SPECTRUM PHARMACEUTICALS INC
Form 10-Q
November 08, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018
¨ 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: 001-35006

SPECTRUM PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	93-0979187
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11500 South Eastern Avenue, Suite 240 Henderson, Nevada	89052
(Address of principal executive offices)	(Zip Code)

(702) 835-6300
(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 ý No ¨
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ý 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	ý
Non-accelerated filer	¨	Smaller reporting company	¨
		Emerging Growth Company	¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý
As of October 31, 2018, 106,913,392 shares of the registrant's common stock were outstanding.

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SPECTRUM PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2018
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Items 2 through 5 of Part II have been omitted because they are not applicable with respect to the current reporting period.

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PART I: FINANCIAL INFORMATION
ITEM 1: CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SPECTRUM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and par value amounts)
(Unaudited)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 166,541	$ 227,323
Marketable securities	54,014	248
Accounts receivable, net of allowance for doubtful accounts of $71 and $71, respectively	29,485	32,260
Other receivables	5,131	2,133
Inventories	3,979	5,715
Prepaid expenses and other assets	8,300	10,067
Total current assets	267,450	277,746
Property and equipment, net of accumulated depreciation	437	589
Intangible assets, net of accumulated amortization	116,273	137,159
Goodwill	18,091	18,162
Other assets	10,376	53,783
Total assets	$ 412,627	$ 487,439
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 57,633	$ 58,117
Accrued payroll and benefits	7,744	9,261
Deferred revenue	—	3,872
FOLOTYN development liability	211	275
Convertible senior notes	35,357	38,224
Total current liabilities	100,945	109,749
FOLOTYN development liability, less current portion	11,905	12,111
Deferred revenue, less current portion	—	315
Acquisition-related contingent obligations	5,555	6,272
Deferred tax liabilities	1,447	1,438
Other long-term liabilities	5,997	6,215
Total liabilities	125,849	136,100
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized; 106,060,681 and 100,742,735 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	106	100
Additional paid-in capital	840,681	837,347
Accumulated other comprehensive (loss) income	(3,342)	15,999
Accumulated deficit	(550,667)	(502,107)
Total stockholders' equity	286,778	351,339
Total liabilities and stockholders' equity	$ 412,627	$ 487,439

See accompanying notes to these unaudited condensed consolidated financial statements.

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SPECTRUM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	$24,556	$31,234	$76,419	$88,235
License fees and service revenue	712	5,161	3,511	11,562
Total revenues	$25,268	$36,395	$79,930	$99,797
Operating costs and expenses:				
Cost of sales (excluding amortization of intangible assets)	6,472	12,179	19,891	31,618
Cost of service revenue	—	—	—	4,221
Selling, general and administrative	19,837	18,527	67,393	55,052
Research and development	21,060	13,815	60,442	43,760
Amortization of intangible assets	6,923	6,928	20,804	20,718
Total operating costs and expenses	54,292	51,449	168,530	155,369
Loss from operations	(29,024)	(15,054)	(88,600)	(55,572)
Other (expense) income:				
Interest expense, net	(12)	(2,014)	(484)	(6,196)
Change in fair value of contingent consideration related to acquisitions	1,200	(2,942)	717	(3,236)
Other (expense) income, net	(40,880)	251	17,583	901
Total other (expense) income	(39,692)	(4,705)	17,816	(8,531)
Loss before income taxes	(68,716)	(19,759)	(70,784)	(64,103)
(Provision) benefit for income taxes	(2)	1,466	(8)	1,412
Net loss	$(68,718)	$(18,293)	$(70,792)	$(62,691)
Net loss per share:				
Basic	$(0.66)	$(0.22)	$(0.69)	$(0.78)
Diluted	$(0.66)	$(0.22)	$(0.69)	$(0.78)
Weighted average shares outstanding:				
Basic	104,106,298	83,463,153	102,571,858	80,177,370
Diluted	104,106,298	83,463,153	102,571,858	80,177,370

See accompanying notes to these unaudited condensed consolidated financial statements.

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SPECTRUM PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$(68,718)	$(18,293)	$(70,792)	$(62,691)
Other comprehensive (loss) income:				
Unrealized loss on available-for-sale securities, net of income tax benefit of $2,068 and $2,068, for the three and nine months ended September 30, 2017	—	5,047	—	3,903
Cumulative effect of ASU 2016-01 adoption on January 1, 2018 for unrealized gains on equity securities, net of income tax; recorded as a reclassification to “accumulated deficit” (see Note 3(a))	—	—	(17,211)	—
Foreign currency translation adjustments	(254)	405	(2,130)	1,349
Other comprehensive (loss) income	(254)	5,452	(19,341)	5,252
Total comprehensive loss	$(68,972)	$(12,841)	$(90,133)	$(57,439)

See accompanying notes to these unaudited condensed consolidated financial statements.

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SPECTRUM PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash Flows From Operating Activities:		
Net loss	$(70,792)	$(62,691)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21,000	20,965
Stock-based compensation	13,197	10,201
Accretion of debt discount on 2018 Convertible Notes, recorded to interest expense (Note 13)	1,558	4,236
Amortization of deferred financing costs on 2018 Convertible Notes, recorded to interest expense (Note 13)	178	491
Unrealized loss (gains) from transactions denominated in foreign currency	17	(18)
Change in cash surrender value of corporate-owned life insurance policy	(5)	(266)
Deferred tax liabilities	9	154
Income tax recognition on unrealized gain for available-for-sale securities	—	(2,068)
Unrealized gains on marketable securities (Note 3(a))	(17,716)	—
Change in fair value of contingent consideration related to the Talon and EVOMELA acquisitions (Note 9)	(717)	3,236
Changes in operating assets and liabilities:		
Accounts receivable, net	3,252	2,143
Other receivables	(3,002)	(88)
Inventories	2,862	554
Prepaid expenses	(2,362)	972
Other assets	4,890	183
Accounts payable and other accrued obligations	(457)	(2,954)
Accrued payroll and benefits	(1,517)	(1,343)
FOLOTYN development liability	(270)	(704)
Deferred revenue	—	(483)
Other long-term liabilities	(218)	1,523
Net cash used in operating activities	(50,093)	(25,957)
Cash Flows From Investing Activities:		
Proceeds from redemption of corporate-owned life insurance policy	4,130	—
Payment for corporate-owned life insurance premiums	—	(601)
Redemption of mutual funds	—	(1)
Purchases of property and equipment	(46)	(412)
Net cash provided by (used in) investing activities	4,084	(1,014)
Cash Flows From Financing Activities:		
Proceeds from employees for exercises of stock options	7,843	3,051
Proceeds from sale of stock under our employee stock purchase plan	734	406
Proceeds from employees, for our remittance to tax authorities, upon vesting of restricted stock and exercises of stock options	4,645	—
Payments to tax authorities upon employees' surrender of restricted stock at vesting and exercises of stock options	(27,686)	(1,476)
Proceeds from sale of common stock under an at-the-market sales agreement (Note 17)	—	113,966

Net cash (used in) provided by financing activities	(14,464)	115,947
Effect of exchange rates on cash and equivalents	(309)	270
Net (decrease) increase in cash and cash equivalents	(60,782)	89,246
Cash and cash equivalents—beginning of period	227,323	158,222
Cash and cash equivalents—end of period	$166,541	$247,468
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$38	$10
Cash paid for interest	$558	$1,513

See accompanying notes to these unaudited condensed consolidated financial statements.

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Spectrum Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)
(Unaudited)

1. DESCRIPTION OF BUSINESS, BASIS OF PRESENTATION, AND OPERATING SEGMENT

(a) Description of Business

Spectrum Pharmaceuticals, Inc. ("Spectrum", the "Company", "we", "our", or "us") is a biopharma company, with a primary strategy comprised of acquiring, developing, and commercializing a broad and diverse pipeline of late-stage clinical and commercial products. We have an in-house clinical development organization with regulatory and data management capabilities, in addition to commercial infrastructure and a field-based sales force for our marketed products. Currently, we have six approved oncology/hematology products (FUSILEV, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA) that target different types of cancer including: non-Hodgkin's lymphoma ("NHL"), advanced metastatic colorectal cancer, acute lymphoblastic leukemia, and multiple myeloma ("MM").

We also have two drugs in mid-to-late stage development (in Phase 2 or Phase 3 clinical trials):

- poziotinib, a novel pan-HER inhibitor used in the treatment of patients with a variety of solid tumors, including breast and lung cancer; and
- ROLONTIS for chemotherapy-induced neutropenia.

(b) Basis of Presentation

Interim Financial Statements

The interim financial data for the three and nine months ended September 30, 2018 and 2017, respectively, is unaudited, and is not necessarily indicative of our operating results for a full year. In the opinion of our management, the interim data includes normal and recurring adjustments necessary for a fair presentation of our financial results for the three and nine months ended September 30, 2018 and 2017. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with United States ("U.S.") generally accepted accounting principles ("GAAP") have been condensed or omitted pursuant to the U.S. Securities and Exchange Commission ("SEC") rules and regulations relating to interim financial statements. The accompanying Condensed Consolidated Financial Statements should be read in conjunction with our audited Consolidated Financial Statements and Notes thereto included within our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (filed with the SEC on March 7, 2018).

Principles of Consolidation

The accompanying Condensed Consolidated Financial Statements have been prepared in accordance with GAAP and with the rules and regulations of the SEC. These financial statements include the financial position, results of operations, and cash flows of Spectrum and its subsidiaries, all of which are wholly-owned (except for Spectrum Pharma Canada ("SPC"), as discussed below). All inter-company accounts and transactions among these legal entities have been eliminated in consolidation.

Variable Interest Entity

We own fifty-percent of SPC, a legal entity organized in Quebec, Canada in January 2008. Some of our clinical studies are conducted through this "variable interest entity" (as defined under applicable GAAP). We fund all of SPC's operating costs, and since we assume all risks and rewards for this entity, we meet the criteria as being its "primary beneficiary" (as defined under applicable GAAP). Accordingly, SPC's balance sheets and statements of operations are included in our Condensed Consolidated Financial Statements as if it were a wholly-owned subsidiary for all periods presented.

(c) Operating Segment

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Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)
(Unaudited)

We operate in one reportable operating segment that is focused exclusively on developing and marketing oncology and hematology drug products. For the three and nine months ended September 30, 2018 and 2017, all of our revenue and related expenses were solely attributable to these activities. Substantially all of our assets (excluding cash held in certain foreign bank accounts and ZEVALIN distribution rights for ex-U.S. territories - see Note 3(f)) are held in the U.S.

2. USE OF ESTIMATES AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The preparation of financial statements in conformity with GAAP requires our management to make informed estimates and assumptions that affect our reported amounts of assets, liabilities, revenues, and expenses. These amounts may materially differ from the amounts ultimately realized and reported due to the inherent uncertainty of any estimate or assumption. On an on-going basis, our management evaluates its most critical estimates and assumptions, including those related to: (i) gross-to-net revenue adjustments; (ii) the timing of revenue recognition; (iii) the collectability of customer accounts; (iv) whether the cost of our inventories can be recovered; (v) the recoverability of our reported goodwill and intangible assets; (vi) the realization of our tax assets and estimates of our tax liabilities; (vii) the likelihood of payment and value of contingent liabilities; (viii) the fair value of our investments; (ix) the valuation of our stock options and the periodic expense recognition of stock-based compensation; and (x) the potential outcome of our ongoing or threatened litigation.

