

# NEKTAR THERAPEUTICS

## FORM 10-Q (Quarterly Report)

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

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2016

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-24006

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**NEKTAR THERAPEUTICS**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of  
incorporation or organization)

94-3134940  
(IRS Employer  
Identification No.)

455 Mission Bay Boulevard South  
San Francisco, California 94158  
(Address of principal executive offices)

415-482-5300  
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

The number of outstanding shares of the registrant's Common Stock, \$0.0001 par value, was 152,835,294 on October 27, 2016.

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## Forward-Looking Statements

This report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). All statements other than statements of historical fact are “forward-looking statements” for purposes of this quarterly report on Form 10-Q, including any projections of market size, earnings, revenue, milestone payments, royalties, sales or other financial items, any statements of the plans and objectives of management for future operations (including, but not limited to, preclinical development, clinical trials and manufacturing), any statements related to our financial condition and future working capital needs, any statements regarding potential future financing alternatives, any statements concerning proposed drug candidates, any statements regarding the timing for the start or end of clinical trials or submission of regulatory approval filings, any statements regarding future economic conditions or performance, any statements regarding the success of our collaboration arrangements, timing of commercial launches and product sales levels by our collaboration partners and future payments that may come due to us under these arrangements, any statements regarding our plans and objectives to initiate or continue clinical trials, and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as “may,” “will,” “expects,” “plans,” “anticipates,” “estimates,” “potential” or “continue,” or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, such expectations or any of the forward-looking statements may prove to be incorrect and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including, but not limited to, the risk factors set forth in Part II, Item 1A “Risk Factors” below and for the reasons described elsewhere in this quarterly report on Form 10-Q. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof and we do not intend to update any forward-looking statements except as required by law or applicable regulations. Except where the context otherwise requires, in this quarterly report on Form 10-Q, the “Company,” “Nektar,” “we,” “us,” and “our” refer to Nektar Therapeutics, a Delaware corporation, and, where appropriate, its subsidiaries.

## Trademarks

The Nektar brand and product names, including but not limited to Nektar<sup>®</sup>, contained in this document are trademarks and registered trademarks of Nektar Therapeutics in the United States (U.S.) and certain other countries. This document also contains references to trademarks and service marks of other companies that are the property of their respective owners.

**PART I: FINANCIAL INFORMATION**

**Item 1. Condensed Consolidated Financial Statements—Unaudited:**

**NEKTAR THERAPEUTICS**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands, except par value)  
(Unaudited)

	September 30, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 63,295	\$ 55,570
Short-term investments	190,216	253,374
Accounts receivable, net	14,249	19,947
Inventory	10,754	11,346
Other current assets	4,008	9,814
Total current assets	282,522	350,051
Property, plant and equipment, net	65,553	71,336
Goodwill	76,501	76,501
Other assets	519	754
Total assets	\$ 425,095	\$ 498,642
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 7,118	\$ 2,363
Accrued compensation	15,733	5,998
Accrued clinical trial expenses	10,946	8,220
Other accrued expenses	6,761	4,156
Interest payable	4,198	4,198
Capital lease obligations, current portion	2,370	4,756
Liability related to refundable upfront payment	12,500	—
Deferred revenue, current portion	14,101	21,428
Other current liabilities	2,578	10,127
Total current liabilities	76,305	61,246
Senior secured notes, net	243,004	241,699
Capital lease obligations, less current portion	2,143	1,073
Liability related to the sale of future royalties, net	108,893	116,029
Deferred revenue, less current portion	57,088	62,426
Other long-term liabilities	5,515	9,740
Total liabilities	492,948	492,213
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 10,000 shares authorized; no shares designated, issued or outstanding at September 30, 2016 or December 31, 2015	—	—
Common stock, \$0.0001 par value; 300,000 shares authorized; 137,796 shares and 135,289 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	13	13
Capital in excess of par value	1,912,907	1,876,072
Accumulated other comprehensive loss	(1,962)	(2,170)
Accumulated deficit	(1,978,811)	(1,867,486)
Total stockholders' equity (deficit)	(67,853)	6,429
Total liabilities and stockholders' equity (deficit)	\$ 425,095	\$ 498,642

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

**NEKTAR THERAPEUTICS**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share information)  
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
<b>Revenue:</b>				
Product sales	\$ 14,698	\$ 7,240	\$ 41,664	\$ 26,182
Royalty revenue	5,573	187	13,150	1,057
Non-cash royalty revenue related to sale of future royalties	7,692	6,050	22,341	14,752
License, collaboration and other revenue	8,373	46,475	50,829	149,423
<b>Total revenue</b>	<b>36,336</b>	<b>59,952</b>	<b>127,984</b>	<b>191,414</b>
<b>Operating costs and expenses:</b>				
Cost of goods sold	7,033	6,760	23,611	25,738
Research and development	51,951	43,229	153,569	135,652
General and administrative	10,253	9,544	31,515	30,031
<b>Total operating costs and expenses</b>	<b>69,237</b>	<b>59,533</b>	<b>208,695</b>	<b>191,421</b>
Income (loss) from operations	(32,901)	419	(80,711)	(7)
<b>Non-operating income (expense):</b>				
Interest expense	(5,614)	(4,202)	(16,918)	(12,491)
Non-cash interest expense on liability related to sale of future royalties	(4,902)	(5,226)	(14,929)	(15,428)
Interest income and other income (expense), net	332	898	1,666	1,355
<b>Total non-operating expense, net</b>	<b>(10,184)</b>	<b>(8,530)</b>	<b>(30,181)</b>	<b>(26,564)</b>
Loss before provision for income taxes	(43,085)	(8,111)	(110,892)	(26,571)
Provision for income taxes	139	92	433	469
<b>Net loss</b>	<b>\$ (43,224)</b>	<b>\$ (8,203)</b>	<b>\$ (111,325)</b>	<b>\$ (27,040)</b>
Basic and diluted net loss per share	\$ (0.32)	\$ (0.06)	\$ (0.82)	\$ (0.21)
Weighted average shares outstanding used in computing net loss per share	137,094	132,631	136,415	131,882

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
(In thousands)  
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Comprehensive loss	\$ (43,167)	\$ (8,526)	\$ (111,117)	\$ (27,294)

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

**NEKTAR THERAPEUTICS**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)  
(Unaudited)

	<u>Nine months ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (111,325)	\$ (27,040)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Non-cash royalty revenue related to sale of future royalties	(22,341)	(14,752)
Non-cash interest expense on liability related to sale of future royalties	14,929	15,428
Stock-based compensation	18,793	14,499
Depreciation and amortization	11,502	9,109
Other non-cash transactions	(2,190)	(1,448)
Changes in operating assets and liabilities:		
Accounts receivable, net	5,698	641
Inventory	592	2,600
Other assets	6,041	3,843
Accounts payable	4,799	(525)
Accrued compensation	9,735	7,056
Accrued clinical trial expenses	2,726	3,394
Other accrued expenses	2,386	949
Interest payable	—	(3,750)
Liability related to refundable upfront payment	12,500	—
Deferred revenue	(12,665)	(11,832)
Other liabilities	(5,793)	3,854
Net cash (used in) provided by operating activities	<u>(64,613)</u>	<u>2,026</u>
<b>Cash flows from investing activities:</b>		
Purchases of investments	(142,972)	(202,870)
Maturities of investments	201,449	155,683
Sales of investments	4,969	23,778
Release of restricted cash	—	25,000
Purchases of property, plant and equipment	(3,741)	(8,722)
Net cash provided by (used in) investing activities	<u>59,705</u>	<u>(7,131)</u>
<b>Cash flows from financing activities:</b>		
Payment of capital lease obligations	(5,376)	(3,798)
Proceeds from shares issued under equity compensation plans	18,041	15,516
Net cash provided by financing activities	<u>12,665</u>	<u>11,718</u>
Effect of exchange rates on cash and cash equivalents	(32)	(159)
Net increase in cash and cash equivalents	<u>7,725</u>	<u>6,454</u>
Cash and cash equivalents at beginning of period	55,570	12,365
Cash and cash equivalents at end of period	<u>\$ 63,295</u>	<u>\$ 18,819</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	<u>\$ 15,513</u>	<u>\$ 16,095</u>
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Accrued debt issuance costs	<u>\$ -</u>	<u>\$ 8,503</u>

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

**NEKTAR THERAPEUTICS**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 2016**  
**(Unaudited)**

**Note 1 — Organization and Summary of Significant Accounting Policies**

***Organization***

We are a biopharmaceutical company headquartered in San Francisco, California and incorporated in Delaware. We are developing a pipeline of drug candidates that utilize our PEGylation and advanced polymer conjugate technology platforms, which are designed to enable the development of new molecular entities that target known mechanisms of action. Our current proprietary pipeline is comprised of drug candidates across a number of therapeutic areas including oncology, pain, anti-infectives, and immunology.

Our research and development activities have required significant ongoing investment to date and are expected to continue to require significant investment. As a result, we expect to continue to incur substantial losses and negative cash flows from operations in the future. We have financed our operations primarily through cash generated from licensing, collaboration and manufacturing agreements and financing transactions. At September 30, 2016, we had approximately \$253.5 million in cash and investments in marketable securities. Also, as of September 30, 2016, we had \$254.5 million in debt, including \$250.0 million in principal of senior secured notes and \$4.5 million of capital lease obligations, of which \$2.4 million is current.

***Basis of Presentation and Principles of Consolidation***

Our consolidated financial statements include the financial position, results of operations and cash flows of our wholly-owned subsidiaries: Nektar Therapeutics (India) Private Limited (Nektar India) and Nektar Therapeutics UK Limited. All intercompany accounts and transactions have been eliminated in consolidation.

We prepared our Condensed Consolidated Financial Statements following the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles (GAAP) for annual periods can be condensed or omitted. In the opinion of management, these financial statements include all normal and recurring adjustments that we consider necessary for the fair presentation of our financial position and operating results.

Our Condensed Consolidated Financial Statements are denominated in U.S. dollars. Accordingly, changes in exchange rates between the applicable foreign currency and the U.S. dollar will affect the translation of each foreign subsidiary's financial results into U.S. dollars for purposes of reporting our consolidated financial results. Translation gains and losses are included in accumulated other comprehensive loss in the stockholders' equity section of the Condensed Consolidated Balance Sheets. To date, such cumulative currency translation adjustments have not been significant to our consolidated financial position.

Our comprehensive loss consists of our net loss plus our foreign currency translation gains and losses and unrealized holding gains and losses on available-for-sale securities, neither of which were significant during the three and nine months ended September 30, 2016 and 2015. In addition, there were no significant reclassifications out of accumulated other comprehensive loss to the statements of operations during the three and nine months ended September 30, 2016 and 2015.

The accompanying Condensed Consolidated Financial Statements are unaudited. The Condensed Consolidated Balance Sheet data as of December 31, 2015 was derived from the audited consolidated financial statements which are included in our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on February 29, 2016. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and the accompanying notes to those financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015.

Revenue, expenses, assets, and liabilities can vary during each quarter of the year. The results and trends in these interim Condensed Consolidated Financial Statements are not necessarily indicative of the results to be expected for the full year or any other periods.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the



consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Accounting estimates and assumptions are inherently uncertain. Actual results could differ materially from those estimates and assumptions. Our estimates include those related to estimated selling prices of deliverables in collaboration agreements, estimated periods of performance, the net realizable value of inventory, the impairment of investments, the impairment of goodwill and long-lived assets, contingencies, accrued clinical trial expenses, estimated non-cash royalty revenue and interest expense from our liability related to our sale of future royalties, stock-based compensation, and ongoing litigation, among other estimates. We base our estimates on historical experience and on other assumptions that management believes are reasonable under the circumstances. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources. As appropriate, estimates are assessed each period and updated to reflect current information and any changes in estimates will generally be reflected in the period first identified.

### ***Reclassifications***

Certain items previously reported in specific financial statement captions have been reclassified to conform to the current period presentation, including as a result of the adoption of new accounting guidance related to debt issuance costs described below. Such reclassifications do not materially impact previously reported revenue, operating income (loss), net income (loss), total assets, liabilities or stockholders' equity (deficit).

### ***Segment Information***

We operate in one business segment which focuses on applying our technology platforms to improve the performance of established and novel drug candidates. We operate in one segment because our business offerings have similar economics and other characteristics, including the nature of products and manufacturing processes, types of customers, distribution methods and regulatory environment. We are comprehensively managed as one business segment by our Chief Executive Officer and his management team.

### ***Significant Concentrations***

Our customers are primarily pharmaceutical and biotechnology companies that are located in the U.S. and Europe. Our accounts receivable balance contains billed and unbilled trade receivables from product sales, milestones, other contingent payments and royalties, as well as time and materials based billings from collaborative research and development agreements. When appropriate, we provide for an allowance for doubtful accounts by reserving for specifically identified doubtful accounts. We generally do not require collateral from our customers. We perform a regular review of our customers' payment histories and associated credit risk. We have not experienced significant credit losses from our accounts receivable and our allowance for doubtful accounts was not significant at either September 30, 2016 or December 31, 2015.

We are dependent on our suppliers and contract manufacturers to provide raw materials, drugs and devices of appropriate quality and reliability and to meet applicable contract and regulatory requirements. In certain cases, we rely on single sources of supply of one or more critical materials. Consequently, in the event that supplies are delayed or interrupted for any reason, our ability to develop and produce our drug candidates or our ability to meet our supply obligations could be significantly impaired, which could have a material adverse effect on our business, financial condition and results of operations.

### ***Revenue Recognition***

Our revenue is derived from our arrangements with pharmaceutical and biotechnology collaboration partners and may result from one or more of the following: upfront and license fees, payments for contract research and development, milestone and other contingent payments, manufacturing and supply payments, and royalties. Our performance obligations under our collaborations may include licensing our intellectual property, manufacturing and supply obligations, and research and development obligations. In order to account for the multiple-element arrangements, we identify the deliverables included within the arrangement and evaluate which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver goods or services, a right or license to use an asset, or another performance obligation. Revenue is recognized separately for each identified unit of accounting when the basic revenue recognition criteria are met: there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured.

At the inception of each new multiple-element arrangement or the material modification of an existing multiple-element arrangement, we allocate all consideration received under multiple-element arrangements to all units of accounting based on the relative selling price method, generally based on our best estimate of selling price (ESP). The objective of ESP is to determine the price at which we would transact a sale if the product or service was sold on a stand-alone basis. We determine ESP for the elements in our collaboration arrangements by considering multiple factors including, but not limited to, technical complexity of the performance obligation and similarity of elements to those performed under previous arrangements. Since we apply significant judgment in arriving at the ESPs, any material change in our estimates would significantly affect the allocation of the total consideration to the different elements of a multiple element arrangement.

#### *Product sales*

Product sales are primarily derived from fixed price and cost-plus manufacturing and supply agreements with our collaboration partners. We have not experienced any significant returns from our customers.

#### *Royalty revenue*

Generally, we are entitled to royalties from our collaboration partners based on the net sales of their approved drugs that are marketed and sold in one or more countries where we hold royalty rights. We recognize royalty revenue when the cash is received or when the royalty amount to be received is estimable and collection is reasonably assured. With respect to the non-cash royalties related to sale of future royalties described in Note 4, revenue is recognized when estimable, otherwise, revenue is recognized during the period in which the related royalty report is received, which generally occurs in the quarter after the applicable product sales are made.

#### *License, collaboration and other revenue*

The amount of upfront fees and other payments received by us in license and collaboration arrangements that are allocated to continuing performance obligations, such as manufacturing and supply obligations, are deferred and generally recognized ratably over our expected performance period under each respective arrangement. We make our best estimate of the period over which we expect to fulfill our performance obligations, which may include technology transfer assistance, research activities, clinical development activities, and manufacturing activities from research and development through the commercialization of the product. Given the uncertainties of these collaboration arrangements, significant judgment is required to determine the duration of the performance period and this estimate is periodically re-evaluated.

Contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which we believe is consistent with the substance of our performance under our various license and collaboration agreements. A milestone is defined as an event (i) that can only be achieved based in whole or in part either on the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement.

Our license and collaboration agreements with our partners provide for payments to us upon the achievement of development milestones, such as the completion of clinical trials or regulatory submissions, approvals by regulatory authorities, and commercial launches of drugs. Given the challenges inherent in developing and obtaining regulatory approval for drug products and in achieving commercial launches, there was substantial uncertainty whether any such milestones would be achieved at the time of execution of these licensing and collaboration agreements. In addition, we evaluated whether the development milestones met the remaining criteria to be considered substantive. As a result of our analysis, we consider our remaining development milestones under all of our license and collaboration agreements to be substantive and, accordingly, we expect to recognize as revenue future payments received from each milestone only if and as such milestone is achieved.

Our license and collaboration agreements with certain partners also provide for contingent payments to us based solely upon the performance of the respective partner. For such contingent amounts, we expect to recognize the payments as revenue when earned under the applicable contract, which is generally upon completion of performance by the respective partner, provided that collection is reasonably assured.

Our license and collaboration agreements with our partners also provide for payments to us upon the achievement of specified sales volumes of approved drugs. We consider these payments to be similar to royalty payments and we will recognize such sales-based payments upon achievement of such sales volumes, provided that collection is reasonably assured.

### ***Research and Development Expense***

Research and development costs are expensed as incurred and include salaries, benefits and other operating costs such as outside services, supplies and allocated overhead costs. We perform research and development for our proprietary drug candidates and technology development and for certain third parties under collaboration agreements. For our proprietary drug candidates and our internal technology development programs, we invest our own funds without reimbursement from a third party.

We record accruals for the estimated costs of our clinical trial activities performed by third parties. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of certain clinical trial activities. We generally accrue costs associated with the start-up and reporting phases of the clinical trials ratably over the estimated duration of the start-up and reporting phases. We generally accrue costs associated with the treatment phase of clinical trials based on the total estimated cost of the treatment phase on a per patient basis and we expense the per patient cost ratably over the estimated patient treatment period based on patient enrollment in the trials. In specific circumstances, such as for certain time-based costs, we recognize clinical trial expenses using a methodology that we consider to be more reflective of the timing of costs incurred. Advance payments for goods or services that will be used or rendered for future research and development activities are capitalized as prepaid expenses and recognized as expense as the related goods are delivered or the related services are performed. We base our estimates on the best information available at the time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Such increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period identified.

### ***Long-Lived Assets***

We assess the impairment of long-lived assets, primarily property, plant and equipment and goodwill, whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. When such events occur, we determine whether there has been an impairment in value by comparing the carrying value of the asset with its fair value, as measured by the anticipated undiscounted net cash flows associated with the asset. In the case of goodwill impairment, we perform an impairment test at least annually, on October 1 of each year, and market capitalization is generally used as the measure of fair value. If an impairment in value exists, the asset is written down to its estimated fair value.

### ***Income Taxes***

For the three and nine months ended September 30, 2016 and 2015, we recorded an income tax provision for our Nektar India operations at an effective tax rate of approximately 35%. The U.S. federal deferred tax assets generated from our net operating losses have been fully reserved, as we believe it is not more likely than not that the benefit will be realized.

### ***Adoption of New Accounting Principle***

In April 2015, the Financial Accounting Standards Board (FASB) issued guidance to simplify the presentation of debt issuance costs by requiring debt issuance costs to be presented as a deduction from the corresponding debt liability. This guidance is effective for our interim and annual periods beginning January 1, 2016. Upon adoption, the new guidance must be applied retrospectively to all periods presented. Accordingly, as of January 1, 2016, we reclassified \$0.4 million and \$3.0 million of capitalized debt issuance costs to senior secured notes, net, and liability related to the sale of future royalties, net, respectively, from our other assets balance. This reclassification has also been applied retrospectively to these balances in our Condensed Consolidated Balance Sheet as of December 31, 2015.

### ***Recent Accounting Pronouncements***

In May 2014, the FASB issued guidance codified in Accounting Standards Codification (ASC) 606, *Revenue Recognition — Revenue from Contracts with Customers*, which amends the guidance in former ASC 605, *Revenue Recognition*, and is effective for public companies for fiscal years beginning after December 15, 2017. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. We are currently evaluating the impact of the provisions of ASC 606.

In March 2016, the FASB issued guidance to simplify several aspects of employee share-based payment accounting, including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This guidance will become effective for us beginning in the first quarter of 2017. Early adoption is permitted. We are currently evaluating the impact of the adoption of this standard.

In February 2016, the FASB issued guidance to amend a number of aspects of lease accounting, including requiring lessees to recognize almost all leases with a term greater than one year as a right-of-use asset and corresponding liability, measured at the present value of the lease payments. The guidance will become effective for us beginning in the first quarter of 2019 and is required to be adopted using a modified retrospective approach. Early adoption is permitted. We are currently evaluating the impact of the adoption of this standard.

## Note 2 — Cash and Investments in Marketable Securities

Cash and investments in marketable securities, including cash equivalents, are as follows (in thousands):

	Estimated Fair Value at	
	September 30, 2016	December 31, 2015
Cash and cash equivalents	\$ 63,295	\$ 55,570
Short-term investments	190,216	253,374
Total cash and investments in marketable securities	<u>\$ 253,511</u>	<u>\$ 308,944</u>

We invest in liquid, high quality debt securities. Our investments in debt securities are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in securities with maturities of two years or less and maintain a weighted average maturity of one year or less. As of September 30, 2016 and December 31, 2015, all of our investments had maturities of one year or less.

Gross unrealized gains and losses were not significant at either September 30, 2016 or December 31, 2015. During the three and nine months ended September 30, 2016, we sold available-for-sale securities totaling \$5.0 million and gross realized gains and losses on those sales were not significant. During the three and nine months ended September 30, 2015, we sold available-for-sale securities totaling \$18.6 million and \$23.8 million, respectively, and gross realized gains and losses on those sales were not significant. The cost of securities sold is based on the specific identification method.

Under the terms of our 7.75% senior secured notes due October 2020, we are required to maintain a minimum cash and investments in marketable securities balance of \$60.0 million during the term of the notes.

Our portfolio of cash and investments in marketable securities includes (in thousands):

	Fair Value Hierarchy Level	Estimated Fair Value at	
		September 30, 2016	December 31, 2015
Corporate notes and bonds	2	\$ 74,564	\$ 181,969
Corporate commercial paper	2	95,924	61,150
Obligations of U.S. government agencies	2	16,798	7,325
Available-for-sale investments		187,286	250,444
Money market funds	1	62,092	53,728
Certificate of deposit	N/A	2,930	2,930
Cash	N/A	1,203	1,842
Total cash and investments in marketable securities		<u>\$ 253,511</u>	<u>\$ 308,944</u>

*Level 1* — Quoted prices in active markets for identical assets or liabilities.

*Level 2* — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

*Level 3* — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

All of our investments are categorized as Level 1 or Level 2, as explained in the table above. We use a market approach to value our Level 2 investments. The disclosed fair value related to our investments is based primarily on the reported fair values in our period-end brokerage statements, which are based on market prices from a variety of industry standard data providers and generally represent quoted prices for similar assets in active markets or have been derived from observable market data. We independently validate these fair values using available market quotes and other information. During the three and nine months ended September 30, 2016 and 2015, there were no transfers between Level 1 and Level 2 of the fair value hierarchy.

Additionally, as of September 30, 2016, based on a discounted cash flow analysis using Level 3 inputs including financial discount rates, we believe the \$250.0 million in principal amount of our 7.75% senior secured notes due October 2020 is consistent with its fair value.

### Note 3 — Inventory

Inventory consists of the following (in thousands):

	September 30, 2016	December 31, 2015
Raw materials	\$ 2,386	\$ 3,236
Work-in-process	6,695	6,087
Finished goods	1,673	2,023
Total inventory	<u>\$ 10,754</u>	<u>\$ 11,346</u>

Inventory is generally manufactured upon receipt of firm purchase orders from our collaboration partners. Inventory includes direct materials, direct labor, and manufacturing overhead and cost is determined on a first-in, first-out basis. Inventory is valued at the lower of cost or market and defective or excess inventory is written down to net realizable value based on historical experience or projected usage.

### Note 4 — Liability Related to Sale of Future Royalties

On February 24, 2012, we entered into a Purchase and Sale Agreement (the Purchase and Sale Agreement) with RPI Finance Trust (RPI), an affiliate of Royalty Pharma, pursuant to which we sold, and RPI purchased, our right to receive royalty payments (the Royalty Entitlement) arising from the worldwide net sales, from and after January 1, 2012, of (a) CIMZIA<sup>®</sup>, under our license, manufacturing and supply agreement with UCB Pharma (UCB), and (b) MIRCERA<sup>®</sup>, under our license, manufacturing and supply agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (together referred to as Roche). We received aggregate cash proceeds of \$124.0 million for the Royalty Entitlement. As part of this sale, we incurred approximately \$4.4 million in transaction costs, which will be amortized to interest expense over the estimated life of the Purchase and Sale Agreement. Although we sold all of our rights to receive royalties from the CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> products, as a result of our ongoing manufacturing and supply obligations related to the generation of these royalties, we will continue to account for these royalties as revenue. We recorded the \$124.0 million in proceeds from this transaction as a liability (Royalty Obligation) that will be amortized using the interest method over the estimated life of the Purchase and Sale Agreement as royalties from the CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> products are remitted directly to RPI. During the nine months ended September 30, 2016 and 2015, we recognized \$22.3 million and \$14.8 million, respectively, in non-cash royalties from net sales of CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> and we recorded \$14.9 million and \$15.4 million, respectively, of related non-cash interest expense.

Since its inception, our estimate of the total interest expense on the Royalty Obligation resulted in an effective annual interest rate of approximately 17%. We periodically assess the estimated royalty payments to RPI from UCB and Roche and to the extent such payments are greater or less than our initial estimates, or the timing of such payments is materially different than our original estimates, we will prospectively adjust the amortization of the Royalty Obligation.

Pursuant to the Purchase and Sale Agreement, in March 2014 and March 2013, we were required to pay RPI \$7.0 million and \$3.0 million, respectively, as a result of worldwide net sales of MIRCERA<sup>®</sup> for the 12 month periods ended December 31, 2013 and 2012 not reaching certain minimum thresholds. The Purchase and Sale Agreement does not include any other potential payments related to minimum net sales thresholds and, therefore, we do not expect to make any further payments to RPI related to this agreement.

In addition, the Purchase and Sale Agreement grants RPI the right to receive certain reports and other information relating to the Royalty Entitlement and contains other representations and warranties, covenants and indemnification obligations that are customary for a transaction of this nature. To our knowledge, we are currently in compliance with these provisions of the Purchase and Sale

Agreement; however, if we were to breach our obligations, we could be required to pay damages to RPI that are not limited to the purchase price we received in the sale transaction.

## **Note 5 — Commitments and Contingencies**

### ***Legal Matters***

From time to time, we are involved in lawsuits, arbitrations, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters, which arise in the ordinary course of business. We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are reviewed at least quarterly and adjusted to reflect the impact of settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. If any unfavorable ruling were to occur in any specific period, there exists the possibility of a material adverse impact on the results of our operations of that period and on our cash flows and liquidity.

On August 14, 2015, Enzon, Inc. filed a breach of contract complaint in the Supreme Court of the State of New York (Court) claiming damages of \$1.5 million plus interest for unpaid licensing fees through the date of the complaint. Enzon alleged that we failed to pay a post-patent expiration immunity fee related to one of the licenses. Following a hearing held on December 21, 2015, the Court granted Nektar's motion to dismiss the Enzon complaint. Enzon filed an appeal to the Court's dismissal decision. On October 25, 2016 the Supreme Court of the State of New York, Appellate Division, reversed the earlier decision by the Court granting Nektar's motion to dismiss the Enzon complaint. As a result, the case has been remanded to the Court for further proceedings.

### ***Indemnifications in Connection with Commercial Agreements***

As part of our collaboration agreements with our partners related to the license, development, manufacture and supply of drugs based on our proprietary technologies and drug candidates, we generally agree to defend, indemnify and hold harmless our partners from and against third party liabilities arising out of the agreement, including product liability (with respect to our activities) and infringement of intellectual property to the extent the intellectual property is developed by us and licensed to our partners. The term of these indemnification obligations is generally perpetual any time after execution of the agreement. There is generally no limitation on the potential amount of future payments we could be required to make under these indemnification obligations.

From time to time we enter into other strategic agreements such as divestitures and financing transactions pursuant to which we are required to make representations and warranties and undertake to perform or comply with certain covenants. In the event it is determined that we breached certain of the representations and warranties or covenants made by us in any such agreements, we could incur substantial indemnification liabilities depending on the timing, nature, and amount of any such claims.

To date, we have not incurred costs to defend lawsuits or settle claims related to these indemnification obligations. Because the aggregate amount of any potential indemnification obligation is not a stated amount, the overall maximum amount of any such obligations cannot be reasonably estimated. No liabilities have been recorded for these obligations in our Condensed Consolidated Balance Sheets at either September 30, 2016 or December 31, 2015.

## **Note 6 — License and Collaboration Agreements**

We have entered into various collaboration agreements including license agreements and collaborative research, development and commercialization agreements with various pharmaceutical and biotechnology companies. Under these collaboration arrangements, we are entitled to receive license fees, upfront payments, milestone and other contingent payments, royalties, sales milestones, and payments for the manufacture and supply of our proprietary PEGylation materials and/or reimbursement for research and development activities. All of our collaboration agreements are generally cancelable by our partners without significant financial penalty. Our costs of performing these services are generally included in research and development expense, except that costs for product sales to our collaboration partners are included in cost of goods sold.

In accordance with our collaboration agreements, we recognized license, collaboration and other revenue as follows (in thousands):

Partner	Drug or Drug Candidate	Three months ended September 30,		Nine months ended September 30,	
		2016	2015	2016	2015
AstraZeneca AB	MOVANTIK™ and MOVANTIK™ fixed-dose combination program	\$ 3,000	\$ 40,000	\$ 31,000	\$ 130,000
Roche	PEGASYS® and MIRCERA®	1,929	3,212	5,771	9,619
Amgen, Inc.	Neulasta®	1,250	1,250	3,750	3,750
Daiichi Sankyo Europe GmbH	ONZEALD™ (NKTR-102)	216	—	3,474	—
Bayer Healthcare LLC	BAY41-6551 (Amikacin Inhale)	357	357	1,072	1,562
Baxalta Incorporated	ADYNOVATE™	336	409	648	607
Other		1,285	1,247	5,114	3,885
License, collaboration and other revenue		\$ 8,373	\$ 46,475	\$ 50,829	\$ 149,423

As of September 30, 2016, our collaboration agreements with partners included potential future payments for development milestones totaling approximately \$147.0 million, including amounts from our agreements with Daiichi, Bayer, Baxalta and Ophthotech described below. In addition, under our collaboration agreements we are entitled to receive contingent development payments and contingent sales milestones and royalty payments, including those related to MOVANTIK™ and the MOVANTIK™ fixed-dose combination drug development programs, as described below.

