Karyopharm Therapeutics Inc. Form 10-Q May 10, 2018 Table of Contents

# **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2018

OR

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

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

Commission file number: 001-36167

Karyopharm Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of 26-3931704 (I.R.S. Employer

**Identification Number**)

incorporation or organization)

85 Wells Avenue, 2nd Floor

Newton, MA (Address of principal executive offices) 02459 (Zip Code)

(617) 658-0600

## (Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§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, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

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

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

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

As of May 4, 2018, there were 49,849,972 shares of Common Stock, \$0.0001 par value per share, outstanding.

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## PART I FINANCIAL INFORMATION

# Item 1. Condensed Consolidated Financial Statements (Unaudited). Karyopharm Therapeutics Inc.

## CONDENSED CONSOLIDATED BALANCE SHEETS

#### (unaudited)

# (in thousands, except share and per share amounts)

	N	Iarch 31, 2018	Dec	cember 31, 2017
Assets				
Current assets:				
Cash and cash equivalents	\$	37,499	\$	68,997
Short-term investments		93,418		77,472
Prepaid expenses and other current assets		2,396		1,754
Restricted cash				200
Total current assets		133,313		148,423
Property and equipment, net		2,454		2,185
Long-term investments		10,314		29,396
Restricted cash		292		290
Total assets	\$	146,373	\$	180,294
Liabilities and stockholders equity				
Current liabilities:				
Accounts payable	\$	4,949	\$	5,665
Accrued expenses		21,545		21,445
Deferred revenue		19,729		21,921
Deferred rent		178		303
Other current liabilities		333		133
Total current liabilities		46,734		49,467
Deferred revenue, net of current portion		2,192		
Deferred rent, net of current portion		1,918		1,363
Total liabilities		50,844		50,830
Stockholders equity:				
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; none issued and				
outstanding		~		~
		5		5

Common stock, \$0.0001 par value; 100,000,000 shares authorized; 49,670,328 and 49,533,150 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively		
Additional paid-in capital	629,610	625,017
Accumulated other comprehensive loss	(286)	(217)
Accumulated deficit	(533,800)	(495,341)
Total stockholders equity	95,529	129,464
Total liabilities and stockholders equity	\$ 146,373	\$ 180,294

See accompanying notes to condensed consolidated financial statements.

# Karyopharm Therapeutics Inc.

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

## (unaudited)

# (in thousands, except share and per share amounts)

	Three Month March			31,	
		2018		2017	
License and other revenue	\$	10,000	\$	68	
Operating expenses:					
Research and development		41,321		24,083	
General and administrative		7,621		6,264	
Total operating expenses		48,942		30,347	
Loss from operations		(38,942)		(30,279)	
Other income (expense): Interest income		509		400	
Other expense		(14)		(15)	
Total other income, net		495		385	
Loss before income taxes		(38,447)		(29,894)	
Provision for income taxes		(12)		(23)	
Net loss	\$	(38,459)	\$	(29,917)	
Net loss per share basic and diluted	\$	(0.78)	\$	(0.71)	
Weighted-average number of common shares outstanding used in net loss per share basic and diluted	4	9,602,809	4	1,894,796	

See accompanying notes to condensed consolidated financial statements.

# Karyopharm Therapeutics Inc.

# CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

## (unaudited)

(in thousands)

		Three Months Ended March 31,		
	2018	2017		
Net loss	\$ (38,459)	\$ (29,917)		
Comprehensive income (loss) Unrealized gain (loss) on investments Foreign currency translation adjustments	(108) 39	59 11		
Comprehensive loss	\$ (38,528)	\$ (29,847)		

See accompanying notes to condensed consolidated financial statements.

