confidential Information subject to an ongoing obligation of confidentiality for archival purposes only, (ii) it is acknowledged that, with regard to any such Confidential Information disclosed to subcontractors, consultants, agents, advisors and other Third Parties as permitted by Section 8.3, Janssen's use of Commercially Reasonable Efforts to return or destroy such Confidential Information shall satisfy its obligation under this Section 11.6.5 and (iii) Janssen may retain and continue to use Confidential Information of Licensee to practice any licenses and other rights granted to Licensee under this Agreement with respect to such Program that expressly survive expiration of this Agreement as to such Program).

11.6.6. **Effects of Expiration.** If the Term expires with respect to a Program or with respect to this Agreement in its entirety pursuant to Section 11.1, then the provisions of Sections 11.6.1(b), 11.6.1(c), and 11.6.1(d) shall apply with respect to the Program with respect to which the Term has expired or, if this Agreement expires in its entirety, with respect to all of the Programs; *provided* that Licensee may retain and continue to use Janssen Program Know-How and other Confidential Information of Janssen to practice any licenses and other rights granted to Licensee under this Agreement with respect to such Program(s) that expressly survive expiration of this Agreement as to such Program(s).

11.6.7. **Additional Effects of Expiration or Termination for any Reason**. Termination or expiration of this Agreement will not relieve the Parties of any obligations accruing prior to such expiration or termination, and any such expiration or termination will be without prejudice to the rights of either Party accruing prior to such expiration or termination. The Parties acknowledge and agree that termination of this Agreement is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies will remain available except as expressly agreed to otherwise herein. The provisions of Article 1, Article 8, Article 12 and Article 13 and Sections 2.2.4 (for the period specified therein), 6.5 (for the period specified therein), 7.2, 9.4, 10.1, 10.2, 10.3, 10.4 (for the period specified therein), 11.1 (the provisos regarding survival of licenses) and 11.6 (and the provisions referenced therein as applicable) shall survive expiration or termination of this Agreement for any reason. If this Agreement expires or is terminated only with respect to one Program, this Agreement shall continue in full force and effect with respect to the other Program and all terms and conditions other than those that apply only to the Terminated Program.

Article 12
DISPUTE RESOLUTION

12.1. **Escalation; Decision-Making Authority.** In the case of any dispute, claim or controversy between the Parties arising from or related to this Agreement, or the interpretation, application, breach, termination or validity of this Agreement (a "**Dispute**"), the Parties will discuss and negotiate in good faith a solution acceptable to the Parties and in the spirit of this Agreement. If, after negotiating in good faith pursuant to the foregoing sentence, the Parties fail to reach agreement within […***…] (or such longer period as agreed in writing by the Parties), then the Dispute may be referred to the Executive Officers for resolution at the request of either Party. If, after negotiating in good faith, the Executive Officers fail to reach agreement within […***…] of submission to the Executive Officers (or such longer period as agreed in writing by the Parties), then either Party may upon written notice to the other submit the Dispute to non-binding mediation pursuant to Section 12.2.

12.2. **Mediation.**

12.2.1. If the Parties fail to resolve the Dispute pursuant to Section 12.1, the Parties shall attempt in good faith to resolve any Dispute by confidential mediation in accordance with the then current *Mediation Procedure of the International Institute for Conflict Prevention and Resolution* ("**CPR Mediation Procedure**") (www.cpradr.org) before initiating arbitration. The CPR Mediation Procedure shall control, except where it conflicts with these provisions, in which case these provisions control. The mediator shall be chosen pursuant to CPR Mediation Procedure. The mediation shall be held in New York, New York.

12.2.2. Either Party may initiate mediation by written notice to the other Party of the existence of a Dispute. The Parties agree to select a mediator within […***…] of the notice and the mediation will begin promptly after the selection. The mediation will continue until the mediator, or either Party, declares in writing, no sooner than after the conclusion of one full day of a substantive mediation conference attended on behalf of each Party by a senior business person with authority to resolve the Dispute, that the Dispute cannot be resolved by mediation. In no event, however, shall mediation continue more than […***…] from the initial notice by a Party to initiate meditation unless the Parties agree in writing to extend that period.

12.2.3. Any period of limitations that would otherwise expire between the initiation of mediation and its conclusion shall be extended until […***…] after the conclusion of the mediation.

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12.3. **Arbitration.**

12.3.1. If the Parties fail to resolve the Dispute pursuant to Section 12.1 or Section 12.2, and a Party desires to pursue resolution of the Dispute, subject to Section 12.3.10, the Dispute shall be submitted by either Party for resolution in arbitration pursuant to the then current *CPR Non- Administered Arbitration Rules* ("**CPR Rules**") (www.cpradr.org), except where they conflict with these provisions, in which case these provisions control. The arbitration will be held in New York, New York. All aspects of the arbitration shall be treated as confidential.

12.3.2. The arbitrators will be chosen from the CPR Panel of Distinguished Neutrals, unless a candidate not on such panel is approved by both Parties. Each arbitrator shall be a lawyer with at least fifteen (15) years' experience with a law firm or corporate law department of over twenty-five (25) lawyers or who was a judge of a court of general jurisdiction. To the extent that the Dispute requires special expertise, the Parties will so inform CPR prior to the beginning of the selection process.

12.3.3. The arbitration tribunal shall consist of three (3) arbitrators, of whom each Party shall designate one in accordance with the "screened" appointment procedure provided in CPR Rule 5.4. The chair will be chosen in accordance with CPR Rule 6.4. If, however, the aggregate award sought by the Parties is less than Five Million U.S. Dollars ($5,000,000) and equitable relief is not sought, a single arbitrator shall be chosen in accordance with the CPR Rules. Candidates for the arbitrator position(s) may be interviewed by representatives of the Parties in advance of their selection, *provided* that all Parties are represented.

12.3.4. The Parties agree to select the arbitrator(s) within forty-five (45) days of initiation of the arbitration. The hearing will be concluded within nine (9) months after selection of the arbitrator(s) and the award will be rendered within sixty (60) days of the conclusion of the hearing, or of any post-hearing briefing, which briefing will be completed by both sides within forty-five (45) days after the conclusion of the hearing. In the event the Parties cannot agree upon a schedule, then the arbitrator(s) shall set the schedule following the time limits set forth above as closely as practical.

12.3.5. The hearing will be concluded in ten (10) hearing days or less. Multiple hearing days will be scheduled consecutively to the greatest extent possible. A transcript of the testimony adduced at the hearing shall be made and shall be made available to each Party.

12.3.6. The arbitrator(s) shall be guided, but not bound, by the *CPR Protocol on Disclosure of Documents and Presentation of Witnesses in Commercial Arbitration* (www.cpradr.org) ("**Protocol**"). The Parties will attempt to agree on modes of document disclosure, electronic discovery, witness presentation, etc. within the parameters of the Protocol. If the Parties cannot agree on discovery and presentation issues, the arbitrator(s) shall decide on presentation modes and provide for discovery within the Protocol, understanding that the Parties contemplate reasonable discovery.

12.3.7. The arbitrator(s) shall decide the merits of any Dispute in accordance with the law governing this Agreement, without application of any principle of conflict of laws that would result in reference to a different law. The arbitrator(s) may not apply principles such as "*amiable compositeur*" or "*natural justice and equity*."

12.3.8. The arbitrator(s) are expressly empowered to decide dispositive motions in advance of any hearing and shall endeavor to decide such motions as would a United States District Court Judge sitting in the jurisdiction whose substantive law governs.

12.3.9. The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. The Parties consent to the jurisdiction of the United States District Court for the district in which the arbitration is held for the enforcement of these provisions and the entry of judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction may act in the same fashion.

12.3.10. Notwithstanding any provision to the contrary contained in this Agreement, each Party has the right to seek from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin or other equitable relief to avoid irreparable harm, maintain the status quo, preserve its status and priority as a creditor or preserve the subject matter of the Dispute. Rule 14 of the CPR Rules does not apply to this Agreement.

Article 13
MISCELLANEOUS

13.1. **Performance by Affiliates.** To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations. A Party may use one or more of its Affiliates to perform its obligations and duties or exercise its rights hereunder, *provided* that such Party will remain liable hereunder for the prompt payment and performance of all of their respective obligations hereunder. Any breach by an Affiliate of a Party of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

13.2. **Retained Rights**. All licenses and rights are granted only as expressly provided in this Agreement, and no license or other right is or shall be created or granted under this Agreement by implication, estoppel, or otherwise. All rights not expressly granted by a Party under this Agreement are reserved by such Party and may not be used by the other Party for any purpose.

13.3. **Entire Agreement.** This Agreement and each of the Schedules and Exhibits hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter of this Agreement and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties (including the Nondisclosure Agreement, *provided* that all information shared by the Parties or their Affiliates pursuant to such Nondisclosure Agreement shall be deemed Confidential Information of the disclosing Party under this Agreement, and the use and disclosure thereof shall be governed by Article 8), whether oral or written, regarding such subject matter.

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

13.5. **Binding Effect.** This Agreement and the rights granted herein will be binding upon, and will inure to the benefit of Janssen, Licensee and their respective lawful successors and permitted assigns.

13.6. **Assignment.** Neither Party may assign or transfer this Agreement in its entirety or any rights or obligations hereunder without the prior written consent of the other Party, except that:

(a) Janssen may assign or transfer this Agreement in its entirety or any rights or obligations hereunder to an Affiliate without Licensee's consent;

(b) after the end of the Development Term of a Program, Licensee may assign any rights or obligations hereunder relating to such Program to an Affiliate without Janssen's consent;

(c) after the end of the Development Terms of both Programs, Licensee may assign or transfer this Agreement in its entirety to an Affiliate without Janssen's consent;

(d) Janssen may assign or transfer this Agreement in its entirety to a Third Party acquirer of that portion of its business relating to the subject matter of this Agreement in a sale of assets or other similar transaction without Licensee's consent;

(e) after the end of the Development Terms of both Programs, Licensee may assign or transfer this Agreement in its entirety to a Third Party acquirer of that portion of its business relating to the subject matter of this Agreement in a sale of assets or other similar transaction without Janssen's consent (other than in a Change of Control); and

(f) either Party may assign or transfer this Agreement in its entirety pursuant to any Change of Control of such Party.

The assigning Party shall provide the other Party with prompt written notice of any such assignment pursuant to any of Section 13.6(b) through 13.6(f). Janssen shall use diligent

efforts to provide Licensee with written notice of any assignment to an Affiliate pursuant to Section 13.6(a) within a reasonable period of time after the occurrence of such assignment. Any permitted assignment shall be binding on the successors and permitted assignees of the assigning Party, and the successor (if the successor is an entity other than a Party) or assignee shall confirm the same in writing to the other Party. Any assignment, transfer or attempted assignment or transfer by either Party in violation of the terms of this Section 13.6 shall be null, void and of no legal effect.

13.7. **Use of Names.** Neither Party shall use the name, physical likeness, employee names or Trademarks of the other Party for any purpose without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed; *provided*, *however*, that nothing contained herein shall be construed to prevent either Party from using the name of the other Party for purposes of preparing necessary filings with the United States Securities and Exchange Commission or complying with its regulations, or other regulations applicable to the public sale of securities, including preparing proxy statements or prospectuses. Nothing contained herein shall be construed as granting either Party any rights or license to use any of the other Party's Trademarks without separate, express written permission of the owner of such Trademark.

13.8. **Amendment; No Waiver.** No waiver, modification or amendment of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition.

13.9. **Force Majeure Event.** Except for obligations to make payments under this Agreement when due, the failure of a Party to perform any obligation under this Agreement by reason of force majeure, limited to acts of God, war, terrorism (actual or threatened), strikes, revolutions, laws or other causes of a similar magnitude beyond the reasonable control of such Party (each, a "**Force Majeure Event**"), will not be deemed to be a breach of this Agreement. The Party affected by any Force Majeure Event will contact the other Party for discussion of possible emergency measures.

13.10. **Independent Contractors.** The Parties are independent contractors and not agents or employees of the other Parties under this Agreement. Nothing contained in this Agreement is intended nor is to be construed so as to constitute Janssen and Licensee as partners or joint venturers with respect to this Agreement. No Party will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Parties or to bind the other Parties to any other contract, agreement or undertaking with any Third Party except as may be explicitly provided for herein or authorized in writing.

13.11. **Notices and Deliveries.** Any notices, request, delivery, approval or consent required or permitted to be given under this Agreement will be in writing and will be deemed to have been sufficiently given when it is received, whether delivered in person, transmitted by facsimile with contemporaneous confirmation, delivered by registered letter (or its equivalent) or delivered by certified overnight courier service, to the Party to which it is directed at its address shown below or such other address as such Party will have last given by notice to the other Party.

If to Licensee:

TRACON Pharmaceuticals, Inc.
8910 University Center Lane
Suite 700
San Diego, CA 92122 USA
Attention: Chief Business Officer
Facsimile No.: +1 858-550-0786

with a copy to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121 USA
Attention: L. Kay Chandler
Facsimile No.: +1 858-550-6420

If to Janssen:

Janssen Pharmaceutica NV
Legal Affairs Department
Turnhoutseweg 30
B-2340 Beerse
Belgium
Facsimile: As may be provided to TRACON by Janssen

with a copy to:

Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Facsimile: 732-524-2788

13.12. **Headings.** The captions to the sections and articles in this Agreement are not a part of this Agreement, and are included merely for convenience of reference only and will not affect its meaning or interpretation.

13.13. **Severability.** In the event that any provision of this Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and this Agreement will be construed as if such invalid or unenforceable provision had not been included herein.

13.14. **Governing Law.** This Agreement will be governed by and interpreted in accordance with the laws of the State of New York without reference to its choice of laws or conflicts of laws provisions. The United Nations Conventions on Contracts for the International Sale of Goods shall not be applicable to this Agreement. Each Party (a) submits to the exclusive jurisdiction of the state and federal courts sitting in New York, New York, with respect to actions or proceedings arising out of or relating to this Agreement in which a Party brings an action in aid of arbitration, (b) agrees that all claims in respect of such action or proceeding may be heard and determined only in any such court, and (c) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court, other than an action or proceeding seeking injunctive relief or brought to enforce an arbitration ruling issued pursuant to Section 12.3. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of the other Party with respect thereto. Each Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 13.11. Nothing in this Section 13.14, however, will affect the right of any Party to serve legal process in any other manner permitted by New York law.

13.15. **Advice of Counsel.** Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will exist or be implied against the Party which drafted such terms and provisions.

13.16. **Counterparts.** This Agreement may be executed in any number of counterparts (including by facsimile or electronic transmission), each of which need not contain the signature of more than one Party, but all such counterparts taken together will constitute one and the same agreement. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

13.17. **Construction.** Whenever this Agreement refers to a number of days without using a term otherwise defined herein, such number refers to calendar days. Except where the context otherwise requires, (a) wherever used, the singular shall include the plural, the plural shall include the singular; (b) the use of any gender shall be applicable to all genders; (c) the terms "including," "include," "includes" or "for example" shall not limit the generality of any description preceding such term and, as used herein, shall have the same meaning as "including, but not limited to," and/or "including, without limitation"; (d) the words "herein", "hereof" and hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (d) the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (e) the word "will" means "shall"; (f) if a period of time is specified and dates from a given day or business day, or the day or business day of an act or event, it is to be calculated exclusive of that day or business day; (g) references to a particular entity include such entity's successors and assigns to the extent not prohibited by this Agreement; (h) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner; and (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein).

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date, each copy of which will for all purposes be deemed to be an original.

JANSSEN PHARMACEUTICA N.V.

By: /s/ Tom Heyman

Name: Tom Heyman

Title: Managing Director

JANSSEN PHARMACEUTICA N.V.

By: /s/ Hilde Claes

Name: Hilde Claes

Title: Member of the Board of Directors

TRACON PHARMACEUTICALS, INC.

By: /s/ Charles P. Theuer

Name: Charles P. Theuer

Title: CEO

EXHIBIT A

AR MUTANT PROGRAM LICENSE AGREEMENT

LICENSE AGREEMENT

BY AND BETWEEN

TRACON PHARMACEUTICALS, INC.

AND

JANSSEN PHARMACEUTICA N.V.

LICENSE AGREEMENT

This LICENSE AGREEMENT (this "**Agreement**") is made and effective as of the Effective Date (as defined below) by and between TRACON Pharmaceuticals, Inc., a Delaware corporation ("**TRACON**") and Janssen Pharmaceutica N.V. ("**Janssen**"). Each of TRACON and Janssen is sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**." In the event a Party assigned the License and Option Agreement (as defined below) in its entirety prior to the Effective Date (as defined below) pursuant to Section 13.6 of the License and Option Agreement, or a lawful successor of a Party became bound by the License and Option Agreement prior to the Effective Date, the references to such Party in this Agreement shall be deemed to refer to such permitted assignee or lawful successor.

RECITALS

WHEREAS, TRACON has developed certain technology and owns or has a license to certain intellectual property rights relating to the AR Mutant Program (as defined below) conducted by TRACON and its Affiliates prior to the Effective Date pursuant to the License and Option Agreement (as defined below); and

WHEREAS, Janssen exercised the exclusive option granted under the License and Option Agreement to terminate the licenses and related rights granted by Janssen to TRACON pursuant to the License and Option Agreement and obtain, and TRACON is obligated to grant to Janssen, an exclusive, worldwide license under the Licensed Technology (as defined below) to develop, manufacture and commercialize Licensed Compounds (as defined below) and Licensed Products (as defined below) on the terms and subject to the conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the various promises and covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

Article 1
DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, will have the meaning set forth below or, if not listed below, the meaning designated where first used in this Agreement.

1.1. "**Acquirer**" means any Third Party that is a party to any Change of Control transaction and any of such Third Party's Affiliates.

1.2. "**Affiliate**" means, with respect to any Party, any corporation or other business entity that directly or indirectly controls, is controlled by, or is under common control with such Party at the time at which the determination of affiliation is being made. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to any Party, means the possession of at least 50% of the voting stock or other ownership interest of the other corporation or entity, or the power to direct or cause the direction of the management and policies of the corporation or other entity or

the power to elect or appoint at least 50% of the members of the governing body of the corporation or other entity through the ownership of the outstanding voting securities or by contract or otherwise.

1.3. "**Applicable Law**" means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Governmental Authority, including the FFDCA, Prescription Drug Marketing Act of 1987 (21 U.S.C. §§331, 333, 353, 381), the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335(a) et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder.

1.4. "**AR Mutant Compound**" means any compound that is (a) (i) described as a composition-of-matter as of the License and Option Agreement Effective Date in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) set forth on Schedule AR Mutant Program Patents of the Schedule Letter or (ii) described after the License and Option Agreement Effective Date in a claim of such a Patent Right filed within […***…], or (b) described in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) Controlled by a Party which also describes as a composition-of-matter a compound described in (a) above as of the […***…]. AR Mutant Compound includes the compound specifically set forth on Schedule AR Mutant Compound of the Schedule Letter.

1.5. "**AR Mutant Development Plan**" shall have the meaning given to it in the License and Option Agreement.

1.6. "**AR Mutant Product**" means any pharmaceutical product in any dosage form containing an AR Mutant Compound.

1.7. "**AR Mutant Program**" means the conduct of Development, Manufacturing and Commercialization activities with respect to AR Mutant Compounds and AR Mutant Products.

1.8. "**Calendar Quarter**" means a financial quarter based on the Johnson & Johnson Universal Calendar; *provided*, *however*, that the first Calendar Quarter of the Term shall begin on the Effective Date and end on the last day of the then-current Calendar Quarter and the last Calendar Quarter of the Term shall begin on the first day of such Calendar Quarter and end on the effective date of termination or expiration of this Agreement.

1.9. "**Calendar Year**" means a year based on the Johnson & Johnson Universal Calendar; *provided*, *however*, that the first Calendar Year of the Term shall begin on the Effective Date and end on the last day of the then-current Calendar Year and the last Calendar Year of the Term shall begin on the first day of such Calendar Year and end on the effective date of termination or expiration of this Agreement.

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1.10. "**Change of Control**" means, with respect to a Party: (a) that any Third Party acquires directly or indirectly the beneficial ownership of any voting securities of such Party, or if the percentage ownership of such person or entity in the voting securities of such Party is increased through stock redemption, cancellation or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of outstanding voting securities representing more than fifty percent (50%) of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization or reorganization of such Party is consummated, other than any such transaction in which stockholders or equity holders of such Party immediately prior to such transaction beneficially own, directly or indirectly, at least fifty percent (50%) of the voting securities of the surviving entity (or its parent entity) immediately following such transaction; (c) that the stockholders or equity holders of such Party approve a plan of complete liquidation of such Party; (d) that individuals who, as of the Effective Date, constitute the Board of Directors of such Party (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the Board of Directors of such Party (*provided*, *however*, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election by such Party's stockholders, was recommended or approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board of Directors of such Party); or (e) the sale or disposition to a Third Party of all or substantially all of such Party's assets taken as a whole.