There have been no material changes to our collaboration agreements in the nine months ended September 30, 2016, except as described below.

#### ***Bristol-Myers Squibb : NKTR-214***

On September 21, 2016, we entered into a Clinical Trial Collaboration Agreement (BMS Agreement) with Bristol-Myers Squibb Company, a Delaware corporation (BMS), pursuant to which we and BMS will collaborate to conduct Phase 1/2 clinical trials evaluating our IL-2-based CD122-biased agonist, known as NKTR-214, and BMS' human monoclonal antibody that binds PD-1, known as Opdivo ( nivolumab ), as a potential combination treatment regimen in five tumor types and seven potential indications, and such other clinical trials evaluating the combined therapy as may be mutually agreed upon by the parties (each, a "Combination Therapy Trial").

We will act as the sponsor of each Combination Therapy Trial. Under the BMS Agreement, BMS will be responsible for 50% of all out-of-pocket costs reasonably incurred in connection with third party contract research organizations, laboratories, clinical sites and institutional review boards. Each party will otherwise be responsible for its own internal costs, including internal personnel costs, incurred in connection with each Combination Therapy Trial. Nektar and BMS will use commercially reasonable efforts to manufacture and supply NKTR-214 and Opdivo (nivolumab), respectively, for each Combination Therapy Trial with each party bearing its own costs related thereto. The parties will form a joint development committee to oversee clinical trial design, regulatory strategy, and other activities necessary to conduct and support the Combination Therapy Trials.

Ownership of, and global commercial rights to, NKTR-214 remain solely with us under the BMS Agreement. If we wish to license the right to commercialize NKTR-214 in one of certain major market territories prior to September 30, 2018 (Exclusivity Expiration Date), we must first negotiate with BMS, for a period of three months (Negotiation Period), to grant an exclusive license to develop and commercialize NKTR-214 in any of these major market territories. If we do not reach an agreement with BMS for an exclusive license within the Negotiation Period, we will be free to license any right to NKTR-214 to other parties in any territory worldwide except that in the event that we receive a license offer from a third party during a period of 90 calendar days after the end of the Negotiation Period, we will provide BMS ten business days to match the terms of such third-party offer. After the Exclusivity Expiration Date, we are free to license NKTR-214 without any further obligation to BMS. Each party grants to the other party a non-exclusive, worldwide (subject to certain exceptions in the case of the license granted by BMS), non-transferable and royalty-free research and development license to such licensing party's patent rights, technology and regulatory documentation to use its compound solely to the extent necessary to discharge its obligations under the BMS Agreement with respect to the conduct of the Combination Therapy Trials.

***Daiichi Sankyo Europe GmbH*** : ONZEALD™ (etirinotecan pegol), also referred to as NKTR-102

Effective May 30, 2016, we entered into a collaboration and license agreement with Daiichi Sankyo Europe GmbH, a German limited liability company (Daiichi), under which we granted Daiichi exclusive commercialization rights in the European Economic Area, Switzerland, and Turkey (collectively, the European Territory) to our proprietary product candidate ONZEALD™ (etirinotecan pegol), which is also known as NKTR-102, a long-acting topoisomerase I inhibitor in clinical development for the treatment of adult patients with advanced breast cancer who have brain metastases (BCBM). Nektar retains all rights to ONZEALD™ in all countries outside the European Territory including the United States.

Under the terms of the agreement and in consideration for the exclusive commercialization rights in the European Territory, Daiichi paid us a \$20.0 million up-front payment in August 2016 and we will be eligible to receive up to an aggregate of \$60.0 million in regulatory and commercial milestones, including a \$10.0 million payment upon the first commercial sale of ONZEALD™ following conditional marketing approval by the European Commission (EC), a \$25.0 million payment upon the first commercial sale following final marketing authorization approval of ONZEALD™ by the EC, and a \$25.0 million sales milestone upon Daiichi's first achievement of a certain specified annual net sales target. We are also eligible to receive a 20% royalty on net sales of ONZEALD™ by Daiichi in all countries in the European Territory except for net sales in Turkey where Nektar is eligible to receive a 15% royalty. The parties will enter into a supply agreement whereby we will be responsible for supplying Daiichi with its requirements for ONZEALD™ on a fully burdened reimbursed cost basis. Daiichi will be responsible for all commercialization activities for ONZEALD™ in the European Territory and will bear all associated costs. In addition, we are responsible for funding and conducting a Phase 3 confirmatory trial in patients with BCBM which we call the ATTAIN study.

Daiichi may terminate the agreement in the event that the EC does not grant conditional marketing approval for ONZEALD™ based on existing clinical data for ONZEALD™ or the conditional marketing approval for ONZEALD™ is not granted prior to a pre-specified future date (Daiichi Pre-Conditional Approval Termination). We may terminate the Agreement in the event that the EC requires changes in the ATTAIN study that materially increase the costs of such trial and Daiichi elects not to reimburse us for such incremental costs (Nektar Pre-Conditional Approval Termination). In the event of a Daiichi Pre-Conditional Approval Termination or a Nektar Pre-Conditional Approval Termination, we would be obligated to pay Daiichi a \$12.5 million termination payment. Following conditional marketing approval of ONZEALD™ by the EC, we would no longer have such termination payment obligation. Each party has certain other termination rights based on the safety or efficacy findings including the outcome of the ATTAIN study and any material uncured breaches of the Agreement. The \$12.5 million contingent termination payment from us to Daiichi is recorded in our liability related to refundable upfront payment balance in our Condensed Consolidated Balance Sheet at September 30, 2016.

We identified our grant of the exclusive license to Daiichi on May 30, 2016 and our ongoing clinical and regulatory development service obligations as the significant, non-contingent deliverables under the agreement and determined that each represents a separate unit of accounting. We made our best estimate of the selling price for the license grant based on a discounted cash flow analysis of projected ONZEALD™ sales and estimated the selling price for the development services based on our experience with the costs of similar clinical studies and regulatory activities. Based on these estimates, we allocated the \$7.5 million non-refundable portion of the \$20.0 million upfront payment from Daiichi to these items based on their relative selling prices. As a result, we recognized \$3.5 million of revenue in the nine months ended September 30, 2016 from this arrangement, primarily related to the delivery of the license. As of September 30, 2016, we have deferred revenue of approximately \$4.0 million related to our development service obligations under this agreement, which we expect to recognize through May 2021, the estimated end of our development obligations. If and when the remaining \$12.5 million portion of the upfront payment becomes non-refundable, we expect to allocate this amount between the license and development service obligation consistent with the estimated selling prices of these deliverables. The license related amount will be recognized immediately and the development service related amount will be recorded as deferred revenue and recognized ratably over the remaining obligation period.

We determined that the milestones noted above payable to us by Daiichi upon the first commercial sale of ONZEALD™ following conditional marketing approval and following final marketing authorization approval of ONZEALD™ by the EC are substantive milestones that will be recognized if and when achieved. In addition, we determined that the sales milestone due to us upon Daiichi's first achievement of a certain specified annual net sales target should be considered a contingent payment and will be recognized if and when achieved.

***AstraZeneca AB*** : MOVANTIK™ (naloxegol oxalate), previously referred to as naloxegol and NKTR-118, and MOVANTIK™ fixed-dose combination program, previously referred to as NKTR-119

We are a party to an agreement with AstraZeneca AB (AstraZeneca) under which we granted AstraZeneca a worldwide, exclusive license under our patents and other intellectual property to develop, market, and sell MOVANTIK™ and MOVANTIK™ fixed-dose combination program. AstraZeneca is responsible for all research, development and commercialization and is responsible



for all drug development and commercialization decisions for MOVANTIK™ and the MOVANTIK™ fixed-dose combination program. AstraZeneca paid us an upfront payment of \$125.0 million, which we received in the fourth quarter of 2009 and which was fully recognized as of December 31, 2010. In addition, we have received the payments described further below based on development events related to MOVANTIK™ completed solely by AstraZeneca. We are entitled to receive up to \$75.0 million of commercial launch contingent payments related to the MOVANTIK™ fixed-dose combination program, based on development events to be pursued and completed solely by AstraZeneca. In addition, we are entitled to significant and escalating double-digit royalty payments and sales milestone payments based on annual worldwide net sales of MOVANTIK™ and MOVANTIK™ fixed-dose combination products.

On September 16, 2014, the United States Food and Drug Administration (FDA) approved MOVANTIK™ for the treatment of opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain. On December 9, 2014, AstraZeneca announced that MOVENTIG® (the naloxegol brand name in the European Union or EU) had been granted Marketing Authorisation by the European Commission (EC) for the treatment of opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxative(s). In March 2015, AstraZeneca announced that MOVANTIK™ launched in the United States which resulted in our receipt of a \$100.0 million non-refundable commercial launch payment on March 31, 2015, which was recognized as revenue in March 2015. In March 2015, we agreed to pay AstraZeneca a total of \$10.0 million to fund U.S. television advertising in consideration for certain additional commercial information rights. We recorded this \$10.0 million obligation as a liability, made the initial \$5.0 million payment to AstraZeneca in July 2015, and the remaining \$5.0 million payment in July 2016. We determined that this \$10.0 million obligation should be recorded as a reduction of revenue, which we recorded in the three months ended March 31, 2015. In August 2015, we received and recognized as revenue an additional \$40.0 million non-refundable payment triggered by the first commercial sale of MOVENTIG® in Germany.

On March 1, 2016, AstraZeneca announced that it had entered into an agreement with ProStrakan Group plc (ProStrakan), a subsidiary of Kyowa HAKKO Kirin Co. Ltd., granting ProStrakan exclusive marketing rights to MOVENTIG® in the EU, Iceland, Liechtenstein, Norway and Switzerland. Under the terms of AstraZeneca's agreement with ProStrakan, ProStrakan made a \$70.0 million upfront payment to AstraZeneca and will make additional payments based on achieving market access milestones, tiered net sales royalties, as well as sales milestones. Under our license agreement with AstraZeneca, AstraZeneca and we will share the upfront payment, market access milestones, royalties and sales milestones from ProStrakan with AstraZeneca receiving 60% and Nektar receiving 40%. This payment sharing arrangement is in lieu of other royalties payable by AstraZeneca to us and a portion of the sales milestones as described below. Our 40% share of royalty payments made by ProStrakan to AstraZeneca will be financially equivalent to us receiving high single-digit to low double-digit royalties dependent on the level of ProStrakan's net sales. ProStrakan's MOVENTIG® net sales will be included for purposes of achieving the annual global sales milestones payable to us by AstraZeneca and will also be included for purposes of determining the applicable ex-U.S. royalty rate, from the tier schedule in our AstraZeneca license agreement, that will be applied to ex-U.S. sales outside of the ProStrakan territory. The global sales milestones under our license agreement with AstraZeneca will be reduced in relation to the amount of ProStrakan MOVENTIG® net sales that contribute to any given annual sales milestone target. As a result, we were entitled to receive 40% (or \$28.0 million) of the \$70.0 million payment received by AstraZeneca from ProStrakan in March 2016, recognized this amount as revenue in March 2016 and received this \$28.0 million in April 2016. In the three months ended September 30, 2016, we recognized \$3.0 million related to our share of an additional sublicense milestone payment made by ProStrakan to AstraZeneca in September 2016. As of September 30, 2016, we do not have deferred revenue related to our agreement with AstraZeneca.

In general, other than as described above and in this paragraph, AstraZeneca has full responsibility for all research, development and commercialization costs under our license agreement. As part of its approval of MOVANTIK™, the FDA required AstraZeneca to perform a post-marketing, observational epidemiological study comparing MOVANTIK™ to other treatments of OIC in patients with chronic, non-cancer pain. As a result, the royalty rate payable to us from net sales of MOVANTIK™ in the U.S. by AstraZeneca will be reduced by up to two percentage points to fund 33% of the external costs incurred by AstraZeneca to fund such post approval study once it is initiated, subject to a \$35.0 million aggregate cap. Any costs incurred by AstraZeneca can only be recovered by the reduction of the royalty paid to us. In no case can amounts be recovered by the reduction of a contingent payment due from AstraZeneca to us or through a payment from us to AstraZeneca.

#### ***Baxalta Incorporated : Hemophilia***

We are a party to an exclusive research, development, license and manufacturing and supply agreement with Baxalta Incorporated (Baxalta) entered into in September 2005 to develop products designed to improve therapies for Hemophilia A patients using our PEGylation technology. Under the terms of the agreement, we are entitled to research and development funding and are responsible for supplying Baxalta with its requirements for our proprietary materials. Baxalta is responsible for all clinical development, regulatory, and commercialization expenses.

This Hemophilia A program includes ADYNOVATE™, which was approved by the FDA in November 2015 for use in adults and adolescents, aged 12 years and older, who have Hemophilia A, and is now marketed in the U.S. As a result of the FDA's approval, we achieved and recognized a \$10.0 million development milestone in November 2015, which was received in January 2016. In addition, under the terms of this agreement, we are entitled to a \$10.0 million development milestone due upon marketing authorization in the EU, as well as sales milestones upon achievement of annual sales targets and royalties based on annual worldwide net sales of products resulting from this agreement. As of September 30, 2016, we do not have deferred revenue related to this agreement.

**Roche : PEGASYS® and MIRCERA®**

In February 2012, we entered into a toll-manufacturing agreement with Roche under which we will manufacture the proprietary PEGylation material used by Roche to produce MIRCERA®. Roche entered into the toll-manufacturing agreement with the objective of establishing us as a secondary back-up supply source on a non-exclusive basis. Under the terms of our toll-manufacturing agreement, Roche paid us an upfront payment of \$5.0 million and an additional \$22.0 million in performance-based milestone payments upon our achievement of certain manufacturing readiness, validation and production milestones, including the delivery of specified quantities of PEGylation materials, all of which were completed as of January 2013. Roche will also pay us additional consideration for any future orders of the PEGylation materials for MIRCERA® beyond the initial quantities manufactured through January 2013. Roche has the right to terminate the toll-manufacturing agreement due to an uncured material default by us. In addition, in August 2013, we agreed to deliver additional quantities of PEGylation materials used by Roche to produce PEGASYS® and MIRCERA®, all of which were delivered in the last quarter of 2013, for total consideration of \$18.6 million. As of September 30, 2016, we have deferred revenue of approximately \$1.9 million related to this agreement, which we expect to recognize through December 2016, the estimated end of our obligations under this agreement.

In February 1997, we entered into a license, manufacturing and supply agreement with Roche, under which we granted Roche a worldwide, exclusive license to certain intellectual property related to our proprietary PEGylation materials used in the manufacture and commercialization of PEGASYS®. Our performance obligations under this PEGASYS® agreement ended on December 31, 2015.

**Amgen, Inc. : Neulasta®**

In October 2010, we amended and restated an existing supply and license agreement by entering into a supply, dedicated suite and manufacturing guarantee agreement (the amended and restated agreement) and a license agreement with Amgen Inc. and Amgen Manufacturing, Limited (together referred to as Amgen). Under the terms of the amended and restated agreement, we received a \$50.0 million payment in the fourth quarter of 2010 in return for our guaranteeing the supply of certain quantities of our proprietary PEGylation materials to Amgen. As of September 30, 2016, we have deferred revenue of approximately \$20.4 million related to this agreement, which we expect to recognize through October 2020, the estimated end of our obligations under this agreement.

**Bayer Healthcare LLC : BAY41-6551 (Amikacin Inhale)**

In August 2007, we entered into a co-development, license and co-promotion agreement with Bayer Healthcare LLC (Bayer) to develop a specially-formulated inhaled Amikacin. We are responsible for development and manufacturing and supply of our proprietary nebulizer device included in the Amikacin product. In April 2013, Bayer initiated a Phase 3 clinical trial in the treatment of intubated and mechanically ventilated patients with Gram-negative pneumonia. As of September 30, 2016, we have received an upfront payment of \$40.0 million (which was paid to us in 2007) and milestone payments totaling \$30.0 million (the last of which was paid to us in 2013). In addition, in June 2013, we made a \$10.0 million payment to Bayer for the reimbursement of some of its costs of the Phase 3 clinical trial.

We are entitled to receive a total of up to an additional \$50.0 million of development milestones upon achievement of certain development objectives, as well as sales milestones upon achievement of annual sales targets and royalties based on annual worldwide net sales of Amikacin Inhale. As of September 30, 2016, we have deferred revenue of approximately \$18.2 million related to this agreement, which we expect to recognize through June 2029, the estimated end of our obligations under this agreement.

**Ophthotech Corporation : Fovista®**

We are a party to an agreement with Ophthotech Corporation (Ophthotech), dated September 30, 2006, under which Ophthotech received a worldwide, exclusive license to certain of our proprietary PEGylation technology to develop, manufacture and sell Fovista®. Under the terms of our agreement, we are the exclusive supplier of all of Ophthotech's clinical and commercial requirements for our proprietary PEGylation reagent used in Fovista®, which is currently in Phase 3 clinical development. On May 19, 2014, Ophthotech entered into a Licensing and Commercialization Agreement with Novartis Pharma AG for Fovista®. Under our agreement with Ophthotech, in June 2014, we received a \$19.8 million payment in connection with this licensing agreement. As of

September 30, 2016, we have deferred revenue of approximately \$17.2 million related to this agreement, which we expect to recognize through March 2029, the estimated end of our obligations under our agreement with Ophthotech.

In addition, we are entitled to up to \$9.5 million in additional payments based upon Ophthotech's potential achievement of certain regulatory and sales milestones, including a \$2.5 million milestone due upon acceptance for review of a regulatory approval application in the U.S. or EU. We are also entitled to royalties on net sales of Fovista<sup>®</sup> that vary based on sales levels, if commercialized.

#### **Other**

In addition, as of September 30, 2016, we have a number of collaboration agreements, including with our collaboration partner UCB, under which we are entitled to up to a total of \$45.5 million of development milestones upon achievement of certain development objectives, as well as sales milestones upon achievement of annual sales targets and royalties based on net sales of commercialized products, if any. However, given the current phase of development of the potential products under these collaboration agreements, we cannot estimate the probability or timing of achieving these milestones. As of September 30, 2016, we have deferred revenue of approximately \$9.4 million related to these other collaboration agreements, which we expect to recognize through 2020, the estimated end of our obligations under those agreements.

#### **Note 7 — Stock-Based Compensation**

Total stock-based compensation expense was recognized in our Condensed Consolidated Statements of Operations as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Cost of goods sold	\$ 396	\$ 274	\$ 1,186	\$ 837
Research and development	3,181	2,208	9,505	6,755
General and administrative	2,589	2,280	8,102	6,907
Total stock-based compensation	<u>\$ 6,166</u>	<u>\$ 4,762</u>	<u>\$ 18,793</u>	<u>\$ 14,499</u>

During the three months ended September 30, 2016 and 2015, we granted options to purchase 657,960 and 483,300 shares, respectively, at a weighted average grant-date fair value of \$8.06 per share and \$5.86 per share, respectively. During the three months ended September 30, 2016 and 2015, we granted 56,000 and 120,000 restricted stock unit awards (RSUs), respectively.

During the nine months ended September 30, 2016 and 2015, we granted options to purchase 1,447,250 and 962,310 shares, respectively, at a weighted average grant-date fair value of \$7.42 per share and \$6.10 per share, respectively. During the nine months ended September 30, 2016 and 2015, we granted 58,000 and 120,000 RSUs, respectively.

As a result of stock issuances under our equity compensation plans, during the three months ended September 30, 2016 and 2015, we issued 1,193,764 and 1,031,573 shares of our common stock, respectively, and during the nine months ended September 30, 2016 and 2015, we issued 2,507,701 and 2,000,823 shares of our common stock, respectively.

#### **Note 8 — Net Loss Per Share**

Basic net loss per share is calculated based on the weighted-average number of common shares outstanding during the periods presented. For all periods presented in the accompanying Condensed Consolidated Statements of Operations, the net loss available to common stockholders is equal to the reported net loss. Basic and diluted net loss per share are the same due to our historical net losses and the requirement to exclude potentially dilutive securities which would have an anti-dilutive effect on net loss per share.

During the three and nine months ended September 30, 2016 and 2015, potentially dilutive securities consisted of common shares underlying outstanding stock options and RSUs. During the three months ended September 30, 2016 and 2015, there were weighted average outstanding stock options and RSUs of 19.1 million and 20.6 million shares, respectively, and during the nine months ended September 30, 2016 and 2015, there were weighted average outstanding stock options and RSUs of 19.4 million and 21.3 million shares, respectively.

**Note 9 — Subsequent Event**

On October 24, 2016, we completed the issuance and sale of 14,950,000 shares of our common stock, including 1,950,000 shares issued upon the full exercise by the underwriters of an option granted by us to the underwriters, in an underwritten public offering with total proceeds of approximately \$189.7 million after deducting the underwriting commissions and discounts of approximately \$12.1 million. In addition, we incurred approximately \$0.6 million in legal and accounting fees, filing fees, and other costs in connection with this offering.

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

The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this section as well as factors described in "Part II, Item 1A-Risk Factors."

### Overview

#### *Strategic Direction of Our Business*

We are a biopharmaceutical company developing a pipeline of drug candidates that utilize our PEGylation and advanced polymer conjugate technology platforms, which are designed to enable the development of new molecular entities that target known mechanisms of action. Our current proprietary pipeline is comprised of drug candidates across a number of therapeutic areas including oncology, pain, anti-infectives, and immunology. Our research and development activities involve small molecule drugs, peptides and protein biologic drug candidates. We create innovative drug candidates by using our proprietary advanced polymer conjugate technologies and expertise to modify the chemical structure of pharmacophores to create new molecular entities. Polymer chemistry is a science focused on the synthesis or bonding of polymer architectures with drug molecules to alter the properties of a molecule. Additionally, we may utilize established pharmacologic targets to engineer a new drug candidate relying on a combination of the known properties of these targets and our proprietary polymer chemistry technology and expertise. Our drug candidates are designed to improve the overall benefits and use of a drug for patients by improving the metabolism, distribution, pharmacokinetics, pharmacodynamics, half-life and/or bioavailability of drugs. Our objective is to apply our advanced polymer conjugate technology platform to create new drug candidates in multiple therapeutic areas that address large potential markets.

In 2014, we achieved the first approval of one of our proprietary drug candidates, MOVANTIK™ (naloxegol), under a global license agreement with AstraZeneca. MOVANTIK™ is an oral peripherally-acting opioid antagonist, for the treatment of opioid-induced constipation, or OIC, a side effect caused by chronic administration of prescription opioid pain medicines. AstraZeneca markets and sells MOVANTIK™ in the United States in collaboration with Daiichi Sankyo, Inc. On March 31, 2015, AstraZeneca and Daiichi launched MOVANTIK™ in the United States. On March 1, 2016, AstraZeneca entered into an agreement with ProStrakan Group plc (ProStrakan), a subsidiary of Kyowa Hakko Kirin Co. Ltd., granting ProStrakan exclusive marketing rights to MOVENTIG® (the naloxegol brand name in the EU) in the EU, Iceland, Liechtenstein, Norway and Switzerland. Under the terms of that agreement, ProStrakan made a \$70 million upfront payment to AstraZeneca and will make future payments based on achieving market access milestones, tiered net sales royalties, as well as sales milestones. Under our license agreement, AstraZeneca and Nektar will share the upfront payment, market access milestones, royalties and sales milestones from ProStrakan with AstraZeneca receiving 60% and Nektar receiving 40%. Given the significant sales milestone and royalty opportunity for us associated with MOVANTIK™ under our AstraZeneca license agreement, the level of sales achieved by AstraZeneca for MOVANTIK™ will have a significant impact on our operating results and financial condition over the coming years.

We have a collaboration with Baxalta to develop and commercialize PEGylated drug candidates with the objective of providing new long-acting therapies for hemophilia patients. Under this collaboration, we worked with Baxalta to develop ADYNOVATE™ (previously referred to as BAX 855), an extended half-life recombinant factor VIII (rFVIII) treatment for Hemophilia A based on ADVATE® [Antihemophilic Factor (Recombinant)]. In November 2015, ADYNOVATE™ was approved by the FDA for use in adults and adolescents, aged 12 years and older, who have Hemophilia A. Baxalta announced the launch and first shipments of ADYNOVATE™ on November 30, 2015. On April 4, 2016, Baxalta announced that the Ministry of Health, Labour and Welfare in Japan approved ADYNOVATE™ for patients aged 12 years and older with Hemophilia A. ADYNOVATE™ is also under regulatory review in Europe, Switzerland and Canada. The level of sales achieved by Baxalta for ADYNOVATE™ and our related royalties will be important to our operating results and financial condition over the coming years.

NKTR-181 is a novel mu-opioid analgesic drug candidate for chronic pain conditions and is currently in Phase 3 clinical development. We enrolled the first patient in the first Phase 3 efficacy study in February 2015 and we recently completed enrollment in the study. In this study, we are randomizing patients with chronic low back pain in an enriched enrollment randomized withdrawal design which will include a qualifying screening period, an open-label titration period where NKTR-181 is given to all patients, followed by a 12 week double-blind randomized period where subjects will be randomized on a 1:1 basis to receive either NKTR-181 or placebo. On February 29, 2016, we increased the sample size of this trial by approximately 200 patients following a pre-specified sample size assessment by the independent analysis center (IAC) after approximately fifty percent of the initially planned 416 patients completed the study. The protocol of the NKTR-181 study defined only two possible outcomes for this pre-planned blinded interim sample size assessment: (1) if the conditional powering at the midpoint of the trial fell between 50-85%, the sample size was to be increased by approximately 200 patients; or (2) if the conditional powering fell below 50%, or above 85%, the sample size was not to be changed. The IAC's determination is nondiscretionary and was based upon our determination of pre-defined acceptable power to detect a statistically significant difference between NKTR-181 and placebo based on the primary efficacy endpoint.

NKTR-102 ( etirinotecan pegol, also known as ONZEALD™ ) is our next-generation topoisomerase I inhibitor proprietary drug candidate. In 2015, we announced topline data from a Phase 3 clinical study for NKTR-102, which we call the BEACON study (BrEAsT Cancer Outcomes with NKTR-102), as a single-agent chemotherapy for women with advanced metastatic breast cancer. The BEACON study compared NKTR-102 to an active control arm comprised of a single chemotherapy agent of physician's choice (TPC) in patients who were heavily pre-treated with a median of three prior therapies for metastatic disease. In a topline analysis of 852 patients from the trial, NKTR-102 provided a 2.1 month improvement in median overall survival over TPC (12.4 months for patients receiving NKTR-102 compared to 10.3 months for patients receiving TPC). Based on a stratified log-rank analysis, the primary endpoint measuring the hazard ratio for survival in the NKTR-102 group compared to the active control arm was 0.87 with a p-value of 0.08, which did not achieve statistical significance. Secondary endpoints in the BEACON study included objective response rate and progression-free survival, which did not achieve statistical significance in the study. We also announced that we observed a significant overall survival benefit in two pre-specified subgroups—patients with a history of brain metastases and patients with baseline liver metastases at study entry.

We have explored future regulatory and development paths forward for ONZEALD™ with the EU and U.S. health authorities. In Europe, we met with the National Authorities in Sweden and the United Kingdom, as well as the European Medicines Agency (EMA) to discuss the BEACON data. On May 26, 2016, the Committee for Medicinal Products for Human Use granted an accelerated assessment procedure for the ONZEALD™ marketing authorization application (MAA) which provides for an accelerated review timeline. In June 2016, we filed an MAA for conditional approval of ONZEALD™ for adult patients with advanced breast cancer who have brain metastases. On July 14, 2016, we received a letter from the EMA notifying us that the ONZEALD™ MAA successfully passed validation to be accepted for review. As contemplated by our recently announced European commercialization collaboration with Daiichi and in connection with our MAA filing for ONZEALD™, before the end of 2016 we plan to initiate a randomized Phase 3 confirmatory study to evaluate ONZEALD™ as compared to a single-agent chemotherapy of physician's choice in approximately 350 adult patients with advanced breast cancer who have brain metastases, which we call the ATTAIn study. The primary endpoint of the ATTAIn study will be overall survival (OS) and the ATTAIn study will include a pre-specified interim analysis for OS which is to be conducted after 130 events have occurred in the study. In addition, based on our meetings with the FDA's Oncology Division, the FDA staff has indicated that positive results from the ATTAIn study could also support a New Drug Application (NDA) filing in the U.S. where Nektar has retained all rights to ONZEALD™.

We are currently conducting a Phase 1/2 clinical study for NKTR-214, which is our engineered immunostimulatory CD122-biased cytokine designed to preferentially activate the beta and gamma sub-units of the IL-2 receptor with the objective to induce proliferation and accumulation of tumor-killing lymphocyte cells within the body (CD8-positive effector T cells and natural killer T cells) with limited activity on regulatory T cells (CD4-positive T cells). The study is being conducted initially at three primary investigator sites: the University of Texas MD Anderson Cancer Center, Yale Cancer Center and the Providence Cancer Center in Portland, Oregon. The dose-escalation stage of the Phase 1/2 study is designed to evaluate safety and efficacy, and define the recommended Phase 2 dose of NKTR-214 in patients with solid tumors. The study will assess the safety profile of NKTR-214, the immunologic effect of NKTR-214 on tumor-infiltrating lymphocytes and other immune activation markers in both blood and tumor tissue, the pharmacokinetic/pharmacodynamic profile as well as preliminary anti-tumor activity based on objective response rate.

We plan to study NKTR-214 in combination with a number of therapeutic approaches where we believe there is a strong biologic rationale for complementary mechanisms of action. On September 21, 2016, we entered into a Clinical Trial Collaboration Agreement (BMS Agreement) with BMS, pursuant to which we and BMS will collaborate to conduct Phase 1/2 clinical trials evaluating NKTR-214 and BMS' human monoclonal antibody that binds PD-1, known as Opdivo (nivolumab), as a potential combination treatment regimen in five tumor types and seven potential indications, and such other clinical trials evaluating the combined therapy as may be mutually agreed upon by the parties (each, a Combination Therapy Trial). Under the BMS Agreement, BMS will be responsible for 50% of all out-of-pocket costs incurred in connection with the Combination Therapy Trials. In addition to the clinical trials in collaboration with BMS, we also plan to initiate a broad clinical development program, both on our own or in collaboration with other potential partners, to explore the potential of combining NKTR-214 with therapies such as cancer vaccines, adoptive cell therapy, small molecules, and other biological agents in order to generate novel immune-oncology approaches. We will also explore potential monotherapy approaches for NKTR-214.