# Karyopharm Therapeutics Inc.

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

# (unaudited)

# (in thousands)

	Three Mon Marc 2018	
Operating activities		
Net loss	\$ (38,459)	\$ (29,917)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	169	183
Net amortization of premiums and discounts on investments	160	267
Stock-based compensation expense	4,164	5,909
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(638)	(61)
Accounts payable	(773)	(522)
Accrued expenses and other liabilities	295	(498)
Deferred rent	430	(69)
		, ,
Net cash used in operating activities	(34,652)	(24,708)
Investing activities		
Purchases of property and equipment	(382)	
Proceeds from maturities of investments	27,602	25,624
Purchases of investments	(24,736)	(25,075)
Net cash provided by investing activities	2,484	549
Financing activities		
Proceeds from the exercise of stock options	429	57
Net cash provided by financing activities	429	57
Effect of exchange rate on cash	43	16
č		
Net decrease in cash and cash equivalents	(31,696)	(24,086)
Cash, cash equivalents and restricted cash at beginning of period	69,487	50,142
Cash, cash equivalents and restricted cash at end of period	\$ 37,791	\$ 26,056
A A	. ,	
Supplemental disclosure of non-cash activities		
Purchases of property and equipment included in accounts payable	\$ 56	\$
Deferred financing costs included in accounts payable	\$	\$ 15

See accompanying notes to condensed consolidated financial statements.

# Karyopharm Therapeutics Inc.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands except share and per share data)

## 1. Summary of Significant Accounting Policies

## Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Karyopharm Therapeutics Inc., a Delaware corporation (the Company ), have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included. When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the three months ended March 31, 2018 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2018. For further information, refer to the financial statements and footnotes included in the Company s Annual Report on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission (SEC) on March 15, 2018.

## Basis of Consolidation

The condensed consolidated financial statements at March 31, 2018 include the accounts of (i) the Company, (ii) Karyopharm Securities Corp. (a wholly-owned Massachusetts corporation of the Company incorporated in December 2013), (iii) Karyopharm Europe GmbH (a wholly-owned German Limited Liability Company formed in August 2014) and (iv) Karyopharm Therapeutics (Bermuda) Ltd. (a wholly-owned Bermuda subsidiary of the Company formed in March 2015). All intercompany balances and transactions have been eliminated in consolidation.

## Revenue Recognition

The Company adopted ASU 2014-09, *Revenue from Contracts with Customers* (ASC 606), as well as subsequent amendments, which were codified in ASC 606, on January 1, 2018, using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for the quarter ended March 31, 2018 reflect the application of ASC 606 while the reported results for 2017 were prepared under the guidance of ASC 605, *Revenue Recognition* (ASC 605), which is also referred to herein as legacy GAAP or the previous guidance . The adoption of ASC 606 did not have a material impact on the Company s consolidated financial position, results of operations, stockholder s equity or cash flows as of the adoption date, as no transition adjustment for any of the Company s contracts with customers was required.

ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps:

(i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company generates revenue from license or similar agreements with pharmaceutical companies for the development and commercialization of certain of its product candidates. Such agreements may include the transfer of intellectual property rights in the form of licenses, transfer of technological know-how, delivery of drug substances, research and development services, and participation on certain committees with the counterparty. Payments made by the customers may include non-refundable upfront fees, payments upon the excercise of customer options, payments based upon the achievement of defined milestones, and royalties on sales of product candidates if they are successfully approved and commercialized.

If the license to the Company s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the license as revenue upon transfer of control of the license. The Company evaluates all other promised goods or services in the agreement to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is

distinct. Optional future services where any additional consideration paid to the Company reflects their standalone selling prices do not provide the customer with a material right and, therefore, are not considered performance obligations. If optional future services are priced in a manner which provides the customer with a significant or incremental discount, they are material rights, and are accounted for as performance obligations.

The Company utilizes judgment to determine the transaction price. In connection therewith, the Company evaluates contingent milestones at contract inception to estimate the amount which is not probable of a material reversal to include in the transaction price using the most likely amount method. Milestone payments that are not within the control of the Company, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore the variable consideration is constrained. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, the Company re-evaluates the probability of achieving development milestone payments which may not be subject to a material reversal and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license and other revenue, as well as earnings, in the period of adjustment.

The Company then determines whether the performance obligations or combined performance obligations are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress, as applicable, each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded within deferred revenue. Contract liabilities within deferred revenue are recognized as revenue after control of the goods or services is transferred to the customer and all revenue recognition criteria have been met.

