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 March 31, 2019

OR

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

For transition period from _____ to _____.

Commission File Number: 001-31918

IDERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-3072298**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
505 Eagleview Blvd., Suite 212 Exton, Pennsylvania	**19341**
(Address of principal executive offices)	(Zip code)

(484) 348-1600

(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	IDRA	Nasdaq Capital Market

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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

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

Common Stock, par value $.001 per share	28,021,756
Class	Outstanding as of April 30, 2019

IDERA PHARMACEUTICALS, INC.
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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, clinical trials, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words “believes,” “anticipates,” “estimates,” “plans,” “expects,” “intends,” “may,” “could,” “should,” “potential,” “likely,” “projects,” “continue,” “will,” and “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth under Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the Securities and Exchange Commission, or the SEC, on March 6, 2019. These factors and the other cautionary statements made in this Quarterly Report on Form 10-Q should be read as being applicable to all related forward-looking statements whenever they appear in this Quarterly Report on Form 10-Q.

In addition, any forward-looking statements, including any statements about the proposed transaction, represent our estimates only as of the date that this Quarterly Report on Form 10-Q is filed with the SEC and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

IDERA PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(In thousands, except per share amounts)	March 31, 2019	December 31, 2018*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,198	$ 71,431
Short-term investments	35,666	—
Prepaid expenses and other current assets	1,736	1,376
Total current assets	61,600	72,807
Property and equipment, net	176	207
Operating lease right-of-use asset	216	—
Other assets	9	9
Total assets	$ 62,001	$ 73,023
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 895	$ 1,134
Accrued expenses	5,179	7,884
Operating lease liability	202	—
Total current liabilities	6,276	9,018
Operating lease liability, net of current portion	35	—
Other liabilities	18	11
Total liabilities	6,329	9,029
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, Authorized — 5,000 shares:		
Series A convertible preferred stock; Designated — 1,500 shares, Issued and outstanding — 1 share	—	—
Common stock, $0.001 par value, Authorized — 70,000 shares; Issued and outstanding — 28,008 and 27,188 shares at March 31, 2019 and December 31, 2018, respectively	28	27
Additional paid-in capital	730,991	728,342
Accumulated deficit	(675,349)	(664,375)
Accumulated other comprehensive income	2	—
Total stockholders' equity	55,672	63,994
Total liabilities and stockholders' equity	$ 62,001	$ 73,023

* The condensed balance sheet at December 31, 2018 has been derived from the audited financial statements at that date.

The accompanying notes are an integral part of these financial statements.

IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

(In thousands, except per share amounts)	Three Months Ended March 31, 2019	2018
Alliance revenue	$ —	$ 255
Operating expenses:		
Research and development	8,102	13,556
General and administrative	3,143	3,481
Merger-related costs, net	—	3,498
Restructuring costs	131	—
Total operating expenses	11,376	20,535
Loss from operations	(11,376)	(20,280)
Other income (expense):		
Interest income	404	211
Interest expense	—	(7)
Foreign currency exchange loss	(2)	(19)
Net loss	$ (10,974)	$ (20,095)
Net loss per share applicable to common stockholders - basic and diluted (Note 12)	$ (0.40)	$ (0.81)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders - basic and diluted	27,676	24,879
Comprehensive loss:		
Net loss	$ (10,974)	$ (20,095)
Other comprehensive income (loss):		
Unrealized gain on available-for-sale securities	2	—
Total other comprehensive income	2	—
Comprehensive loss	$ (10,972)	$ (20,095)

The accompanying notes are an integral part of these financial statements.

IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

(In thousands)	Three Months Ended March 31, 2019	2018
Cash Flows from Operating Activities:		
Net loss	$ (10,974)	$ (20,095)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,016	1,589
Issuance of common stock for services rendered	23	23
Accretion of discounts on short-term investments	(181)	—
Unrealized gain on available-for-sale securities	2	—
Depreciation and amortization expense	35	169
Gain on disposal of property and equipment	(8)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(576)	1,341
Accounts payable, accrued expenses, and other liabilities	(2,694)	2,416
Deferred revenue	—	(190)
Net cash used in operating activities	(13,357)	(14,747)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	(35,485)	—
Proceeds from the sale of property and equipment	8	—
Purchases of property and equipment	(4)	(14)
Net cash used in investing activities	(35,481)	(14)
Cash Flows from Financing Activities:		
Proceeds from equity financings, net of issuance costs	1,585	—
Proceeds from employee stock purchases	26	81
Proceeds from exercise of common stock options and warrants	—	9,591
Payments on note payable	—	(78)
Other	(6)	(3)
Net cash provided by financing activities	1,605	9,591
Net decrease in cash and cash equivalents	(47,233)	(5,170)
Cash, cash equivalents and restricted cash, beginning of period	71,431	112,940
Cash, cash equivalents and restricted cash, end of period	$ 24,198	$ 107,770

The accompanying notes are an integral part of these financial statements.

IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(UNAUDITED)

	For the Three Months Ended March 31, 2018					
	Common Stock		Additional		Accumulated Other	Total
(In thousands, except per share amounts)	Number of Shares	$0.001 Par Value	Paid-In Capital	Accumulated Deficit	Comprehensive Income	Stockholders' Equity
Balance, December 31, 2017	24,453	$ 24	$ 712,165	$ (604,494)	$ —	$ 107,695
Issuance of common stock under stock purchase plan	7	—	81	—	—	81
Issuance of common stock upon exercise of common stock warrants	2,551	3	9,588	—	—	9,591
Issuance of common stock for services rendered	1	—	23	—	—	23
Stock-based compensation	—	—	1,589	—	—	1,589
Net loss	—	—	—	(20,095)	—	(20,095)
Balance, March 31, 2018	27,012	$ 27	$ 723,446	$ (624,589)	$ —	$ 98,884

	For the Three Months Ended March 31, 2019					
	Common Stock		Additional		Accumulated Other	Total
(In thousands, except per share amounts)	Number of Shares	$0.001 Par Value	Paid-In Capital	Accumulated Deficit	Comprehensive Income	Stockholders' Equity
Balance, December 31, 2018	27,188	$ 27	$ 728,342	$ (664,375)	$ —	$ 63,994
Sale of common stock, net of issuance costs	533	1	1,584	—	—	1,585
Issuance of commitment shares	270	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	11	—	26	—	—	26
Issuance of common stock for services rendered	6	—	23	—	—	23
Stock-based compensation	—	—	1,016	—	—	1,016
Unrealized gain on marketable securities	—	—	—	—	2	2
Net loss	—	—	—	(10,974)	—	(10,974)
Balance, March 31, 2019	28,008	$ 28	$ 730,991	$ (675,349)	$ 2	$ 55,672

The accompanying notes are an integral part of these financial statements

IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
March 31, 2019

(UNAUDITED)

Note 1. Business and Organization

Business Overview

Idera Pharmaceuticals, Inc. (“Idera” or the “Company”), a Delaware corporation, is a clinical-stage biopharmaceutical company with a business strategy focused on the clinical development, and ultimately the commercialization, of drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet medical needs. The Company’s current focus is on its Toll-like receptor, or TLR, agonist, tilsotolimod (IMO-2125), for oncology. The Company believes it can develop and commercialize targeted therapies on its own. To the extent the Company seeks to develop drug candidates for broader disease indications, it has entered into and may explore additional collaborative alliances to support development and commercialization.

Liquidity and Financial Condition

As of March 31, 2019, the Company had an accumulated deficit of $675.3 million and a cash, cash equivalents and investments balance of $59.9 million. The Company expects to incur substantial operating losses in future periods and will require additional capital as it seeks to advance tilsotolimod and any future drug candidates through development to commercialization. The Company does not expect to generate product revenue, sales-based milestones or royalties until the Company successfully completes development of and obtains marketing approval for tilsotolimod or other future drug candidates, either alone or in collaboration with third parties, which the Company expects will take a number of years. In order to commercialize tilsotolimod and any future drug candidates, the Company needs to complete clinical development and comply with comprehensive regulatory requirements. The Company is subject to a number of risks and uncertainties similar to those of other companies of the same size within the biotechnology industry, such as uncertainty of clinical trial outcomes, uncertainty of additional funding and history of operating losses.

The Company believes, based on management’s current operating plan, that its existing balance of cash, cash equivalents and investments on hand as of March 31, 2019 is sufficient to enable the Company to continue as a going concern through the one-year period subsequent to the filing date of this Quarterly Report on Form 10-Q. Further, management has concluded that it is probable that management’s plans can be effectively implemented and will mitigate the relevant conditions that raise substantial doubt about the Company’s ability to continue as a going concern while not impeding the advancement of its drug development. These plans may also include the possible deferral of certain operating expenses unless additional capital is received. The Company has and will continue to evaluate available alternatives to extend its operations beyond this date.

Reverse Stock Split

On July 27, 2018, the Company effected a 1-for-8 reverse stock split of the Company's outstanding shares of common stock, as authorized at a special meeting of stockholders on June 20, 2018. All share and per share amounts of common stock, options and warrants in the accompanying financial statements and notes thereto have been retroactively adjusted for all periods presented to reflect the reverse stock split.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three months ended March 31, 2019 are not necessarily indicative of results that may be expected for the year ending December 31, 2019. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 ("2018 Form 10-K"), which was filed with the SEC on March 6, 2019.

Reclassifications

The prior year financial statements contain certain reclassifications to the results of operations for the three months ended March 31, 2018 to conform to the current year presentation and presentation for the year ended December 31, 2018 included in the Company's 2018 Form 10-K. Merger-related costs of approximately $3.5 million were reclassified from general and administrative expenses to merger-related costs, net for the three months ended March 31, 2018.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be "cash equivalents." Cash and cash equivalents at March 31, 2019 and December 31, 2018 consisted of cash, commercial paper and money market funds.

Financial Instruments

The fair value of the Company's financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in Note 3. The Company is required to disclose the estimated fair values of its financial instruments. As of March 31, 2019 and December 31, 2018, the Company's financial instruments consisted of cash, cash equivalents, investments and receivables and the estimated fair values of such financial instruments approximated their carrying values. As of March 31, 2019, the Company did not have any derivatives, hedging instruments or other similar financial instruments.

Revenue Recognition

In accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services.

The Company's revenues have primarily been generated through collaborative research, development and/or commercialization agreements. The terms of these agreements may include payment to the Company of one or more of the following: nonrefundable, up-front license fees; research, development and commercial milestone payments; and other contingent payments due based on the activities of the counterparty or the reimbursement by licensees of costs associated with patent maintenance. Each of these types of revenue are recorded as Alliance revenues in the Company's statement of operations.

See Note 8, "Collaboration and License Agreements" for additional details surrounding the Company's collaboration arrangements.

Note 2. Summary of Significant Accounting Policies (Continued)

Income Taxes

In accordance with ASC 270, *Interim Reporting*, and ASC 740, *Income Taxes*, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three months ended March 31, 2019 and 2018, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. The Company has not recorded its net deferred tax asset as of either March 31, 2019 or December 31, 2018 because it maintained a full valuation allowance against all deferred tax assets as of these dates as management has determined that it is not more likely than not that the Company will realize these future tax benefits. As of March 31, 2019 and December 31, 2018, the Company had no uncertain tax positions.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB and rules are issued by the SEC that the Company has or will adopt as of a specified date. Unless otherwise noted, management does not believe that any other recently issued accounting pronouncements issued by the FASB or guidance issued by the SEC had, or is expected to have, a material impact on the Company's present or future financial statements.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 requires organizations that lease assets, with lease terms of more than 12 months, to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. Consistent with GAAP, the recognition, measurement and presentation of expenses and cash flows arising from a lease by a lessee will depend primarily on its classification as a finance or operating lease. However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, ASU No. 2016-02 requires both types of leases to be recognized on the balance sheet. This guidance was applicable to the Company's fiscal year beginning January 1, 2019, and the Company adopted ASU 2016-02 in the first quarter of 2019 using the alternative modified retrospective transition method, which allowed the Company to apply the new lease standard to the beginning of the 2019 period and did not require adjusting comparative period financial information. Additionally, the Company elected the package of practical expedients to not reassess prior conclusions related to contracts containing leases, lease classification and initial direct costs. As a result of adopting ASU 2016-02, the primary impact on the Company's financial statements was the recognition of a right-of-use asset and corresponding liability of approximately $0.3 million on its balance sheet as of January 1, 2019 related to its existing Exton, PA facility operating lease.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718) ("ASU 2018-07").* ASU 2018-07 simplifies the accounting for nonemployee share-based payment transactions and was adopted by the Company in the first quarter of 2019. The adoption of this ASU did not have a material impact on the Company's financial statements.

Note 3. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company applies the guidance in ASC 820, *Fair Value Measurement*, to account for financial assets and liabilities measured on a recurring basis. Fair value is measured at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability.

The Company uses a fair value hierarchy, which distinguishes between assumptions based on market data (observable inputs) and an entity's own assumptions (unobservable inputs). The guidance requires that fair value measurements be classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 and 3 during the three months ended March 31, 2019.

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at March 31, 2019 and December 31, 2018 categorized by the level of inputs used in the valuation of each asset and liability:

	March 31, 2019			
(In thousands)	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash	$ 221	$ 221	$ —	$ —
Money market funds	18,580	18,580	—	—
Other cash equivalents – commercial paper	5,397	—	5,397	—
Short-term investments – commercial paper	17,772	—	17,772	—
Short-term investments – U.S. treasury bills	17,894	17,894	—	—
Total assets	$ 59,864	$ 36,695	$ 23,169	$ —
Total liabilities	$ —	$ —	$ —	$ —

	December 31, 2018			
(In thousands)	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash	$ 8,446	$ 8,446	$ —	$ —
Money market funds	61,177	61,177	—	—
Other cash equivalents – commercial paper	1,808	—	1,808	—
Total assets	$ 71,431	$ 69,623	$ 1,808	$ —
Total liabilities	$ —	$ —	$ —	$ —

The Level 1 assets include money market funds, which are actively traded daily.

Note 4. Investments

The Company's available-for-sale investments at fair value consisted of the following at March 31, 2019:

	March 31, 2019			
(In thousands)	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
Short-term investments – commercial paper	$ 17,772	$ —	$ —	$ 17,772
Short-term investments – U.S. treasury bills	17,892	—	2	17,894
Total short-term investments	$ 35,664	$ —	$ 2	$ 35,666
Total investments	$ 35,664	$ —	$ 2	$ 35,666

The Company had no realized gains or losses from the sale of investments in available-for-sale securities in each of the three months ended March 31, 2019 and 2018. There were no losses or other-than-temporary declines in value included in "Interest income" on the Company's condensed statements of operations and comprehensive loss for any securities for each of the three months ended March 31, 2019 and 2018.

Note 5. Property and Equipment

At March 31, 2019 and December 31, 2018, property and equipment, net, consisted of the following:

(In thousands)	March 31, 2019	December 31, 2018
Leasehold improvements	$ 107	$ 104
Laboratory equipment and other	762	767
Total property and equipment, at cost	869	871
Less: Accumulated depreciation and amortization	693	664
Property and equipment, net	$ 176	$ 207

Depreciation and amortization expense on property and equipment was less than $0.1 million during the three months ended March 31, 2019 and approximately $0.2 million during the three months ended March 31, 2018. There were no non-cash property additions during each of the three months ended March 31, 2019 and 2018.

Note 6. Accrued Expenses

At March 31, 2019 and December 31, 2018, accrued expenses consisted of the following:

(In thousands)	March 31, 2019	December 31, 2018
Payroll and related costs	$ 982	$ 1,962
Clinical and nonclinical trial expenses	2,908	3,958
Professional and consulting fees	329	605
Restructuring expenses	823	1,147
Other	137	212
Total accrued expenses	$ 5,179	$ 7,884

Included in accrued Payroll and related costs as of March 31, 2019 and December 31, 2018 is $0.4 million and $0.7 million, respectively, of salary continuation severance benefits to be paid in equal installments through October 31, 2019 to former executives.

Note 7. Stockholders' Equity

Equity Financings

Common Stock Purchase Agreement

On March 4, 2019, the Company entered into a Purchase Agreement with Lincoln Park Capital Fund, LLC ("Investor"), pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, Investor has committed to purchase an aggregate of $35.0 million of shares of Company common stock from time to time at the Company's sole discretion (the "Purchase Agreement"). As consideration for entering into the Purchase Agreement, the Company issued 269,749 shares of Company common stock to Investor as a commitment fee (the "Commitment Shares"). The closing price of the Company's common stock on March 4, 2019 was $2.84 and the Company did not receive any cash proceeds from the issuance of the Commitment Shares. Accordingly, there was no net impact to total stockholders' equity as a result of the issuance. Additionally, no shares were sold to Investor under the Purchase Agreement through March 31, 2019.

"At-The-Market" Equity Program

In November 2018, the Company entered into an Equity Distribution Agreement (the "ATM Agreement") with JMP Securities LLC ("JMP") pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $50.0 million (the "Shares") through JMP as its agent. Subject to the terms and conditions of the Agreement, JMP will use its commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions, by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or if specified by the Company, by any other method permitted by law, including but not limited to in negotiated transactions. The Company has no obligation to sell any of the Shares, and the Company or JMP may at any time suspend sales under the ATM Agreement or terminate the ATM Agreement. JMP is entitled to a fixed commission of 3.0% of the gross proceeds from Shares sold. During the three months ended March 31, 2019, the Company sold 532,700 Shares pursuant to the ATM Agreement resulting in net proceeds, after deduction of commissions and other offering expenses, of $1.6 million.

Common Stock Warrants

In connection with various financing transactions, the Company has issued warrants to purchase shares of the Company's common stock. The Company accounts for common stock warrants as equity instruments, derivative liabilities or liabilities, depending on the specific terms of the warrant agreement. As of March 31, 2019 and December 31, 2018, all of the Company's outstanding common stock warrants were equity-classified.

The following table summarizes outstanding warrants to purchase shares of the Company's common stock as of March 31, 2019 and December 31, 2018:

	Number of Shares			
Description	March 31, 2019	December 31, 2018	Weighted-Average Exercise Price	Expiration Date
Issued in May 2013 financing (pre-funded)	1,977,041	1,977,041	$ 0.08	May 2020
Issued in September 2013 financing (pre-funded)	521,997	521,997	$ 0.08	Sep 2020
Issued in February 2014 financing (pre-funded)	269,844	269,844	$ 0.08	Feb 2021
Total	2,768,882	2,768,882		

The table below is a summary of the Company's warrant activity for the three months ended March 31, 2019:

	Number of Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2018	2,768,882	$ 0.08
Issued	—	—
Exercised	—	—
Expired	—	—
Outstanding at March 31, 2019	2,768,882	$ 0.08

Note 8. Collaboration and License Agreements

Collaboration with Vivelix

In November 2016, the Company entered into an exclusive license and collaboration agreement with Vivelix pursuant to which the Company granted Vivelix worldwide rights to develop and market IMO-9200, an antagonist of TLR7, TLR8, and TLR9, for non-malignant gastrointestinal disorders, and certain back-up compounds to IMO-9200 (the "Vivelix Agreement"). The Company was previously developing IMO-9200 for potential use in selected autoimmune disease indications. However, the Company determined not to proceed with internal development of IMO-9200 because the large autoimmune disease indications for which IMO-9200 had been developed did not fit within the strategic focus of the Company. Under the terms of the Vivelix Agreement, Vivelix was solely responsible for the development and commercialization of IMO-9200 and any designated back-up compounds. In connection with the Vivelix Agreement, Idera also transferred certain drug material to Vivelix for Vivelix's use in its development activities.

Under the terms of the Vivelix Agreement, the Company received an upfront, non-refundable fee of $15 million and was eligible for future IMO-9200 related development, regulatory and sales milestone payments and sales-based royalties. However, on March 4, 2019, the Company and Vivelix mutually agreed to terminate the Vivelix Agreement. Accordingly, the Company is no longer eligible to receive any future milestone or royalty-based payments and all rights previously granted to Vivelix with respect to IMO-9200 and certain back-up compounds to IMO-9200 reverted back to the Company.

For the three months ended March 31, 2018, the Company recognized Alliance revenues of less than $0.1 million related to certain research activities performed by the Company at Vivelix's request, pursuant to the Vivelix Agreement. No such services were performed during the three months ended March 31, 2019.

Collaboration with GSK

In November 2015, the Company entered into a collaboration and license agreement with GSK to license, research, develop and commercialize pharmaceutical compounds from the Company's nucleic acid chemistry technology for the treatment of selected targets in renal disease (the "GSK Agreement"). In connection with the GSK Agreement, GSK identified an initial target for the Company to attempt to identify a potential population of development candidates to address such target under a mutually agreed upon research plan. From the population of identified development candidates, GSK may designate one development candidate in its sole discretion to move forward into clinical development. Once GSK designates a development candidate, GSK would be solely responsible for the development and commercialization activities for that designated development candidate.

The GSK Agreement also provided GSK with the option to select up to two additional targets at any time during the first two years of the GSK Agreement for further research under mutually agreed upon research plans. Upon selecting additional targets, GSK then had the option to designate one development candidate for each additional target, at which time GSK would have sole responsibility to develop and commercialize each such designated development candidate. GSK did not select any additional targets for research through expiry of the option period.

Under the terms of the GSK Agreement, the Company received a $2.5 million upfront, non-refundable, non-creditable cash payment upon the execution of the GSK Agreement. Additionally, as of March 31, 2019, the Company is eligible to receive an additional $18 million in license, research, clinical development and commercialization milestone payments, of which $1 million would be payable by GSK upon the designation of a development candidate from the initial target and $17 million would be payable by GSK upon the achievement of clinical milestones and commercial milestones. In addition, the Company is eligible to receive royalty payments on sales of licensed products following commercialization at varying rates of up to 5% on annual net sales, as defined in the GSK Agreement.

For the three months ended March 31, 2018, the Company recognized Alliance revenues of less than $0.1 million related to the amortization of the deferred up-front payment received at inception of the GSK Agreement, over the 36-month anticipated performance period, which concluded in the fourth quarter of 2018. Accordingly, no such revenues were recognized during the three months ended March 31, 2019.

Note 9. Restructuring Costs

In July 2018, the Company determined to wind-down its discovery operations, reduce the workforce in Cambridge, Massachusetts that supports such operations, and close its Cambridge facility. In connection with the reduction-in-workforce, 18 positions are being eliminated, primarily in the area of discovery, representing approximately 40% of the Company's employees. Of the 18 positions being eliminated, 15 were effective July 31, 2018 with the remaining expected to be eliminated by the end of the second quarter of 2019.