We also have two significant drug development programs with Bayer. The first is a collaboration to develop BAY41-6551 (Amikacin Inhale, formerly known as NKTR-061), which is an inhaled solution of amikacin, an aminoglycoside antibiotic. We originally developed the liquid aerosol inhalation platform and the NKTR-061 drug candidate and entered into a collaboration agreement with Bayer to further advance the drug candidate's development and potential commercialization. Bayer is currently enrolling patients in a Phase 3 clinical study for Amikacin Inhale. Bayer is conducting this study under a Special Protocol Assessment process agreed to with the FDA. The second is our significant royalty rights in the Cipro DPI (Cipro Dry Powder Inhaler, previously called Cipro Inhale) program with Bayer that we transferred to Novartis as part of the 2008 pulmonary asset divestiture transaction. In August 2012, Bayer initiated a global Phase 3 program called RESPIRE for the Cipro DPI product candidate in patients with non-cystic fibrosis bronchiectasis. These programs represent a significant future economic opportunity for us.

While the approved drugs and clinical development programs described above are key elements of our future success, we believe it is critically important that we continue to make substantial investments in our earlier-stage drug candidate pipeline. We have several drug candidates in earlier stage clinical development or being explored in research that we are preparing to advance into the clinic in future years. We are also advancing several other drug candidates in preclinical development in the areas of cancer immunotherapy, pain and other therapeutic indications. While we believe that our substantial investment in research and development has the potential to create significant value if one or more of our drug candidates demonstrates positive clinical results, receives regulatory approval in one or more major markets and achieves commercial success, drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval and the timing and outcome of clinical trial results are extremely difficult to predict. Clinical development successes and failures can have a disproportionately positive or negative impact on our scientific and medical prospects, financial condition and prospects, results of operations and market value.

Historically, we have entered into a number of license and supply contracts under which we manufactured and supplied our proprietary PEGylation reagents on a fixed price or cost-plus basis. Our current strategy is to manufacture and supply PEGylation reagents to support our proprietary drug candidates or our third-party collaborators where we have a strategic development and commercialization relationship or where we derive substantial economic benefit.

### **Key Developments and Trends in Liquidity and Capital Resources**

As of September 30, 2016, we estimated that we had at least twelve months of working capital to fund our current business plans. At September 30, 2016, we had approximately \$253.5 million in cash and investments in marketable securities. Also, as of September 30, 2016, we had \$254.5 million in debt, including \$250.0 million in principal of senior secured notes and \$4.5 million of capital lease obligations. On October 24, 2016, we completed a public offering of common stock with net proceeds of approximately \$189.1 million.

### **Results of Operations**

*Three and Nine Months Ended September 30, 2016 and 2015*

*Revenue (in thousands, except percentages)*

	<u>Three months ended September 30,</u>		<u>Increase/ (Decrease) 2016 vs. 2015</u>	<u>Percentage Increase/ (Decrease) 2016 vs. 2015</u>
	<u>2016</u>	<u>2015</u>		
Product sales	\$ 14,698	\$ 7,240	\$ 7,458	>100%
Royalty revenue	5,573	187	5,386	>100%
Non-cash royalty revenue related to sale of future royalties	7,692	6,050	1,642	27%
License, collaboration and other revenue	8,373	46,475	(38,102)	(82)%
<b>Total revenue</b>	<b>\$ 36,336</b>	<b>\$ 59,952</b>	<b>\$ (23,616)</b>	<b>(39)%</b>

	<u>Nine months ended September 30,</u>		<u>Increase/ (Decrease) 2016 vs. 2015</u>	<u>Percentage Increase/ (Decrease) 2016 vs. 2015</u>
	<u>2016</u>	<u>2015</u>		
Product sales	\$ 41,664	\$ 26,182	\$ 15,482	59%
Royalty revenue	13,150	1,057	12,093	>100%
Non-cash royalty revenue related to sale of future royalties	22,341	14,752	7,589	51%
License, collaboration and other revenue	50,829	149,423	(98,594)	(66)%
<b>Total revenue</b>	<b>\$ 127,984</b>	<b>\$ 191,414</b>	<b>\$ (63,430)</b>	<b>(33)%</b>

Our revenue is derived from our collaboration agreements, under which we may receive product sales revenue, royalties, license fees, milestone and other contingent payments and/or contract research payments. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured. The amount of upfront fees received under our license and collaboration agreements allocated to continuing obligations, such as manufacturing and supply commitments, is recognized ratably over our expected performance period under the arrangement. As a result, there may be significant variations in the timing of receipt of cash payments and our recognition of revenue. We make our best

estimate of the period over which we expect to fulfill our performance obligations. Given the uncertainties in research and development collaborations, significant judgment is required by us to determine the performance periods.

### ***Product sales***

Product sales include predominantly fixed price manufacturing and supply agreements with our collaboration partners and result from the receipt of firm purchase orders from those partners. The timing of shipments is based solely on the demand and requirements of our collaboration partners and is not ratable throughout the year.

Product sales increased for the three and nine months ended September 30, 2016 compared to the three and nine months ended September 30, 2015 primarily due to increased product demand from one of our collaboration partners. For the same reason, we expect product sales for the full year of 2016 will increase as compared to 2015.

### ***Royalty revenue and non-cash royalty revenue related to sale of future royalties***

We receive royalty revenue from certain of our collaboration partners based on their net sales of commercial products. Royalty revenue received in cash increased for the three and nine months ended September 30, 2016 compared to the three and nine months ended September 30, 2015 primarily due to the launch of commercial sales by AstraZeneca of MOVANTIK™ in the U.S. in March 2015 and MOVENTIG® in the EU in August 2015 and the launch of ADYNOVATE™ by Baxalta in the U.S. in November 2015. We expect royalty revenue for the full year of 2016 will increase as compared to 2015 due to royalties we expect to receive from MOVANTIK™, MOVENTIG® and ADYNOVATE™.

In February 2012, we sold all of our rights to receive future royalty payments on CIMZIA® and MIRCERA®. As described in Note 4 to our Condensed Consolidated Financial Statements, this royalty sale transaction has been recorded as a liability that amortizes over the estimated royalty payment period. As a result of this liability accounting, even though the royalties from UCB and Roche are remitted directly to the purchaser of these royalty interests, we will continue to record revenue for these royalties. We expect non-cash royalties from net sales of CIMZIA® and MIRCERA® for the full year of 2016 will increase as compared to 2015.

### ***License, Collaboration and Other Revenue***

License, collaboration and other revenue includes the recognition of upfront payments, milestone and other contingent payments received in connection with our license and collaboration agreements and reimbursed research and development expenses. The level of license, collaboration and other revenue depends in part upon the estimated amortization period of the upfront payments, the achievement of milestones and other contingent events, the continuation of existing collaborations, the amount of reimbursed research and development work, and entering into new collaboration agreements, if any.

License, collaboration and other revenue decreased for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 primarily due to the recognition of the \$40.0 million milestone payment received in August 2015 as a result of the EU commercial launch of MOVENTIG®. License, collaboration and other revenue decreased for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 primarily as a result of the recognition in March 2015 of the \$100.0 million milestone payment received from AstraZeneca as a result of the U.S. commercial launch of MOVANTIK™ and the \$40.0 million milestone payment received in August 2015 partially offset by the recognition of \$28.0 million in March 2016 for our 40% share of the \$70.0 million sublicense payment received by AstraZeneca from ProStrakan. In addition, in March 2015, we agreed to pay AstraZeneca \$10.0 million, including \$5.0 million paid in July 2015 and \$5.0 million paid in July 2016, to fund U.S. television advertising in consideration for certain additional commercial information rights. We determined that this \$10.0 million obligation should be recorded as a reduction of revenue, which we recorded in the three months ended March 31, 2015.

We expect our license, collaboration and other revenue for the full year of 2016 will decrease significantly as compared to 2015 primarily due to the recognition in 2015 of the significant non-recurring payments resulting from AstraZeneca's commercial launches of MOVANTIK™ and MOVENTIG®.



**Cost of Goods Sold and Product Gross Margin (in thousands, except percentages)**

	<b>Three months ended September 30,</b>		<b>Increase/ (Decrease) 2016 vs. 2015</b>	<b>Percentage Increase/ (Decrease) 2016 vs. 2015</b>
	<b>2016</b>	<b>2015</b>		
Cost of goods sold	\$ 7,033	\$ 6,760	\$ 273	4%
Product gross profit	7,665	480	\$ 7,185	>100%
Product gross margin	52%	7%		

	<b>Nine months ended September 30,</b>		<b>Increase/ (Decrease) 2016 vs. 2015</b>	<b>Percentage Increase/ (Decrease) 2016 vs. 2015</b>
	<b>2016</b>	<b>2015</b>		
Cost of goods sold	\$ 23,611	\$ 25,738	\$ (2,127)	(8)%
Product gross profit	18,053	444	\$ 17,609	>100%
Product gross margin	43%	2%		

Cost of goods sold during the three months ended September 30, 2016 increased marginally compared to the three months ended September 30, 2015. Cost of goods sold decreased during the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 primarily due to the mix of product sales, which resulted in decreases to cost of goods sold even though product sales increased during the same period.

The improvement in product gross profit and product gross margin during the three and nine months ended September 30, 2016 compared to the three and nine months ended September 30, 2015 is primarily due to a more favorable product mix in 2016 compared to 2015. In particular, the increased demand from our collaboration partners in 2016 results in product sales where we have a relatively higher gross margin. This increased margin is partially offset by a manufacturing arrangement with another partner that includes a fixed price which is less than the fully burdened manufacturing cost for the reagent in 2016 and 2015 and we expect this situation to continue with this partner in future years. There were fewer shipments to this partner relative to shipments to other customers during the three and nine months ended September 30, 2016 compared to the three and nine months ended September 30, 2015. In addition to product sales from reagent materials supplied to the partner where our sales are less than our fully burdened manufacturing cost, we also receive royalty revenue from this collaboration. In the three and nine months ended September 30, 2016 and 2015, the royalty revenue from this collaboration exceeded the related negative gross profit.

We expect product gross margin to continue to fluctuate in future periods depending on the level and mix of manufacturing orders from our customers due to the predominantly fixed cost base associated with our manufacturing activities. We expect product gross margin for the full year of 2016 to be substantially similar to the nine months ended September 30, 2016, as a result of anticipated collaboration partner demand and product mix.

**Research and Development Expense (in thousands, except percentages)**

	<b>Three months ended September 30,</b>		<b>Increase/ (Decrease) 2016 vs. 2015</b>	<b>Percentage Increase/ (Decrease) 2016 vs. 2015</b>
	<b>2016</b>	<b>2015</b>		
Research and development expense	\$ 51,951	\$ 43,229	\$ 8,722	20%

	<b>Nine months ended September 30,</b>		<b>Increase/ (Decrease) 2016 vs. 2015</b>	<b>Percentage Increase/ (Decrease) 2016 vs. 2015</b>
	<b>2016</b>	<b>2015</b>		
Research and development expense	\$ 153,569	\$ 135,652	\$ 17,917	13%

Research and development expense consists primarily of clinical study costs, direct costs of outside research, materials, supplies, licenses and fees as well as personnel costs (including salaries, benefits, and stock-based compensation). Research and development expense also includes certain overhead allocations consisting of support and facilities-related costs.

Research and development expense increased during the three and nine months ended September 30, 2016 compared to the three and nine months ended September 30, 2015 primarily due to costs incurred in our Phase 3 clinical program for NKTR-181 and our NKTR-214 Phase 1/2 clinical study. We expect research and development expense in the full year of 2016 to increase as compared to 2015.

Other than as described in the Overview section above, there have been no material changes to the status of clinical programs in the nine months ended September 30, 2016 from the activities discussed in our Annual Report on Form 10-K for the year ended December 31, 2015 on file with the Securities and Exchange Commission.

**General and Administrative Expense (in thousands, except percentages)**

	<u>Three months ended September 30,</u>		<u>Increase/ (Decrease) 2016 vs. 2015</u>	<u>Percentage Increase/ (Decrease) 2016 vs. 2015</u>
	<u>2016</u>	<u>2015</u>		
General and administrative expense	\$ 10,253	\$ 9,544	709	7%

  

	<u>Nine months ended September 30,</u>		<u>Increase/ (Decrease) 2016 vs. 2015</u>	<u>Percentage Increase/ (Decrease) 2016 vs. 2015</u>
	<u>2016</u>	<u>2015</u>		
General and administrative expense	\$ 31,515	\$ 30,031	1,484	5%

General and administrative expense includes the cost of administrative staffing, business development, marketing, finance, and legal activities. General and administrative expense during the three and nine months ended September 30, 2016 increased marginally compared with the three and nine months ended September 30, 2015. We expect general and administrative expenses in the full year of 2016 to be consistent with 2015.

**Interest Expense (in thousands, except percentages)**

	<u>Three months ended September 30,</u>		<u>Increase/ (Decrease) 2016 vs. 2015</u>	<u>Percentage Increase/ (Decrease) 2016 vs. 2015</u>
	<u>2016</u>	<u>2015</u>		
Interest expense	\$ 5,614	\$ 4,202	\$ 1,412	34%
Non-cash interest expense on liability related to sale of future royalties	4,902	5,226	(324)	(6)%

  

	<u>Nine months ended September 30,</u>		<u>Increase/ (Decrease) 2016 vs. 2015</u>	<u>Percentage Increase/ (Decrease) 2016 vs. 2015</u>
	<u>2016</u>	<u>2015</u>		
Interest expense	\$ 16,918	\$ 12,491	\$ 4,427	35%
Non-cash interest expense on liability related to sale of future royalties	14,929	15,428	(499)	(3)%

Interest expense for the three and nine months ended September 30, 2016 increased as compared to the three and nine months ended September 30, 2015 primarily as a result of our secured notes transaction completed in October 2015. In October 2015, we issued \$250.0 million in aggregate principal amount of 7.75% senior secured notes due October 2020 and used a portion of the proceeds from these notes to redeem the \$125.0 million in aggregate principal amount of 12% senior secured notes due July 2017. Interest on the 7.75% senior secured notes is calculated based on actual days outstanding over a 360 day year. We expect interest expense during the full year of 2016 to increase compared to 2015 as a result of the year over year increase to the principal balance of our outstanding secured notes, partially offset by the reduction in the secured note interest rate from 12% to 7.75%.

Non-cash interest expense on the liability related to sale of future royalties for the three and nine months ended September 30, 2016 decreased marginally compared with the three and nine months ended September 30, 2015. In February 2012, we sold all of our

rights to receive future royalty payments on CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> in exchange for \$124.0 million. As described in Note 4 to our Condensed Consolidated Financial Statements, this royalty sale transaction has been recorded as a liability that amortizes over the estimated royalty payment period as CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> royalties are remitted directly to the purchaser. We impute interest on the transaction and record interest expense at the effective interest rate, which we currently estimate to be approximately 17%. There are a number of factors that could materially affect the estimated interest rate, in particular, the amount and timing of royalty payments from future net sales of CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup>, and we assess this estimate on a periodic basis. As a result, future interest rates could differ significantly and any such change in interest rate will be adjusted prospectively. Unless we adjust our estimated interest rate, we expect non-cash interest expense on the liability related to sale of future royalties for the full year of 2016 to decrease marginally compared to 2015 as a result of the decreasing royalty liability balance.

### **Liquidity and Capital Resources**

We have financed our operations primarily through revenue from product sales, royalties and research and development contracts, as well as public offering and private placements of debt and equity securities. At September 30, 2016, we had approximately \$253.5 million in cash and investments in marketable securities. Also, as of September 30, 2016, we had \$254.5 million in debt, including \$250.0 million in principal of senior secured notes and \$4.5 million of capital lease obligations. As described in Note 9 to our Condensed Consolidated Financial Statements, on October 24, 2016, we completed a public offering of common stock with net proceeds of approximately \$189.1 million.

As of September 30, 2016, we estimated that we had at least twelve months of working capital to fund our current business plans. We expect the clinical development of our proprietary drug candidates including NKTR-181, Amikacin Inhale, NKTR-102 (also known as ONZEALD<sup>™</sup>), NKTR-214, and NKTR-358, will require significant investment in order to continue to advance in clinical development with the objective of entering into a collaboration partnership or obtaining regulatory approval. However, we have no credit facility or any other sources of committed capital. In the past we have received a number of significant payments from collaboration agreements and other significant transactions. In the future, we expect to continue to receive increasing royalties from commercial sales of products such as MOVANTIK<sup>™</sup>, MOVENTIG<sup>®</sup> and ADYNOVATE<sup>™</sup> as they continue to increase sales after their recent product launches and potential substantial payments from future collaboration transactions if drug candidates in our pipeline achieve positive clinical or regulatory outcomes. Our current business plan is also subject to significant uncertainties and risks as a result of, among other factors, the sales levels of products for which we are entitled to royalties such as MOVANTIK<sup>™</sup>, MOVENTIG<sup>®</sup> and ADYNOVATE<sup>™</sup>, clinical program outcomes, whether, when and on what terms we are able to enter into new collaboration transactions, expenses being higher than anticipated, unplanned expenses, cash receipts being lower than anticipated, and the need to satisfy contingent liabilities, including litigation matters and indemnification obligations.

The availability and terms of various financing alternatives substantially depend on many factors including the success or failure of drug development programs in our pipeline, including NKTR-181, Amikacin Inhale, CIPRO DPI, Fovista, NKTR-102 (also known as ONZEALD<sup>™</sup>), NKTR-214 and NKTR-358, as well as other early stage development programs. The availability and terms of financing alternatives and any future significant payments from existing or new collaborations depend on the positive outcome of ongoing or planned clinical studies, whether we or our partners are successful in obtaining regulatory authority approvals in major markets, and if approved, the commercial success of these drugs, as well as general capital market conditions. We will pursue various financing alternatives as needed to continue to fund our research and development activities and to fund the expansion of our business as appropriate.

Due to the potential for adverse developments in the credit markets in 2016 and thereafter, we may experience reduced liquidity with respect to some of our investments in marketable securities. These investments are generally held to maturity, which, in accordance with our investment policy, is less than two years. However, if the need arises to liquidate such securities before maturity, we may experience losses on liquidation. At September 30, 2016, the average time to maturity of the investments held in our portfolio was approximately four months and the maturity of any single investment did not exceed one year. To date we have not experienced any liquidity issues with respect to these securities, but if such issues arise, we may be required to hold some, or all, of these securities until maturity. We believe that, even allowing for potential liquidity issues with respect to these securities, our remaining cash and investments in marketable securities will be sufficient to meet our anticipated cash needs for at least the next twelve months.

### ***Cash flows from operating activities***

Cash flows used in operating activities for the nine months ended September 30, 2016 totaled \$64.6 million, which includes \$107.9 million of net operating cash uses as well as \$14.7 million for interest payments on our senior secured notes, partially offset by the receipt of a \$28.0 million payment in April 2016 from AstraZeneca related to its sub-license to ProStrakan, the receipt of a \$20.0 million upfront payment in August 2016 from Daiichi Sankyo related to our NKTR-102 collaboration arrangement in Europe, as well as the receipt of a \$10.0 million milestone in January 2016 from our Baxalta collaboration agreement, which was recorded in accounts receivable in our Condensed Consolidated Balance Sheet at December 31, 2015. We expect that cash flows used in operating

activities, excluding upfront, milestone and other contingent payments received, if any, will decrease in the full year of 2016 compared to 2015 primarily as a result of increased cash receipts from product sales and royalties.

Cash flows provided by operating activities for the nine months ended September 30, 2015 totaled \$2.0 million, which includes the receipt of \$142.0 million for milestones from collaboration agreements, including the \$100.0 million payment received as a result of the US launch of MOVANTIK™ and the \$40.0 million payment received as a result of the EU launch of MOVENTIG®, partially offset by \$125.0 million of net operating cash uses as well as \$15.0 million for interest payments on our senior secured notes.

#### ***Cash flows from investing activities***

We paid \$3.7 million and \$8.7 million to purchase property, plant and equipment in the nine months ended September 30, 2016 and 2015, respectively. We expect our capital expenditures in the full year of 2016 to decrease marginally compared to 2015.

Restricted cash of \$25.0 million was required to be maintained in a separate account until July 1, 2015 under the terms of our 12% senior secured notes due July 2017. This restriction expired on July 1, 2015 and the restricted funds were returned to us.

#### ***Cash flows from financing activities***

We received proceeds from issuance of common stock related to our employee option and stock purchase plans of \$18.0 million and \$15.5 million in the nine months ended September 30, 2016 and 2015, respectively.

#### ***Contractual Obligations***

There were no material changes during the nine months ended September 30, 2016 to the summary of contractual obligations included in our Annual Report on Form 10-K for the year ended December 31, 2015 on file with the Securities and Exchange Commission.

#### ***Off-Balance Sheet Arrangements***

We do not utilize off-balance sheet financing arrangements as a source of liquidity or financing.

#### **Critical Accounting Policies and Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period.

We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates on an ongoing basis. Actual results may differ from those estimates under different assumptions or conditions. There have been no material changes to our critical accounting policies and estimates discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

#### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Our market risks at September 30, 2016 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2015 on file with the Securities and Exchange Commission.

#### **Item 4. Controls and Procedures**

##### ***Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 (Exchange Act) reports is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon, and as of the date of, this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

***Changes in Internal Control Over Financial Reporting***

We continuously seek to improve the efficiency and effectiveness of our internal controls. This results in refinements to processes throughout the Company. However, there was no change in our internal control over financial reporting that occurred in the three months ended September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

***Limitations on the Effectiveness of Controls***

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## PART II: OTHER INFORMATION

### Item 1. Legal Proceedings

Reference is hereby made to our disclosures in “Legal Matters” under Note 5 to our Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q and the information under the heading “Legal Matters” is incorporated by reference herein.

### Item 1A. Risk Factors

Investors in Nektar Therapeutics should carefully consider the risks described below before making an investment decision. The risks described below may not be the only ones relating to our company. This description includes any material changes to and supersedes the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015. Additional risks that we currently believe are immaterial may also impair our business operations. Our business, results of operations, financial condition, cash flows and future prospects and the trading price of our common stock and our abilities to repay our senior secured notes could be harmed as a result of any of these risks, and investors may lose all or part of their investment. In assessing these risks, investors should also refer to the other information contained or incorporated by reference in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2015, including our consolidated financial statements and related notes, and our other filings made from time to time with the Securities and Exchange Commission (SEC).

#### Risks Related to Our Business

***Drug development is a long and inherently uncertain process with a high risk of failure at every stage of development.***

We have a number of proprietary drug candidates and partnered drug candidates in research and development ranging from the early discovery research phase through preclinical testing and clinical trials. Preclinical testing and clinical studies are long, expensive, difficult to design and implement and highly uncertain as to outcome. It will take us, or our collaborative partners, many years to conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. The start or end of a clinical study is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes, or our and our partners’ financial constraints.

Drug development is a highly uncertain scientific and medical endeavor, and failure can unexpectedly occur at any stage of preclinical and clinical development. Typically, there is a high rate of attrition for drug candidates in preclinical and clinical trials due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The risk of failure increases for our drug candidates that are based on new technologies, such as the application of our advanced polymer conjugate technology to NKTR-102, NKTR-181, NKTR-214 and other drug candidates currently in discovery research or preclinical development. For example, while we believe our NKTR-181 Phase 3 clinical program employs the most appropriate clinical trial design, we were unable to identify a single cause for the Phase 2 study for NKTR-181 not meeting its primary efficacy endpoint, and therefore there is increased risk in effectively designing a Phase 3 clinical program for NKTR-181. The failure of one or more of our drug candidates could have a material adverse effect on our business, financial condition and results of operations.

***The risk of clinical failure for any drug candidate remains high prior to regulatory approval.***

A number of companies have suffered significant unforeseen failures in clinical studies due to factors such as inconclusive efficacy or safety, even after achieving preclinical proof-of-concept or positive results from earlier clinical studies that were satisfactory both to them and to reviewing regulatory authorities. Clinical study outcomes remain very unpredictable and it is possible that one or more of our clinical studies could fail at any time due to efficacy, safety or other important clinical findings or regulatory requirements. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA, IRB, an independent ethics committee, or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects. Similarly, an IRB or ethics committee may suspend a clinical trial at a particular trial site. If one or more of our drug candidates fail in clinical studies, it could have a material adverse effect on our business, financial condition and results of operations.

***Our results of operations and financial condition depend significantly on the ability of our collaboration partners to successfully develop and market drugs and they may fail to do so.***

Under our collaboration agreements with various pharmaceutical or biotechnology companies, our collaboration partner is generally solely responsible for:

- designing and conducting large scale clinical studies;
- preparing and filing documents necessary to obtain government approvals to sell a given drug candidate; and/or
- marketing and selling the drugs when and if they are approved.

Our reliance on collaboration partners poses a number of significant risks to our business, including risks that:

- we have very little control over the timing and level of resources that our collaboration partners dedicate to commercial marketing efforts such as the amount of investment in sales and marketing personnel, general marketing campaigns, direct-to-consumer advertising, product sampling, pricing agreements and rebate strategies with government and private payers, manufacturing and supply of drug product, and other marketing and selling activities that need to be undertaken and well executed for a drug to have the potential to achieve commercial success;
- collaboration partners with commercial rights may choose to devote fewer resources to the marketing of our partnered drugs than they devote to their own drugs or other drugs that they have in-licensed;
- we have very little control over the timing and amount of resources our partners devote to development programs in one or more major markets;
- disagreements with partners could lead to delays in, or termination of, the research, development or commercialization of product candidates or to litigation or arbitration proceedings;
- disputes may arise or escalate in the future with respect to the ownership of rights to technology or intellectual property developed with partners;
- we do not have the ability to unilaterally terminate agreements (or partners may have extension or renewal rights) that we believe are not on commercially reasonable terms or consistent with our current business strategy;
- partners may be unable to pay us as expected; and
- partners may terminate their agreements with us unilaterally for any or no reason, in some cases with the payment of a termination fee penalty and in other cases with no termination fee penalty.

Given these risks, the success of our current and future collaboration partnerships is highly unpredictable and can have a substantial negative or positive impact on our business—in particular, we expect the commercial outcomes of MOVANTIK™, MOVENTIG® and ADYNOVATE™ (previously referred to as BAX 855) to have a particularly significant impact on our near to mid-term financial results and financial condition. Additionally, there are also several important drugs in later stage development with collaboration partners including Amikacin Inhale, Cipro DPI, and Fovista®. If the approved drugs fail to achieve commercial success or the drugs in development fail to have positive late stage clinical outcomes sufficient to support regulatory approval in major markets, it could significantly impair our access to capital necessary to fund our research and development efforts for our proprietary drug candidates. If we are unable to obtain sufficient capital resources to advance our drug candidate pipeline, it would negatively impact the value of our business, results of operations and financial condition.

***We are a party to numerous collaboration agreements and other significant agreements which contain complex commercial terms that could result in disputes, litigation or indemnification liability that could adversely affect our business, results of operations and financial condition.***

We currently derive, and expect to derive in the foreseeable future, all of our revenue from collaboration agreements with biotechnology and pharmaceutical companies. These collaboration agreements contain complex commercial terms, including:

- clinical development and commercialization obligations that are based on certain commercial reasonableness performance standards that can often be difficult to enforce if disputes arise as to adequacy of our partner's performance;
- research and development performance and reimbursement obligations for our personnel and other resources allocated to partnered drug candidate development programs;
- clinical and commercial manufacturing agreements, some of which are priced on an actual cost basis for products supplied by us to our partners with complicated cost allocation formulas and methodologies;

- intellectual property ownership allocation between us and our partners for improvements and new inventions developed during the course of the collaboration;
- royalties on drug sales based on a number of complex variables, including net sales calculations, geography, scope of patent claim coverage, patent life, generic competitors, bundled pricing and other factors; and
- indemnity obligations for intellectual property infringement, product liability and certain other claims.

We are a party to numerous significant collaboration agreements and other strategic transaction agreements (e.g., financings and asset divestitures) that contain complex representations and warranties, covenants and indemnification obligations. If we are found to have materially breached such agreements, it could subject us to substantial liabilities and harm our financial condition.

From time to time, we are involved in litigation matters involving the interpretation and application of complex terms and conditions of our agreements. For example, in February 2015 we filed a claim against Allergan and MAP seeking monetary damages related to a dispute over the economic sharing provisions of our collaboration agreement with MAP. On August 14, 2015, Enzon, Inc. filed a breach of contract claim for alleged unpaid licensing fees. In 2013, we settled a breach of contract litigation matter with the Research Foundation of the State University of New York (SUNY) pursuant to which we paid an aggregate of \$12.0 million. One or more disputes may arise or escalate in the future regarding our collaboration agreements, transaction documents, or third-party license agreements that may ultimately result in costly litigation and unfavorable interpretation of contract terms, which would have a material adverse effect on our business, financial condition and results of operations.

***If we or our partners do not obtain regulatory approval for our drug candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, our business, results of operations and financial condition will be negatively affected.***

We or our partners may not obtain regulatory approval for drug candidates on a timely basis, or at all, or the terms of any approval (which in some countries includes pricing approval) may impose significant restrictions or limitations on use. Drug candidates must undergo rigorous animal and human testing and an extensive review process for safety and efficacy by the FDA and equivalent foreign regulatory authorities. The time required for obtaining regulatory decisions is uncertain and difficult to predict. The FDA and other U.S. and foreign regulatory authorities have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. For example, while data from certain pre-specified subgroups in the BEACON study was positive, the study did not achieve statistical significance for its primary endpoint and the FDA and European Medicines Agency rarely approve drugs on the basis of studies that do not achieve statistical significance on the primary endpoint. Further, regulatory authorities have the discretion to analyze data using their own methodologies that may differ from those used by us or our partners which could lead such authorities to arrive at different conclusions regarding the safety or efficacy of a drug candidate. In addition, undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities. For example, AstraZeneca will be conducting a post-marketing, observational epidemiological study comparing MOVANTIK™ to other treatments of OIC in patients with chronic, non-cancer pain and the results of this study could at some point in the future negatively impact the labeling, regulatory status, and commercial potential of MOVANTIK™.