Our accounting policies and estimates that most significantly impact the presented amounts within our Condensed Consolidated Financial Statements are further described below:

(i) Revenue Recognition

Impact of the Adoption of the New Revenue Recognition Standard: ASU No. 2014-09, Revenue from Contracts with Customers (“Topic 606”), became effective for us on January 1, 2018. Our disclosure within the below sections to this footnote reflects our updated accounting policies that are affected by this new standard. We applied the “modified retrospective” transition method for open contracts for the implementation of Topic 606; this resulted in the recognition of an aggregate $4.7 million, net of tax, decrease to our January 1, 2018 “accumulated deficit” on our accompanying Condensed Consolidated Balance Sheets for the cumulative impact of applying this new standard. We made no adjustments to our previously-reported total revenues, as those periods continue to be presented in accordance with our historical accounting practices under Topic 605, Revenue Recognition (“Topic 605”). See Notes 4, 5, and 19 for additional quantitative and qualitative revenue disclosures in accordance with Topic 606.

Required Elements of Our Revenue Recognition: Revenue from our (a) product sales, (b) out-license arrangements, and (c) service arrangements is recognized under Topic 606 in a manner that reasonably reflects the delivery of our goods and/or services to customers in return for expected consideration and includes the following elements:

(1) we ensure that we have an executed contract(s) with our customer that we believe is legally enforceable;
(2) we identify the “performance obligations” in the respective contract;
(3) we determine the “transaction price” for each performance obligation in the respective contract;
(4) we allocate the transaction price to each performance obligation; and
(5) we recognize revenue only when we satisfy each performance obligation.

These five elements, as applied to each of our revenue categories, are summarized below:

(a) Product Sales: We sell our products to pharmaceutical wholesalers/distributors (i.e., our customers), except for our U.S. sales of ZEVALIN in which case the end-user (i.e., clinic or hospital) is our customer. Our wholesalers/distributors in turn sell our products directly to clinics, hospitals, and private oncology-based practices. Revenue from our product sales is recognized as physical delivery of product occurs (when our customer obtains control of the product), in return for agreed-upon consideration.

Our gross product sales (i.e., delivered units multiplied by the contractual price per unit) are reduced by our corresponding gross-to-net (“GTN”) estimates using the “expected value” method, resulting in our reported “product sales, net” in the accompanying Condensed Consolidated Statements of Operations, reflecting the amount we ultimately

expect to realize in net cash proceeds, taking into account our current period gross sales and related cash receipts, and the subsequent cash disbursements on these sales that we estimate for the various GTN categories discussed below. These estimates are based upon

information received from external sources (such as written or oral information obtained from our customers with respect to their period-end inventory levels and sales to end-users during the period), in combination with management's informed judgments. Due to the inherent uncertainty of these estimates, the actual amount incurred (of some, or all) of product returns, government chargebacks, prompt pay discounts, commercial rebates, Medicaid rebates, and distribution, data, and GPO administrative fees may be materially above or below the amount estimated, then requiring prospective adjustments to our reported net product sales.

These GTN estimate categories are each discussed below:

Product Returns Allowances: Our FUSILEV, MARQIBO, and BELEODAQ customers are contractually permitted to return purchased products beginning at its expiration date and within six months thereafter. Our EVOMELA customers are permitted to return purchased product beginning at six months prior to its expiration date, and within 12 months thereafter (as well as for overstock inventory, as determined by end-users). ZEVALIN and FOLOTYN returns for expiry are not contractually permitted. Returns outside of this aforementioned criteria are not customarily allowed. We estimate expected product returns for our allowance based on our historical return rates. Returned product is typically destroyed, since substantially all returns are due to expiry and cannot be resold.

Government Chargebacks: Our products are subject to pricing limits under certain federal government programs (e.g., Medicare and 340B Drug Pricing Program). Qualifying entities (i.e., end-users) purchase products from our customers at their qualifying discounted price. The chargeback amount we incur represents the difference between our contractual sales price to our customer, and the end-user's applicable discounted purchase price under the government program. There may be significant lag time between our reported net product sales and our receipt of the corresponding government chargeback claims from our customers.

Prompt Pay Discounts: Discounts for prompt payment are estimated at the time of sale, based on our eligible customers' prompt payment history and the contractual discount percentage.

Commercial Rebates: Commercial rebates are based on (i) our estimates of end-user purchases through a group purchasing organization ("GPO"), (ii) the corresponding contractual rebate percentage tier we expect each GPO to achieve, and (iii) our estimates of the impact of any prospective rebate program changes made by us.

Medicaid Rebates: Our products are subject to state government-managed Medicaid programs, whereby rebates are issued to participating state governments. These rebates arise when a patient treated with our product is covered under Medicaid, resulting in a discounted price for our product under the applicable Medicaid program. Our Medicaid rebate accrual calculations require us to project the magnitude of our sales, by state, that will be subject to these rebates. There is a significant time lag in us receiving rebate notices from each state (generally several months or longer after our sale is recognized). Our estimates are based on our historical claim levels by state, as supplemented by management's judgment.

Distribution, Data, and GPO Administrative Fees: Distribution, data, and GPO administrative fees are paid to authorized wholesalers/distributors of our products (except for U.S. sales of ZEVALIN) for various commercial services including: contract administration, inventory management, delivery of end-user sales data, and product returns processing. These fees are based on a contractually-determined percentage of our applicable sales.

(b) License Fees: Our out-license arrangements allow licensees to market our product(s) in certain territories for a specific term (representing the out-license of "functional intellectual property"). These arrangements may include one or more of the following forms of consideration: (i) upfront license fees, (ii) sales royalties, (iii) sales milestone-achievement fees, and (iv) regulatory milestone-achievement fees. We recognize revenue for each based on the contractual terms that establish our right to collect payment once the performance obligation is achieved, as follows:

(1) Upfront License Fees: We determine whether upfront license fees are earned at the time of contract execution (i.e., when rights transfer to the customer) or over the actual (or implied) contractual period of the out-license. As part of this determination, we evaluate whether we have any other requirements to provide substantive services that are

inseparable from the performance obligation of the license transfer. Our customers' "distinct" rights to licensed "functional intellectual property" at the time of contract execution results in concurrent revenue recognition of all upfront license fees (assuming that there are no other performance obligations at contract execution that are inseparable from this license transfer).

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Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)
(Unaudited)

(2) Royalties: Under the "sales-or-usage-based royalty exception" we recognize revenue in the same period that our licensees complete product sales in their territory for which we are contractually entitled to a percentage-based royalty receipt.

(3) Sales Milestones: Under the "sales-or-usage-based royalty exception" we recognize revenue in full within the period that our licensees achieve annual or aggregate product sales levels in their territories for which we are contractually entitled to a specified lump-sum receipt.

(4) Regulatory Milestones: Under the terms of the respective out-license, regulatory achievements may either be our responsibility, or that of our licensee.

- When our licensee is responsible for the achievement of the regulatory milestone, we recognize revenue in full (for the contractual amount due from our licensee) in the period that the approval occurs (i.e., when the "performance obligation" is satisfied by our customer) under the "most likely amount" method. This revenue recognition remains "constrained" (i.e., not recognized) until regulatory approval occurs, given its inherent uncertainty and the requirement of a significant revenue reversal not being probable if achievement does not occur. At each reporting period, we re-evaluate the probability of milestone achievement and the associated revenue constraint; any resulting adjustments would be recorded on a cumulative catch-up basis, thus reflected in our financial statements in the period of adjustment.

When we are responsible for the achievement of a regulatory milestone, the "relative selling price method" is applied for purposes of allocating the transaction price to our performance obligations. In such case, we consider (i) the extent of our effort to achieve the milestone and/or the enhancement of the value of the delivered item(s) as a result of milestone achievement and (ii) if the milestone payment is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. We have historically assessed the contractual value of these milestones upon their achievement to be identical to the allocation of value of our performance obligations and thus representing the "transaction price" for each milestone at contract inception. We recognize this revenue in the period that the regulatory approval occurs (i.e., when we complete the "performance obligation") under the "most likely amount" method, and revenue recognition is otherwise "constrained" until regulatory approval occurs, given its inherent uncertainty and the requirement of a significant revenue reversal not being probable if achievement does not occur. At each reporting period, we re-evaluate the probability of milestone achievement and the associated revenue constraint; any resulting adjustments would be recorded on a cumulative catch-up basis, thus reflected in our financial statements in the period of adjustment.

- (c) Service Revenue: We receive fees under certain arrangements for (i) sales and marketing services, (ii) supply chain services, (iii) research and development services, and (iv) clinical trial management services.

Our rights to receive payment for these services may be established by (1) a fixed-fee schedule that covers the term of the arrangement, so long as we meet ongoing performance obligations, (2) our completion of product delivery in our capacity as a procurement agent, (3) the successful completion of a phase of drug development, (4) favorable results from a clinical trial, and/or (5) regulatory approval events.

We consider whether revenue associated with these service arrangements is reportable each period, based on our completed services or deliverables (i.e., satisfied "performance obligations") during the reporting period, and the terms of the arrangement that contractually result in fixed payments due to us. The promised service(s) within these arrangements are distinct and explicitly stated within each contract, and our customer benefits from the separable service(s) delivery/completion. Further, the nature of the promise to our customer as stated within the respective contract is to deliver each named service individually (not a transfer of combined items to which the promised goods

or services are inputs), and thus are separable for revenue recognition.

(ii) Cash and Cash Equivalents

Cash and cash equivalents consist of bank deposits and highly liquid investments with maturities of three months or less from the purchase date.

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Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)
(Unaudited)

(iii) Marketable Securities

Our marketable securities consist of our holdings in equity securities (beginning January 1, 2018 - see Note 3(a)), mutual funds, and bank certificates of deposit ("Bank CDs"). Beginning January 1, 2018, our realized and unrealized (losses) gains on marketable securities are included in "Other (expense) income, net" on the accompanying Condensed Consolidated Statements of Operations. Prior to January 1, 2018, our unrealized (losses) gains were included in "other comprehensive (loss) income" on our accompanying Condensed Consolidated Statements of Comprehensive Loss.

(iv) Accounts Receivable

Our accounts receivable are derived from our product sales and license fees (our service revenue is recorded in "other receivables"), and do not bear interest. The allowance for doubtful accounts is management's best estimate of the amount of probable credit losses in our existing accounts receivable. Account balances are charged off against the allowance after appropriate collection efforts are exhausted.

(v) Inventories

We value our inventory at the lower of (i) the actual cost of its purchase or manufacture, or (ii) its net realizable value. Inventory cost is determined on the first-in, first-out method. We regularly review our inventory quantities in process of manufacture and on hand. When appropriate, we record a provision for obsolete and excess inventory to derive its new cost basis, which takes into account our sales forecast by product and corresponding expiry dates of each product lot.

Manufacturing costs of drug products that are pending U.S. Food and Drug Administration ("FDA") approval are expensed through "research and development," on the accompanying Condensed Consolidated Statements of Operations (rather than being capitalized to "inventories").

(vi) Property and Equipment

Our property and equipment is stated at historical cost, and is depreciated on a straight-line basis over an estimated useful life that corresponds with its designated asset category. We evaluate the recoverability of "long-lived assets" (which includes property and equipment) whenever events or changes in circumstances in our business indicate that the asset's carrying amount may not be recoverable through our on-going operations.