Restructuring-related charges to date are comprised of (i) one-time termination costs in connection with the reduction in workforce, including severance, benefits and related costs, of approximately $3.2 million; (ii) contract termination costs of approximately $0.2 million in connection with the early lease termination for the Cambridge facility; and (iii) non-cash asset impairments of approximately $0.7 million, which includes $0.5 million of fixed asset impairments and $0.2 million in write-offs of facility-related prepaid expenses; offset by (iv) a non-cash gain of approximately $0.4 million related to the write-off of the remaining deferred rent liability associated with the Cambridge facility lease.

The following summarizes restructuring-related activity for the three months ended March 31, 2019:

(in thousands)	Employee Severance and Benefits	Contract Termination Costs	Asset Impairments	Total
Accrued restructuring balance as of December 31, 2018	$ 1,147	$ —	$ —	$ 1,147
Charges incurred	131	—	—	131
Cash payments	(437)	—	—	(437)
Accrued restructuring balance as of March 31, 2019	$ 841	$ —	$ —	$ 841

As of March 31, 2019, the short-term portion of the accrued restructuring balance, or $0.8 million, is included in "Accrued expenses" in the accompanying condensed balance sheets. See Note 6. The long-term portion of less than $0.1 million is included within "Other liabilities" in the accompanying condensed balance sheets.

Note 10. Stock-Based Compensation

As of March 31, 2019, the only equity compensation plans from which the Company may currently issue new awards are the Company's 2013 Stock Incentive Plan (as amended to date, the "2013 Plan") and 2017 Employee Stock Purchase Plan (the "2017 ESPP"), each as more fully described below.

Equity Incentive and Employee Stock Purchase Plans

2013 Stock Incentive Plan

The Company's board of directors adopted the 2013 Plan, which was approved by the Company's stockholders effective July 26, 2013. The 2013 Plan is intended to further align the interests of the Company and its stockholders with its employees, including its officers, non-employee directors, consultants and advisers by providing equity-based incentives. The 2013 Plan allows for the issuance of up to such number of shares of the Company's common stock as equal to (i) 3,153,057 shares of common stock; plus (ii) such additional number of shares of common stock (up to 868,372 shares) as is equal to the sum of the number of shares of common stock subject to awards granted under the Company's 2005 Stock Incentive Plan (the "2005 Plan") or the Company's 2008 Stock Incentive Plan (the "2008 Plan" and, together with the 2005 Plan, the "Existing Plans") which awards expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right (subject, however, in the case of incentive stock options to any limitations of the Internal Revenue Code).

Note 10. Stock-Based Compensation (Continued)

As of March 31, 2019, options to purchase a total of 2,880,400 shares of common stock and 193,625 restricted stock units were outstanding and up to 323,418 shares of common stock remained available for grant under the 2013 Plan. The Company has not made any awards pursuant to other equity incentive plans, including the Existing Plans, since the Company's stockholders approved the 2013 Plan. As of March 31, 2019, options to purchase a total of 464,247 shares of common stock were outstanding under the 2008 Plan.

In addition, as of March 31, 2019, non-statutory stock options to purchase an aggregate of 393,750 shares of common stock were outstanding that were issued outside of the 2013 Plan to certain employees in 2017, 2015 and 2014 pursuant to the Nasdaq inducement grant exception as a material component of new hires' employment compensation.

2017 *Employee Stock Purchase Plan*

The Company's board of directors adopted the 2017 ESPP, which was approved by the Company's stockholders and became effective on June 7, 2017. The 2017 ESPP provides for the issuance of up to 62,500 shares of common stock to participating employees of the Company or its subsidiaries. Participation is limited to employees that would not own 5% or more of the total combined voting power or value of the stock of the Company after the grant. As of March 31, 2019, 21,198 shares remained available for issuance under the 2017 ESPP.

For the three months ended March 31, 2019 and 2018, the Company issued 11,096 and 6,702 shares of common stock, respectively, under the 2017 ESPP and received proceeds of less than $0.1 million during each period, as a result of employee stock purchases.

Accounting for Stock-based Compensation

The Company recognizes non-cash compensation expense for stock-based awards under the Company's equity incentive plans over an award's requisite service period, or vesting period, using the straight-line attribution method, based on their grant date fair value determined using the Black-Scholes option-pricing model. The Company also recognizes non-cash compensation for stock purchases made under the 2017 ESPP. The fair value of the discounted purchases made under the Company's 2017 ESPP is calculated using the Black-Scholes option-pricing model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over each plan period.

Total stock-based compensation expense attributable to stock-based payments made to employees and directors and employee stock purchases included in operating expenses in the Company's statements of operations for the three months March 31, 2019 and 2018 was as follows:

	Three Months Ended March 31,	
(in thousands)	**2019**	**2018**
Stock-based compensation:		
Research and development		
Employee Stock Purchase Plans	$ 6	$ 22
Equity Incentive Plans	330	556
	$ 336	$ 578
General and administrative		
Employee Stock Purchase Plans	$ 6	$ 14
Equity Incentive Plans	674	997
	$ 680	$ 1,011
Total stock-based compensation expense	$ 1,016	$ 1,589

During the three months ended March 31, 2019 and 2018, the weighted average fair market value of stock options granted was $1.83 and $9.92, respectively.

Note 10. Stock-Based Compensation (Continued)

The following weighted average assumptions apply to the options to purchase 480,502 and 514,600 shares of common stock granted to employees and directors during the three months ended March 31, 2019 and 2018, respectively:

	Three Months Ended March 31,	
	2019	2018
Average risk-free interest rate	2.4%	2.1%
Expected dividend yield	—	—
Expected lives (years)	3.6	3.8
Expected volatility	82.0%	74.9%
Weighted average exercise price (per share)	$ 3.14	$ 17.92

All options granted during three months ended March 31, 2019 and 2018 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant**.**

Stock Option Activity

The following table summarizes stock option activity for the three months ended March 31, 2019:

($ in thousands, except per share data)	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	3,304,531	$ 18.41	6.6	$ —
Granted	480,502	3.14		
Exercised	—	—		
Forfeited	(46,636)	13.52		
Expired	—	—		
Outstanding at March 31, 2019 (1)	3,738,397	$ 16.51	6.7	$ —
Exercisable at March 31, 2019	2,136,642	$ 21.64	4.9	$ —

(1) Includes both vested stock options as well as unvested stock options for which the requisite service period has not been rendered but that are expected to vest based on achievement of a service condition.

The fair value of options that vested during the three months ended March 31, 2019 was $1.6 million. As of March 31, 2019, there was $6.8 million of unrecognized compensation cost related to unvested options, which the Company expects to recognize over a weighted average period of 2.6 years.

Restricted Stock Activity

The following table summarizes restricted stock activity for the three months ended March 31, 2019:

($ in thousands, except per share data)	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested shares at December 31, 2018	—	$ —
Granted	194,550	3.14
Cancelled	(925)	3.14
Vested	—	—
Nonvested shares at March 31, 2019	193,625	$ 3.14

As of March 31, 2019, there was $0.6 million of unrecognized compensation expense related to the restricted stock units, which is expected to be recognized over a weighted-average period of 3.8 years.

Note 11. Related Party Transactions

Overview of Related Parties

Julian C. Baker, a member of the Company's board of directors until his resignation in September 2018, is a principal of Baker Bros. Advisors LP. Baker Bros. Advisors LP, and certain of its affiliated funds (collectively, "Baker Brothers") owned approximately 17% of the Company's common stock as of March 31, 2019. Additionally, one of the Company's directors, Kelvin M. Neu, is an employee of Baker Bros. Advisors, LP as of March 31, 2019. Mr. Neu will resign from the Company's board of directors effective June 4, 2019.

During the three months ended March 31, 2018, Baker Brothers exercised warrants to purchase 2,539,541 shares of the Company's common stock at an exercise price of $3.76 per share for a total exercise price of approximately $9.5 million.

As of March 31, 2019, Baker Brothers held pre-funded warrants to purchase up to 2,768,882 shares of the Company's common stock at an exercise price of $0.08 per share.

Board Fees Paid in Stock

Pursuant to the Company's director compensation program, in lieu of director board and committee fees incurred of less than $0.1 million during both the three months ended March 31, 2019 and 2018, the Company issued 13,719 and 1,668 shares of common stock, respectively, to certain of its directors. Director board and committee fees are paid in arrears (including fees paid in stock) and the number of shares issued was calculated based on the market closing price of the Company's common stock on the issuance date.

Note 12. Net Loss per Common Share

Basic and diluted net loss per common share applicable to common stockholders is calculated by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. The Company's potentially dilutive shares, which include outstanding stock option awards, common stock warrants and convertible preferred stock, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. For the three months ended March 31, 2019 and 2018, diluted net loss per common share applicable to common stockholders was the same as basic net loss per common share applicable to common stockholders as the effects of the Company's potential common stock equivalents are antidilutive.

Total antidilutive securities that were excluded from the calculation of diluted net loss per share, due to their anti-dilutive effect, were 6,702,830 and 5,946,315 as of March 31, 2019 and 2018, respectively, and consisted of stock options, preferred stock and warrants.

Note 13. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

Subsequent to March 31, 2019, the Company out-licensed certain non-core technology to a third-party under which the Company will receive, among other things, approximately $1.4 million in cash during the second quarter of 2019.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with:

- *our unaudited condensed financial statements and accompanying notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q; and*
- *our audited financial statements and accompanying notes included in our Annual Report on Form 10-K for 2018, or our 2018 Form 10-K, as well as the information contained under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2018 Form 10-K.*

Overview

We are a clinical-stage biopharmaceutical company with a business strategy focused on the clinical development, and ultimately the commercialization, of drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet medical needs. Our current focus is on our Toll-like receptor, or TLR, agonist, tilsotolimod (IMO-2125), for oncology. We believe we can develop and commercialize targeted therapies on our own. To the extent we seek to develop drug candidates for broader disease indications, we have entered into and may explore additional collaborative alliances to support development and commercialization.

TLRs are key receptors of the immune system and play a role in innate and adaptive immunity. As a result, we believe TLRs are potential therapeutic targets for the treatment of a broad range of diseases. Using our chemistry-based platform, we have designed both TLR agonists and antagonists to act by modulating the activity of targeted TLRs. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. A TLR antagonist is a compound that inhibits an immune response by blocking the targeted TLR.

Our current TLR-targeted clinical-stage drug candidate, tilsotolimod, is an agonist of TLR9. We are currently developing tilsotolimod, via intratumoral injection, for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab, an anti-CTLA4 antibody marketed as Yervoy® by Bristol-Myers Squibb Company, or BMS, in a Phase 3 trial. We are also evaluating intratumoral tilsotolimod in combination with nivolumab, an anti-PD1 antibody marketed as Opdivo® by BMS, and ipilimumab for the treatment of multiple solid tumors in a Phase 2 trial.

Clinical Development

Tilsotolimod (IMO-2125)

Tilsotolimod (IMO-2125) is a synthetic phosphorothioate oligonucleotide that acts as a direct agonist of TLR9 to stimulate the innate and adaptive immune systems. We are developing tilsotolimod for administration via intratumoral injection in combination with systemically administered checkpoint inhibitors for the treatment of various solid tumors, including (i) anti-PD1 refractory metastatic melanoma in combination with ipilimumab, (ii) squamous cell carcinoma of the head and neck in combination with nivolumab and ipilimumab, and (iii) microsatellite stable colorectal cancer in combination with nivolumab and ipilimumab. We refer to our tilsotolimod development program as the ILLUMINATE development program.

Advancements in cancer immunotherapy have included the approval and late-stage development of multiple checkpoint inhibitors, which are therapies that target mechanisms by which tumor cells evade detection by the immune system. Despite these advancements, many patients fail to respond to these therapies. For instance, approximately 50% of patients with melanoma fail to respond to therapy with approved checkpoint inhibitors. Current published data suggests that the lack of response to checkpoint inhibition is related to a non-immunogenic tumor micro environment. We also believe TLR9 agonists may be useful in other solid tumor types that are refractory to anti-PD1 treatment due, in part, to low mutation load and low dendritic cell infiltration. Because TLR9 agonists, such as tilsotolimod, stimulate the immune system, we believe there is a scientific rationale to evaluate the combination of intratumoral injection of tilsotolimod with checkpoint inhibitors. Specifically, we believe

intratumoral injection of tilsotolimod activates a local immune response in the injected tumor, which may complement the effect of the systemically administered checkpoint inhibitors. Currently, there is minimal immunotherapy benefit, post chemotherapy, for patients with squamous cell carcinoma of the head and neck and no approved immunotherapy options for patients with microsatellite stable colorectal cancer.

In studies in preclinical cancer models conducted in our laboratories, intratumoral injection of TLR9 agonists, such as tilsotolimod, has potentiated the anti-tumor activity of multiple checkpoint inhibitors in multiple tumor models. We believe these data support evaluation of combination regimens including the combination of a TLR9 agonist, such as tilsotolimod, with one or more checkpoint inhibitors for the treatment of cancer.

Melanoma

Melanoma is a type of skin cancer that begins in a type of skin cell called melanocytes. Although melanoma is a rare form of skin cancer, it causes the majority of skin cancer deaths. As is the case in many forms of cancer, melanoma becomes more difficult to treat once the disease has spread beyond the skin to other parts of the body such as the lymphatic system (metastatic disease). We believe, based on internally conducted commercial research, that in the United States, by 2025, approximately 25,000 people will have advanced melanoma appropriate for systemic treatment. Recent advances in therapy, such as immune checkpoint inhibitors, given as single agents or in combination, have improved long-term survival outcomes. However, advanced metastatic melanoma continues to present significant morbidity and mortality as not all patients respond to treatment with checkpoint inhibitors. Some patients who initially respond develop progressive disease requiring further treatment which means that about half of the patients who receive anti-PD1 therapy will require further treatment.

We are currently developing tilsotolimod for use in combination with checkpoint inhibitors for the treatment of patients with anti-PD1 refractory metastatic melanoma. Tilsotolimod has received Orphan Drug Designation for the treatment of melanoma Stages IIb to IV and Fast Track designation for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab therapy from the U.S. Food and Drug Administration, or FDA.

ILLUMINATE-301 - Phase 3 Trial of Tilsotolimod (IMO-2125) in Combination with Ipilimumab in Patients with Anti-PD1 Refractory Metastatic Melanoma

In the first quarter of 2018, we initiated a Phase 3 trial of the tilsotolimod–ipilimumab combination in patients with anti-PD1 refractory metastatic melanoma, which we refer to as ILLUMINATE-301. This trial will compare the results of the tilsotolimod–ipilimumab combination to those of ipilimumab alone in a 1:1 randomization, will have a sample size of approximately 300 patients and will be conducted at up to 110 sites worldwide. The primary endpoints of the trial are overall response rate (ORR) by RECIST v1.1 and median overall survival (OS). Key secondary endpoints include ORR by irRECIST, durable response rate, median time to response, median progression free survival (PFS) and patient reported outcomes using a validated scale. Enrollment is ongoing and expected to be completed by the end of 2019.

We have held discussions with and plan to continue to engage with regulatory authorities regarding the paths to registration for tilsotolimod in combination with ipilimumab in anti-PD1 refractory metastatic melanoma patients, including potentially through an accelerated approval process based on the analysis of the ORR in the Phase 3 trial with the final analysis of OS providing the confirmatory data for full approval. We believe that positive results in either of the primary endpoints could lead to approval in the United States.

As discussed below under the heading “Collaborative Alliances,” in May 2018, we entered into a clinical trial collaboration and supply agreement with BMS under which BMS has agreed to manufacture and supply YERVOY® (ipilimumab), at its cost and for no charge to us, for use in ILLUMINATE-301.

ILLUMINATE-204 - Phase 1/2 Trial of Tilsotolimod (IMO-2125) in Combination with Ipilimumab or Pembrolizumab in Patients with Anti-PD1 Refractory Metastatic Melanoma

In December 2015, we initiated a Phase 1/2 clinical trial to assess the safety and efficacy of tilsotolimod, administered intratumorally, in combination with ipilimumab, in patients with metastatic melanoma (refractory to treatment with a PD1 inhibitor, also referred to as anti-PD1 refractory), which we refer to as ILLUMINATE-204. We subsequently amended the trial protocol to enable an additional arm to study the combination of tilsotolimod with pembrolizumab, an anti-PD1 antibody marketed as Keytruda® by Merck & Co., Inc., in the same patient population. The Phase 2 expansion of our ILLUMINATE-204 trial closed for enrollment in February 2019 with a total of 52 patients dosed at 8 mg tilsotolimod in combination with ipilimumab. Final ORR data is expected during the fourth quarter of 2019.

In this clinical trial, tilsotolimod is administered intratumorally into a selected tumor lesion at weeks 1, 2, 3, 5, 8, 11, 17, 23 and 29 (total of 9 doses) together with the standard dosing regimen of ipilimumab or pembrolizumab, administered intravenously. For patients who lack superficially accessible disease for injection, tilsotolimod is administered via injection into deep lesions, such as liver metastases, using interventional radiology guidance.

The trial was initiated at The University of Texas, MD Anderson Cancer Center, or MD Anderson, under the strategic research alliance we entered into with MD Anderson in June 2015, and additional sites have been added through the fourth quarter of 2018. The primary objectives of the Phase 1 portion of the trial include characterizing the safety of the combinations and determining the recommended Phase 2 dose. A secondary objective of the Phase 1 portion of the trial is describing the anti-tumor activity of tilsotolimod when administered intratumorally in combination with ipilimumab or pembrolizumab. The primary objective of the Phase 2 portion of the trial is to determine the objective response rate to the combinations using immune-related response criteria (irRC) and RECIST v1.1 criteria. The secondary objectives of the Phase 2 portion of the trial include the assessment of treatment response utilizing irRC, determination of median progression free survival (PFS) and median overall survival (OS), and to continue to characterize the safety of the combinations. In the Phase 1 portion of the trial, serial biopsies are being taken of selected injected and non-injected tumor lesions pre- and post-24 hours of the first dose of tilsotolimod, as well as at 8 and 13 weeks, to assess immune changes and response assessments. In the Phase 2 portion of the trial, biopsies are optional.

Ipilimumab Arm

In the Phase 1 portion of the ipilimumab arm of our Phase 1/2 clinical trial of tilsotolimod, escalating doses of tilsotolimod ranging from 4 mg through 32 mg were evaluated in a total of 18 patients, each of which but one had progressed on nivolumab or pembrolizumab prior to enrollment in the trial. The combination of tilsotolimod and ipilimumab had been well tolerated at all dose levels studied. In April 2017, we completed tilsotolimod dose escalation and based on the safety and efficacy data and data from translational immune parameters, selected the 8 mg dose level as the recommended dose level for the Phase 2 portion of the ipilimumab arm of the trial.

In April 2017, we initiated enrollment in the Phase 2 portion of the ipilimumab arm of our Phase 1/2 clinical trial of tilsotolimod with the 8 mg dose of intratumoral tilsotolimod. The Phase 2 portion of the trial utilizes a Simon two-stage design to evaluate the objective response rate of tilsotolimod in combination with ipilimumab, compared to historical data for ipilimumab alone in the anti-PD1 refractory metastatic melanoma population. Based on the responses observed, the trial met the pre-specified futility assessment and advanced into the second stage of the Phase 2 portion.

At the 37th Annual J.P. Morgan Healthcare Conference in January 2019, we provided an update on our Phase 1/2 trial evaluating tilsotolimod in combination with ipilimumab at the recommended 8 mg dose level, noting that as of our December 2018 data-cut, a total of 37 patients had been dosed at the 8 mg dose level and 34 patients treated at the 8 mg dose level had at least one post-baseline disease assessment. Of these 34 patients, three had a complete response and eight had a partial response, representing an overall response rate of 32.4%. One of the three patients who had a complete response has been continuing off active treatment for more than two years and

has remained disease free. Additionally, fifteen other patients who were treated at the 8 mg dose level experienced stable disease. In the aggregate, 26 of the 34 patients achieved stable disease or better, representing a disease control rate of 76.5%. Additionally, as of the response data cutoff date, one patient who was treated at the 4 mg dose had an ongoing partial response and had been off active treatment for more than two years. The combination of tilsotolimod and ipilimumab continues to be well-tolerated.

In addition, other key findings include data demonstrating a clear systemic antitumor effect on distant uninjected tumors from the treatment of tilsotolimod in combination with ipilimumab. Also, data was presented showing that clinical responses were observed in patients whose tumors had low HLA-ABC expression at baseline, before treatment was started. Given that HLA-ABC expression is required for ipilimumab anti-tumor activity (Rodig, 2018), this demonstrates the contribution of tilsotolimod to overcome resistance to ipilimumab in tumors with low HLA-ABC expression, thereby enhancing the overall response rate compared to that expected with ipilimumab alone.

Pembrolizumab Arm

In the Phase 1 portion of the pembrolizumab arm of our Phase 1/2 clinical trial of tilsotolimod, we are evaluating escalating doses of tilsotolimod ranging from 8 mg through 32 mg.

We completed enrollment with a total of nine patients dosed in the 8 mg, 16 mg and 32 mg dosing cohorts in the Phase 1 dose escalation portion of the pembrolizumab arm of the trial. One patient who was treated at the 16 mg dose has experienced an ongoing complete response by RECIST v1.1 criteria.

Refractory Solid Tumors

ILLUMINATE-101 - Phase 1b Trial of Intra-tumoral Tilsotolimod (IMO-2125) Monotherapy in Patients with Refractory Solid Tumors

In March 2017, we initiated a Phase 1b dose escalation trial of tilsotolimod administered intratumorally as a single agent in multiple tumor types, which we refer to as ILLUMINATE-101. In this trial, tilsotolimod is administered intratumorally on days 1, 8 and 15 of cycle 1 and on day 1 of each subsequent 21-day cycle, up to 17 cycles (19 total doses). We completed enrollment of a total of 38 patients in four dose-escalation cohorts at doses of 8mg (cohort 1, n=11), 16mg (cohort 2, n=8), 23mg (cohort 3, n=10) and 32mg (cohort 4, n=9). There were no dose-limiting toxicities observed and tilsotolimod appeared to be well tolerated at each of the dose levels tested. We are also enrolling a melanoma expansion cohort to assess whether tilsotolimod as a single agent (8mg dose) has any clinical activity, as demonstrated for objective response according to RECIST v1.1 criteria, in patients with metastatic melanoma who have progressed on or after treatment with a PD-(L)1 inhibitor. We believe this is unlikely and are therefore utilizing a Simon's optimal two-stage design to test for clinically and statistically relevant clinical activity. With this method, eight patients were to be treated and monitored for a RECIST v1.1 response in Stage 1. If two or more patients have a response, then the cohort will continue to Stage 2, in which 14 more patients will be treated, for a total of 22 patients. To date, 16 patients have been enrolled, however, no objective responses were reported in the first eight patients, therefore, further enrollment has been stopped.