For arrangements that include sales-based royalties, including sales-based milestone payments, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of when the related sales occur or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

# 2. Recent Accounting Pronouncements

# Recently Adopted Accounting Standards

As detailed above, the Company adopted ASC 606 on January 1, 2018. Under the modified retrospective transition method, the Company applied ASC 606 to all contracts within scope as of January 1, 2018. Under the practical expedient concerning contract modifications contained in the transitional provisions of ASC 606, the Company has not retrospectively restated its contracts for modifications prior to the earliest period presented, and instead has reflected the aggregate effect of all modifications when identifying the satisfied and unsatisfied performance obligations, determining the transaction price and allocating the transaction price. Qualitatively, the effect of applying this practical expedient is not material to the periods presented in the consolidated financial statements. As more fully discussed in Note 3, Asset Purchase and License Agreements, only the Company s arrangement with Ono Pharmaceutical Co., Ltd. was determined to have unsatisfied performance obligations as of the adoption date. However, the pattern of revenue recognition was not affected and, therefore, no transition adjustment was recorded to the opening balance of accumulated deficit on January 1, 2018. All other agreements subject to transition, which only

included the Company s arrangement with Anivive Lifesciences Inc., were unaffected by the adoption of ASC 606 in all periods presented in the consolidated financial statements through application of the modified retrospective transition method.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments* (ASU 2016-15). ASU 2016-15. This standard addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. The Company adopted ASU 2016-05 effective January 1, 2018 and the adoption did not have a material impact on the Company s statements of cash flows.

In October 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-16, Accounting for Income Taxes: Intra-Entity Asset Transfers of Assets Other than Inventory (Topic 740). Topic 740 eliminates the ability to defer the tax expense related to intra-entity asset transfers other than inventory. Under the new standard, entities should recognize the income tax consequences on an intra-entity transfer of an asset other than inventory when the transfer occurs. The Company adopted Topic 740 effective January 1, 2018 and the adoption did not have a material impact on the Company s financial position or results of operations.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash.* The new standard requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-

period total amounts shown on the statement of cash flows. The Company adopted this standard effective January 1, 2018 and reclassified restricted cash in the statements of cash flows to be included in the cash and cash equivalents balance. The standard resulted in the reclassification of \$292 and \$479 into the balance of cash, cash equivalents and restricted cash on the statement of cash flows for the periods ended March 31, 2018 and 2017, respectively.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718)* (ASU 2017-09) *Scope of Modification Accounting*. ASU 2017-09 provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. This ASU does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The Company adopted this standard effective January 1, 2018 and the adoption did not have a material impact on the Company s consolidated financial statements.

## Recently Issued Accounting Standards

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for the Company on January 1, 2019. The Company is in process of evaluating this guidance and determining the potential impact on its consolidated financial statements; however, it anticipates that the new standard will result in the Company recording additional right of use assets and corresponding liabilities on its consolidated balance sheet.

# 3. Asset Purchase and License Agreements

# **Biogen Asset Purchase Agreement**

On January 24, 2018, the Company entered into an Asset Purchase Agreement (the APA ) and Letter Agreement with Biogen MA Inc., a Massachusetts corporation and subsidiary of Biogen, Inc. (Biogen ).

Under the terms of the APA and Letter Agreement, the Company sold Biogen exclusive worldwide rights to develop and commercialize the Company s oral Selective Inhibitor of Nuclear Export (SINE) compound KPT-350 and certain related assets with an initial focus in amyotrophic lateral sclerosis (ALS) (the Transfer of IP), and also granted Biogen: (i) an exclusive worldwide license under certain of the Company s intellectual property to manufacture or have manufactured KPT-350 (the Manufacturing License ), (ii) a technology transfer package, consisting of information and the Company s know-how regarding the manufacture of KPT-350 (the Manufacturing Technology Transfer ), (iii) a right, at Biogen s request, to have the Company provide transition assistance regarding manufacturing and other matters (the Transition Assistance), (iv) existing inventory of KPT-350 (the Inventory), (v) an initial supply of KPT-350 (the Initial Supply ), and (vi) a right, at Biogen s request, to have the Company manufacture and supply the active pharmaceutical ingredient for an additional supply of KPT-350 (the Additional Supply ). In consideration for these rights, the Company received an upfront payment of \$10,000, and is eligible to receive additional payments of up to \$142,000 based on the achievement by Biogen of future specified development milestones, and up to \$65,000 based on the achievement by Biogen of future specified commercial milestones. The Company will also be eligible to receive tiered royalty payments that reach low double-digits based on future net sales until the later of the tenth anniversary of the first commercial sale of the applicable product and the expiration of specified patent protection for the applicable product, determined on a country-by-country basis.