(vii) Goodwill and Intangible Assets

Our goodwill represents the excess of our business acquisition cost over the estimated fair value of the net assets acquired in the corresponding transaction. Goodwill has an indefinite accounting life and is therefore not amortized. Instead, goodwill is evaluated for impairment on an annual basis (as of each October 1st), unless we identify impairment indicators that would require earlier testing.

We evaluate the recoverability of indefinite-lived intangible assets at least annually, or whenever events or changes in our business indicate that an intangible asset's (whether indefinite or definite-lived) carrying amount may not be recoverable. Such circumstances could include, but are not limited to the following:

(a) a significant decrease in the market value of an asset;
(b) a significant adverse change in the extent or manner in which an asset is used; or
(c) an accumulation of costs significantly in excess of the amount originally expected for the acquisition of an asset.

Intangible assets with finite useful lives are amortized over their estimated useful lives on a straight-line basis. We review these assets for potential impairment if/when facts or circumstances suggest that the carrying value of these assets may not be recoverable.

(viii) Stock-Based Compensation

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Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)
(Unaudited)

Stock-based compensation expense for equity awards granted to our employees and members of our Board of Directors is recognized on a straight-line basis over each award's vesting period. Recognized compensation expense is net of an estimated forfeiture rate, representing the percentage of awards that are expected to be forfeited prior to vesting, though is ultimately adjusted for actual forfeitures. We use the Black-Scholes option pricing model to determine the fair value of stock options (as of the date of grant) that have service conditions for vesting. We use the Monte Carlo valuation model to value equity awards (as of the date of grant) that have combined market conditions and service conditions for vesting.

The recognition of stock-based compensation expense and the initial calculation of stock option fair value requires uncertain assumptions, including (a) the pre-vesting forfeiture rate of the award, (b) the expected term that the stock option will remain outstanding, (c) our stock price volatility over the expected term (and that of our designated peer group with respect to certain market-based awards), and (d) the prevailing risk-free interest rate for the period matching the expected term.

With regard to (a)-(d): We estimate forfeiture rates based on our employees' overall forfeiture history, which we believe will be representative of future results. We estimate the expected term of stock options granted based on our employees' historical exercise patterns, which we believe will be representative of their future behavior. We estimate the volatility of our common stock on the date of grant based on the historical volatility of our common stock for a look-back period that corresponds with the expected term. We estimate the risk-free interest rate based upon the U.S. Department of the Treasury yields in effect at award grant, for a period equaling the expected term of the stock option.

(ix) Foreign Currency Translation

Our foreign subsidiaries' separate financial statements are stated in their functional currencies (i.e., local operating currencies). To create the accompanying Condensed Consolidated Financial Statements, we translate the assets and liabilities of our subsidiaries to U.S. dollars at the rates of exchange in effect at the reported balance sheet date; revenues and expenses are translated using the monthly average exchange rates during the reported period. Unrealized gains and losses from these translations are included in "accumulated other comprehensive (loss) income" in the Condensed Consolidated Balance Sheets.

We record foreign currency-based transactions (i.e., when not denominated in the functional currency of our transacting legal entity) at the prevailing exchange rate on the date of the transaction. Resulting unrealized foreign exchange gains and losses from these unsettled transactions are included in "accumulated other comprehensive (loss) income" in the Condensed Consolidated Balance Sheets.

All unrealized foreign exchange gains and losses associated with our intercompany loans are included in "accumulated other comprehensive (loss) income" in the Condensed Consolidated Balance Sheets, as these loans with our foreign subsidiaries are not expected to be settled in the "foreseeable future."

(x) Basic and Diluted Net Loss per Share

We calculate basic and diluted net loss per share using the weighted average number of common shares outstanding during the periods presented. In periods of a net loss, basic and diluted loss per share are the same. For the diluted earnings per share calculation, we adjust the weighted average number of common shares outstanding to include only dilutive stock options, warrants, and other common stock equivalents outstanding during the period.

(xi) Income Taxes

Deferred tax assets and liabilities are recorded based on the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the financial statements, as well as operating losses and tax credit carry forwards using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain.

We have recorded a valuation allowance to reduce our deferred tax assets, because we believe that, based upon a weighting of positive and negative factors, it is more likely than not that these deferred tax assets will not be realized.

If/when we were to determine that our deferred tax assets are realizable, an adjustment to the corresponding valuation allowance would increase our net income in the period that such determination was made.

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In the event that we are assessed interest and/or penalties from taxing authorities that have not been previously accrued, such amounts would be included in "(provision) benefit for income taxes" within the Condensed Consolidated Statements of Operations for the period in which we received the notice.

(xii) Research and Development Costs

Our research and development costs are expensed as incurred (see Note 15(c)), or as certain milestone payments become contractually due to our licensors, as triggered by the achievement of clinical or regulatory events.

(xiii) Fair Value Measurements

We determine measurement-date fair value based on the proceeds that would be received through the sale of the asset, or that we would pay to settle or transfer the liability, in an orderly transaction between market participants. We utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. These tiers include the following:

Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that are publicly accessible at the measurement date.

Level 2: Observable prices that are based on inputs not quoted on active markets, but that are corroborated by market data. These inputs may include quoted prices for similar assets or liabilities or quoted market prices in markets that are not active to the general public.

Level 3: Unobservable inputs are used when little or no market data is available.

3. BALANCE SHEET ACCOUNT DETAIL

The composition of selected financial statement captions that comprise the accompanying Condensed Consolidated Balance Sheets are summarized below:

(a) Cash and Cash Equivalents and Marketable Securities

As of September 30, 2018 and December 31, 2017, our "cash and cash equivalents" were held with major financial institutions. Our "marketable securities" primarily relate to our equity holdings in CASI (as defined below).

We maintain cash balances in excess of federally insured limits with reputable financial institutions. To a limited degree, the Federal Deposit Insurance Corporation and other third parties insure these investments. However, these investments are not insured against the possibility of a complete loss of earnings or principal and are inherently subject to the credit risk related to the continued credit worthiness of the underlying issuer and general credit market risks. We manage such risks in our portfolio by investing in highly liquid, highly-rated instruments, and limit investing in long-term maturity instruments.

Our investment policy requires that purchased investments in marketable securities may only be in highly-rated instruments, which are primarily U.S. treasury bills or treasury-backed securities, and also limits our investments in securities of any single issuer (excluding any debt or equity securities received from our strategic partners in connection with an out-license arrangement, as discussed in Note 10).

The carrying amount of our equity securities, money market funds, and Bank CDs approximates their fair value (utilizing "Level 1" or "Level 2" inputs – see Note 2(xiii)) because of our ability to immediately convert these instruments into cash with minimal expected change in value.

The following is a summary of our presented "cash and cash equivalents" and "marketable securities":

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	Cost	Foreign Currency Translation	Gross Unrealized Gains*	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
September 30, 2018							
Equity securities* (see Note 3(g) and Note 10)	$8,710	$ (1,920)	$ 47,138	$ —	$53,928	$ —	$ 53,928
Bank deposits	22,256	—	—	—	22,256	22,256	—
Money market funds	144,285	—	—	—	144,285	144,285	—
Bank certificates of deposits	87	—	—	—	87	—	87
Total cash and cash equivalents and marketable securities	$175,338	$ (1,920)	$ 47,138	$ —	$220,556	$ 166,541	$ 54,015
December 31, 2017							
Bank deposits	$10,965	$ —	$ —	$ —	$10,965	$ 10,965	$ —
Money market funds	216,358	—	—	—	216,358	216,358	—
Bank certificates of deposits	248	—	—	—	248	—	248
Total cash and cash equivalents and marketable securities	$227,571	$ —	$ —	$ —	$227,571	$ 227,323	$ 248

* Beginning January 1, 2018, under the new requirements of ASU 2016-01, Recognition and Measurement of Financial Assets and Liabilities, the unrealized (losses) gains on our CASI Pharmaceuticals, Inc. (NASDAQ: CASI) ("CASI") equity securities are recognized as a (decrease) increase to "other (expense) income, net" on the Consolidated Statements of Operations (rather than through "other comprehensive (loss) income" on the Consolidated Statements of Comprehensive Loss). Our adoption of ASU 2016-01 on January 1, 2018, resulted in a $17.2 million cumulative-effect adjustment, net of income tax, recorded as a decrease to "accumulated other comprehensive (loss) income" and a decrease to "accumulated deficit" on the accompanying Condensed Consolidated Balance Sheets. Our recognized unrealized loss on these equity securities for the three months ended September 30, 2018 was $40.9 million and our recognized unrealized gain on these equity securities for the nine months ended September 30, 2018 was $17.7 million, as reported in "other (expense) income, net" on the accompanying Condensed Consolidated Statements of Operations.

As of September 30, 2018, none of our securities were in an unrealized loss position.

(b) Property and Equipment, net of Accumulated Depreciation

"Property and equipment, net of accumulated depreciation" consists of the following:

	September 30, 2018	December 31, 2017
Computer hardware and software	$ 3,076	$ 2,994
Laboratory equipment	635	630
Office furniture	212	218
Leasehold improvements	2,938	2,938
Property and equipment, at cost	6,861	6,780
(Less): Accumulated depreciation	(6,424)	(6,191)
Property and equipment, net of accumulated depreciation	$ 437	$ 589

Depreciation expense (included within "total operating costs and expenses" in the accompanying Condensed Consolidated Statements of Operations) for the three and nine months ended September 30, 2018 and 2017, was $0.1 million, $0.1 million, $0.2 million, and $0.2 million, respectively.

New Accounting Standard for Leases, effective January 1, 2019

In February 2016, the FASB issued ASU 2016-02, which amends the FASB Accounting Standards Codification and creates Topic 842, Leases ("Topic 842"). The new topic supersedes Topic 840, Leases and requires additional disclosures regarding our lease arrangements, as well as our presentation of lease assets and lease liabilities (including those for operating leases) on the balance sheet at the present value of lease payments not yet paid, and for us to subsequently apply the "effective

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interest rate" method" to reduce the lease liability, while amortizing the right-of-use asset for straight-line expense recognition over the lease term.
Topic 842 is effective for us beginning January 1, 2019, and mandates a "modified retrospective" transition method. We are currently assessing the quantitative impact this guidance will have on our consolidated financial statements. However, we presently do not have any capital lease arrangements, or any active contracts that would contain an "embedded lease". Our current operating lease arrangements affected by this "gross-up" presentation are limited to (1) our executive, administrative, and research and development office facilities and (2) certain office equipment.