1.11. "**Clinical Trial**" means any Phase I Clinical Trial, Phase II Clinical Trial, Phase II/III Clinical Trial or Phase III Clinical Trial.

1.12. "**Combination Product**" means: (a) any Licensed Product that contains a Licensed Compound and one or more other active pharmaceutical ingredient(s), where such Licensed Compound and other active pharmaceutical ingredient(s) are co-formulated into a single product; or (b) any combination, package or bundle of a Licensed Product with one or more other pharmaceutical products that are not Licensed Products sold together for a single invoiced price.

1.13. "**Commercialization**" means any activities directed to marketing, promoting, educating, informing, distributing, importing, offering to sell and/or selling a pharmaceutical product. When used as a verb, "**Commercialize**" means to engage in Commercialization activities.

1.14. "**Commercially Reasonable Efforts**" means: (a) with respect to the Development, seeking and obtaining Marketing Approval, Manufacture or Commercialization of a Licensed Product in a country by or on behalf of Janssen during the License Term, those reasonable, good faith efforts normally used by biopharmaceutical companies of similar size and stage of development under similar circumstances for similar products or product candidates owned or controlled by such company, or to which such company has similar rights, which product or product candidate is of similar market potential in such country and is at a similar stage in its development or product life, taking into account (with respect to those efforts described in this clause (b) only) all Relevant Factors; or (b) with respect to the efforts to be expended by either Party with respect to any objective or activity other than those described in clause (a) of this Section 1.14, those

reasonable, good faith efforts to accomplish such objective or perform such activity as such Party would normally use to accomplish a similar objective under similar circumstances.

1.15. "**Competing Product**" means a therapeutic product, an active pharmaceutical ingredient of which […***…].

1.16. "**Confidential Information**" means: (a) all non-public or proprietary information (including Know-How) that is disclosed by a Party (or any of its Affiliates) to the other Party (or any of its Affiliates) pursuant to or in connection with this Agreement or the License and Option Agreement; and (b) all other non-public or proprietary information (including Know-How) that is expressly deemed in this Agreement or the License and Option Agreement to be Confidential Information, whether or not disclosed by a Party (or any of its Affiliates) to the other Party (or any of its Affiliates), in each case ((a) or (b)), without regard as to whether any of the foregoing is marked "confidential" or "proprietary," or in oral, written, graphic or electronic form.

1.17. "**Control**" or "**Controlled**" means, with respect to any Know-How, Patent Right or other intellectual property right, possession by a Party (whether by ownership or license or otherwise, but without taking into account any rights granted pursuant to this Agreement), directly or through an Affiliate of such Party, of the ability to transfer, or grant a license or sublicense under, such right as provided for herein without violating the terms of any contract with any Third Party that exists on the Effective Date or other binding arrangement with any Third Party that exists on the Effective Date, or, subject to Section 2.2, any contract with any Third Party or other binding arrangement with any Third Party that exists after the Effective Date with regard to any Know-How, Patent Right or other intellectual property right licensed to or acquired by a Party from a Third Party after the Effective Date; *provided*, *however*, that any Know-How, Patent Right or other intellectual property right that is owned or licensed by an Acquirer of a Party or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of such Party prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control) shall not be deemed to be Controlled by such Party for purposes of this Agreement, except to the extent, and only to the extent that, such Know-How, Patent Right or other intellectual property right is either (a) actually used by such Party, the Acquirer or any of their respective Affiliates in the performance of Development, Manufacturing or Commercialization activities with respect to any Licensed Compound or Licensed Product following the consummation of the Change of Control of such Party, or (b) made, conceived or reduced to practice by the Acquirer or any such Affiliates through the use of any Licensed Technology, Development Program Know-How or Development Program Patents following the consummation of the Change of Control of such Party.

1.18. "**Cover**", "**Covering**" and "**Covered**" means, with respect to a Patent Right and an invention, that, in the absence of ownership of or a license under such Patent Right, the practice of such invention (e.g., with respect to a Patent Right in the U.S., the manufacture, use, sale, offer for sale or importation of such invention) would infringe a Valid Claim of such Patent Right (in the case of a pending patent application, if the claims of such patent application as then existing were issued).

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1.19. "**Data Package**" shall have the meaning given to it in the License and Option Agreement.

1.20. "**Development**" means all research and non-clinical and clinical drug development activities and processes, including toxicology, pharmacology, project management and other non-clinical efforts, formulation development, delivery system development, statistical analysis, manufacturing development, the performance of Clinical Trials (including the manufacturing of products for use in clinical trials), or other activities reasonably necessary in order to obtain and maintain, Marketing Approval of a pharmaceutical product. When used as a verb, "**Develop**" means to engage in Development activities.

1.21. "**Development Program Invention**" means any Development Program Know-How that is an invention.

1.22. "**Development Program Know-How**" means any Know-How that was generated (or in the case of an invention, reduced to practice) by a Party's or its Affiliates' or Third Party subcontractors' employees or agents in performing any Development activities with AR Mutant Compounds or AR Mutant Products during the Development Term, including all preclinical and clinical data generated in the course of performing such activities; *provided* that Third Party Subcontractor Reserved Technology (as defined in the License and Option Agreement) shall be excluded to the extent not assigned or licensed to a Party.

1.23. "**Development Program Patent**" means any Patent Right that claims one or more Development Program Inventions.

1.24. "**Development Term**" means the period beginning on the License and Option Agreement Effective Date and ending immediately prior to the Effective Date of this Agreement.

1.25. "**Drug Approval Application**" means: (a) a new drug application submitted to the FDA pursuant to Section 505(b) of the FFDCA, 21 U.S.C. § 355(b) (an "**NDA**"); or (b) an application for authorization to market and/or sell a drug product submitted to a Regulatory Authority in any country or jurisdiction other than the U.S., in each case ((a) and (b)), including all amendments and supplements thereto.

1.26. "**Effective Date**" means the Option Exercise Effective Date as defined in the License and Option Agreement.[1]

1.27. "**EMA**" means the European Medicines Agency or any successor agency for the EU with responsibilities comparable to those of the European Medicines Agency.

1.28. "**EPO**" means the European Patent Organization, or any successor entity with responsibilities comparable to those of the European Patent Organization.

1.29. "**EU**" means the countries of the European Economic Area, as it is constituted on the Effective Date and as it may be modified from time to time after the Effective Date.

[1] Note to Draft: Actual calendar date to be inserted by Parties after Option is exercised.

1.30. "**Executive Officers**" means the Chief Executive Officer of TRACON and the Global Head, Oncology Therapeutic Area of Janssen Research & Development LLC, an Affiliate of Janssen.

1.31. "**FDA**" means the United States Food and Drug Administration or any successor agency in the United States with responsibilities comparable to those of the United States Food and Drug Administration.

1.32. "**FFDCA**" means the U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.), as amended from time to time.

1.33. "**Field**" means all uses.

1.34. "**First Commercial Sale**" means, with respect to a given Licensed Product and a given country, the first arm's-length commercial sale of such Licensed Product to a Third Party in the Field in such country after the receipt of Marketing Approval for such Licensed Product in such country. Sales for Clinical Trial purposes, early access or compassionate use programs, or similar uses, shall not constitute a First Commercial Sale. In addition, sales of a Licensed Product by and between Janssen and its Affiliates, distributors and (sub)licensees, or between the Parties (or their respective Affiliates, distributors or (sub)licensees), shall not constitute a First Commercial Sale.

1.35. "**Governmental Authority**" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any nation, state, province, county, city or other political subdivision thereof or (c) any supranational body.

1.36. "**IND**" means (a) an Investigational New Drug application as defined in the FFDCA and applicable regulations promulgated thereunder by the FDA; (b) a clinical trial authorization application for a product filed with a Regulatory Authority in any other regulatory jurisdiction outside the U.S., the filing of which (in the case of (a) or (b)) is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction; or (c) documentation issued by a Regulatory Authority that permits the conduct of clinical testing of a product in humans in such jurisdiction.

1.37. "**Indication**" means a discrete clinically recognized form of a disease. For purposes of this Agreement, treatment of different subpopulations within a population of patients having a disease shall not be treated as separate Indications (e.g., front-line treatment, second-line or relapsed refractory treatment and maintenance treatment of prostate cancer shall not be treated as separate Indications) and treatment of different signs or symptoms of the same disease shall not be treated as separate Indications; *provided*, *however*, that front-line treatment, second-line treatment or relapsed refractory treatment and maintenance treatment of prostate cancer shall be treated as separate Indications.

1.38. "**Janssen-Owned Development Program Know-How**" means any Development Program Know-How that is owned by Janssen pursuant to Section 7.2.1 of the License and Option Agreement.

1.39. "**Janssen-Owned Development Program Patents**" means any Development Program Patent that is owned solely by Janssen pursuant to Section 7.2.1 of the License and Option Agreement and any Patent Rights that arise from the Janssen-Owned Development Program Know-How or any Development Program Know-How included in the Transferred Assets.

1.40. "**Janssen Program Patents**" means any Patent Rights Controlled by Janssen or any of its Affiliates during the Development Term, on the Effective Date or during the Term (other than Development Program Patents) that Cover any Licensed Compound or Licensed Product, including the Patent Rights set forth on Schedule AR Mutant Program Patents of the Schedule Letter and all Patent Rights arising therefrom; *provided*, *however*, that with regard to Patent Rights regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Patent Rights that are applied to or used to make any Licensed Product as such Licensed Product existed as of the License and Option Agreement Effective Date is included, and any other formulation or Manufacturing method Patent Rights are excluded. For clarification, Janssen Program Patents does not include any Patent Rights with respect to any active ingredient(s) in any Combination Product other than a Licensed Compound.

1.41. "**Johnson & Johnson Universal Calendar**" means the universal calendar system used by Johnson & Johnson, a New Jersey Corporation, and its Affiliates (including Janssen) for internal and external reporting purposes, a copy of which for each year shall be provided by Janssen to TRACON prior to the beginning of such year.

1.42. "**Joint Development Program Patents**" means any Development Program Patent that is owned jointly by TRACON and Janssen pursuant to Section 7.2.1 of the License and Option Agreement.

1.43. "**Know-How**" means any non-public or proprietary information, inventions, discoveries, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, trade secrets, technology, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies, Regulatory Documentation, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority or patent office, data (including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions), devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.

1.44. "**License and Option Agreement**" means that certain License and Option Agreement by and between TRACON and Janssen, dated as of the License and Option Agreement Effective Date.

1.45. "**License and Option Agreement Effective Date**" means September 27, 2016.

1.46. "**Licensed Compound**" means any AR Mutant Compound.

1.47. "**Licensed Product**" means any AR Mutant Product.

1.48. "**Licensed Technology**" means (a) the TRACON Program Know-How, (b) the TRACON Program Patents, (c) the TRACON-Owned Development Program Patents and (d) TRACON's interest in the Joint Development Program Patents.

1.49. "**Major European Countries**" means France, Germany, Italy, Spain and the United Kingdom.

1.50. "**Manufacturing**" means any activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a pharmaceutical product. When used as a verb, "**Manufacture**" means to engage in Manufacturing activities.

1.51. "**Marketing Approval**" means the approval of the applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical product for an Indication in the Field in a country, including any and all approvals that may be required in such country for pricing and reimbursement. For clarity, as of the Effective Date, no pricing and reimbursement approvals are required to market or sell a pharmaceutical product in the United States.

1.52. "**Net Sales**" means the gross amounts invoiced on sales of a Licensed Product by Janssen, or any of its Affiliates or (sub)licensees, to a Third Party purchaser in an arm's-length transaction, less the following customary and commercially reasonable deductions, determined in accordance with US generally accepted accounting principles and internal policies and actually taken, paid, accrued, allocated, or allowed based on good faith estimates:

(a) trade, cash and/or quantity discounts, allowances, deductions, fees and credits, excluding commissions for commercialization;

(b) excise taxes, use taxes, tariffs, sales taxes and customs duties and/or other government charges or fees imposed on the sale of Licensed Product (including VAT, but only to the extent that such VAT taxes are not reimbursable or refundable), specifically excluding, for clarity, any income taxes assessed against the income arising from such sale;

(c) compulsory or negotiated payments and cash rebates or other expenditures to Governmental Authorities (or designated beneficiaries thereof) in the context of any national or local health insurance programs or similar programs, including pay-for-performance agreements, risk sharing agreements and government-levied fees as a result of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148;

(d) rebates, chargebacks, administrative fees and discounts (or equivalent thereof) to managed health care organizations, group purchasing organizations, insurers, pharmacy benefit managers (or equivalent thereof), specialty pharmacy providers, Governmental Authorities, or their agencies or purchasers, reimbursers, or trade customers, as well as amounts owed to patients through co-pay assistance cards or similar forms of rebate to the extent the latter are directly related to the prescribing of Licensed Product;

(e) outbound freight, shipment, insurance and other distribution costs to the extent included in the invoiced price and separately itemized on the invoice;

(f) retroactive price reductions, credits or allowances actually granted upon claims, rejections or returns of Licensed Product, including for recalls or damaged or expired goods, billing errors and reserves for returns; and

(g) any invoiced amounts that are not collected by the selling party or its Affiliates, including bad debts.

All of the aforementioned deductions shall only be allowable to the extent they are commercially reasonable and shall be determined, on a country-by-country basis, as incurred in the ordinary course of business in type and amount verifiable based on Janssen's and its Affiliates' reporting system. All such discounts, allowances, credits, rebates, and other deductions shall be fairly and equitably allocated to Licensed Product and other products of Janssen and its Affiliates and (sub)licensees such that Licensed Product does not bear a disproportionate portion of such deductions.

For clarity, (x) sales of a Licensed Product by and between Janssen and any of its Affiliates or (sub)licensees shall not be considered sales to unaffiliated Third Parties and shall be excluded from Net Sales calculations for all purposes as long as such Licensed Product is subsequently resold to an unaffiliated Third Party and (y) only a single sales transaction with respect to a particular unit of Licensed Product, made at the time Janssen or any of its Affiliates or (sub)licensees sells such unit of Licensed Product to an unaffiliated Third Party purchaser in arms-length transaction, will qualify as the basis for determining the Net Sales amount for such unit of Licensed Product.

Notwithstanding the foregoing, the following sales of a Licensed Product shall be excluded from Net Sales calculations for all purposes: (i) transfer or dispositions of reasonable quantities of samples of such Licensed Product at no cost for promotional or educational purposes; (ii) transfers or dispositions of reasonable and customary quantities of such Licensed Product as free samples or donations, or for patient assistance, testing marketing programs or other similar programs at no cost; and (iii) use or sale of such Licensed Product for clinical study or other scientific testing purposes, early access programs (such as to provide patients with such Licensed Product prior to Regulatory Approval pursuant to treatment INDs or protocols, named patient programs or compassionate use programs) or any similar use.

In the event a Licensed Product is sold as part of a Combination Product in a country, the Net Sales with respect to the Combination Product in such country shall be determined by multiplying the Net Sales amount for the Combination Product during the applicable reporting period, calculated as set forth above, by the fraction A/(A+B), where A is the weighted average sale price (by sales volume) of the Licensed Product when sold separately, and B is the weighted average sales price of the other active ingredient(s) or product(s) in the Combination Product when sold separately, in each case in the same dosage and dosage form and in the same country as the Combination Product during the applicable reporting period. If the other active ingredient(s) or product(s) in the Combination Product is not sold separately during the applicable reporting period in a country, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by a fraction A/C where A is the weighted average sale price (by sales volume) of the Licensed Product in such country when sold separately, and C is the weighted average sale price (by Sales volume) of the Combination Product in such country. If

neither sales of the Licensed Product sold separately nor sales of the other active ingredient(s) or product(s) sold separately occurred during the applicable reporting period, then the respective average sales prices during the most recent reporting period in which sales of both occurred in the same country as the Combination Product. In the event that the weighted average sale price (by sales volume) of the Licensed Product is not available in a given country for any reporting period, then the average sales prices (weighted by sales volume) of the respective products described above (in the same dosage and dosage form as the Combination Product) in a proxy country to be agreed upon by both Parties will be used (such agreement not be unreasonably withheld, delayed or conditioned), and if the Parties cannot agree upon such proxy country, or no such comparable sales figures are available in an appropriate proxy country, Net Sales for the applicable Combination Product shall be allocated based on the relative value contributed by each component (such relative value to be agreed upon by the Parties or, if the Parties cannot agree, to be determined by the dispute resolution procedures set forth in Article 11).

1.53. "**Nondisclosure Agreement"** means the Confidential Disclosure Agreement between the Parties dated January 25, 2016.

1.54. "**Patent Costs**" means any out-of-pocket costs and expenses incurred by a Party or its Affiliates in prosecuting any Patent Rights.

1.55. "**Patent Rights**" means any and all (a) patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) any other form of government-issued right substantially similar to any of the foregoing, and (f) all United States and foreign counterparts of any of the foregoing.

1.56. "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.

1.57. "**Phase I Clinical Trial**" means, in reference to a clinical trial of a Licensed Product, that such trial would satisfy the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a) or a Phase I study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).

1.58. "**Phase II Clinical Trial**" means, in reference to a clinical trial of a Licensed Product, that such trial would satisfy the requirements for a Phase 2 study as defined in 21 C.F.R. § 312.21(b) or a Phase II study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).

1.59. "**Phase II/III Clinical Trial**" means a Phase II Clinical Trial involving a sufficient number of subjects that, prior to commencement of the trial or at any other defined point in the trial, satisfies both of the following ((a) and (b)):

(a) such trial is designed to (i) establish that the applicable Licensed Product is safe and efficacious for its intended use, and (ii) define and determine warnings,

precautions, and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed, which trial is intended to support Marketing Approval of such Product or a similar clinical study prescribed by the FDA; and

(b) such trial is or becomes a registration trial sufficient for filing an application for a Marketing Approval for such Licensed Product in the U.S., as evidenced by (i) an agreement with or statement from the FDA on a Special Protocol Assessment or equivalent, or (ii) other guidance or minutes issued by the FDA, for such registration trial.

1.60. "**Phase III Clinical Trial**" means, in reference to a clinical trial of a Licensed Product, that such trial is would satisfy the requirements for a Phase 3 study as defined in 21 C.F.R. § 312.21(c) or a Phase III study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).

1.61. **"Program Records"** shall have the meaning given to it in the License and Option Agreement.

1.62. "**Regulatory Authority**" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing and sale of a pharmaceutical product in a country, such as the FDA in the United States or EMA in the EU.

1.63. "**Regulatory Approval**" means any and all approvals (including Marketing Approvals), licenses (including import licenses), registrations or authorizations of any national, regional, state or local Regulatory Authority, department, bureau, commission, council or other governmental entity, that are necessary or useful to Development, Manufacture or Commercialize a pharmaceutical product in any country or jurisdiction in the Territory for one or more uses.

1.64. "**Regulatory Documentation**" means: (a) all applications for Regulatory Approval of any Licensed Compound or Licensed Product; (b) all Regulatory Approvals for any Licensed Compound or Licensed Product, including INDs, Drug Approval Applications and Marketing Approvals; (c) all supporting documents created for, referenced in, submitted to or received from an applicable Regulatory Authority relating to any of the applications or Regulatory Approvals described in clauses (a) or (b), including drug master files (or any equivalent thereof outside the U.S.), annual reports, regulatory drug lists, advertising and promotion documents shared with Regulatory Authorities, adverse event files, complaint files and Manufacturing records; and (d) all correspondence made to, made with or received from any Regulatory Authority (including written and electronic mail correspondence and minutes from meetings, discussions or conferences (whether in person or by audio conference or videoconference)).

1.65. "**Regulatory Exclusivity Period**" means, with respect to a given Licensed Product and given country, a period of exclusivity (other than patent exclusivity), granted or afforded by Applicable Laws or by a Regulatory Authority in such country, that confers exclusive marketing rights with respect to such Licensed Product in such country and prevents the initial market entry of a generic product with respect to such Licensed Product. In the event that such exclusivity is not available with respect to a Licensed Product in a country, the Regulatory Exclusivity Period for such Licensed Product in such country shall be deemed to expire upon the First Commercial Sale of such Licensed Product in such country

1.66. "**Relevant Factors**" means all relevant scientific, technical, operational, commercial, economic and other factors that may affect the development, Marketing Approval, manufacture or commercialization of a product, including (as applicable): actual and potential issues of safety, efficacy and/or stability; expected and actual product profile (including product modality, category and mechanism of action); stage of development or life cycle status; actual and projected development, Marketing Approval, manufacturing, and commercialization costs, timelines and budgets; any issues regarding the ability to manufacture or have manufactured the Licensed Product; the likelihood of obtaining Marketing Approvals (including satisfactory reimbursement or pricing approvals); the timing of such approvals; labeling or anticipated labeling; the then-current competitive environment and the likely competitive environment at the time of projected entry into the market, including the expected and actual competitiveness of alternative products sold by Third Parties in the market; past performance of the product or similar products; present and future market potential; existing or projected pricing, sales, reimbursement and profitability; and expected and actual proprietary position, strength and duration of patent protection and anticipated regulatory or other exclusivity.