Even if we or our partners receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. Our partnered drugs that have obtained regulatory approval, and the manufacturing processes for these products, are subject to continued review and periodic inspections by the FDA and other regulatory authorities. Discovery from such review and inspection of previously unknown problems may result in restrictions on marketed products or on us, including withdrawal or recall of such products from the market, suspension of related manufacturing operations or a more restricted label. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

***We have substantial future capital requirements and there is a risk we may not have access to sufficient capital to meet our current business plan. If we do not receive substantial milestone or royalty payments from our existing collaboration agreements, execute new high value collaborations or other arrangements, or are unable to raise additional capital in one or more financing transactions, we would be unable to continue our current level of investment in research and development.***

As of September 30, 2016, we had cash and investments in marketable securities valued at approximately \$253.5 million. Also, as of September 30, 2016, we had \$254.5 million in debt, including \$250.0 million in principal of senior secured notes and \$4.5 million of capital lease obligations. On October 24, 2016, we completed the issuance and sale of 14,950,000 shares of our common stock, including 1,950,000 shares issued upon the full exercise by the underwriters of an option granted by us to the underwriters, in an underwritten public offering with total proceeds of approximately \$189.7 million after deducting the underwriting commissions and



discounts of approximately \$12.1 million. In addition, we incurred approximately \$0.6 million in legal and accounting fees, filing fees, and other costs in connection with this offering. While we believe that our cash position will be sufficient to meet our liquidity requirements through at least the next 12 months, our future capital requirements will depend upon numerous unpredictable factors, including:

- the cost, timing and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates that we have licensed to our collaboration partners —important examples include Amikacin Inhale and CIPRO Inhale licensed to Bayer;
- the commercial launch and sales levels of products marketed by our collaboration partners for which we are entitled to royalties and sales milestones —importantly, the level of success in marketing and selling MOVANTIK™ by AstraZeneca in the U.S. and ADYNOVATE™ by Baxalta globally, as well as MOVENTIG® (the naloxegol brand name in the EU) by ProStrakan in the EU;
- if and when we receive potential milestone payments and royalties from our existing collaborations if the drug candidates subject to those collaborations achieve clinical, regulatory or commercial success;
- the progress, timing, cost and results of our clinical development programs;
- the success, progress, timing and costs of our efforts to implement new collaborations, licenses and other transactions that increase our current net cash, such as the sale of additional royalty interests held by us, term loan or other debt arrangements, and the issuance of securities;
- the number of patients, enrollment criteria, primary and secondary endpoints, and the number of clinical studies required by the regulatory authorities in order to consider for approval our drug candidates and those of our collaboration partners;
- our general and administrative expenses, capital expenditures and other uses of cash; and
- disputes concerning patents, proprietary rights, or license and collaboration agreements that negatively impact our receipt of milestone payments or royalties or require us to make significant payments arising from licenses, settlements, adverse judgments or ongoing royalties.

A significant multi-year capital commitment is required to advance our drug candidates through the various stages of research and development in order to generate sufficient data to enable high value collaboration partnerships with significant upfront payments or to successfully achieve regulatory approval. In the event we do not enter into any new collaboration partnerships with significant upfront payments and we choose to continue our later stage research and development programs, we may need to pursue financing alternatives, including dilutive equity-based financings, such as an offering of convertible debt or common stock, which would dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. If sufficient capital is not available to us or is not available on commercially reasonable terms, it could require us to delay or reduce one or more of our research and development programs. If we are unable to sufficiently advance our research and development programs, it could substantially impair the value of such programs and result in a material adverse effect on our business, financial condition and results of operations.

***While we have conducted numerous experiments using laboratory and home-based chemistry techniques that have not been able to convert NKTR-181 into a rapid-acting and more abusable opioid, there is a risk that a technique could be discovered in the future to convert NKTR-181 into a rapid-acting and more abusable opioid, which would significantly diminish the value of this drug candidate.***

An important objective of our NKTR-181 drug development program is to create a unique opioid molecule that does not rapidly enter a patient's central nervous system and therefore has the potential to be less susceptible to abuse than alternative opioid therapies. To date, we have conducted numerous experiments using laboratory and home-based chemistry techniques that have been unable to convert NKTR-181 into a rapidly-acting, more abusable form of opioid. In the future, an alternative chemistry technique, process or method of administration, or combination thereof, may be discovered to enable the conversion of NKTR-181 into a more abusable opioid, which could significantly and negatively impact the commercial potential or diminish the value of NKTR-181.

***The commercial potential of a drug candidate in development is difficult to predict. If the market size for a new drug is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.***

It is very difficult to estimate the commercial potential of product candidates due to important factors such as safety and efficacy compared to other available treatments, including potential generic drug alternatives with similar efficacy profiles, changing standards of care, third party payer reimbursement standards, patient and physician preferences, drug scheduling status, the availability of

competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic versions of our product candidates following approval by regulatory authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to one or more of these risks the market potential for a drug candidate is lower than we anticipated, it could significantly and negatively impact the commercial terms of any collaboration partnership potential for such drug candidate or, if we have already entered into a collaboration for such drug candidate, the revenue potential from royalty and milestone payments could be significantly diminished and this would negatively impact our business, financial condition and results of operations. We also depend on our relationships with other companies for sales and marketing performance and the commercialization of product candidates. Poor performance by these companies, or disputes with these companies, could negatively impact our revenue and financial condition.

***If we are unable to establish and maintain collaboration partnerships on attractive commercial terms, our business, results of operations and financial condition could suffer.***

We intend to continue to seek partnerships with pharmaceutical and biotechnology partners to fund a portion of our research and development capital requirements. The timing of new collaboration partnerships is difficult to predict due to availability of clinical data, the outcomes from our clinical studies, the number of potential partners that need to complete due diligence and approval processes, the definitive agreement negotiation process and numerous other unpredictable factors that can delay, impede or prevent significant transactions. If we are unable to find suitable partners or negotiate collaboration arrangements with favorable commercial terms with respect to our existing and future drug candidates or the licensing of our intellectual property, or if any arrangements we negotiate, or have negotiated, are terminated, it could have a material adverse effect on our business, financial condition and results of operations.

***Preliminary and interim data from our clinical studies that we announce or publish from time to time are subject to audit and verification procedures that could result in material changes in the final data and may change as more patient data become available.***

From time to time, we publish preliminary or interim data from our clinical studies. Preliminary data remain subject to audit confirmation and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Interim data are also subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. As a result, preliminary and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data could significantly harm our business prospects.

***Delays in clinical studies are common and have many causes, and any significant delay in clinical studies being conducted by us or our partners could result in delay in regulatory approvals and jeopardize the ability to proceed to commercialization.***

We or our partners may experience delays in clinical trials of drug candidates. We currently have ongoing clinical studies for NKTR-181 in patients with chronic lower back pain and initiated a Phase 1/2 clinical study for NKTR-214 in December 2015. In addition, our collaboration partners have several ongoing Phase 3 clinical programs including Baxalta for ADYNOVATE™ (previously referred to as BAX 855) in the EU, Bayer for Amikacin Inhale and CIPRO Inhale, and Ophthotech for Fovista®. These and other clinical studies may not begin on time, enroll a sufficient number of patients or be completed on schedule, if at all. Clinical trials for any of our product candidates could be delayed for a variety of reasons, including:

- delays in obtaining regulatory authorization to commence a clinical study;
- delays in reaching agreement with applicable regulatory authorities on a clinical study design;
- imposition of a clinical hold by the FDA or other health authorities, which may occur at any time including after any inspection of clinical trial operations or trial sites;
- suspension or termination of a clinical study by us, our partners, the FDA or foreign regulatory authorities due to adverse side effects of a drug on subjects in the trial;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment rates;
- delays in manufacturing and delivery of sufficient supply of clinical trial materials; and
- changes in regulatory authorities policies or guidance applicable to our drug candidates.

If the initiation or completion of any of the planned clinical studies for our drug candidates is delayed for any of the above or other reasons, the regulatory approval process would be delayed and the ability to commercialize and commence sales of these drug candidates could be materially harmed, which could have a material adverse effect on our business, financial condition and results of operations.

***We may not be able to obtain intellectual property licenses related to the development of our drug candidates on a commercially reasonable basis, if at all.***

Numerous pending and issued U.S. and foreign patent rights and other proprietary rights owned by third parties relate to pharmaceutical compositions, methods of preparation and manufacturing, and methods of use and administration. We cannot predict with any certainty which, if any, patent references will be considered relevant to our or our collaboration partners' technology or drug candidates by authorities in the various jurisdictions where such rights exist, nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third parties. In certain cases, we have existing licenses or cross-licenses with third parties; however, the scope and adequacy of these licenses is very uncertain and can change substantially during long development and commercialization cycles for biotechnology and pharmaceutical products. There can be no assurance that we can obtain a license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternate technology. If we are required to enter into a license with a third party, our potential economic benefit for the products subject to the license will be diminished. If a license is not available on commercially reasonable terms or at all, we may be prevented from developing and commercializing the drug, which could significantly harm our business, results of operations, and financial condition.

***If any of our pending patent applications do not issue, or are deemed invalid following issuance, we may lose valuable intellectual property protection.***

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. We own more than 215 U.S. and 750 foreign patents and a number of pending patent applications that cover various aspects of our technologies. There can be no assurance that patents that have issued will be held valid and enforceable in a court of law. Even for patents that are held valid and enforceable, the legal process associated with obtaining such a judgment is time consuming and costly. Additionally, issued patents can be subject to opposition or other proceedings that can result in the revocation of the patent or maintenance of the patent in amended form (and potentially in a form that renders the patent without commercially relevant and/or broad coverage). Further, our competitors may be able to circumvent and otherwise design around our patents. Even if a patent is issued and enforceable, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire early and provide only a short period of protection, if any, following the commercialization of products encompassed by our patents. We may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, which could result in a loss of the patent and/or substantial cost to us.

We have filed patent applications, and plan to file additional patent applications, covering various aspects of our PEGylation and advanced polymer conjugate technologies and our proprietary product candidates. There can be no assurance that the patent applications for which we apply would actually issue as patents, or do so with commercially relevant and/or broad coverage. The coverage claimed in a patent application can be significantly reduced before the patent is issued. The scope of our claim coverage can be critical to our ability to enter into licensing transactions with third parties and our right to receive royalties from our collaboration partnerships. Since publication of discoveries in scientific or patent literature often lags behind the date of such discoveries, we cannot be certain that we were the first inventor of inventions covered by our patents or patent applications. In addition, there is no guarantee that we will be the first to file a patent application directed to an invention.

An adverse outcome in any judicial proceeding involving intellectual property, including patents, could subject us to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require us to cease using the technology in dispute. In those instances where we seek an intellectual property license from another, we may not be able to obtain the license on a commercially reasonable basis, if at all, thereby raising concerns on our ability to freely commercialize our technologies or products.

***We are involved in legal proceedings related to the intellectual property claims and may incur substantial litigation costs and liabilities that will adversely affect our business, financial condition and results of operations.***

From time to time, third parties have asserted, and may in the future assert, that we or our partners infringe their proprietary rights, such as patents and trade secrets, or have otherwise breached our obligations to them. A third party often bases its assertions on a claim that its patents cover our technology platform or drug candidates or that we have misappropriated its confidential or proprietary information. Similar assertions of infringement could be based on future patents that may issue to third parties. In certain of our agreements with our partners, we are obligated to indemnify and hold harmless our collaboration partners from intellectual property infringement, product liability and certain other claims, which could cause us to incur substantial costs and liability if we are called upon to defend ourselves and our partners against any claims. If a third party obtains injunctive or other equitable relief against

us or our partners, they could effectively prevent us, or our partners, from developing or commercializing, or deriving revenue from, certain drugs or drug candidates in the U.S. and abroad. Costs associated with litigation, substantial damage claims, indemnification claims or royalties paid for licenses from third parties could have a material adverse effect on our business, financial condition and results of operations.

We are involved in legal proceedings where we or other third parties are enforcing or seeking intellectual property rights, invalidating or limiting patent rights that have already been allowed or issued, or otherwise asserting proprietary rights through one or more potential legal remedies. For example, we are currently involved in a German litigation proceeding whereby Bayer is seeking co-ownership rights in certain of our patent filings pending at the European Patent Office covering (among other things) PEGylated Factor VIII which we have exclusively licensed to Baxalta. The subject matter of our patent filings in this proceeding relates to Bayer's investigational PEGylated recombinant Factor VIII compound. We believe that Bayer's claim to an ownership interest in these patent filings is without merit and are vigorously defending sole and exclusive ownership rights to this intellectual property. We are also regularly involved in opposition proceedings at the European Patent Office where third parties seek to invalidate or limit the scope of our allowed European patent applications covering (among other things) our drugs and platform technologies. The cost to us in initiating or defending any litigation or other proceeding, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts or result in financial implications either in terms of seeking license arrangements or payment of damages or royalties.

***Our manufacturing operations and those of our contract manufacturers are subject to laws and other governmental regulatory requirements, which, if not met, would have a material adverse effect on our business, results of operations and financial condition.***

We and our contract manufacturers are required in certain cases to maintain compliance with current good manufacturing practices (cGMP), including cGMP guidelines applicable to active pharmaceutical ingredients, and with laws and regulations governing manufacture and distribution of controlled substances, and are subject to inspections by the FDA, the Drug Enforcement Administration or comparable agencies in other jurisdictions administering such requirements. We anticipate periodic regulatory inspections of our drug manufacturing facilities and the manufacturing facilities of our contract manufacturers for compliance with applicable regulatory requirements. Any failure to follow and document our or our contract manufacturers' adherence to such cGMP and other laws and governmental regulations or satisfy other manufacturing and product release regulatory requirements may disrupt our ability to meet our manufacturing obligations to our customers, lead to significant delays in the availability of products for commercial use or clinical study, result in the termination or hold on a clinical study or delay or prevent filing or approval of marketing applications for our products. Failure to comply with applicable laws and regulations may also result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures, administrative detention, or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. Regulatory inspections could result in costly manufacturing changes or facility or capital equipment upgrades to satisfy the FDA that our manufacturing and quality control procedures are in substantial compliance with cGMP. Manufacturing delays, for us or our contract manufacturers, pending resolution of regulatory deficiencies or suspensions could have a material adverse effect on our business, results of operations and financial condition.

***If we or our contract manufacturers are not able to manufacture drugs or drug substances in sufficient quantities that meet applicable quality standards, it could delay clinical studies, result in reduced sales or constitute a breach of our contractual obligations, any of which could significantly harm our business, financial condition and results of operations.***

If we or our contract manufacturers are not able to manufacture and supply sufficient drug quantities meeting applicable quality standards required to support large clinical studies or commercial manufacturing in a timely manner, it could delay our or our collaboration partners' clinical studies or result in a breach of our contractual obligations, which could in turn reduce the potential commercial sales of our or our collaboration partners' products. As a result, we could incur substantial costs and damages and any product sales or royalty revenue that we would otherwise be entitled to receive could be reduced, delayed or eliminated. In some cases, we rely on contract manufacturing organizations to manufacture and supply drug product for our clinical studies and those of our collaboration partners. Pharmaceutical manufacturing of drugs and devices involves significant risks and uncertainties related to the demonstration of adequate stability, sufficient purification of the drug substance and drug product, the identification and elimination of impurities, optimal formulations, process and analytical methods validations, device performance and challenges in controlling for all of these variables. We have faced and may in the future face significant difficulties, delays and unexpected expenses as we validate third party contract manufacturers required for drug and device supply to support our clinical studies and the clinical studies and products of our collaboration partners. Failure by us or our contract manufacturers to supply drug product or devices in sufficient quantities that meet all applicable quality requirements could result in supply shortages for our clinical studies or the clinical studies and commercial activities of our collaboration partners. Such failures could significantly and materially delay clinical trials and

regulatory submissions or result in reduced sales, any of which could significantly harm our business prospects, results of operations and financial condition.

Building and validating large scale clinical or commercial-scale manufacturing facilities and processes, recruiting and training qualified personnel and obtaining necessary regulatory approvals is complex, expensive and time consuming. In the past we have encountered challenges in scaling up manufacturing to meet the requirements of large scale clinical trials without making modifications to the drug formulation, which may cause significant delays in clinical development. We experienced repeated significant delays in starting the Phase 3 clinical development program for Amikacin Inhale as we sought to finalize and validate the device design with a demonstrated capability to be manufactured at commercial scale. Drug/device combination products are particularly complex, expensive and time-consuming to develop due to the number of variables involved in the final product design, including ease of patient and doctor use, maintenance of clinical efficacy, reliability and cost of manufacturing, regulatory approval requirements and standards and other important factors. There continues to be substantial and unpredictable risk and uncertainty related to manufacturing and supply until such time as the commercial supply chain is validated and proven.

***Our revenue is exclusively derived from our collaboration agreements, which can result in significant fluctuation in our revenue from period to period, and our past revenue is therefore not necessarily indicative of our future revenue.***

Our revenue is exclusively derived from our collaboration agreements, from which we receive upfront fees, contract research payments, milestone and other contingent payments based on clinical progress, regulatory progress or net sales achievements, royalties and manufacturing revenue. Significant variations in the timing of receipt of cash payments and our recognition of revenue can result from significant payments based on the execution of new collaboration agreements, the timing of clinical outcomes, regulatory approval, commercial launch or the achievement of certain annual sales thresholds. The amount of our revenue derived from collaboration agreements in any given period will depend on a number of unpredictable factors, including our ability to find and maintain suitable collaboration partners, the timing of the negotiation and conclusion of collaboration agreements with such partners, whether and when we or our collaboration partners achieve clinical, regulatory and sales milestones, the timing of regulatory approvals in one or more major markets, reimbursement levels by private and government payers, and the market introduction of new drugs or generic versions of the approved drug, as well as other factors. Our past revenue generated from collaboration agreements is not necessarily indicative of our future revenue. If any of our existing or future collaboration partners fails to develop, obtain regulatory approval for, manufacture or ultimately commercialize any product candidate under our collaboration agreement, our business, financial condition, and results of operations could be materially and adversely affected.

***If we are unable either to create sales, marketing and distribution capabilities or to enter into agreements with third parties to perform these functions, we will be unable to commercialize our product candidates successfully.***

We currently have no sales, marketing or distribution capabilities. To commercialize any of our drugs that receive regulatory approval for commercialization, we must either develop internal sales, marketing and distribution capabilities, which would be expensive and time consuming, or enter into collaboration arrangements with third parties to perform these services. If we decide to market our products directly, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution, administration and compliance capabilities. Factors that may inhibit our efforts to commercialize our products directly or indirectly with our partners include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to use or prescribe our products;
- the lack of complementary products or multiple product pricing arrangements may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

***If we, or our partners through our collaborations, are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our products, which would adversely affect our business, results of operations and financial condition.***

To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market our products, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, any revenue we receive will depend upon the efforts of third parties, which may not be successful and over which we have little or no control—important examples of this risk include MOVANTIK™ partnered with AstraZeneca and ADYNOVATE™ (previously referred to as

BAX 855) partnered with Baxalta. In the event that we market our products without a partner, we would be required to build a sales and marketing organization and infrastructure, which would require a significant investment, and we may not be successful in building this organization and infrastructure in a timely or efficient manner.

***We purchase some of the starting material for drugs and drug candidates from a single source or a limited number of suppliers, and the partial or complete loss of one of these suppliers could cause production delays, clinical trial delays, substantial loss of revenue and contract liability to third parties.***

We often face very limited supply of a critical raw material that can only be obtained from a single, or a limited number of, suppliers, which could cause production delays, clinical trial delays, substantial lost revenue opportunities or contract liabilities to third parties. For example, there are only a limited number of qualified suppliers, and in some cases single source suppliers, for the raw materials included in our PEGylation and advanced polymer conjugate drug formulations. Any interruption in supply or failure to procure such raw materials on commercially feasible terms could harm our business by delaying our clinical trials, impeding commercialization of approved drugs or increasing our costs.

***We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.***

We rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets. In addition, unpatented proprietary rights, including trade secrets and know-how, can be difficult to protect and may lose their value if they are independently developed by a third party or if their secrecy is lost. Any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

***We expect to continue to incur substantial losses and negative cash flow from operations and may not achieve or sustain profitability in the future.***

For the nine months ended September 30, 2016, we reported a net loss of \$111.3 million. If and when we achieve profitability depends upon a number of factors, including the timing and recognition of milestone and other contingent payments and royalties received, the timing of revenue under our collaboration agreements, the amount of investments we make in our proprietary product candidates and the regulatory approval and market success of our product candidates. We may not be able to achieve and sustain profitability.

Other factors that will affect whether we achieve and sustain profitability include our ability, alone or together with our partners, to:

- develop drugs utilizing our technologies, either independently or in collaboration with other pharmaceutical or biotech companies;
- effectively estimate and manage clinical development costs, particularly the cost of the clinical studies for NKTR-181 and NKTR-214;
- receive necessary regulatory and marketing approvals;
- maintain or expand manufacturing at necessary levels;
- achieve market acceptance of our partnered products;
- receive royalties on products that have been approved, marketed or submitted for marketing approval with regulatory authorities; and
- maintain sufficient funds to finance our activities.

***If government and private insurance programs do not provide payment or reimbursement for our partnered products or proprietary products, those products will not be widely accepted, which would have a negative impact on our business, results of operations and financial condition.***

In both domestic and foreign markets, sales of our partnered and proprietary products that have received regulatory approval will depend in part on market acceptance among physicians and patients, pricing approvals by government authorities and the availability of payment or reimbursement from third-party payers, such as government health administration authorities, managed care providers, private health insurers and other organizations. Such third-party payers are increasingly challenging the price and cost

effectiveness of medical products and services. Therefore, significant uncertainty exists as to the pricing approvals for, and the payment or reimbursement status of, newly approved healthcare products. Moreover, legislation and regulations affecting the pricing of pharmaceuticals may change before regulatory agencies approve our proposed products for marketing and could further limit pricing approvals for, and reimbursement of, our products from government authorities and third-party payers. A government or third-party payer decision not to approve pricing for, or provide adequate coverage and reimbursements of, our products would limit market acceptance of such products.

***We depend on third parties to conduct the clinical trials for our proprietary product candidates and any failure of those parties to fulfill their obligations could harm our development and commercialization plans.***

We depend on independent clinical investigators, contract research organizations and other third-party service providers to conduct clinical trials for our proprietary product candidates. We rely heavily on these parties for successful execution of our clinical trials. Though we are ultimately responsible for the results of their activities, many aspects of their activities are beyond our control. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trials, but the independent clinical investigators may prioritize other projects over ours or communicate issues regarding our products to us in an untimely manner. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The early termination of any of our clinical trial arrangements, the failure of third parties to comply with the regulations and requirements governing clinical trials or the failure of third parties to properly conduct our clinical trials could hinder or delay the development, approval and commercialization of our product candidates and would adversely affect our business, results of operations and financial condition.

***Significant competition for our polymer conjugate chemistry technology platforms and our partnered and proprietary products and product candidates could make our technologies, products or product candidates obsolete or uncompetitive, which would negatively impact our business, results of operations and financial condition.***

Our PEGylation and advanced polymer conjugate chemistry platforms and our partnered and proprietary products and product candidates compete with various pharmaceutical and biotechnology companies. Competitors of our PEGylation and polymer conjugate chemistry technologies include Biogen Inc., Savient Pharmaceuticals, Inc., Dr. Reddy's Laboratories Ltd., SunBio Corporation, Mountain View Pharmaceuticals, Inc., Novo Nordisk A/S (formerly assets held by Neose Technologies, Inc.), and NOF Corporation. Several other chemical, biotechnology and pharmaceutical companies may also be developing PEGylation technologies or technologies that have similar impact on target drug molecules. Some of these companies license or provide the technology to other companies, while others are developing the technology for internal use.

There are many competitors for our proprietary product candidates currently in development. For Amikacin Inhale, the current standard of care includes several approved intravenous antibiotics for the treatment of either hospital-acquired pneumonia or ventilator-associated pneumonia in patients on mechanical ventilators. For MOVANTIK™, there are currently several alternative therapies used to address opioid-induced constipation (OIC) and opioid-induced bowel dysfunction (OBD), including Relistor® (methylnaltrexone bromide) Subcutaneous Injection, oral Amitizia (lubiprostone), and oral and rectal over-the-counter laxatives and stool softeners such as docusate sodium, senna and milk of magnesia. In addition, there are a number of companies developing potential products which are in various stages of clinical development and are being evaluated for the treatment of OIC and OBD in different patient populations, including Merck & Co., Inc., Progenics Pharmaceuticals, Inc. in collaboration with Salix Pharmaceuticals, Ltd., Mundipharma Int. Limited, Sucampo Pharmaceuticals, Inc., Develco Pharma GmbH, Alkermes plc, GlaxoSmithKline plc, Theravance, Inc., and Takeda Pharmaceutical Company Limited. For ADYNOVATE™, on June 6, 2014, the FDA approved Biogen Idec's ELOCTATE™ for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with Hemophilia A, and Bayer Healthcare and Novo Nordisk have ongoing Phase 3 clinical development programs for longer acting Factor VIII proteins based on pegylation technology approaches. For NKTR-181, there are numerous companies developing pain therapies designed to have less abuse potential primarily through formulation technologies and techniques applied to existing pain therapies. For NKTR-102 there are a number of chemotherapies and cancer therapies approved today and in various stages of clinical development for breast cancer, including, but not limited to: Abraxane® (paclitaxel protein-bound particles for injectable suspension (albumin bound)), Xeloda® (capecitabine), Afinitor® (everolimus), Doxil® (doxorubicin HCl), Ellence® (epirubicin), Gemzar® (gemcitabine), Halaven® (eribulin), Herceptin® (trastuzumab), Hycamtin® (topotecan), Ibrance® (palbociclib), Ixempra® (ixabepilone), Navelbine® (vinorelbine), Iniparib, Paraplatin® (carboplatin), Taxol® (paclitaxel) and Taxotere® (docetaxel). Major pharmaceutical or biotechnology companies with approved drugs or drugs in development for breast cancers include, but are not limited to, Bristol-Meyers Squibb Company, Eli Lilly & Co., Roche, GlaxoSmithKline plc, Johnson and Johnson, Pfizer Inc., Eisai Inc., and Sanofi Aventis S.A. There are numerous companies engaged in developing immunotherapies to be used alone, or in combination, to treat a wide range of oncology indications targeting both solid and liquid tumors. In particular, we expect to compete with therapies with tumor infiltrating lymphocytes, or TILS, chimeric antigen receptor-expressing T cells, or CAR-T, cytokine-based therapies, and checkpoint inhibitors. Potential competitors in the TIL and CAR-T space include Kite Pharma/NCI, Adaptimmune LLC, Celgene Corporation, Juno Therapeutics, and Novartis, Alkermes, Altor,

and Armo in the cytokine-based therapies space, and Tesaro, MacroGenics, Merck, BMS, and Roche in the checkpoint inhibitor space.

There can be no assurance that we or our partners will successfully develop, obtain regulatory approvals for and commercialize next-generation or new products that will successfully compete with those of our competitors. Many of our competitors have greater financial, research and development, marketing and sales, manufacturing and managerial capabilities. We face competition from these companies not just in product development but also in areas such as recruiting employees, acquiring technologies that might enhance our ability to commercialize products, establishing relationships with certain research and academic institutions, enrolling patients in clinical trials and seeking program partnerships and collaborations with larger pharmaceutical companies. As a result, our competitors may succeed in developing competing technologies, obtaining regulatory approval or gaining market acceptance for products before we do. These developments could make our products or technologies uncompetitive or obsolete.

***If product liability lawsuits are brought against us, we may incur substantial liabilities.***

The manufacture, clinical testing, marketing and sale of medical products involve inherent product liability risks. If product liability costs exceed our product liability insurance coverage, we may incur substantial liabilities that could have a severe negative impact on our financial position. Whether or not we are ultimately successful in any product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources and might result in adverse publicity, all of which would impair our business. Additionally, we may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses.

***Our future depends on the proper management of our current and future business operations and their associated expenses.***

Our business strategy requires us to manage our business to provide for the continued development and potential commercialization of our proprietary and partnered drug candidates. Our strategy also calls for us to undertake increased research and development activities and to manage an increasing number of relationships with partners and other third parties, while simultaneously managing the capital necessary to support this strategy. If we make a decision to bear a majority or all of the clinical development costs of NKTR-102 this will substantially increase our future capital requirements. If we are unable to manage effectively our current operations and any growth we may experience, our business, financial condition and results of operations may be adversely affected. If we are unable to effectively manage our expenses, we may find it necessary to reduce our personnel-related costs through reductions in our workforce, which could harm our operations, employee morale and impair our ability to retain and recruit talent. Furthermore, if adequate funds are not available, we may be required to obtain funds through arrangements with partners or other sources that may require us to relinquish rights to certain of our technologies, products or future economic rights that we would not otherwise relinquish or require us to enter into other financing arrangements on unfavorable terms.

***We are dependent on our management team and key technical personnel, and the loss of any key manager or employee may impair our ability to develop our products effectively and may harm our business, operating results and financial condition.***

Our success largely depends on the continued services of our executive officers and other key personnel. The loss of one or more members of our management team or other key employees could seriously harm our business, operating results and financial condition. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are also dependent on the continued services of our technical personnel because of the highly technical nature of our products and the regulatory approval process. Because our executive officers and key employees are not obligated to provide us with continued services, they could terminate their employment with us at any time without penalty. We do not have any post-employment noncompetition agreements with any of our employees and do not maintain key person life insurance policies on any of our executive officers or key employees.

***Because competition for highly qualified technical personnel is intense, we may not be able to attract and retain the personnel we need to support our operations and growth.***

We must attract and retain experts in the areas of clinical testing, manufacturing, research, regulatory and finance, and may need to attract and retain marketing and distribution experts and develop additional expertise in our existing personnel. We face intense competition from other biopharmaceutical companies, research and academic institutions and other organizations for qualified personnel. Many of the organizations with which we compete for qualified personnel have greater resources than we have. Because competition for skilled personnel in our industry is intense, companies such as ours sometimes experience high attrition rates with regard to their skilled employees. Further, in making employment decisions, job candidates often consider the value of the stock options they are to receive in connection with their employment. Our equity incentive plan and employee benefit plans may not be effective in motivating or retaining our employees or attracting new employees, and significant volatility in the price of our stock may



adversely affect our ability to attract or retain qualified personnel. If we fail to attract new personnel or to retain and motivate our current personnel, our business and future growth prospects could be severely harmed.