(c) Inventories
"Inventories" consists of the following:

	September 30, 2018	December 31, 2017
Raw materials	$ 1,870	$ 1,077
Work-in-process	2,569	2,551
Finished goods	1,515	5,187
(Less:) Non-current portion of inventories included within "other assets" *	(1,975)	(3,100)
Inventories	$ 3,979	$ 5,715

* The "non-current" portion of inventories is presented within "other assets" in the accompanying Condensed Consolidated Balance Sheets at September 30, 2018 and December 31, 2017, respectively. This value of $2 million at September 30, 2018 represents product that we expect to sell beyond September 30, 2019, and the value at December 31, 2017 represented product that we expected to sell beyond December 31, 2018.
(d) Prepaid Expenses and Other Assets
"Prepaid expenses and other assets" consists of the following:

	September 30, 2018	December 31, 2017
Other miscellaneous prepaid operating expenses	$ 7,186	$ 3,389
Prepaid insurance	131	645
Research and development supplies	983	1,883
Key employee life insurance - cash surrender value	—	4,150
Prepaid expenses and other assets	$ 8,300	$ 10,067

(e) Other Receivables
"Other receivables" consists of the following:

	September 30, 2018	December 31, 2017
Other miscellaneous receivables (including Medicaid rebate credits and royalty receivables)	$ 1,147	$ 1,152
Income tax receivable	632	665
Insurance receivable	1,458	53
CASI note - short term	1,523	—
Reimbursements due from development partners for incurred research and development expenses	371	263

Other receivables	$	5,131	$	2,133

(f) Intangible Assets and Goodwill

Intangible assets, net of accumulated amortization and impairment charges consists of the following:

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	September 30, 2018						
	Historical Cost	Accumulated Amortization	Foreign Currency Translation	Impairment	Net Amount	Full Amortization Period (months)	Remaining Amortization Period (months)
MARQIBO IPR&D (NHL and other novel indications)	$17,600	$—	$ —	$ —	$ 17,600	n/a	n/a
EVOMELA distribution rights	7,700	(1,481)	—	—	6,219	156	126
BELEODAQ distribution rights	25,000	(7,969)	—	—	17,031	160	109
MARQIBO distribution rights	26,900	(20,420)	—	—	6,480	81	21
FOLOTYN distribution rights (1)	118,400	(63,918)	—	—	54,482	152	50
ZEVALIN distribution rights – U.S.	41,900	(40,163)	—	—	1,737	123	6
ZEVALIN distribution rights – ex-U.S.	23,490	(17,913)	(3,132)	—	2,445	96	18
FUSILEV distribution rights (2)	16,778	(9,618)	—	(7,160)	—	56	0
FOLOTYN out-license (3)	27,900	(16,598)	—	(1,023)	10,279	110	46
Total intangible assets	$305,668	$(178,080)	$ (3,132)	$ (8,183)	$ 116,273		

(1) Beginning June 2016, we adjusted the amortization period of our FOLOTYN distribution rights to November 2022 from March 2025, representing the period through which we expect to have patent protection from generic competition.

(2) On February 20, 2015, the United States District Court for the District of Nevada found the patent covering FUSILEV to be invalid, which was upheld on appeal. On April 24, 2015, Sandoz began to commercialize a generic version of FUSILEV. This represented a “triggering event” under applicable GAAP in evaluating the value of our FUSILEV distribution rights as of March 31, 2015, resulting in a recognized $7.2 million impairment charge (non-cash) in 2015. We accelerated amortization expense recognition in 2015 for the then remaining net book value of FUSILEV distribution rights.

(3) On May 29, 2013, we amended our FOLOTYN collaboration agreement with Mundipharma. As a result of the amendment, Europe and Turkey were excluded from Mundipharma’s commercialization territory, and their royalty rates and milestone payments to us were modified. This constituted a change under which we originally valued the FOLOTYN out-license as part of business combination accounting, resulting in a recognized impairment charge (non-cash) of $1 million in 2013.

	December 31, 2017				
	Historical Cost	Accumulated Amortization	Foreign Currency Translation	Impairment	Net Amount
MARQIBO IPR&D (NHL and other novel indications)	$17,600	$—	$ —	$ —	$ 17,600
EVOMELA distribution rights	7,700	(1,037)	—	—	6,663

BELEODAQ distribution rights	25,000	(6,563)	—	—	18,437
MARQIBO distribution rights	26,900	(17,182)	—	—	9,718
FOLOTYN distribution rights	118,400	(54,111)	—	—	64,289
ZEVALIN distribution rights – U.S.	41,900	(37,557)	—	—	4,343
ZEVALIN distribution rights – ex-U.S.	23,490	(17,232)	(2,471)	—	3,787
FUSILEV distribution rights	16,778	(9,618)	—	(7,160)	—
FOLOTYN out-license	27,900	(14,555)	—	(1,023)	12,322
Total intangible assets	$305,668	$(157,855)	$ (2,471)	$ (8,183)	$ 137,159

Intangible asset amortization expense recognized during the three and nine months ended September 30, 2018 and 2017, was $6.9 million, $6.9 million, $20.8 million and $20.7 million, respectively.

Estimated intangible asset amortization expense for the remainder of 2018 and the five succeeding fiscal years and thereafter is as follows:

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Years Ending December 31,	
Remainder of 2018	$6,923
2019	25,084
2020	19,754
2021	18,266
2022	15,882
2023	2,467
2024 and thereafter	10,297
	$98,673

“Goodwill” consists of the following, by source:

	September 30, 2018	December 31, 2017
Acquisition of Talon (MARQIBO distribution rights)	$ 10,526	$ 10,526
Acquisition of ZEVALIN ex-U.S. distribution rights	2,525	2,525
Acquisition of Allos (FOLOTYN distribution rights)	5,346	5,346
Foreign currency exchange translation effects	(306)	(235)
Goodwill	$ 18,091	$ 18,162

(g) Other Assets

“Other assets” consists of the following:

	September 30, 2018	December 31, 2017
Equity securities (see Note 10)*	$ —	$ 37,530
Key employee life insurance – cash surrender value	6,382	10,737
Inventories - non-current portion	1,975	3,100
CASI note - long term (see Note 10)	—	1,517
Income tax receivable**	668	668
Research & development supplies and other	1,351	231
Other assets	$ 10,376	$ 53,783

* As of March 31, 2018, we reclassified our presentation of these equity securities from this account caption to “marketable securities” on our accompanying Condensed Consolidated Balance Sheets - (see Note 3(a)).

** This value represents the non-current portion of the refundable alternative minimum tax credit that is expected to be received over the next few years (see Note 16).

(h) Accounts Payable and Other Accrued Liabilities

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"Accounts payable and other accrued liabilities" consists of the following:

	September 30, 2018	December 31, 2017
Trade accounts payable and other accrued liabilities	$ 35,535	$ 33,648
Accrued rebates	8,228	7,990
Accrued product royalty	3,992	4,339
Allowance for returns	4,715	4,045
Accrued data and distribution fees	2,701	4,305
Accrued GPO administrative fees	244	296
Accrued inventory management fee	428	1,126
Allowance for chargebacks	1,790	2,368
Accounts payable and other accrued liabilities	$ 57,633	$ 58,117

Amounts presented within "accounts payable and other accrued liabilities" in the accompanying Condensed Consolidated Balance Sheets for our categories of GTN estimates (see Note 2(i)) were as follows:

	Commercial/Medicaid Rebates and Government Chargebacks	Distribution, Data, Inventory and GPO Administrative Fees	Product Return Allowances
Balance as of December 31, 2016	$ 9,817	$ 5,146	$ 2,309
Add: provisions	106,647	20,104	2,807
(Less): credits or actual allowances	(106,106)	(19,523)	(1,071)
Balance as of December 31, 2017	10,358	5,727	4,045
Add: provisions	47,130	10,425	1,207
(Less): credits or actual allowances	(47,470)	(12,779)	(537)
Balance as of September 30, 2018	$ 10,018	$ 3,373	$ 4,715

(i) Deferred Revenue

Deferred revenue (current and non-current) consists of the following:

	September 30, 2018	December 31, 2017
EVOMELA deferred revenue	$ —	$ 3,819
ZEVALIN out-license in India territory (see Note 15(b)(iii))	—	368
Deferred revenue*	$ —	$ 4,187

* On January 1, 2018, we reclassified the deferred revenue related to our EVOMELA product sales and our ZEVALIN out-license in the India territory of $3.8 million and $0.4 million, respectively. These amounts were included in the $4.7 million aggregate decrease to "accumulated deficit" on January 1, 2018, in accordance with the adoption of Topic 606 (see Note 2(i)).

(j) Other Long-Term Liabilities

"Other long-term liabilities" consists of the following:

	September 30, 2018	December 31, 2017
Accrued executive deferred compensation	$ 5,764	$ 5,928
Deferred rent (non-current portion)	1	52
Clinical study holdback fees, non-current	56	59
Other tax liabilities	176	176
Other long-term liabilities	$ 5,997	$ 6,215

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4. GROSS-TO-NET PRODUCT SALES

The below table presents a GTN (see Note 2(i)) product sales reconciliation for the accompanying Condensed Consolidated Statements of Operations:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018		2017		2018		2017	
Gross product sales	$46,052	187.5 %	$66,517	213.0 %	$139,703	182.8 %	$192,443	218.1 %
Commercial rebates and government chargebacks	(17,272)	(70.3)%	(28,075)	(89.9)%	(50,355)	(65.9)%	(85,400)	(96.8)%
Data and distribution fees, GPO fees, and inventory management fees	(3,415)	(13.9)%	(5,864)	(18.8)%	(10,509)	(13.8)%	(15,503)	(17.6)%
Prompt pay discounts	(420)	(1.7)%	(455)	(1.5)%	(1,133)	(1.5)%	(1,143)	(1.3)%
Product returns	(389)	(1.6)%	(889)	(2.8)%	(1,287)	(1.7)%	(2,162)	(2.5)%
Product sales, net	$24,556	100.0 %	$31,234	100.0 %	$76,419	100.0 %	$88,235	100.0 %

5. COMPOSITION OF TOTAL REVENUE

The below table presents our net product sales by geography for the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018		2017		2018		2017	
United States	$22,131	90.1 %	$29,184	93.4 %	$66,676	87.3 %	$82,049	93.0 %
International:								
Europe/Canada	2,425	9.9 %	2,050	6.6 %	8,319	10.9 %	6,186	7.0 %
Asia Pacific	—	— %	—	— %	1,424	1.9 %	—	— %
Total International	2,425	9.9 %	2,050	6.6 %	9,743	12.7 %	6,186	7.0 %
Product sales, net	$24,556	100.0%	$31,234	100.0%	$76,419	100.0%	$88,235	100.0%

The below table presents our net sales by product for the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018		2017		2018		2017	
FOLOTYN	$11,341	46.2 %	$11,576	37.1 %	$35,742	46.8 %	$32,031	36.3 %
EVOMELA	6,850	27.9 %	10,503	33.6 %	20,763	27.2 %	26,862	30.4 %
BELEODAQ	3,212	13.1 %	3,399	10.9 %	8,628	11.3 %	9,666	11.0 %
ZEVALIN	1,463	6.0 %	2,737	8.8 %	6,125	8.0 %	7,881	8.9 %
MARQIBO	1,121	4.6 %	1,227	3.9 %	3,163	4.1 %	5,369	6.1 %
FUSILEV	569	2.3 %	1,792	5.7 %	1,998	2.6 %	6,426	7.3 %
Product sales, net	$24,556	100.0%	$31,234	100.0%	$76,419	100.0%	$88,235	100.0%

The below table presents our license fees and service revenue by source for the three and nine months ended September 30, 2018 and 2017:

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	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018		2017		2018		2017	
Out-license of FOLOTYN in all countries except the United States, Canada, Europe, and Turkey: royalties (Note 14)	$712	100.0%	$5,148	99.7%	1,504	42.8%	5,530	47.8%
Out-license of ZEVALIN: recognition of milestone achievement, upfront cash receipt and subsequent royalties for Asia and certain other territories, excluding China (Note 11)	—	—%	—	—%	2,001	57.0%	1,245	10.8%
Out-license of ZEVALIN: amortization of upfront cash receipt related to India territory (Note 15(b)(iii)) and other	—	—%	13	0.3%	6	0.2%	37	0.3%
Out-license of ZEVALIN, FOLOTYN, BELEODAQ, MARQIBO: upfront cash receipt and subsequent royalties for the Canada territory (Note 15(b)(xiv))	—	—%	—	—%	—	—%	3	—%
Sales and marketing contracted services (Note 12)	—	—%	—	—%	—	—%	4,747	41.1%
License fees and service revenues	$712	100.0%	$5,161	100.0%	$3,511	100.0%	$11,562	100.0%

6. STOCK-BASED COMPENSATION

We report our stock-based compensation expense (inclusive of our incentive stock plan, employee stock purchase plan, and 401(k) contribution matching program) in the accompanying Condensed Consolidated Statements of Operations, based on the assigned department of the recipient. Stock-based compensation expense, included within "total operating costs and expenses" for the three and nine months ended September 30, 2018 and 2017, was as follows (see Note 18 for a discussion of certain immaterial corrections affecting the presented 2017 amounts below):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of sales	$80	$68	$146	$150
Selling, general and administrative	3,151	2,398	10,673	8,523
Research and development	755	529	2,378	1,528
Total stock-based compensation	$3,986	$2,995	$13,197	$10,201

7. NET LOSS PER SHARE

Net loss per share was computed by dividing net loss by the weighted average number of common shares outstanding for the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Weighted average shares outstanding - basic and diluted	104,106,295	83,463,153	102,571,858	80,177,370
Net loss	$(68,718)	$(18,293)	$(70,792)	$(62,691)
Net loss per share – basic and diluted	$(0.66)	$(0.22)	$(0.69)	$(0.78)

The below outstanding securities for the three and nine months ended September 30, 2018, were excluded from the calculation above because their impact under the “treasury stock method” and “if-converted method” would have been anti-dilutive due to our net loss per share in each respective period, as summarized below:

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
2018 Convertible Notes	3,403,659	10,454,799	3,403,659	10,454,799
Common stock options	3,702,092	3,144,969	4,175,866	1,504,155
Restricted stock awards	1,751,876	2,025,661	1,751,876	2,025,661
Restricted stock units	245,214	217,206	245,214	217,206
Common stock warrants	—	111,441	—	32,833
Employee stock purchase plan shares	21,033	50,474	21,033	50,474
Total	9,123,874	16,004,550	9,597,648	14,285,128

8. FAIR VALUE MEASUREMENTS

The table below summarizes certain asset and liability fair values that are included within our accompanying Condensed Consolidated Balance Sheets, and their designations among the three fair value measurement categories (see Note 2(xiii)):

	September 30, 2018 Fair Value Measurements				
	Level 1	Level 2	Level 3	Total	
Assets:					
Bank certificates of deposits	$—	$87	$—	$87	
Money market funds	—	144,285	—	144,285	
Equity securities (Note 10)	53,928	—	—	53,928	
Mutual funds	—	88	—	88	
Deferred compensation investments (life insurance cash surrender value (Note 3(g))	—	6,382	—	6,382	*
	$53,928	$150,842	$—	$204,770	
Liabilities:					
Deferred executive compensation liability (Note 15(f))	$—	$6,536	$—	$6,536	*
Drug development liability (Note 14)	—	—	12,116	12,116	
Talon CVR (Note 9(a))	—	—	5,555	5,555	
	$—	$6,536	$17,671	$24,207	

	December 31, 2017 Fair Value Measurements				
	Level 1	Level 2	Level 3	Total	
Assets:					
Bank certificates of deposits	$—	$248	$—	$248	
Money market funds	—	216,358	—	216,358	
Equity securities (Note 10)	37,530	—	—	37,530	
Mutual funds	—	59	—	59	
Deferred compensation investments (life insurance cash surrender value (Note 3(g))	—	14,887	—	14,887	*
	$37,530	$231,552	$—	$269,082	
Liabilities:					

Deferred executive compensation liability (Note 15(f))	$—	$11,038	$—	$11,038 *
Drug development liability (Note 14)	—	—	12,386	12,386
Talon CVR (Note 9(a))	—	—	6,210	6,210
Corixa Liability (Note 15(b)(i))	—	—	62	62
	$—	$11,038	$18,658	$29,696

* The reported amount of “deferred compensation investments” is based on the cash surrender value of employee life insurance policies at period-end, while the reported amount of “deferred executive compensation liability” is based on the period-end market value of investments selected by plan participants.

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We did not have any transfers between “Level 1” and “Level 2” (see Note 2(xiii)) measurement categories for any periods presented.
The table below summarizes the 2017 and 2018 activity of our liabilities that are valued with unobservable inputs:

	Fair Value Measurements of Unobservable Inputs (Level 3)
Balance as of December 31, 2016	$ 14,445
FOLOTYN development liability (see Note 14)	(744)
Talon CVR fair value adjustment - MARQIBO (see Note 9(a))	4,957
Balance as of December 31, 2017	18,658
FOLOTYN development liability (see Note 14)	(270)
Talon CVR fair value adjustment - MARQIBO (see Note 9(a))	(655)
Corixa Liability (see Note 15(b)(i))	(62)
Balance as of September 30, 2018	$ 17,671

Our carrying amounts of financial instruments such as cash equivalents, accounts receivable, prepaid expenses, accounts payable, and accrued liabilities, excluding acquisition-related contingent obligations, approximate their related fair values due to their short-term nature.

9. BUSINESS COMBINATIONS AND CONTINGENT CONSIDERATION
(a) Acquisition of Talon Therapeutics, Inc.
Overview of Talon Acquisition
On July 17, 2013, we purchased all of the outstanding shares of common stock of Talon Therapeutics, Inc. (“Talon”). Through the acquisition of Talon, we gained worldwide rights to MARQIBO. The Talon purchase consideration consisted of (i) an aggregate upfront cash amount of $11.3 million, (ii) issuance of 3 million shares of our common stock, then equivalent to $26.3 million (based on a closing price of $8.77 per share on July 17, 2013), and (iii) the issuance of a contingent value right (“CVR”) initially valued at $6.5 million.
The CVR was valued using a valuation model that probability-weights expected outcomes (ranging from 50% to 100%) and discounts those amounts to their present value, using an appropriate discount rate (these represent unobservable inputs and are therefore classified as Level 3 inputs – see Note 2 (xiii)). The CVR has a maximum payout of $195 million if all sales and regulatory approval milestones are achieved, as summarized below:

- $5 million upon the achievement of net sales of MARQIBO in excess of $30 million in any calendar year
- $10 million upon the achievement of net sales of MARQIBO in excess of $60 million in any calendar year
- $25 million upon the achievement of net sales of MARQIBO in excess of $100 million in any calendar year
- $50 million upon the achievement of net sales of MARQIBO in excess of $200 million in any calendar year
- $100 million upon the achievement of net sales of MARQIBO in excess of $400 million in any calendar year
- $5 million upon receipt of marketing authorization from the FDA regarding Menadione Topical Lotion

Talon CVR Fair Value as of September 30, 2018 and December 31, 2017
The CVR fair value will continue to be evaluated on a quarterly basis. Current and future changes in its fair value results from the likelihood and timing of milestone achievement and/or the corresponding discount rate applied thereon. Adjustments to CVR fair value are recognized within “change in fair value of contingent consideration related to acquisitions” in the accompanying Condensed Consolidated Statements of Operations.

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	Fair Value of Talon CVR
December 31, 2017	$ 6,210
Fair value adjustment for the nine months ended September 30, 2018	(655)
September 30, 2018	$ 5,555

(b) Acquisition of Rights to EVOMELA and Related Contingent Consideration

Overview of Acquisition of Rights to EVOMELA

In March 2013, we completed the acquisition of exclusive global development and commercialization rights to Captisol-enabled®, propylene glycol-free MELPHALAN (which we branded as “EVOMELA”) for use as a conditioning treatment prior to autologous stem cell transplant for patients with MM. We acquired these rights from CyDex pharmaceuticals, Inc. (“Cydex”) a wholly-owned subsidiary of Ligand Pharmaceuticals Inc. (“Ligand”) for an initial license fee of $3 million, and assumed responsibility for EVOMELA’s then-ongoing clinical and regulatory development program. We accounted for this transaction as a business combination, which required that assets acquired and liabilities assumed be recognized on the balance sheet at their fair values as of the transaction date.

We are required to pay Ligand additional amounts up to an aggregate of $60 million upon the achievement of annual net sales thresholds (exclusive of the $6 million milestone payment triggered in March 2016, as discussed below), however, we do not expect to achieve these sales thresholds based on our estimated market size for this product and our projected market share at the time of the acquisition and to date. We also must pay Ligand royalties of 20% on our net sales of EVOMELA in all territories.

Our EVOMELA royalty obligation and sales-based milestones are jointly treated as part of an “executory contract” (as defined under GAAP) that is connected with an at-market supply agreement for Captisol that was executed concurrently with this acquisition (requiring the continuing involvement of CyDex). As a result, our royalty obligation and sales-based milestone arrangements are treated as separate transactions, distinct from the consideration for the EVOMELA rights. Our royalty expenses are reported through “cost of sales” in our Condensed Consolidated Statements of Operations in the same period of our recognized revenue for the product sale.

Consideration Transferred

The acquisition-date fair value of the consideration transferred consisted of the following:

Cash consideration	$3,000
Ligand contingent consideration	4,700
Total purchase consideration	$7,700

Fair Value Estimate of Asset Acquired and Liability Assumed

The total purchase consideration is allocated to the acquisition of the net tangible and intangible assets based on their estimated fair values as of the transaction date. The allocation of the total purchase price to the net assets acquired is as follows:

EVOMELA IPR&D rights $7,700

We estimated the fair value of the in-process research and development using the income approach. The income approach uses valuation techniques to convert future net cash flows to a single present value (discounted) amount. We applied our net cash flow projections for EVOMELA over 10 years and a discount rate of 25%, taking into account our estimates of future incremental earnings that may be achieved upon regulatory approval and commercialization of the product(s). The fair value of the Ligand Contingent Consideration (as defined below) liability was determined using the probability of success and the discounted cash flow method of the income approach (representing unobservable “Level 3” inputs (see Note 2(xiii)) for regulatory and sales-based milestones due to Ligand upon achievement).

In March 2016, the FDA approved EVOMELA, triggering a $6 million milestone payment to Ligand ("Ligand Contingent Consideration") that was paid in April 2016. "EVOMELA IPR&D" of $7.7 million was reclassified in April 2016 to

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"EVOMELA distribution rights" that is reported within "Intangible assets, net of accumulated amortization" in the accompanying Condensed Consolidated Balance Sheets as of September 30, 2018 (see Note 3(f)). Amortization related to this intangible asset commenced on April 1, 2016.

(c) Allos Acquisition

We acquired Allos Therapeutics, Inc. ("Allos") in September 2012 for cash consideration of $205.2 million and assumed its FOLOTYN distribution rights (see Note 14). We accounted for this transaction as a business combination, which required that assets acquired and liabilities assumed be reported on our balance sheet at their fair values as of the transaction date. We have no ongoing contingent consideration obligations from this transaction.