At the American Association for Cancer Research (AACR) 2019 Annual Meeting in April 2019, we provided an update on ILLUMINATE-101, noting that as of February 28, 2019, a total of 54 patients had been dosed, including 38 patients in the dose-evaluation portion of the trial and 16 patients in the melanoma does-expansion cohort. Of the 29 evaluable patients, 13 had a RECIST v1.1 disease assessment of stable disease, with a disease control rate of 45%. Of the 13 patients with stable disease, five had maximum tumor shrinkage greater than 10% below baseline and duration of stable disease ranged from 1.3 to 9.7+ months from start of treatment, with three patients ongoing. There were no correlations between dose and efficacy observed.

An additional purpose of this study was to obtain tumor biopsies to assess the effect of tilsotolimod on the tumor microenvironment in multiple types of solid tumors and inform the expansion of the development program beyond melanoma. Initial translational data confirms robust Type I IFN pathway activation 24 hours following a

single intratumoral dose of tilsotolimod, which is similar to that observed and previously reported in the tumor biopsies from the ILLUMINATE-204 melanoma subjects. This observation provided additional rationale to expand the tilsotolimod program to additional solid tumors.

Other Solid Tumors

Advancements in cancer immunotherapy have included the approval and late-stage development of multiple checkpoint inhibitors, as single agents or in combination, for other solid tumors including, among others, squamous cell carcinoma of the head and neck (SCCHN) and dMMR/MSI-H colorectal cancer (CRC).

Squamous cell carcinoma is the most frequent malignant tumor of the head and neck region and develops from the mucosal linings of the upper aerodigestive tract. Although the majority of patients present with loco-regional disease, more than 50% will succumb to recurrent or metastatic disease despite aggressive therapy with surgery, radiation, and/or chemotherapy. Relapsed or metastatic SCCHN (RM SCCHN) is currently an incurable disease with a poor prognosis and the mortality rate of patients presenting with advanced disease remains high. Recently, the results from prospectively conducted trials employing the immune-modulating antibodies nivolumab and pembrolizumab following chemotherapy heralded a new era of treatment for RM SCCHN. Patients responding to these agents have seen durable responses and in controlled studies an overall survival benefit has been demonstrated for the anti PD-1 antibodies versus standard of care chemotherapy. The challenge remains to increase the percentage of patients responding to these treatments, which currently ranges from 13% to 23% depending on the line of therapy.

Nivolumab administered as monotherapy or in combination with ipilimumab, has demonstrated benefit and is approved for the treatment of dMMR/MSI-H mCRC. However, in a previously treated microsatellite stable (MSS) CRC patient population, nivolumab + ipilimumab combination therapy did not produce objective responses. MSS CRC has been shown to be highly immunosuppressive. Moreover, the tumor microenvironment in MSS CRC has been shown to keep dendritic cells in an immature state. Given tilsotolimod's mechanism of action of activating dendritic cells, it may serve a complementary function to nivolumab and ipilimumab, within the immunosuppressive TME of MSS CRC patients.

We believe, based on internally conducted research, that annually in the United States, approximately 140,000 people are diagnosed with CRC, of which 85% are MSS, and there are approximately 50,000 deaths attributed to CRC. Additionally, we believe that annually in the United States, approximately 64,000 people are diagnosed with SCCHN and there are approximately 14,000 deaths attributed to SCCHN.

ILLUMINATE-206 - Phase 2 Trial of Tilsotolimod (IMO-2125) in Combination with Nivolumab and Ipilimumab for the treatment of Solid Tumors

In December 2018, we submitted an IND application to the FDA to evaluate tilsotolimod administered intratumorally, in combination with nivolumab and ipilimumab in a Phase 2, multi-cohort study that anticipates the study of multiple solid tumors. We received notification from the FDA in January 2019 that the study may proceed and expect to initiate the Phase 2, multicohort study for the treatment of specific solid tumors in the second quarter of 2019. We refer to this study as ILLUMINATE-206.

Each cohort in this study is designed to be conducted in two parts. The purpose of the first part (Part 1) is for signal finding and utilizes a Simon's minimax two-stage design in a single-arm. The primary objective of Part 1 is to evaluate the efficacy (measured by ORR based on RECIST v1.1) of intratumoral tilsotolimod in combination with nivolumab and ipilimumab. The secondary objectives of Part 1 are to assess tilsotolimod in combination with nivolumab and ipilimumab by evaluating safety, tolerability, plasma concentrations and immunogenicity. Based on the data from Part 1 of each cohort, expansion of a cohort may be conducted as Part 2. Part 2 objectives will be determined after the decision is made to initiate Part 2 of a given cohort. The start and end of the study will be independent for each cohort.

The initial ILLUMINATE-206 cohorts are as follows:

- Cohort 1: RM SCCHN in immunotherapy-naïve patients treated with tilsotolimod in combination with nivolumab and ipilimumab;
- Cohort 2: RM SCCHN in immunotherapy-refractory patients treated with tilsotolimod in combination with nivolumab and ipilimumab; and
- Cohort 3: Relapsed/refractory MSS CRC in immunotherapy-naïve patients treated with tilsotolimod in combination with nivolumab and ipilimumab.

Within Cohort 1, 41 patients are planned to be enrolled (22 patients in Stage 1 and 19 patients in Stage 2). Within Cohorts 2 and 3, 36 patients each are planned for enrollment (20 patients in Stage 1 and 16 patients in Stage 2). Each cohort is planned to be recruited for the first stage of Part 1.

We expect to initiate enrollment for cohorts 1 and 3 (immunotherapy-naïve patients) at approximately 12 total sites within the United States and Spain in the second quarter of 2019. We intend to initiate cohort 2 (immunotherapy-refractory patients) at the appropriate time.

As discussed below under the heading “Collaborative Alliances,” in March 2019, we entered into a clinical trial collaboration and supply agreement with BMS under which BMS has agreed to manufacture and supply YERVOY® (ipilimumab) and OPDIVO® (nivolumab), at its cost and for no charge to us, for use in ILLUMINATE-206.

Collaborative Alliances

In addition to our current alliances, we may explore potential collaborative alliances to support development and commercialization of our TLR agonists and antagonists. Our current alliances include collaborations with BMS, as described below, GlaxoSmithKline Intellectual Property Development Limited, or GSK, and Abbott Molecular as described in Note 8 of the notes to our condensed financial statements in this Quarterly Report on Form 10-Q and/or in our Annual Report on Form 10-K for the year ended December 31, 2018.

Collaboration with Bristol-Myers Squibb

Effective May 18, 2018, we entered into a clinical trial collaboration and supply agreement with BMS to clinically evaluate the combination of tilsotolimod with BMS’s therapy YERVOY® (ipilimumab), which agreement we refer to as the May 2018 BMS Agreement. Under the May 2018 BMS Agreement, we will sponsor, fund and conduct our ongoing global, open-label, multi-center Phase 3 clinical trial of tilsotolimod in combination with YERVOY® entitled “A Randomized Phase 3 Comparison of IMO-2125 with Ipilimumab versus Ipilimumab Alone in Patients with Anti-PD-1 Refractory Melanoma” in accordance with an agreed-upon protocol, which we refer to as ILLUMINATE-301. Under the May 2018 BMS Agreement, BMS has granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use YERVOY® in ILLUMINATE-301 and has agreed to manufacture and supply YERVOY®, at its cost and for no charge to us, for use in ILLUMINATE-301.

Effective March 11, 2019, we entered into a second clinical trial collaboration and supply agreement with BMS to clinically evaluate the combination of tilsotolimod with BMS’s therapy YERVOY® (ipilimumab) and OPDIVO® (nivolumab), which agreement we refer to as the March 2019 BMS Agreement. Under the March 2019 BMS Agreement, we will sponsor, fund and conduct a Phase 2, open-label, global, multi-center, multi-cohort study of intratumoral tilsotolimod in combination with YERVOY® and OPDIVO® entitled “Study of Tilsotolimod in Combination with Nivolumab and Ipilimumab For the Treatment of Solid Tumors” in accordance with an agreed-upon protocol, which we refer to as ILLUMINATE-206. Under the March 2019 BMS Agreement, BMS has granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use YERVOY® and OPDIVO® in ILLUMINATE-206 and has agreed to manufacture and supply YERVOY® and OPDIVO®, at its cost and for no charge to us, for use in ILLUMINATE-206.

Critical Accounting Policies and Estimates

This management's discussion and analysis of financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates and judgments, which are affected by the application of our accounting policies. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We regard an accounting estimate or assumption underlying our financial statements as a "critical accounting estimate" where:

(i) the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

(ii) the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are described in Note 2 of the notes to our financial statements included in our 2018 Form 10-K. However, please refer to Note 2 in the accompanying notes to the condensed financial statements contained in this Quarterly Report on Form 10-Q for updated policies and estimates, if applicable, that could impact our results of operations, financial position, and cash flows. Not all of these significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policies relating to revenue recognition, stock-based compensation and research and development prepayments, accruals and related expenses, as described under the caption "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates" in our 2018 Form 10-K, fit the description of critical accounting estimates and judgments.

New Accounting Pronouncements

New accounting pronouncements are discussed in Note 2 in the notes to the condensed financial statements in this Quarterly Report on Form 10-Q.

Financial Condition, Liquidity and Capital Resources

Financial Condition

We have incurred operating losses in all fiscal years since our inception except 2002, 2008 and 2009. As of March 31, 2019, we had an accumulated deficit of $675.3 million. To date, substantially all of our revenues have been from collaboration and license agreements and we have received no revenues from the sale of commercial products. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any commercial products. Our research and development activities, together with our selling, general and administrative expenses, are expected to continue to result in substantial operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital. Because of the numerous risks and uncertainties associated with developing drug candidates, and if approved, commercial products, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available or when we will become profitable, if at all.

Liquidity and Capital Resources

Overview

We require cash to fund our operating expenses and to make capital expenditures. Historically, we have funded our cash requirements primarily through the following:

(i) sale of common stock, preferred stock and warrants;

(ii) exercise of warrants;

(iii) debt financing, including capital leases;

(iv) license fees, research funding and milestone payments under collaborative and license agreements; and

(v) interest income.

We filed a shelf registration statement on Form S-3 on August 10, 2017, which was declared effective on September 8, 2017. Under this registration statement, we may sell, in one or more transactions, up to $250.0 million of common stock, preferred stock, depository shares and warrants. As of April 30, 2019, we may sell up to an additional $190.7 million of securities under this registration statement, such amount which includes $35.0 million shares which may be issued pursuant to our common stock purchase agreement with Lincoln Park, as described below, and additional shares which may be issued under our "At-the-market" equity program.

See Note 7 to the condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for additional information regarding our recent equity financings.

Funding Requirements

We had cash, cash equivalents and investments of approximately $59.9 million at March 31, 2019. We believe that, based on our current operating plan, our existing cash, cash equivalents and investments will enable us to fund our operations through the one-year period subsequent to the filing date of this Quarterly Report on Form 10-Q. Specifically, we believe that our available funds will be sufficient to enable perform the following:

(i) complete enrollment, where applicable, and continue to execute on:

a) the Phase 1 portion of our ongoing Phase 1/2 clinical trial of tilsotolimod in combination with pembrolizumab in anti-PD1 refractory melanoma (ILLUMINATE-204);

b) the Phase 2 portion of our ongoing Phase 1/2 clinical trial of tilsotolimod in combination with ipilimumab in anti-PD1 refractory melanoma (ILLUMINATE-204);

c) the Phase 3 clinical trial of tilsotolimod in combination with ipilimumab for the treatment of anti-PD1 refractory metastatic melanoma (ILLUMINATE-301); and

d) the Phase 1b monotherapy clinical trial of tilsotolimod in multiple refractory tumor types (ILLUMINATE-101);

(ii) initiate our Phase 2 study of tilsotolimod in combination with nivolumab and ipilimumab for the treatment of certain solid tumors (ILLUMINATE-206);

(iii) fund certain investigator initiated clinical trials of tilsotolimod; and

(iv) maintain our current level of general and administrative expenses in order to support the business.

We expect that we will need to raise additional funds in order to complete our ongoing clinical trials of tilsotolimod and to continue to fund our operations. We are seeking and expect to continue to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain funding are:

(i) the results of our clinical development activities in our tilsotolimod program or any other drug candidates we develop on the timelines anticipated;

(ii) the cost, timing, and outcome of regulatory reviews;

(iii) competitive and potentially competitive products and technologies and investors' receptivity to tilsotolimod or any other drug candidates we develop and the technology underlying them in light of competitive products and technologies;

(iv) the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies similar to ours specifically;

(v) the receptivity of the capital markets to any in-licensing, product acquisition or other transaction we may enter into; and

(vi) our ability to enter into additional collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or cost reductions.

Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders may experience dilution. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. An equity financing that involves existing stockholders may cause a concentration of ownership. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our common stock. Any additional debt or equity financing may contain terms which are not favorable to us or to our stockholders, such as liquidation and other preferences, or liens or other restrictions on our assets. As discussed in Note 13 to the financial statements included in our 2018 Form 10-K, additional equity financings may also result in cumulative changes in ownership over a three-year period in excess of 50% which would limit the amount of net operating loss and tax credit carryforwards that we may utilize in any one year.

If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay our clinical trials of tilsotolimod, or relinquish rights to portions of our technology, drug candidates and/or products.

Common Stock Purchase Agreement

On March 4, 2019, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park, pursuant to which, upon the terms and subject to the conditions and limitations set forth therein,

Lincoln Park has committed to purchase an aggregate of $35.0 million of shares of Company common stock from time to time at the Company's sole discretion, which we refer to as the Purchase Agreement. As consideration for entering into the Purchase Agreement, the Company issued 269,749 shares of Company common stock to Lincoln Park as a commitment fee, or the Commitment Shares. The Company did not receive any cash proceeds from the issuance of the Commitment Shares. See Item 9B, Other Information, in our 2018 Form 10-K for additional information.

Cash Flows

The following table presents a summary of the primary sources and uses of cash for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,	
(in thousands)	**2019**	**2018**
Net cash provided by (used in):		
Operating activities	$ (13,357)	$ (14,747)
Investing activities	(35,481)	(14)
Financing activities	1,605	9,591
Decrease in cash and cash equivalents	**$ (47,233)**	**$ (5,170)**

Operating Activities. Net cash used in operating activities in both periods presented resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The decrease in cash used in operating activities for the three months ended March 31, 2019, as compared to the 2018 period, was primarily due to decreases in cash outflows related to our prior discovery and development programs, including payments to contract research organizations, and merger-related costs.

Investing Activities. Net cash used in investing activities primarily reflect the transfer of cash and cash equivalents into short-term investments and purchases of property and equipment as follows:

- for the three months ended March 31, 2019, purchases of $35.5 million in available-for-sale securities; and
- for the three months ended March 31, 2018, purchases of less than $0.1 million of property and equipment.

Financing Activities. Net cash provided by financing activities primarily consisted of the following amounts received in connection with the issuances of common stock and payments on our note under our loan and security agreement with Oxford Finance LLC, or our note payable:

- for the three months ended March 31, 2019, $1.6 million in net proceeds from the issuance of common stock under our "At-the-market" equity program and employee stock purchases under our 2017 Employee Stock Purchase Plan, or 2017 ESPP; and
- for the three months ended March 31, 2018, $9.7 million in aggregate proceeds from the exercise of common stock warrants and employee stock purchases under our 2017 ESPP, partially offset by $0.1 million in payments made on our note payable.

Contractual Obligations

During the three months ended March 31, 2019, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

Off-Balance Sheet Arrangements

As of March 31, 2019, we had no off-balance sheet arrangements.

Results of Operations

Three Months Ended March 31, 2019 and 2018

Alliance Revenue

Alliance revenues consist of revenue generated through collaborative research, development and/or commercialization agreements. The terms of these agreements may include payment to us of one or more of the following: nonrefundable, up-front license fees; research, development and commercial milestone payments; and other contingent payments due based on the activities of the counterparty or the reimbursement by licensees of costs associated with patent maintenance.

Alliance revenue for the three months ended March 31, 2018 totaled $0.3 million and primarily related to the recognition of the $2.5 million upfront payment received in connection with the execution of the GSK Agreement in November 2015, which has been recognized on a straight-line basis through the fourth quarter of 2018, the end of the anticipated performance period of the agreement. Accordingly, no such revenues were recognized during the three months ended March 31, 2019. See Note 8 to the condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for additional information on our collaboration with GSK. Other amounts recognized during the 2018 period relate to amounts earned in connection with collaborations which are not material to our current operations nor expected to be material in the future, including reimbursements by licensees of costs associated with patent maintenance.

Research and Development Expenses

For each of our research and development programs, we incur both direct and indirect expenses. We track direct research and development expenses by program, which include third party costs such as contract research, consulting and clinical trial and manufacturing costs. We do not allocate indirect research and development expenses, which may include regulatory, laboratory (equipment and supplies), personnel, facility and other overhead costs (including depreciation and amortization), to specific programs.

In the table below, research and development expenses are set forth in the following categories which are discussed beneath the table:

($ in thousands)	Three months ended March 31, 2019	2018	% Change
IMO-2125 external development expense	$ 5,414	$ 6,518	(17%) (1)
IMO-8400 external development expense	38	1,216	(97%) (2)
Other drug development expense	2,650	3,755	(29%) (3)
Basic discovery expense	—	2,067	(100%) (4)
Total research and development expenses	$ 8,102	$ 13,556	(40%)

(1) *IMO-2125 External Development Expenses.* These expenses include external expenses that we have incurred in connection with the development of tilsotolimod (IMO-2125) as part of our immuno-oncology program. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of tilsotolimod clinical development in immuno-oncology, but exclude internal costs such as payroll and overhead expenses. We commenced clinical development of tilsotolimod as part of our immuno-oncology program in July 2015 and from July 2015 through March 31, 2019 we incurred approximately $45.1 million in IMO-2125 external development expenses as part of our immuno-oncology program, including costs associated with the preparation for and conduct of the ongoing Phase 1/2 clinical trial to assess the safety and efficacy of tilsotolimod in combination with ipilimumab and with pembrolizumab in patients with metastatic melanoma (ILLUMINATE-204), the preparation and conduct of our ongoing Phase 1b clinical trial of tilsotolimod monotherapy in patients with refractory solid tumors (ILLUMINATE-101), the preparation for, initiation and conduct of our ongoing Phase 3 clinical trial of tilsotolimod in combination with ipilimumab in patients with metastatic melanoma (ILLUMINATE-301), the preparation for our Phase 2 clinical trial of

tilsotolimod in combination with nivolumab and ipilimumab for the treatment of solid tumor (ILLUMINATE-206), and the manufacture of additional drug substance for use in our clinical trials and additional nonclinical studies.

The decrease in our IMO-2125 external development expenses during the three months ended March 31, 2019, as compared to the 2018 period, was primarily due to decreases in manufacturing-related costs associated due to the timing of manufacture and receipt of bulk drug product.

Going forward, we expect ongoing IMO-2125 external development expenses to be significant as our focus in 2019 continues to be on the clinical development of tilsotolimod (IMO-2125). See additional information under the heading “Financial Condition, Liquidity and Capital Resources” regarding our future funding requirements.

(2) *IMO-8400 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-8400 since October 2012, when we commenced clinical development of IMO-8400. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-8400 clinical development but exclude internal costs such as payroll and overhead expenses. Since October 2012, we have incurred approximately $45.4 million in IMO-8400 external development expenses through March 31, 2019, including costs associated with our Phase 1 clinical trial in healthy subjects; our Phase 2 clinical trial in patients with psoriasis, our Phase 1/2 clinical trial in patients with Waldenström’s macroglobulinemia and our Phase 1/2 clinical trial in patients with diffuse large B-cell lymphoma, or DLBCL, harboring the MYD88 L265P oncogenic mutation, which we discontinued in September 2016; our Phase 2 clinical trial in patients with dermatomyositis, which we determined in July 2018 to discontinue upon completion of final close-out activities; the manufacture of additional drug substance for use in our clinical trials; and expenses associated with our collaboration with Abbott Molecular for the development of a companion diagnostic for identification of patients with DLBCL harboring the MYD88 L265P oncogenic mutation. In July 2018, we terminated further development of IMO-8400. As a result, we expect IMO-8400 external development expenses to be insignificant in future periods.

The decrease in our IMO-8400 external development expenses during the three months ended March 31, 2019, as compared to the 2018 period, was primarily due to our decision to discontinue all development of IMO-8400.

(3) *Other Drug Development Expenses.* These expenses include external expenses associated with preclinical development of identified compounds in anticipation of advancing these compounds into clinical development, including IDRA-008. In addition, these expenses include internal costs, such as payroll and overhead expenses, associated with preclinical development and products in clinical development. The external expenses associated with preclinical compounds include payments to contract vendors for manufacturing and the related stability studies, preclinical studies, including animal toxicology and pharmacology studies, and professional fees. Other drug development expenses also include costs associated with compounds that were previously being developed but are not currently being developed. In July 2018, we suspended further preclinical research. As a result, we expect other drug development expenses to be lower in future periods.

The decrease in other drug development expenses during the three months ended March 31, 2019, as compared to the 2018 period, was primarily due to a decrease in internal employee and facility overhead related costs and external costs of preclinical programs, including related toxicology studies, bulk drug manufacturing and awareness and education programs, as we suspended preclinical research activities in July 2018 and focused on the development of our clinical drug candidates.

(4) *Basic Discovery Expenses.* These expenses include our internal and external expenses relating to our discovery efforts with respect to our TLR-targeted programs, including agonists and antagonists of TLR3, TLR7, TLR8 and TLR9, and our nucleic acid chemistry research programs. These expenses reflect charges for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. In July 2018, we suspended all internal discovery programs. As a result, we expect basic discovery expenses to be insignificant in future periods.

We do not know if we will be successful in developing and commercializing any drug candidate. At this time, and without knowing the results from our ongoing clinical trial of tilsotolimod, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the remainder of the development of, or the period, if any, in which material net cash inflows may commence from, any drug candidate. Moreover, the clinical development of tilsotolimod is subject to numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of unanticipated events arising during clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll, stock-based compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives. For the three months ended March 31, 2019 and 2018, general and administrative expenses totaled $3.1 million and $3.5 million, respectively.

The decrease in general and administrative expenses during the three months ended March 31, 2019, as compared to the 2018 period, was primarily due to lower employee-related costs and facility-related costs as a result of cost savings realized in connection with our restructuring activities and the closing of our Cambridge, Massachusetts facility post-restructuring in July 2018.

Merger-related Costs, net

Merger-related costs, net consists of charges and, where applicable, credits for transaction and integration-related professional fees, employee retention, and other incremental costs directly related to these activities, which are offset by merger termination fees. See our 2018 Form 10-K for additional information on our previously contemplated merger transaction.