1.67. "**Royalty Term**" means, with respect to a given Licensed Product and a given country, the period beginning on the date of First Commercial Sale of such Licensed Product in such country and ending on the later of: (a) […***…] the date of First Commercial Sale of such Licensed Product in such country; (b) the expiration of […***…]; or (c) […***…].

1.68. "**Schedule Letter**" means the letter dated as of the License and Option Agreement Effective Date between TRACON and Janssen delivering copies of certain schedules with respect to the License and Option Agreement.

1.69. "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon).

1.70. "**Territory**" means worldwide.

1.71. "**Third Party**" means any Person other than a Party or any of its Affiliates.

1.72. "**TRACON License Agreements**" means the agreements set forth on Schedule TRACON License Agreements to the TRACON Schedule Letter.

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1.73. "**TRACON-Owned Development Program Patents**" means any Development Program Patent that is owned solely by TRACON pursuant to Section 7.2.1 of the License and Option Agreement.

1.74. "**TRACON Program Know-How**" means any Know-How Controlled by TRACON or any of its Affiliates during the Development Term, on the Effective Date or during the Term (other than Development Program Know-How) that is necessary to make, have made, use, have used, import, have imported, sell, have sold, offer for sale or have offered for sale Licensed Compounds and Licensed Products; *provided, however,* that with regard to Know-How regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Know-How that is applied to or used to make any Licensed Product as such Licensed Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Know-How is excluded. For clarification, TRACON Program Know-How does not include any Know-How with respect to any active ingredient(s) in any Combination Product other than a Licensed Compound.

1.75. "**TRACON Program Patents**" means any Patent Rights Controlled by TRACON or any of its Affiliates during the Development Term, on the Effective Date or during the Term (other than Development Program Patents) that Cover any Licensed Compound or Licensed Product, including the Patent Rights set forth on Schedule TRACON Program Patents of the TRACON Schedule Letter and all Patent Rights arising therefrom; *provided, however,* that with regard to Patent Rights regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Patent Rights that are applied to or used to make any AR Mutant Product as such AR Mutant Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Patent Rights are excluded. For clarification, Janssen Program Patents does not include any Patent Rights with respect to any active ingredient(s) in any Combination Product other than a Licensed Compound.

1.76. "**TRACON Schedule Letter**" means the letter dated as of the Effective Date between TRACON and Janssen delivering copies of certain schedules with respect to this Agreement pursuant to Section 3.2.1 of the License and Option Agreement.

1.77. "**Trademark**" means any word, name, symbol, color, designation, or device or any combination thereof, whether registered or unregistered, including any trademark, trade dress, service mark, service name, brand mark, trade name, brand name, logo or business symbol.

1.78. "**Valid Claim**" means: (a) a claim of any issued and unexpired patent that (i) has not been dedicated to the public, disclaimed, revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or a decision of a court or governmental agency of competent jurisdiction that can be appealed, but with respect to which an appeal has not taken within the time allowed for appeal, and (ii) has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (b) a claim of any pending patent application that (i) has not been cancelled, withdrawn or abandoned, without being re-filed in another application in the applicable jurisdiction, (ii) has not been finally rejected by an administrative agency or other governmental action from which no appeal can be taken and (iii) has not been pending or filed more than […***…] from the earliest possible priority date for such patent application.

1.79. **Additional Definitions.** Each of the following definitions are found in the body of this Agreement as indicated:

Defined Term	Section
Action	6.2.2
Anti-Corruption Laws	8.4.3
AR Mutant Transferred Assets	2.1.2
AR Mutant Transferred Contracts	2.1.2
Assumed Liabilities	2.1.3
Bankruptcy Code	10.3.1
Breaching Party	10.2.1
CPR Mediation Procedure	11.2.1
CPR Rules	11.3.1
Cure Period	10.2.1
Currency Hedge Rate(s)	5.4.2
Disclosing Party	7.1.1
Dispute	11.1
Existing Licensed Patents	8.2.1
Existing TRACON Know-How	8.2.4
Force Majeure Event	12.9
GTSC	5.4.2
Indemnified Party	9.2
Indemnifying Party	9.2
Insolvency Event	10.3.1
Janssen Indemnified Party	9.1.2
Knowledge	8.2
Licensee Party	10.3.1
Licensor Party	10.3.1
Losses	9.1.1
NDA	1.25
Patent Representative	6.1.1
Patent Term Extension	6.4

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Permitted Liens	8.2
Post-Development Term Acquirer Activities	4.4.2
Product Infringement	6.2.2
Protocol	11.3.6
Receiving Party	7.1.1
Regulatory Milestone Event	5.1
Regulatory Milestone Payment	5.1
Restricted Contract	2.1.2
Royalty Records	5.5
Sales Milestone Event	5.2
Term	10.1
Terminating Party	10.2.1
Third Party Claim	9.1.1
Third Party Consent	2.1.2
TRACON Indemnified Party	9.1.1
TRACON Personnel	8.2
Transition Period	2.1.4
Transition Plan	2.1.4

Article 2
TRANSFER OF AR MUTANT PROGRAM TO JANSSEN

2.1. **Termination of License and Option Agreement; Transfer of AR Mutant Program to Janssen**.

2.1.1. **Termination of License and Option Agreement with respect to AR Mutant Program**. The License and Option Agreement, including the licenses and other rights granted to TRACON thereunder, shall terminate in its entirety with respect to the AR Mutant Program, AR Mutant Compounds and AR Mutant Products on the Effective Date; *provided*, *however*, that any payment due and owing with respect to the AR Mutant Program shall survive and Sections 7.1 and 7.2 of the License and Option Agreement (without limiting the assignment of Development Program Know-How pursuant to Section 2.1.2(c) of this Agreement) shall survive with respect to the AR Mutant Program.

2.1.2. **Assignment of Transferred Assets.** Subject to the terms and conditions of this Agreement, TRACON, on behalf of itself and its Affiliates, hereby irrevocably sells, conveys, transfers and assigns to Janssen all of TRACON's and its Affiliates' right, title and interest in, to and under the following assets (collectively, the "**AR Mutant Transferred Assets**"):

(a) all Transferred Assets (as defined in the License and Option Agreement) to the extent such Transferred Assets relate to the AR Mutant Program;

(b) all Regulatory Documentation with respect to the AR Mutant Compounds and AR Mutant Products that is Controlled by TRACON on the Effective Date, including Regulatory Approvals, if any;

(c) the Development Program Know-How (other than (x) Development Program Inventions that are claimed in a TRACON-Owned Development Program Patent or Joint Development Program Patent and (y) Janssen-Owned Development Program Know-How) and all physical embodiments of such Development Program Know-How, including (i) the AR Mutant Development Plan provided by TRACON to Janssen pursuant to Section 2.2.2 of the License and Option Agreement, (ii) the Program Records generated by TRACON during TRACON's conduct of the AR Mutant Program pursuant to Section 2.2.4 of the License and Option Agreement, (iii) the Data Package(s), interim data packages and additional information delivered by TRACON to Janssen with respect to the AR Mutant Program pursuant to Section 3.2 of the License and Option Agreement, (iv) the reports and other information delivered by TRACON to Janssen with respect to the AR Mutant Program pursuant to Section 2.2.5 of the License and Option Agreement, and (v) the global safety database for any AR Mutant Product;

(d) any inventory of AR Mutant Compounds or AR Mutant Products in TRACON's possession or Control;

(e) the Third Party agreements relating to the AR Mutant Program listed on Schedule TRACON Transferred Contracts of the TRACON Schedule Letter; and

(f) all claims, counterclaims, defenses, causes of action, rights under express or implied warranties, rights of recovery, rights of set-off, rights of subrogation and all other rights of any kind against any Third Party, solely to the extent relating to any Assumed Liabilities or AR Mutant Transferred Assets identified in clauses (a) through (e).

Notwithstanding anything in this Agreement to the contrary, this Agreement shall not constitute an agreement to assign or transfer any Third Party agreement within the AR Mutant Transferred Assets ("**AR Mutant Transferred Contracts**") that is not assignable or transferable without the consent of any Third Party (each, a "**Restricted Contract**"), to the extent that such consent has not been obtained prior to the Effective Date (each, a "**Third Party Consent**"). TRACON shall use, during the Transition Period, Commercially Reasonable Efforts to obtain, and Janssen shall use Commercially Reasonable Efforts to assist and cooperate with TRACON to obtain, all Third Party Consents; *provided*, *however*, that none of TRACON, Janssen or any of their respective Affiliates shall be required to pay money to any Third Party, commence any litigation or offer or grant any accommodation (financial or otherwise) to any Third Party to obtain any Third Party Consent. During the period beginning on the Effective Date and ending on the earlier of (a) the date on which […***…] and (b) the […***…], TRACON shall (i) use Commercially Reasonable Efforts to provide Janssen with the benefits of such Restricted Contract (or benefits substantially comparable to the benefits of such Restricted Contract), *provided* that Janssen performs the obligations of TRACON under such Restricted Contract, and (ii) upon the request of, for the benefit of and at the expense of Janssen, enforce any rights of TRACON arising under such Restricted Contract against any Person, including the right to seek any available remedies or to terminate such Restricted Contract. TRACON provides no assurances to Janssen that any Third Party Consent will be granted. Subject to TRACON's compliance with this Section 2.1.2, the Parties acknowledge and agree that (x) neither TRACON nor any of its Affiliates shall be obligated to obtain any Third Party Consent and (y) neither TRACON's failure to obtain any Third Party Consent, nor any default, termination, lawsuit, action, claim, proceeding or investigation commenced or threatened by or on behalf of any Person arising from TRACON's failure to obtain any Third Party Consent, shall be deemed to be a breach of any representation, warranty or covenant of TRACON contained in this Agreement.

2.1.3. **Assumption of Assumed Liabilities.** Subject to the terms and conditions of this Agreement, TRACON hereby conveys, assigns and transfers to Janssen and its successors and assignees, forever, and Janssen hereby assumes, and agrees to satisfy, perform and otherwise discharge when due, all liabilities arising from or relating to the AR Mutant Transferred Contracts arising on or after the Effective Date, but excluding all liabilities resulting from any breach of or non-compliance with any AR Mutant Transferred Contract by TRACON or any of its Affiliates prior to the Effective Date (the

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"**Assumed Liabilities**"). All risk of loss with respect to the AR Mutant Transferred Assets (whether or not covered by insurance) shall pass to Janssen on the Effective Date or, if later with respect to any AR Mutant Transferred Asset, the date that such AR Mutant Transferred Asset is actually transferred to Janssen pursuant to the Transition Plan. Janssen does not assume any liabilities with respect to the AR Mutant Transferred Assets other than the Assumed Liabilities.

2.1.4. **Transition Plan**. Within […***…] following the Effective Date, the Parties shall mutually agree upon a plan for the transition of the AR Mutant Program, and the transfer of the AR Mutant Transferred Assets, from TRACON to Janssen providing for the following activities ("**Transition Plan**"):

(a) the return of any physical embodiments of Know-How that was licensed by Janssen to TRACON pursuant to the License and Option Agreement to the extent that such Know-How relates to the AR Mutant Program;

(b) the delivery of the tangible AR Mutant Transferred Assets and physical embodiments of the intangible AR Mutant Transferred Assets to Janssen;

(c) the transfer of ownership of any intangible AR Mutant Transferred Assets, including the transfer of ownership of any Regulatory Approvals within the AR Mutant Transferred Assets;

(d) the delivery of physical embodiments of the TRACON Program Know-How to Janssen;

(e) the completion or transfer of any Development activities with respect to the AR Mutant Compounds or AR Mutant Products that are ongoing as of the Effective Date;

(f) a technology transfer with respect to TRACON's Manufacturing processes for the AR Mutant Compounds and AR Mutant Products; and

(g) the provision of additional assistance reasonably requested by Janssen (including access to personnel who worked on the AR Mutant Program during the Development Term).

Each Party shall appoint one individual to have primary responsibility and oversight for, and to serve as the primary point of contact regarding, the transition and transfer activities for the AR Mutant Program contemplated by this Section 2.1.4 and the Transition Plan. Each Party shall bear its own costs in performing its obligations under this Section 2.1.4 and the Transition Plan.

Unless the Parties agree otherwise, the Parties shall use Commercially Reasonable Efforts to complete the activities set forth in the Transition Plan within […***…] after the Effective Date (the "**Transition Period**"). After expiration of the Transition Period,

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TRACON will have no further obligation to provide any additional information, documents, electronic files or support to Janssen in connection with the AR Mutant Program or AR Mutant Transferred Assets; *provided, however,* that following the Transition Period, if (i) either Party identifies any assets that were not transferred prior to the end of the Transition Period but that, pursuant to the provisions of this Agreement, were AR Mutant Transferred Assets that were required to be transferred, TRACON and its Affiliates shall, at no additional cost to Janssen, promptly take all actions to transfer such AR Mutant Transferred Assets to Janssen, and (ii) TRACON and its Affiliates shall provide reasonable support to Janssen and its Affiliates after the Transition Period to the extent reasonably necessary to allow TRACON and its Affiliates to respond to requirements or requests of any Regulatory Authority or other Governmental Authority with respect to Licensed Compounds or Licensed Products.

2.2. **Third Party Contracts**. If any Know-How, Patent Right or other intellectual property right would first become Controlled by a Party after the Effective Date through a license from a Third Party, and […***…], such licensee Party shall first notify the other Party of […***…], and such Know-How, Patent Right or other intellectual property right shall not be deemed to be Controlled by such licensee Party for purposes of this Agreement, except to the extent, and only to the extent that, […***…], and to acknowledge that its sublicense under such license is subject to the terms and conditions of the license agreement with the Third Party.

Article 3
DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION

3.1. **Development**.

3.1.1. **General**. Janssen shall have the sole right and responsibility, at its sole cost and expense, to Develop Licensed Compounds and Licensed Products in the Field in the Territory, and for all regulatory matters relating to such activities. Janssen will conduct such Development activities in accordance with the terms and conditions of this Agreement, in good scientific manner and in compliance with all Applicable Laws.

3.1.2. **Diligence**. Janssen shall use Commercially Reasonable Efforts to […***…].

3.1.3. **Records**. Janssen shall prepare and maintain, and shall cause its Affiliates, (sub)licensees and Third Party Subcontractors to prepare and maintain, complete and accurate Program Records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in conformity with Applicable Law and Janssen's standard practices, which Program Records shall reflect all work done and results achieved in connection with the Programs. Janssen shall retain, and cause its Affiliates, (sub)licensees and Third Party Subcontractors to retain, the Program Records for at least […***…] or such longer period as may be required by Applicable Law.

3.1.4. **Reports**. Janssen shall provide TRACON with a written summary of its progress with respect to the Development of Licensed Compounds and Licensed Products in the Field in the Territory […***…], including the […***…]. Upon TRACON's reasonable

request, Janssen shall be available for an in-person or telephonic meeting to discuss its progress on the Development of the Licensed Compounds and Licensed Products with TRACON.

3.2. **Manufacturing**. Janssen shall have the sole right and responsibility, at its sole cost and expense, to Manufacture clinical and commercial supplies of Licensed Compounds and Licensed Products. Janssen will conduct such Manufacturing activities in accordance with the terms and conditions of this Agreement and in compliance with all Applicable Laws.

3.3. **Commercialization**.

3.3.1. **General**. Janssen shall have the sole right and responsibility, at its sole cost and expense, to Commercialize Licensed Compounds and Licensed Products in the Field in the Territory. Janssen will conduct such Commercialization activities in accordance with the terms and conditions of this Agreement and in compliance with all Applicable Laws.

3.3.2. **Diligence**. Janssen shall use Commercially Reasonable Efforts to Commercialize […***…].

Article 4
LICENSE GRANT

4.1. **License Grant**. Subject to the terms and conditions of this Agreement, during the Term, TRACON grants to Janssen an exclusive (subject to Section 4.2), royalty-bearing, non-transferable (except to the extent permitted under Section12.6), sublicensable (subject to Section 4.3) license under the Licensed Technology to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale Licensed Compounds and Licensed Products in the Field in the Territory.

4.2. **TRACON Retained Rights**. Janssen acknowledges and agrees that TRACON and its Affiliates may use for any purpose (other than those purposes for which Janssen is granted an exclusive license pursuant to Section 4.1) […***…]; *provided, however,* that the foregoing is not intended to grant, and shall not be deemed to grant, […***…].

4.3. **Sublicensing**. Janssen may sublicense the rights granted to it by TRACON under Section 4.1 to any Third Party or any of its Affiliates. Any such sublicense shall (i) be in writing and (ii) be subject to, and consistent with, the terms of this Agreement. Janssen shall remain responsible to TRACON for the performance of the financial and other obligations of its sublicensees.

4.4. **Exclusivity**.

4.4.1. During the period beginning on the Effective Date and ending on the […***…] anniversary of the Effective Date, neither TRACON nor any of its Affiliates shall: […***…].

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4.4.2. Notwithstanding the foregoing:

(a) Section 4.4.1 does not prohibit TRACON and its Affiliates that are subject to Section 4.4.1, alone or through work conducted in collaboration with an Affiliate or Third Party, from conducting research and non-clinical development (or licensing or otherwise granting rights to an Affiliate or a Third Party to conduct research and non-clinical development) of compounds (other than Licensed Compounds) that […***…].

(b) Section 4.4.1 shall not apply to the Acquirer of TRACON or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of TRACON prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control), *provided* that, if the Acquirer or such Affiliate conducts any activities described in Section 4.4.1 during the period described in Section 4.4.1 (the "**Post-Development Term Acquirer Activities**"), such Acquirer or Affiliate shall use reasonable good faith efforts to segregate such Post-Development Term Acquirer Activities from activities conducted with respect to the Licensed Compounds and Licensed Products pursuant to this Agreement.

(c) TRACON shall not be limited or prohibited by Section 4.4.1 from negotiating and completing a Change of Control, or taking any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party relating to, or engage in discussions with any Third Party relating to, a Change of Control.

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Article 5
FINANCIAL TERMS

5.1. **Regulatory Milestones**. Janssen will notify TRACON in writing within […***…] after the first achievement by Janssen or any of its Affiliates, licensees or sublicensees of any of the milestone events set forth in the table below (each, a "**Regulatory Milestone Event**"). In consideration of the licenses and rights granted to Janssen under this Agreement, Janssen shall pay to TRACON the applicable milestone payment set forth in the table below (each, a "**Regulatory Milestone Payment**") within […***…] after receipt of an invoice from TRACON with respect to achievement of each Regulatory Milestone Event. Each Regulatory Milestone Payment shall be made only once, and shall be non-refundable and non-creditable.

Regulatory Milestone Event	Milestone Payment
A.[…***…]	$[…***…]
B.[…***…]	$[…***…]
C.[…***…]	$[…***…]

[…***…].

5.2. **Sales Milestones.** Solely upon the first occurrence (if any) of aggregate worldwide Net Sales of a given Licensed Product during a Calendar Year attaining the sales threshold as specified in the table below (each, a "**Sales Milestone Event**"), Janssen shall notify TRACON in writing that such Sales Milestone Event has occurred within […***…] following the end of the Calendar Quarter during which such Sales Milestone Event occurred. Following receipt of such notice, TRACON shall invoice Janssen for, and Janssen shall pay to TRACON with […***…] after receipt of such invoice, the corresponding Milestone Payment. […***…].

Sales Milestone Event	Milestone Payment
A.[…***…]	$[…***…]
B.[…***…]	$[…***…]
C.[…***…]	$[…***…]

5.3. **Royalties**.

5.3.1. **Royalty Rate**. In consideration of the licenses and rights granted to Janssen under this Agreement, Janssen shall pay to TRACON a royalty of […***…] on Net Sales of each Licensed Product in each country during the Royalty Term for such Licensed Product in such country.

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5.3.2. **Royalty Reductions**.

(a) Janssen shall be responsible for the payment of any amounts that become due to any Third Party(ies) under any TRACON License Agreement as a result of Janssen's activities with respect to the Licensed Compounds or Licensed Products under this Agreement during the Term, only to the extent […***…]. In the event TRACON makes any such payment to a Third Party, Janssen shall reimburse TRACON for such amount.