10. OUT-LICENSE OF MARQIBO, ZEVALIN, & EVOMELA IN CHINA TERRITORY

Overview of CASI Out-License

In September 2014, we executed three perpetual out-license agreements for ZEVALIN, MARQIBO, and EVOMELA ("CASI Out-Licensed Products") with CASI, a publicly-traded biopharmaceutical company (NASDAQ: CASI) with a primary focus on the China market (collectively, the "CASI Out-License"). Under the CASI Out-License, we received CASI common stock and a secured promissory note; CASI gained the exclusive rights to distribute these drug products in greater China (which includes Taiwan, Hong Kong and Macau).

CASI is responsible for the development and commercialization of these drugs, including the submission of import drug registration applications to regulatory authorities and conducting any confirmatory clinical studies in greater China. We will provide CASI with future commercial supply of the CASI Out-Licensed Products under typical market terms.

Our Ownership in CASI at September 30, 2018

Under certain conditions that expired in December 2017, we had a right to purchase additional shares of CASI common stock in order to maintain our post-investment ownership percentage. During 2017 and 2016, we acquired an additional 1.5 million and 4.6 million CASI common shares at par value, respectively. Our aggregate holding of 11.5 million common shares as of September 30, 2018 represented an approximate 12.36% ownership in CASI, with a fair market value of $53.9 million (see Note 3(a)).

Proceeds Received from CASI in 2014

The proceeds we received in 2014, and its fair value on the CASI Out-License execution date, consisted of the following:

CASI common stock (5.4 million shares)	$8,649	(a)
CASI secured promissory note, net of fair value discount ($1.5 million face value and 0.5% annual coupon)	1,310	(b)
Total consideration received, net of fair value discount	$9,959	(c)

(a) Value determined based on the September 17, 2014 closing price of 5.4 million shares of CASI common stock on the NASDAQ Capital Market of $1.60 per share.

(b) Value estimated using the terms of the $1.5 million promissory note, the application of a synthetic debt rating based on CASI's publicly-available financial information, and the prevailing interest yields on similar public debt securities as of September 17, 2014. This full balance was reclassified beginning December 31, 2017 to "other assets" (presented within non-current assets on the accompanying Condensed Consolidated Balance Sheets) from "other receivables" (presented within current assets) due to an amended maturity date of September 17, 2019.

(c) Presented within "license fees and service revenue" in the Consolidated Statements of Operations for the year ended December 31, 2015 (see below).

In addition, CASI will be responsible for paying any royalties or milestones that we are obligated to pay to our third-party licensors resulting from the achievement of certain milestones and/or sales of CASI Out-Licensed Products, but only to the extent of the greater China portion of such royalties or milestones.

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License Fee Revenue Recognized in 2015

The $9.7 million value of the upfront proceeds (undiscounted, and net of certain foreign exchange adjustments) from CASI were recognized in 2015 within “license fees and service revenue” on our Consolidated Statements of Operations. The delayed timing of this revenue recognition corresponded with the execution of certain supply agreements with CASI for ZEVALIN, MARQIBO, and EVOMELA. These agreements allow CASI to procure CASI Out-Licensed Products directly from approved third parties, and in such case, do not require our future involvement for its commercial supply.

11. OUT-LICENSE OF ZEVALIN IN CERTAIN EX-U.S. TERRITORIES

In November 2015, we entered into an out-license agreement with Mundipharma AG (“Mundipharma”) for its commercialization of ZEVALIN in Asia (excluding India and greater China), Australia, New Zealand, Africa, the Middle East, and Latin America (including the Caribbean). In return, we received $18 million (comprised of $15 million received in December 2015 and $3 million received in January 2016). Of these proceeds, $15 million was recognized and reported within “license fees and service revenue” in the fourth quarter of 2015, and the remaining $3 million payment was recognized in full by June 30, 2017.

In April 2018, we received $2 million due to Mundipharma’s achievement of a specified sales milestone which was recognized in the first quarter of 2018 and reported within “license fees and service revenue” on our accompanying Condensed Consolidated Statements of Operations for the nine months ended September 30, 2018 (see Note 5). Mundipharma is required to reimburse us for our payment of royalties due to Bayer Pharma AG (“Bayer”) from its ZEVALIN sales - see Note 15(b)(ii).

12. CO-PROMOTION ARRANGEMENT WITH EAGLE PHARMACEUTICALS

In November 2015, we executed an agreement with Eagle Pharmaceuticals, Inc. (“Eagle”) whereby designated members of our sales force concurrently marketed up to six of Eagle’s products (along with our products). This arrangement was in return for fixed monthly payments (aggregating $12.8 million) and variable sales-based milestones from Eagle over an 18 month contract term from January 1, 2016 through June 30, 2017 (the “Eagle Agreement”). On July 1, 2017, our sales force ceased marketing Eagle products and the Eagle Agreement expired under its terms.

The fixed receipts from Eagle for our sales activities, as well as reimbursements of third-party marketing services, are recognized within “license fees and service revenue” on our accompanying Condensed Consolidated Statements of Operations, and was $4.7 million for the nine months ended September 30, 2017. No sales-based milestones were achieved.

An allocation of costs for our sales personnel that were dedicated to the Eagle Agreement are reported within “cost of service revenue” on our accompanying Condensed Consolidated Statements of Operations, as are reimbursed costs for Eagle marketing activities; these were an aggregate $4.2 million for the nine months ended September 30, 2017.

13. CONVERTIBLE SENIOR NOTES

Overview of Convertible Notes and Conversion Hedge

On December 17, 2013, we entered into an agreement for the sale of $120 million aggregate principal amount of 2.75% Convertible Senior Notes (equaling 120,000 notes, denominated in $1,000 principal units) due December 2018 (the “2018 Convertible Notes”). As of September 30, 2018 and December 31, 2017, $35.8 million and $40.6 million of principal of the 2018 Convertible Notes was outstanding, respectively, due to our open market purchases discussed below, as well as $4.7 million of principal value, converted by a holder in July 2018 into 451,300 common shares.

The 2018 Convertible Notes are convertible into shares of our common stock at a conversion rate of 95 shares per $1,000 principal units, equating to 3.4 million common shares if fully converted at September 30, 2018. The

in-the-money conversion price is equivalent to $10.53 per common share. The conversion rate and conversion price is subject to adjustment under certain limited circumstances. The 2018 Convertible Notes bear interest at a rate of 2.75% per year, payable semiannually in arrears on June 15 and December 15 of each year. The 2018 Convertible Notes will mature and become payable on December 15, 2018, subject to earlier conversion into common stock at the holders' option.

The sale of the 2018 Convertible Notes closed on December 23, 2013 and we received net proceeds of $115.4 million, after deducting banker and professional fees of $4.6 million. We used a portion of these net proceeds to simultaneously enter into "bought call" and "sold warrant" transactions with Royal Bank of Canada (collectively, the "Conversion Hedge"). We

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recorded the Conversion Hedge on a net cost basis of $13.1 million, as a reduction to “additional paid-in capital” in our accompanying Condensed Consolidated Balance Sheets. Under applicable GAAP, the Conversion Hedge transaction has not been (and is not expected to be) marked-to-market through earnings or comprehensive income.

On and after June 15, 2018, and until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all, or a portion, of their 2018 Convertible Notes. Our stockholders’ approved “flexible settlement” our Annual Meeting of Stockholders on June 29, 2015, though on September 27, 2018, we elected to exclusively settle any and all conversions with our common stock. However, if the holders of our 2018 Convertible Notes do not elect to convert, our December 2018 obligation to repay the remaining principal amount of $35.8 million in cash, plus any accrued and unpaid interest, will remain unchanged.

We entered into Conversion Hedge transactions in December 2013 to reduce the potential dilution to our stockholders and/or offset any cash payments that we are required to make in excess of the principal amount, upon conversion of the 2018 Convertible Notes (in the event that the market price of our common stock is greater than the conversion price). The strike price of the “bought call” is equal to the conversion price and conversion rate of the 2018 Convertible Notes (at such time, it matched the 11.4 million common shares into which the holders could convert the 2018 Convertible Notes); the strike price of our “sold warrant” is $14.03 per share of our common stock, and is also for 11.4 million common shares (reduced by the partial unwinding of these instruments, as discussed above).

Open Market Purchases of 2018 Convertible Notes and Conversion Hedge Unwind in December 2016 and October 2017

In December 2016, we completed two open market purchases of our 2018 Convertible Notes, aggregating 9,963 note units (equivalent to $10 million principal value) for $9 million in cash. We recognized an aggregate loss of $25 thousand on the retirement of these 2018 Convertible Notes (based on their carrying value under GAAP), which is included in “other income (expense), net” on the Consolidated Statements of Operations for the year ended December 31, 2016. Concurrent with these two open market purchases in December 2016, we unwound a portion of our previously sold warrants and previously purchased call options (which were part of our Conversion Hedge described below) for aggregate net proceeds of $21 thousand. We recorded a corresponding net increase to “additional paid-in capital” in the Consolidated Balance Sheets as of December 31, 2016.

In October 2017, we completed an additional open market purchase of our 2018 Convertible Notes, aggregating 69,472 note units (equivalent to $69.5 million principal value) for $27.3 million in cash and 5.4 million newly-issued shares of our common stock, then worth $73 million. We recognized a loss of $0.8 million on the retirement of these 2018 Convertible Notes (based on their carrying value under GAAP), which was included in “other (expense) income, net” on the Consolidated Statements of Operations for the year ended December 31, 2017.

Concurrent with this open market purchase in October 2017, we also unwound a portion of the previously sold warrants and previously purchased call options that were part of our Conversion Hedge for aggregate net proceeds of $5.8 million. We recorded a corresponding net increase to “additional paid-in capital” in the Consolidated Balance Sheets as of December 31, 2017.

Carrying Value and Fair Value of 2018 Convertible Notes at September 30, 2018 and December 31, 2017

The carrying value of the 2018 Convertible Notes as of September 30, 2018 and December 31, 2017, is summarized as follows:

	September 30, 2018	December 31, 2017
Principal amount	$ 35,815	$ 40,565
(Less): Unamortized debt discount (amortized through December 2018)	(412)	(2,101)
(Less): Debt issuance costs	(46)	(240)
Carrying value	$ 35,357	$ 38,224

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As of September 30, 2018 and December 31, 2017, the estimated aggregate fair value of the 2018 Notes is $55.8 million and $74.3 million, respectively. These estimated fair values represent a Level 2 measurement (see Note 2(xiii)), based upon the 2018 Convertible Notes quoted bid price at each date in a thinly-traded market.

Components of Interest Expense on 2018 Convertible Notes

The following table sets forth the components of interest expense recognized in the accompanying Condensed Consolidated Statements of Operations for the 2018 Convertible Notes for the three and nine months ended September 30, 2018 and 2017:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Contractual coupon interest expense	$246	$757	$798	$2,270
Amortization of debt issuance costs	56	170	178	491
Accretion of debt discount	491	1,442	1,558	4,236
Total	$793	$2,369	$2,534	$6,997
Effective interest rate	8.41 %	8.65 %	8.41 %	8.65 %

14. FOLOTYN LICENSE AGREEMENT AND DEVELOPMENT LIABILITY

As the result of our acquisition of Allos on September 5, 2012 (see Note 9(c)), we assumed a strategic collaboration agreement with Mundipharma (as amended and/or restated, the “Mundipharma Collaboration Agreement”), as well as certain FOLOTYN clinical development obligations (the “FOLOTYN Development Liability”).