Merger-related costs, net for the three months ended March 31, 2018 amounted to a net charge of $3.5 million. No such costs were incurred during the three months ended March 31, 2019.

Restructuring Costs

Restructuring costs consist primarily of severance and related benefit costs related to workforce reductions, contract termination and wind-down costs and asset impairments.

Restructuring costs for the three months ended March 31, 2019 totaled approximately $0.1 million and relate to our decision in July 2018 to wind-down our discovery operations, reduce the workforce in Cambridge, Massachusetts that supported such operations, and close our Cambridge facility. No such costs were incurred during the three months ended March 31, 2018.

Interest Income

Interest income for each of the three months ended March 31, 2019 and 2018 totaled approximately $0.4 million and $0.2 million, respectively. Amounts may fluctuate from period to period due to changes in average investment balances, including commercial paper and money market funds classified as cash equivalents, and composition of investments. Interest income increased by approximately $0.2 million, or 92%, in the 2019 period, as compared to 2018, primarily due to an increase in average investment balances, including certain investments classified as cash equivalents, during the three months ended March 31, 2019 as a result of our decision to invest more cash in income-generating investments.

Interest Expense

Interest expense for the three months ended March 31, 2018 totaled less than $0.1 million and related to interest incurred on the outstanding principal balance of our note payable, which was paid off in June 2018. No such expenses were incurred during the three months ended March 31, 2019.

Net Loss Applicable to Common Stockholders

As a result of the factors discussed above, our net loss applicable to common stockholders was $11.0 million and $20.1 million for the three months ended March 31, 2019 and 2018, respectively.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

As of March 31, 2019, all of our material assets and liabilities are in U.S. dollars, which is our functional currency.

We maintain investments in accordance with our investment policy. The primary objectives of our investment activities are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. We regularly review our investment holdings in light of the then current economic environment. At March 31, 2019, our invested funds were invested in money market funds and commercial paper, classified in cash and cash equivalents on the accompanying balance sheet, and commercial paper and U.S. treasury bills classified in investments on the accompanying balance sheet.

Based on a hypothetical 10% adverse movement in interest rates, the potential losses in future earnings, fair value of risk sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.

Item 4. Controls and Procedures.

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2019. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of March 31, 2019, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports 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.

(b) *Changes in Internal Controls*. There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended March 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. In addition to the other information contained elsewhere in this report, you should carefully consider the factors discussed in "Part I, Item 1A. Risk Factors" in our most recent Annual Report on Form 10-K for the year ended December 31, 2018, which could be materially and adversely affect our business, financial condition or future results.

Item 6. Exhibits.

Exhibit No.	Description
10.1*	Clinical Trial Collaboration and Supply Agreement, by and between Idera Pharmaceuticals, Inc. and Bristol-Myers Squibb Company, dated March 11, 2019
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* In accordance with Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted in order for them to remain confidential.

SIGNATURES

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

IDERA PHARMACEUTICALS, INC.

Date: May 2, 2019

/s/ Vincent J. Milano

Vincent J. Milano
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 2, 2019

/s/ John J. Kirby

John J. Kirby
Vice President of Finance
(Principal Financial and Accounting Officer)

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This **CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT** (the "***Agreement***") is made and entered into effective as of the date signed by the last Party to sign below (the "***Effective Date***") by and between Idera Pharmaceuticals Inc., having a place of business at **505 Eagleview Boulevard, Suite 212, Exton, PA 19341** (the "***Recipient***") and **Bristol-Myers Squibb Company**, having a place of business at 345 Park Avenue, New York, NY 10154 ("***BMS***"). The Recipient and BMS are sometimes individually referred to in this Agreement as a "***Party***" and collectively as the "***Parties***."

PRELIMINARY STATEMENTS

A. The Recipient desires to conduct, and BMS desires to supply the BMS Study Drug (as defined below) for the conduct of, a Combined Therapy Clinical Trial (as defined below) in accordance with the Protocol (as defined below) therefor and in accordance with the terms of this Agreement.

B. The Parties desire to agree on various terms and conditions to govern the Parties' obligations in connection with the performance of the Combined Therapy Clinical Trial.

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

ARTICLE 1

DEFINITIONS

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

"***Adverse Event***," ("AE") "***Serious Adverse Event***" ("SAE") and "***Serious Adverse Drug Reaction***" ("SADR") shall have the meanings provided to such terms in the International Conference on Harmonization ("ICH") guideline for industry on Clinical Safety Data Management (E2A, Definitions and Standards for Expedited Reporting).

"***Affiliate***" means, with respect to a particular Party, an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Party. As used in this definition, the term "controls" (with correlative meanings for the terms "controlled by" or "under common control with") means (a) that an entity owns, directly or indirectly, more than fifty percent (50%) of the voting stock of another entity, or (b) that an entity, person or group otherwise has the actual ability to control and direct the management of the entity, whether by contract or otherwise.

"***Agreement***" shall have the meaning set forth in the preamble to this Agreement, and includes the Appendices attached hereto, the Supply and Quality Documentation and any and all amendments of any of the foregoing hereafter signed by the Parties with reference to this Agreement and made part hereof.

"***Applicable Law***" means all applicable laws, rules and regulations (whether federal, state or local) that may be in effect from time to time, including current Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP).

"***Arbitration Matter***" means any disputed matter that relates to or arises out of the validity, interpretation or construction of, or the compliance with or breach of, this Agreement; *provided that* such disputed matter has been considered, but not resolved, by the Executive Officers as set forth in Section 13.3. For clarity, no Publication Dispute, or any matter requiring mutual agreement of both Parties shall be an Arbitration Matter.

"***BMS Class Drug***" means (i) the BMS Study Drug(s) and (ii) any other antibodies that are designed to selectively bind to cytotoxic T-lymphocyte-associated antigen ("CTLA-4") or PD-1 or PD-L1].

"***BMS Indemnitees***" shall have the meaning set forth in Section 11.2.

"***BMS Independent Patent Rights***" means any Patent Rights Controlled by BMS (or its Affiliates) (a) as of the Effective Date or (b) during the Term the subject matter of which was conceived or first reduced to practice through activities other than those performed pursuant to this Agreement, in each case of (a) or (b) that Cover the use (whether alone or in combination with other agents), manufacture, formulation or composition of matter of the BMS Study Drug.

"***BMS Regulatory Documentation***" means any Regulatory Documentation pertaining to the BMS Study Drug that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

"***BMS Study Data***" shall have the meaning set forth in Section 8.1

"***BMS Study Drug***" means either BMS's proprietary monoclonal antibody product known as Yervoy® (ipilimumab) and/or BMS's proprietary anti-PD-1 monoclonal antibody known as Opdivo® (nivolumab), as applicable.

"***BMS Study Invention***" means any Invention that pertains solely to (a) the composition of matter of any BMS Class Drug (and not any Recipient Class Drug), (b) method of manufacture or formulation of any BMS Class Drug (and not any Recipient Class Drug) as a Single Agent Compound, and/or (c) a method of use of any BMS Class Drug (and not any Recipient Class Drug) as a monotherapy or as used with other agents, antibodies or compounds (other than an Invention pertaining, whether generically or specifically, to the composition of matter, method of manufacture or formulation, or a method of use of both a BMS Class Drug and a Recipient Class Drug).

"***BMS Study Patent Rights***" means any Patent Rights that Cover any BMS Study Invention (and not a Recipient Study Invention or Combined Therapy Invention), excluding BMS Independent Patent Rights and BMS Technology. For avoidance of doubt, any Patent Rights that cover both (a) a BMS Study Invention and (b) any other type of Invention is included within the Combined Therapy Patent Rights.

"***BMS Technology***" means all Technology Controlled by BMS (or its Affiliates) as of the Effective Date or during the Term created through efforts outside of this Agreement related to the BMS Study Drug or the Combined Therapy and necessary for the conduct of the Combined Therapy Clinical Trial. For clarity, BMS Technology does not include (a) Inventions, (b) Study Data, or (c) Combined Therapy Clinical Trial Regulatory Documentation.

"***Breaching Party***" shall have the meaning set forth in Section 12.2(a).

"***Business Day***" means a day other than Saturday, Sunday or any day on which commercial banks located in New York, NY are authorized or obligated by Applicable Law to close.

"***Clinical Hold***" means that (a) the FDA has issued an order to a Party pursuant to 21 CFR §312.42 to delay a proposed clinical investigation or to suspend an ongoing clinical investigation of the Combined

Therapy or such Party's Single Agent Compound in the United States or (b) a Regulatory Authority other than the FDA has issued an equivalent order to that set forth in (a) in any other country or group of countries.

"***Combined Therapy***" means a therapy using the Recipient Study Drug and the BMS Study Drug together concomitantly or sequentially, whether with or without another agent.

"***Combined Therapy Clinical Trial***" means the human clinical trial using the Recipient Study Drug and the BMS Study Drug, which will be conducted under the Recipient's protocol (said, protocol, as it may be amended from time to time in accordance with this Agreement, the "***Protocol***") and is incorporated herein by reference. The draft Protocol as of the Effective Date is attached as Appendix A hereto.

"***Combined Therapy IND***" shall have the meaning set forth in Section 2.1(b).

"***Combined Therapy Invention***" means any Invention that is not a Recipient Study Invention or a BMS Study Invention.

"***Combined Therapy Patent Right(s)***" means any Patent Rights that Cover any Combined Therapy Invention or Combined Therapy Study Data, excluding BMS Independent Patent Rights and Recipient Independent Patent Rights.

"***Combined Therapy Clinical Trial Regulatory Documentation***" means any Regulatory Documentation to be submitted for the conduct of the Combined Therapy Clinical Trial, but excluding (a) any Recipient Regulatory Documentation and (b) any BMS Regulatory Documentation.

"***Combined Therapy Study Data***" shall have the meaning set forth in Section 8.2.

"***Commercially Reasonable Efforts***" means, with respect to a Party, the level of effort and resources normally devoted by such Party to conduct a clinical trial for a biopharmaceutical product or compound that is owned by it or to which it has rights, which is of similar market potential, profit potential or strategic value and at a similar stage in its development or product life based on conditions then prevailing.

"***Confidential Information***" shall have the meaning set forth in Section 9.1(a).

"***Control***" or "***Controlled***" means, with respect to particular information or intellectual property, that the applicable Party owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense to the other Party as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

"***Cover***" means, with respect to a Patent Right, that, but for rights granted to a Person under such Patent Right, the practice by such Person of an invention described in such Patent Right would infringe a claim included in such Patent Right, or in the case of a Patent Right that is a patent application, would infringe a claim in such patent application if it were to issue as a patent. "***Covered***" or "***Covering***" shall have correlative meanings.

"***CRO***" means any Third Party contract research organization used to conduct the Combined Therapy Clinical Trial, including laboratories and Third Parties used to maintain the safety database from the Combined Therapy Clinical Trial, but, for clarity, excluding clinical trial sites and any Third Parties who are individuals.

"***Cure Period***" shall have the meaning set forth in Section 12.2(a).

"***[**]***" means [**].

"***[**]***" means [**].

"***Date of First Receipt***" means, with respect to a Party, the date on which any employee of such Party, its Affiliates or its Third Party subcontractors first becomes aware of safety-related information.

"***Designated Clinical Contact***" shall have the meaning set forth in Section 2.3.

"***Designated Supply Contact***" shall have the meaning set forth in Section 4.7.

"***Dispute***" shall have the meaning set forth in Section 13.3(b).

"***Effective Date***" shall have the meaning set forth in the preamble to this Agreement.

"***Executive Officers***" means the Chief Executive Officer of the Recipient and the Head of Oncology Development of BMS (or their respective designees).

"***FDA***" means the United States Food and Drug Administration, or any successor agency having the same or similar authority.

"***Filing Party***" shall have the meaning set forth in Section article 6(c).

"***Global Safety Database***" means the database containing Adverse Events, Serious Adverse Events, Serious Adverse Drug Reactions and pregnancy reports for the Combined Therapy, and shall be the authoritative data source for regulatory reporting and responding to regulatory queries with respect to the Combined Therapy Clinical Trial.

"***Good Clinical Practices***" or "***GCP***" means, as to the United States and the European Union, applicable good clinical practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, clinical practices equivalent to good clinical practices as then in effect in the United States or the European Union.

"***Good Laboratory Practices***" or "***GLP***" means, as to the United States and the European Union, applicable good laboratory practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, laboratory practices equivalent to good laboratory practices as then in effect in the United States or the European Union.

"***Good Manufacturing Practices***" or "***GMP***" means, as to the United States and the European Union, applicable good manufacturing practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, manufacturing practices equivalent to good manufacturing practices as then in effect in the United States or the European Union.

"***ICF***" shall have the meaning set forth in Section 5.1(f).

"***IND***" means (a) an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a drug in humans in the United States, (b) a counterpart of such an Investigational New Drug Application that is required in any other country before beginning clinical testing of a drug in humans in such country, including, for clarity, a "***Clinical Trial Application***" in the European Union, and (c) all supplements and amendments to any of the foregoing.

"***Indemnify***" shall have the meaning set forth in Section 11.1.

"***Infringe***" and "***Infringement***" means any alleged or threatened (in writing) infringement, or misappropriation by a Third Party, of any Patent Rights.

"***Invention***" means any invention or Technology, whether or not patentable, that is made, conceived, or first actually reduced to practice following the Effective Date by, for or on behalf of a Party, or by, for or on behalf of the Parties together (including by a Third Party in the performance of the Combined Therapy Clinical Trial), (a) in relation to the Combined Therapy Clinical Trial to be conducted under this Agreement or (b) by the use of unpublished Study Data, but excluding in each case any Study Data.

"***IRB***" means an Investigational Review Board or Ethics Committee (or similar body in a given country).

"***Licensee***" shall have the meaning set forth in Section 13.10(b).

"***Losses***" shall have the meaning set forth in Section 11.1.

"***Manufacture"*** or "***Manufacturing***" means manufacturing, processing, formulating, packaging, labeling, holding (including storage), and quality control testing of a Single Agent Compound or the Combined Therapy, in each case so as to be suitable for use in the Combined Therapy Clinical Trial under Applicable Law.

"***Material Safety Issue***" means a Party's good faith belief that there is an unacceptable risk for harm in humans based upon: (a) pre-clinical safety data, including data from animal toxicology studies, or (b) the observation of Serious Adverse Events in humans after the Recipient Study Drug or the BMS Study Drug, either as a Single Agent Compound or in combination with another pharmaceutical agent (including as the Combined Therapy), has been administered to or taken by humans, such as during the Combined Therapy Clinical Trial.

"***NDA***" means (a) any new drug application or biologics license application filed with the FDA, or any successor application or procedure required to introduce a drug or biologic into commerce in the United States, (b) a counterpart of such a new drug application or biologics license application that is required in any other country before beginning the commercialization of a drug or a biologic in humans in such country, and (c) all supplements and amendments to any of the foregoing.

"***Non-Breaching Party***" shall have the meaning set forth in Section 12.2(a).

"***Officials***" shall have the meaning set forth in Section 10.9.

"***Ono***" means Ono Pharmaceutical Co., Ltd.

"***Ono-BMS Agreements***" means those certain Collaboration Agreements between BMS and Ono dated as of September 20, 2011 and as of July 23, 2014, as amended from time to time, and agreements between Ono and BMS and their Affiliates relating thereto that may be in effect from time to time.

"***Ono Territory***" means Japan, South Korea and Taiwan.

"***Operational Matters***" shall have the meaning set forth in Section 5.1.

"***Party***" or "***Parties***" shall have the meaning set forth in the preamble to this Agreement.

"***Patent Rights***" means any (a) United States or foreign patents, (b) United States or foreign patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon, (c) United States or foreign patents-of-addition, reissues, reexaminations (including *ex parte* reexaminations, *inter partes* reviews, *inter partes* reexaminations, post grant reviews and supplemental examinations) and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates,

patent term extensions, or the equivalents thereof, and (d) any other form of government-issued right substantially similar to any of the foregoing.

"***Payment***" shall have the meaning set forth in Section 10.9.

"***Person***" means any individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

"***Personal Data***" means any information relating to an identified or identifiable natural person.

"***POTV***" shall have the meaning set forth in Section 9.7(a).

"***Protocol***" shall have the meaning set forth in the definition of Combined Therapy Clinical Trial.

"***Publication Dispute***" shall have the meaning set forth in Section 9.6(b).

"***Quarter***" means a calendar quarter.

"***Recipient Class Drug***" means the Recipient Study Drug and any other TLR-9 Agonist.

"***Recipient Indemnitees***" shall have the meaning set forth in Section 11.1.

"***Recipient Independent Patent Rights***" means any Patent Rights Controlled by the Recipient or a Recipient Affiliate (a) as of the Effective Date or (b) during the Term the subject matter of which was conceived or first reduced to practice through activities other than those performed pursuant to this Agreement, in each case (a) and (b) that Cover the use (either alone or in combination with other agents), manufacture, formulation or composition of matter of the Recipient Study Drug.

"***Recipient Regulatory Documentation***" means any Regulatory Documentation pertaining to the Recipient Study Drug that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

"***Recipient Study Data***" shall have the meaning set forth in Section 8.2.

"***Recipient Study Drug***" means the Recipient's TLR-9 Agonist (Toll-Like Receptor Agonist), IMO-2125.

"***Recipient Study Invention***" means any Invention that pertains solely to (a) the composition of matter of any Recipient Class Drug (and not any BMS Class Drug), (b) method of manufacture or formulation of any Recipient Class Drug (and not any BMS Class Drug) as a Single Agent Compound, or (c) a method of use of the Recipient Class Drug (and not any BMS Class Drug) as a monotherapy or as used in combination with other agents, antibodies or compounds (other than Invention pertaining, whether generically or specifically, to the composition of matter, method of manufacture, formulation or a method of use of both a BMS Class Drug and a Recipient Class Drug.

"***Recipient Study Patent Rights***" means any Patent Rights that Cover any Recipient Study Invention (and not a BMS Study Invention or a Combined Therapy Invention), excluding Recipient Independent Patent Rights and Recipient Technology. For avoidance of doubt, any Patent Rights that cover both (a) a Recipient Study Invention and (b) any other type of Invention is included within the Combined Therapy Patent Rights.

"***Recipient Technology***" means all Technology Controlled by the Recipient or a Recipient Affiliate as of the Effective Date or during the Term created through efforts outside of this Agreement related to the Recipient Study Drug or the Combined Therapy. For clarity, Recipient Technology does not include (a) Inventions, (b) Study Data, or (c) Combined Therapy Clinical Trial Regulatory Documentation.

"***Regulatory Authority***" means the FDA or any other governmental authority outside the United States (whether supranational, national, federal, provincial and/or local) that is the counterpart to the FDA, including the European Medicines Agency for the European Union.

"***Regulatory Documentation***" means, with respect to a Party's Single Agent Compound, all submissions to Regulatory Authorities in connection with the development of such Single Agent Compound, as applicable, including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents that include clinical data).

"***Results***" shall have the meaning set forth in Section 9.6(b).

"***Right of Cross-Reference***" means, with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to a Party's Single Agent Compound (and, in the case of BMS, the Right to Cross-Reference the Combined Therapy IND and any Regulatory Documentation and data contained therein), only to the extent necessary for the conduct of the Combined Therapy Clinical Trial in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder, and, except as to information contained in the Combined Therapy IND pertaining to the Combined Therapy, without the disclosure of such information to such Party.

"***Safety Issue***" means any information suggesting an emerging safety concern or possible change in the risk-benefit balance for the BMS Study Drug, including information on a possible causal relationship between an Adverse Event and a drug, the relationship being unknown or incompletely documented previously.

"***Safety Signal***" means information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

"***Samples***" means biological specimens collected from Combined Therapy Clinical Trial study subjects (including fresh and/or archived tumor samples, serum, peripheral blood mononuclear cells, plasma, and whole blood for RNA and DNA sample isolation).

"***Shortage***" shall have meaning set forth in Section 4.5.

"***Single Agent Compound***" or "***Compound***" means, with respect to (a) the Recipient, the Recipient Study Drug, as monotherapy, and (b) BMS, the BMS Study Drug, as monotherapy.

"***Sponsor***" means an applicant or holder of clinical studies applications/notifications.

"***Study Data***" shall have the meaning set forth in Section 8.1.

"***Sunshine Laws***" shall have the meaning set forth in Section 9.7(c).

"***Supply and Quality Documentation***" shall have the meaning set forth in Section 4.3.

"***Technology***" means information, inventions, discoveries, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results not generally known to the public (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, whether or not patentable, in written, electronic or any other form now known or hereafter developed and materials, including Regulatory Documentation.

"***Term***" shall have the meaning set forth in Section 12.1.

"***Territory***" means all countries excluding the Ono Territory.

"***Third Party***" means any Person or entity other than the Recipient and BMS and their respective Affiliates.

"***Third Party Claim***" shall have the meaning set forth in Section 11.1.

"***Third Party License Payments***" means any payments (e.g., upfront payments, milestones, royalties) due to any Third Party under license agreements or other written agreements granting rights to intellectual property owned or controlled by such Third Party to the extent that such rights are necessary for (a) the making, using or importing of a Party's Single Agent Compound for the conduct of the Combined Therapy Clinical Trial, or (b) the conduct of the Combined Therapy Clinical Trial.

"***TP Study Costs***" shall have the meaning set forth in Section 7.2.

ARTICLE 2

SCOPE

2.1 Scope.

(a) The Recipient will conduct the Combined Therapy Clinical Trial in accordance with the agreed upon Protocol and the terms of this Agreement. The Recipient shall be solely responsible for the content of the Protocol; *provided that*: (i) the Recipient will notify BMS of any proposed material amendments to the draft Protocol attached as Appendix A to this Agreement (or to the final Protocol initially approved by an IRB) and the Recipient will consider any comments provided by BMS regarding the proposed amendments and (ii) any changes to the draft Protocol attached as Appendix A (or to the final Protocol initially approved by an IRB) that pertain to the administration of the BMS Study Drug must be reviewed and expressly approved by BMS in writing or the change may not be implemented. BMS shall have [**] from the date on which the Recipient provides the applicable Protocol amendment to BMS to approve or provide any comments to the Recipient concerning the proposed amendment.

(b) The Combined Therapy Clinical Trial shall be conducted under the Recipient's IND, and shall be conducted only in the Territory. The Recipient shall be the sole holder of all legal interests in its IND; *provided, however, that* the Recipient may not grant any Third Party any Right of Cross-Reference with respect to any portion of its IND pertaining to BMS's Single Agent Compound for use as monotherapy or for use in combination with any molecules, agents, antibodies or compounds other than the Recipient Study Drug.