(b) If Janssen or its Affiliate or (sub)licensee is required or reasonably deems it necessary to obtain a license from a Third Party under any intellectual property rights of such Third Party that […***…], Janssen shall have the right to deduct, from the royalties due to TRACON pursuant to Section 5.3.1 with respect to a Licensed Product containing such Licensed Compound during a Calendar Quarter, […***…] of the […***…] payments made by Janssen or its Affiliate or (sub)licensee to such Third Party(ies) in exchange for such license with respect to such Licensed Compound during such Calendar Quarter, *provided* that if any agreement with such Third Party includes rights to additional compounds or products other than such Licensed Compound, any such payment that is not triggered by sales of such Licensed Product containing such Licensed Compound shall be equitably allocated by Janssen in good faith among all compounds and products under such agreement. Janssen shall provide documentation of such allocation to TRACON and any dispute regarding such allocation shall be subject to resolution under Article 11.

(c) On a country-by-country and Licensed Product-by-Licensed Product basis, the royalties due to TRACON pursuant to Section 5.3.1 shall be reduced during the Royalty Term for such Licensed Product in such country to […***…] of the amount otherwise payable from and after the date that: (i) […***…].

(d) Notwithstanding the foregoing, in no event shall the total deductions under Sections 5.3.2(b) and 5.3.2(c) reduce the royalties payable to TRACON under Section 5.3.1 with respect to a given Licensed Product in a given country in any Calendar Quarter by more than […***…].

5.3.3. **Royalty Reports and Payments.** Commencing with the First Commercial Sale of a Licensed Product by Janssen or its Affiliates or (sub)licensees, Janssen shall provide written reports to TRACON within […***…] after the end of each Calendar Quarter, stating in each such report, by Licensed Product and by country, the aggregate Net Sales in U.S. Dollars of Licensed Products sold during such Calendar Quarter by Janssen and its Affiliates and (sub)licensees. Such report shall also include: (a) the calculation of the royalty payments due to TRACON on such Net Sales; and (b) the exchange rates used in calculating the payments due TRACON, which exchange rates shall comply with Section 5.4.2. Simultaneously with the delivery of each such report, Janssen shall pay to TRACON the total royalties, if any, due to TRACON for the Calendar Quarter that is the

subject of such report. If no royalties are due with respect to a particular Calendar Quarter, Janssen shall so report.

5.4. **Payment Terms**.

5.4.1. **Payments**. All payments due under this Agreement shall be made in U.S. Dollars by wire transfer in immediately available funds to an account designated by the receiving Party or by other mutually acceptable means.

5.4.2. **Currency Conversion.**

(a) All payments under this Agreement will be made in U.S. Dollars.

(b) For purposes of computing royalty payments for Net Sales made in currencies other than U.S. Dollars, such Net Sales shall be converted into U.S. Dollars using the Currency Hedge Rate(s). For purposes of this Section 5.4.2, the "**Currency Hedge Rate(s)**" shall be calculated as a weighted average hedge rate of the outstanding external foreign currency forward hedge contract(s) of Johnson & Johnson's global treasury services center ("**GTSC**") and its Affiliates with Third Party banks, which hedge contract(s) is entered into to protect the transactional foreign exchange risk exposures of Janssen by reducing the impact of foreign currency volatility through a systematic build-up of a yearly currency hedge rate(s).

(c) For the upcoming Calendar Year, Janssen shall provide in writing to TRACON not later than ten (10) business days after the Currency Hedge Rate(s) are available from the GTSC (which is customarily at the end of October): (i) a Currency Hedge Rate(s) to be used for the local currency of each country of the Territory; and (ii) the details of such Currency Hedge Rate(s).

(d) The Currency Hedge Rate(s) will remain constant throughout the upcoming Calendar Year, and Janssen shall use the Currency Hedge Rate(s) to convert Net Sales to U.S. Dollars for the purpose of calculating royalties.

5.4.3. **Late Payments.** If a Party does not receive payment of any amount due to it under this Agreement on or before the due date, such payment shall bear interest at a rate per annum equal to […***…] in excess of overnight LIBOR or a comparable reference interbank rate per currency or the maximum rate allowable by Applicable Law, whichever is lower.

5.5. **Records; Inspection**. Janssen shall keep (and cause its Affiliates and (sub)licensees to keep) complete, true and accurate books of account and records for the purpose of determining the royalties payable by Janssen to TRACON under Section 5.3 (the "**Royalty Records**"), which Royalty Records shall be retained for at least […***…] following the end of the Calendar Year to which they pertain. Janssen shall, and shall cause its Affiliates and (sub)licensees to, make the Royalty Records available for inspection by an independent public accounting firm of national

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prominence selected by TRACON, and reasonably acceptable to Janssen, during normal business hours, as may be reasonably necessary for the sole purpose of verifying the royalty reports and payments delivered by Janssen pursuant to Section 5.3 during the preceding […***…] full Calendar Years. The records for a given Calendar Year shall be subject to audit no more than one time. Such independent public accounting firm shall execute a reasonable confidentiality agreement with Janssen prior to commencing any such inspection. Such inspections shall be made no more than once each Calendar Year at reasonable times and on reasonable notice. TRACON shall bear the costs and expenses of any inspection conducted under this Section 5.5 unless such inspection reveals an underpayment in royalties payable pursuant to Section 5.3 of more than […***…] of the amount payable for the period covered by such inspection, in which case Janssen shall bear the costs and expenses of such inspection. If such inspection reveals an overpayment by Janssen pursuant to Section 5.3, then Janssen shall deduct the amount of such overpayment from any payment that subsequently becomes due and payable by Janssen under this Agreement or, if no payment is anticipated to be due and payable by Janssen in the following Calendar Quarter, Janssen shall invoice TRACON for the amount of the underpayment and TRACON shall pay such invoice within […***…] after receipt thereof. If such inspection reveals an underpayment by Janssen pursuant to Section 5.3, then TRACON shall invoice Janssen for the amount of the underpayment and Janssen shall pay such invoice within […***…] after receipt thereof.

5.6. **Withholding Taxes**.

5.6.1. Janssen will make all payments to TRACON under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.

5.6.2. Any Tax required to be withheld on amounts payable under this Agreement will be paid by Janssen on behalf of TRACON to the appropriate Governmental Authority, and Janssen will furnish TRACON with proof of payment of such Tax. Any such Tax required to be withheld will be an expense of and borne by TRACON.

5.6.3. Janssen and TRACON will cooperate with respect to all documentation required by any taxing authority or reasonably requested by Janssen to secure a reduction in the rate of applicable withholding Taxes.

Article 6
INTELLECTUAL PROPERTY

6.1. **Prosecution of Patent Rights.**

6.1.1. **Communications.** Each Party shall designate a patent attorney or agent as its contact to coordinate with the other Party the filing, prosecution and maintenance of Patent Rights as provided in this Article (the "**Patent Representative**"). Each Party shall use reasonable efforts to handle all communications between the Parties under this Section 6.1 through their Patent Representatives and keep such communications in strict confidence to protect their attorney-client privileged status.

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6.1.2. **Reporting of Filings.** A Party planning on filing any priority-establishing or original (in each case, with respect to any claims or new matter described in the patent specification) patent application within the Development Program Patents hereunder shall use reasonable efforts to provide to the other Party with reasonable advance time prior to proposed prosecution filing in a patent office (such as a draft application or response to an official action), provide the other Party an opportunity to comment thereon through its Patent Representative, and give good faith consideration to the other Party's comments. Each Party shall provide to the other, promptly after filing, a copy of each priority-establishing or original (whether provisional or non-provisional) patent application within the Development Program Patents as filed in the patent office and each other substantive prosecution filing (including any other patent application filed within the Development Program Patents).

6.1.3. **Prosecution Responsibility and Coordination.**

(a) *Janssen Program Patents and Janssen-Owned Development Program Patents.* With respect to the Janssen Program Patents and Janssen-Owned Development Program Patents, after the Effective Date, Janssen shall be solely responsible, through patent counsel selected by Janssen, to prosecute such Patent Rights. Janssen shall be solely responsible for all Patent Costs incurred in prosecuting any Janssen Program Patents or Janssen-Owned Development Program Patents.

(b) *TRACON Program Patents, TRACON-Owned Development Program Patents and Joint Development Program Patents.* Janssen shall be primarily responsible, through outside patent counsel mutually selected and engaged by the Parties, for prosecuting any TRACON Program Patents, TRACON-Owned Development Program Patents and Joint Development Program Patents, *provided* that Janssen shall: (i) consider the reasonable suggestions of TRACON's Patent Representative as to selection of country patent offices in the Territory for filing or validating applications to form a family of related such Patent Rights and as to the abandonment of any such Patent Rights; and (ii) consider in good faith any reasonable comments of TRACON as provided by its designated Patent Representative in prosecuting any such Patent Rights, including with respect to the filing of any continuation, divisional, or other continuing applications. Subject to Section 6.1.3(d), Janssen shall be solely responsible for all Patent Costs incurred by or on behalf of Janssen in prosecuting any TRACON Program Patents, TRACON-Owned Development Program Patents and Joint Development Program Patents.

(c) *Duties Imposed by Law*. Section 6.1.3(b) notwithstanding, it will not be a breach of this Agreement that a Party, in good faith, does not execute a document or withholds or revokes consent to an action in the course of filing, prosecuting or maintaining a Patent Right hereunder that such Party reasonably believes to violate a duty imposed by law on such Party as the owner of such a Patent Right.

(d) *Step-In Rights*. If Janssen intends in its discretion to abandon or not maintain (so as to permit to lapse) any TRACON Program Patent, TRACON-Owned Development Program Patent or Joint Development Program Patent in any jurisdiction in the Territory, then Janssen shall provide TRACON with written notice of such intent within a period of time reasonably necessary to allow TRACON to determine its interest in such Patent Right (which notice from Janssen shall be given no later than […***…] prior to any final deadline for any pending action or response that may be due with respect to such Patent Right with the applicable patent office). If TRACON provides written notice to Janssen expressing its interest in preserving such Patent Right, Janssen shall cooperate with TRACON in providing TRACON the right to prosecute such Patent Right in such jurisdiction. If TRACON assumes the right to prosecute a Patent Right under this Section, TRACON shall be responsible for all Patent Costs incurred by TRACON in prosecuting such Patent Right and such Patent Right shall no longer be a TRACON Program Patent, TRACON-Owned Development Program Patent or Joint Development Program Patent, as applicable, for purposes of this Agreement.

6.1.4. **Prosecution Cooperation.** Each Party shall, at its own expense, provide all reasonable assistance requested by the other Party for prosecuting any TRACON Program Patents, Janssen Program Patents or Development Program Patents consistent with the terms hereof, including with respect to the timely completion of filings of prosecution papers, compliance with Applicable Laws and recording of assignments to reflect ownership consistent with the terms hereof. A Party prosecuting any TRACON Program Patents, Janssen Program Patents or Development Program Patents hereunder shall use reasonable efforts to provide the other Party with copies of all material prosecution papers as filed in or received from any patent offices. The Party prosecuting any TRACON Program Patents, Janssen Program Patents or Development Program Patents hereunder shall, on an annual basis during the Term, provide the other Party with a report identifying the status of any such Patent Rights; *provided*, *however*, that for Joint Development Program Patents, the Parties shall cooperate to jointly prepare such status report.

6.2. **Patent Enforcement.**

6.2.1. **Notice.**

(a) Each Party shall notify the other promptly of any apparent, threatened, or actual infringement by a Third Party of any Janssen Program Patent, TRACON Program Patent or Development Program Patent, or misappropriation of any Janssen Program Know-How, TRACON Program Know-How or Development Program Know-How, of which the Party becomes aware. The notifying Party shall promptly furnish the other with all known details or evidence of such infringement or misappropriation.

***Confidential Treatment Requested

(b) Each Party shall promptly notify the other of any Third Party communications pertaining to any Janssen Program Patent, TRACON Program Patent or Development Program Patent that the Party receives pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 or similar such notice, including notices pursuant to §§ 101 and 103 of such act from Persons who have filed an abbreviated NDA (ANDA) or a paper NDA.

6.2.2. **Enforcement Actions.** During the Term, Janssen shall have the initial right, at its expense and in its own name (or in the name of TRACON as may be required under Applicable Law), for bringing any infringement suit or other enforcement action (an "**Action**") on account of any Third Party infringement of any Janssen Program Patent, TRACON Program Patent or Development Program Patent based on any alleged making, using, selling, offering for sale, importing or other exploitation of any product that is competitive with a Licensed Product in the infringement of any such Patent Rights, or based on misappropriation of any Janssen Program Know-How, TRACON Program Know-How or Development Program Know-How providing any Regulatory Exclusivity for any such Licensed Product (each a "**Product Infringement**"), by counsel of its own choice, and TRACON will cooperate with Janssen as Janssen may reasonably request in connection with any such Action, including by becoming a party to such Action at Janssen's cost, *provided* that Janssen shall reimburse TRACON for its out-of-pocket costs reasonably incurred in connection with rendering such assistance. If Janssen declines to initiate such an Action against any unabated Product Infringement, it shall so notify TRACON, who shall thereafter have the right (but not the obligation), at TRACON's expense and in its own name, to initiate such Action on account of any Third Party infringement of any TRACON Program Patent, TRACON-Owned Development Program Patent or Joint Development Program Patent by counsel of its choice, and Janssen shall cooperate with TRACON as TRACON may reasonably request, including by becoming a party to such action at TRACON's cost, and TRACON shall reimburse Janssen for its out-of-pocket costs reasonably incurred in connection with rendering such assistance. A settlement or consent judgment or other voluntary final disposition of an Action brought by a Party under this Section may be entered into without the consent of the other Party, *provided* that such settlement, consent judgment, or other disposition does not admit the invalidity or unenforceability of any Patent Rights Controlled by the other Party and, *provided further* that any rights granted to a Third Party to continue any activity upon which such Action was based in such settlement, consent judgment, or other disposition shall be limited to the Third Party's product or activity that was the subject of the Action. Damages recovered and any other amounts awarded in any Actions for Product Infringement under this Section shall be allocated to the Party who brought the Action, after reimbursement of each Party's actual expenses incurred in such Actions as provided hereunder, *provided* that Janssen shall pay to TRACON: (a) as to damage amounts recovered by Janssen due to a Product Infringement in the form of lost profits or reasonable royalties assessed on account of the Third Party's sales of infringing product, an amount equal to the royalty that would be payable pursuant to this Agreement on the imputed amount of Net Sales of the relevant Licensed Product(s) in the country(ies) where such Product Infringement occurred; and (b) as to damage amounts recovered by Janssen due to a Product Infringement other than in the form of lost profits

or reasonable royalties assessed on account of the Third Party's sales of infringing product, an amount equal to the royalty that would be payable pursuant to this Agreement on such damage amounts treated as Net Sales of the relevant Licensed Product(s) in the country(ies) where such Product Infringement occurred.

6.2.3. **Other Enforcement Actions.** TRACON acknowledges that the outcome of any Action on account of any Third Party infringement, other than a Product Infringement, of any TRACON Program Patent or Development Program Patent licensed to Janssen under this Agreement may detrimentally impact the scope, validity, or enforceability of such Patent Right with respect to potential Product Infringements. Accordingly, the Parties shall reasonably cooperate with each other with respect to any Action on account of any Third Party infringement of any Janssen Program Patent, TRACON Program Patent or Development Program Patent other than Product Infringements. For clarity, TRACON will not be required to enforce any TRACON Program Patent against any Third Party infringement.

6.3. **Third Party Patent Rights.** Each Party shall promptly inform the other Party, orally through the Patent Representatives, in the event such Party becomes aware of any Third Party's Patent Rights that may pertain to any Development, Manufacturing or Commercialization activities of Janssen related to a Licensed Compound or Licensed Product.

6.4. **Patent Term Extensions.** During the Term, upon Janssen's written request (which shall be by a written notice identifying the date of the applicable Marketing Approval of a Licensed Product and the deadline for filing a patent term extension, supplemental protection certificate or their equivalent (each a "**Patent Term Extension**")), the Party prosecuting a relevant Patent Right shall use reasonable efforts, in each country or jurisdiction where Marketing Approval for any such Licensed Product has been obtained, and if the Applicable Law of such country or jurisdiction permits application for a Patent Term Extension, to apply, at the reasonable direction of Janssen's Patent Representative, for a Patent Term Extension for a patent within the TRACON Program Patents or TRACON-Owned Development Program Patents including a Valid Claim Covering such Licensed Product, which patent (if any) shall be selected at Janssen's reasonable judgment after considering the opinion of Janssen's patent counsel regarding its eligibility for a Patent Term Extension. Janssen shall have the right to: (a) identify in any list of patents in a Drug Approval Application for a Licensed Product with respect to such Program the applicable Janssen Program Patent(s), TRACON Program Patent(s) and Development Program Patent(s), as Janssen reasonably believes is appropriate; (b) for clarity, commence an Action for any Product Infringement of any such TRACON Program Patent(s) or TRACON-Owned Development Program Patent(s) under Applicable Law as permitted under Section 6.2.2; and (c) subject to specific limitations of this Agreement, exercise any rights that may be exercisable by a patent owner, including applying for a Patent Term Extension, of any TRACON Program Patent(s) or TRACON-Owned Development Program Patent(s) pertaining to an approved Licensed Product licensed to Janssen and Commercialized by Janssen during the Term. TRACON agrees to cooperate with Janssen and its Affiliate and Third Party (sub)licensees of Licensed Products, as applicable, upon Janssen's reasonable request in the exercise of the authorizations under this Section, and TRACON shall execute such documents and take such additional action as Janssen may reasonably request in

connection therewith, *provided* that Janssen shall reimburse TRACON all reasonable out-of-pocket costs incurred by TRACON in taking such action.

6.5. **Product Trademarks.** During the Term, Janssen shall have (directly and through its Affiliates and Third Party (sub)licensees Commercializing Licensed Products with respect to such Program) the right to brand, at its discretion, Licensed Products using Trademarks and trade names selected at its discretion and to file for, obtain, and maintain at its discretion and cost Trademarks for Licensed Products in its own name.

6.6. **Correction of Licensed Patents without Patent Challenge.** During the Term, if a Party becomes aware of any good-faith error in any TRACON Program Patent or Development Program Patent that would render the only issued claim(s) therein Covering any marketed Licensed Product invalid, such Party shall inform the other Party (orally through the Parties' Patent Representatives) and the applicable Party prosecuting such Patent Right shall, subject to this Article 6, use Commercially Reasonable Efforts to correct such error by reissue or reexamination (if such error is so correctable under Applicable Law).

Article 7
CONFIDENTIALITY; PUBLICITY

7.1. **Nondisclosure**.

7.1.1. Each Party agrees that, during the Term and for a period of five (5) years thereafter, the Party (the "**Receiving Party**") receiving Confidential Information of the other Party (the "**Disclosing Party**") shall: (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential or proprietary information of similar kind and value (but no less than reasonable efforts); (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted in Sections 7.3 and 7.4; and (c) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this Article 7 shall not create or imply any rights or licenses not expressly granted under this Agreement).

7.1.2. Notwithstanding anything to the contrary in this Agreement, any information embodied or contained in the AR Mutant Transferred Assets shall be deemed to be Confidential Information of Janssen for purposes of this Article 7, regardless of which Party is the Receiving Party and which Party is the Disclosing Party.

7.2. **Exceptions.** The obligations in Section 7.1 shall not apply to the extent of any portion of the Confidential Information that the Receiving Party can show by competent evidence:

(a) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party under this Agreement;

(b) is known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, in each case, to the Disclosing Party, prior to disclosure to the Receiving Party or any of its Affiliates by the Disclosing Party;

(c) is subsequently disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party that, to the Receiving Party's knowledge, is not bound by a similar duty of confidentiality or restriction on its use, in each case, to the Disclosing Party;

(d) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its Affiliates in violation of this Agreement, generally known or available, either before or after it is disclosed to the Receiving Party by the Disclosing Party; or

(e) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the use of or reference to the Confidential Information of the Disclosing Party.

7.3. **Authorized Disclosure.** The Receiving Party may disclose Confidential Information of the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances, or to the extent permissible under the other applicable provisions of this Agreement:

(a) filing, prosecuting, maintaining, enforcing or defending Patent Rights as permitted by this Agreement;

(b) as reasonably required in generating Regulatory Documentation and obtaining Regulatory Approvals as permitted by this Agreement;

(c) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;

(d) subject to Section 7.4, complying with Applicable Law or court or administrative orders;

(e) complying with any obligation under this Agreement;

(f) in communications with existing investors or bona fide prospective investors, consultants and advisors of the Receiving Party in connection with equity financing transactions or bona fide prospective equity financing transactions with the foregoing, in each case on a "need-to-know" basis and under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided*, *however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Third Party who receives Confidential Information pursuant to this Section 7.3(f);

(g) to its Affiliates, (sub)licensees or prospective (sub)licensees, subcontractors or prospective subcontractors, consultants, agents and advisors on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided*, *however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person who receives Confidential Information pursuant to this Section 7.3(g); or

(h) by either Party to one or more Third Parties regarding an actual or potential Change of Control of such Party, each of whom prior to disclosure must be bound under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided*, *however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person who receives Confidential Information pursuant to this Section 7.3(h).