***If earthquakes or other catastrophic events strike, our business may be harmed.***

Our corporate headquarters, including a substantial portion of our research and development operations, are located in the San Francisco Bay Area, a region known for seismic activity and a potential terrorist target. In addition, we own facilities for the manufacture of products using our PEGylation and advanced polymer conjugate technologies in Huntsville, Alabama and own and lease offices in Hyderabad, India. There are no backup facilities for our manufacturing operations located in Huntsville, Alabama. In the event of an earthquake or other natural disaster, political instability, or terrorist event in any of these locations, our ability to manufacture and supply materials for drug candidates in development and our ability to meet our manufacturing obligations to our customers would be significantly disrupted and our business, results of operations and financial condition would be harmed. Our collaborative partners may also be subject to catastrophic events, such as earthquakes, floods, hurricanes and tornadoes, any of which could harm our business, results of operations and financial condition. We have not undertaken a systematic analysis of the potential consequences to our business, results of operations and financial condition from a major earthquake or other catastrophic event, such as a fire, sustained loss of power, terrorist activity or other disaster, and do not have a recovery plan for such disasters. In addition, our insurance coverage may not be sufficient to compensate us for actual losses from any interruption of our business that may occur.

***We have implemented certain anti-takeover measures, which make it more difficult to acquire us, even though such acquisitions may be beneficial to our stockholders.***

Provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even though such acquisitions may be beneficial to our stockholders. These anti-takeover provisions include:

- establishment of a classified board of directors such that not all members of the board may be elected at one time;
- lack of a provision for cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates;
- the ability of our board to authorize the issuance of “blank check” preferred stock to increase the number of outstanding shares and thwart a takeover attempt;
- prohibition on stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders;
- establishment of advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings; and
- limitations on who may call a special meeting of stockholders.

Further, provisions of Delaware law relating to business combinations with interested stockholders may discourage, delay or prevent a third party from acquiring us. These provisions may also discourage, delay or prevent a third party from acquiring a large portion of our securities or initiating a tender offer or proxy contest, even if our stockholders might receive a premium for their shares in the acquisition over the then-current market prices. We also have a change of control severance benefit plan, which provides for certain cash severance, stock award acceleration and other benefits in the event our employees are terminated (or, in some cases, resign for specified reasons) following an acquisition. This severance plan could discourage a third party from acquiring us.

***The price of our common stock is expected to remain volatile.***

Our stock price is volatile. During the three months ended September 30, 2016, based on closing prices on The NASDAQ Global Select Market, the closing price of our common stock ranged from \$14.09 to \$19.68 per share. We expect our stock price to remain volatile. A variety of factors may have a significant effect on the market price of our common stock, including the risks described in this section titled “Risk Factors” and the following:

- announcements of data from, or material developments in, our clinical studies and those of our collaboration partners, including data regarding efficacy and safety, delays in clinical development, regulatory approval or commercial launch;
- announcements by collaboration partners as to their plans or expectations related to drug candidates and approved drugs in which we have a substantial economic interest;
- announcements regarding terminations or disputes under our collaboration agreements;

- fluctuations in our results of operations;
- developments in patent or other proprietary rights, including intellectual property litigation or entering into intellectual property license agreements and the costs associated with those arrangements;
- announcements of technological innovations or new therapeutic products that may compete with our approved products or products under development;
- announcements of changes in governmental regulation affecting us or our competitors;
- litigation brought against us or third parties to whom we have indemnification obligations;
- public concern as to the safety of drug formulations developed by us or others;
- our financing needs and activities; and
- general market conditions.

At times, our stock price has been volatile even in the absence of significant news or developments. The stock prices of biotechnology companies and securities markets generally have been subject to dramatic price swings in recent years.

***The indenture governing our 7.75% senior secured notes imposes significant operating and financial restrictions on us and our subsidiaries that may prevent us from pursuing certain business opportunities and restrict our ability to operate our business.***

On October 5, 2015, we issued \$250.0 million in aggregate principal amount of 7.75% senior secured notes due October 2020. The indenture governing the senior secured notes contains covenants that restrict our and our subsidiaries' ability to take various actions, including, among other things:

- incur or guarantee additional indebtedness or issue disqualified capital stock or cause certain of our subsidiaries to issue preferred stock;
- pay dividends or distributions, redeem equity interests or subordinated indebtedness or make certain types of investments;
- create or incur liens;
- transfer, sell, lease or otherwise dispose of assets and issue or sell equity interests in certain of our subsidiaries;
- incur restrictions on certain of our subsidiaries' ability to pay dividends or other distributions to the Company or to make intercompany loans, advances or asset transfers;
- enter into transactions with affiliates;
- engage in any business other than businesses which are the same, similar, ancillary or reasonably related to our business as of the date of the indenture; and
- consummate a merger, consolidation, reorganization or business combination, sell, lease, convey or otherwise dispose of all or substantially all of our assets or other change of control transaction.

This indenture also requires us to maintain a minimum cash balance of \$60.0 million. We have certain reporting obligations under the indenture regarding cash position and royalty revenue. The indenture specifies a number of events of default, some of which are subject to applicable grace or cure periods, including, among other things, non-payment defaults, covenant defaults, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults, non-payment of material judgments, loss of any material business license, criminal indictment of the Company, and certain civil forfeiture proceedings involving material assets of the Company. Our ability to comply with these covenants will likely be affected by many factors, including events beyond our control, and we may not satisfy those requirements. Our failure to comply with our obligations could result in an event of default under our other indebtedness and the acceleration of our other indebtedness, in whole or in part, could result in an event of default under the indenture governing the senior secured notes.

The restrictions contained in the indenture governing the senior secured notes could also limit our ability to plan for or react to market conditions, meet capital needs or otherwise restrict our activities or business plans and adversely affect our ability to finance our operations, enter into acquisitions or to engage in other business activities that would be in our interest.

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

None, including no purchases of any class of our equity securities by us or any affiliate pursuant to any publicly announced repurchase plan in the three months ended September 30, 2016.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

Except as so indicated in Exhibits 32.1 and 101, the following exhibits are filed as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

<b>Exhibit Number</b>	<b>Description of Documents</b>
10.1(1)	Clinical Trial Collaboration Agreement dated as of September 21, 2016, by and between Bristol-Myers Squibb Company and Nektar Therapeutics.+
31.1(1)	Certification of Nektar Therapeutics' principal executive officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2(1)	Certification of Nektar Therapeutics' principal financial officer required by Rule 13a-14(a) or Rule 15d-14(a).
32.1*	Section 1350 Certifications.
101**	The following materials from Nektar Therapeutics' Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Condensed Consolidated Balance Sheets, (ii) the unaudited Condensed Consolidated Statements of Operations, (iii) the unaudited Condensed Consolidated Statements of Comprehensive Loss, (iv) the unaudited Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.

+ Confidential treatment with respect to specific portions of this Exhibit has been requested, and such portions are omitted and have been filed separately with the SEC.

(1) Filed herewith.

\* Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act, except as otherwise stated in such filing.

\*\* XBRL information is filed herewith.

**SIGNATURES**

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

By: /s/ GIL M. LABRUCHERIE

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**Gil M. Labrucherie**  
**Senior Vice President and Chief Financial Officer**  
Date: November 3, 2016

By: /s/ JILLIAN B. THOMSEN

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**Jillian B. Thomsen**  
**Senior Vice President, Finance and Chief Accounting Officer**  
Date: November 3, 2016

## EXHIBIT INDEX

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31.2(1)	Certification of Nektar Therapeutics' principal financial officer required by Rule 13a-14(a) or Rule 15d-14(a).
32.1*	Section 1350 Certifications.
101**	The following materials from Nektar Therapeutics' Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Condensed Consolidated Balance Sheets, (ii) the unaudited Condensed Consolidated Statements of Operations, (iii) the unaudited Condensed Consolidated Statements of Comprehensive Loss, (iv) the unaudited Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.
+	Confidential treatment with respect to specific portions of this Exhibit has been requested, and such portions are omitted and have been filed separately with the SEC.
(1)	Filed herewith.
*	Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act, except as otherwise stated in such filing.
**	XBRL information is filed herewith.

## CLINICAL TRIAL COLLABORATION AGREEMENT

CLINICAL TRIAL COLLABORATION AGREEMENT (the “*Agreement*”) is made and entered into effective as of September 21, 2016 (the “*Effective Date*”) by and between Nektar Therapeutics, a Delaware corporation, headquartered at 455 Mission Bay Boulevard South, San Francisco, CA 94158 (“*Nektar*”), and Bristol-Myers Squibb Company, a Delaware corporation, headquartered at 345 Park Avenue, New York, New York 10154 (“*BMS*”). Nektar and BMS may be referred to herein individually as a “*Party*,” or collectively as the “*Parties*.”

### RECITALS

AS, Nektar and BMS desire to collaborate on one or more clinical trials of a combination therapy using Nektar’s IL2-based CD122-biased agonist, known as “*NKTR-214*”, and BMS’s human monoclonal antibody that binds PD-1 known as “*Nivolumab*”, certain rights to which are licensed by BMS from, and shared by BMS with, Ono Pharmaceutical Co. Ltd. (“*Ono*”).

HEREFORE, 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.

1.1 “*Affiliate*” shall mean, with respect to a particular Entity, any other Entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such particular Entity, but only for so long as such Entity meets the definition of Affiliate hereunder. As used in this section, 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 such Entity otherwise has the actual ability to control and direct the management of the other Entity, whether by contract or otherwise.

1.2 “*Aggregate Safety Information*” shall mean, with respect to a Party’s Single Agent Compound, the (a) safety and toxicity information for such Single Agent Compound that is Combined Therapy Study Data, plus (b) safety and toxicity information from all other clinical trials of such Single Agent Compound, whether alone or in combination with another pharmaceutical agent, in each case including information related to serious adverse events, adverse drug reactions, adverse events, discontinuations due to adverse events and Grade 3 and Grade 4 laboratory abnormalities. Aggregate Safety Information shall be provided by a Party to

the other in the same format as is contained in the investigators' brochures prepared by such Party for its Compound in each country where a Combined Therapy Trial will be conducted.

**1.3 “ Agreement ”** shall have the meaning set forth in the preamble to this Agreement, as it may be amended by the Parties from time to time.

**1.4 “ Applicable Law ”** shall mean all applicable laws, rules and regulations (whether federal, state or local) that may be in effect from time to time and applicable to conduct under this Agreement, including current Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP).

**1.5 “ Arbitration Matter ”** shall mean 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(a). For clarity, no JDC Dispute that is subject to Sections 2.8(a) or 2.8(b), no Publication Dispute nor any other matter requiring mutual agreement of both Parties shall be an Arbitration Matter.

**1.6 “ Bioanalysis Plan ”** shall mean the bioanalysis plan for any Samples as may be contemplated by a Combined Therapy Trial, Protocol or another subsequent written agreement between the Parties, as described in Section 13.7.

**1.7 “ BMS ”** shall have the meaning set forth in the preamble to this Agreement.

**1.8 “ BMS Compound ”** shall mean BMS's proprietary anti-PD-1 monoclonal antibody known as Nivolumab.

**1.9 “ BMS Indemnitees ”** shall have the meaning set forth in Section 11.2 of this Agreement.

**1.10 “ BMS Independent Patent Rights ”** shall mean any Patent Rights Controlled by BMS (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement that Cover the use (whether alone or in combination with other agents), manufacture, formulation or composition of matter of the BMS Compound, but which do not Cover any Collaboration Invention.

**1.11 “ BMS Regulatory Documentation ”** shall mean any Regulatory Documentation related to the BMS Compound that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

**1.12 “ BMS Study Data ”** shall have the meaning set forth in Section 8.2 of this Agreement.

**1.13 “ BMS Study Invention ”** shall mean any invention or Technology that would be a Collaboration Invention (except for the exclusion set forth therein) *and* that relates to (a) the composition of matter of the BMS Compound (and not the Nektar Compound), (b) method of



manufacture or formulation of the BMS Compound (and not the Nektar Compound) as a single agent, and/or (c) a method of use of the BMS Compound (and not the Nektar Compound) as a monotherapy or as used with agents, antibodies or compounds (other than a Collaboration Invention comprising, whether generically or specifically, the use of both the BMS Compound (and/or any other antibodies that are designed to selectively bind to PD-1 or PD-L1 ) and a Nektar Compound (and/or any other IL2-based CD122 agonist)).

**1.14 “ BMS Study Patent Rights ”** shall mean any Patent Rights that are Controlled by BMS and Cover any BMS Study Invention (and not a Nektar Study Invention or Combined Therapy Trial Invention) or BMS Study Data, excluding BMS Independent Patent Rights and BMS Technology. For avoidance of doubt, any such Patent Rights that Cover both (x) a BMS Study Invention and (y) any other type of Collaboration Invention are included within the Combined Therapy Patent Rights.

**1.15 “ BMS Technology ”** shall mean all Technology Controlled by BMS (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement related to the BMS Compound or the Combined Therapy and necessary for the conduct of the Combined Therapy Trials. For clarity, BMS Technology does not include (a) Collaboration Inventions, (b) Study Data, or (c) Combined Therapy Trial Regulatory Documentation.

**1.16 “ Business Day ”** shall mean 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.

**1.17 “ Clinical Hold ”** shall mean (i) an order issued by the FDA 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 (ii) an equivalent order to that set forth in (i) issued by a Regulatory Authority other than the FDA in any other country or group of countries.

**1.18 “ Collaboration Invention ”** shall mean any invention or Technology, whether or not patentable, that is made, conceived, or first actually reduced to practice by or on behalf of a Party, or by or on behalf of the Parties together (including by a Third Party in the performance of the Combined Therapy Trial), in the performance of the Combined Therapy Trials, Statistical Analysis Plan or Bioanalysis Plan to be conducted under this Agreement, but excluding any Study Data, or any Nektar Study Invention or BMS Study Invention.

**1.19 “ Combined Therapy ”** shall mean a therapy using the Nektar Compound and the BMS Compound in combination use as individual formulations, for use in the Field, with or without another agent.

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

**1.21 “ Combined Therapy Trial Invention(s) ”** shall mean all Collaboration Inventions that are not Nektar Study Inventions or BMS Study Inventions. For clarity, Combined Therapy

Trial Inventions include any Collaboration Invention comprising, whether generically or specifically, the use of both the BMS Compound (and/or any other antibodies that are designed to selectively bind to PD-1 or PD-L1) and a Nektar Compound (and/or any other IL2-based CD122 agonist).

**1.22 “ Combined Therapy Patent Right(s) ”** shall mean any Patent Rights that are Controlled by either Party that Cover any Combined Therapy Trial Invention or Combined Therapy Study Data, excluding BMS Independent Patent Rights or Nektar Independent Patent Rights.

**1.23 “ Combined Therapy Study Data ”** shall have the meaning set forth in Section 8.2 of this Agreement.

**1.24 “ Combined Therapy Trial ”** or **“ Combined Therapy Trials ”** shall have the meaning set forth in Section 2.1(a) of this Agreement.

**1.25 “ Combined Therapy Trial Regulatory Documentation ”** shall mean any Regulatory Documentation to be submitted for the conduct of the Combined Therapy Trial, but excluding (a) any Nektar Regulatory Documentation and (b) any BMS Regulatory Documentation.

**1.26 “ Commercially Reasonable Efforts ”** means: (a) the carrying out of a Party’s obligations or tasks, other than as set forth in clause (b), with a level of efforts and resources consistent with the commercially reasonable practices normally devoted by a similarly situated company, subject to and in accordance with the terms and conditions of this Agreement; and (b) where applied to a Party’s efforts to conduct any Combined Therapy Trial under the applicable Protocol, 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.

**1.27 “ Confidential Information ”** shall have the meaning set forth in Section 9.1 of this Agreement.

**1.28 “ Control ”** or **“ Controlled ”** shall mean, 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.

**1.29 “ Cover ”** means, with respect to a Patent, that, but for rights granted to a Person under such Patent, the practice by such Person of an invention described in such Patent would infringe a claim included in such Patent, or in the case of a Patent 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.

**1.30** “ *CRO* ” means any Third Party contract research organization used to conduct a Combined Therapy Trial, including laboratories and Third Parties used to maintain the Global Safety Database from a Combined Therapy Trial, but, for clarity, excluding clinical trial sites and any Third Parties who are individuals.

**1.31** “ *Database Lock* ” means, with respect to each Combined Therapy Trial, such actions as are taken with approval of the JDC to prevent any modification to the database of Study Data generated in the course of such Combined Therapy Trial.

**1.32** “ *Effective Date* ” shall have the meaning set forth in the preamble to this Agreement.

**1.33** “ *Entity* ” means a partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization.

**1.34** “ *Executive Officers* ” shall mean the Chief Medical Officer of Nektar and the Senior Vice President, Global Development & Medical Affairs of BMS (or their respective designees).

**1.35** “ *Exclusive Collaboration Period* ” shall mean the period commencing on the Effective Date, and ending on the earlier of (a) September 30, 2018 or (b) the effective date of termination of this Agreement pursuant to Section 12.2 or Section 12.3.

**1.36** “ *FDA* ” shall mean the United States Food and Drug Administration, or any successor agency having the same or similar authority.

**1.37** “ *Field* ” shall mean treatment of patients with cancer.

**1.38** “ *Global Safety Database* ” shall mean the database containing 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.

**1.39** “ *Good Clinical Practices* ” or “ *GCP* ” shall mean the standards, practices and procedures set forth in the International Conference on Harmonization guidelines entitled in “Good Clinical Practice: Consolidated Guideline,” including related regulatory requirements imposed by the FDA and (as applicable) any equivalent or similar standards in jurisdictions outside the United States, to the extent that such standards are applicable in the jurisdiction in which the relevant Combined Therapy Trial is conducted or required to be followed in the jurisdiction in which Regulatory Authority approval of a product will be sought.

**1.40** “ *Good Laboratory Practices* ” or “ *GLP* ” shall mean the regulations set forth in 21 C.F.R. Part 58 and the requirements expressed or implied thereunder imposed by the FDA and (as applicable) any equivalent or similar standards in jurisdictions outside the United States.

1.41 “ **Good Manufacturing Practices** ” or “ **GMP** ” means the regulations set forth in 21 C.F.R. Parts 210–211, and the requirements thereunder imposed by the FDA, and, as applicable, any similar or equivalent regulations and requirements in jurisdictions outside the United States.

1.42 “ **IND** ” shall mean (a) an Investigational New Drug Application as defined in the Federal 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.

1.43 “ **Initiation** ” shall mean dosing of the first patient in any Combined Therapy Trial.

1.44 “ **Major Market** ” shall mean [\*\*\*].

1.45 “ **Manufacture** ” or “ **Manufacturing** ” shall mean 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 Trials under Applicable Law.

1.46 “ **Material Safety Issue** ” means a Party’s good faith belief that there is an unacceptable risk for harm in humans based upon: (i) pre-clinical safety data, including data from animal toxicology studies; or (ii) the observation of serious adverse effects in humans after the Nektar Compound or the BMS Compound, either as a single agent 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 Trial.

1.47 “ **Nektar** ” shall have the meaning set forth in the preamble to this Agreement.

1.48 “ **Nektar Compound** ” shall mean NKTR-214, as set forth on the attached Exhibit E.

1.49 “ **Nektar Indemnitees** ” shall have the meaning set forth in Section 11.1 of this Agreement.

1.50 “ **Nektar Independent Patent Rights** ” shall mean any Patent Rights Controlled by Nektar (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement that Cover the use (whether alone or in combination with other agents), manufacture, formulation , or composition of matter of the Nektar Compound, but which do not Cover any Collaboration Invention.

1.51 “ **Nektar Regulatory Documentation** ” shall mean any Regulatory Documentation related to the Nektar Compound that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

1.52 “ *Nektar Study Data* ” shall have the meaning set forth in Section 8.2 of this Agreement.

1.53 “ *Nektar Study Invention* ” shall mean any invention or Technology that would be a Collaboration Invention (except for the exclusion set forth therein) and that relates to (a) the composition of matter of the Nektar Compound (and not the BMS Compound), (b) method of manufacture or formulation of the Nektar Compound (and not the BMS Compound) as a single agent, or (c) a method of use of the Nektar Compound (and not the BMS Compound) as a monotherapy or as used in combination with agents, antibodies or compounds (other than an Collaboration Invention comprising, whether generically or specifically, both the BMS Compound (and/or any other antibodies that are designed to selectively bind to PD-1 or PD-L1) and a Nektar Compound (and/or any other IL2-based CD122 agonist)).

1.54 “ *Nektar Study Patent Rights* ” shall mean any Patent Rights that are Controlled by Nektar and Cover any Nektar Study Invention (and not a BMS Study Invention or the Combined Therapy Trial Invention) or Nektar Study Data, excluding Nektar Independent Patent Rights and Nektar Technology. For avoidance of doubt, any Patent Rights that Cover both (x) a Nektar Study Invention and (y) any other type of Collaboration Invention are included within the Combined Therapy Patent Rights.

1.55 “ *Nektar Technology* ” shall mean all Technology Controlled by Nektar (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement related to the Nektar Compound or the Combined Therapy and necessary for the conduct of the Combined Therapy Trials. For clarity, Nektar Technology does not include (a) Collaboration Inventions, (b) Study Data, or (c) Combined Therapy Trial Regulatory Documentation.

1.56 “ *Ono* ” shall have the meaning set forth in the recitals of this Agreement.

1.57 “ *Ono-BMS Agreements* ” means those certain Collaboration Agreements between BMS and Ono dated as 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.

1.58 “ *Ono Territory* ” means Japan, Korea and Taiwan.

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

1.60 “ *Patent Rights* ” shall mean any and all (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, and “**Patent**” shall mean any of the foregoing issued or granted rights.

1.61 “**PD-1**” shall mean programmed cell death protein 1.

1.62 “**PD-L1**” shall mean programmed death-ligand 1.

1.63 “**Person**” shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, Entity or other similar entity or organization, including a government or political subdivision, department or agency of a government.

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

1.65 “**Regulatory Documentation**” shall mean, with respect to a product containing the BMS Compound as monotherapy, the Nektar Compound as monotherapy or the BMS Compound and Nektar Compound in combination use as individual formulations, all submissions to Regulatory Authorities in connection with the development of such product, 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 with respect to clinical data).

1.66 “**Restricted Third Party**” shall mean [\*\*\*].

1.67 “**Right of Cross-Reference**” shall mean, with regard to a Party, an authorization that permits an applicable Regulatory Authority in a country to rely on 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 such Party’s Single Agent Compound (including, in the case of BMS, the Nektar IND and the Combined Therapy IND), only to the extent necessary for the conduct of a Combined Therapy 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 Nektar IND relating to the Combined Therapy or the Combined Therapy IND, without the disclosure of such information to such Party.

1.68 “**Samples**” shall mean biological specimens collected from Combined Therapy 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).

1.69 “**Serious Adverse Event**” or “**SAE**” shall mean an adverse event that results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization

or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

**1.70** “ *Single Agent Compound* ” or “ *Compound* ” shall mean, (a) with respect to Nektar, the Nektar Compound, and (b) with respect to BMS, the BMS Compound.

**1.71** “ *Statistical Analysis Plan* ” shall mean the set of analyses of the Study Data for each Combined Therapy Trial conducted hereunder prepared by Nektar (in consultation with BMS) and approved by the JDC and shall include safety analyses for the Combined Therapy in each Combined Therapy Trial. The Statistical Analysis Plan document for a Combined Therapy Trial will be agreed to by the JDC before Database Lock and any material amendments thereto will require JDC approval.

**1.72** “ *Technology* ” shall mean 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, materials, data and results, including Regulatory Documentation.

**1.73** “ *Third Party* ” shall mean any Person or Entity other than Nektar and BMS and their respective Affiliates.

**1.74** “ *Third Party License Payments* ” shall mean any payments (e.g., upfront payments, maintenance 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 (i) the making, using or importing of a Party’s Single Agent Compound for the conduct of the Combined Therapy Trial, or (ii) the conduct of any Combined Therapy Trial.

**Additional Definitions.** In addition to those terms defined above, definitions for each of the following terms are found in the body of this Agreement as indicated below:

<b><u>Defined Term</u></b>	<b><u>Section</u></b>
<i>AAA</i>	13.3(b)
<i>Alliance Manager</i>	2.7
<i>Annual Report</i>	9.3
<i>Breaching Party</i>	12.2(a)
<i>CDA</i>	9.1(a)
<i>Co-Chair</i>	2.3

<b>CSRs</b>	5.1(a)(xvi)
<b>CRO Agreement</b>	2.4(o)
<b>Cure Period</b>	12.2(a)
<b>Current Report</b>	9.3
<b>Dispute</b>	13.3(a)
<b>Final Match Date</b>	3.7
<b>Indemnify</b>	11.1
<b>Informed Consent Form (ICF)</b>	2.6(a)
<b>Infringe or Infringement</b>	6.3(a)
<b>Initial Trial</b>	2.1(a)
<b>IRBs</b>	9.3(d)
<b>JDC or Joint Development Committee</b>	2.3
<b>JDC Dispute</b>	2.8
<b>Licensee</b>	13.10(b)
<b>Losses</b>	11.1
<b>Monthly Report</b>	7.3(a)
<b>Nektar IND</b>	2.1(b)
<b>Non-Breaching Party</b>	12.2(a)
<b>Officials</b>	10.9
<b>Operational Matters</b>	2.6(a)
<b>Payment</b>	10.9
<b>Permitted Research</b>	Exhibit C
<b>Permitted IL2 Research</b>	Exhibit C
<b>Pharmaceutical Entity</b>	1.66
<b>Payment or Other Transfers of Value (POTV)</b>	9.6(a)
<b>Protocol</b>	2.1(a)
<b>Publication Dispute</b>	9.5(b)
<b>Quality Agreement</b>	4.3
<b>Recipients</b>	9.6(c)
<b>Restricted Combination</b>	Exhibit C
<b>Restricted IL2 Combination</b>	Exhibit C
<b>Results</b>	9.5(b)
<b>Right of First Refusal (ROFR)</b>	3.7



<i>ROFR Offer Period</i>	3.7
<i>ROFR Negotiation Period</i>	3.7
<i>SEC</i>	9.3
<i>Site/CRO List</i>	2.6(d)
<i>Study Data</i>	8.1
<i>Sunshine Laws</i>	9.6(c)
<i>Supply Agreement</i>	4.4
<i>Term</i>	12.1
<i>Third Party Claim</i>	11.1
<i>Third Party Terms</i>	3.7
<i>Third Party Study Costs</i>	7.2

## ARTICLE 2

### COLLABORATION SCOPE; GOVERNANCE

#### 2.1 Scope of Collaboration; Governance of Agreement.

(a) The Parties shall, pursuant to this Agreement, collaborate to conduct the following clinical trials (each, a “ **Combined Therapy Trial** ”) (i) a Phase I-II clinical trial evaluating the Combined Therapy (the “ **Initial Trial** ”), and (ii) such other clinical trials evaluating the Combined Therapy as may be mutually agreed upon by the Parties. Each Combined Therapy Trial shall be conducted in accordance with a protocol (each, a “ **Protocol** ”) to be drafted by Nektar (in consultation with BMS) and mutually agreed upon by the Parties at a meeting of the JDC. Any substantive amendments to the Protocol will be subject to mutual agreement of the Parties at a meeting of the JDC or by written agreement (including by email acknowledgment) of the JDC Co-Chairs (including by email acknowledgment) without a meeting. The Protocol, [\*\*\*], is attached hereto as Exhibit A.

(b) The Combined Therapy Trials shall be conducted under either (1) Nektar’s existing IND as of the Effective Date for the Nektar Compound (the “ **Nektar IND** ”) or (2) a new IND, for which Nektar will be the sponsor of record (the “ **Combined Therapy IND** ”).

(i) Nektar IND. Nektar shall have complete legal interest in and control of the Nektar IND. In no event will Nektar be required to obtain the consent of BMS to transfer or encumber the Nektar IND, and Nektar shall not have any obligation to share with BMS any consideration received in connection with the sale, license, use or other conveyance of the Nektar IND. Nektar shall have complete control as to any Right of Cross-Reference granted by Nektar to a Third Party with respect to any portion of the Nektar IND relating to the Nektar Compound for use as monotherapy or for use in combination with any other molecules (other than for use with the BMS Compound).

**(ii) Combined Therapy IND.** Each Party shall have a beneficial one-half interest in such Combined Therapy IND ; *provided , however ,* that: (i) in no event will either Party be required to obtain the consent of the other Party to transfer or encumber its interest in the Combined Therapy IND; *provided* that (a) the transferee or encumbrance holder agrees to abide by the terms and conditions of this Agreement, (b) any transfer occurs only in connection with, and to the same transferee of, a transfer of all of a Party's rights in its Single Agent Compound, and (c) each Party provide written notice of such transfer or encumbrance to the other Party within [\*\*\*] of such transfer or encumbrance; (ii) Nektar shall be the sole holder of all legal interests in the Combined Therapy IND, and neither Party shall have any obligation to share with the other Party any consideration received in connection with the sale, license or use of its interest in the Combined Therapy IND where permitted by this Agreement; and (iii) neither Party shall be permitted to grant any third Person any Right of Cross-Reference with respect to any portion of the Combined Therapy IND relating to the other Party's Single Agent Compound for use as monotherapy or for use in combination with any other molecules (other than for use with Nivolumab, in the case of BMS, or NKTR-214, in the case of Nektar, in each case as permitted by this Agreement), except as required by a governmental authority. Each Party shall provide a Right of Cross-Reference to its existing respective IND for its respective Single Agent Compound as necessary to allow the Combined Therapy Trials to be conducted under the Combined Therapy IND. For the avoidance of doubt, each Party shall be responsible for (x) drafting and updating as necessary the investigator's brochure for its respective Single Agent Compound, and (y) filing all necessary Regulatory Documentation to the existing IND for its respective Single Agent Compound, including the submission to such existing IND of serious adverse event and adverse drug reaction cases emerging from any Combined Therapy Trial.

**(c) Information to be Provided by Nektar**

**(i)** Nektar shall provide BMS with the following relating to the Nektar Compound: (i) the latest investigator's brochure (and annual updates), list of ongoing clinical studies and clinically relevant safety information that emerges from other clinical studies, in each case within [\*\*\*] (or as soon as reasonably practicable) after general distribution of final versions of such documents within Nektar, and further to the extent any applicable confidentiality obligations relating to other combination therapy trials involving the Nektar Compound and a Third Party's compound do not prevent Nektar from sharing such documents with BMS, (ii) [\*\*\*] notice of any material safety related communications with any Regulatory Authority and the substance of such communications regarding any clinical trials of the Nektar Compound during the Term; (iii) a summary of all new clinically relevant toxicology study data on the Nektar Compound within [\*\*\*] (or as soon as reasonably practicable) after generation within Nektar ; and (iv) Aggregate Safety Information from all other clinical trials of the Nektar Compound (if not provided elsewhere) [\*\*\*] or as otherwise agreed to by the JDC. BMS shall use any such data provided pursuant to this Section 2.1(c)(i) solely to evaluate the safety of (x) the Nektar Compound for use in the Combined Therapy Trials and (y) the Combined Therapy. All such disclosures are Confidential Information of Nektar.