(c) BMS will make available its current package insert for the BMS Study Drug in the Territory available to the Recipient and will provide any updates thereto at the same time as the same are made publicly available.

(d) If the Recipient and BMS agree that the Recipient will require access to the investigator's brochure for the BMS Study Drug in order for the site to conduct the Combined Therapy Clinical Trial, then (i) BMS will provide the current version of its Investigator Brochure to the Recipient promptly and (ii) will thereafter, until the conclusion of the Combined Therapy Clinical Trial, provide to the Recipient, upon reasonable request, the latest investigator's brochure for the BMS Study Drug or any amendments thereto in accordance with BMS's customary practices for same. The Recipient shall, and shall require that any clinical trial sites for the Combined Therapy Clinical Trial shall, use any such data provided pursuant to this Section 2.1(d) solely (A) to evaluate the safety and efficacy of the BMS Study Drug and the Combined Therapy for use in Combined Therapy Clinical Trial, (B) to meet any regulatory requirements pertaining to the conduct of the Combined Therapy Clinical Trial and (C) to enable the Recipient to draft and update as necessary the investigator's brochure for the Combined Therapy Clinical Trial. The Recipient will ensure that clinical trial sites for the Combined Therapy Clinical Trial are obligated to protect such information and disclosures as set forth in Article 9. The Recipient's right to use the investigator's brochure provided by BMS shall terminate upon the expiration or termination of the Combined Therapy Clinical Trial and shall not be used for purposes of conducting any other clinical studies.

(e) If requested in writing by the Recipient and agreed to by BMS (such consent not to be unreasonably withheld), BMS shall provide a Right of Cross-Reference as needed to its existing Regulatory Documentation for BMS's Single Agent Compound for those countries in the Territory where the Combined Therapy Clinical Trial will be conducted solely as necessary to allow the Combined Therapy Clinical Trial to be conducted under the Combined Therapy IND in an applicable country; *provided that* such Right of Cross-Reference shall terminate upon the expiration or termination of this Agreement and shall not be used for purposes of conducting any other clinical studies, except that, in the case of termination for a Material Safety Issue pursuant to Section 12.4, such Right of Cross-Reference shall remain in effect solely (i) to the extent necessary to permit the Recipient to comply with any outstanding obligations required by a Regulatory Authority and/or Applicable Law or (ii) as necessary to permit the Recipient to continue to dose subjects enrolled in the Combined Therapy Clinical Trial through completion of the Protocol if required by the applicable Regulatory Authority(ies) and/or Applicable Laws.

(f) If PDL-1 biomarker testing is incorporated into the Protocol, the Recipient agrees to use the commercially available [**] to perform such testing.

(g) The Recipient shall refer to the applicable BMS Study identification number (CA209-8MN) in all Combined Therapy Clinical Trial reports, reports of Serious Adverse Events, BMS Study Drug requests, and all other material submissions or communications to BMS relating to the Protocol.

2.2 Adverse Event Reporting.

(a) This Section 2.2 shall govern safety reporting arising from the Combined Therapy Clinical Trial. The Recipient will manage all drug safety reporting activities for the Combined Therapy Clinical Trial.

(b) The Recipient will forward to BMS at the contact information below via fax or secure e-mail in a CIOMS form all fatal or life threatening SAE reports within [**] of Date of First Receipt, all other SAE reports, reports of exposure during pregnancy (maternal and paternal) and reports of suspected transmission of an infectious agent via the BMS Study Drug or Combined Therapy within [**] of Date of First Receipt, in each case for the BMS Study Drug and the Combined Therapy administered in the Combined Therapy Clinical Trial.

BMS – Adverse Event Reporting Contact	
E-mail	[**]
Fax	[**]
Acknowledgment of ICSR receipt:	[**]

(c) Each Party shall collect, use and disclose Personal Data obtained in the course of performing the pharmacovigilance activities under this Section 2.2 solely for the purposes of complying with the regulatory obligations as described in this Agreement, or as otherwise required by Applicable Law or by a court order. Both Parties will use electronic, physical, and other safeguards appropriate to the nature of the information to prevent any use or disclosure of Personal Data other than as provided for by this Agreement and permitted under the ICF. Both Parties will also take reasonable precautions to protect such Personal Data from accidental, unauthorized, or unlawful alteration or destruction. Each Party will notify the other Party promptly of any accidental, unauthorized, or unlawful destruction, loss, alteration, or disclosure of, or access of such Personal Data.

(d) The Recipient will promptly make available to BMS upon request such records that the Recipient Controls as is necessary or useful to perform medical assessment of any Adverse Event associated with the use of the BMS Study Drug or Combined Therapy reported during the Combined Therapy Clinical Trial that is forwarded to BMS under this Agreement. The Recipient will designate a single point of contact within its organization (and will provide to BMS the email address of such point of contact prior to the start of the Combined Therapy Clinical Trial) for any pharmacovigilance-related follow-up questions that BMS would have.

(e) The Recipient shall perform case level reconciliation to confirm that BMS has received all reports required under this Agreement. The Recipient shall e-mail [**] to request a reconciliation report for the Combined Therapy Clinical Trial. The Recipient shall reconcile the cases identified as being transmitted to BMS on BMS's reconciliation report and those contained in the Combined Therapy Clinical Trial database. The Recipient shall send missing case-level events to BMS Global Pharmacovigilance at [**] or by fax at [**]. The Recipient shall perform such reconciliation every [**], unless otherwise agreed by BMS in writing.

(f) As Sponsor, the Recipient will be responsible for submitting all applicable Individual Case Safety Report (ICSRs) and aggregate report submissions to Regulatory Authorities for the Combined Therapy Clinical Trial. The Recipient will provide BMS with the final version of any aggregate report relating to the Combined Therapy Clinical Trial at the time of submission. The Recipient will also submit appropriate safety letters or safety reports to study investigators, the reviewing IRB and authorized Regulatory Authorities in accordance with Applicable Law.

(g) In the event that BMS produces any Development Safety Update Report ("***DSUR***") in respect to the BMS Study Drug, BMS will provide to the Recipient upon request, and for the duration of the Combined Therapy Clinical Trial, copies of the executive summary and any line listings of Serious Adverse Drug Reactions extracted from the final DSUR for information purposes only and to assist the Recipient in generation of their own clinical trial aggregate report, where applicable. The Recipient agrees not to forward such BMS DSUR sections to any Third Party, except to its Affiliates, consultants, advisors and contractors under obligations of confidentiality for generation of such a clinical trial aggregate report.

(h) If the Recipient determines there is a significant Safety Issue or significant Safety Signals arising in a clinical trial that may be associated with the BMS Study Drug or Combined Therapy, the Recipient will disclose such information to BMS promptly after such determination.

(i) BMS will ensure that any urgent Safety Issues or Safety Signals relating to the BMS Study Drug will be communicated to the Recipient promptly after such determination.

2.3 Clinical Study Designated Contact. Each Party will designate an employee within its organization (the "***Designated Clinical Contact***") who will coordinate and/or facilitate:

(a) the review of Protocol amendments submitted by the Recipient for BMS approval and with whom comments thereon may be discussed;

(b) any BMS clinical and regulatory responsibilities and communications regarding the Combined Therapy Clinical Trial;

(c) internal BMS review of any document or regulatory communication and the provision of any BMS comments; and

(d) discussion of any other topics or issues relating to the Combined Therapy Clinical Trial requested by the Recipient or BMS.

2.4 Conduct. Each Party shall use Commercially Reasonable Efforts to (a) perform and fulfill its respective activities under the Combined Therapy Clinical Trial and this Agreement on a timely basis and in an effective manner consistent with prevailing standards, (b) supply the quantities of its Compound in accordance with Article 4 as needed to conduct the Combined Therapy Clinical Trial on a timely basis, and, in the case of the Recipient, package and deliver same to study sites on a timely basis, and (c) in the case of the Recipient, conduct and complete the Combined Therapy Clinical Trial on a timely basis in accordance with the Protocol and Third Party agreements relating thereto, and provide sufficient resources, funding and personnel to conduct and perform the Combined Therapy Clinical Trial on a timely basis in accordance with the Protocol for same and the terms of this Agreement. Each Party shall perform its duties for the Combined Therapy Clinical Trial in accordance with Applicable Law, including GCP, GLP and GMP as applicable.

ARTICLE 3

LICENSE GRANTS

3.1 Grant by BMS. Subject to the terms of this Agreement, BMS hereby grants, and shall cause its Affiliates to grant, to the Recipient a non-exclusive, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.2) under the BMS Independent Patent Rights and BMS Technology to use the BMS Study Drug solely within the Territory and solely to the extent necessary to discharge the Recipient's obligations under this Agreement with respect to the conduct of the Combined Therapy Clinical Trial in the Territory.

3.2 Sublicensing.

(a) The Recipient shall have the right to grant sublicenses under the licenses granted to it under Section 3.1, to Affiliates and to Third Parties, if required for an Affiliate or a Third Party to perform its duties with respect to the conduct of the Combined Therapy Clinical Trial, solely as necessary to assist the Recipient in carrying out its responsibilities with respect to the Combined Therapy Clinical Trial.

(b) With regard to any such sublicenses permitted and made under this Agreement, (i) the sublicensees, except Affiliates (so long as they remain Affiliates of the Recipient), shall be subject to written agreements that bind such sublicensees to obligations that are consistent with the Recipient's

obligations under this Agreement including confidentiality and non-use provisions no less restrictive than those set forth in herein, and provisions regarding intellectual property that ensure that the Parties will have the rights provided under this Agreement to any intellectual property relating to their Single Agent Compound and/or the Combined Therapy created by such sublicensee, (ii) the Recipient shall provide written notice to BMS of any such sublicense (and obtain approval for sublicenses to Third Parties other than clinical trial sites); and (c) the Recipient shall remain liable to the other Party for all actions of the Recipient's sublicensees.

3.3 No Implied Licenses. Unless and except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any intellectual property of the other Party, including Confidential Information disclosed to it under this Agreement or under any Patent Rights Controlled by the other Party or its Affiliates.

ARTICLE 4

MANUFACTURE AND SUPPLY

4.1 Recipient Study Drug Manufacture and Supply.

(a) The Recipient shall be responsible, at its sole costs and expense, for manufacturing, packaging and labeling (or having manufactured, packaged or labeled) GMP-grade quantities of the Recipient Study Drug, as well as obtaining any other drug (other than the BMS Study Drug provided by BMS pursuant to Section 4.2) required for the conduct of the Combined Therapy Clinical Trial, and shall package and label if and as required by the Protocol and/or applicable Regulatory Authorities all drugs (including the BMS Study Drug) used in the Combined Therapy Clinical Trial, on a timely basis and in accordance with applicable specifications as required for the conduct of the Combined Therapy Clinical Trial. The Recipient Study Drug shall be manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the Recipient Study Drug used by the Recipient for its other clinical trials of the Recipient Study Drug.

(b) The Recipient shall provide BMS with prompt notice of any Manufacturing and supply issues with respect to the Recipient Study Drug or BMS Study Drug that may adversely impact the conduct or timelines of the Combined Therapy Clinical Trial.

4.2 BMS Study Drug.

(a) Manufacture and Supply. BMS shall Manufacture or have Manufactured the BMS Study Drug in reasonable quantities needed, and at the points in time as agreed to by the Parties, for the Combined Therapy Clinical Trial, and shall supply such BMS Study Drug as commercially labeled to the Recipient or its designee for use solely in the Combined Therapy Clinical Trial. The Recipient will at its sole expense, package and label the BMS Study Drug for use in the Combined Therapy Clinical Trial to the extent necessary. The cost of Manufacture and supply (including shipping, taxes and duty, if applicable) of the BMS Study Drug for the Combined Therapy Clinical Trial shall be borne solely by BMS, and BMS shall bear the risk of loss for such quantities of BMS Study Drug until delivery of such quantities of BMS Study Drug to the Recipient or its Designated Supply Contact(s). BMS shall also be responsible for the payment of any Third Party License Payments that may be due based on the manufacture, supply and use of the BMS Study Drug used in the Combined Therapy Clinical Trial. The BMS Study Drug shall be manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the BMS Study Drug used by BMS for its other clinical trials of the BMS Study Drug. BMS shall deliver certificates of analysis, and any other documents specified in the Supply and Quality Documentation, including such documentation as is necessary to allow the Recipient to compare the BMS Study Drug

certificate of analysis to the BMS Study Drug specifications. Pursuant to the Supply and Quality Documentation, BMS shall be responsible for the regulatory compliance of the quality of the BMS Study Drug at the time the BMS Study Drug is delivered to the Recipient with the regulatory filings in the countries in the Territory where the Combined Therapy Clinical Trial will be performed. Subject to Section 4.4, the Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) relating to the BMS Study Drug in connection with this Agreement.

(b) Use of BMS Study Drug Supplied by BMS to the Recipient. The Recipient shall use the quantities of BMS Study Drug supplied to it under this Agreement solely as necessary for, and in accordance with, this Agreement and the Protocol, and for no other purpose, including as a reagent or tool to facilitate its internal research efforts, for any commercial purpose, or for other clinical or non-clinical research unrelated to the Combined Therapy Clinical Trial. Except as may be required or expressly permitted by the Protocol or the Supply and Quality Documentation, the Recipient shall not perform, and shall not allow any Third Party to perform, any analytical testing of the quantities of BMS Study Drug supplied to it under this Agreement. If Study Drug supplied by BMS is lost, damaged, destroyed or becomes unable to comply with applicable specifications while under the control of the Recipient or any of its (sub)contractors, including common carriers and clinical study sites contracted by the Recipient, BMS shall not be obligated to replace same and if BMS does elect to do so, BMS may elect to charge the Recipient a reasonable replacement cost to replace same...

4.3 Supply and Quality Documentation. BMS shall supply the BMS Study Drug to the Recipient in accordance with such supply and quality addenda or agreement(s) as the Parties may agree (the "***Supply and Quality Documentation***"). The Supply and Quality Documentation will, among other things, (i) specify the vial sizes of BMS Study Drug to be supplied by BMS to the Recipient, (ii) confirm that the BMS Study Drug shall be supplied in commercially labeled vials, (iii) address the acceptable expiration dates of such supplied BMS Study Drug to align with the needs of the Combined Therapy Clinical Trial; and (iv) memorialize the Parties' agreement regarding appropriate BSE/TSE statements.. The Parties shall finalize and execute the Supply and Quality Documentation within [**] of the Effective Date, but in no event later than the date on which the first shipment of the BMS Study Drug is supplied for use in the Combined Therapy Clinical Trial. The Supply and Quality Documentation shall outline the additional roles and responsibilities relative to the quality of BMS Study Drug in support of the Combined Therapy Clinical Trial. It shall include the responsibility for quality elements as well as exchanged GMP documents and certifications required to release the BMS Study Drug for the Combined Therapy Clinical Trial. In addition, the Supply and Quality Documentation shall detail the documentation required for each shipment of BMS Study Drug supplied to the Recipient or its designee for use in the Combined Therapy Clinical Trial.

4.4 Supply Forecast. Estimated supply and delivery details will be outlined in the Supply and Quality Documentation and will be updated by the Parties by mutual agreement (which agreement can be effected by the Parties' Designated Supply contacts and without need for an amendment to this Agreement) based on the actual enrollment. The Recipient will promptly inform BMS of any change in its requirements, and BMS will endeavor to accommodate any change in the supply quantities requested by the Recipient so long as it does not unduly disrupt BMS's ongoing business activities.

4.5 Shortages. In the event of a supply or manufacturing issues, interruption or shortage of BMS Study Drug as determined by BMS pursuant to its internal processes and policies (a "***Shortage***"), such that BMS reasonably believes that it will not be able to fulfill its supply obligations under this Agreement or may adversely impact the conduct or timelines of the Combined Therapy Clinical Trial, BMS will provide written notice thereof as soon as reasonably practicable to the Recipient (including the quantity of BMS Study Drug that BMS reasonably estimates it will be able to supply) and, upon request, the Parties will promptly discuss such situation (including how the quantities of BMS Study Drug that BMS is able to

supply under this Agreement will be allocated within the Combined Therapy Clinical Trial). Notwithstanding anything to the contrary contained herein, in the event of a Shortage of the BMS Study Drug, BMS will have sole discretion, subject to Applicable Law, to determine the quantity of BMS Study Drug it will be able to supply as a result of such Shortage; provided, however, that BMS shall consider in good faith the needs of patients who are actively being treated with BMS Study Drug, including Combined Therapy Clinical Trial patients, in making such determination. BMS will not be deemed to be in breach of this Agreement for failure to supply any other quantities of BMS Study Drug hereunder as a result of a Shortage. Any such allocation of the BMS Study Drug in accordance with this Section 4.5 will the Recipient's exclusive remedy with respect to a Shortage.

4.6 Customs Valuation. The Recipient will provide BMS in writing with a list of each country in which it proposes to conduct the Combined Therapy Clinical Trial and for which it has executed or plans to execute any site agreement or CRO agreement. During the conduct of the Combined Therapy Clinical Trial, the Recipient will send in writing any changes to the list of participating countries to BMS one month prior to the end of each Quarter. If no changes are sent to BMS by the Recipient for a particular Quarter, the prior Quarter's participating country list will be used as the basis for customs valuation for that Quarter. BMS will provide the Recipient with country-specific customs valuations initially for the BMS Study Drug prior to initiation of the Combined Therapy Clinical Trial and at the end of each Quarter during the conduct of the Combined Therapy Clinical Trial. The Recipient will use the BMS provided values for the import/export process to the listed participating countries and not make any change to such valuations without BMS's prior written consent.

4.7 Designated Supply Contact. Each Party will designate an individual (the "***Designated Supply Contact***") that a Party may contact to assist with coordinating supplies and facilitating the resolution of any issues or concerns arising in connection with the supply of the BMS Study Drug for use in the Combined Therapy Clinical Trial.

ARTICLE 5

RESPONSIBILITIES

5.1 Specific Responsibilities of the Recipient. The Recipient shall, subject to the terms of the Protocol, applicable terms and conditions of this Agreement, and any other agreement between the Parties relating to the Combined Therapy Clinical Trial, manage and be responsible for the conduct of the Combined Therapy Clinical Trial, including timelines and contingency planning. In particular, and not in limitation of the foregoing, the Recipient shall perform (itself and/or through Third Parties, including clinical trial sites, CROs and investigators) and/or be responsible for the following (items (a) to (p) below, collectively the "***Operational Matters***") with respect to the Combined Therapy Clinical Trial:

(a) compiling, amending and filing all necessary Combined Therapy Clinical Trial Regulatory Documentation with Regulatory Authority(ies), maintaining and acting as the sponsor of record as provided in 21 CFR 312.50 (and applicable comparable ex-US laws) with responsibility, unless otherwise delegated in accordance with 21 CFR 312.52 (and applicable comparable ex-US laws), for the Combined Therapy Clinical Trial and making all required submissions to Regulatory Authorities related thereto on a timely basis;

(b) conducting clinical study start-up activities, communicating with and obtaining approval from IRBs for the Protocol and other relevant documents for the Combined Therapy Clinical Trial as applicable, as well as patient recruitment and retention activities;

(c) listing of the Combined Therapy Clinical Trial, if it is required to be listed on a public database on www.clinicaltrials.gov or other public registry in any country in which such Combined Therapy Clinical Trial is being conducted, all in accordance with Applicable Law and in accordance with its internal policies relating to clinical trial registration;

(d) whenever reasonably feasible, providing BMS with reasonable advance notice of meetings or other non-written communications with a Regulatory Authority and the opportunity (unless prohibited by a Regulatory Authority) to participate in each such meeting or other non-written communication, to the extent involving a safety, efficacy or toxicology issue relating to the Combined Therapy or the BMS Study Drug or any other matter that could have an adverse effect on the BMS Study Drug. In such case, whenever reasonably feasible consistent with Regulatory Authority demands, the Recipient will provide BMS with the opportunity to review, provide comments to the Recipient within [**] on, and, if inconsistent with the Protocol, approve all submissions and written correspondence with a Regulatory Authority that relates to the BMS Study Drug;

(e) provide BMS (i) a written summary of meetings or other non-written communications with a Regulatory Authority within [**] of such meeting or communication, except in instances in which BMS participated in such meetings or other non-written communications, and (ii) copies of any official correspondence to or from a Regulatory Authority within [**] of receipt or provision, in each case of (i) or (ii) to the extent involving a safety, efficacy or toxicology issue relating to the Combined Therapy or the BMS Study Drug or any other matter that could have an adverse effect on the BMS Study Drug, and copies of all material Combined Therapy Clinical Trial Regulatory Documentation and correspondence that relates to same within [**] of submission to Regulatory Authorities;

(f) subject to the terms of this Agreement, the selection and payment of, negotiation of the terms of, contracting with, managing and overseeing compliance of its agreement by and the receipt of contract deliverables from, any CRO or vendor selected by the Recipient to assist in the performance of the Combined Therapy Clinical Trial. The Recipient shall determine and approve contract deliverables and manage contract performance, including executing site contracts, drafting and obtaining IRB approval for site informed consent forms (each an "***ICF***"), obtaining signed ICFs, monitoring plans, etc. The Recipient will be responsible for ensuring that all such contracts and ICFs: (i) do not conflict with the terms of this Agreement, (ii) allow the Recipient to provide BMS with access to and use of Study Data, Samples, and other information and documents as required pursuant to this Agreement (and in no event less than the same use rights granted to the Recipient), (iii) do not adversely affect the BMS Technology or BMS Independent Patent Rights (or the enforcement or defense thereof), the [**], the Combined Therapy, or the BMS Study Drug as monotherapy, (iv) do not impose a new obligation, whether direct, indirect, or contingent, upon BMS that is not set forth in this Agreement, (v) do not confer a benefit upon the Recipient that is not also conferred upon BMS, (vi) retain each of the Parties' respective intellectual property rights in the Recipient Study Drug, BMS Study Drug and Combined Therapy consistent with this Agreement, and (vii) comply with Applicable Law;

(g) providing BMS (if requested by BMS) with copies of each final site template of the Combined Therapy Clinical Trial's ICF. The Recipient shall ensure that each ICF does not impose any financial obligation, liability, damages or other cost upon BMS with respect to any injury (including death) suffered by a Combined Therapy Clinical Trial subject whether or not resulting from the administration of the BMS Study Drug or direct a study subject to BMS to seek reimbursement for any costs or seek compensation for any injury incurred in connection with the Combined Therapy Clinical Trial;

(h) if requested by BMS, providing BMS within [**] with minutes from any and all external drug safety monitoring boards for the Combined Therapy Clinical Trial after receipt by the Recipient, to the extent relating to the BMS Study Drug or the Combined Therapy;

(i) informing and updating BMS on a [**] basis (with significant issues to be communicated promptly after the Recipient becomes aware of same) regarding all Operational Matters, so that if BMS has any significant concerns or material disagreements regarding same, the matter can be discussed with the Recipient. Without limiting the foregoing, the Recipient shall inform BMS [**] as to the overall Combined Therapy Clinical Trial progress, [**], and any other Combined Therapy Clinical Trial-related matters requested by BMS to the extent involving a safety, efficacy or toxicology issue relating to the Combined Therapy or the BMS Study Drug or any other matter that could have an adverse effect on the BMS Study Drug;

(j) owning and being responsible for (or appointing a Third Party to be responsible for) the maintenance of the Global Safety Database and being responsible for safety reporting, collecting, evaluating and reporting Serious Adverse Events, other safety data and any further pharmacovigilance information from the Combined Therapy Clinical Trial;

(k) analyzing the Study Data and providing BMS with access to the Study Data as follows:

(i) top line data and a copy of all Clinical Study Reports (CSRs), including all Appendices and Addendums, in each case, reasonably promptly as and when received by the Recipient's clinical management;

(ii) if requested by BMS, sharing with BMS for review and comment drafts of interim and/or final clinical trial report (and/or statistical analysis in accordance with the Protocol) from the Combined Therapy Clinical Trial;

(iii) if requested by BMS, within [**] after database lock, access to those safety databases that will be used for any interim review by an external consultant (or drug safety monitoring board, if required);

(iv) if requested by BMS, within [**] after database lock, access to case report forms or patient profiles for all patients in the Combined Therapy Clinical Trial;

(v) if requested by BMS, within [**] of the creation of an electronic clean database for the Combined Therapy Clinical Trial, an electronic copy of the clean database (the form and format of the clean database to be reasonably acceptable to both Parties);

(vi) if requested by BMS, subject to any third party requirements, providing BMS with raw or derived datasets and any programs or SAS codes, including associated documentation, to be used for any statistical analysis plan for the Combined Therapy Clinical Trial; and

(vii) (A) safety analyses, (B) new and/or changing Safety Signals and Safety Issues, (C) new and/or changing toxicology and efficacy signals, and (D) any statistical analysis, immunogenicity analysis, or bioanalysis, in each case relating to the BMS Study Drug, the Recipient Study Drug and/or the Combined Therapy, as and when the same are received by the Recipient;

(l) obtaining supplies of any co-medications, to the extent any such co-medications are required for use in the Combined Therapy Clinical Trial, and providing to BMS any information related to the Combined Therapy Clinical Trial that is provided to the manufacturer of any co-medication within [**] after the provision of the information to the manufacturer;

(m) if requested by BMS, information regarding the pharmacokinetics, efficacy and safety of the Recipient Study Drug alone or in combination with the BMS Study Drug;

(n) performing either directly or through third parties collection of Samples required by the Protocol;

(o) handling and addressing inquiries from the Combined Therapy Clinical Trial subjects and investigators; and

(p) such other responsibilities as may be agreed to by the Parties.