If and whenever any Confidential Information is disclosed in accordance with this Section 7.3, such disclosure shall not cause any such information to cease to be Confidential Information for purposes of this Agreement, except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing: (x) in the event a Party intends to make a disclosure of the other Party's Confidential Information pursuant to Section 7.3(c) or Section 7.3(d), it will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure.

7.4. **Terms of this Agreement**. The Parties acknowledge and agree that this Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of each Party. In addition to the disclosures permitted under Section 7.3, either Party may disclose the terms of this Agreement and other information relating to this Agreement or the transactions contemplated by this Agreement to the extent required, in the reasonable opinion of such Party's counsel, to comply with the rules and regulations promulgated by the United States Securities and Exchange Commission or the Nasdaq Stock Market or similar security regulatory authorities or stock market in other countries. If a Party intends to disclose this Agreement or any of its terms or other such information in accordance with this Section 7.4, such Party will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure and seek confidential treatment of portions of this Agreement or such terms or information, as may be reasonably requested by the other Party.

7.5. **Public Announcements.** Except as required to comply with Applicable Law, TRACON agrees not to issue any press release or other public statement disclosing the execution of this Agreement or any other information relating to this Agreement or the transactions contemplated by this Agreement without the prior written consent of Janssen, such consent not to be unreasonably withheld, conditioned or delayed. In the event that TRACON intends to issue such a press release or other public statement as required to comply with Applicable Law, TRACON will, except where impracticable or not legally permitted, give reasonable advance notice to Janssen of such disclosure.

7.6. **Prior Non-Disclosure Agreement.** As of the Effective Date, the terms of this Article 7 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement, including the Nondisclosure Agreement and, to the extent of the AR Mutant Program only, Article 8 of the License and Option Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

7.7. **Equitable Relief.** Given the nature of the Confidential Information and the competitive damage that may result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 7. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 7.

Article 8
REPRESENTATIONS AND WARRANTIES

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

8.1.1. it is duly organized and validly existing under the laws of its state or country of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions of this Agreement;

8.1.2. this Agreement has been duly executed by it and constitutes a legal, valid and binding obligation of it, enforceable in accordance with its terms;

8.1.3. the execution, delivery and performance of this Agreement by it does not conflict with any material agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and

8.1.4. it has not granted, and shall not grant during the Term, any right to any Third Party that would conflict with the rights granted to the other Party under this Agreement (including by granting a license after the Effective Date to a Third Party under any intellectual property that is Controlled by the granting Party on the Effective Date that would conflict with the rights to such intellectual property granted to the other Party under this Agreement).

8.2. **Additional Representations and Warranties of TRACON.** TRACON represents and warrants to Janssen that, as of the Effective Date:

8.2.1. Schedule Existing Licensed Patents of the TRACON Schedule Letter lists all Patent Rights existing as of the Effective Date that are owned or licensed by TRACON or any of its Affiliates (excluding any owned or licensed by an Affiliate that would be excluded by the definition of Control and excluding any Joint Development Program Patents) and include any claim Covering any AR Mutant Compound or AR Mutant Product, or its formulation, Manufacture or use (the "**Existing Licensed Patents**");

8.2.2. Schedule Existing Licensed Patents of the TRACON Schedule Letter identifies any TRACON License Agreement pursuant to which any Existing Licensed Patents are licensed to TRACON or any of its Affiliates;

8.2.3. TRACON or its Affiliate is the sole and exclusive owner or exclusive licensee of the Existing Licensed Patents (as specified in Schedule Existing Licensed Patents of the TRACON Schedule Letter) and is listed (or is in the process of becoming listed) in the records of the appropriate Governmental Authorities as the sole and exclusive owner of record, if applicable, for each registration, grant and application included in such Patent Rights, except as otherwise noted therein; and TRACON is entitled to grant the licenses under such Patent Rights specified herein;

8.2.4. to the Knowledge of TRACON, TRACON has the right to use and disclose and to enable Janssen to use and disclose (in each case under appropriate conditions of confidentiality) the TRACON Program Know-How existing on the Effective Date (the "**Existing TRACON Know-How**") to the extent that Janssen is granted the right to use and disclose such Existing TRACON Know-How pursuant to this Agreement;

8.2.5. to the Knowledge of TRACON, neither TRACON nor any of its Affiliates owns or licenses, with the right to sublicense, any Know-How or Patent Rights used by TRACON and its Affiliates in the conduct of the AR Mutant Program during the Development Term, other than the Existing TRACON Know-How, Existing Licensed Patents and Joint Development Program Patents;

8.2.6. neither TRACON nor any of its Affiliates is subject to any royalty or other payment obligation to any Third Party with respect to the practice, or the grant of rights to Janssen to practice, any of the Existing TRACON Know-How and Existing Licensed Patents with respect to the Licensed Compounds or Licensed Products under this Agreement, other than those set forth in the TRACON License Agreements as specifically described on Schedule TRACON License Agreements of the TRACON Schedule Letter;

8.2.7. neither TRACON nor any of its Affiliates has received written notice of any claim or threatened claim by any Third Party, and to the Knowledge of TRACON, TRACON is not otherwise aware, that (i) any Third Party has any rights to any of the Existing TRACON Know-How or Existing Licensed Patents, (ii) any of the Existing Licensed Patents (to the extent representing issued Patent Rights) are invalid or unenforceable, or

(iii) any research, Development or Manufacture of any AR Mutant Compound or AR Mutant Product by or on behalf of TRACON or its Affiliate during the Development Term infringed or misappropriated the intellectual property rights of such Third Party;

8.2.8. there are no pending actions, claims, investigations, suits or proceedings against TRACON or any of its Affiliates, at law or in equity, or before or by any Regulatory Authority, and neither TRACON nor any of its Affiliates has received any written notice regarding any pending or threatened actions, claims, investigations, suits or proceedings against TRACON or any of its Affiliates, at law or in equity, or before or by any Regulatory Authority, in either case with respect to the Existing TRACON Know-How or Existing Licensed Patents, and no Existing Licensed Patent is the subject of any interference, opposition, cancellation or other protest proceeding;

8.2.9. to the Knowledge of TRACON, there is no actual infringement of any Existing Licensed Patents by any Third Party;

8.2.10. neither TRACON nor any of its Affiliates, nor its or their employees, officers, directors, or agents, has been debarred by the FDA, is the subject of a conviction described in 21 U.S.C. 335a, or is subject to any similar sanction;

8.2.11. TRACON and its Affiliates have conducted Development activities with respect to the AR Mutant Program in material compliance with Applicable Law and regulatory standards, including as applicable those relating to GLP, GCP, pharmacovigilance and safety reporting, and requirements for the protection of human subjects;

8.2.12. TRACON owns good and valid title to and has the right to transfer (or cause to be transferred), the AR Mutant Transferred Assets as provided for herein, free and clear of all liens and other encumbrances, except for Permitted Liens (except to the extent of any issues relating to title or right to transfer in connection with Janssen's assignment of Transferred Assets pursuant to the License and Option Agreement);

8.2.13. TRACON has made available to Janssen true and complete copies of each AR Mutant Transferred Contract;

8.2.14. each AR Mutant Transferred Contract is in effect and is valid and binding on TRACON or its Affiliate, enforceable in accordance with its terms, and neither TRACON nor any of its Affiliates, nor to the Knowledge of TRACON any Third Party thereto, is in material breach of, or material default under, any AR Mutant Transferred Contract, and no event has occurred that, with the giving of notice or lapse of time or both, would constitute a material breach or material default by TRACON or any of its Affiliates thereunder or result in the payment of any damages or penalties or result in the creation of any lien or encumbrance with respect thereto; and

8.2.15. neither TRACON nor any of its Affiliates has received any written notice from a Third Party at any time during the Development Term regarding any actual, alleged or potential material breach or default under any of the AR Mutant Transferred Contracts or

stating that such Third Party intends to terminate, cancel or make any material change to any AR Mutant Transferred Contract.

As used in this Section 8.2: (a) "**Knowledge**" means the actual knowledge of the TRACON Personnel after reasonable inquiry of individuals responsible for operational activities with respect to the applicable Program; (b) "**TRACON Personnel**" means the individuals whose names are set forth on Schedule TRACON Personnel of the TRACON Schedule Letter; and (c) "**Permitted Liens**" means (i) liens for taxes not yet due, payable, delinquent or subject to penalties for nonpayment, or which are being contested in good faith in the ordinary course of business by appropriate proceedings or (ii) mechanics', materialmens', carriers', workmens', warehousemens', repairmens', landlords' or other like liens and security obligations that are incurred in the ordinary course of business and are not delinquent.

8.3. **Disclaimer of Warranties; Limitations.**

8.3.1. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY NOR ANY OF ITS AFFILIATES MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE PROGRAMS, LICENSED COMPOUNDS, LICENSED PRODUCTS, TRANSFERRED ASSETS OR LICENSED TECHNOLOGY THAT IS LICENSED OR TRANSFERRED TO THE OTHER PARTY OR SUBJECT TO ANY OPTION OR RIGHT TO LICENSE UNDER THIS AGREEMENT, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT ANY OF THE DEVELOPMENT, MANUFACTURING OR COMMERCIALIZATION EFFORTS WITH REGARD TO ANY LICENSED COMPOUND OR LICENSED PRODUCT WILL BE SUCCESSFUL.

8.3.2. Subject to Section 4.4, each Party acknowledges that (a) the other Party and its Affiliates may have present or future initiatives or opportunities, including initiatives or opportunities with Third Parties, involving similar products, programs, technologies or processes that may compete with products, programs, technologies or processes covered by this Agreement; (b) nothing in this Agreement will be construed as a representation, warranty, covenant or inference that the other Party or its Affiliates will not itself develop, manufacture or market or enter into business relationships with one or more Third Parties to develop, manufacture or market products, programs, technologies or processes that are similar to or that may compete with any product, program, technology or process covered by this Agreement (including those in the Field); and (c) the other Party or any of its Affiliates may, in their sole discretion, decide to acquire, research, develop and/or market devices, drugs or other products which may compete with any Licensed Product or continue such activity in which they currently are engaged; *provided* that, in each case of clauses (a), (b) and (c), in no event shall a Party or its Affiliates use Confidential Information of the other Party in breach of this Agreement, and in no event may TRACON or its Affiliates practice or use, or grant any Third Party the right to practice or use, any Licensed Technology in conflict with the licenses granted hereunder.

8.4. **Additional Representations, Warranties and Covenants**.

8.4.1. **Healthcare Compliance**.

(a) **Anti-Kickback and Stark Compliance**. Janssen represents and warrants to TRACON as of the Effective Date, and covenants to TRACON, that Janssen and its Affiliates that are or have been involved in a Program is in compliance and will continue to comply with all applicable state and federal laws, rules and regulations, including the federal anti-kickback statute (42 U.S.C. § 1320a-7b), the related safe harbor regulations, and the Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. § 1395nn) in connection with its activities under this Agreement. No part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business.

(b) **Exclusion from Federal Health Care Programs**. Janssen shall conduct activities pursuant to this Agreement in accordance with applicable state and federal laws and any applicable regulations regarding Medicare, Medicaid, and other third party-payer programs, if any. Janssen represents and warrants to TRACON, as of the Effective Date, that (1) it is not excluded from, and has not been convicted of any crime or engaged in any conduct that could result in exclusion from, participation in any state or federal healthcare program, as defined in 42 U.S.C. §1320a-7b(f), for the provision of items or services for which payment may be made by a federal healthcare program; (2) it has not contracted with any employee, contractor, agent, or vendor to perform work under this Agreement who is excluded from participation in any state or federal healthcare program; and (3) it is not subject to a final adverse action, as defined in 42 U.S.C. § 1320a-7a(e) and 42 U.S.C. § 1320a-7a(g), and has no adverse action pending or threatened against it. Janssen shall notify TRACON of any final adverse action, discovery of contract with an excluded entity or individual, or exclusion within thirty (30) days of such action.

8.4.2. **No Debarred Individuals**. Janssen agrees that it shall not engage, in any capacity in connection with this Agreement, any person who has been debarred by FDA, is the subject of a conviction described in 21 U.S.C. 335a, or is subject to any similar sanction. Janssen shall promptly inform TRACON in writing if Janssen or any person performing activities under this Agreement on Janssen's behalf is debarred or is the subject of a conviction described in 21 U.S.C. 335a, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or threatened relating to the debarment of conviction of Janssen or any such person performing activities in connection with this Agreement on Janssen's behalf. Upon written request from TRACON, Janssen shall, within ten (10) days, provide written confirmation that it has complied with the foregoing obligation.

8.4.3. **Anti-Corruption Laws**. Neither Janssen nor any of its Affiliates shall perform any actions in connection with this Agreement that are prohibited by local and other anti-

corruption laws (collectively "**Anti-Corruption Laws**") that may be applicable to Janssen. Without limiting the foregoing, Janssen nor any of its Affiliates shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other Third Party related to the transactions contemplated by this Agreement in a manner that would violate Anti-Corruption Laws.

8.4.4. **Amendment to TRACON License Agreements**. TRACON may not amend any TRACON License Agreement in any manner that would adversely affect any rights granted to Janssen hereunder, including to increase any amount payable by TRACON for which Janssen would be responsible pursuant to Section 5.3.2(a), except with Janssen's prior written consent.

Article 9
INDEMNIFICATION AND INSURANCE

9.1. **Indemnification.**

9.1.1. **Indemnification by Janssen.** Subject to Section 9.2, Janssen shall defend, indemnify and hold harmless TRACON and any of its Affiliates, and each of its and their directors, officers, employees and agents (each, a "**TRACON Indemnified Party**") from and against any and all damages, losses, liabilities, judgments, fines, amounts paid in settlement, costs and expenses (including the reasonable costs and expenses of attorneys and other professionals) (collectively, "**Losses**") incurred by any TRACON Indemnified Party resulting from any claim, action or proceeding brought or initiated by a Third Party ("**Third Party Claim**") against a TRACON Indemnified Party, to the extent that such Losses arise out of or relate to, directly or indirectly:

(a) the Assumed Liabilities;

(b) the breach by Janssen of any of its representations, warranties or covenants set forth herein;

(c) the negligence, recklessness or wrongful intentional acts or omissions of any Janssen Indemnified Party; or

(d) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Janssen or any of its Affiliates on or after the Effective Date;

except, in each case ((a) through (d)), to the extent such Losses arise directly or indirectly from (i) the breach by TRACON of any of its representations, warranties, or covenants set forth herein, (ii) the negligence, recklessness or wrongful intentional acts or omissions of any TRACON Indemnified Party, or (iii) the Development or Manufacture of any AR Mutant Compound or AR Mutant Product by or on behalf of TRACON or any of its Affiliates during the Development Term and the Transition Period.

9.1.2. **Indemnification by TRACON.** Subject to Section 9.2, TRACON shall defend, indemnify and hold harmless Janssen and any of their Affiliates, and each of its and their directors, officers, employees and agents (each, a "**Janssen Indemnified Party**"), from and against any and all Losses incurred by any Janssen Indemnified Party resulting from any Third Party Claim against a TRACON Indemnified Party, to the extent that such Losses arise out of or relate to, directly or indirectly:

(a) all liabilities arising from or relating to the AR Mutant Transferred Assets arising prior to the Effective Date, or after the Effective Date to the extent of any breach of or non-compliance with any AR Mutant Transferred Contract by TRACON or any of its Affiliates prior to the Effective Date;

(b) the breach by TRACON of any of its representations, warranties or covenants set forth herein; and

(c) the negligence, recklessness or wrongful intentional acts or omissions of any TRACON Indemnified Party; or

(d) the Development or Manufacture of any AR Mutant Compound or AR Mutant Product by or on behalf of TRACON or any of its Affiliates during the Development Term and the Transition Period;

except, in each case ((a) through (d)), to the extent such Losses arise directly or indirectly from (i) the breach by Janssen of any of its representations, warranties, or covenants set forth herein, (ii) the negligence, recklessness or wrongful intentional acts or omissions of any Janssen Indemnified Party, or (iii) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Janssen or any of its Affiliates on or after the Effective Date.

9.2. **Conditions to Indemnification.** If either a TRACON Indemnified Party or a Janssen Indemnified Party (each, an "**Indemnified Party**") intends to seek indemnification under Section 9.1, the Indemnified Party must: (a) give the other Party (the "**Indemnifying Party**") reasonably prompt written notice of any Loss with respect to which such Indemnified Party intends to seek indemnification; (b) reasonably cooperate with the Indemnifying Party at the Indemnifying Party's request and expense, in the defense or settlement of the claim; and (c) give the Indemnifying Party the right to control the defense or settlement of the claim, *provided* that the Indemnifying Party will not enter into any settlement that adversely affects the Indemnified Party's rights or obligations without the Indemnified Party's prior express written consent, which will not be unreasonably withheld, conditioned or delayed. The Indemnified Party may participate in the defense or settlement of any such claim at its own expense with counsel of its choosing. Notwithstanding the foregoing, any failure of the Indemnified Party to comply with the provisions of clause (a) of this Section 9.2 will not relieve the Indemnifying Party of any defense or indemnity obligations under this Agreement except to the extent that the Indemnifying Party is prejudiced by such failure.

9.3. **Limitations of Liability.** EXCEPT TO THE EXTENT INCLUDED IN LOSSES RESULTING FROM A THIRD PARTY CLAIM FOR WHICH ONE PARTY IS OBLIGATED TO INDEMNIFY THE OTHER PARTY (OR AN INDEMNIFIED PARTY OF SUCH OTHER PARTY) PURSUANT TO THIS ARTICLE 9 OR ANY BREACH OF ARTICLE 7 (CONFIDENTIALITY), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES OR (SUB)LICENSEES) IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

9.4. **Insurance.** Janssen shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated, at all times during which any Licensed Product is being tested by or on behalf of Janssen, during the period of commercialization of any Licensed Product and for at least […***…] thereafter. At a minimum, Janssen shall be insured for […***…] to cover its obligations under this Agreement. TRACON shall be named as an additional insured under Janssen's general liability insurance policy. It is understood that such insurance shall not be construed to create a limit of Janssen's liability with respect to its indemnification obligations under this Article 9. Janssen shall provide TRACON with written evidence of such insurance upon request and shall provide TRACON with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance which materially adversely affects the rights of TRACON hereunder.

Article 10
TERM AND TERMINATION

10.1. **Term.** The term of this Agreement (the "**Term**") will commence on the Effective Date and, unless this Agreement is terminated earlier in accordance with this Article 10, this Agreement will expire upon expiration of all of the payment obligations under Article 5 with respect to all Licensed Products in all countries; *provided* that, on a Licensed Product-by-Licensed Product and country-by-country basis, upon expiration of all of the payment obligations under Article 5 with respect to a given Licensed Product in a given country, the licenses granted herein with respect to such Licensed Product in such country shall survive on a fully-paid, royalty-free, non-exclusive, irrevocable and perpetual basis.

10.2. **Termination for Breach.**

10.2.1. A Party (the "**Terminating Party**") may terminate this Agreement in its entirety in the event the other Party (the "**Breaching Party**") has materially breached this Agreement and such material breach has not been cured within sixty (60) days after written notice of such breach is given by the Terminating Party to the Breaching Party

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(the "**Cure Period**"). The written notice describing the alleged material breach shall provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement in its entirety pursuant to this Section 10.2.1 shall become effective at the end of the Cure Period unless the Breaching Party has cured any such material breach prior to the expiration of such Cure Period (or, if such breach (other than a breach of payment obligations) is not reasonably able to be cured within the Cure Period, such termination shall not become effective until the earlier of the date such breach is cured or one hundred and twenty (120) days after notice of termination is given pursuant to this Section 10.2.1, *provided* that (i) the Breaching Party notifies the other Party of its plan for curing such breach during the Cure Period, (ii) the Breaching Party commences such plan during the Cure Period and (iii) the Breaching Party uses diligent efforts to perform such plan and cure such breach as soon as reasonably practicable). The right of either Party to terminate this Agreement in its entirety as provided in this Section 10.2.1 shall not be affected in any way by such Party's waiver of or failure to take action with respect to any previous breach under this Agreement.

10.2.2. If the Parties reasonably and in good faith disagree as to whether there has been a material breach or a cure thereof, the Party that disputes whether there has been a material breach or a cure may contest the allegation in accordance with Article 11. Notwithstanding anything to the contrary contained in Section 10.2.1, the Cure Period for any material breach that is the subject of a Dispute will run from the date that written notice was first given to the Breaching Party by the Terminating Party through the resolution of such Dispute pursuant to Article 11 and for 10 days thereafter, and no termination pursuant to Section 10.2.1 shall become effective during such period. During the pendency of such Dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder; *provided* that the Parties' performance of their respective obligations and exercise of their respective rights hereunder that specify a date by which such obligations must be performed or such rights must be exercised shall be tolled through the resolution of such Dispute pursuant to Article 11 and for 10 days thereafter.