**(ii)** Nektar shall provide BMS with safety analyses for each Combined Therapy Trial in accordance with the applicable Statistical Analysis Plan. Each Party shall use

any such data provided pursuant to this Section 2.1(c)(ii) solely to evaluate the safety of (x) its own Compound for use in the Combined Therapy Trials, (y) the Combined Therapy and (z) as permitted elsewhere in this Agreement. All such disclosures are Confidential Information of both Parties.

(iii) Nektar shall provide BMS with safety analyses for the BMS Compound as monotherapy from each Combined Therapy Trial in accordance with the applicable Statistical Analysis Plan. BMS may use such information for any purpose and all such information and data shall be Confidential Information of BMS.

(d) *Information to be Provided by BMS.* BMS shall provide Nektar with the following relating to the BMS Compound: (i) the latest investigator's brochure (and annual updates), list of ongoing clinical studies and clinically relevant safety information that emerges from other clinical studies, in each case within [\*\*\*] (or as soon as reasonably practicable) after general distribution of final versions of such documents within BMS, and further to the extent any applicable confidentiality obligations relating to other combination therapy trials involving the BMS Compound and a Third Party's compound do not prevent BMS from sharing such documents with Nektar, (ii) reasonably prompt notice of any material safety related communications with any Regulatory Authority and the substance of such communications regarding any clinical trials of the BMS Compound during the Term; (iii) a summary of all new clinically relevant toxicology study data on the BMS Compound within [\*\*\*] (or as soon as reasonably practicable) after generation within BMS; and (iv) Aggregate Safety Information from all other clinical trials of the BMS Compound (if not provided elsewhere) on an annual basis or as otherwise agreed to by the JDC. Nektar shall use any such data provided pursuant to this Section 2.1(d) solely to evaluate the safety of (1) the BMS Compound for use in the Combined Therapy Trials and (2) the Combined Therapy. All such disclosures are Confidential Information of BMS.

(e) If further studies, including toxicity studies, are required or suggested by a Regulatory Authority as a prerequisite for conducting any of the Combined Therapy Trials, then the Parties agree to hold good faith discussions in a timely manner to agree upon a protocol for such studies, each of which will be considered a Combined Therapy Trial and conducted on substantially the same terms as set forth herein (including the cost-sharing provisions of Section 7.2); *provided that*, if the Parties are unable to agree upon a protocol for such study or if the conduct of such study shall cause a delay deemed unsatisfactory by either Party, then any disputed matters precluding agreement shall be referred to the Executive Officers (or their respective designees) for resolution. If the Executive Officers are unable to reach resolution within [\*\*\*] after such referral to them (and do not mutually agree to an extension of time to arrive at such resolution), then this Agreement shall automatically terminate following the conclusion of any then-active Combined Therapy Trial (unless and until the Protocol for such required/suggested study(ies) is finalized by mutual agreement prior to the completion of such Combined Therapy Trial) and the provisions of Section 12.5 shall apply to any such termination.

## 2.2 Adverse Event Reporting .

(a) This Section 2.2 shall govern safety reporting arising from Combined Therapy Trials . Nektar, or its designee, will manage all drug safety activities.

(b) Nektar, or its designee, will forward to BMS, at the contact information below via fax or secure e-mail in a format to be agreed to by the Parties, all fatal or life threatening SAE reports within [\*\*\*] of date of first receipt and 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, each within [\*\*\*] of date of first receipt. Every [\*\*\*], the SAE reports exchanged will be reconciled.

BMS – Adverse Event Reporting Contact:  
E-mail: worldwide.safety@bms.com  
Fax: 609-818-5506

Acknowledgement of ICSR receipt:  
E-mail: worldwide.safety@bms.com

(c) Nektar shall perform case level reconciliation to confirm that BMS has received all reports required under this Agreement. Nektar shall e-mail [aepbusinessprocess@bms.com](mailto:aepbusinessprocess@bms.com) to request a reconciliation report for each Combined Therapy Trial. Nektar shall reconcile the cases identified as being transmitted to BMS on BMS's reconciliation report and those contained in the Global Safety Database. Missing case-level events shall be sent to BMS Global Pharmacovigilance by e-mail at [worldwide.safety@bms.com](mailto:worldwide.safety@bms.com) or by fax to (609) 818-3804. Nektar shall perform such reconciliation every [\*\*\*], unless otherwise agreed by BMS in writing.

**2.3 Joint Development Committee.** [\*\*\*], the Parties shall form a Joint Development Committee (the “*JDC*”). The JDC shall consist of [\*\*\*]. Each Party shall be responsible for determining the qualifications and substitutions of its JDC members. It is anticipated that each Party's representatives may include experts in finance, clinical development, patient safety and regulatory affairs and CMC. The JDC shall be co-chaired with one chairperson designated by each Party (each, a “*Co-Chair*”). The JDC shall meet [\*\*\*], or at such other frequency as the JDC agrees (and it may appoint subteams to meet more frequently), provided that either Party through its Co-Chair may request a meeting of the JDC at any time upon [\*\*\*] notice to the other Party, with the understanding that the other Party will use reasonable efforts to comply with such request but such other Party will not be in breach of this Agreement in the event that it is unable to comply with such request but is using reasonable efforts to conduct a JDC meeting as promptly as practicable. Upon request by either Party, such meetings will be held by audio or video teleconference; provided that face-to-face meetings shall occur at least [\*\*\*], alternating between Princeton, NJ and San Francisco, CA unless otherwise agreed upon by the Parties. There must be a minimum of [\*\*\*] from each Party at any meeting of the JDC. No fewer than [\*\*\*] prior to each meeting, and in any event as soon as reasonably practicable, each Party shall use good faith efforts to disclose to the other Party any proposed agenda items together with appropriate supporting information. The JDC Co-Chairs shall alternate responsibility for preparing and circulating definitive minutes of each meeting of the

JDC. Such minutes shall provide a description, in reasonable detail, of the discussions at the meeting, a list of material actions and decisions made by the JDC, a list of action items made by the JDC and a list of material issues not resolved by the JDC. The JDC Co-Chair who drafts the minutes shall provide the other Co-Chair and each Party's Alliance Managers with the initial draft meeting minutes, who shall return the draft with any proposed changes, and this process shall be repeated until a final version of the meeting minutes is agreed upon and signed (or acknowledged as final via email) by the two Co-Chairs. The Parties shall reasonably cooperate to complete and agree upon a final version of meeting minutes within [\*\*\*] from the date of the relevant meeting. The final version of the meeting minutes shall be signed (or acknowledged as final via email) by the two Co-Chairs, and each Party shall be provided with a copy of the final meeting minutes for its safekeeping. A [\*\*\*] of additional representatives of a Party may attend meetings of the JDC in advisory capacity with the prior written consent of the other Party; provided that any JDC meetings that includes representatives of either Party who are not JDC members may, at the request of any JDC member, include a closed session consisting of only JDC members and Alliance Managers. All representatives to the JDC or attending JDC meetings shall be subject to confidentiality and nonuse restrictions at least as restrictive as those set forth herein.

**2.4 Responsibilities of the Joint Development Committee.** Each Party shall use Commercially Reasonable Efforts to keep the JDC informed about activities performed by that Party hereunder. The JDC (or in the absence of a formal JDC meeting the Co-Chairs) shall be responsible for the following:

(a) overseeing the activities of the Parties with respect to the Combination Therapy Trials, and providing a forum for the Parties to discuss, monitor and coordinate all activities and communications regarding the Combined Therapy Trials;

(b) approving a budget for each Combined Therapy Trial and any material amendments thereto, including reviewing and approving any costs for a given budget of a Combined Therapy Trial that are reasonably anticipated to be greater than [\*\*\*] of the JDC-approved budget;

(c) reviewing (i) the progress of each Combined Therapy Trial, (ii) the proposed plan for medical monitoring and site audits (with Nektar to take comments of the JDC members to such proposed plan into account) and (iii) the results of such medical monitoring and site audits;

(d) reviewing and approving with respect to each Combined Therapy Trial (i) the applicable Protocol and the Statistical Analysis Plan, and any proposed substantive amendment thereto and (ii) the CRO Agreement(s) and, to the extent provided in Section 2.4(o), proposed material amendments thereto;

(e) reviewing and approving any immunogenicity analysis for each Combined Therapy Trial, including protocol and Entity to do the analysis;

(f) reviewing and approving any Bioanalysis Plan not set forth in the Protocol, and any material amendments thereto;

(g) reviewing and providing timely comments to proposed communication strategies and communications with any Regulatory Authority regarding the conduct of the Combined Therapy Trials and, if applicable, approving such proposed communications and communication strategies;

(h) approving any IND submitted for a Combined Therapy Trial, as well as reviewing material submissions to any such IND in accordance with Article 5;

(i) reviewing any Combined Therapy Trial Regulatory Documentation, or portions thereof, that relate to the Combined Therapy, in accordance with Article 5;

(j) subject to Section 2.6(d), agreeing on the final list of proposed clinical trial sites pursuant to Section 2.6(d), and agreeing on communications to clinical trial sites or IRBs relating to patient safety or early termination/cessation of a Combined Therapy Trial;

(k) appointing working teams, including a clinical execution working team, to be made up of an equal number of representatives from each Party, that will hold telephone discussions at a mutually agreed-upon frequency to review clinical development, patient safety and regulatory issues that arise in the course of the Combined Therapy Trials, and delegating certain decision-making authority to such working teams;

(l) determining the quantities of Nektar Compound, BMS Compound and any co-medications, necessary for the Combined Therapy Trials within a sufficient minimum lead time and coordinating the supply of such quantities by the respective Party in accordance with Article 4 and the Supply Agreement;

(m) reviewing and approving, in advance, any additional analyses of, or that include, the Combined Therapy Study Data proposed by either Party that are not included in the Statistical Analysis Plan; *provided* that, for clarity, such review and approval shall not apply to analyses by a Party of the monotherapy data for its own Compound from a Combined Therapy Trial;

(n) reviewing and approving use of any Samples in accordance with Section 8.5 that are not described in the Protocol and ICF, so long as the JDC remains in force and effect;

(o) for any CROs or Third Party contactors engaged after the Effective Date, reviewing and approving (1) the selection of any such CRO and Third Party contractor (other than individuals in a Party's workforce who are engaged on an independent contractor basis) that has a material role in each Combined Therapy Trial pursuant to Section 2.6(d) and (2) the terms of any such CRO contract or pharmacovigilance contract ("**CRO Agreement**") with a Third Party;

(p) reviewing and approving the template ICF form, template case report form and template clinical site study agreement to be used in a given Combined Therapy Trial;

(q) reviewing and approving the countries in which each Combined Therapy Trial will be conducted, as set forth in Section 2.6(d);

(r) approving the final clinical trial report (and/or final statistical analysis in accordance with the Statistical Analysis Plan) from each Combined Therapy Trial; and

(s) discussing any other topics or issues relating to the Combined Therapy Trials that either Party requests that cannot be resolved at the working team level.

## **2.5 Joint Development Committee Authority.**

(a) The JDC shall take action by unanimous consent, with each Party having a single vote, irrespective of the number of its representatives actually in attendance at a meeting. In the absence of a formal meeting, the Co-Chairs shall have decision-making authority for the JDC, so long as any decisions are documented as provided below.

(b) The JDC shall have the right to make only those determinations expressly enumerated as decisions of the JDC in this Agreement; *provided that* such determinations are documented in the written minutes signed (or acknowledged as final via email) by the JDC Co-Chairs.

(c) Notwithstanding anything to the contrary in this Agreement, the JDC will have no power (i) to amend this Agreement, or the Quality Agreement, or (ii) to modify either Party's obligations with regard to the Combined Therapy Trials without such Party's prior written consent; in each case, except by a writing (and that is not the minutes of a meeting) signed by both Parties.

## **2.6 Nektar Operational Authority Generally.**

(a) Nektar shall, subject to the oversight and determinations of the JDC as provided in Sections 2.3 and 2.4, the terms of the applicable Combined Therapy Protocol, the decisions and guidance of applicable committee(s) and/or working teams, and applicable terms and conditions of this Agreement: (i) manage and be primarily responsible for the conduct of the Combined Therapy Trials; (ii) be the Sponsor and regulatory lead with respect to the Combined Therapy Trials; and (iii) as between the Parties, be the lead with respect to (1) the selection and management of clinical study sites (including budget negotiations with vendors, timelines and contingency planning), subject to Sections 5.1(a)(x) and 5.1(b)(vi) with respect to site selection and subject to BMS's consent as to the country(ies) where each Combined Therapy Trial will be conducted, (2) conducting clinical study start-up activities, communicating with and obtaining approval from institutional review boards and/or ethics committees, as applicable, and drafting for both Parties' approval the template informed consent form (" *ICF* ") for each Combined Therapy Trial, (3) subject recruitment and retention activities, (4) ongoing site monitoring and quality assurance audits, (5) management of safety reporting by contract research organizations

and clinical study sites, (6) ongoing medical monitoring, (7) management, monitoring and audits of CROs in connection with each CRO involved in the conduct of the Combined Therapy Trial, and (8) inquiries from clinical study subjects ((1) -(8), collectively, the “**Operational Matters**”). Nektar shall use Commercially Reasonable Efforts to perform such Operational Matters. The JDC shall set up a mechanism for BMS or a working team of the JDC to be informed and updated on a timely periodic basis regarding Operational Matters, so that if BMS has any concerns or disagreements regarding same, the matter can be escalated to the JDC for review.

(b) Each Party shall be responsible for paying the full amount of any Third Party License Payments that it is obligated to pay pursuant to its agreement with a Third Party on account of the conduct of any Combined Therapy Trial and/or pursuant to Sections 4.1(a) and 4.2(a).

(c) Nektar shall provide BMS with access to the safety information and Study Data in accordance with Sections 5.1(a)(xvi) and 5.1(a)(xvii).

(d) BMS acknowledges that Nektar, prior to the Effective Date, has (i) selected and entered into agreements with certain CROs, investigators and Third Party contractors, (ii) identified a number of clinical trial sites, and (iii) completed study initiation visits, and BMS approves of such sites, investigators, CROs and Third Party contractors. BMS acknowledges that the CRO Agreements and/or any other documents related to such CROs, investigators, Third Party contractors and clinical trial sites have been made available to BMS prior to the Effective Date, and BMS hereby approves the continuation of such agreements on their terms (including the budgets and pricing included therein), and hereby ratifies, on behalf of its appointees to the JDC, the decisions taken by Nektar prior to the Effective Date that would otherwise be under the purview of the JDC pursuant to this Agreement. For any additional CROs, investigators, Third Party contractors or clinical trial sites proposed after the Effective Date, Nektar, after discussion with BMS, will create and provide the JDC with a proposed list of potential clinical trial site(s), CROs, investigators (including IMS grant plan analysis and/or a model investigator grant budget) and Third Party contractors that may be used to conduct each Combined Therapy Trial, with the final list to be subject to JDC (or Co-Chairs) approval (such JDC-approved list being the “**Site/CRO List**”). Except as otherwise noted in this Section 2.6(d), the proposed Site/CRO List will be provided to the JDC [\*\*\*] Nektar initiating site selection negotiations or visits (for sites/investigators) or CRO negotiations (for CROs). Nektar shall have the authority to select the final clinical trial sites, CROs, investigators and Third Party contractors from the Site/CRO List. In the event that additional sites, CROs, investigators or Third Party contractors need to be added after the initial list is approved, a new list will be created by Nektar that includes the proposed new sites, CROs, investigators or Third Party contractors and such list will be provided to the JDC for approval by the JDC (or Co-Chairs) per this Section 2.6(d).

**2.7 Alliance Managers.** Each of the Parties will appoint one representative to act as its Alliance Manager (each, an “**Alliance Manager**”). The role of the Alliance Manager is to act as a primary point of contact between the Parties to assure a successful relationship between the Parties. The Alliance Managers will attend all meetings of the JDC and support the JDC in the



discharge of its responsibilities. An Alliance Manager may bring any matter concerning a Party's performance under this Agreement to the attention of the JDC if the Alliance Manager reasonably believes that such attention is warranted. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of such Alliance Manager upon written notice to the other Party's Alliance Manager. Each Alliance Manager will be charged with creating and maintaining a collaborative work environment within the JDC. Each Alliance Manager also will:

(a) be the point of first referral in all matters of dispute resolution in accordance with Section 13.3;

(b) provide a point of communication both internally within its respective Party's organizations and between the Parties regarding the Combined Therapy Trials;

(c) assist in coordinating any collaborative efforts under this Agreement, if any, and any external communications; and

(d) take responsibility for ensuring that JDC activities, such as the conduct of required JDC meetings, occur as set forth in this Agreement and that relevant action items, if any, resulting from such meetings are appropriately carried out or otherwise addressed.

**2.8 Dispute Resolution.** The representatives of the JDC shall attempt in good faith to reach consensus on all matters properly brought before the JDC. Except as otherwise provided in this Agreement, if, after a good faith, reasonable and open discussion among the members of the JDC, the JDC is unable to agree on a matter that has been properly before it for a period of [\*\*\*] and that calls for a decision, either Party may refer the dispute (a "*JDC Dispute*") to the Executive Officers for resolution. If the Executive Officers are unable to reach a resolution within [\*\*\*] of such referral, then the JDC Dispute will be referred to the Chief Executive Officer and Chief Medical Officer of Nektar or his or her designee and the Chief Scientific Officer of BMS or his or her designee for attempted resolution by good faith negotiations within [\*\*\*] after such referral is made. In the event such officers are unable to resolve such JDC Dispute within such [\*\*\*] period then:

(a) if such JDC Dispute regards whether or not to commence a new Combined Therapy Trial, then such Combined Therapy Trial shall not proceed absent mutual agreement of the Parties; provided that any then-active Combined Therapy Trial shall continue;

(b) if such JDC Dispute occurs subsequent to the commencement of a Combined Therapy Trial, and relates to either (1) a material amendment requiring mutual agreement proposed by either Party to an agreed-upon Protocol or protocol synopsis, CRO Agreement, Bioanalysis Plan or Statistical Analysis Plan relating to such Combined Therapy Trial or (2) any other matter relating to the strategy, conduct, rationale, or safety of such Combined Therapy Trial, there shall be no decision on the matter and the then existing terms of the applicable Protocol, protocol synopsis, CRO Agreement, Bioanalysis Plan or Statistical

Analysis Plan relating to such Combined Therapy Trial shall govern. Notwithstanding the foregoing, neither Party shall be required to continue a Combined Therapy Trial if a Party reasonably deems there to be a Material Safety Issue for such Combined Therapy Trial. Each Party's safety committee shall, to the extent practicable, meet and discuss in good faith the Material Safety Issue and if unresolved within [\*\*\*], escalate such Material Safety Issue to the Executive Officers. If the Executive Officers are unable to reach a resolution within [\*\*\*] of such referral, then the dispute will be referred to the Chief Executive Officer and Chief Medical Officer of Nektar or his or her designee and the Chief Scientific Officer of BMS or his or her designee for attempted resolution by good faith negotiations within [\*\*\*] after such referral is made. In the event such officers are unable to resolve the Material Safety Issue, the applicable Combined Therapy Trial shall be discontinued. The Parties shall use reasonable efforts to wind down activities related solely to such discontinued Combined Therapy Trial in accordance with Section 12.5 ; and

(c) if such JDC Dispute is not otherwise addressed by Section 2.8(a) or (b), the dispute shall be resolved through arbitration as provided for in Section 13.3 .

**2.9 Conduct.** Each Party shall use Commercially Reasonable Efforts to perform and fulfill its respective activities under this Agreement, and shall do so in accordance with Applicable Law, including GCP, GLP and GMP.

### 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 Nektar (and Nektar hereby accepts) a non-exclusive, worldwide (other than within the Ono Territory), non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) under the BMS Independent Patent Rights, BMS Technology, and BMS Regulatory Documentation to use the BMS Compound, solely to the extent necessary to discharge Nektar's obligations under this Agreement with respect to the conduct of the Combined Therapy Trials.

**3.2 Grant by Nektar.** Subject to the terms of this Agreement, Nektar hereby grants, and shall cause its Affiliates to grant, to BMS (and BMS hereby accepts) a non-exclusive, worldwide, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) under the Nektar Independent Patent Rights, Nektar Technology, and Nektar Regulatory Documentation to use the Nektar Compound, solely to the extent necessary to discharge BMS's obligations under this Agreement with respect to the conduct of the Combined Therapy Trials.

#### **3.3 Sublicensing.**

(a) Subject to Section 3.3(b) and Section 3.3(c), each Party shall have the right to grant sublicenses under the licenses granted to it under Section 3.1 to Affiliates and, if

required for a Third Party to perform its duties with respect to the conduct of the Combined Therapy Trials (and agreed to by the other Party, such consent not to be unreasonably withheld), to Third Parties, solely as necessary to assist a Party in carrying out its responsibilities with respect to the Combined Therapy Trials.

(b) For the avoidance of doubt, in no event shall BMS (or any of its sublicensees) have the right to grant Ono or any of Ono's Affiliates any sublicense under the license granted to BMS in Section 3.2.

(c) With regard to any such sublicenses permitted and made under this Agreement, (i) such sublicensees, except Affiliates (so long as they remain Affiliates of a Party), shall be subject to written agreements that bind such sublicensees to obligations that are consistent with a Party's obligations under this Agreement including confidentiality and non-use provisions no less restrictive than those set forth in Sections 8.2 and 8.3 and Article 9, and provisions regarding intellectual property that ensure that the Parties will have the rights, title, and interest provided under this Agreement to any intellectual property created by such sublicensee, (ii) each Party shall provide written notice to the other of any such sublicense (and obtain approval for sublicenses to Third Parties); and (iii) the licensing Party shall remain liable for all actions or inactions of its sublicensees.

**3.4 No Implied Licenses.** 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.

**3.5 Exclusivity.** To maximize focus, value and efficiencies in the collaboration contemplated by this Agreement and avoid intellectual property conflicts and other issues from related transactions with Third Parties, Nektar and BMS hereby agree to the exclusivity provisions set forth on Exhibit C hereto.

**3.6 Access to Information.** During the period from the Effective Date until the expiration of the Exclusive Collaboration Period, BMS shall have the right to conduct due diligence on the Nektar Compound, in order to determine whether BMS is interested in exclusively licensing the right to develop and commercialize the Nektar Compound. In furtherance of the foregoing, if requested by BMS, Nektar will disclose to BMS all material information and results reasonably relating to the Nektar Compound as promptly as practicable after such information and results become available. Any such information and results shall be treated as Confidential Information of Nektar hereunder.

**3.7 Right of First Refusal.** If at any time during the Term and prior to the expiration of the Exclusive Collaboration Period (such period, the "**ROFR Offer Period**") Nektar determines that it wishes to out-license the right to commercialize the Nektar Compound in any Major Market territory, Nektar will promptly notify BMS in writing of same and the territory as to which the license will cover, and BMS will have the exclusive right to negotiate for the right to obtain an exclusive license to develop and commercialize the Nektar Compound in such

territory or in any other Major Market (the “ **Right of First Refusal** ”), for a period of three (3) months thereafter (the “ **ROFR Negotiation Period** ”); provided that the ROFR Negotiation Period shall be extended for any period during which Nektar has not complied with Section 3.6 above ; *provided further that* BMS shall promptly provide written notice to Nektar regarding such noncompliance and the Parties shall mutually agree on any extension of the ROFR Negotiation Period, such extension not to exceed thirty (30) calendar days . For clarity, if the original notice is for any territory in a Major Market, then BMS’s Right of First Refusal applies to all territories in the Major Market. During the ROFR Negotiation Period, if requested by BMS, Nektar will disclose to BMS all material information and results reasonably relating to the Nektar Compound as promptly as practicable after such information and results become available. Any such information and results shall be treated as Confidential Information of Nektar hereunder. If BMS and Nektar do not reach an agreement for such rights within the ROFR Negotiation Period, then Nektar will be free to out-license any and all rights (subject to the terms of this Agreement ) to the Nektar Compound in any territory worldwide; *provided, however* , that Nektar shall not out-license the right to commercialize the Nektar Compound in any Major Market territory (including any modification to such territory that was previously considered by BMS) to a Third Party within the ninety (90) calendar day period after the end of the ROFR Negotiation Period without first offering to BMS the same terms that such Third Party offered to Nektar (with such terms being memorialized in a written term sheet or proposed definitive agreement) (such terms, “ **Third Party Terms** ”) and allowing BMS ten (10) Business Days to accept such Third Party Terms (the end of such ten (10) Business Day period, the “ **Final Match Date** ”). In the event that Nektar does not enter into a transaction with a Third Party with respect to the rights that are the subject of such Right of First Refusal within a period of ninety (90) days subsequent to the Final Match Date, or Nektar does not receive (or make) an offer to any such Third Party that would give rise to the existence of any Third Party Terms, and in either instance the ROFR Offer Period has not expired , then BMS’s rights under this Section 3.7 shall be reinstated for the remainder of the ROFR Offer Period, such that in the event that Nektar determines that it wishes to out-license the right to commercialize the Nektar Compound in any Major Market territory prior to the end of the ROFR Offer Period, Nektar will again promptly notify BMS in writing of same and the territory as to which the license will cover, and BMS’s Right of First Refusal will once again apply on the same terms and conditions described above.

## ARTICLE 4

### MANUFACTURE AND SUPPLY

#### 4.1 Nektar Compound.

**(a) Manufacture and Supply.** Nektar shall use Commercially Reasonable Efforts to Manufacture or have Manufactured the Nektar Compound in drug product and/or drug substance form (as necessary) in reasonable quantities, within minimum lead times and at the points in time as agreed by the JDC for each Combined Therapy Trial. Nektar or a Third Party conducting activities on behalf of Nektar will package, label and distribute the Nektar Compound for use in the Combined Therapy Trials, with associated costs and expenses (and any related taxes) of such activities to be split between the Parties in accordance with Sections 7.2 and 7.3.

The cost of Manufacture and supply (including shipping, taxes and duty, if applicable) of Nektar Compound for the Combined Therapy Trials shall be borne solely by Nektar, and Nektar shall bear the risk of loss for the Nektar Compound. Nektar shall also be responsible for the payment of any Third Party License Payments that may be due exclusively on the supply of Nektar Compound for the Combined Therapy Trials. The Nektar Compound shall be Manufactured in accordance with Applicable Law (including GM P) and shall be of similar quality to the Nektar Compound used by Nektar for its other clinical trials of the Nektar Compound. Nektar shall deliver to BMS certificates of analysis, and any other documents specified in the Quality Agreement, including such documentation as is necessary to allow BMS to compare the Nektar Compound certificate of analysis to the Nektar Compound specifications.

#### **4.2 BMS Compound.**

**(a) Manufacture and Supply.** BMS shall use Commercially Reasonable Efforts to Manufacture or have Manufactured the BMS Compound in drug substance and/or drug product form (as necessary) in reasonable quantities, within minimum lead times and at the points in time as agreed by the JDC for each Combined Therapy Trial, and shall supply such BMS Compound in unmarked vials to Nektar or its designee for use in the Combined Therapy Trials. All BMS Compound supplied to Nektar shall have sufficient expiration dates to complete the Combined Therapy Trial. Nektar or a Third Party conducting activities on behalf of Nektar will package, label and distribute the BMS Compound for use in the Combined Therapy Trials, with associated costs and expenses (and any related taxes) of such activities to be split between the Parties in accordance with Sections 7.2 and 7.3. The cost of Manufacture, supply and distribution (including shipping, taxes and duty, if applicable) of the BMS Compound to Nektar shall be borne solely by BMS, and BMS shall bear the risk of loss for the BMS Compound at all times during the Term; except that Nektar shall bear the risk of loss of the BMS Compound to the extent that the loss arises or results from the gross negligence or intentional misconduct of Nektar or of any Third Party conducting packaging, labeling or distribution activities on behalf of Nektar. BMS shall also be responsible for the payment of any Third Party License Payments that may be due to Ono or to others exclusively on the supply of BMS Compound hereunder for the Combined Therapy Trials. The BMS Compound shall be Manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the BMS Compound used by BMS for its other clinical trials of the BMS Compound. BMS shall deliver to Nektar certificates of analysis, and any other documents specified in the Quality Agreement, including such documentation as is necessary to allow Nektar to compare the BMS Compound certificate of analysis to the BMS Compound specifications. 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 Compound in connection with this Agreement. BMS will provide Nektar with country-specific customs valuations for the BMS Compound, which Nektar must use for deliveries to each country. Nektar must request these valuations at least [\*\*\*] prior to each shipment through BMS's clinical supply organization.

**(b) Use of BMS Compound Supplied by BMS to Nektar.** Nektar shall use the quantities of BMS Compound supplied to it under this Agreement solely as necessary for, and in accordance with, this Agreement and the Protocols, and for no other purpose, including

without limitation as a reagent or tool to facilitate its internal research efforts, for any commercial purpose, or for other research unrelated to the Combined Therapy Trials. Except as may be required under this Agreement, a Bioanalysis Plan, or a Protocol, Nektar shall not perform, and shall not allow any Third Parties to perform, any analytical testing of the quantities of BMS Compound supplied to it under this Agreement.

**4.3 Quality Agreement.** Within [\*\*\*] after the Effective Date, but in no event later than the date on which the first shipment of bulk BMS Compound is supplied for use in the Combined Therapy Trials, the Parties shall enter into a quality agreement (the “*Quality Agreement*”). The Quality Agreement shall outline the additional roles and responsibilities relative to the quality of Nektar Compound and BMS Compound in support of the Combined Therapy Trials. The Quality Agreement shall include the responsibility for quality elements including, by way of example, audits & inspections, sub-contractors and suppliers, change control, OOS results, deviations and investigations required to conduct the Combined Therapy Trials. In addition, the Quality Agreement shall detail the documentation required for each shipment of BMS Compound supplied to Nektar or its designee for use in the Combined Therapy Trials. The Quality Agreement shall also indicate whether any required transfer from BMS to Nektar of analytical methods will be necessary to support identity testing by Nektar of the BMS Compound supplied to Nektar under this Agreement.