5.2 BMS Operational Responsibilities. BMS shall be responsible for the following activities:

(a) Manufacturing and supplying GMP-grade quantities of the BMS Study Drug, as further described in Article 4 above, and, where and to the extent provided in the Supply and Quality Documentation, providing necessary GMP information and documentation that enables the Recipient Qualified Person (as such term will be defined in the Supply and Quality Documentation) to release BMS Study Drug for the Combined Therapy Clinical Trial;

(b) where and to the extent provided in the Supply and Quality Documentation, providing for the release by a Qualified Person or providing the necessary documentation in support of such quality release, of the BMS Study Drug if such release is required for the Combined Therapy Clinical Trial;

(c) to the extent necessary for the conduct of the Combined Therapy Clinical Trial, providing a Right of Cross-Reference to the relevant Regulatory Documentation for the BMS Study Drug as set forth in Section 2.1(b) and/or (e), if applicable, to the BMS investigator's brochure for the BMS Study Drug (and updates thereto) as provided in Section 2.1(d);

(d) informing Recipient as soon as reasonably practicable about any recall of any BMS Study Drug supplied to Recipient pursuant to this Agreement and, thereafter, replacing at its own expense any such supplied but recalled BMS Study Drug with other, non-recalled BMS Study Drug as soon as reasonably practicable;

(e) responding to questions or requests from Regulatory Authorities related to the BMS Study Drug in connection with the Combined Therapy Clinical Trial to the extent either required by Regulatory Authorities or because the Recipient does not have the requested information or answers; and

(f) such other responsibilities as may be agreed to by the Parties.

5.3 Other Clinical Trials. Nothing in this Agreement shall preclude either Party from conducting any other clinical trials as it may determine in its discretion, so long as it does not use or rely on the Confidential Information that is solely owned by the other Party in doing so.

(a) Subsequent Studies. After completion of the Combined Therapy Clinical Trial, the Parties agree to discuss in good faith additional Combined Therapy Clinical Trials of the BMS Study Drug with the Recipient Study Drug. If the Parties jointly agree to conduct any such further clinical trials, such further clinical trials will, unless otherwise mutually agreed in writing, be conducted in accordance with a separate agreement.

INTELLECTUAL PROPERTY

6.1 Inventions and related Patent Rights. All rights to Inventions shall be allocated as follows:

(a) Recipient Ownership. Subject to the terms of this Agreement, all Recipient Study Inventions and Recipient Study Patent Rights shall be owned solely by the Recipient, and the Recipient will have the full right to exploit such Recipient Study Inventions and Recipient Study Patent Rights without

the consent of, or any obligation to account to, BMS. BMS shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) its right, title and interest in any Recipient Study Inventions and Recipient Study Patent Rights to the Recipient. BMS shall execute such further documents and provide other assistance as may be reasonably requested by the Recipient to perfect the Recipient's rights in such Recipient Study Inventions and Recipient Study Patent Rights, all at the Recipient's expense. The Recipient shall have the sole right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any Recipient Study Patent Rights at its own expense.

(b) BMS Ownership. Subject to the terms of this Agreement, all BMS Study Inventions and BMS Study Patent Rights shall be owned solely by BMS, and BMS will have the full right to exploit such BMS Study Inventions and BMS Study Patent Rights without the consent of, or any obligation to account to, the Recipient. The Recipient shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) all its right, title and interest in any BMS Study Inventions and BMS Study Patent Rights to BMS. The Recipient shall execute such further documents and provide other assistance as may be reasonably requested by BMS to perfect BMS's rights in such BMS Study Inventions and BMS Study Patent Rights, all at BMS's expense. BMS shall have the sole right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any BMS Study Patent Rights at its own expense.

(c) Combined Therapy Inventions. All Combined Therapy Inventions and Combined Therapy Patent Rights shall be jointly owned by the Parties, and either Party shall have the right to freely exploit the Combined Therapy Inventions and Combined Therapy Patent Rights, both within and outside the scope of this Agreement, without accounting or any other obligation to the other Party (except as expressly set forth in this Section 6.1(c) and Section 6.3(d) with regard to the filing, prosecution, maintenance and enforcement of Combined Therapy Patent Rights) and each Party may use, exploit and grant licenses (with right to sublicense) to Third Parties under its interest in such Combined Therapy Inventions and Combined Therapy Patent Rights. The Recipient, using outside counsel acceptable to both Parties, shall be responsible, at its sole discretion, for preparing and prosecuting Patent applications and maintaining Patents within the Combined Therapy Patent Rights. The Recipient shall keep BMS advised as to material developments and steps to be taken with respect to prosecuting any such Patent Rights and shall furnish BMS with copies of applications for such Patent Rights, amendments thereto and other related correspondence to and from patent offices, and permit BMS a reasonable opportunity to review and offer comments prior to submitting such applications and correspondence to the applicable governmental authority (and will take BMS's comments into account in preparing same). BMS shall reasonably assist and cooperate in obtaining, prosecuting and maintaining the Combined Therapy Patent Rights. Notwithstanding the foregoing, the Recipient shall not take any position in a submission to a patent office concerning a Combined Therapy Invention that interprets the scope of a Patent Right of BMS without the prior written consent of BMS. The Recipient shall be reimbursed for any costs and expenses incurred in prosecuting Combined Therapy Patent Rights and the subsequent maintenance of Combined Therapy Patent Rights by BMS such that BMS shall be responsible for [**] percent ([**]%) of such costs. From time-to-time, the Recipient shall invoice BMS such amounts and BMS shall pay the Recipient such invoiced amounts within [**] after receipt of an invoice therefor. The Parties shall discuss in good faith the countries in which the Combined Therapy Patent Rights will be filed. In case one of the two Parties decides not to file or maintain a Combined Therapy Patent Right in a given country (and also elects not to reimburse the other Party for [**] percent ([**]%) of the costs of prosecution and maintenance of such Combined Therapy Patent Right in such country), the other Party shall have the right to file, prosecute and maintain such Combined Therapy Patent Right in such country in its own name and at its own expense. In this case, the Party who decides not to file or maintain (and also decides not to reimburse the other Party for its share of the costs of) a Combined Therapy Patent Right for a given country shall promptly assign its rights to the

Combined Therapy Patent Right in said country to the Party (the "***Filing Party***") who wishes to file or maintain said Combined Therapy Patent Right in such country and the Filing Party shall grant, and hereby grants, to the other Party an irrevocable, perpetual, fully-paid, non-exclusive license, with the right to grant and authorize sublicenses, under such Combined Therapy Patent Rights to make, have made, use, sell, offer for sale, import and other exploit products and services in such country. The Party who does not wish to file or maintain a Combined Therapy Patent Right in any country shall assist in the timely provision of all documents required under national provisions to register said assignment of rights with the corresponding national authorities at the sole expenses of the Party who wishes to file or maintain such Combined Therapy Patent Right in that given country. If the Parties cannot agree with respect to the decision to file or maintain a Combined Therapy Patent Right within [**] subsequent to the initiation of the Parties' good faith efforts to resolve any disagreement, then either Party shall have the right to file or maintain any Combined Therapy Patent Right in the names of both Parties, provided that: (i) any such Combined Therapy Patent Right shall be jointly owned by the Parties and subject to the freedom to use and operate under such Combined Therapy Patent Right as set forth in the first sentence of this Section 6.1(c); (ii) such prosecuting Party obtains the prior consent of the non-prosecuting Party, which consent shall not be unreasonably withheld or delayed, and (iii) the non-prosecuting party reimburses the prosecuting party for its [**] share of the patent costs.

(d) Separation of Patent Rights. In order to more efficiently enable the prosecution and maintenance of the BMS Study Patent Rights, the Recipient Study Patent Rights and Combined Therapy Patent Rights relating to Inventions as described above, the Parties will use good faith efforts to separate BMS Study Patent Rights, the Recipient Study Patent Rights, Combined Therapy Patent Rights, BMS Independent Patent Rights and the Recipient Independent Patent Rights into separate patent filings to the extent possible and without adversely impacting such prosecution and maintenance or the scope of the protected subject matter.

6.2 Disclosure and Assignment of Inventions. Each Party shall disclose promptly to the other Party in writing and on a confidential basis all Inventions, prior to any public disclosure thereof or filing of Patent Rights therefor and allowing sufficient time for comment by the other Party. In addition, each Party shall, and does hereby, assign, and shall cause its Affiliates and contractors to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions as well as any Patent Rights and other intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the sole ownership provided for in Sections 6.1(a) and 6.1(b) and the joint ownership provided for in Section 6.1(c).

6.3 Infringement of Patent Rights by Third Parties.

(a) Notice. Each Party shall promptly notify the other Party in writing of any Infringement of Combined Therapy Patent Rights, of which its in-house patent counsel becomes aware.

(b) Infringement of Recipient Study Patent Rights. For all Infringements of Recipient Study Patent Rights anywhere in the world, the Recipient shall have the exclusive right to prosecute such Infringements as it may determine in its sole and absolute discretion, and the Recipient shall bear all related expenses and retain all related recoveries. BMS shall reasonably cooperate with the Recipient or its designee (to the extent BMS has relevant information arising out of this Agreement), at the Recipient's request and expense, in any such action.

(c) Infringement of BMS Study Patent Rights. For all Infringements of BMS Study Patent Rights anywhere in the world, BMS shall have the exclusive right to prosecute such Infringements as it may determine in its sole and absolute discretion, and BMS shall bear all related expenses and retain all related recoveries. The Recipient shall reasonably cooperate with BMS or its designee (to the extent that the Recipient has relevant information arising out of this Agreement), at BMS's request and expense, in any such action.

(d) Infringement of Combined Therapy Patent Rights.

(i) With respect to Infringements of Combined Therapy Patent Rights, the Parties shall mutually agree as to whether to bring an enforcement action to seek the removal or prevention of such Infringements and damages therefor and, if so, which Party shall bring such action, with any costs and expenses relating thereto to be allocated in accordance with Section 6.3(d)(ii).

(ii) Regardless of which Party brings an enforcement action pursuant to Section 6.3(d)(i) or whether the Parties reach agreement to initiate such an enforcement action, the other Party hereby agrees to cooperate reasonably in any such action, including, if required, by bringing a legal action, furnishing a power of attorney or joining as a plaintiff to such a legal action. If the Parties mutually agree to bring an enforcement action, BMS shall be responsible for [**] percent ([**]%), and the Recipient shall be responsible for [**] percent ([**]%), of the reasonable and verifiable costs and expenses incurred in connection with any such action. If either Party recovers monetary damages from any Third Party in an action agreed to by the Parties, such recovery shall be allocated first to the reimbursement of any actual, unreimbursed costs and expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel) pro rata in accordance with the aggregate amounts spent by both Parties, and any remaining amounts shall be split [**] percent ([**]%) to the Recipient and [**] percent ([**]%) to BMS, unless the Parties agree in writing to a different allocation. If the Parties do not agree to initiating such an enforcement action, (A) the Party initiating such enforcement action shall be responsible for the costs and expenses incurred in connection with such action and shall reimburse the other Party for the costs the other Party incurs for the assistance and cooperation requested by such Party and (B) the Party initiating such enforcement action shall retain all recoveries from such enforcement action. Neither Party shall enter into any settlement without the prior written consent of the other Party in connection with any proceeding under this Section 6.3(d).

6.4 Infringement of Third Party Rights.

(a) Notice. If the activities relating to the Combined Therapy Clinical Trial become the subject of a claim of infringement of a patent, copyright or other proprietary right by a Third Party anywhere in the world, the Party first having notice of the claim shall promptly notify the other Party and, without regard to which Party is charged with said infringement and the venue of such claim, the Parties shall promptly confer to discuss the claim.

(b) Defense. If both Parties are charged with infringement pursuant to a claim described in Section 6.4(a), each Party shall have the right to defend itself against such claim and the Parties shall discuss in good faith defending such claim jointly. If only one Party is charged with infringement, such Party will have the first right but not the obligation to defend such claim. If the charged Party does not commence actions to defend such claim within [**] after request by the other Party to do so, then the other Party shall have the right, but not the obligation, to defend any such claim to the extent such claim pertains to the other Party's Compound. In any event, the non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim and shall have the right to participate with separate counsel at its own expense, and the defending Party shall consider comments and suggestions on strategy for defending the action by the non-defending Party in good faith. The Party defending the claim shall bear the cost and expenses of the defense of any such Third Party infringement claim and shall have sole rights to any recovery. If the Parties jointly defend the claim, the Recipient shall bear [**] percent ([**]%), and BMS shall bear [**] percent ([**]%) of any costs and expenses of the defense of any such Third Party infringement claim; *provided, however, that*, notwithstanding the foregoing, if the claim relates solely to one Party's Compound, such Party will bear [**] percent ([**]%) of the costs and expenses of the defense of such claim and shall have the sole right, but not the obligation, to defend, settle and otherwise handle the disposition of such claim. Neither Party shall enter into any settlement concerning activities under this Agreement or the Combined Therapy that affects the other Party's rights under this Agreement or imposes

any obligations on the other Party, including any admissions of wrongdoing on behalf of the other Party, without such other Party's prior written consent, not to be unreasonably withheld or delayed, except that a Party may settle any claim that solely relates to its Compound without the consent of the other Party as long as such other Party's rights under this Agreement are not adversely impacted (in which case, it will obtain such other Party's prior written consent, not to be unreasonably withheld or delayed).

6.5 Combined Therapy Clinical Trial Regulatory Documentation. Subject to the license and other rights granted by each Party to the other Party pursuant to this Agreement, the Recipient shall solely own all right, title and interest in and to the Combined Therapy Clinical Trial Regulatory Documentation; *provided*, *however*, *that* BMS shall retain sole and exclusive ownership of any BMS Regulatory Documentation that is submitted with or referenced in the Combined Therapy Clinical Trial Regulatory Documentation and that the Recipient shall retain sole and exclusive ownership of any Recipient Regulatory Documentation that is submitted with or referenced in the Combined Therapy Clinical Trial Regulatory Documentation. This Section 6.5 is without limitation of any other disclosure obligations under this Agreement.

6.6 No Other Use. Except as expressly provided in Section 6.1, the Recipient agrees not to apply for any Patent Rights based on or containing BMS Confidential Information, and to give no assistance to any Third Party for such application without BMS's prior written authorization, and BMS agrees not to apply for any Patent Rights based on or containing the Recipient's Confidential Information, and to give no assistance to any Third Party for such application without the Recipient's prior written authorization.

6.7 Joint Research Agreement. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 USC § 100 (h).

ARTICLE 7

COSTS AND EXPENSES

7.1 Manufacturing and IP Costs. Expenses incurred as described in Article 4 (regarding Manufacturing and Supply) and Article 6 (regarding Intellectual Property) shall be borne or shared by the Parties as provided in such Articles.

7.2 TP Study Costs. For all expenses (other than those set forth in section 7.1) that are directly attributable or reasonably allocable to the conduct of the Combined Therapy Clinical Trial: (a) the Recipient will solely bear all out-of-pocket costs reasonably incurred by the Recipient (or by BMS pursuant to the following sentence) to Third Parties (including to CROs, laboratories, investigators, and clinical sites/IRBs) in connection with the performance of the Combined Therapy Clinical Trial ("***TP Study Costs***"), and (b) each Party shall be solely responsible for all of its own internal costs (including costs of individual independent contractors) incurred by such Party or any of its Affiliates. It is not expected that BMS will incur any TP Study Costs; however, in the event BMS should incur any TP Study Costs in connection with the conduct of the Combined Therapy Clinical Trial, the Recipient will reimburse BMS for same on a [**] basis within [**] following submission of an invoice therefor and appropriate supporting documentation,

provided that BMS has provided Recipient a reasonable opportunity to address the legitimacy of any TP Study Costs.

7.3 Third Party License Payments. If the conduct of the Combined Therapy Clinical Trial requires a Third Party License Payment, then the Party required to make such payment shall be responsible for same.

ARTICLE 8

RECORDS AND STUDY DATA

8.1 Records. Each Party shall maintain complete and accurate records of all work conducted with respect to the Combined Therapy Clinical Trial and of all results, information, data, data analyses, reports, records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences and developments made by or provided to either Party, or by the Parties together, in the course of such Party(ies)' efforts with respect to the Combined Therapy Clinical Trial (including any statistical analysis plan and any bioanalysis plan to be conducted pursuant to the Protocol or otherwise agreed to by the Parties) (such results, information, data, data analyses, reports, case report forms, adverse event reports, trial records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, developments, and the Protocol referred to as the "***Study Data***"). Such records shall fully and properly reflect all work done and results achieved in the performance of the Combined Therapy Clinical Trial in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

8.2 Ownership of Study Data. BMS shall own the Study Data to the extent that it relates exclusively to the BMS Study Drug ("***BMS Study Data***"), and the Recipient shall own the Study Data to the extent that it relates exclusively to the Recipient Study Drug ("***Recipient Study Data***"). Both Parties shall jointly own any Study Data that does not relate exclusively to the Recipient Study Drug or the BMS Study Drug ("***Combined Therapy Study Data***"). Each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Study Data as is necessary to fully effect the foregoing, and agrees to execute all instruments as may be reasonably necessary to effect same.

8.3 Use of Study Data.

(a) Use of a Party's Own Study Data. BMS may use and analyze the BMS Study Data for any purpose without obligation or accounting to the Recipient, who shall hold the BMS Study Data in confidence pursuant to this Agreement. The Recipient may use and analyze the Recipient Study Data for any purpose without obligation or accounting to BMS, who shall hold the Recipient Study Data in confidence pursuant to this Agreement.

(b) Use of Combined Therapy Study Data by BMS. BMS, Ono and their respective Affiliates and (sub)licensees shall have the right to use and analyze the Combined Therapy Study Data (i) in connection with the independent development, commercialization or other exploitation of the BMS Study Drug (alone or in combination with other drugs and/or other pharmaceutical agents) and/or for inclusion in the safety database for the BMS Study Drug, in each case without the consent of, or any obligation to account to, the Recipient, and (ii) to conduct studies with Samples pursuant to Section 8.5. Subject to Section 8.5, the results of all such analyses or uses shall be owned by BMS, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in a writing separate from this Agreement. BMS, Ono, and their respective Affiliates and (sub)licensees shall also be entitled to use the Combined Therapy Study Data during and following the Term to (1) make regulatory filings, meet regulatory requirements, and seek approvals for the BMS Study Drug, either alone or as part of the Combined Therapy, (2) evaluate the safety and efficacy of the Combined Therapy and the BMS Study

Drug, and (3) promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the BMS Study Drug, either alone or as part of the Combined Therapy, where permitted by and in accordance with Applicable Law; *provided that* nothing in the foregoing is intended or shall be construed as granting BMS any right or license, expressly or impliedly to make, have made, use, sell, offer for sale, or import the Recipient Study Drug. The Recipient grants BMS, Ono, their respective Affiliates and (sub)licensees a Right of Cross-Reference to the Recipient Regulatory Documentation and the Combined Therapy Clinical Trial Documentation for the Recipient Study Drug or the Combined Therapy for the sole purpose of enabling BMS, Ono and their Affiliates and sublicensees to exercise its rights under clause (1) of this Section 8.3(b), which right shall survive any expiration or termination of this Agreement.