The Company and Biogen have made customary representations and warranties and agreed to customary covenants in the APA, including covenants requiring Biogen to use commercially reasonable efforts to develop KPT-350 in

specified neurological indications, including ALS, in any of the United States, United Kingdom, France, Spain, Germany or Italy. The APA will continue in effect until the expiration of all royalty obligations, provided that the APA may be terminated earlier by Biogen, subject to the requirements that Biogen (i) negotiate in good faith with the Company regarding an assignment or license back to the Company of the purchased assets and (ii) not transfer or license the purchased assets to a third party unless such third party assumes Biogen s obligations to the Company under the APA.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Biogen, is a customer. The Company identified the following material promises in the arrangement: the Transfer of IP and the Manufacturing License. The Company also identified other immaterial promises under the contract that were not deemed performance obligations. The Company further determined other promises for Additional Supply and Transition Assistance represented customer options, which would create an obligation for the Company if exercised by Biogen. Since either no additional or immaterial consideration is owed to the Company by Biogen upon exercise of the customer options for Additional Supply and Transition Assistance, the Company determined both are offered at significant and incremental discounts. Accordingly, they were assessed as material rights and, therefore, separate performance obligations in the arrangement.

The Company then determined the Transfer of IP and the Manufacturing License were not distinct from one another and must be combined as a performance obligation (the Combined Performance Obligation ). This is because Biogen requires the Manufacturing License to derive benefit from the Transfer of IP. Based on these determinations, as well as the considerations noted above with respect to the material rights for Additional Supply and Transition Assistance, the Company identified three distinct performance obligations at the inception of the contract: (i) the Combined Performance Obligation, (ii) the material right for Additional Supply, and (iii) the material right for Transition Assistance.

The Company further determined that the up-front payment of \$10,000 constituted the entirety of the consideration to be included in the transaction price at contract inception, which was allocated to the performance obligations based on their relative stand-alone selling prices. In connection therewith, the Company estimated the stand-alone selling price of the (i) Combined Performance Obligation, (ii) material right for Additional Supply, and (iii) material right for Transition Assistance, and determined the stand-alone selling price of the material rights for Additional Supply and Transition Assistance were insignificant based on various quantitative and qualitative considerations. Accordingly, the Company further determined the allocation of the transaction price to the material rights for Additional Supply and Transition Assistance was insignificant. Based on the estimates of the stand-alone selling prices for each of the performance obligations, the Company determined that substantially all the \$10,000 transaction price should be allocated to the Combined Performance Obligation. The Company believes that a change in the assumptions used to determine its best estimate of the stand-alone selling prices for the identified performance obligations would not have a significant effect on the allocation of the underlying transaction price to the performance obligations.

Upon execution of the Biogen Agreement, the transaction price included only the \$10,000 up-front payment owed to the Company. The Company may receive further payments upon the achievement of certain regulatory and sales milestones, as detailed above, as well as tiered royalty payments that reach low double-digits based on future net sales. The future regulatory milestones, which represent variable consideration, were evaluated under the most likely amount method, and were not included in the transaction price, because the amounts are fully constrained as of March 31, 2018. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of such milestones is outside the control of the Company. Separately, any consideration related to sales-based milestones, as well as royalties on net sales upon commercialization by Biogen, will be recognized when the related sales occur, as they were determined to relate predominantly to the intellectual property and, therefore, have also been excluded from the transaction price in accordance with the sales-based royalty exception, as well as the Company s accounting policy. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

During the quarter ended March 31, 2018, the Company recognized \$10,000 of revenue, as it had satisfied its promises under the Combined Performance Obligation by transferring the underlying promised goods at a point in time during the quarter ended March 31, 2018.