**4.4 Supply Agreement.** Within [\*\*\*] after the Effective Date, the Parties shall enter into a supply agreement (the “*Supply Agreement*”). The Supply Agreement shall govern forecasting, ordering, expiration dates, procedures for acceptance and rejection and other customary provisions for the supply of the BMS Compound for the Combined Therapy Trials.

## ARTICLE 5

### RESPONSIBILITIES

**5.1 Specific Responsibilities of the Parties.** Subject to the terms of this Agreement, each Party shall use Commercially Reasonable Efforts to (i) supply the quantities of its Compound as needed to conduct a Combined Therapy Trial on a timely basis, with Nektar packaging, labeling and delivering same to study sites, in accordance with the time frame(s) established by the JDC; (ii) to conduct and complete each Combined Therapy Trial and any Statistical Analysis Plans and Bioanalysis Plans relating thereto on a timely basis in accordance with the Protocol, Bioanalysis Plans, Statistical Analysis Plans and Third Party agreements relating thereto, and (iii) to timely provide Rights of Cross-Reference where required by this Agreement.

y shall be responsible for activities assigned to it by the Protocol and/or JDC that such Party is not otherwise obligated to perform by this Agreement, *provided that*, except as set forth in this Agreement, in no event shall either Party be obligated to perform any such assigned activities without its prior written consent (which may be reflected in the minutes of meetings of the JDC or in the Protocol). As of the Effective Date, each Party shall be responsible for the following activities:

**(a) Responsibilities of Nektar.** Subject to JDC direction and oversight as provided in Section 2.4 and Nektar's Commercially Reasonable Efforts, Nektar shall be responsible for the following activities, subject in each case (except as expressly provided in Section 4.1(a) with respect to the Manufacture and supply of the Nektar Compound) to the Parties sharing the applicable Third Party Study Costs related to such activities in accordance with Section 7.2 :

(i) (A) manufacturing, packaging and labeling the Nektar Compound for use in the Combined Therapy Trials, (B) packaging and labeling the vials provided by BMS of the BMS Compound for use in the Combined Therapy Trials, and (C) providing the JDC (or a working team designated by the JDC) on a monthly basis with a clinical drug supply forecast for the BMS Compound and the Nektar Compound that includes strategy for drug supply overages, drug supply quantity and required delivery dates;

(ii) with the cooperation of BMS, compiling, amending and filing all necessary Combined Therapy Trial Regulatory Documentation with Regulatory Authority(ies), maintaining and acting as the sponsor of record as provided in 21 C.F.R. 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 each Combined Therapy Trial and making all required submissions to Regulatory Authorities related thereto on a timely basis;

(iii) with the cooperation of BMS, and subject to the provisions of Section 9.5, listing any Combined Therapy Trial required to be listed on a public database such as www.clinicaltrials.gov or other public registry in any country in which such Combined Therapy Trial is being conducted in accordance with Applicable Law and in accordance with Nektar's internal policies relating to clinical trial registration; *provided that* BMS shall provide Nektar with written notice of any comments to a proposed listing within [\*\*\*] of the date on which Nektar provides the applicable information to BMS;

(iv) providing BMS with reasonable advance notice of scheduled meetings or other material non-written communications with a Regulatory Authority and the opportunity to participate in each such meeting or other non-written communication, to the extent that it relates to the Combined Therapy or the BMS Compound, and providing BMS with the opportunity to review, provide comments to Nektar within [\*\*\*] on, and, if inconsistent with the applicable Protocol(s) or JDC guidance, approve all submissions and written correspondence with a Regulatory Authority that relates to the Combined Therapy or the BMS Compound; *provided , however ,* in no event shall Nektar or any Affiliate of Nektar initiate communications with or respond to any communications initiated by any Regulatory Authority solely with respect to the BMS Compound without the prior written consent of BMS and *provided further that* BMS, if requested, shall step out of any portions of such meetings or other non-written communications with a Regulatory Authority that relate solely to the use of the Nektar Compound as a monotherapy or in combination with other compounds and Nektar, if requested, shall step out of any portions of such meetings or other non-written communications with a Regulatory Authority that relate solely to the use of the BMS Compound as a monotherapy or in combination with other compounds;

(v) providing to BMS a written summary of meetings or a summary of other non-written communications with a Regulatory Authority within [\*\*\*] of such meeting or communication, and copies of any official correspondence to or from a Regulatory Authority within [\*\*\*] of receipt or provision, in each case to the extent that it relates to the Combined Therapy or the BMS Compound (or, to the extent the communication would adversely impact the performance of a Combined Therapy Trial, the Nektar Compound), and copies of all Combined Therapy Trial Regulatory Documentation that relate to the Combined Therapy or the BMS Compound within [\*\*\*] of submission to Regulatory Authorities;

(vi) drafting, and, subject to Sections 2.4 and 2.6(d), providing to BMS (through the JDC or otherwise) for its review and approval, each Protocol and investigator's brochure for a Combined Therapy Trial, and the related template ICF, template clinical site agreement, Bioanalysis Plan and Statistical Analysis Plan, and any material amendments to each of the foregoing ( *provided that* BMS shall provide Nektar such approval or rejection within [\*\*\*] of the date on which Nektar provides the applicable document to BMS);

(vii) coordinating with BMS and providing to the JDC (or a subcommittee designated by the JDC for such purpose) drafts of (1) submissions to the Nektar IND (if applicable) and/or the Combined Therapy IND (if applicable); and (2) Combined Therapy Trial Regulatory Documentation, or portions thereof, that relate to the Combined Therapy or the BMS Compound, for JDC review and approval, and providing BMS with the opportunity to review, comment on and approve all other written correspondence with a Regulatory Authority relating to the Combined Therapy Trials, to the extent such correspondence relates to the Combined Therapy or the BMS Compound; *provided that* BMS shall provide Nektar with written notice of any such comments (and, where applicable, approvals or rejections) within [\*\*\*] of the date on which Nektar provides the applicable document to BMS;

(viii) to the extent necessary for the conduct of any Combined Therapy Trial, providing BMS a Right of Cross-Reference to the relevant Regulatory Documentation for the Nektar Compound, provided that, such Right of Cross-Reference shall terminate upon the expiration or termination of this Agreement for purposes of conducting any new 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 (1) to the extent necessary to permit Nektar to comply with any outstanding obligations required by a Regulatory Authority and/or Applicable Law or (2) as necessary to permit Nektar to continue to dose subjects enrolled in each Combined Therapy Trial through completion of the applicable Protocol if required by the applicable Regulatory Authority(ies) and/or Applicable Laws;

(ix) managing the operations of the Combined Therapy Trials in accordance with the applicable Protocol, including overseeing compliance by any CRO with the terms of its agreement with Nektar relating to the Combined Therapy Trial;

(x) subject to Sections 2.4 and 2.6(d), providing to BMS a list of all proposed clinical trial sites and principal investigator(s) for each Combined Therapy Trial;



(xi) subject to Sections 2.4 and 2.6(d), ensuring that all clinical trial service agreements and clinical trial site agreements (A) contain intellectual property provisions that retain each of the Parties' respective intellectual property rights in the Nektar Compound, BMS Compound and Combined Therapy, and (B) allow for BMS, as well as Nektar, to the extent permitted by Applicable Law and any Third Party confidentiality restrictions or obligations, to audit Combined Therapy Trial study sites for quality assurance and to inspect and copy data, documentation and work products relating to the activities performed by the site, including the medical records of any patient participating in any clinical study; *provided that* should BMS seek to audit a study site (1) BMS shall solely bear the cost and expense for such audit, (2) Nektar shall accompany BMS to such audit, at date and time mutually agreed upon by the Parties and the applicable study site, and (3) BMS shall provide Nektar with a copy of any reports resulting from such audit. This right to inspect and copy data, documentation, and work products of a study site may be exercised at any time during the Term, or such longer period as shall be required by Applicable Law;

(xii) providing BMS with copies of each final site template ICF (if requested by BMS);

(xiii) providing BMS with minutes from any and all external drug safety monitoring boards for the Combined Therapy Trials, if applicable, within [\*\*\*] (or as soon as practicable) after receipt by Nektar;

(xiv) providing BMS with updates on the status of the Combined Therapy Trials at each teleconference for the clinical execution working group, or upon BMS's reasonable request, including information regarding the number and status of study sites, the number of screened subjects (actual to target), the number of randomized subjects (actual to target), the number of dosed, ongoing, discontinued and completed subjects, and any safety updates as contemplated by the applicable Protocol, Section 2.1(c), and/or routinely performed by a Party in its normal course of trial management and reporting;

(xv) subject to the provisions of Section 2.2, owning and being responsible for (or appointing a Third Party reasonably acceptable to BMS to be responsible for) the maintenance of the Global Safety Database and safety reporting for the Combined Therapy, collecting, evaluating and reporting serious adverse events, other safety data and any further pharmacovigilance information from the Combined Therapy Trials, and providing BMS with the opportunity to participate in and comment on such pharmacovigilance activities;

(xvi) providing BMS with access to all safety information (including any updates to the investigator's brochure for the Nektar Compound) in the Global Safety Database through the provision of case safety reports ("CSRs") and listings related to the Combined Therapy or the BMS Compound during the Combined Therapy Trials in accordance with Section 2.2;

(xvii) analyzing the Study Data in a timely fashion and providing BMS with access to the Study Data from the applicable Combined Therapy Trial as follows:

(1) pursuant to an appropriate timetable determined by the JDC: (A) sharing with BMS for review and comment drafts of interim, ongoing and/or final clinical trial reports (and/or statistical analyses in accordance with the Statistical Analysis Plan) from each Combined Therapy Trial and (B) providing the raw Study Data in electronic or other mutually agreed format;

(2) within [\*\*\*] after Database Lock, access to safety databases that will be used for an interim review by an external consultant (or drug safety monitoring board, if required) to be agreed upon by the Parties;

(3) within [\*\*\*] after Database Lock, access to case report forms or patient profiles for all patients in each Combined Therapy Trial; and

(4) within [\*\*\*] of the creation of a quality checked and closed database for the Combined Therapy Trial, copies of the Form 1572s, financial disclosures and other relevant documents required to meet regulatory requirements related to the Combined Therapy Trials (including any data or documents that may be required to provide Aggregate Safety Information to a Regulatory Authority with respect to the BMS Compound);

(5) within [\*\*\*] of the creation of an electronic quality checked and closed database for the Combined Therapy Trial, an electronic copy of the such database (it being understood that the form and format of such database must be reasonably acceptable to both Parties and shall be determined by the JDC); and

(6) providing BMS with any programs or SAS codes to be used for the Statistical Analysis Plan for the Combined Therapy Trial;

(xviii) obtaining supplies of any co-medications, to the extent any such co-medications are required for use in any Combined Therapy Trial, and providing to BMS any information related to each Combined Therapy Trial that is provided to the manufacturer of any co-medication pursuant to Section 9.5 herein within [\*\*\*] after the provision of the information to the manufacturer;

(xix) providing BMS with any information regarding the pharmacokinetics, efficacy and safety of the BMS Compound alone or in combination with the Nektar Compound;

(xx) providing for the release by a Qualified Person (as such term will be defined in the Quality Agreement), or providing the necessary documentation in support of such quality release, of the Nektar Compound if such release is required for any Combined Therapy Trial;

(xxi) performing either directly or through Third Parties collection of Samples; and

(xxii) such other responsibilities as may be agreed to by the Parties or determined by the JDC.

**(b) Responsibilities of BMS.** Subject to JDC direction as provided in Section 2.4 and BMS's Commercially Reasonable Efforts, BMS shall be responsible for the following activities, subject in each case (except as expressly provided in Section 4.2(a) with respect to the Manufacture and supply of the BMS Compound and any Third Party License Payments due Ono) to the Parties sharing the applicable Third Party Study Costs related to such activities in accordance with Section 7.2:

(i) manufacturing and supplying unlabeled vials of the BMS Compound, as further described in Article 4, and providing for the release by a Qualified Person or providing the necessary documentation in support of quality release, of the BMS Compound if such release is required for the Combined Therapy Trial;

(ii) promptly reviewing and providing comments on and communicating its approval (or rejection) of each Protocol, the BMS and Nektar investigator's brochures for each Combined Therapy Trial (as it relates to the BMS Compound and the Combined Therapy), any template ICF, Bioanalysis Plan and Statistical Analysis Plan, and any amendments to each of the foregoing (provided that BMS shall provide Nektar with written notice of any such comments (and, where applicable, approvals or rejections) within [\*\*\*] of the date on which Nektar provides the applicable document to BMS;

(iii) to the extent necessary for the conduct of any Combined Therapy Trial, providing Nektar a Right of Cross-Reference to the relevant Regulatory Documentation for the BMS Compound, provided that, except as provided in Section 3.2, such Right of Cross-Reference shall terminate upon the expiration or termination of this Agreement for purposes of conducting any new 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 (1) to the extent necessary to permit Nektar to comply with any outstanding obligations required by a Regulatory Authority and/or Applicable Law or (2) as necessary to permit Nektar to continue to dose subjects enrolled in each Combined Therapy Trial through completion of the applicable Protocol if required by the applicable Regulatory Authority(ies) and/or Applicable Laws;

(iv) jointly reviewing, providing comments to Nektar within [\*\*\*] on, and (if inconsistent with the applicable Protocol(s)) approving all Combined Therapy Trial Regulatory Documentation and providing Nektar with copies of BMS Regulatory Documentation, as both Parties agree is necessary or reasonably expected to be necessary, and is requested by Nektar, (1) to obtain and maintain the IND for the Combined Therapy Trials and prepare and file any Combined Therapy Trial Regulatory Documentation in accordance with this Agreement, or (2) to comply with Applicable Law with regard to the Nektar Compound and the Combined Therapy Trials, which may include information regarding the pharmacokinetics,

efficacy and safety of the BMS Compound alone or in combination with the Nektar Compound ( *provided that* BMS shall provide Nektar with written notice of any such comments (and, where applicable, approvals or rejections) within [\*\*\*] of the date on which Nektar provides the applicable document to BMS;

(v) providing comment and input on the management of each Combined Therapy Trial pursuant to the applicable Protocol;

(vi) reviewing and, if applicable, suggesting alternatives to Nektar's proposed list of clinical trial sites and principal investigator(s) for each Combined Therapy Trial;

(vii) providing Nektar with access to an investigator's brochure for the BMS Compound as determined by BMS (and any updates thereto), as well as all relevant safety information for the BMS Compound;

(viii) providing and making available as necessary information and/or persons with knowledge concerning the BMS Compound to support the Combined Therapy Trials, including any interactions with a Regulatory Authority; and

(ix) such other responsibilities as may be agreed to by the Parties or determined by the JDC.

## **5.2 Documents and Combined Therapy Trial Contracts.**

(a) The Parties agree that Nektar bears primary responsibility for conduct of each Combined Therapy Trial and the analysis of the Study Data under the applicable Statistical Analysis Plan. In consultation with BMS, Nektar shall draft the Protocols and Statistical Analysis Plans, and any amendments to each of the foregoing, and shall provide such documents to BMS for review, comment, and if applicable, approval pursuant to Section 5.1(a)(vi) and Sections 2.4 and 2.6(d). BMS shall have [\*\*\*] from the date on which Nektar provides the applicable document to BMS to provide any comments, and if applicable, approvals or rejections to Nektar concerning the applicable draft Protocol or Statistical Analysis Plan, or any amendment to each of the foregoing.

(b) Subject to Sections 2.4 and 2.6(d), Nektar shall be responsible for negotiating and entering into contracts for services relating to the Combined Therapy Trials, including selecting vendors, approving contract deliverables and managing contract performance, including site contracts, obtaining IRB approval for site informed consent forms, obtaining signed informed consents, monitoring plans, etc. Nektar will be responsible for ensuring that any such contracts allow Nektar 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 not less than the same access or use as is granted to Nektar).

**5.3 Other Clinical Trials.** Except for the Combined Therapy Trials, each clinical trial for the BMS Compound and the Nektar Compound, alone or in combination with other pharmaceutical agents, is independently conducted and shall not be subject to this Agreement

(but without limiting each Party's obligation to share relevant safety information as provided in Section 2.1(c), Section 2.1(d) and Section 2.2). The BMS Compound provided to Nektar under this Agreement shall not be used for such other clinical trials. The Nektar Compound provided to BMS under this Agreement shall not be used for such other clinical trials. Except as provided in Section 3.5 and Exhibit C, nothing in this Agreement shall preclude either Party from conducting any such other clinical trials as it may determine in its discretion, so long as it does not use or rely on the Confidential Information of the other Party in doing so.

**5.4 Additional Studies.** After completion of the Combined Therapy Trials, the Parties agree to discuss in good faith additional clinical trials (other than clinical trials contemplated by Section 2.1(a)) of the Combined Therapy. If the Parties jointly agree to conduct any such further clinical trials, such further clinical trials will be conducted in accordance with a separate agreement between the Parties. For clarity, no Party shall be obligated to collaborate with the other Party or agree on terms with the other Party with respect to such additional clinical trials.

## ARTICLE 6

### INTELLECTUAL PROPERTY

**6.1 Collaboration Inventions.** All rights to Collaboration Inventions shall be allocated as follows:

**(a) Nektar Ownership.** Subject to the terms of this Agreement, all Nektar Study Inventions shall be owned solely by Nektar, and Nektar will have the full right to exploit such Nektar Study Inventions 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) all right, title and interest in any Nektar Study Inventions to Nektar. Any assignments necessary to accomplish the foregoing are hereby made, and BMS shall execute such further documents and provide other assistance as may be reasonably requested by Nektar to perfect Nektar's rights in such Nektar Study Inventions, all at Nektar's expense. Nektar 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 Nektar Study Patent Rights at its own expense.

**(b) BMS Ownership.** Subject to the terms of this Agreement, all BMS Study Inventions shall be owned solely by BMS, and BMS will have the full right to exploit such BMS Study Inventions without the consent of, or any obligation to account to, Nektar. Nektar shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) all right, title and interest in any BMS Study Inventions to BMS. Any assignments necessary to accomplish the foregoing are hereby made, and Nektar 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, 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 Trial Inventions.** All Combined Therapy Trial Inventions shall be jointly owned by the Parties, and either Party shall have the right to freely exploit the Combined Therapy Trial 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 Trial Inventions and Combined Therapy Patent Rights. Nektar, using outside counsel acceptable to both Parties, shall be responsible for preparing and prosecuting Patent applications and maintaining Patents within the Combined Therapy Patent Rights. Nektar shall keep BMS advised as to material developments and all steps to be taken with respect to any such Patents and shall furnish the BMS with copies of applications for such Patents, amendments thereto and other related correspondence to and from Patent offices, and permit the BMS a reasonable opportunity to review and offer comments. Nektar shall take any comments of BMS into good faith consideration. BMS shall reasonably assist and cooperate in obtaining, prosecuting and maintaining the Combined Therapy Patent Rights. Notwithstanding the foregoing, Nektar shall not take any position in a submission to a Patent office that interprets the scope of a Patent or Patent application of BMS without the prior written consent of BMS. Nektar shall be reimbursed for any Third Party 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 fifty percent (50%) of such costs and expenses and Nektar shall be responsible for fifty percent (50%) of such costs and expenses. Nektar will report all such costs and expenses to BMS in accordance with Sections 7.2 and 7.3.

**(i) Abandonment of Patent or Patent application.** In the event that Nektar determines either (a) not to continue the prosecution or maintenance of a Patent application or Patent within the Combined Therapy Patent Rights or (b) not to file any new Patent application requested to be filed by BMS, in each case other than to optimize overall Patent protection of claimed inventions, Nektar shall provide BMS with notice of this decision at least [\*\*\*] prior to any pending lapse or abandonment thereof. In such event, Nektar shall provide BMS with an opportunity to assume responsibility for all costs associated with the filing or further prosecution and maintenance of such Patent application and any Patent issuing thereon (such filing to occur prior to the issuance of the Patent to which the application claims priority or expiration of the applicable filing deadline, as set forth above). In the event that BMS assumes such responsibility for such filing, prosecution and maintenance costs, BMS shall have the right to transfer the responsibility for such filing, prosecution and maintenance of such Patent applications and Patents to patent counsel selected by it and reasonably acceptable Nektar. In such case, Section 6.1(c) shall apply to such Patent applications and Patents mutatis mutandis. Such Patent applications and Patents shall otherwise continue to be subject to all of the terms and conditions of this Agreement in the same manner and to the same extent as the other Patent applications or Patents within the Combined Therapy Patent Rights.

(ii) Failure to Reimburse. If a Party elects not to reimburse the other Party for fifty percent (50%) of the costs of prosecution and maintenance of a Patent application or Patent within the Combined Therapy Patent Rights in a given country, the non-reimbursed Party shall have the right to file or maintain such Patent or Patent application in such country in its own name and at its own expense, with the prior written consent of the other Party (which shall not be unreasonably withheld) and the other Party shall promptly assign its rights to the joint invention in said country to the non-reimbursed Party if the non-reimbursed Party wishes to file or maintain said Patent application or Patent. After giving effect to such assignment, such assigned invention and any corresponding Combined Therapy Patent Rights thereto shall be treated as a Nektar Independent Patent Rights or BMS Independent Patent Rights, as applicable. The Party who does not wish to file or maintain a Patent application or Patent within the Combined Therapy Patent 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 expense of the Party who wished to file or maintain such Patent application or Patent in that given country.

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

**6.2 Disclosure and Assignment of Collaboration Inventions.** Each Party shall disclose [\*\*\*] to the other Party in writing and on a confidential basis all Collaboration Inventions, prior to any public disclosure or filing of Patent applications 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 Collaboration Inventions as well as any 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 [\*\*\*] notify the other Party in writing of any alleged or threatened (in writing) infringement, or misappropriation by a Third Party, of Combined Therapy Patent Rights, of which its in-house patent counsel becomes aware (such infringement, “*Infringement*,” and “*Infringe*” shall be interpreted accordingly).

(b) **Infringement of Nektar Study Patent Rights.** For all Infringement of Nektar Study Patent Rights or Nektar Independent Patent Rights anywhere in the world, Nektar shall have the exclusive right to prosecute such Infringement as it may determine in its sole and absolute discretion, and Nektar shall bear all related expenses and retain all related recoveries.

BMS shall reasonably cooperate with Nektar or its designee (to the extent BMS has relevant information arising out of this Agreement), at Nektar's request and expense, in any such action.

**(c) Infringement of BMS Study Patent Rights.** For all Infringement of BMS Study Patent Rights or BMS Independent Patent Rights anywhere in the world, BMS shall have the exclusive right to prosecute such Infringement as it may determine in its sole and absolute discretion, and BMS shall bear all related expenses and retain all related recoveries. Nektar shall reasonably cooperate with BMS or its designee (to the extent Nektar 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 Infringement 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 Infringement 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), the other Party hereby agrees to cooperate reasonably in any such action, including, if required, by bringing a legal action or furnishing a power of attorney. If the Parties mutually agree to bring an enforcement action, BMS shall be responsible for fifty percent (50%), and Nektar shall be responsible for fifty percent (50%), 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 approved by the Parties and brought under this Section 6.3(d)(ii), 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), then pro rata in accordance with the aggregate amounts spent by both Parties, and any remaining amounts shall be split fifty percent (50%) to Nektar and fifty percent (50%) to BMS, unless the Parties agree in writing to a different allocation. In connection with any proceeding under this Section 6.3(d), neither Party shall enter into any settlement without the prior written consent of the other Party.

**6.4 Infringement of Third Party Rights.**

**(a) Notice.** If the activities relating to the Combined Therapy Trials 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 [\*\*\*] confer to discuss the claim.

**(b) Defense.** If both Parties are charged with infringement pursuant to a claim described in Section 6.4(a), the Parties shall defend such claim jointly, unless they agree otherwise. 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 being so charged, then the other Party shall have the right, but not the obligation, to defend any such claim. 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 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, Nektar shall bear fifty percent (50%), and BMS shall bear fifty percent (50%) 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 one hundred percent (100%) of the costs and expenses of the defense of such claim, shall have sole rights to any recovery and shall have the sole right, but not the obligation, to defend, settle and otherwise handle the disposition of such claim. If either Party recovers monetary damages from any Third Party while jointly defending the claim, 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 fifty percent (50%) to Nektar and fifty percent (50%) to BMS, unless the Parties agree in writing to a different allocation. 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 Trial Regulatory Documentation.** Subject to the license and other rights granted by each Party to the other Party pursuant to this Agreement, Nektar and BMS shall jointly own all right, title and interest in and to the Combined Therapy Trial Regulatory Documentation; *provided, however*, that BMS shall retain sole and exclusive ownership of any BMS Regulatory Documentation provided to Nektar under this Agreement that is submitted with or referenced in the Combined Therapy Trial Regulatory Documentation and that Nektar shall retain sole and exclusive ownership of any Nektar Regulatory Documentation that is submitted with or referenced in the Combined Therapy Trial Regulatory Documentation. This Section 6.5 is without limitation of any other disclosure obligations under this Agreement.

## ARTICLE 7

### COLLABORATION COSTS AND EXPENSES

#### *7.1 Intentionally omitted.*

**7.2 Combined Therapy Trial Expenses.** 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. In addition, each Party shall bear its own Third Party License Payments as set forth in Section 2.6 (b) . For all other expenses that are directly attributable or reasonably allocable to the conduct of the Combined Therapy Trials, (a) BMS will be responsible for fifty percent (50%) of all out-of-pocket costs (including taxes) reasonably incurred in connection with Third Party CROs and laboratories and clinical sites/IRBs or otherwise by either Party in connection with the performance of each Combined Therapy Trial and that are incurred consistent with the JDC-approved budget for the Combined Therapy Trial (“ **Third Party Study Costs** ”), and (b) each Party shall be solely responsible for all of its own internal costs (including all internal full-time equivalents and all costs of individuals engaged as independent contractors) incurred by such Party or any of its Affiliates, to the extent not included in the definition of Third Party Study Costs. For avoidance of doubt, Third Party Study Costs do not include Third Party License Payments by BMS, Nektar or any Third Party Claims.

### 7.3 Invoicing; Payment.

**(a) Reconciliation.** BMS shall reimburse Nektar, on a [\*\*\*] basis in arrears, for all Third Party Study Costs and all Section 2.2 , Section 4.2(a) , Section 5.1(a) , Section 8.5 and Article 6 costs and expenses actually invoiced to Nektar during the prior [\*\*\*]. At the end of each [\*\*\*], Nektar shall (1) submit to BMS an invoice for BMS’s fifty percent (50%) share of all such costs and expenses and (2) an electronic report that specifies in reasonable detail all such expenses included in such Third Party Study Costs and all Section 2.2 , Section 4.2(a), Section 5.1(a) , Section 8.5 and Article 6 costs during such [\*\*\*] (a “[\*\*\*] **Report** ”). BMS agrees to accept electronic copies of invoices and reports, in .pdf format, emailed to BMS at an address provided by the BMS Alliance Manager as sufficient delivery thereof to process payments to Nektar. Nektar shall provide invoices or other appropriate supporting documentation for any payments to a Third Party exceeding [\*\*\*]. The Parties shall seek to resolve any questions related to such invoices and/or reports within [\*\*\*] following receipt by BMS of Nektar’s invoice and report hereunder. Based on the invoices and reports, payment will be made by BMS within [\*\*\*] after the delivery of such invoice and report. If BMS disputes an amount due on an invoice, BMS will notify Nektar of such dispute within [\*\*\*] of receipt of such invoice and shall pay the amount not in dispute after Nektar submits a new invoice for the undisputed amount. The Parties shall use good faith efforts to discuss and resolve any disputed amounts. Any undisputed invoiced amount which is not paid by its due date shall be assessed a late payment fee at the rate of [\*\*\*], compounded [\*\*\*], or at the highest rate permitted under Applicable Law, if less.

**(b) Payment Method.** BMS shall pay all amounts due hereunder in United States dollars by electronic funds transmission to the Nektar account below or such bank account Nektar designates in writing from time to time.

[\*\*\*]

**7.4 Audit.** At the request (and expense) of BMS, Nektar shall permit an independent certified public accountant appointed by BMS and reasonably acceptable to Nektar (provided that such accountant shall not be retained or compensated on a contingency basis and shall have

entered into a confidentiality agreement with Nektar), at reasonable times and upon reasonable notice, to examine only those records as may be reasonably necessary to determine, with respect to any calendar year ending not more than [\*\*\*] prior to BMS 's request, the correctness or completeness of any invoice submitted to BMS or other payment made to Nektar pursuant to this Agreement. The foregoing right of review may be exercised only [\*\*\*] and only [\*\*\*] with respect to each such periodic report and payment. Results of any such examination shall be (a) made available to both Parties and (b) subject to Article 9 . BMS shall bear the full cost of the performance of any such audit, unless such audit discloses a variance to the detriment of BMS of more than [\*\*\*] from the amount of the original report, royalty or payment calculation, in which case, Nektar shall bear the full cost of the performance of such audit. Nektar shall have reciprocal audit rights for any Third Party Study Costs incurred by BMS in connection with the performance of each Combined Therapy Trial. If, as a result of any audit, it is shown that payments received by the Parties un der this Agreement were less or more than the amount which should have been received, then the appropriate Party shall make or refund all payments required to be made to eliminate any discrepancy revealed by said audit within [\*\*\*].

## 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 Trials 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 Trials (including the Statistical Analysis Plan and any Bioanalysis Plan to be conducted pursuant to this Agreement) (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 each 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 Trials 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 Compound (“ *BMS Study Data* ”), and Nektar shall own the Study Data to the extent that it relates exclusively to the Nektar Compound (“ *Nektar Study Data* ”). Both Parties shall jointly own any Study Data that does not relate exclusively to the Nektar Compound or the BMS Compound (“ *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.** Each Party may use and analyze its own Study Data for any purpose without obligation or accounting to the other.

**(b) Use of Combined Therapy Study Data by BMS.** BMS (and its respective Affiliates), Ono, and each of their respective (sub)licensees shall have the right to use and analyze the Combined Therapy Study Data (x) in connection with its independent development, commercialization or other exploitation of the BMS Compound (alone or in combination with other compounds) and/or for inclusion in the safety database for the BMS Compound, in each case without the consent of, or any obligation to account to, Nektar, and (y) 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 writing. BMS, its Affiliates and licensees shall also be entitled to use the Combined Therapy Study Data during and following the Term to (1) make regulatory filings and seek approvals for the BMS Compound, either alone or in combination with other compounds and (2) to promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the BMS Compound, 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 Nektar Compound. Nektar grants BMS, its Affiliates and licensees of the BMS Compound a Right of Cross-Reference to the relevant Regulatory Documentation Controlled by Nektar for the Nektar Compound or the Combined Therapy for the sole purpose of enabling each of them to exercise its rights under clause (1) of this Section 8.3(b) (other than for use in the Ono Territory), which right shall survive any expiration or termination of this Agreement.