(c) Use of Combined Therapy Study Data by the Recipient. The Recipient and its Affiliates and licensees shall have the right to use and analyze the Combined Therapy Study Data (i) in connection with the independent development, commercialization or other exploitation of the Recipient Study Drug (alone or in combination with other drugs and/or other pharmaceutical agents and/or for inclusion in the safety database for the Recipient Study Drug, in each case without the consent of, or any obligation to account to, BMS and (ii) to conduct studies with Samples pursuant to Section 8.5. Subject to Section 8.5, the results of all such analyses or uses shall be owned by the Recipient, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in a writing separate from this Agreement. The Recipient, its Affiliates and licensees shall be entitled to use the Combined Therapy Study Data during and following the Term to (1) make regulatory filings, meet regulatory requirements and seek approvals for the Recipient Study Drug, either alone or as part of the Combined Therapy, (2) evaluate the safety and efficacy of the Combined Therapy and the Recipient Study Drug, and (3) promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the Recipient Study Drug, either alone or as part of the Combined Therapy, where permitted by and in accordance with Applicable Law; *provided that* nothing in the foregoing is intended or shall be construed as granting the Recipient any right or license, expressly or impliedly, to make, have made, use, sell, offer for sale, or import the BMS Study Drug. BMS grants the Recipient, its Affiliates and licensees of the Recipient Study Drug a Right of Cross-Reference to the relevant Regulatory Documentation Controlled by BMS for the BMS Study Drug for the sole purpose of enabling the Recipient to exercise its rights under clause (1) of this Section 8.3(c) in the Territory (for clarity, such Right of Cross-Reference shall not extend to the Ono Territory or use of any Ono-controlled Regulatory Documentation), which right shall survive any expiration or termination of this Agreement.

(d) Biomarker/Dx Agent Development. Each Party may use and disclose to a Third Party the Combined Therapy Study Data and its Compound's Study Data, under obligations of confidentiality consistent with this Agreement, to develop and commercialize a biomarker or diagnostic test for use with its Compound and/or the Combined Therapy, and, unless otherwise mutually agreed by the Parties in writing, will own any intellectual property arising out of the work funded or conducted by it with or through such Third Party and shall grant, and hereby grants, to the other Party a worldwide, perpetual, irrevocable, fully paid-up, royalty-free non-exclusive license, with the right to grant and authorize sublicenses, under such intellectual property arising out of the Combined Therapy Clinical Trial, solely to develop and commercialize biomarkers and/or diagnostic tests for use with such other Party's Compound and/or the Combined Therapy. The Parties will discuss in good faith any opportunities to jointly participate in the development of any such biomarker or diagnostic test for use with the Combined Therapy.

(e) No Other Uses. All other uses of Study Data are limited solely to those permitted by this Agreement, and neither Party may use Study Data for any other purpose without the consent of the other Party during and after the Term.

8.4 Access to Study Data. Subject to the provisions of Sections 8.1, each Party shall have access to all Study Data (including de-identified patient records). The Recipient shall make such Study

Data in its possession available to BMS within a reasonable period, not to exceed [**], after such Study Data is available to or generated by the Recipient.

8.5 Samples.

(a) Samples shall be owned by the Recipient (to the extent not owned by the patient and/or the clinical trial site). Any such Samples shall be collected in accordance with the Protocol and applicable ICFs. Recipient shall be permitted to use such Samples for any purpose , including for those purposes set forth in the Protocol, without the prior written consent of BMS, provided, however, such uses that are not already set forth in the Protocol and are directed to the Combined Therapy shall be disclosed to BMS at reasonable amount of time prior to commencement of such Sample studies, such that BMS will have the opportunity to review the potential use or study design and the opportunity to remit payment for the cost of such use or associated with the performance of such study in return for co-ownership of the rights to such Samples and the data generated from such use, with the terms of such use to be set forth in a written agreement between the Parties setting forth the Samples to be used, and any appropriate terms/restrictions on such use, and costs to be borne by such parties, such terms to be agreed upon in each party's reasonable discretion. Nothing in this section 8.5(a) shall prevent BMS from remitting payment to the extent that it should require any samples. Except for intellectual property pertaining to the [**] (which shall be owned by BMS), any data and intellectual property arising out of such Sample use shall be owned by the Party conducting such study using same, *provided that*, to the extent that any such data or intellectual property relates solely to the Combined Therapy (or biomarkers solely for use with the Combined Therapy), shall be considered Combined Therapy Study Data, Combined Therapy Inventions and/or Combined Therapy Patent Rights, as the case may be. Samples for PK and ADA serum analysis will be stored for future use in the Recipient's sample repository, unless the Parties agree that BMS would store such samples, *provided that*, if the Party holding the Samples determines that it no longer has a use for the Samples and the other Party determines that it does, then the Samples shall, subject to Applicable Law and the terms of the signed ICFs, be transferred to the other Party and may be used solely thereafter by the other Party. If neither Party has any further use for the Samples, then the remaining Samples will be destroyed pursuant to the respective Party's standard operating procedures for sample retention and destruction, subject to the terms of and permission(s) granted in the informed consent forms signed by the subjects contributing the Samples in the Combined Therapy Clinical Trial.

(b) If mutually agreed, BMS will arrange for the Recipient to use BMS's preferred Third Party vendor(s), at the Recipient's expense, for bioanalytical work of Samples from Combined Therapy Clinical Trial subjects on the BMS Study Drug. Such vendor(s) will provide the results of their bioanalytical work of such Samples to the Recipient and BMS, which results will be included in the final clinical study report, along with the bioanalytical work of the Recipient Study Drug and BMS Study Drug performed by or on behalf of the Recipient. For the avoidance of doubt, all bioanalytical results for the BMS Study Drug and the Recipient Study Drug are deemed Study Data. All data derived pursuant to the Protocol from such Samples is deemed Study Data.

ARTICLE 9

CONFIDENTIALITY

9.1 Nondisclosure of Confidential Information.

(a) All written, visual, oral and electronic data, information, know-how or other proprietary information or materials, both technical and non-technical, disclosed by one Party to any other Party pursuant to this Agreement, or prior to the Effective Date and relating to matters contemplated by this agreement, and disclosed in the manner specified herein, that (a) if in tangible form, is labeled in writing as

"proprietary" or "confidential" (or similar reference) or which by its nature would reasonably be understood to be of a proprietary or confidential nature, or (b) if in oral or visual form, is identified as proprietary or confidential or for internal use only at the time of disclosure or within [**] thereafter shall be "***Confidential Information***" of the disclosing Party, and all Study Data and Inventions shall be the Confidential Information of the Party owning such Study Data or Invention (as provided in Section 8.2 with regard to Study Data and Section 6.1 with regard to Inventions). For purposes of this Agreement, regardless of which Party discloses such Confidential Information to the other, (i) all Recipient Study Inventions, Recipient Technology and Recipient Regulatory Documentation shall be Confidential Information of the Recipient and BMS shall be the receiving Party, (ii) all BMS Study Inventions, BMS Technology, and BMS Regulatory Documentation shall be Confidential Information of BMS and the Recipient shall be the receiving Party.

(b) The Parties agree that the terms of this Agreement shall be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 9.3. Except as required by Applicable Law, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party, except as permitted by Sections 9.3 and 9.6(b).

(c) Except to the extent expressly authorized in this Section 9.1 and Sections 9.2, 9.3 and 9.6 below, or as otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for a period of seven (7) years thereafter (or, in the case of Confidential Information that constitutes a trade secret of either Party, indefinitely thereafter until the Party owning such Confidential Information informs the other Party that such information is no longer considered a trade secret, *provided, however,* that such Confidential Information is clearly labeled as a trade secret in writing), it shall (A) keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other Party (including information relating to this Agreement or the transactions contemplated hereby or the terms hereof), (B) treat the other Party's Confidential Information with the same degree of care the receiving Party uses for its own confidential information but in no event with less than a reasonable degree of care; and (C) reproduce the disclosing Party's Confidential Information solely to the extent necessary or reasonably useful to accomplish the receiving Party's obligations under this Agreement or exercise the receiving Party's rights to use and disclose such Confidential Information as expressly provided for in this Agreement, with all such reproductions being considered the disclosing Party's Confidential Information, *provided that*, with respect to BMS Confidential Information that was received as confidential information from Ono, the obligations of confidentiality and nonuse shall continue until BMS has obtained Ono's written consent that the same may be freely used. Notwithstanding anything to the contrary in this Section 9.1, and subject to Section 8.3, the receiving Party may disclose the disclosing Party's Confidential Information to its employees, consultants, agents or permitted (sub)licensees solely on a need-to-know basis for the purpose of fulfilling the receiving Party's obligations under this Agreement or exercising the receiving Party's rights to use and disclose such Confidential Information as expressly provided for in this Agreement; *provided, however, that* (1) any such employees, consultants, agents or permitted (sub)licensees are bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Agreement, and (2) the receiving Party remains liable for the compliance of such employees, consultants, agents or permitted (sub)licensees with such obligations. Each receiving Party acknowledges that in connection with its and its representatives examination of the Confidential Information of the disclosing Party, the receiving Party and its representatives may have access to material, non-public information, and that the receiving Party is aware, and will advise its representatives who are informed as to the matters that are the subject of this Agreement, that State and Federal laws, including United States securities laws, may impose restrictions on the dissemination of such information and trading in securities when in possession of such information. Each receiving Party agrees that it will not, and will advise its representatives who are informed as to the matters that are the subject of this Agreement to not, purchase or sell any security of the disclosing Party on the

basis of the Confidential Information to the extent such Confidential Information constitute material nonpublic information about the disclosing Party or such security.

(d) Combined Therapy Study Data shall be treated as Confidential Information of each Party and shall not be disclosed to Third Parties except to the extent it falls within the exceptions set forth in Section 9.2 below, is authorized under this Section 9.1 or Section 9.3, is required to be filed with a Regulatory Authority or included in a product's label or package insert, is reasonably necessary to be disclosed in order for a Party to exercise its rights under Section 8.3(b) or 8.3(c) or it is disclosed pursuant to Section 9.6.

9.2 Exceptions. The obligations in Section 9.1 shall not apply with respect to any portion of Confidential Information that the receiving Party can demonstrate by contemporaneous tangible records or other competent proof:

(a) was already known to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, either (i) at the time of disclosure by the disclosing Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(b) was generally available to the public or otherwise part of the public domain either (i) at the time of its disclosure to the receiving Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, by a Third Party who had no obligation to the Party owning or Controlling the information not to disclose such information to others; or

(e) was independently discovered or developed by the receiving Party (or its Affiliates) without the use of, or reference to, the Confidential Information belonging to the disclosing Party.

9.3 Authorized Disclosure. Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patent Rights pursuant to Section 6.1(c);

(b) prosecuting or defending litigation;

(c) complying with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock is listed;

(d) disclosure, in connection with the performance of this Agreement, to Affiliates, permitted (sub)licensees, contractors, IRBs, CROs, academic institutions, consultants, agents, investigators, and employees and contractors engaged by study sites and investigators involved with the Combined Therapy Clinical Trial, each of whom prior to disclosure must be bound by terms of confidentiality and non-use at least as protective of Confidential Information as those set forth in this Article 9;

(e) disclosure of the Combined Therapy Study Data, Combined Therapy Inventions and Combined Therapy Patent Rights to Regulatory Authorities in connection with the development of the Combined Therapy, the Recipient Study Drug or the BMS Study Drug;

(f) disclosure of relevant safety information contained within the Combined Therapy Study Data to investigators, IRBs and/or ethics committees and Regulatory Authorities that are involved in other clinical trials of the Recipient Study Drug with respect to the Recipient, and the BMS Study Drug with respect to BMS, and, in the event of a Material Safety Issue, to Third Parties that are collaborating with the Recipient or BMS, respectively in the conduct of such other clinical trials of the Recipient Study Drug or the BMS Study Drug, in each case solely to the extent necessary for the conduct of such clinical trials and/or to comply with Applicable Law and regulatory requirements; and

Notwithstanding the foregoing, if a Party is required or otherwise intends to make a disclosure of any other Party's Confidential Information pursuant to Section 9.3(b) and/or Section 9.3(c), it shall give advance notice to such other Party of such impending disclosure and endeavor in good faith to secure confidential treatment of such Confidential Information and/or reasonably assist the Party that owns such Confidential Information in seeking a protective order or other confidential treatment.

9.4 Disclosure to Ono. Notwithstanding any other provision of this Agreement, BMS shall be entitled to disclose to Ono (a) the existence (but not the terms) of this Agreement, the Combined Therapy Clinical Trial and the Protocol, and (b) any other Recipient Confidential Information necessary for BMS to fulfill its obligations to Ono under the Ono-BMS Agreements; *provided that* Ono is under confidentiality obligations at least as restrictive as set forth herein. BMS shall be free to disclose to Ono and permit Ono to use the BMS Study Data and the Combined Therapy Study Data as BMS may determine (so long as such use is consistent with BMS's permitted uses under Section 8.3(b)).

9.5 Press Releases and Publications.

(a) The Parties shall jointly agree to the content and timing of all public communications with respect to this Agreement, press releases, Q&As, and the content of, and wording for, any listing the Combined Therapy Clinical Trial required to be listed on a public database or other public registry such as www.clinicaltrials.gov). For clarity, if either Party terminates this Agreement pursuant to Section 12.4, the Parties shall mutually agree upon any external communication related to such termination, which shall not include the rationale for such termination unless (and to the extent) mutually agreed by the Parties; *provided that* either Party shall be permitted to publicly disclose information that such Party determines in good faith is necessary to be disclosed to comply with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock may be listed, or pursuant to an order of a court or governmental entity.

(b) The Recipient and BMS agree to collaborate to publicly disclose, publish or present (i) top-line results from the Combined Therapy Clinical Trial, limited if possible to avoid jeopardizing the future publication of the Study Data at a scientific conference or in a scientific journal, solely for the purpose of disclosing, as soon as reasonably practicable, the safety or efficacy results and conclusions that are material to either Party under applicable securities laws, and (ii) the conclusions and outcomes (the "***Results***") of the Combined Therapy Clinical Trial at a scientific conference as soon as reasonably practicable following the completion of such Combined Therapy Clinical Trial, subject in the case of (ii) to the following terms and conditions. The Party proposing to disclose, publish or present the Results shall deliver to the other Party a copy of the proposed disclosure, publication or presentation at least [**] before submission to a Third Party. The reviewing Party shall determine whether any of its Confidential Information that may be contained in such disclosure, publication or presentation should be

modified or deleted, whether to file a patent application on any Recipient Study Invention (solely with respect to the Recipient) or BMS Study Invention (solely with respect to BMS) or Combined Therapy Invention disclosed therein. The disclosure, publication or presentation shall be delayed for an additional [**] (i.e., a total of [**] from the initial proposal) if the reviewing Party reasonably requests such extension to allow time for the preparation and filing of relevant patent applications. If the reviewing Party reasonably requests modifications to the disclosure, publication or presentation to prevent the disclosure of Confidential Information of the reviewing Party (other than the Results or Study Data), the publishing Party shall edit such publication to prevent the disclosure of such information prior to submission of the disclosure, publication or presentation. In the event of a disagreement as to content, timing and/or venue or forum for any disclosure, publication or presentation of the Results, such dispute (a "***Publication Dispute***") shall be referred to the Executive Officers (or their respective designees); provided that, in the absence of agreement after such good faith discussions, and upon expiration of the additional [**]-period, (A) academic collaborators or clinical trial sites engaged by the Recipient in connection with the performance of the Combined Therapy Clinical Trial may publish Combined Therapy Study Data obtained by such academic collaborator or clinical trial site solely to the extent that such ability to publish such Combined Therapy Study Data is set forth in an agreement between the Recipient and such academic collaborator or clinical trial site relating to the conduct of Combined Therapy Clinical Trial and (B) the publishing Party may proceed with the disclosure, publication or presentation provided that such disclosure, publication or presentation is consistent with its internal publication guidelines and customary industry practices for the publication of similar data and does not disclose the Confidential Information of the other Party (other than the Results or Study Data). Authorship of any publication shall be determined based on the accepted standards used in peer-reviewed academic journals at the time of the proposed disclosure, publication or presentation. The Parties agree that they shall make reasonable efforts to prevent publication of a press release that could jeopardize the future publication of Study Data at a scientific conference or in a scientific journal but in no way will this or any other provision of this Agreement supersede the requirements of any Applicable Law or the rules or regulations of any securities exchange or listing entity on which a Party's stock is listed (including any such rule or regulation that may require a Party to make public disclosures about interim results of the Combined Therapy Clinical Trial). Notwithstanding the foregoing, nothing herein shall prevent or restrict Ono from making any disclosures of unpublished Study Data disclosed to it by BMS pursuant to Section 9.4 or of the existence of this Agreement, in each case in order for Ono to comply with requirements of Applicable Law, the rules or regulations of any securities exchange or listing entity on which its stock may be traded or pursuant to an order of a court or governmental entity to publicly disclose the existence of the Agreement and the Study Data, provided that if any such disclosure is made by Ono it will only disclose the minimum amount of information necessary to achieve compliance and will provide the Recipient with reasonable advance notice of such disclosure.

(c) The Recipient agrees to include in all press releases, presentations and publications it makes related to the Combined Therapy Clinical Trial specific mention, if applicable, of the BMS Study Drug and the support and involvement of BMS. BMS agrees to include in all press releases, presentations and publications it makes related to the Combined Therapy Clinical Trial specific mention, if applicable, of the Recipient Study Drug and the support and involvement of the Recipient.

9.6 Compliance with Sunshine Laws.

(a) For purposes of compliance with reporting obligations under Sunshine Laws, as between the Parties, the Recipient represents that it is not, as of the Effective Date, subject to reporting obligations under the Sunshine Laws. Therefore, as between the Parties, BMS[1] will report payments or other transfers of value ("***POTV***") made by the Recipient or the CRO related to the conduct of the Combined

[1] Note to drafter: select the appropriate option: if the Recipient is not subject to reporting obligations under Sunshine Laws, BMS will be responsible for the reporting obligations.

Therapy Clinical Trial and any applicable associated contractor engagements as required under the Sunshine Laws for the Combined Therapy Clinical Trial. BMS shall request delayed publication for any reported POTV for studies sponsored by the Recipient as permitted under the Sunshine Laws and if consistent with BMS's normal business practices. In the event that the Recipient becomes responsible for reporting POTV for studies sponsored by it in a given country during the Term, the Recipient shall provide written notification to BMS and the Parties will meet to confer to discuss how they wish to handle reporting thereafter. Interpretation of the Sunshine Laws for purposes of reporting any POTV by a Party shall be in such Party's sole discretion so long as the interpretation complies with Applicable Law.

(b) The Recipient (i) will provide (to the extent in the possession of the Recipient), or will utilize Commercially Reasonable Efforts to obligate and ensure that each CRO and other applicable Third Party contractors for the Combined Therapy Clinical Trial provides, BMS with any information requested by BMS as BMS may reasonably determine is necessary for BMS to comply with its reporting obligations under Sunshine Laws (with such amounts paid to, or at the direction of, healthcare providers, teaching hospitals and/or any other persons for whom POTVs must be reported under Sunshine Laws to be reported to BMS within a reasonable time period specified by BMS) and (ii) will reasonably cooperate with, and will utilize Commercially Reasonable Efforts to obligate and ensure that each CRO and other applicable Third Party contractors for the Combined Therapy Clinical Trial reasonably cooperates with, BMS in connection with its compliance with such Sunshine Laws. The form in which the Recipient provides any such information shall be mutually agreed but sufficient to enable BMS to comply with its reporting obligations and BMS may disclose any information that it believes is necessary to comply with Sunshine Laws. Without limiting the foregoing, BMS shall have the right to allocate POTVs in connection with this Agreement in any required reporting under Sunshine Laws in accordance with its normal business practices. These obligations shall survive the expiration and termination of this Agreement to the extent necessary for BMS to comply with Sunshine Laws. The Recipient shall not be required to provide any information to BMS that is subject to disclosure pursuant to the Recipient's own obligations under the Sunshine Laws.

(c) For purposes of this Section 9.7, "***Sunshine Laws***" shall mean Applicable Laws requiring collection, reporting and disclosure of POTVs to certain healthcare providers, entities and individuals. These Applicable Laws may include relevant provisions of the Patient Protection and Affordable Health Care Act of 2010 and implementing regulations thereunder.

9.7 Destruction of Confidential Information. Upon expiration or termination of the Agreement, the receiving Party shall, upon request by the other Party, immediately destroy or return all of the other Party's Confidential Information relating solely to its Compound as monotherapy (but not to the Combined Therapy or the Combined Therapy Study Data) in its possession; *provided*, *however*, *that* the receiving Party shall be entitled to retain one (1) copy of Confidential Information solely for record-keeping purposes and shall not be required to destroy any Confidential Information required, or reasonably necessary, to be retained for any clinical trial activities that continue after expiration or termination, or off-site computer files created during automatic system back up which are subsequently stored securely by the receiving Party.

9.8 Nonsolicitation of Employees. Each Party agrees that, during the conduct of the Combined Therapy Clinical Trial and for six (6) months thereafter, neither it nor any of its Affiliates shall recruit, solicit or induce any employee of the other Party directly involved in the development or other activities conducted by the other Party under this Agreement to terminate his or her employment with such other Party and become employed by or consult for such other Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing, "recruit", "solicit" or "induce" shall not be deemed to mean (a) circumstances where an employee of one Party initiates contact with the other Party or any of

its Affiliates with regard to possible employment, or (b) general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements.

ARTICLE 10

REPRESENTATIONS AND WARRANTIES

10.1 Authority and Binding Agreement. Each Party represents and warrants to the other Party that (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder, and (c) the Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms subject to bankruptcy, insolvency, reorganization, arrangement, winding-up, moratorium, and similar laws of general application affecting the enforcement of creditors' rights generally, and subject to general equitable principles, including the fact that the availability of equitable remedies, such as injunctive relief or specific performance, is in the discretion of the court.

10.2 No Conflicts. Each Party represents and warrants to the other Party that, to the best of its knowledge, it has not entered, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted to the other Party under this Agreement, and has not taken any action that would in any way prevent it from granting the rights granted to the other Party under this Agreement, or that would otherwise materially conflict with or adversely affect the rights granted to the other Party under this Agreement.

10.3 Litigation. Each Party represents and warrants to the other Party, to the best of its knowledge, it is not aware of any pending or threatened litigation (and has not received any communication) that alleges that its activities related to this Agreement have violated, or that by conducting the activities as contemplated in this Agreement it would violate, any of the intellectual property rights of any other Person (after giving effect to the license grants in this Agreement).

10.4 No Adverse Proceedings. Each Party represents and warrants to the other Party that, except as otherwise notified to the other Party, there is not pending or, to the knowledge of such Party, threatened, against such Party, any claim, suit, action or governmental proceeding that would, if adversely determined, materially impair the ability of such Party to perform its obligations under this Agreement.

10.5 Consents. Each Party represents and warrants to the other Party that, to the best of its knowledge, all necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons (a) required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained (or will have been obtained prior to such execution and delivery) and (b) required to be obtained by such Party in connection with the performance of its obligations under this Agreement have been obtained or will be obtained prior to such performance.