# **Ono License Agreement**

Effective October 11, 2017 (the Effective Date ), the Company entered into a license agreement (the License Agreement ) with Ono Pharmaceutical Co., Ltd., a corporation organized and existing under the laws of Japan (Ono), pursuant to which the Company granted Ono exclusive rights to develop and commercialize, at its own cost, selinexor (KPT-330), the Company s lead, novel, oral SINE compound, as well as eltanexor (KPT-8602), the Company s second-generation oral SINE compound, for the diagnosis, treatment and/or prevention of all human oncology indications (the Field ) in Japan, Republic of Korea, Republic of China (Taiwan) and Hong Kong, as well as in the ten Southeast Asian countries currently comprising the Association of Southeast Asian Nations (the Ono Territory ) (the Exclusive License ). Pursuant to the terms of the License Agreement, the Company received an upfront payment of

¥2.5 billion (US\$21,916 on the date received), and could receive up to ¥10.15 billion (approximately US\$90,500 at the exchange rate as of the Effective Date) in milestone payments if certain development goals are achieved and up to ¥9.0 billion (approximately US\$80,200 at the exchange rate as of the Effective Date) in milestone payments if certain sales milestones are achieved, as well as a low double-digit royalty based on future net sales of selinexor and eltanexor in the Ono Territory. In addition, upon Ono s election and the parties full execution of a manufacturing technology transfer plan and satisfaction of other specified conditions (the Manufacturing Election ), the Company will grant to Ono non-exclusive rights to manufacture selinexor, eltanexor and products containing such compounds in or outside of the Ono Territory solely for development and commercialization in the Field in the Ono Territory.

As part of the License Agreement, Ono will also have the right to participate in global clinical studies of selinexor and eltanexor, and will bear the cost and expense for patients enrolled in clinical studies in the Ono Territory. Ono is responsible for seeking regulatory and marketing approvals for selinexor and eltanexor in the Ono Territory, as well as any development of the products specifically necessary to obtain such approvals. Ono is also responsible for the commercialization of products containing selinexor or eltanexor in the Field in the Ono Territory at its own cost and expense.

Subject to Ono s Manufacturing Election, the Company will furnish clinical supplies of drug substance to Ono for use in Ono s development efforts pursuant to a clinical supply agreement to be entered into by the Company and Ono, and Ono may elect to have the Company provide commercial supplies of drug product to Ono pursuant to a commercial supply agreement to be entered into by the Company and Ono, in each case the costs of which will be borne by Ono.

The License Agreement will continue in effect on a product-by-product, country-by-country basis until the later of the tenth anniversary of the first commercial sale of the applicable product in such country or the expiration of specified patent protection and regulatory exclusivity periods for the applicable product in such country. However, the License Agreement may be terminated earlier by (i) either party for breach of the License Agreement by the other party or in the event of the insolvency or bankruptcy of the other party, (ii) Ono on a product-by-product basis for certain safety reasons or on a product-by-product, country-by-country basis for any reason with 180 days prior notice or (iii) the Company in the event Ono challenges or assists with a challenge to certain of the Company s patent rights.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Ono, is a customer. The Company identified the following material promises under the contract: (i) Exclusive Licenses for selinexor and eltanexor, (ii) Initial Data Transfer for selinexor and eltanexor, which consisted of regulatory data compiled by the Company for the licensed compounds and products as of the Effective Date, (iii) Initial Clinical Supply for selinexor, which consisted of units of clinical supply for Ono to conduct its Phase I Trial, and (iv) an obligation to stand-ready to provide Initial Clinical Supply for eltanexor. The Company also identified several immaterial promises under the contract relating to information exchanges, and participation on operating committees and other working groups. Separately, the Company also identified certain customer options that would create an obligation for the Company if exercised by Ono, including the (i) Additional Data Transfer for selinexor and eltanexor, which would consist of the transfer of additional regulatory data compiled by the Company for the licensed compounds and products after the Effective Date, (ii) Additional Clinical Supply and Related Substance Supply for selinexor and eltanexor, which would consist of supplying Ono with units and substance of selinexor and eltanexor incremental to the Initial Clinical Supply for selinexor and the obligation to stand-ready to provide Initial Clinical Supply for eltanexor, as noted above, (iii) Manufacturing Technology Transfer and License for selinexor and eltanexor under Ono s Manufacturing Election, as detailed above, and (iv) Option for Backup Compound, which represents Ono s option to select a replacement compound in the event it elects to discontinue to development of either of the licensed compounds. Collectively, these options are referred to herein as the Transfer Option. The Transfer Options individually represent material rights, as they were offered at a significant and incremental discount. Therefore, they were further assessed as performance obligations under the Licen