**(c) Use of Combined Therapy Study Data by Nektar.** Nektar its Affiliates and each of its and their respective (sub)licensees shall have the right to use and analyze the Combined Therapy Study Data (x) in connection with its independent development, commercialization or other exploitation of the Nektar Compound (alone or in combination with other compounds) and/or for inclusion in the safety database for the Nektar Compound, in each case without the consent of, or any obligation to account to, BMS and (y) 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 Nektar, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in writing. Nektar, its Affiliates and licensees shall be entitled to use the Combined Therapy Study Data during and following the Term to (1) make regulatory filings and seek approvals for the Nektar Compound, either alone or in combination with other compounds and (2) to promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the Nektar Compound, 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 Nektar any right or license, expressly or impliedly, to make, have made, use, sell, offer for sale, or import the BMS Compound. BMS grants Nektar, its Affiliates and licensees of the Nektar Compound a Right of

Cross-Reference to the relevant Regulatory Documentation Controlled by BMS for the BMS Compound for the sole purpose of enabling each of them to exercise its rights under clause (1) of this Section 8.3(c) (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/Diagnostic 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. 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 written consent of the other Party during and after the Term of this Agreement.

**8.4 Access to Study Data.** Subject to the provisions of Sections 2.2 , 5.1(a)(xvi) and 5.1(a)(xvii), each Party shall have access to all Combined Therapy Study Data (including de-identified patient records) as soon as reasonably practicable after such Study Data is reasonably available to or generated by the Party responsible for generating or collecting such Study Data.

**8.5 Samples.** Samples collected in the course of activities conducted under this Agreement shall be jointly owned by the Parties (to the extent not owned by the patient and/or the clinical trial site). Any such Samples shall be collected in accordance with the applicable Protocol and ICFs. Neither Party shall be permitted to use such Samples for any purpose without the prior written consent of the other Party, which consent shall not be unreasonably withheld if such use is directed to the Combined Therapy and 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. 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), such data or intellectual property shall be considered Combined Therapy Study Data or Combined Therapy Trial Inventions/Combined Therapy Patent Rights, as the case may be. Samples for PK and ADA serum analysis will be stored for future use in Nektar's sample repository (with the expectation that BMS will store, at its own expense, those samples that it expects to use in studies), *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 ICFs by the subjects contributing the

Samples in the Combined Therapy Trials. All Third Party Costs for collecting, testing and storing the Samples will be split between the Parties in accordance with Sections 7.2 and 7.3, except as otherwise noted in this Section 8.5.

## ARTICLE 9

### CONFIDENTIALITY

#### 9.1 Nondisclosure of Confidential Information.

(a) Prior to the Effective Date of this Agreement, Nektar and BMS entered into a certain Mutual Confidentiality Agreement dated December 13, 2012 (“**CDA**”). As it relates to disclosures involving nivolumab and NKTR-214 only, the CDA is hereby terminated and replaced by the terms of this Agreement. Any Confidential Information relating thereto previously disclosed by the Parties pursuant to the CDA shall now be Confidential Information for purposes of this Agreement and the Parties shall treat it as such in accordance with the terms hereof. 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 that (a) if in tangible form, is labeled in writing as “proprietary” or “confidential” (or similar reference); 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 Collaboration Inventions shall be the Confidential Information of the Party owning such Study Data or Collaboration Invention (as provided in Section 8.2 with regard to Study Data and Section 6.1 with regard to Collaboration Inventions). For purposes of this Agreement, regardless of which Party discloses such Confidential Information to the other, (i) all Nektar Study Inventions, Nektar Technology and Nektar Regulatory Documentation shall be Confidential Information of Nektar and BMS shall be deemed the receiving Party, (ii) all BMS Study Inventions, BMS Technology, and BMS Regulatory Documentation shall be Confidential Information of BMS and Nektar shall be deemed the receiving Party and (iii) all Combined Therapy Inventions, Combined Therapy Study Data and Combined Therapy Trial Regulatory Documentation shall be Confidential Information of each Party.

(b) Except to the extent expressly authorized in this Section 9.1 and Sections 9.2, 9.3 and 9.5 below, or as otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for a period of [\*\*\*] thereafter (or for any Confidential Information that is identified in writing at the time of disclosure as a trade secret related to each Party’s Compound, for as long as it is not part of the public domain), it shall (x) 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 owned by the other Party, (y) 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 (z) reproduce the disclosing Party’s Confidential Information solely to the extent necessary to accomplish the receiving Party’s obligations under this Agreement, with all such reproductions being considered the disclosing Party’s Confidential Information; *provided*, that

with respect to BMS Confidential Information that BMS received as confidential information from Ono, the obligations of confidentiality and non-use shall continue for the longer of the period set forth above or [\*\*\*] after the termination of the Ono-BMS Agreements.

(c) 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 sublicensees solely on a need-to-know basis for the purpose of fulfilling the receiving Party's obligations under this Agreement; *provided* , *however* , that (1) any such employees, consultants, agents or permitted sublicensees are bound by obligations of confidentiality 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 sublicensees 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, 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 constitutes material non-public information about the disclosing Party or such security.

**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 solely owned by the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patent Rights;

(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 sublicensees, contractors, ethics committees and institutional review boards (collectively, "**IRBs**"), CROs, academic institutions, consultants, agents, investigators, and employees and contractors engaged by study sites and investigators involved with the Combined Therapy Trials, each of whom, subject to Section 2.6(d), prior to disclosure must be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9;

(e) disclosure that is deemed necessary by either Party to be disclosed to its respective Affiliates, agents, consultants or actual or prospective licensees (or other bona fide collaborators) in furtherance of the development, manufacture and/or commercialization of such Party's Compound, on the condition that such Third Parties agree to be bound by confidentiality and non-use obligations that are substantially consistent with the confidentiality and non-use provisions contained in this Agreement;

(f) disclosure to its attorneys, accountants, auditors and other advisors on a need to know basis provided such individuals or Entities are bound to confidentiality and nondisclosure requirements by professional rules of conduct or nondisclosure agreements, and to actual or prospective acquirers, lenders, financiers, or investors as may be necessary to comply with the terms, or in connection with their evaluation, of such potential or actual acquisition, loan, financing, or investment; on the condition that such acquires, lenders, financiers, or investors agree to be bound by confidentiality and non-use obligations that are substantially consistent with the confidentiality and non-use provisions contained in this Agreement;

(g) disclosure of the Combined Therapy Study Data, Combined Therapy Trial Inventions and Combined Therapy Patent Rights to Regulatory Authorities in connection with the development of the Combined Therapy, the Nektar Compound or the BMS Compound; and

(h) disclosure of relevant safety information contained within the Combined Therapy Study Data to investigators, IRBs/or ethics committees and Regulatory Authorities that are involved in other clinical trials of the Nektar Compound with respect to Nektar, and the BMS



Compound with respect to BMS, and (in the event of a Material Safety Issue) to Third Parties that are collaborating with Nektar or BMS, respectively in the conduct of such other clinical trials of the Nektar Compound or the BMS Compound, 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.

Notwithstanding the foregoing, if a Party is required or otherwise intends to make a disclosure of the 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, Nektar hereby expressly authorizes BMS to disclose to Ono (i) the existence (but not the terms) of this Agreement, the Combined Therapy Trials and the Protocols, and (ii) any other Nektar Confidential Information, BMS Study Data and the Combined Therapy Study Data solely to the extent 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.

#### **9.5 Press Releases and Publications.**

(a) Subject to this Section 9.5, the Parties shall jointly agree to the content and timing of all external communications with respect to this Agreement (including an initial press release, the content of which shall be as attached hereto as Exhibit B, subsequent press releases, Q&As, and the content and wording of any listing any Combined Therapy Trial required to be listed on a public database or other public registry such as [www.clinicaltrials.gov](http://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. Notwithstanding any provision of this Agreement to the contrary, each 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) Nektar and BMS agree to collaborate to publicly disclose, publish or present (1) top-line results from each Combined Therapy 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 (2) the conclusions and outcomes (the "**Results**") of each Combined Therapy Trial at a scientific conference as soon as reasonably practicable following the completion of such Combined Therapy Trial, subject in the case of (2) 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 (i) any abstract or press release at least [\*\*\*] before submission to a Third Party and (ii) any proposed slide presentation, publication, poster presentation or any other 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 Nektar Study Invention (solely with respect to Nektar) or BMS Study Invention (solely with respect to BMS) or Combined Therapy Trial Invention disclosed therein. If practicable, the disclosure, publication or presentation shall be delayed for an additional [\*\*\*] 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 a material trade secret or proprietary business information, 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 [\*\*\*] (to the extent provided pursuant to the above), (A) academic collaborators engaged by Nektar in connection with the performance of the Combined Therapy Trials may publish Combined Therapy Study Data obtained by such academic collaborator solely to the extent that such ability to publish such Combined Therapy Study Data is set forth in an agreement between Nektar and such academic collaborator relating to the conduct of Combined Therapy Trials 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. 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 or ongoing results of a Combined Therapy Trial). Notwithstanding the foregoing, Nektar hereby authorizes disclosure to Ono in accordance with Section 9.4 above. Notwithstanding the foregoing, nothing herein shall prevent or restrict Ono from making any disclosures of published 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.

#### **9.6 Compliance with Sunshine Laws.**

(a) For purposes of compliance with reporting obligations under Sunshine Laws, Nektar represents that it is not, as of the Effective Date, subject to reporting obligations

under the Sunshine Laws. Therefore, as between the Parties, BMS will report payments or other transfers of value (“*POTV*”) made by Nektar or the CRO related to the conduct of the Combined Therapy Trials and any applicable associated contractor engagements as required under the Sunshine Laws, for each Combined Therapy Trial initiated prior to such date that Nektar becomes responsible for reporting POTV for studies sponsored by it. BMS shall request delayed publication for any reported POTV for the studies sponsored by Nektar as permitted under the Sunshine Laws and if consistent with BMS’s normal business practices. In the event Nektar becomes responsible for reporting POTV for studies sponsored by it in a given country during the Term, Nektar shall provide written notification to BMS, and the Parties will meet and 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) Nektar (i) will provide (to the extent in the possession of Nektar), or will utilize Commercially Reasonable Efforts to obligate and ensure that each CRO and other applicable Third Party contractors for a Combined Therapy 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, each Recipient to be reported to BMS within a reasonable time period specified by BMS and agreed by Nektar) 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 a Combined Therapy Trial reasonably cooperate with, BMS in connection with its compliance with such Sunshine Laws. The form in which Nektar 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 payments or other transfers of value 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 the agreement to the extent necessary for BMS to comply with Sunshine Laws.

(c) For purposes of this Section 9.6, “*Sunshine Laws*” means 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. “*Recipients*” means healthcare providers, teaching hospitals and/or any other Persons for whom transfers of value or payments must be reported under Sunshine Laws.

**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 off-site computer files created during automatic system back up which are subsequently stored securely by the receiving Party.

## ARTICLE 10

### REPRESENTATIONS AND WARRANTIES

**10.1 Authority and Binding Agreement.** Nektar and BMS each represents and warrants to the other 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.** Nektar and BMS each represents and warrants that, to the best of its knowledge as of the Effective Date, 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 materially adversely affect the rights granted to the other Party under this Agreement.

**10.3 Litigation.** Nektar and BMS each represents and warrants that, to the best of its knowledge as of the Effective Date, 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.** Except as otherwise notified to the other Party, there is not pending or, to the knowledge of such Party as of the Effective Date, 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.** Nektar and BMS each represents and warrants that, to the best of its knowledge, all necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons (i) 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 (ii) 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 any Combined Therapy 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 five years 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.** Nektar and BMS each represents and warrants that it shall comply with all Applicable Laws 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 and reporting of information, such as those set forth by the Regulatory Agencies, as applicable, and the applicable terms of this Agreement, in the performance of its obligations hereunder.

**10.8 Affiliates.** Nektar and BMS each represents and warrants 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 and subject to any restrictions expressly disclosed in writing to the other Party.

**10.9 Ethical Business Practices.** Nektar and BMS each represents and warrants 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 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.

**10.11 Accounting.** Each Party represents and warrants 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.

**10.12 Compliance with Ono Agreements.** BMS will comply with its obligations under the Ono-BMS Agreements (and not to voluntarily terminate same) to the extent necessary for each Combined Therapy Trial to be completed in accordance with the terms of this Agreement and for Nektar to receive the rights and benefits provided to it under this Agreement.

**10.13 Intentionally omitted .**

**10.14 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*") Nektar, its Affiliates, and its and their agents, directors, officers, and employees (the "*Nektar Indemnitees*") from and against any and all liabilities, expenses and/or losses, including reasonable cost of investigations, experts, 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 gross negligence or intentional misconduct of BMS, any BMS Indemnitee or any (sub)licensee of BMS conducting activities on behalf of BMS under this Agreement or pursuant to a (sub)license granted by BMS; (b) any breach by BMS of any representation, warranty or covenant set forth in Article 10, or any material breach by BMS of any provision of this Agreement; (c) any injury to a subject in a Combined Therapy Trial caused solely by the development, use or manufacture of the BMS Compound; (d) any injury to a subject in a Combined Therapy Trial where it ultimately cannot be or is not determined if such injury is the direct result of the BMS Compound on the one hand or the Nektar Compound on the other hand, *provided that*, in the case of this clause (d), BMS shall only Indemnify the Nektar Indemnitees for fifty percent (50%) of any such Loss; or (e) 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

Trial Inventions and Combined Therapy Patent Rights outside the scope of this Agreement (other than with respect to Third Party Claims that are covered under Section 6.4 )); but excluding, in each case with respect to clauses (a) through (c), or (e), any such Losses to the extent Nektar is obligated to Indemnify the BMS Indemnitees pursuant to Section 11.2 .

**11.2 Nektar Indemnification.** Nektar hereby agrees to Indemnify BMS, its Affiliates, and its and their agents, directors, officers, and employees (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 gross negligence or intentional misconduct of Nektar or any Nektar Indemnitee or any (sub) licensee of Nektar conducting activities on behalf of Nektar under this Agreement or pursuant to a (sub)license granted by Nektar; (b) any breach by Nektar of any representation, warranty or covenant set forth in Article 10, or any material breach by Nektar of any provision of this Agreement; (c) any injury to a subject in a Combined Therapy Trial caused solely by the development, use or manufacture of the Nektar Compound; (d) any injury to a subject in a Combined Therapy Trial where it ultimately cannot be or is not determined if such injury is the direct result of the Nektar Compound on the one hand or the BMS Compound on the other hand; *provided that* , in the case of this clause (d), Nektar shall only Indemnify the BMS Indemnitees for fifty percent (50%) of any such Loss; or (e) the use by Nektar, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, Nektar Study Data, Nektar Study Inventions, Nektar Study Patent Rights, Combined Therapy Trial Inventions and Combined Therapy Patent Rights outside the scope of this Agreement (other than with respect to Third Party Claims that are covered under Section 6.4 )), but excluding, in each case with respect to clauses (a) through (c), or (e), any such Losses to the extent BMS is obligated to Indemnify the Nektar 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 of the types set forth in Section 11.1 and 11.2 within [\*\*\*] after the Party seeking indemnification has knowledge of such 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 (but without any reservation of rights or recovery against the Indemnified Party) to investigate, prepare for and defend against any such Loss; (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 (d) not compromising or settling such Loss 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 , 11.2 and/or 11.3 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 , 11.2 and/or 11.3 upon resolution of the underlying claim, notwithstanding clause (b) of Section 11.3.

**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 that 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.**

(a) NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES, INCLUDING BUT NOT LIMITED TO 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(a) IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER SECTIONS 11.1 OR 11.2, OR DAMAGES AVAILABLE FOR BREACHES OF PAYMENT OBLIGATIONS IN SECTIONS 7.2 OR 7.3, CONFIDENTIALITY OBLIGATIONS IN ARTICLE 9 OR FOR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

(b) EACH PARTY'S MAXIMUM, CUMULATIVE LIABILITY ARISING OUT OF OR RELATING TO A GIVEN COMBINED THERAPY TRIAL PERFORMED PURSUANT TO THIS AGREEMENT AND/OR SUCH PARTY'S PERFORMANCE RELATING THERETO, REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY, INDEMNITY OR OTHERWISE), WILL NOT EXCEED IN THE AGGREGATE FOR ALL CLAIMS RELATING TO SUCH COMBINED THERAPY TRIAL [\*\*\*]; PROVIDED, HOWEVER, THAT NOTHING IN THIS SECTION 11.6(b) IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER SECTIONS 11.1 OR 11.2, OR ANY DAMAGES AVAILABLE FOR BREACHES OF PAYMENT OBLIGATIONS IN SECTIONS 7.2 OR 7.3, 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 by all centers or institutions participating in the Combined Therapy Trials, the 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 Trials, to both Parties, and the completion of any then agreed upon



Protocol, Statistical Analysis and Bioanalysis Plan (the “ *Term* ”); *provided* that if termination language in Sections 2.1(e) applies, then the Term shall expire.

### 12.2 Termination for Material Breach.

(a) **Notice and Cure Period.** If a Party (the “ *Breaching Party* ”) is in material breach, 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 reasonably be cured within the Cure Period, and the Breaching Party notifies the non-Breaching Party of its intent to cure such material breach, commences actions to cure such material breach within the Cure Period and thereafter diligently continues 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 (or, if earlier, abandonment of the dispute by such 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 upon written notice if it reasonably deems it necessary to protect the safety, health or welfare of subjects enrolled in any Combined Therapy 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 Sections 2.8 or 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 Sections 2.8 or 13.3 .

(b) If a Clinical Hold with respect to either the BMS Compound or the Nektar Compound 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 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 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 each Party to conduct a Combined Therapy Trial in Sections 3.1 and 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, Nektar may continue to dose subjects enrolled in any then ongoing Combined Therapy Trial through completion of the applicable Protocol if dosing is required by the applicable Regulatory Authority(ies) and/or Applicable Law(s). Any such wind-down activities will include the return to BMS, or destruction, of all BMS Compound provided to Nektar and not consumed in the Combined Therapy Trials. If applicable, upon termination of this Agreement, the Parties shall remain responsible pursuant to the terms of this Agreement for any expenses incurred prior to such termination and that are associated with terminating any ongoing clinical trial work and/or result from such ongoing activities under this Agreement solely to the extent such activities are deemed necessary by Nektar (after discussion at a meeting of the JDC) based on reasonable medical judgment to protect the health of subjects participating in any Combined Therapy 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)(i), Section 2.1(b)(ii) (first sentence), Section 2.2 (“ *Adverse Event Reporting* ”), Section 5.1(a)(viii) , Section 5.1(b)(iii) , Article 6 (“ *Intellectual Property* ”), Section 7.2 (“ *Combined Therapy Trial Expenses* ”), Section 7.3 (“ *Invoicing; Payment* ”), Section 8.1 (“ *Records* ”), Section 8.2 (“ *Ownership of Study Data* ”), Section 8.3 (“ *Use of Study Data* ”), Section 8.4 (“ *Access to Study Data* ”), Section 8.5 (“ *Samples* ”), 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; Licensees* ”), Section 13.11 (“ *Headings* ”), Section 13.13 (“ *Severability* ”), Section 13.14 (“ *Further Assurances* ”), 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 Trials from the Effective Date forward. This Agreement, including the Exhibits hereto and together with the Protocol, Quality Agreement, Statistical Analysis Plan, and Supply Agreement, 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 and all claims relating to or arising out of this Agreement or the breach thereof shall be governed and construed in accordance with the internal laws of the State of New York, USA, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

#### **13.3 Dispute Resolution.**

(a) 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 JDC Dispute or a Publication Dispute or a dispute as to whether a Material Safety Issue exists, the Parties shall refer such Dispute promptly to the Alliance Managers for resolution. If the Alliance Managers are unable to resolve such Dispute within [\*\*\*] after a matter has been presented to them, 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 them in good faith negotiations within [\*\*\*] after such referral to them, such unresolved Dispute shall be referred to the Chief Executive Officer of Nektar or his or her designee and the Chief Scientific Officer of BMS or his or her designee for attempted resolution by good faith negotiations within [\*\*\*] after such referral is made. In the event such officers are unable to resolve such Dispute within such [\*\*\*] period then, if such Dispute constitutes an Arbitration Matter, such Dispute shall be resolved through arbitration in accordance with Section 13.3(b); *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 [\*\*\*] negotiation period, and with respect to any JDC Dispute or Publication Dispute, the specific dispute resolution processes contained in Sections 2.8 or 9.5(b), as applicable, will apply.

(b) If a Dispute that constitutes an Arbitration Matter remains unresolved after escalation to the senior executives as described above, either Party may refer the matter to arbitration as described herein, the results of which shall be binding upon the Parties. Any

arbitration under this Agreement shall be conducted under the auspices of the American Arbitration Association (“AAA”) by a panel of three (3) arbitrators pursuant to that organization’s Commercial Arbitration Rules then in effect; *provided, however*, that the Parties hereby agree that the time schedule for the appointment of arbitrators and the time schedule for submission of the statement of defense shall follow the American Arbitration Association Arbitration Rules. 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. Notwithstanding anything to the contrary in this Agreement, each Party shall be entitled to recover its attorneys’ fees and arbitration fees and expenses to the extent it is successful in bringing an action to enforce its rights to indemnification under this Agreement against the other Party.

**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 Nektar) the BMS Compound or BMS Technology or (in the case of BMS) the Nektar Compound or Nektar 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 Nektar Compound (by BMS) or the BMS Compound (by Nektar), 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 applicable activity 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 (except for strikes or other concerted acts of a Party’s respective 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 Nektar: Nektar Therapeutics  
455 Mission Bay Boulevard South  
San Francisco, CA 94158  
Attention: Chief Medical Officer

With a copy to: Nektar Therapeutics  
455 Mission Bay Boulevard South  
San Francisco, CA 94158  
Attention: VP & General Counsel

For BMS: Bristol-Myers Squibb Company  
Route 206 and Province Line Road  
Princeton, NJ 08543-4000  
Attention: Fouad Nouami, VP, Global Development Lead - Nivolumab

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. The failure of either Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of any such obligation. No amendment, modification, release or discharge to this Agreement, the Quality Agreement or any material amendment, modification, release or discharge to a Bioanalysis Plan, a Statistical Analysis Plan, or a CRO Agreement (to the extent provided in Section 2.4(o)) 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, provided that such Party provide written notice of such assignment to the other Party within [\*\*\*] of such assignment, (a) to an Affiliate, (b) to a Third Party that merges with, consolidates with or acquires substantially all of the assets or voting control of the assigning Party or (c) to a Third Party that acquires all the rights to the Nektar Compound, in the case of Nektar, or the BMS Compound, in the case of BMS. Any assignment or attempted assignment by any Party in violation of the terms of this Section 13.10 shall be null and void and of no legal effect.

**(b) Licensees.** If a Party grants its or the other Party's Affiliate or 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 licensor Party and to not take any action that is inconsistent with such Party's obligations under Exhibit C.

**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 signatures.

**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, (a) 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; (b) 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; (c) words in the singular or plural form include the plural and singular form, respectively; (d) 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”; and (e) the words “hereof,” “herein,” “hereunder,” “hereby” and derivative or similar words refer to this Agreement. 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.** Where a provision of this Agreement provides for a Party to respond within a designated period following written notice from the other Party (e.g., Sections 5.1(a)(vi) and 5.1(b)(iv)), and if such Party fails to respond within the designated period, then the failure to respond shall create or imply: (i) that the non-responding Party agrees with the proposed action to be taken by the other Party, or (ii) consent that an action proposed to be taken may be taken, except if such consent expressly conflicts with the terms of this Agreement.

[ *Signature page follows* ]

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

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

**Nektar Therapeutics**                      **Bristol-Myers Squibb Company**

By: /s/ John Nicholson                      By: /s/ Fouad Namouni

Name: John Nicholson                      Name: Fouad Namouni

Title: Senior Vice President                      Title: Oncology Department Head

Date: September 21, 2016                      Date: September 22, 2016

*Signature Page to Clinical Trial Collaboration Agreement*

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**Exhibit Index**

Attached :

Exhibit A :Draft Initial Trial Protocol Synopsis

Exhibit B :Press Release

Exhibit C :Exclusivity

Exhibit D :BMS Studies

Exhibit E :Nektar Compound

Exhibit Index

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\*\*\*] NKTR-214

**EXHIBIT A**

**INITIAL TRIAL PROTOCOL SYNOPSIS**

**1.0 Study Synopsis**

<b>Name of Sponsor:</b>	Nektar Therapeutics
<b>Name of Finished Product:</b>	NKTR-214 drug product Opdivo®
<b>Name of Active Ingredient:</b>	NKTR-214 drug substance Nivolumab (anti-PD-1)
<b>Title of Study:</b>	A Phase 1/2, Open-label, Multicenter, Dose Escalation and Dose Expansion Study of NKTR-214 and Nivolumab in Patients with Select Locally Advanced or Metastatic Solid Tumor Malignancies
***]	***]
<b>Phase of Development:</b>	Phase 1/2
***]	***]
***]	***]
***]	***]
***]	***]
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Exhibit A

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

**[\*\*\*] NKTR-214**

Exhibit A

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

**EXHIBIT B**

**FORM OF PRESS RELEASE**

*Please refer to Nektar Therapeutics' Current Report on Form 8-K filed with the Securities and Exchange Commission on September 27, 2016.*

Exhibit B

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## EXHIBIT C

### EXCLUSIVITY

The Parties desire to agree on the following terms in order to develop innovative medicines as promptly as reasonably practicable, to avoid IP and other conflicts with Third Parties in related subject matter transactions, and to better ensure that each Party focuses its efforts on the development of appropriate Combined Therapy Trials and that the agreed-upon Combined Therapy Trials proceed in an effective, cost-efficient and timely manner:

a. Nektar Exclusivity. During the Exclusive Collaboration Period, except for Permitted Research (as defined below), Nektar will not (A) conduct any preclinical or clinical research with a Restricted Third Party regarding an anti-PD-1 antagonist or anti-PD-L1 antagonist, together with the Nektar Compound (a “**Restricted Combination**”), (B) license any rights under its proprietary intellectual property to any Restricted Third Party to enable the study of any Restricted Combination, (C) grant any right to a Restricted Third Party under its Nektar IND, NDA or other Regulatory Documentation for the Nektar Compound during the Exclusive Collaboration Period to enable a Restricted Third Party to research or develop a Restricted Combination, or (D) grant any right to a Third Party under the Combined Therapy Trial IND, during the Exclusive Collaboration Period, to enable a Restricted Third Party to research or develop a Restricted Combination. The foregoing shall not (1) restrict or preclude any combination studies between Nektar and any Third Party other than those containing a Restricted Combination, (2) restrict or preclude the out-license or sale of the Nektar Compound (provided that the licensee or acquirer of the Nektar Compound agrees to comply with the restrictions set forth herein) or (3) restrict or preclude Nektar from performing preclinical or clinical research using a Restricted Combination on its own or with any non-profit Entities (including university and academic research institutions) (collectively, “**Permitted Research**”), *provided that* with respect to clause (3) above, Nektar shall share with BMS during the Exclusive Collaboration Period any data generated from such preclinical or clinical research to the extent relating to a Restricted Combination and, in Nektar’s sole discretion, any other information related to a Restricted Combination, subject in each case to any conditions and restrictions that apply to Nektar’s use of such data and information.

b. BMS Exclusivity. Except with respect to those studies that are underway as of the Effective Date, as described on the attached Exhibit D, or Permitted IL2 Research (as defined below), during the Exclusive Collaboration Period, BMS will not conduct any preclinical or clinical research with a Restricted Third Party regarding the BMS Compound together with an IL2-based CD122 agonist (a “**Restricted IL2 Combination**”). The foregoing shall not (1) restrict or preclude any combination studies between BMS and any Third Party other than those containing a Restricted IL2 Combination (2) restrict or preclude the out-license or sale of the BMS Compound (provided that any such licensee or acquirer agrees to comply with the restrictions set forth herein) or (3) restrict or preclude BMS from performing preclinical or clinical research using a Restricted IL2 Combination on its own or with any non-profit Entities

(including university and academic research institutions) (collectively, “ **Permitted IL2 Research** ”), *provided that* with respect to clause (3) above, BMS shall share with Nektar during the Exclusive Collaboration Period any data generated from such preclinical or clinical research to the extent relating to a Restricted IL2 Combination and , in BMS’s sole discretion, any other information related to a Restricted IL2 Combination, subject in each case to any conditions and restrictions that apply to BMS’s use of such data and information.

c. Negotiations. As to other Restricted Third Parties, BMS shall have the sole right during the Exclusive Collaboration Period to negotiate with Nektar for follow-on clinical trials for a combination therapy involving a Restricted Combination, and Nektar shall not negotiate with any Restricted Third Party any Restricted Combination therapy development during the Exclusive Collaboration Period (other than Permitted Research).

Exhibit C

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

**EXHIBIT D**

**BMS STUDIES**

None.

Exhibit D

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

**EXHIBIT E**

**NEKTAR COMPOUND**

The CD122-biased IL-2 pathway agonist [\*\*\*]

Exhibit E



## CERTIFICATIONS

I, Howard W. Robin, certify that:

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

Date: November 3, 2016

/s/ HOWARD W. ROBIN

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**Howard W. Robin**  
**Chief Executive Officer, President and Director**

## CERTIFICATIONS

I, Gil M. Labrucherie, certify that:

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

Date: November 3, 2016

/s/ GIL M. LABRUCHERIE

**Gil M. Labrucherie**

**Senior Vice President and Chief Financial Officer**

## SECTION 1350 CERTIFICATIONS\*

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Howard W. Robin, Chief Executive Officer, President and Director of Nektar Therapeutics (the "Company"), and Gil M. Labrucherie, Senior Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2016, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 3, 2016

/s/ HOWARD W. ROBIN

**Howard W. Robin**

**Chief Executive Officer, President and Director**

/s/ GIL M. LABRUCHERIE

**Gil M. Labrucherie**

**Senior Vice President and Chief Financial Officer**

- \* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.