10.6 No Debarment. Each Party hereby certifies to the other that it has not used, and will not use the services of any person disqualified, debarred, banned, subject to debarment or convicted of a crime for which a person could be debarred by the FDA under 21 U.S.C. 335a, as amended (or subject to a similar sanction of any other Regulatory Authority), in any capacity in connection with any of the services or work provided under the Combined Therapy Clinical Trial and that this certification may be relied upon in any applications to the FDA or any other Regulatory Authority. It is understood and agreed that this certification imposes a continuing obligation upon each Party to notify the other promptly of any change in the truth of this certification. Upon request by a Party, the other Party agrees to provide a list of persons used to perform the services or work provided under any activities conducted for or on behalf of such Party or any of its

Affiliates pursuant to this Agreement who, within the [**] preceding the Effective Date, or subsequent to the Effective Date, were or are convicted of one of the criminal offenses required by 21 U.S.C. 335a, as amended, to be listed in any application for approval of an abbreviated application for drug approval.

10.7 Compliance with Applicable Law. Each Party represents and warrants to the other Party that it shall comply with all Applicable Law of the country or other jurisdiction, or any court or agency thereof, applicable to the performance of its activities hereunder or any obligation or transaction hereunder, including those pertaining to the production and handling of drug products, such as those set forth by the Regulatory Authorities, as applicable, and the applicable terms of this Agreement in the performance of its obligations hereunder.

10.8 Affiliates. Each Party represents and warrants to the other Party that, to the extent the intellectual property, Regulatory Documentation or Technology licensed by it hereunder are Controlled by its Affiliates or a Third Party, it has the right to use, and has the right to grant (sub)licenses to the other Party to use, such intellectual property, Regulatory Documentation or Technology in accordance with the terms of this Agreement.

10.9 Ethical Business Practices. Each Party represents and warrants to the other Party that neither it nor its Affiliates will make any payment, either directly or indirectly, of money or other assets, including the compensation such Party derives from this Agreement (collectively a "***Payment***"), to government or political party officials, officials of International Public Organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (collectively "***Officials***") where such Payment would constitute violation of any law, including the Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1, et seq. In addition, regardless of legality, neither it nor its Affiliates will make any Payment either directly or indirectly to Officials if such Payment is for the purpose of improperly influencing decisions or actions with respect to the subject matter of this Agreement. All activities will be conducted in compliance with the U.S. False Claims Act and the U.S. Anti-Kickback Statute.

10.10 Accounting. Each Party represents and warrants to the other Party that all transactions under the Agreement shall be properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects.

10.11 Single Agent Compound Safety Issues. Each Party represents and warrants that, to the best of its knowledge, it is not aware of any material safety or toxicity issue with respect to its Single Agent Compound that are not reflected in the investigator's brochure for its Single Agent Compound existing as of the Effective Date.

10.12 Compliance with Licensor Agreements. Each Party will use, and will cause its Affiliates to use, Commercially Reasonable Efforts to comply with its obligations under any agreements entered into by it or its Affiliates with a Third Party under which it is licensed any intellectual property rights or confidential information relating to a Compound (and not to voluntarily terminate same) to the extent necessary for the Combined Therapy Clinical Trial to be conducted and completed in accordance with the terms of this Agreement and for the other Party to receive the rights and benefits provided to it under this Agreement.

10.13 DISCLAIMER OF WARRANTY. THE EXPRESS REPRESENTATIONS AND WARRANTIES STATED IN THIS ARTICLE 10 ARE IN LIEU OF, AND THE PARTIES DO HEREBY DISCLAIM, ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 11

INDEMNIFICATION

11.1 BMS Indemnification. BMS hereby agrees to defend, hold harmless and indemnify (collectively, "***Indemnify***") the Recipient, its Affiliates, and its and their agents, directors, officers, employees and subcontractors (the "***Recipient Indemnitees***") from and against any and all liabilities, expenses and/or losses, including reasonable legal expenses and attorneys' fees (collectively "***Losses***") resulting from Third Party suits, claims, actions and demands (each, a "***Third Party Claim***") to the extent that they arise or result from (a) the negligence or intentional misconduct of any BMS Indemnitee or any (sub)licensee of BMS conducting activities on behalf of BMS under this Agreement, (b) any breach by BMS of any provision of this Agreement, (c) any injury (other than resulting from known adverse effects) to a subject in the Combined Therapy Clinical Trial to the extent caused solely by the BMS Study Drug, or (d) the use by BMS, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, BMS Study Data, BMS Study Inventions, BMS Study Patent Rights, Combined Therapy Inventions and Combined Therapy Patent Rights (other than with respect to Third Party Claims that are covered under Section 6.4); but excluding, in each case ((a) through (d)), any such Losses to the extent arising or resulting from a cause or event for which the Recipient is obligated to Indemnify the BMS Indemnitees pursuant to Section 11.2.

11.2 Recipient Indemnification. The Recipient hereby agrees to Indemnify BMS, its Affiliates, and its and their agents, directors, officers, employees and subcontractors (the "***BMS Indemnitees***") from and against any and all Losses resulting from Third Party Claims to the extent that they arise or result from (a) the negligence or intentional misconduct of any Recipient Indemnitee or any (sub)licensee of the Recipient conducting activities on behalf of the Recipient under this Agreement, (b) any breach by the Recipient of any provision of this Agreement, (c) any injury (other than resulting from known adverse effects) to a subject in the Combined Therapy Clinical Trial to the extent caused solely by the Recipient Study Drug, or (d) the use by the Recipient, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, Recipient Study Data, Recipient Study Inventions, Recipient Study Patent Rights, Combined Therapy Inventions and Combined Therapy Patent Rights (other than with respect to Third Party Claims that are covered under Section 6.4); but excluding, in each case ((a) through (d)), any such Losses to the extent arising or resulting from a cause or event for which BMS is obligated to Indemnify the Recipient Indemnitees pursuant to Section 11.1.

11.3 Indemnification Procedure. Each Party's agreement to Indemnify the other Party is conditioned on the performance of the following by the Party seeking indemnification: (a) providing written notice to the Indemnifying Party of any Loss and/or Third Party Claim of the types set forth in Section 11.1 and 11.2 promptly, and in any event within [**], after the Party seeking indemnification has knowledge of such Loss and/or Third Party Claim; *provided that*, any delay in complying with the requirements of this clause (a) will only limit the Indemnifying Party's obligation to the extent of the prejudice caused to the Indemnifying Party by such delay, (b) permitting the Indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such Loss and/or Third Party Claim, (c) providing reasonable assistance to the Indemnifying Party, at the Indemnifying Party's expense, in the investigation of, preparation for and defense of any Loss and/or Third Party Claim, and (d) not compromising or settling such Loss and/or Third Party Claim without the Indemnifying Party's written consent, such consent not to be unreasonably withheld or delayed.

11.4 Separate Defense of Claims. In the event that the Parties cannot agree as to the application of Sections 11.1 and/or 11.2 to any particular Loss, the Parties may conduct separate defenses of such Loss.

Each Party further reserves the right to claim indemnity from the other in accordance with Sections 11.1 and/or 11.2 upon resolution of the underlying claim, notwithstanding the provisions of Section 11.3(b).

11.5 Insurance. Each Party shall maintain commercially reasonable levels of insurance or other adequate and commercially reasonable forms of protection or self-insurance to satisfy its indemnification obligations under this Agreement. Each Party shall provide the other Party with written notice at least [**] prior to the cancellation, non-renewal or material change in such insurance or self-insurance which would materially adversely affect the rights of the other Party hereunder. The maintenance of any insurance shall not constitute any limit or restriction on damages available to a Party under this Agreement.

11.6 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT AND/OR SUCH PARTY'S PERFORMANCE HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES AND REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY OR OTHERWISE). NOTHING IN THIS SECTION 11.6 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER SECTIONS 11.1 OR 11.2 IN RELATION TO, OR DAMAGES AVAILABLE FOR, BREACHES OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 9 OR FOR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

ARTICLE 12

TERM AND TERMINATION

12.1 Term. This Agreement shall be effective as of the Effective Date and, unless earlier terminated pursuant to Sections 12.2, 12.3 or 12.4 or any other termination right expressly stated in this Agreement, shall continue in effect until completion of the Combined Therapy Clinical Trial by all centers participating in the Combined Therapy Clinical Trial, delivery of all Study Data, including all completed case report forms, all final analyses and all final clinical study reports contemplated by the Combined Therapy Clinical Trial to both Parties, and the completion of any statistical analyses and bioanalyses contemplated by the Protocol or otherwise agreed to by the Parties to be conducted under this Agreement (the "***Term***").

12.2 Termination for Material Breach.

(a) Notice and Cure Period. If a Party (the "***Breaching Party***") is in material breach of its obligations under this Agreement, the other Party (the "***Non-Breaching Party***") shall have the right to give the Breaching Party notice specifying the nature of such material breach. The Breaching Party shall have a period of [**] after receipt of such notice to cure such material breach (the "***Cure Period***") in a manner reasonably acceptable to the Non-Breaching Party. For the avoidance of doubt, this provision is not intended to restrict in any way either Party's right to notify the other Party of any other breach or to demand the cure of any other breach.

(b) Termination Right. The Non-Breaching Party shall have the right to terminate this Agreement, upon written notice, in the event that the Breaching Party has not cured such material breach within the Cure Period, *provided, however, that* if such breach is capable of cure but cannot be cured within the Cure Period, and the Breaching Party commences actions to cure such material breach within the Cure Period and thereafter diligently continue such actions, the Breaching Party shall have an additional [**] to cure such breach. If a Party contests such termination pursuant to the dispute resolution procedures under Section 13.3, such termination shall not be effective until a conclusion of the dispute resolution

procedures in Section 13.3, as applicable, resulting in a determination that there has been a material breach that was not cured within the Cure Period (which Cure Period shall be tolled for the period from notice of such dispute until resolution of such dispute pursuant to Section 13.3 or abandonment of such dispute by the disputing Party).

12.3 Termination for Bankruptcy. Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of such other Party's assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within [**] after the filing thereof, or if the other Party will propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

12.4 Termination due to Material Safety Issue; Clinical Hold.

(a) Either Party shall have the right to terminate this Agreement immediately (after meeting and discussing with the other Party in good faith as described in the following sentence) upon written notice if it deems it necessary to protect the safety, health or welfare of subjects enrolled in the Combined Therapy Clinical Trial due to the existence of a Material Safety Issue. In the event of a termination due to a Material Safety Issue, prior to the terminating Party providing written notice, each Party's safety committee shall, to the extent practicable, meet and discuss in good faith the safety concerns raised by the terminating Party and consider in good faith the input, questions and advice of the non-terminating Party, but should any dispute arise in such discussion, the dispute resolution processes set forth in Section 13.3 shall not apply to such dispute and the terminating Party shall have the right to issue such notice and such termination shall take effect without the Parties first following the procedures set forth in Section 13.3.

(b) If a Clinical Hold with respect to either the BMS Study Drug or the Recipient Study Drug should arise at any time after the Effective Date, the Parties will meet and discuss the basis for the Clinical Hold, how long the Clinical Hold is expected to last, and how they might address the issue that caused the clinical hold. If, after [**] of discussions following the Clinical Hold, either Party reasonably concludes that the issue adversely impacts the Combined Therapy Clinical Trial and is not solvable or that unacceptable and material additional costs/delays have been and/or will continue to be incurred in the conduct of the Combined Therapy Clinical Trial, then such Party may immediately terminate this Agreement.

12.5 Effect of Termination. Upon expiration or termination of this Agreement, (a) the licenses granted to the Recipient to conduct the Combined Therapy Clinical Trial in Section 3.1 (and any sublicenses granted under Section 3.2) shall terminate, and (b) the Parties shall use reasonable efforts to wind down activities under this Agreement in a reasonable manner and avoid incurring any additional expenditures or non-cancellable obligations; *provided that*, in the case of termination pursuant to Section 12.4, the Recipient may continue to dose subjects enrolled in the Combined Therapy Clinical Trial through completion of the Protocol if dosing is required by the applicable Regulatory Authority(ies) and/or Applicable Law. Any such wind-down activities will include the return to BMS, or destruction, of all BMS Study Drug provided to the Recipient and not consumed in the Combined Therapy Clinical Trial, except in the event that the Recipient terminates this Agreement pursuant to Section 12.2 or 12.3, in which case the Recipient shall continue to have the right to use any BMS Study Drug provided to Recipient for the conduct of the Combined Therapy Clinical Trial.

12.6 Survival. The following Articles and Sections of this Agreement and all definitions relating thereto shall survive any expiration or termination of this Agreement for any reason: Section 2.1(b),

Section 2.4, Section 4.5, Sections 5.1(e)-(h), Section 5.1(j), Section 5.1(k), Section 5.1(o), Article 6 ("*Intellectual Property*"), Article 7 ("*Costs and Expenses)*, Article 8 ("*Records and Study Data*"), Article 9 ("*Confidentiality*"); Article 10 ("*Representations and Warranties*"), Article 11 ("*Indemnification*"), Section 12.5 ("*Effect of Termination*"), Section 12.6 ("*Survival*"), Section 13.1 ("*Entire Agreement*"), Section 13.2 ("*Governing Law*"), Section 13.3 ("*Dispute Resolution*"), Section 13.4 ("*Injunctive Relief*"), Section 13.6 ("*Notices*"), Section 13.7 ("*No Waiver, Modifications*"), Section 13.8 ("*No Strict Construction*"), Section 13.9 ("*Independent Contractor*"), Section 13.10 ("*Assignment, Licenses*"), Section 13.11 ("*Headings*"), Section 13.13 ("*Severability*"), Section 13.15 ("*No Benefit to Third Parties*"), and Section 13.16 ("*Construction*").

ARTICLE 13

MISCELLANEOUS

13.1 Entire Agreement. The Parties acknowledge that this Agreement shall govern all activities of the Parties with respect to the Combined Therapy Clinical Trial from the Effective Date forward. This Agreement, including the Exhibits hereto and together with the Supply and Quality Documentation, sets forth the complete, final and exclusive agreement between the Parties concerning the subject matter hereof and supersedes all prior agreements and understandings between the Parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to such subject matter other than as are set forth in this Agreement. All Exhibits attached hereto are incorporated herein as part of this Agreement.

13.2 Governing Law. This Agreement shall be governed and construed in accordance with the internal laws of the State of Delaware, USA, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

13.3 Dispute Resolution.

(a) The Parties' Designated Clinical Contacts (for clinical and regulatory matters) and the Parties Designated Supply Contacts (for supply matters) shall attempt in good faith to resolve any dispute or concern that either Party may bring to the other Party's attention.

(b) In the event of any dispute, controversy or claim arising out of, relating to or in connection with any provision of this Agreement (each a "***Dispute***"), other than a Publication Dispute or a dispute as to whether a Material Safety Issue exists, that cannot be resolved by the applicable Designated Contacts of each Party, then upon the request of either Party by written notice, the Parties shall refer such Dispute to the Executive Officers. This Agreement shall remain in effect during the pendency of any such dispute. In the event that no resolution is made by the Executive Officers (or their designee) in good faith negotiations within [**] after such referral to them, then:

(i) if such Dispute constitutes an Arbitration Matter, such Dispute shall be resolved through arbitration in accordance with the remainder of this Section 13.3; *provided*, *however*, *that* with respect to any such Dispute that relates to a matter described in Section 13.4, either Party shall have the right to seek an injunction or other equitable relief without waiting for the expiration of such [**]-period

(ii) if such Dispute constitutes a Publication Dispute, the specific dispute resolution processes contained in Section 9.6(b) will apply;

(iii) if such Dispute regards the supply, quality or compliance with specifications of the Recipient Study Drug, the Dispute will be resolved by the Recipient; *provided that* (A)

the Recipient shall have no authority to amend, change or waive compliance with this Agreement, which matters may be approved only by the written consent of both Parties, (B) all determinations made by the Recipient shall be consistent with the terms of this Agreement, and (C) any disputes relating to the supply, quality or compliance with specifications of the BMS Study Drug shall be the responsibility of BMS.

(c) If a Dispute that constitutes an Arbitration Matter remains unresolved after escalation to the Executive Officers as described above, either Party may refer the matter to arbitration as described herein. Any arbitration under this Agreement shall be conducted under the auspices of the American Arbitration Association by a panel of three (3) arbitrators pursuant to that organization's Commercial Arbitration Rules then in effects. The fees and expenses of the arbitrators shall be borne in equal shares by the Parties. Each Party shall bear the fees and expenses of its legal representation in the arbitration. The arbitral tribunal shall not reallocate either the fees and expenses of the arbitrators or of the Parties' legal representation. The arbitration shall be held in New York, New York, USA, which shall be the seat of the arbitration. The language of the arbitration shall be English.

13.4 Injunctive Relief. Notwithstanding anything herein to the contrary, a Party may seek an injunction or other injunctive relief from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss or damage on a provisional basis. For the avoidance of doubt, if either Party (a) discloses Confidential Information of the other Party other than as permitted under Article 9, (b) uses (in the case of the Recipient) the BMS Study Drug or BMS Technology or (in the case of BMS) the Recipient Study Drug or Recipient Technology in any manner other than as expressly permitted under this Agreement or (c) otherwise is in material breach of this Agreement and such material breach could cause immediate harm to the value of the Recipient Study Drug (if BMS is in material breach) or the BMS Study Drug (if the Recipient is in material breach), the other Party shall have the right to seek an injunction or other equitable relief precluding the other Party from continuing its activities related to the Combined Therapy Clinical Trial without waiting for the conclusion of the dispute resolution procedures under Section 13.3.

13.5 Force Majeure. The Parties shall be excused from the performance of their obligations under this Agreement (other than the payment of monies owed to the other Party) to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean acts of God, strikes or other concerted acts of workers, civil disturbances, fires, earthquakes, acts of terrorism, floods, explosions, riots, war, rebellion, sabotage or failure or default of public utilities or common carriers or similar conditions beyond the control of the Parties.

13.6 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if such notice is timely and is: (a) mailed by first class certified or registered mail, postage prepaid, return receipt requested, (b) sent by express delivery service, or (c) personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For the Recipient:
Idera Pharmaceuticals Inc.
505 Eagleview Boulevard, Suite 212
Exton, PA 19425
Attention: VP, Business Development

With a copy to:
Idera Pharmaceuticals Inc.
505 Eagleview Boulevard, Suite 212
Exton, PA 19425
Attention: General Counsel

For BMS: Bristol-Myers Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543-4000
Attention: VP, Business Development

With a copy to: Bristol-Myers Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543-4000
Attention: VP & Assistant General Counsel, Licensing and Business Development

Any such communication shall be deemed to have been received when delivered. It is understood and agreed that this Section 13.6 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

13.7 No Waiver; Modifications. It is agreed that no waiver by a Party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

13.8 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

13.9 Independent Contractor. The Parties are independent contractors of each other, and the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall be the agent of the other or have any authority to act for, or on behalf of, the other Party in any matter.

13.10 Assignment; Licensees.

(a) Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, *except* that a Party may make such an assignment without the other Party's consent (i) to an Affiliate, (ii) to a Third Party that merges with, consolidates with or acquires substantially all of the assets or voting control of the assigning Party or (iii) to a Third Party that acquires all the rights of the assigning Party to the Recipient Study Drug, in the case of the Recipient, or the BMS Study Drug, in the case of BMS. If assigned or transferred to an Affiliate, the assigning/transferring Party shall remain jointly and severally responsible and liable with the assignee/transferee Affiliate for the assigned rights and/or obligations. If assigned to a Third Party, any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any assignment or attempted assignment by any Party in violation of the terms of this Section 13.10(a) shall be null and void and of no legal effect.

(b) Licensees. If a Party grants a third party a license (other than a license solely to make a product for a Party and other than any license rights granted to Ono for the Ono Territory) to develop and commercialize its Single Agent Compound on a worldwide basis or in any geographic region and/or for all purposes or a limited field, (a "***Licensee***"), such Party will obtain the Licensee's agreement to abide by the terms of this Agreement in the same manner as the licensing Party.

13.11 Headings. The captions to the several Sections and Articles hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

13.12 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by facsimile or electronic (e.g., pdf) signatures and such signatures shall be deemed to bind each Party hereto as if they were original signature.

13.13 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of a Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

13.14 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in order to perfect any license, assignment or other transfer or any properties or rights under, or pursuant, to this Agreement.

13.15 No Benefit to Third Parties. The representations, warranties and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other parties.

13.16 Construction.

(a) General. Except as otherwise explicitly specified to the contrary, (i) references to a Section, Article or Exhibit means a Section or Article of, or Exhibit to, this Agreement and all subsections thereof, unless another agreement is specified, (ii) references to a particular statute or regulation include all rules and regulations promulgated thereunder and any successor statute, rules or regulations then in effect, in each case including the then-current amendments thereto, (iii) words in the singular or plural form include the plural and singular form, respectively, (iv) the terms "including," "include(s)," "such as," and "for example" used in this Agreement mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation", (v) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Agreement, (vi) "or" is used in the conjunctive ("and/or") unless the context requires otherwise, (vii) "will" and "shall" are synonyms, and (viii) days means calendar days. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

(b) No Response. Except as expressly set forth in this Agreement, where a provision of this Agreement provides for a Party to respond within a designated period following written notice from the other Party, and if such Party fails to respond, then the failure to respond shall not be deemed to create or imply: (i) that the non-responding Party agrees or disagrees with the proposed action to be taken by the other Party, (ii) any amendment, change or waiver of the terms of this Agreement, or (iii) any consent that an action proposed to be taken may be taken if it conflicts with the terms of this Agreement and/or waiver of any rights it may have to seek remedies at law or in equity for breach of this Agreement as a result of the action taken.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties, intending to be legally bound hereby, have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Idera Pharmaceuticals, Inc.		**Bristol-Myers Squibb Company**	
By:	/s/ Vincent Milano	By:	/s/ Fouad Namouni
Name:	Vincent Milano	Name:	Fouad Namouni
Title:	Chief Executive Officer	Title:	SVP Head of Oncology Development
Date:	3/11/2019	Date:	3/11/2019

Exhibit Index

Attached:

Appendix A: Draft Protocol

APPENDIX A

PROTOCOL

Confidential Materials omitted and filed separately with the Securities and Exchange Commission.
A total of 154 pages were omitted. [**].

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14 AND 15d-14, AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Vincent J. Milano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Idera 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 2, 2019

/s/ VINCENT J. MILANO
Vincent J. Milano
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14 AND 15d-14, AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, John J. Kirby, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Idera 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 2, 2019

/s/ JOHN J. KIRBY

John J. Kirby
Vice President of Finance
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Vincent J. Milano, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: May 2, 2019

/s/ VINCENT J. MILANO
Vincent J. Milano
Chief Executive Officer

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, John J. Kirby, Principal Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: May 2, 2019

/s/ JOHN J. KIRBY

John J. Kirby
Vice President of Finance
(Principal Financial Officer and Principal Accounting Officer)