10.3. **Termination for Bankruptcy.**

10.3.1. A Party may terminate this Agreement in its entirety upon providing written notice to the other Party on or after the time that such other Party makes a general assignment for the benefit of creditors, files a voluntary petition in bankruptcy, consents to an order for relief in connection with an involuntary petition in bankruptcy filed against such Party (or an involuntary petition in bankruptcy filed against such Party remains un-dismissed or un-stayed for a period of more than sixty (60) days), petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above (each, an "**Insolvency Event**").

10.3.2. All rights and licenses now or hereafter granted under or pursuant to any Section of this Agreement are rights to "intellectual property" (as defined in Section 101(35A) of Title 11 of the United States Code, as amended (such Title 11, the "**Bankruptcy Code**")). In the event this Agreement is rejected under Section 365 of the Bankruptcy Code by or on behalf of a Party (including by any receiver, trustee or similar officer appointed with respect to such Party), such Party (the "**Licensor Party**") hereby grants to the other Party (the "**Licensee Party**"), subject to the Licensee Party's obligations under Sections 365(n)(2)(A) and (B), a right of access and to obtain possession of and to benefit from embodiments of intellectual property pursuant to Section 365(n) of the Bankruptcy Code (including Know-How Controlled by the Licensor Party with respect to Licensed Compounds or Licensed Products)**,** all of which constitute embodiments of intellectual property pursuant to Section 365(n) of the Bankruptcy Code) to the extent related to the Licensee Party's exercise of its license rights to any Licensed Compound or Licensed Product or otherwise related to any rights or licenses granted to the Licensee Party under or pursuant to any Section of this Agreement. The Licensor Party agrees not to interfere with the Licensee Party's exercise under the Bankruptcy Code of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement.

10.4. **Termination Without Cause**. Janssen shall have the right to terminate this Agreement in its entirety without cause at any time during the Term by providing TRACON sixty (60) days' prior written notice of such termination; *provided*, *however*, that Janssen's obligations under Article 5 shall survive with respect to […***…].

10.5. **Effects of Termination or Expiration.** If this Agreement is terminated or expires, all rights and obligations under this Agreement, other than those that expressly survive termination or expiration of this Agreement, shall terminate on the effective date of termination or expiration. Termination or expiration of this Agreement will not relieve the Parties of any obligations accruing prior to such termination or expiration, and any such termination or expiration will be without prejudice to the rights of either Party against the other. The Receiving Party shall, within […***…] after the effective date of termination or expiration of this Agreement, and at the Receiving Party's expense, return or destroy, at the Disclosing Party's election, all Confidential Information of the Disclosing Party (*provided* that (i) the Receiving Party may keep one copy of such Confidential Information subject to an ongoing obligation of confidentiality for archival purposes only, (ii) it is acknowledged that, with regard to any such Confidential Information disclosed to subcontractors, consultants, agents, advisors and other Third Parties as permitted by Section 7.3, the Receiving Party's use of Commercially Reasonable Efforts to return or destroy such Confidential Information shall satisfy its obligation under this Section and (iii) the Receiving Party may retain and continue to use Confidential Information of the Disclosing Party to practice any licenses and other rights granted to the Receiving Party under this Agreement that expressly survive expiration of this Agreement). The Parties acknowledge and agree that termination of this Agreement is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies will remain available except as expressly agreed to otherwise herein. The provisions of Article 1, Article 7, Article 11 and Article 12 and Sections 5.5 (for the period specified therein), 8.3, 9.1, 9.2, 9.3, 9.4 (for the period

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specified therein), 10.1 (the proviso regarding survival of license) and 10.5 shall survive expiration or termination of this Agreement for any reason.

Article 11
DISPUTE RESOLUTION

11.1. **Escalation; Decision-Making Authority.** In the case of any dispute, claim or controversy between the Parties arising from or related to this Agreement, or the interpretation, application, breach, termination or validity of this Agreement (a "**Dispute**"), the Parties will discuss and negotiate in good faith a solution acceptable to the Parties and in the spirit of this Agreement. If, after negotiating in good faith pursuant to the foregoing sentence, the Parties fail to reach agreement within […***…] (or such longer period as agreed in writing by the Parties), then the Dispute may be referred to the Executive Officers for resolution at the request of either Party. If, after negotiating in good faith, the Executive Officers fail to reach agreement within […***…] of submission to the Executive Officers (or such longer period as agreed in writing by the Parties), then either Party may upon written notice to the other submit the Dispute to non-binding mediation pursuant to Section 11.2.

11.2. **Mediation.**

11.2.1. If the Parties fail to resolve the Dispute pursuant to Section 11.1, the Parties shall attempt in good faith to resolve any Dispute by confidential mediation in accordance with the then current *Mediation Procedure of the International Institute for Conflict Prevention and Resolution* ("**CPR Mediation Procedure**") (www.cpradr.org) before initiating arbitration. The CPR Mediation Procedure shall control, except where it conflicts with these provisions, in which case these provisions control. The mediator shall be chosen pursuant to CPR Mediation Procedure. The mediation shall be held in New York, New York.

11.2.2. Either Party may initiate mediation by written notice to the other Party of the existence of a Dispute. The Parties agree to select a mediator within […***…] of the notice and the mediation will begin promptly after the selection. The mediation will continue until the mediator, or either Party, declares in writing, no sooner than after the conclusion of one full day of a substantive mediation conference attended on behalf of each Party by a senior business person with authority to resolve the Dispute, that the Dispute cannot be resolved by mediation. In no event, however, shall mediation continue more than […***…] from the initial notice by a Party to initiate meditation unless the Parties agree in writing to extend that period.

11.2.3. Any period of limitations that would otherwise expire between the initiation of mediation and its conclusion shall be extended until […***…] after the conclusion of the mediation.

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11.3. **Arbitration.**

11.3.1. If the Parties fail to resolve the Dispute pursuant to Section 11.1 or Section 11.2, and a Party desires to pursue resolution of the Dispute, subject to Section 11.3.10, the Dispute shall be submitted by either Party for resolution in arbitration pursuant to the then current *CPR Non- Administered Arbitration Rules* ("**CPR Rules**") (www.cpradr.org), except where they conflict with these provisions, in which case these provisions control. The arbitration will be held in New York, New York. All aspects of the arbitration shall be treated as confidential.

11.3.2. The arbitrators will be chosen from the CPR Panel of Distinguished Neutrals, unless a candidate not on such panel is approved by both Parties. Each arbitrator shall be a lawyer with at least fifteen (15) years' experience with a law firm or corporate law department of over twenty-five (25) lawyers or who was a judge of a court of general jurisdiction. To the extent that the Dispute requires special expertise, the Parties will so inform CPR prior to the beginning of the selection process.

11.3.3. The arbitration tribunal shall consist of three (3) arbitrators, of whom each Party shall designate one in accordance with the "screened" appointment procedure provided in CPR Rule 5.4. The chair will be chosen in accordance with CPR Rule 6.4. If, however, the aggregate award sought by the Parties is less than Five Million U.S. Dollars ($5,000,000) and equitable relief is not sought, a single arbitrator shall be chosen in accordance with the CPR Rules. Candidates for the arbitrator position(s) may be interviewed by representatives of the Parties in advance of their selection, *provided* that all Parties are represented.

11.3.4. The Parties agree to select the arbitrator(s) within forty-five (45) days of initiation of the arbitration. The hearing will be concluded within nine (9) months after selection of the arbitrator(s) and the award will be rendered within sixty (60) days of the conclusion of the hearing, or of any post-hearing briefing, which briefing will be completed by both sides within forty-five (45) days after the conclusion of the hearing. In the event the Parties cannot agree upon a schedule, then the arbitrator(s) shall set the schedule following the time limits set forth above as closely as practical.

11.3.5. The hearing will be concluded in ten (10) hearing days or less. Multiple hearing days will be scheduled consecutively to the greatest extent possible. A transcript of the testimony adduced at the hearing shall be made and shall be made available to each Party.

11.3.6. The arbitrator(s) shall be guided, but not bound, by the *CPR Protocol on Disclosure of Documents and Presentation of Witnesses in Commercial Arbitration* (www.cpradr.org) ("**Protocol**"). The Parties will attempt to agree on modes of document disclosure, electronic discovery, witness presentation, etc. within the parameters of the Protocol. If the Parties cannot agree on discovery and presentation issues, the arbitrator(s) shall decide on presentation modes and provide for discovery within the Protocol, understanding that the Parties contemplate reasonable discovery.

11.3.7. The arbitrator(s) shall decide the merits of any Dispute in accordance with the law governing this Agreement, without application of any principle of conflict of laws that would result in reference to a different law. The arbitrator(s) may not apply principles such as "*amiable compositeur*" or "*natural justice and equity*."

11.3.8. The arbitrator(s) are expressly empowered to decide dispositive motions in advance of any hearing and shall endeavor to decide such motions as would a United States District Court Judge sitting in the jurisdiction whose substantive law governs.

11.3.9. The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. The Parties consent to the jurisdiction of the United States District Court for the district in which the arbitration is held for the enforcement of these provisions and the entry of judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction may act in the same fashion.

11.3.10. Notwithstanding any provision to the contrary contained in this Agreement, each Party has the right to seek from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin or other equitable relief to avoid irreparable harm, maintain the status quo, preserve its status and priority as a creditor or preserve the subject matter of the Dispute. Rule 14 of the CPR Rules does not apply to this Agreement.

Article 12
MISCELLANEOUS

12.1. **Performance by Affiliates.** To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations. A Party may use one or more of its Affiliates to perform its obligations and duties or exercise its rights hereunder, *provided* that such Party will remain liable hereunder for the prompt payment and performance of all of their respective obligations hereunder. Any breach by an Affiliate of a Party of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

12.2. **Retained Rights**. All licenses and rights are granted only as expressly provided in this Agreement, and no license or other right is or shall be created or granted under this Agreement by implication, estoppel, or otherwise. All rights not expressly granted by a Party under this Agreement are reserved by such Party and may not be used by the other Party for any purpose.

12.3. **Entire Agreement.** This Agreement and each of the Schedules and Exhibits hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter of this Agreement and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter.

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

12.5. **Binding Effect.** This Agreement and the rights granted herein will be binding upon, and will inure to the benefit of TRACON, Janssen and their respective lawful successors and permitted assigns.

12.6. **Assignment.** Neither Party may assign or transfer this Agreement in its entirety or any rights or obligations hereunder without the prior written consent of the other Party, except that:

(a) either Party may assign or transfer this Agreement in its entirety or any rights or obligations hereunder to an Affiliate without the other Party's consent;

(b) either Party may assign or transfer this Agreement in its entirety pursuant to any Change of Control of such Party without the other Party's consent, or to a Third Party acquirer of that portion of its business relating to the subject matter of this Agreement in a sale of assets or other similar transaction without the other Party's consent.

The assigning Party shall provide the other Party with prompt written notice of any such assignment; provided, however, that Janssen shall be obligated only to use diligent efforts to provide TRACON with written notice of any assignment to an Affiliate pursuant to Section 12.6(a) within a reasonable period of time after the occurrence of such assignment. Any permitted assignment shall be binding on the successors and permitted assignees of the assigning Party, and the successor (if the successor is an entity other than a Party) or assignee shall confirm the same in writing to the other Party. Any assignment, transfer or attempted assignment or transfer by either Party in violation of the terms of this Section 12.6 shall be null, void and of no legal effect.

12.7. **Use of Names.** Neither Party shall use the name, physical likeness, employee names or Trademarks of the other Party for any purpose without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed; *provided*, *however*, that nothing contained herein shall be construed to prevent either Party from using the name of the other Party for purposes of preparing necessary filings with the United States Securities and Exchange Commission or complying with its regulations, or other regulations applicable to the public sale of securities, including preparing proxy statements or prospectuses. Nothing contained herein shall be construed as granting either Party any rights or license to use any of the other Party's Trademarks without separate, express written permission of the owner of such Trademark.

12.8. **Amendment; No Waiver.** No waiver, modification or amendment of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition.

12.9. **Force Majeure Event.** Except for obligations to make payments under this Agreement when due, the failure of a Party to perform any obligation under this Agreement by reason of force majeure, limited to acts of God, war, terrorism (actual or threatened), strikes, revolutions, laws or other causes of a similar magnitude beyond the reasonable control of such Party (each, a

"**Force Majeure Event**"), will not be deemed to be a breach of this Agreement. The Party affected by any Force Majeure Event will contact the other Party for discussion of possible emergency measures.

12.10. **Independent Contractors.** The Parties are independent contractors and not agents or employees of the other Parties under this Agreement. Nothing contained in this Agreement is intended nor is to be construed so as to constitute TRACON and Janssen as partners or joint venturers with respect to this Agreement. No Party will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Parties or to bind the other Parties to any other contract, agreement or undertaking with any Third Party except as may be explicitly provided for herein or authorized in writing.

12.11. **Notices and Deliveries.** Any notices, request, delivery, approval or consent required or permitted to be given under this Agreement will be in writing and will be deemed to have been sufficiently given when it is received, whether delivered in person, transmitted by facsimile with contemporaneous confirmation, delivered by registered letter (or its equivalent) or delivered by certified overnight courier service, to the Party to which it is directed at its address shown below or such other address as such Party will have last given by notice to the other Party.

If to TRACON:

TRACON Pharmaceuticals, Inc.
8910 University Center Lane
Suite 700
San Diego, CA 92122 USA
Attention: Chief Business Officer
Facsimile No.: +1 858-550-0786

with a copy to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121 USA
Attention: L. Kay Chandler
Facsimile No.: +1 858-550-6420

If to Janssen:

Janssen Pharmaceutica NV
Legal Affairs Department
Turnhoutseweg 30
B-2340 Beerse
Belgium
Facsimile: As may be provided to TRACON by Janssen

with a copy to:

Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Facsimile: 732-524-2788

12.12. **Headings.** The captions to the sections and articles in this Agreement are not a part of this Agreement, and are included merely for convenience of reference only and will not affect its meaning or interpretation.

12.13. **Severability.** In the event that any provision of this Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and this Agreement will be construed as if such invalid or unenforceable provision had not been included herein.

12.14. **Governing Law.** This Agreement will be governed by and interpreted in accordance with the laws of the State of New York without reference to its choice of laws or conflicts of laws provisions. The United Nations Conventions on Contracts for the International Sale of Goods shall not be applicable to this Agreement. Each Party (a) submits to the exclusive jurisdiction of the state and federal courts sitting in New York, New York, with respect to actions or proceedings arising out of or relating to this Agreement in which a Party brings an action in aid of arbitration, (b) agrees that all claims in respect of such action or proceeding may be heard and determined only in any such court, and (c) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court, other than an action or proceeding seeking injunctive relief or brought to enforce an arbitration ruling issued pursuant to Section 11.3. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of the other Party with respect thereto. Each Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 12.11. Nothing in this Section 12.14, however, will affect the right of any Party to serve legal process in any other manner permitted by New York law.

12.15. **Advice of Counsel.** Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will exist or be implied against the Party which drafted such terms and provisions.

12.16. **Counterparts.** This Agreement may be executed in any number of counterparts (including by facsimile or electronic transmission), each of which need not contain the signature of more than one Party, but all such counterparts taken together will constitute one and the same agreement. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

12.17. **Construction.** Whenever this Agreement refers to a number of days without using a term otherwise defined herein, such number refers to calendar days. Except where the context

otherwise requires, (a) wherever used, the singular shall include the plural, the plural shall include the singular; (b) the use of any gender shall be applicable to all genders; (c) the terms "including," "include," "includes" or "for example" shall not limit the generality of any description preceding such term and, as used herein, shall have the same meaning as "including, but not limited to," and/or "including, without limitation"; (d) the words "herein", "hereof" and hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (d) the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (e) the word "will" means "shall"; (f) if a period of time is specified and dates from a given day or business day, or the day or business day of an act or event, it is to be calculated exclusive of that day or business day; (g) references to a particular entity include such entity's successors and assigns to the extent not prohibited by this Agreement; (h) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner; and (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein).

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date, each copy of which will for all purposes be deemed to be an original.

JANSSEN PHARMACEUTICA N.V.

By: _____

Name: _____

Title: _____

JANSSEN PHARMACEUTICA N.V.

By: _____

Name: _____

Title: _____

TRACON PHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

EXHIBIT B

[…*…]**

***Confidential Treatment Requested

EXHIBIT C

[…***…]

***Confidential Treatment Requested

Exhibit 10.2

STOCK PURCHASE AGREEMENT

By and Between

JOHNSON & JOHNSON INNOVATION-JJDC, INC.

AND

TRACON PHARMACEUTICALS, INC.

Dated as of September 27, 2016

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STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "**Agreement**"), dated as of September 27, 2016, by and between Johnson & Johnson Innovation-JJDC, Inc. (the "**Investor**"), a New Jersey corporation with its principal place of business at 410 George Street, New Brunswick, New Jersey 08901, and TRACON Pharmaceuticals, Inc. (the "**Company**"), a Delaware corporation, with its principal place of business at 8910 University Center Lane, Suite 700, San Diego, CA 92122.

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value $0.001 per share, of the Company (the "**Common Stock**").

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor and the Company agree as follows:

1. Definitions.

1.1. Defined Terms. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"**Affiliate**" shall mean, with respect to any Person, another Person that controls, is controlled by or is under common control with such Person; provided, that with respect to the Investor, "Affiliate" shall mean only the Investor's subsidiaries that are wholly-owned directly or indirectly, by the Investor and any Person that wholly-owns, directly or indirectly, the Investor. 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 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 Investor 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 Investor or any of its Affiliates.

"**Agreement**" shall have the meaning set forth in the Preamble, including all Exhibits attached hereto.

"**Business Day**" shall mean a weekday on which banking institutions in the United States are generally open for business.

"**Company's Knowledge**" shall mean, with respect to the Company and its Subsidiaries, the knowledge of the Company's executive officers.

"**Effect**" shall have the meaning set forth in the definition of "Material Adverse Effect."

"**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.

"**Intellectual Property**" shall mean trademarks, trade names, trade dress, service marks, copyrights, and similar rights (including registrations and applications to register or renew the registration of any of the foregoing), patents and patent applications, trade secrets, and any other similar intellectual property rights.

"**Intellectual Property License**" shall mean any license, permit, authorization, approval, contract or consent granted, issued by or with any Person relating to the use of Intellectual Property.

"**Investor Agreement**" shall mean that certain Investor Agreement between the Investor and the Company, to be dated as of the Closing Date, in substantially the form of Exhibit A attached hereto, as the same may be amended from time to time.

"**Law**" or "**Laws**" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

"**Material Adverse Effect**" shall mean any change, event or occurrence (each, an "**Effect**") that, individually or when taken together with all other Effects, has had, or would reasonably be expected to have, (i) a material adverse effect on the business, financial condition, assets or results of operations of the Company and its Subsidiaries, taken as a whole, or (ii) a material adverse effect on the Company's ability to perform its obligations, or consummate the Transaction, in accordance with the terms of this Agreement, except in the case of (i) to the extent that any such Effect results from or arises out of: (A) changes in conditions in the United States or global economy, capital or financial markets or the pharmaceutical industry generally, including changes in interest or exchange rates, (B) changes in general legal, regulatory, political, economic or business conditions or changes in generally accepted accounting principles in the United States or interpretations thereof, (C) acts of war, sabotage or terrorism, or any escalation or worsening of any such acts of war, sabotage or terrorism, (D) earthquakes, hurricanes, floods or other natural disasters, (E) the announcement of this Agreement or the Transaction, or (F) any change in the Company's stock price or trading volume or any failure to meet internal projections or forecasts or published revenue or earnings projections of industry analysts (provided that the underlying events giving rise to any such change shall not be excluded), provided, however, that the Effects excluded in clauses (A), (B), (C) and (D) shall only be excluded to the extent such Effects are not disproportionately adverse on the Company and its Subsidiaries as compared to other companies of similar size and stage of development operating in the Company's industry.

"**Organizational Documents**" shall mean (i) the Amended and Restated Certificate of Incorporation of the Company, as amended through the date of this Agreement and (ii) the Amended and Restated Bylaws of the Company, as amended through the date of this Agreement.

"**Per Share Purchase Price**" shall mean $5.95222 (which represents the simple average of the daily volume weighted average prices of the Common Stock as reported on the Trading Market for the five (5) consecutive Trading Days ending the Trading Day prior to the date of this Agreement), provided, however, that in the event of any stock dividend, stock split, combination of shares, recapitalization or other similar change in the capital structure of the Company after the date hereof and on or prior to the Closing which affects or relates to the Common Stock, the Per Share Purchase Price shall be appropriately adjusted.