Overview of Mundipharma Collaboration Agreement

Under the Mundipharma Collaboration Agreement, we retained full commercialization rights for FOLOTYN in the United States and Canada, with Mundipharma having exclusive rights to commercialize FOLOTYN in all other countries in the world. On May 29, 2013, the Mundipharma Collaboration Agreement was amended and restated, in order to modify: (i) the scope of the licensed territory, (ii) milestone payments, (iii) royalty rates, and (iv) drug development obligations. In connection with the amendment and restatement of the Mundipharma Collaboration Agreement, we received a one-time $7 million payment from Mundipharma for certain research and development activities to be performed by us.

As a result of the amendment and restatement of the Mundipharma Collaboration Agreement, (a) Europe and Turkey were excluded from Mundipharma’s commercialization territory, (b) we may receive regulatory milestone payments of up to $16 million, and commercial progress and sales-dependent milestone payments of up to $107 million (see Note 15(b)(vii) for July 2017 achievement), (c) we will receive tiered double-digit royalties based on net sales of FOLOTYN within Mundipharma’s licensed territories, and (d) we and Mundipharma will each bear our own FOLOTYN development costs. Effective as of May 1, 2015, we modified the Mundipharma Collaboration Agreement to revise the conditions for our exercise of the option to gain commercialization rights in Switzerland from Mundipharma, as well as royalties payable to us (in the tiered double-digits) on Mundipharma’s net sales in Switzerland.

FOLOTYN Development Liability

The fair value of the FOLOTYN Development Liability within the accompanying Consolidated Balance Sheets was estimated using the discounted income approach model. The unobservable inputs (i.e., “Level 3” inputs - see Note

2(xiii)) in this valuation model that have the most significant effect on these liabilities include (i) estimates of research and development personnel costs needed to perform the research and development services contractually required, (ii) estimates of expected cash outflows to third parties for these clinical services and supplies during the expected period of performance through 2031, and (iii) an appropriate discount rate for these expenditures. These inputs are reviewed by management on a quarterly basis for continued applicability.

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We adjust this liability at each quarter-end, with corresponding adjustments for incurred costs recorded as credits to "research and development" expense in our accompanying Condensed Consolidated Statements of Operations.

	FOLOTYN Development Liability, Current	FOLOTYN Development Liability, Long Term	FOLOTYN Development Liability, Total
Balance as of December 31, 2017	$ 275	$ 12,111	$ 12,386
Transfer from long-term to current in 2018	206	(206)	—
(Less): Expenses incurred in 2018	(270)	—	(270)
Balance as of September 30, 2018	$ 211	$ 11,905	$ 12,116

15. FINANCIAL COMMITMENTS & CONTINGENCIES AND LICENSE AGREEMENTS

(a) Facility Leases
We lease our principal executive office in Henderson, Nevada under a non-cancelable operating lease expiring April 30, 2019. We also lease our research and development facility in Irvine, California under a non-cancelable operating lease expiring May 31, 2019, in addition to several other administrative office leases. Each lease agreement contains scheduled rent increases which are accounted for on a straight-line basis.
(b) In/Out Licensing Agreements and Co-Development Arrangements
The in-license agreements for our commercialized and development-stage drug products provide us with territory-specific rights to their manufacture and distribution (including further sub-licensing/out-licensing, rights). We are generally responsible for all related clinical development costs, patent filings and maintenance costs, marketing costs, and liability insurance costs. We are also obligated to make specified milestone payments to our licensors upon the achievement of certain regulatory and sales milestones, and to pay royalties based on our net sales of all in-licensed products. We also enter into out-license agreements for territory-specific rights to our drug products which include one or more of: upfront license fees, royalties from our licensees' sales, and/or milestone payments from our licensees' sales or regulatory achievements. For certain development-stage drug products, we may enter into cost-sharing arrangements with our licensees and licensors.
Our most significant of these agreements, and the key financial terms and our accounting for each, are summarized below:
(i) ZEVALIN U.S.: In-Licensing and Development in the United States
In December 2008, we acquired rights to commercialize and develop ZEVALIN in the United States as the result of a transaction with Cell Therapeutics, Inc. through our wholly-owned subsidiary, RIT Oncology LLC. In accordance with the terms of assumed contracts, we were required to meet specified payment obligations, including a milestone payment to Corixa Corporation of $5 million based on ZEVALIN sales in the United States. As of September 30, 2018 all the patents licensed from Corixa had expired under the terms of the agreement. Under the terms of the agreement, we are no longer obligated to pay U.S. net sales-based royalties in the low to mid-single digits to Genentech, Inc. and mid-teens to Biogen, Inc.
(ii) ZEVALIN Ex-U.S.: In-License and Asset Purchase Agreement with Bayer Pharma
In April 2012, through our wholly-owned subsidiary, Spectrum Pharmaceuticals Cayman, L.P., we completed a €19 million acquisition of licensing rights to market ZEVALIN outside of the U.S. from Bayer. ZEVALIN is currently approved in approximately 40 countries outside the U.S. for the treatment of B-cell NHL, including countries in Europe, Latin America, and Asia.
We amended the agreement in February 2016, which adjusted our tiered royalty to Bayer from the single-digits to 20%. The term of the agreement, as amended, continues until the expiration of the last-to-expire ZEVALIN patent in

the relevant country, or 15 years from the date of first commercial sale of ZEVALIN in such country, whichever is longer.

(iii) ZEVALIN Ex-U.S.: Out-License Agreement with Dr. Reddy's

In June 2014, we executed an exclusive License Agreement with Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's") for ZEVALIN distribution rights within India. The agreement term is 15 years from the receipt of pending approval of ZEVALIN from the Drug Controller General of India. In December 2014, upon our execution of a drug supply agreement, an upfront and non-refundable payment of $0.5 million was triggered and paid to us in February 2015. The recognition of the applicable portion of this upfront receipt is no longer reported on a straight-line basis within "license fees and service revenue" on our accompanying Condensed Consolidated Statements of Operations, due to the adoption of Topic 606 as of January 1, 2018 (see Note 2(i)). Additionally, sales and regulatory milestones, each aggregating $1.5 million (for a total of $3 million if both are achieved) are due to us upon Dr. Reddy's achievement of such milestones, as well as a 20% royalty on its net sales of ZEVALIN in India.

(iv) ZEVALIN Ex-U.S.: Out-License Agreement with Mundipharma

In November 2015, we entered into an out-license agreement with Mundipharma for its commercialization of ZEVALIN in Asia (excluding India and Greater China), Australia, New Zealand, Africa, the Middle East, and Latin America (including the Caribbean islands). In return, we received $18 million (comprised of $15 million received in December 2015 and $3 million received in January 2016). Of these proceeds, $15 million was recognized within "license fees and service revenue" in the fourth quarter of 2015, and the remaining $3 million payment was recognized in full by June 30, 2017. Mundipharma is required to reimburse us for our payment of royalties due to Bayer from its ZEVALIN sales (see Note 15(b)(ii)).

In March 2018, Mundipharma achieved a specified sales milestone, resulting in a $2 million receipt due to us (subsequently received in April 2018); this amount was recognized within "license fees and service revenue" on our accompanying Condensed Statements of Operations for the nine months ended September 30, 2018 (see Note 5).

(v) FUSILEV: In-License Agreement with Merck & Cie AG

In May 2006, we amended and restated a license agreement with Merck & Cie AG ("Merck"), which we assumed in connection with our March 2006 acquisition of the assets of Targent, Inc. This provided us with an exclusive license to use regulatory filings related to FUSILEV, and a non-exclusive license under certain patents and know-how to develop, manufacture, and sell FUSILEV in the field of oncology in North America.

The contractual royalty percentage on our FUSILEV net sales due to Merck is set at the mid-single digits; however, in September 2017, we paid Merck $2.6 million in full settlement of all royalty obligations under the agreement. As a result, we are no longer contractually obligated to pay any royalties or milestones for our net sales of FUSILEV.

(vi) FOLOTYN: In-License Agreement with Sloan-Kettering Institute, SRI International and Southern Research Institute

In December 2002, Allos entered into an in-license agreement for the drug now marketed as FOLOTYN with Sloan-Kettering Institute for Cancer Research, SRI International (SRI), and Southern Research Institute. We assumed this agreement when we acquired Allos in September 2012. The agreement provides for our exclusive worldwide rights to a portfolio of patents and patent applications related to FOLOTYN, though we are required to fund certain drug development programs. In addition, we pay graduated royalties to our licensors based on our worldwide annual net sales of FOLOTYN (including our sub- licensees). These royalties are 8% of annual worldwide net sales up to $150 million; 9% of annual worldwide net sales of $150 million through $300 million; and 11% of annual worldwide net sales in excess of $300 million. We are also obligated to remit a $3.5 million payment to SRI upon approval of FOLOTYN by the European Medicines Agency ("EMA") approval of FOLOTYN. This regulatory milestone has not been met, and no amounts have been accrued in our accompanying Condensed Balance Sheets for its potential achievement.

(vii) FOLOTYN: Out-License Agreement with Mundipharma

As a result of our acquisition of Allos (see Note 10(c)), we assumed "the Mundipharma Collaboration Agreement" as well as certain FOLOTYN clinical development obligations. Under the Mundipharma Collaboration Agreement (see Note 14), we retained full commercialization rights for FOLOTYN in the U.S. and Canada, with Mundipharma having

exclusive rights to commercialize FOLOTYN in all other countries in the world, except in Europe and Turkey. We are contractually entitled to receive regulatory and sales milestone payments from Mundipharma upon its achievement of such milestones, which aggregate $16 million and $107 million, respectively, as well as tiered double-digit royalties on Mundipharma's net sales.

In July 2017, FOLOTYN was approved in Japan for the treatment of adult patients with relapsed or refractory peripheral T-cell lymphoma. Consequently, we received $3 million from Mundipharma in August 2017 for this milestone achievement.

This amount was recognized within “license fees and service revenue” on our Consolidated Statements of Operations for the year ended December 31, 2017.

In August 2017, FOLOTYN was commercially launched in Japan. This triggered a contractual milestone of $2 million from Mundipharma. This amount was recorded within “license fees and service revenue” on our Consolidated Statements of Operations for the year ended December 31, 2017.

(viii) EVOMELA: In-License Agreement with CyDex Pharmaceuticals, Inc.

In March 2013, we completed the acquisition of exclusive global development rights to EVOMELA from CyDex, a wholly-owned subsidiary of Ligand (see Note 9(b)), and assumed responsibility for its then-ongoing clinical and regulatory development program. We filed a New Drug Application (“NDA”) with the FDA in December 2015 for its use as a conditioning treatment prior to autologous stem cell transplant for patients with MM, and in March 2016, the FDA communicated its approval. Consequently, we made a $6 million contractual milestone payment to Ligand in April 2016. We reclassified $7.7 million from “EVOMELA IPR&D rights” to “EVOMELA distribution rights” which is presented within “intangible assets, net of accumulated amortization and impairment charges” (see Note 3(f)) within our accompanying Condensed Consolidated Balance Sheets as of September 30, 2018.

We are required to pay Ligand additional amounts of up to $60 million (exclusive of the $6 million milestone paid in April 2016), upon our achievement of specified net sales thresholds. We are also responsible to pay Ligand royalties of 20% on our net sales of EVOMELA in all territories.

