Karyopharm Therapeutics Inc.
Form 10-Q
August 07, 2018
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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 June 30, 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	**26-3931704**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
85 Wells Avenue, 2nd Floor	
Newton, MA	**02459**
(Address of principal executive offices)	**(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 August 2, 2018, there were 60,563,449 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)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 118,966	$ 68,997
Short-term investments	122,155	77,472
Prepaid expenses and other current assets	3,438	1,754
Restricted cash		200
Total current assets	244,559	148,423
Property and equipment, net	2,611	2,185
Long-term investments	8,781	29,396
Restricted cash	638	290
Total assets	$ 256,589	$ 180,294
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 3,794	$ 5,665
Accrued expenses	22,969	21,445
Deferred revenue	9,363	21,921
Deferred rent	189	303
Other current liabilities	229	133
Total current liabilities	36,544	49,467
Deferred revenue, net of current portion	4,532	
Deferred rent, net of current portion	2,041	1,363
Total liabilities	43,117	50,830
Stockholders equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; none issued and outstanding		
	6	5

Common stock, $0.0001 par value; 100,000,000 shares authorized; 60,501,260 and 49,533,150 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively		
Additional paid-in capital	781,180	625,017
Accumulated other comprehensive loss	(260)	(217)
Accumulated deficit	(567,454)	(495,341)
Total stockholders equity	213,472	129,464
Total liabilities and stockholders equity	$ 256,589	$ 180,294

See accompanying notes to condensed consolidated financial statements.

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Karyopharm Therapeutics Inc.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended, June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
License and other revenue	$ 19,891	$ 3	$ 29,891	$ 71
Operating expenses:				
Research and development	44,734	23,120	86,055	47,203
General and administrative	9,489	6,635	17,110	12,899
Total operating expenses	54,223	29,755	103,165	60,102
Loss from operations	(34,332)	(29,752)	(73,274)	(60,031)
Other income (expense):				
Interest income	653	412	1,162	812
Other income (expense)	7	(29)	(7)	(44)
Total other income, net	660	383	1,155	768
Loss before income taxes	(33,672)	(29,369)	(72,119)	(59,263)
Income tax benefit (provision)	17	(18)	5	(41)
Net loss	$ (33,655)	$ (29,387)	$ (72,114)	$ (59,304)
Net loss per share basic and diluted	$ (0.60)	$ (0.64)	$ (1.36)	$ (1.35)
Weighted-average number of common shares outstanding used in net loss per share basic and diluted	56,089,159	45,831,239	52,862,194	43,873,892

See accompanying notes to condensed consolidated financial statements.

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Karyopharm Therapeutics Inc.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(unaudited)

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	$ (33,655)	$ (29,387)	$ (72,114)	$ (59,304)
Comprehensive income (loss)				
Unrealized gain (loss) on investments	104	(34)	(5)	25
Foreign currency translation adjustments	(78)	73	(38)	84
Comprehensive loss	$ (33,629)	$ (29,348)	$ (72,157)	$ (59,195)

See accompanying notes to condensed consolidated financial statements.

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Karyopharm Therapeutics Inc.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Six Months Ended June 30,	
	2018	**2017**
Operating activities		
Net loss	$ (72,114)	$ (59,304)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	353	363
Net amortization of premiums and discounts on investments	270	592
Stock-based compensation expense	8,604	11,038
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,685)	19
Accounts payable	(1,870)	(1,507)
Accrued expenses and other liabilities	1,624	1,484
Deferred revenue	(8,026)	1,025
Deferred rent	564	(139)
Net cash used in operating activities	(72,280)	(46,429)
Investing activities		
Purchases of property and equipment	(779)	
Proceeds from maturities of investments	50,602	60,979
Purchases of investments	(74,943)	(61,564)
Net cash used in investing activities	(25,120)	(585)
Financing activities		
Proceeds from the issuance of common stock, net of issuance costs	145,720	52,323
Proceeds from the exercise of stock options and shares issued under employee stock purchase plan	1,841	303
Net cash provided by financing activities	147,561	52,626
Effect of exchange rate on cash, cash equivalents and restricted cash	(44)	111
Net increase in cash, cash equivalents and restricted cash	50,117	5,723
Cash, cash equivalents and restricted cash at beginning of period	69,487	50,142
Cash, cash equivalents and restricted cash at end of period	$ 119,604	$ 55,865
Reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets		

Cash and cash equivalents	$ 118,966	$ 55,381
Short-term restricted cash		200
Long-term restricted cash	638	284
Total cash, cash equivalents and restricted cash	$ 119,604	$ 55,865

See accompanying notes to condensed consolidated financial statements.

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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 and six months ended June 30, 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.

At June 30, 2018, the Company had $249,902 in cash, cash equivalents and short- and long-term investments. The Company has had recurring losses and incurred a loss of $72,114 for the six months ended June 30, 2018. Net cash used in operations for the six months ended June 30, 2018 was $72,280. The Company expects that cash, cash equivalents and short- and long-term investments at June 30, 2018 will be sufficient to fund its current operating plans and capital expenditure requirements for at least twelve months from the date of issuance of the financial statements contained in this Form 10-Q while it establishes the commercial infrastructure for a potential launch of selinexor in the United States.

Basis of Consolidation

The condensed consolidated financial statements at June 30, 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), (iv) Karyopharm Therapeutics (Bermuda) Ltd. (a wholly-owned Bermuda subsidiary of the Company formed in March 2015), and (v) Karyopharm Israel Ltd. (a wholly-owned Israeli subsidiary of the Company formed in June 2018). All intercompany balances and transactions have been eliminated in consolidation.

Revenue Recognition

The Company adopted Accounting Standards Update (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 three and six month periods ended June 30, 2018 reflect the application of ASC 606 while the reported results for the three and six month periods ended June 30, 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.

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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 exercise 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 a 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 a license of intellectual property 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 Financial Accounting Standards Boards (FASB) issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments* (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.

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In October 2016, the FASB issued 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 and 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 $490 and $479 into cash, cash equivalents and restricted cash within the beginning of period balance on the condensed consolidated statements of cash flows for the six-month periods ended June 30, 2018 and 2017, respectively. This adoption also resulted in an immaterial adjustment to the effect of exchange rate on cash, cash equivalents and restricted cash during the six-month period ended June 30, 2017.

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