"**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.

"**Subsidiary**" shall mean any direct or indirect subsidiary of the Company.

"**Third Party**" shall mean any Person (other than a Governmental Authority) other than the Investor, the Company or any Affiliate of the Investor or the Company.

"**Trading Day**" shall mean any day on which the Trading Market is open for business.

"**Trading Market**" shall mean The NASDAQ Global Market.

"**Transaction**" shall mean the issuance and sale of the Shares by the Company, and the purchase of the Shares by the Investor, in accordance with the terms hereof.

"**Transaction Agreements**" shall mean this Agreement and the Investor Agreement.

1.2. Additional Defined Terms. In addition to the terms defined in Section 1.1, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

Defined Term	Section
Aggregate Purchase Price	Section 2
Closing	Section 3.1
Closing Date	Section 3.1
Common Stock	Preamble
Company	Preamble
Company Rights	Section 4.21(b)

Company SEC Documents	Section 4.11(a)
Environmental Claim	Section 4.26
Environmental Laws	Section 4.26
Exchange Act	Section 4.11(a)
FDA	Section 4.22
GAAP	Section 4.11(c)
Investor	Preamble
LAS	Section 4.7
Permits	Section 4.10
Proprietary Rights	Section 4.21(b)
Rule 144	Section 5.9
SEC	Section 4.7
Securities Act	Section 4.11(a)
Shares	Section 2
Termination Date	Section 9.1(b)
Transfer Agent	Section 10.4(c)

2. Purchase and Sale of Common Stock. Subject to the terms and conditions of this Agreement, at the Closing, the Company shall issue and sell to the Investor, free and clear of all liens, other than any liens arising as a result of any action by the Investor, the Exchange Act or the Securities Act or the Transaction Agreements, and the Investor shall purchase from the Company, a number of shares of Common Stock (the "**Shares**") equal to the amount obtained by dividing US $5,000,000 by the Per Share Purchase Price, rounded down to the nearest whole Share, for a total purchase price equal to the number of Shares multiplied by the Per Share Purchase Price (such amount, the "**Aggregate Purchase Price**").

3. Closing Date; Deliveries.

3.1. Closing Date. Subject to the satisfaction or waiver of all the conditions to the Closing set forth in Sections 6, 7 and 8 hereof, the closing of the purchase and sale of the Shares hereunder (the "**Closing**") shall be held on the Business Day after the satisfaction of the

conditions to Closing set forth in Sections 6, 7 and 8 (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction at such time of such conditions), at 9:00 a.m. New York City time, at the offices of Dechert LLP, 1095 Avenue of the Americas, New York, NY, 10036, or at such other time, date and location as the parties may agree. The date the Closing occurs is hereinafter referred to as the "**Closing Date**."

3.2. Deliveries.

(a) Deliveries by the Company. At the Closing, the Company shall deliver to the Investor the Shares, registered in the name of the Investor, and the Company shall instruct its transfer agent to register such issuance at the time of such issuance. The Company shall also deliver at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Investor and duly executed on behalf of the Company by an authorized executive officer of the Company, certifying that the conditions to Closing set forth in Sections 6 and 8.1 of this Agreement have been fulfilled; (ii) the Investor Agreement, duly executed by the Company; and (iii) a certificate of the secretary of the Company dated as of the Closing Date certifying (A) that attached thereto is a true and complete copy of the by-laws or equivalent organizational documents, in each case as applicable, for the Company as in effect at the time of the actions by the Board of Directors of the Company referred to in clause (B) below, and on the Closing Date; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board of Directors of the Company authorizing the execution, delivery and performance of the Transaction Agreements and the Transaction and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby as of the Closing Date; (C) that attached thereto is a true and complete copy of the certificate of incorporation or equivalent organizational documents, in each case as applicable, for the Company as in effect at the time of the actions by the Board of Directors of the Company referred to in clause (B) above, and on the Closing Date; and (D) as to the incumbency and specimen signature of any officer of the Company executing a Transaction Agreement on behalf of the Company.

(b) Deliveries by the Investor. At the Closing, the Investor shall deliver, or cause to be delivered, to the Company the Aggregate Purchase Price by wire transfer of immediately available United States funds to an account designated by the Company. The Company shall notify the Investor in writing of the wiring instructions for such account not less than five (5) Business Days before the Closing Date. The Investor shall also deliver, or cause to be delivered, at the Closing, the Investor Agreement, duly executed by the Investor.

4. Representations and Warranties of the Company. The Company hereby represents and warrants to the Investor, as of the date hereof and as of the Closing, as follows:

4.1. Organization, Good Standing and Qualification.

(a) The Company is a corporation duly incorporated or otherwise organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. The Company has all requisite corporate power and corporate authority to own, lease and operate its properties and assets, to carry on its

business as now conducted as described in the Company SEC Documents. The Company has all requisite corporate power and corporate authority to enter into the Transaction Agreements, to issue and sell the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements.

(b) The Company and each Subsidiary is qualified to transact business and is in good standing in each jurisdiction in which the character of the properties owned, leased or operated by it, or the nature of the business conducted by it, makes such qualification necessary, except where the failure to be so qualified would not have a Material Adverse Effect.

4.2. Capitalization and Voting Rights.

(a) The authorized capital of the Company as of the date hereof consists of: (i) 200,000,000 shares of Common Stock of which, as of September 22, 2016, (x) 12,216,221 shares were issued and outstanding, (y) 3,164,267 shares were reserved for issuance pursuant to the Company's stock incentive and employee stock purchase plans, of which 1,977,988 shares were issuable upon the exercise or settlement of stock options or restricted stock units outstanding on such date, and (z) 57,173 shares were reserved for issuance upon the exercise of warrants to purchase Common Stock that were outstanding on the date hereof, and (ii) 10,000,000 shares of preferred stock, par value $0.001 per share, of which no shares are issued and outstanding as of the date of this Agreement. All of the issued and outstanding shares of Common Stock (A) have been duly authorized and validly issued, (B) are fully paid and nonassessable and (C) were issued in compliance with all applicable federal and state securities Laws and not in violation of any preemptive rights.

(b) All of the authorized shares of Common Stock are entitled to one (1) vote per share.

(c) Except as described or referred to in Section 4.2(a) above, as disclosed in the Company SEC Documents, or as provided in the Investor Agreement, as of the date hereof, there are not: (i) any outstanding equity securities, options, warrants, rights (including conversion or preemptive rights) or other agreements pursuant to which the Company is or may become obligated to issue, sell or repurchase any shares of its capital stock or any other securities of the Company or (ii) any restrictions on the transfer of capital stock of the Company other than pursuant to state and federal securities Laws.

(d) Except as provided in the Investor Agreement or as disclosed in the Company SEC Documents, the Company is not a party to or subject to any agreement or understanding relating to the voting of shares of capital stock of the Company or the giving of written consents by a stockholder or director of the Company.

(e) Except as provided in the Investor Agreement or disclosed in the Company SEC Documents, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company.

(f) The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the SEC is contemplating terminating such registration.

4.3. Subsidiaries. The Company does not have any Subsidiaries that would, individually or in the aggregate, be a significant subsidiary as defined in Rule 1.02 of Regulation S-X promulgated by the SEC.

4.4. Authorization.

(a) All requisite corporate action on the part of the Company, its directors and stockholders required by applicable Law for the authorization, execution and delivery by the Company of the Transaction Agreements, and the performance of all obligations of the Company hereunder and thereunder, including the authorization, issuance and delivery of the Shares, has been taken.

(b) This Agreement has been, and upon the execution and delivery of the Investor Agreement by the Company at the Closing, the Investor Agreement will be, duly executed and delivered by the Company, and upon the due execution and delivery of this Agreement and the Investor Agreement by the Investor, this Agreement and the Investor Agreement will constitute, valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms (except with respect to this Agreement and the Investor Agreement as such enforceability may be limited by (i) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights, (ii) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy and (iii) to the extent that the enforceability of indemnification obligations may be limited by applicable Laws).

(c) No stop order or suspension of trading of the Common Stock has been imposed by the Trading Market, the SEC or any other Governmental Authority and remains in effect.

4.5. No Defaults. The Company and each Subsidiary is not in default under or in violation, and there exists no condition, event or act to the Company's Knowledge which after notice, lapse of time, or both, would constitute a default or violation by the Company, of (a) its Organizational Documents, (b) any provision of applicable Law or any ruling, writ, injunction, order, Permit, judgment or decree of any Governmental Authority or (c) any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound, except in the case of clauses (b) or (c) as would not have a Material Adverse Effect.

4.6. No Conflicts. The execution, delivery and performance of the Transaction Agreements, and compliance with the provisions hereof and thereof by the Company do not and shall not: (a) violate in any material respect any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a material 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 material agreement, arrangement or instrument, whether written or oral, by which the Company, any of its Subsidiaries, or any of its assets are bound, (c) violate or conflict with any of the provisions of the Company's Organizational Documents or (d) result in any encumbrance upon any of the Shares, other than restrictions pursuant to the Investor Agreement or securities Laws, or on any of the properties or assets of the Company.

4.7. No Governmental Authority or Third Party Consents. No consent, approval, authorization or other order of, or filing with, or notice to, any Governmental Authority or other Third Party is required to be obtained or made by the Company in connection with the authorization, execution and delivery by the Company of any of the Transaction Agreements, or with the authorization, issue and sale by the Company of the Shares, except (a) such filings as may be required to be made with the Securities and Exchange Commission (the "**SEC**") and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws, (b) with respect to the Shares, the filing with the Trading Market of, and the absence of unresolved issues with respect to, a Notification Form: Listing of Additional Shares (the "**LAS**").

4.8. Valid Issuance of Shares. When issued, sold and delivered at the Closing in accordance with the terms hereof for the Aggregate Purchase Price, the Shares shall be duly authorized, validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal or other similar rights, other than pursuant to the Transaction Agreements, solely as a result of any action by the Investor or under federal or state securities Laws.

4.9. Litigation. There is no material action, suit, proceeding or investigation pending (of which the Company or any of its Subsidiaries has received notice or otherwise has knowledge) or, to the Company's Knowledge, threatened, against the Company or any of its Subsidiaries, or which the Company intends to initiate which has had or is reasonably likely to have a Material Adverse Effect.

4.10. Licenses and Other Rights; Compliance with Laws. Except as would not result in a Material Adverse Effect, (a) the Company and each Subsidiary has all franchises, permits, licenses and other rights and privileges ("**Permits**") necessary to permit it to own its properties and to conduct its business as presently conducted and is in compliance thereunder, (b) the Company and each Subsidiary has not taken any action that would interfere with the Company's or its Subsidiaries' ability to renew all such Permit(s) and (c) the Company and each Subsidiary is and has been in compliance with all Laws applicable to its business, properties and assets, and to the products and services sold by it.

4.11. Company SEC Documents; Financial Statements; Trading Market.

(a) Since January 1, 2016, the Company has timely filed 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 (the "**Company SEC Documents**"). As of their respective filing dates, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act of 1933,

as amended (the "**Securities Act**"), and the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), and the rules and regulations of the SEC promulgated thereunder 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.

(b) As of the date of this Agreement, there are no outstanding or unresolved comments in comment letters received from the SEC or its staff.

(c) The financial statements of the Company included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and in its subsequent quarterly reports on Form 10-Q through the date of this Agreement comply 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 ("**GAAP**") applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to the omission of certain notes not ordinarily accompanying such unaudited financial statements and to normal, year-end audit adjustments. Except (i) as set forth in the Company SEC Documents 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, the Company and each Subsidiary has no material liabilities, whether absolute or accrued, contingent or otherwise. There are no material unconsolidated Subsidiaries of the Company or any material off-balance sheet arrangements of any type (including any off balance sheet arrangements required to be disclosed pursuant to Item 303(a)(4) of Regulation S-K promulgated under the Securities Act) that have not been so described in the Company SEC Documents filed prior to the date hereof nor any obligations to enter into any such arrangements.

(d) The Common Stock is listed on the Trading Market, and the Company has taken no action designed to, or which is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Trading Market. The Company has not received any notification that, and to the Company's Knowledge there is no indication that, the SEC or the Trading Market is contemplating terminating such listing or registration.

(e) The Company has implemented and maintains a system of internal control over financial reporting (to the extent required by Rule 13a-15(a) under the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes, and, to the Company's Knowledge, such system of internal control over financial reporting is effective. The Company has implemented and maintains disclosure controls and procedures (to the extent required by Rule 13a-15(a) of the Exchange Act) that are designed to ensure 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 timeframes specified by the SEC's rules and forms (and such disclosure controls and procedures are effective at the reasonable assurance

level), and has disclosed, based on its most recent evaluation of its system of internal control over financial reporting prior to the date of this Agreement, to the Company's outside auditors and the audit committee of the Company Board (i) any significant deficiencies and material weaknesses to the Company's Knowledge in the design or operation of its internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that would reasonably be expected to adversely affect the Company's ability to record, process, summarize and report financial information and (ii) any fraud to the Company's Knowledge, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

(f) To the Company's Knowledge, as of the date hereof, no employee of the Company has provided or is providing information to any law enforcement agency regarding the violation of any applicable Law of the type described in Section 806 of the Sarbanes-Oxley Act by the Company. The Company has not discharged, demoted or suspended an employee of the Company in the terms and conditions of employment because of any lawful act of such employee described in Section 806 of the Sarbanes-Oxley Act.

4.12. Absence of Certain Changes.

(a) Except as disclosed in the Company SEC Documents filed prior to the date hereof, there has not occurred any event that has caused or, to the Company's Knowledge would reasonably be expected to cause, a Material Adverse Effect.

(b) Except as set forth in the Company SEC Documents filed prior to the date hereof, the Company has not (i) declared or paid any dividends, or authorized or made any distribution upon or with respect to any class or series of its capital stock, or (ii) sold, exchanged or otherwise disposed of any of its material assets or rights.

(c) The Company has not admitted in writing its inability to pay its debts generally as they become due, filed or consented to the filing against it of a petition in bankruptcy or a petition to take advantage of any insolvency act, made an assignment for the benefit of creditors, consented to the appointment of a receiver for itself or for the whole or any substantial part of its property, or had a petition in bankruptcy filed against it, been adjudicated a bankrupt, or filed a petition or answer seeking reorganization or arrangement under the federal bankruptcy laws or any other Laws of the United States or any other jurisdiction.

4.13. Offering. Subject to the accuracy of the Investor's representations set forth in Sections 5.5, 5.6, 5.7, 5.9 and 5.10, the offer, sale and issuance of the Shares to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements. Neither the Company nor any Person acting on its behalf will take any action that would cause the loss of such exemption.

4.14. No Integration. The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act) which is or will be integrated with the Shares sold pursuant to this Agreement in a manner that would require the registration of the Shares under the Securities Act.

4.15. No Brokers' or Finders' Fees. No broker, finder, investment banker or other Person is entitled to any brokerage, finder's or other fee or commission from the Company in connection with the transactions contemplated by the Transaction Agreements.

4.16. Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Shares, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

4.17. No General Solicitation. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Shares by any form of general solicitation or general advertising. The Company has offered the Shares for sale only to the Investor.

4.18. Foreign Corrupt Practices. Neither the Company, nor to the Company's Knowledge, any agent or other person acting on behalf of the Company, has: (a) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (b) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (c) except as would not result in a Material Adverse Effect, failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (d) violated in any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable non-U.S. anti-bribery Law.

4.19. Regulation M Compliance. The Company has not, and to the Company's Knowledge no one acting on its behalf has, (a) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares, (b) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Shares, or (c) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company.

4.20. Office of Foreign Assets Control. Neither the Company nor, to the Company's Knowledge, any director, officer, agent, employee or Affiliate of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

4.21. Intellectual Property.

(a) Except as set forth in the Company SEC Documents, the Intellectual Property that is owned by the Company and each Subsidiary is owned free from any liens or restrictions (other than any restrictions set forth in any Intellectual Property License relating to such Intellectual Property), and all of the Company's and its Subsidiaries' material Intellectual Property Licenses are in full force and effect in accordance with their terms, are, to the Company's Knowledge, free of any liens or restrictions (other than any restrictions set forth in

any such Intellectual Property License relating to such Intellectual Property), and neither the Company nor to the Company's Knowledge any other party thereto, is in material breach of any such material Intellectual Property License, and no event has occurred to the Company's Knowledge that with notice or lapse of time or both would constitute such a breach or default thereunder or would result in the termination thereof or would cause or permit the acceleration or other change of any right or obligation of the loss of any benefit thereunder by the Company except as set forth in any such Intellectual Property License. Except as set forth in the Company SEC Documents filed prior to the date hereof, there is no material legal claim or demand of any Person pertaining to, or any proceeding which is pending (of which the Company has received notice or otherwise exists to the Company's Knowledge) or, to the Company's Knowledge, threatened, (i) challenging the right of the Company in respect of any Intellectual Property owned or licensed by the Company, or (ii) that claims that any default exists under any Intellectual Property License, except, in the case of (i) and (ii) above, where any such claim, demand or proceeding would not have or reasonably be expected to have a Material Adverse Effect.

(b) Except as set forth in the Company's SEC Documents: (i) the Company and each Subsidiary owns, free and clear of any material lien or encumbrance, or has a valid license to, or has an enforceable right to use, as it is used or held for use, all material U.S. and non-U.S. patents, trade secrets, know-how, trademarks, service marks, copyrights, and other proprietary and intellectual property rights, and all grants and applications with respect to the foregoing (collectively, the "**Proprietary Rights**") necessary for the conduct of the Company's business (such Proprietary Rights owned by or licensed to the Company and each Subsidiary, collectively, the "**Company Rights**"); and (ii) the Company and each Subsidiary has taken reasonable measures to protect the Company Rights, consistent with prudent commercial practices in the biotechnology industry.

4.22. Tests and Preclinical and Clinical Trials. The studies, tests and preclinical and clinical trials conducted by or, to the Company's Knowledge, on behalf of the Company that are described in the Company SEC Documents were and, if still pending, are being, conducted in all material respects in accordance with any applicable protocols submitted to the U.S. Food and Drug Administration (the "**FDA**") or any Governmental Authority exercising comparable authority, procedures and controls pursuant to, where applicable, accepted professional and scientific standards, and all applicable Laws and regulations; the descriptions of the studies, tests and preclinical and clinical trials conducted by or, to the Company's Knowledge, on behalf of the Company, and the results thereof, contained in the Company SEC Documents are accurate and complete in all material respects; to the Company's Knowledge, there are no subsequent studies, tests or preclinical and clinical trials, the results of which call into question the results described in the Company SEC Documents; and the Company has not received any notices or correspondence from the FDA, any Governmental Authority exercising comparable authority or any Institutional Review Board requiring the termination, suspension, material modification or clinical hold of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company.

4.23. Compliance with Health Care Law. The Company and each Subsidiary is, and, to the Knowledge of Company, at all times for the two years immediately preceding the date of this Agreement has been, in compliance with all applicable federal, state and municipal

statutes, regulations, rules and orders and other requirements of any Governmental Authority to which it is subject with respect to health care Laws and health care regulatory and fraud and abuse matters, including, without limitation, those relating to third-party reimbursement, the federal health care program anti-kickback law, 42 U.S.C. § 1320a-7b, the federal physician self-referral law, 42 U.S.C. § 1395nn, the federal False Claims Act, 31 U.S.C. § 3729 et seq., the Health Insurance Portability and Accountability Act of 1996, Pub. Law. 104-99, and any and all other health care Laws and regulations, each as amended from time to time, applicable to the operations of the Company or its Subsidiaries, except for any such non-compliance which would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect. Neither the Company nor, to the Company's Knowledge, any Subsidiary is a party to or has any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any Governmental Authority. Additionally, none of the Company or its Subsidiaries nor, to the Company's Knowledge, any of its respective employees, officers or directors has been excluded, suspended or debarred from participation in any U.S. federal health care program or, to the Company's Knowledge, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

4.24. Sensitive Payments. None of the Company or any Subsidiary, or, to the Company's Knowledge, any of the Company's or Subsidiaries' respective directors, officers, agents, representatives, shareholders or employees acting on behalf of the Company, has directly or indirectly made or offered to make any contribution, gift, bribe, rebate, payoff, influence payment, kickback or other payment to any Person, regardless of form, whether in money, property or services, including without limitation: (a) to obtain favorable treatment in securing business, (b) to pay for favorable treatment for business secured, (c) to obtain special concessions or for special concessions already obtained, for or in respect of the Company or any Subsidiary or any Affiliate of any of them, or (d) to induce or reward the referral of business or services that are billed to any government or private program.

4.25. Taxes. The Company has timely filed (after giving effect to any duly obtained extensions of time in which to make such filings) all material tax returns that are or were, at any time, required to be filed by it, such tax returns are complete and accurate in all material respects and all taxes required, at any time, to be paid have been timely paid or, if not yet due, are properly accrued for by the Company in accordance with GAAP. All material taxes that the Company is or was required by law to have withheld or collected have been duly withheld or collected and, to the extent required, have been timely paid to the proper Governmental Authority. The Company has not received notice from the taxing authority of any jurisdiction that there are and to the Company's Knowledge there are no past-due unpaid taxes in any material amount except as may be being contested in good faith and by appropriate proceedings. The Company has not received notice of, and to the Company's Knowledge there are not, any material actions, suits, investigations or audits by any taxing authority in progress with respect to taxes of or relating to the Company and the Company has not received notice of, and to the Company's Knowledge there are not, any outstanding material assessments, claims or deficiencies with respect to any taxes of the Company that have been proposed, asserted or assessed.

4.26. Environmental Matters. To the Company's Knowledge, neither the Company nor any Subsidiary (a) is in violation of any statute, rule, regulation, decision or order of any Governmental Authority relating to the use, disposal or release of hazardous or toxic substances or relating to the protection or restoration of the environment or human exposure to hazardous or toxic substances (collectively, "**Environmental Laws**"), (b) owns or operates any real property contaminated with any substance that is in violation of any Environmental Laws, (c) is liable for any off-site disposal or contamination pursuant to any Environmental Laws, or (d) has received any claim alleging liability under any Environmental Laws ("**Environmental Claim**"), which in each case as to clauses (a), (b), (c) and (d), individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect. To the Company's Knowledge there is no pending investigation or investigation threatened in writing by any Governmental Authority that reasonably is expected to result in an Environmental Claim that would reasonably be expected to have a Material Adverse Effect.

4.27. Labor Matters.

(a) The Company and each Subsidiary is not a party to or bound by any collective bargaining agreements or other agreements with labor organizations. Neither the Company nor any Subsidiary has violated any Laws, regulations, orders or contract terms, affecting the collective bargaining rights of employees, labor organizations or any Laws, regulations or orders affecting employment discrimination, equal opportunity employment, or employees' health, safety, welfare, wages and hours, except as would not, individually or in the aggregate, result in a Material Adverse Effect.

(b) (i) There are no labor disputes existing, or to the Company's Knowledge, threatened, involving strikes, slow-downs, work stoppages, job actions, disputes, lockouts or any other disruptions of or by the Company's employees, (ii) there are no unfair labor practices or petitions for election pending or, to the Company's Knowledge, threatened before the National Labor Relations Board or any other federal, state or local labor commission relating to the Company's employees, (iii) no demand for recognition or certification heretofore made by any labor organization or group of employees is pending with respect to the Company and (iv) to the Company's Knowledge, the Company and each Subsidiary enjoys good labor and employee relations with its employees and labor organizations.

(c) The Company and each Subsidiary is, and at all times has been, in compliance in all material respects with all applicable Laws respecting employment (including Laws relating to classification of employees and independent contractors) and employment practices, terms and conditions of employment, wages and hours, and immigration and naturalization. To the Company's Knowledge, there are no claims pending against the Company before the Equal Employment Opportunity Commission or any other administrative body or in any court asserting any violation of Title VII of the Civil Rights Act of 1964, the Age Discrimination Act of 1967, 42 U.S.C. §§ 1981 or 1983 or any other federal, state or local law, statute or ordinance barring discrimination in employment.

(d) Except as disclosed in the Company's SEC Documents filed prior to the date hereof, the Company is not a party to, or bound by, any employment or other contract or agreement that contains any severance, termination pay or change of control liability or obligation which, if such payment or obligation were required to be made or fulfilled, would have a Material Adverse Effect.

(e) To the Company's Knowledge, each of the Company's employees is a Person who is either a United States citizen or a permanent resident entitled to work in the United States. To the Company's Knowledge, the Company has no material liability for the improper classification by the Company of such employees as independent contractors or leased employees prior to the Closing.

4.28. Insurance. The Company maintains insurance of the type and in the amount that the Company reasonably believes is adequate for its business as conducted as of the date hereof, including, but not limited to, liability insurance for clinical testing and insurance covering all real and personal property owned or leased by the Company against theft, damage, destruction, acts of vandalism and all other risks customarily insured against by similarly situated companies, all of which insurance is in full force and effect. The Company has not received any written notice of cancellation of any such insurance from the provider thereof (except for written notices of cancellation delivered by providers in connection with the expiration of insurance policies in accordance with their terms, in the ordinary course of the Company's business), nor, to the Company's Knowledge, will it be unable to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

4.29. Property. Neither the Company nor any Subsidiary owns any real property; and any real property and buildings held under lease by the Company or any Subsidiary are held under valid, existing and enforceable leases with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property and buildings by the Company or its Subsidiaries.

4.30. Transactions with Affiliates. Except as set forth in the Company SEC Documents, none of the officers or directors of the Company or its Subsidiaries and, to the Company's Knowledge, none of the employees of the Company or any Subsidiary is presently a party to any transaction, agreement arrangement with the Company or any Subsidiary (other than as holders of securities and for services as employees, officers and directors), that would be required to be disclosed pursuant to Item 404 of Regulation S-K promulgated under the Securities Act.

4.31. Full Disclosure. To the Company's Knowledge, as of the date hereof, and other than the transactions that are the subject of the Transaction Agreements and that certain License and Option Agreement between the Company and an Affiliate of the Investor dated on or about the date hereof , no material fact or circumstance exists that would be required to be disclosed in a current report on Form 8-K or in a registration statement filed under the Securities Act, were such a registration statement filed on the date hereof, that has not been disclosed in a Company SEC Document or otherwise disclosed in writing to the Investor.

5. Representations and Warranties of the Investor. The Investor hereby represents and warrants to the Company that:

5.1. Organization; Good Standing. The Investor is a corporation duly organized, validly existing and in good standing under the Laws of New Jersey. The Investor 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.

5.2. Authorization. All requisite action on the part of the Investor and its directors and stockholders, required by applicable Law for the authorization, execution and delivery by the Investor of the Transaction Agreements, and the performance of all of its obligations thereunder, including the subscription for and purchase of the Shares, has been taken. This Agreement has been, and upon the execution and delivery of the Investor Agreement at the Closing by the Investor, the Investor Agreement will be, duly executed and delivered by the Investor and upon the due execution and delivery thereof by the Company, will constitute valid and legally binding obligations of the Investor, enforceable against the Investor in accordance with their respective terms (except as such enforceability may be limited by (a) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights and (b) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).

5.3. No Conflicts. The execution, delivery and performance of the Transaction Agreements and compliance with the provisions thereof by the Investor 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 Investor or any of its assets, are bound, or (c) violate or conflict with any of the provisions of the Investor's organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents), except as would not impair or adversely affect the ability of the Investor to consummate the Transaction 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 Investor's ability to perform its obligations under the Transaction Agreements or consummate the Transaction in accordance with the terms of this Agreement.

5.4. No Governmental Authority or Third Party Consents. No consent, approval, authorization or other order of any Governmental Authority or other Third Party is required to be obtained by the Investor in connection with the authorization, execution and delivery of any of the Transaction Agreements or with the subscription for and purchase of the Shares.

5.5. Purchase Entirely for Own Account. The Shares shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation or otherwise distributing the Shares. The Investor does not have and

will not have as of the Closing any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participation to a Person any of the Shares.

5.6. Disclosure of Information. The Investor has received all the information from the Company and its management that the Investor considers necessary or appropriate for deciding whether to purchase the Shares hereunder. The Investor further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the Company, its financial condition, results of operations and prospects and the terms and conditions of the offering of the Shares sufficient to enable it to evaluate its investment.

5.7. Investment Experience and Accredited Investor Status. The Investor is an "accredited investor" (as defined in Regulation D under the Securities Act). The Investor has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder.

5.8. Acquiring Person. As of the date of this Agreement and immediately prior to the Closing, neither the Investor nor any of its Affiliates beneficially owns, or will beneficially own (as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership, and without regard to Investor's rights under this Agreement), any securities of the Company, except for securities that may be owned by employee benefit plans of the Investor or any of its Affiliates.

5.9. Restricted Securities. The Investor understands that the Shares, when issued, shall be "restricted securities" under the 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 the Shares may be resold without registration under the Securities Act only in certain limited circumstances. The Investor represents that it is familiar with Rule 144 of the Securities Act ("**Rule 144**"), as presently in effect.

5.10. Legends. The Investor understands that any certificates representing the Shares shall bear the following legends:

(a) "These securities have not been registered under the Securities Act of 1933. They may not be sold, offered for sale, pledged or hypothecated in the absence of a registration statement in effect with respect to the securities under the Securities Act or an opinion of counsel (which counsel shall be reasonably satisfactory to the Company) that such registration is not required or unless sold pursuant to Rule 144 of the Securities Act.";

(b) any legend required by applicable state securities Laws; and

(c) "The securities represented by this certificate are subject to and shall be transferable only upon the terms and conditions of an Investor Agreement dated as of _____ __, 2016, by and between TRACON Pharmaceuticals, Inc. and Johnson & Johnson Innovation-JJDC, Inc., a copy of which is on file with the Secretary of TRACON Pharmaceuticals, Inc."

6. Investor's Conditions to Closing. The Investor's obligation to purchase the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Investor):

6.1. Representations and Warranties. The representations and warranties made by the Company in Section 4 hereof shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 6.1, all such representations and warranties of the Company (other than Sections 4.1(a), 4.3, 4.4, 4.5(a), 4.6(c), 4.8, and the first sentence of 4.11(c) of this Agreement) shall be deemed to be true and correct for purposes of this Section 6.1 unless the failure or failures of such representations and warranties to be so true and correct, without regard to any "material," "materiality" or "Material Adverse Effect" qualifiers set forth therein, constitute a Material Adverse Effect.

6.2. Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.

6.3. Investor Agreement. The Company shall have duly executed and delivered to the Investor, pursuant to Section 3.2(a) of this Agreement, the Investor Agreement, and (subject to execution by the Investor) such agreement shall be in full force and effect.

6.4. No Material Adverse Effect. From and after the date of this Agreement until the Closing Date, there shall have occurred no event that has caused a Material Adverse Effect except any event previously disclosed to the Investor in writing.

6.5. [Reserved].

6.6. Listing. The Shares shall be eligible and approved for listing on the Trading Market.

7. Company's Conditions to Closing. The Company's obligation to issue and sell the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Company):

7.1. Representations and Warranties. The representations and warranties made by the Investor in Section 5 hereof shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date, in the case of Sections 5.1-5.4, and 5.11, except where any failure to be true and correct would not have a material adverse effect on the Investor's ability to perform its obligations, or consummate the Transaction in accordance with the terms of this Agreement, in the case of Section 5.5, 5.6 and 5.7, except where any inaccuracy would not result in the issuance of the Shares hereunder failing to qualify as an offering of securities not involving any public offering under the federal securities Laws, and in the case of Section 5.8, except where any inaccuracy would not be

material on the Investor's ability to perform its obligations, or consummate the Transaction in accordance with the terms of this Agreement.

7.2. Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Investor on or prior to the Closing Date shall have been performed or complied with in all material respects.

7.3. Investor Agreement. The Investor shall have duly executed and delivered to the Company, pursuant to Section 3.2(b) of this Agreement, the Investor Agreement, and (subject to execution by the Company) such agreement shall be in full force and effect.

8. Mutual Conditions to Closing. The obligations of the Investor and the Company to consummate the Closing are subject to the fulfillment as of the Closing Date of the following conditions:

8.1. Absence of Litigation. There shall be no action, suit, proceeding or investigation by a Governmental Authority pending or currently threatened in writing against the Company or the Investor that challenges the validity of any of the Transaction Agreements, the right of the Company or the Investor to enter into any Transaction Agreement or to consummate the transactions contemplated hereby or thereby or otherwise relating to the transactions contemplated by any Transaction Agreement.

8.2. No Prohibition. No provision of any applicable Law and no judgment, injunction (preliminary or permanent), order or decree that prohibits, makes illegal or enjoins the consummation of the Transaction shall be in effect.

9. Termination.

9.1. Ability to Terminate. This Agreement may be terminated at any time prior to the Closing by:

(a) mutual written consent of the Company and the Investor;

(b) either the Company or the Investor, upon written notice to the other no later than seven (7) calendar days after the date of this Agreement (the "**Termination Date**"), if the Transaction shall not have been consummated by the Termination Date; provided, however, that the right to terminate this Agreement under this Section 9.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Termination Date;

(c) either the Company or the Investor, upon written notice to the other, if any of the mutual conditions to the Closing set forth in Section 8 shall have become incapable of fulfillment by the Termination Date and shall not have been waived in writing by the other party within three (3) Business Days after receiving receipt of written notice of an intention to terminate pursuant to this clause (c) provided, however, that the right to terminate this Agreement under this Section 9.1(c) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Termination Date;

9.2. Effect of Termination. In the event of the termination of this Agreement pursuant to Section 9.1 hereof, (a) this Agreement (except for this Section 9.2 and Section 11 hereof (other than Section 11.13), and any definitions set forth in this Agreement and used in such sections) shall forthwith become void and have no effect, without any liability on the part of any party hereto or its Affiliates, and (b) all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other Person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; provided, however, that nothing contained in this Section 9.2 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

10. Additional Covenants and Agreements.

10.1. Market Listing. From the date hereof through the Closing Date, the Company shall use reasonable efforts to (a) maintain the listing and trading of the Common Stock on the Trading Market and (b) effect the listing of the Shares on the Trading Market, including, if necessary, submitting an LAS to the Trading Market no later than fifteen (15) calendar days prior to the Closing Date.

10.2. Assistance and Cooperation. Prior to the Closing, upon the terms and subject to the conditions set forth in this Agreement, each of the parties agrees to use reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement, including using reasonable efforts to accomplish the following: (a) causing the conditions precedent set forth in Sections 6, 7 and 8 to be satisfied (including, in the case of the Company, promptly notifying the Investor of any notice from the Trading Market with respect to an LAS, if required to be filed); (b) obtaining all necessary waivers, consents, approvals, orders and authorizations from Governmental Authorities and the making of all necessary registrations, declarations and filings (including registrations, declarations and filings with Governmental Authorities, if any); (c) obtaining all necessary consents, approvals or waivers from Third Parties; and (d) defending any suits, claims, actions, investigations or proceedings, whether judicial or administrative, challenging this Agreement or the consummation of the transactions contemplated hereby, including seeking to have any stay or temporary restraining order entered by any court or other Governmental Authority vacated or reversed.

10.3. Blue Sky Filings. 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 Investor at the Closing 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 Investor.

10.4. Legend Removal.

(a) Upon request of the Investor and subject to Section 10.4(c), the Company shall cause the certificates evidencing the Shares to not contain the legend set forth in Section 5.10(a): (i) following a sale of such Shares pursuant to a registration statement covering the resale of such

Shares, while such registration statement is effective under the Securities Act, (ii) following any sale of such Shares pursuant to Rule 144, (iii) if such Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such Shares and without volume or manner-of-sale restrictions under Rule 144 or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the SEC).

(b) Upon request of the Investor and subject to Section 10.4(c), the Company shall cause the certificates evidencing the Shares to not contain the legend set forth in Section 5.10(c) following: (i) a transfer of such Shares to a Person that is not bound or required to be bound by either the standstill or lock-up restrictions contained in the Investor Agreement or (ii) the expiration of the Standstill Term (as defined in the Investor Agreement) and the Lock-Up Term (as defined in the Investor Agreement); provided that any transfer described in clause (i) or (ii) above shall have been in compliance with all applicable provisions of the Investor Agreement.

(c) The Company agrees that at such time as any legend set forth in Section 5.10 is no longer required under this Section 10.4, the Company will, no later than three (3) Business Days following the delivery by the Investor to the Company or the Company's transfer agent (the "**Transfer Agent**") of a certificate representing Shares issued with such legend, deliver or cause to be delivered to the Investor a certificate representing such Shares that is free from such legend, or, in the event that such shares are uncertificated, remove any such legend in the Company's stock records. 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 Section 5.10.

10.5. Conduct of Business. During the period from the date hereof until the Closing, except as consented to in writing by the Investor, the Company shall not (a) declare, set aside or pay any dividend or make any other distribution or payment (whether in cash, stock or property or any combination thereof) in respect of its capital stock, or establish a record date for any of the foregoing, or (b) make any other actual, constructive or deemed distribution in respect of any shares of its capital stock or otherwise make any payments to stockholders in their capacity as such, except pursuant to repurchases of equity pursuant to the terms of its equity compensation plans.

10.6. Securities Laws Disclosure; Publicity. Any press release the Company or the Investor, or any of their respective Affiliates, issues with respect to the Transaction must be agreed to by both parties. The Company shall not publicly disclose the name of the Investor or an Affiliate of the Investor, or include the name of the Investor or an Affiliate of the Investor in any press release or filing with the SEC or any regulatory agency or Trading Market, without the prior written consent of the Investor, except (a) as required by federal securities law in connection with (i) any registration statement contemplated by the Investor Agreement and (ii) the filing of final Transaction Agreements (including signature pages thereto) with the SEC, (b) to the extent such disclosure is required by law, request of the staff of the SEC or Trading Market regulations, in which case the Company shall provide the Investor with prior written

notice of such disclosure permitted under this subclause (b) or (c) the information is already in the public domain through no breach of this Section 10.6.

11. Miscellaneous.

11.1. Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 11.3 or in such other manner as may be permitted by law, shall be valid and sufficient thereof.

11.2. Waiver. Waiver by a party of a breach hereunder by the other party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

11.3. Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit C attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission or electronic mail, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile or electronic mail (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either party may change its address by giving notice to the other party in the manner provided above.

11.4. Entire Agreement. This Agreement and the Investor Agreement (once executed) contain the entire agreement among the parties with respect to the subject matter

hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.

11.5. Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the Investor and the Company.

11.6. Headings; Nouns and Pronouns; Section References. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

11.7. Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("**Modified Clause**"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

11.8. Assignment. Except for an assignment of this Agreement or any rights hereunder by the Investor to an Affiliate, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either the Investor or the Company without (a) the prior written consent of Company in the case of any assignment by the Investor or (b) the prior written consent of the Investor in the case of an assignment by the Company.

11.9. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

11.10. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

11.11. 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.

11.12. No Strict Construction. This Agreement has been prepared jointly and will not be construed against either party.

11.13. Survival of Warranties. The representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing and the delivery of the Shares for a period of one year.

11.14. Remedies. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

11.15. Expenses. Each party shall pay its own fees and expenses in connection with the preparation, negotiation, execution and delivery of the Transaction Agreements.

11.16. Limitation of Liability. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES) IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

(*Signature Page Follows*)

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

JOHNSON & JOHNSON INNOVATION-JJDC, INC.

By: /s/ Marian T Nakada
Name: Marian T Nakada
Title: VP Venture Investments

TRACON PHARMACEUTICALS, INC.

By: /s/ Charles Theuer
Name: Charles Theuer
Title: CEO

(*Signature Page to Stock Purchase Agreement)*

EXHIBIT A

FORM OF INVESTOR AGREEMENT

EXHIBIT B

NOTICES

(a) If to the Investor:

Johnson & Johnson Innovation--JJDC, Inc.
255 Main Street 7th floor
Cambridge, MA 02142
Attention: Marian T. Nakada, Ph.D
Facsimile: (732) 247-5309

with a copy to:

Johnson & Johnson Law Department
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Attention: Steven Rosenberg & Scott Orchard

Facsimile: (732) 524-5334

with a copy to (which shall not constitute notice pursuant to Section 11.3):

Dechert LLP
1095 Avenue of the Americas
New York, NY 10036
Attention: Kristopher Brown & Tony Chan
Facsimile: (212) 698-3599"

(b) If to the Company:

TRACON Pharmaceuticals, Inc.
8910 University Center Lane, Suite 700
San Diego, CA 92122
Attention: Charles Theuer & Patricia Bitar

with a copy to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Attention: Sean Clayton & Kay Chandler

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles P. Theuer, M.D., Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TRACON Pharmaceuticals, 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 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)) 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. 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

c. 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 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.

Date: November 8, 2016

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Patricia L. Bitar, CPA, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TRACON Pharmaceuticals, 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 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)) 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. 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

c. 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 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.

Date: November 8, 2016

/s/ Patricia L. Bitar, CPA
Patricia L. Bitar, CPA
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles P. Theuer, M.D., PhD., President and Chief Executive Officer of TRACON Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) this Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 8, 2016

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Patricia L. Bitar, CPA, Chief Financial Officer of TRACON Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) this Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 8, 2016

/s/ Patricia L. Bitar, CPA
Patricia L. Bitar, CPA
Chief Financial Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.