(ix) MARQIBO: Acquisition of Talon Therapeutics, Inc. and Related Contingent Consideration Agreement

In July 2013, we completed the acquisition of Talon, through which we obtained exclusive global development and commercialization rights to MARQIBO (see Note 9(a)). As part of this acquisition, the former Talon stockholders have contingent financial rights that we have valued and presented on our accompanying Condensed Consolidated Balance Sheets as a $5.6 million and $6.2 million liability within “acquisition-related contingent obligations” as of September 30, 2018 and December 31, 2017, respectively. The maximum payout value of the contingent financial rights to the former Talon shareholders is $195 million, assuming we achieve all sales and regulatory approval milestones. In addition, we are contractually obligated to pay royalties in the single digits on our net sales of MARQIBO and a portion of sublicensing revenue may be due upon our receipt of such revenue for MARQIBO.

(x) QAPZOLA: License Agreements with Allergan, Inc. and NDDO Research Foundation

In October 2008, we entered into an exclusive development and commercialization collaboration agreement with Allergan, Inc. (“Allergan”) for QAPZOLA pursuant to which Allergan paid us an up-front non-refundable fee of $41.5 million at execution (which we had recognized in full within “license fees and service revenue” by December 31, 2013). Concurrently we also entered into a letter agreement with NDDO Research Foundation (“NDDO”), pursuant to which we agreed to pay NDDO the following in relation to QAPZOLA milestones: (a) upon FDA acceptance of our NDA, the issuance of 25,000 of our common shares (which occurred in March 2016 and the $0.1 million value of these shares was included in “research and development” expense for the year ended December 31, 2016), and (b) upon FDA approval, a one-time payment of $0.3 million (which has not yet been met, and no amounts have been accrued in our accompanying Consolidated Balance Sheets for its potential achievement).

In January 2013, we entered into a second amendment to the license, development, supply and distribution agreement with Allergan. This amendment relieved Allergan of its development and commercialization obligations and resulted in our acquisition of its rights in the U.S., Europe, and other territories, in exchange for our agreement to pay a tiered single-digit royalty on our sales of certain products containing QAPZOLA.

(xi) QAPZOLA: Collaboration Agreement with Nippon Kayaku Co. LTD.

In November 2009, we entered into a collaboration agreement with Nippon Kayaku Co., LTD. (“Nippon Kayaku”) for the development and commercialization of QAPZOLA in Asia, except North and South Korea (the “Nippon Kayaku Territory”). In addition, Nippon Kayaku received exclusive rights to QAPZOLA for the treatment of Non-Muscle

Invasive Bladder Cancer in the Nippon Kayaku Territory, including Japan and China. Nippon Kayaku will conduct QAPZOLA clinical trials in the Nippon Kayaku Territory pursuant to a development plan. Further, Nippon Kayaku will be responsible for all expenses relating to the development and commercialization of QAPZOLA in the Nippon Kayaku Territory.

Under the terms of this agreement, Nippon Kayaku paid us an upfront fee of $15 million (which we recognized within "license fees and service revenue" in full by December 31, 2013). Under the terms of the agreement, we are entitled to receive $10 million and $126 million from Nippon Kayaku upon the achievement of certain regulatory and commercialization milestones, respectively (some of which are our responsibility to achieve). Nippon Kayaku is also obligated to pay us royalties on its net sales of QAPZOLA in the mid-teen digits.

(xii) BELEODAQ: In-License and Collaboration Agreement with Onxeo

In February 2010, we entered into an in-license and collaboration agreement with TopoTarget A/S (now Onxeo DK) ("Onxeo"), for the development and commercialization of BELEODAQ, as amended in October 2013. We paid Onxeo an upfront fee of $30 million (and agreed to additional payments described below) for rights in North America and India, with an option for China. We are contractually obligated to pay royalties in the mid-teen digits on our net sales of BELEODAQ.

All development and studies of BELEODAQ are conducted under a joint development plan (of which we fund 70% and Onxeo funds 30%). We have final decision-making authority for all developmental activities in North America and India (and China upon exercise of our option). Onxeo has final decision-making authority for all developmental activities in all other jurisdictions. In February 2014, upon FDA acceptance of our NDA, we were contractually obligated to issue Onxeo one million shares of our common stock and to make a $10 million milestone payment. The aggregate value of this milestone at achievement was $17.8 million, and was recognized within "research and development" expense in the first quarter of 2014.

In July 2014, we received approval from the FDA for BELEODAQ's use for injection and treatment of relapsed or refractory peripheral T-cell lymphoma. As a result, we made a second milestone payment to Onxeo of $25 million in November 2014. This amount was capitalized as "BELEODAQ distribution rights" and is presented within "intangible assets, net of accumulated amortization and impairment charges" (see Note 3(f)). We are also contractually obligated to pay Onxeo upon our achievements of other regulatory events and sales thresholds, up to $88 million and $190 million, respectively. These milestone amounts are not included within "total liabilities" in our accompanying Consolidated Balance Sheets.

(xiii) ROLONTIS: Co-Development and Commercialization Agreement with Hanmi Pharmaceutical Co. Ltd

In October 2014, we exercised our option under a License Option and Research Collaboration Agreement dated January 2012 (as amended) with Hanmi Pharmaceutical Co. Ltd., or Hanmi, for ROLONTIS (formerly referred to as "LAPS-G-CSF" or "SPI-2012"), a drug based on Hanmi's proprietary LAPSCOVERY™ technology for the treatment of chemotherapy induced neutropenia. Under the terms of this agreement, as amended, we have primary financial responsibility for the ROLONTIS development plan and hold its worldwide rights (except for Korea, China, and Japan). We are contractually obligated to pay Hanmi royalties in the mid-teen digits on our net sales of ROLONTIS.

In January 2016, the first patient was dosed with ROLONTIS in a clinical trial. This triggered our contractual milestone payment to Hanmi, and in April 2016, we (i) issued 318,750 shares of our common stock, then valued at $2.3 million, and (ii) remitted a $0.4 million payment to the Internal Revenue Service (the IRS) on its behalf for related tax obligations. This aggregate $2.7 million value was recognized within "research and development" expense in our Consolidated Statements of Operations for the year ended December 31, 2016. We are responsible for further contractual payments upon our achievement of regulatory and sales milestones, up to $13 million and $225 million, respectively. These amounts are not included within "total liabilities" in our accompanying Condensed Consolidated Balance Sheets.

(xiv) Poziotinib: In-License Agreement with Hanmi and Exclusive Patent and Technology License Agreement with MD Anderson

In February 2015, we executed an in-license agreement with Hanmi for poziotinib, a pan-HER inhibitor in Phase 2 clinical trials, (which has also shown single agent activity in the treatment of various cancer types during Phase I studies, including breast, gastric, colorectal, and lung cancers), and made an upfront payment for these rights. This

payment was recognized within “research and development” expense in our Consolidated Statements of Operations for the year ended December 31, 2015. We are also contractually obligated to pay Hanmi royalties in the low to mid-teen digits on our net sales of poziotinib.

Under the terms of this agreement, we received the exclusive rights to commercialize poziotinib, excluding Korea and China. Hanmi and its development partners are fully responsible for the completion of on-going Phase 2 trials in Korea. We are financially responsible for all other clinical studies. We are contractually obligated to make payments to Hanmi upon our achievement of certain regulatory and sales milestones, aggregating $33 million and $325 million, respectively, which are not included within “total liabilities” in our accompanying Condensed Consolidated Balance Sheets. We will pay Hanmi royalties

in the low to mid-teen digits on our net sales of poziotinib. These amounts are not included within “total liabilities” in our accompanying Condensed Consolidated Balance Sheets.

In April 2018, we executed an exclusive patent and technology agreement for poziotinib’s use in treating patients with EGFR and HER2 exon 20 mutations in cancer and HER2 exon 19 mutations in cancer with The University of Texas M.D. Anderson Cancer Center (“MD Anderson”) that had discovered its use in treating these patient-types (“Exon 19/20 Patients”). We made an upfront payment of $0.5 million upon this agreement’s execution that was recognized within “research and development” expense in the accompanying Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2018.

We are contractually obligated to make payments to MD Anderson upon our achievement of certain regulatory and sales milestones, aggregating $11 million and $23 million, respectively, which are not included within “total liabilities” in our accompanying Condensed Consolidated Balance Sheets. We will also pay MD Anderson royalties in the low single-digits on our net sales of poziotinib that relate to the treatment of Exon 19/20 Patients.

(xv) ZEVALIN, FOLOTYN, BELEODAQ, and MARQIBO: Out-License Agreement with Servier in Canada, Inc. in Canada

In January 2016, we entered into a strategic partnership with Servier Canada, Inc. (“Servier”) for the out-licenses of ZEVALIN, FOLOTYN, BELEODAQ, and MARQIBO. We received an aggregate $6 million of upfront proceeds in the first quarter of 2016, which was recognized within “license fees and service revenue” in our Consolidated Statements of Operations for the year ended December 31, 2016. We are also entitled to milestone receipts (aggregating $2 million) upon Servier’s achievement of specific regulatory approvals, and a high single-digit royalty on its sales of these products.

(c) Service Agreements for our Research and Development Activities

We have entered into various contracts with numerous third party service providers for the execution of our research and development initiatives (to which we assign discreet project codes in order to compile and monitor such expenses). These vendors include raw material suppliers and contract manufacturers for drug products not yet FDA approved, clinical trial sites, clinical research organizations, and data monitoring centers, among others. The financial terms of these agreements are varied and generally obligate us to pay in stages, depending on the achievement of certain events specified in the agreements - such as contract execution, progress of service completion, delivery of drug supply, and the dosing of patients in clinical studies.

We recognize these “research and development” expenses and corresponding “accounts payable and other accrued liabilities” in the accompanying financial statements based on estimates of our vendors’ progress of performed services, patient enrollments and dosing, completion of clinical studies, and other events. Should we decide to discontinue and/or slow-down the work on any project, the associated costs for those projects would typically be limited to the extent of the work completed, as we are generally able to terminate these contracts with adequate notice.

(d) Supply and Service Agreements for our Commercial Products

We have entered into various supply and service agreements, and/or have issued purchase orders, which obligate us to complete agreed-upon raw material purchases from certain vendors for the production of our commercialized drug products through designated contract manufacturers. These commitments do not exceed our planned commercial requirements, and the contracted prices do not exceed current fair market value.

(e) Employment Agreements

We previously entered into an employment agreement with our former Chief Executive Officer, Rajesh C. Shrotriya, M.D., under which cash compensation and benefits would become payable to him in the event of termination by us for any reason other than cause, his resignation for good reason, or upon a change in control of our Company. Effective December 17, 2017, Dr. Shrotriya’s employment was terminated without cause. As of December 31, 2017, we accrued for all contractual cash amounts due and unpaid to him within “accrued payroll and benefits” on the accompanying

Condensed Consolidated Balance Sheets.

We entered into new employment agreements with each of our named executive officers (chief executive officer, chief operating officer, chief financial officer, and chief legal officer) in April and June 2018, which supersede any prior Change in Control Severance Agreements with such individuals. These new agreements provide for the payment of certain benefits to each executive upon his separation of employment under specified circumstances. These arrangements are designed to encourage each

to act in the best interests of our stockholders at all times during the course of a change in control event or other significant transaction.

(f) Deferred Compensation Plan

The Spectrum Pharmaceuticals, Inc. Deferred Compensation Plan (the "DC Plan") is administered by the Compensation Committee of our Board of Directors and is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended.

The DC Plan is maintained to provide special benefits for a select group of our employees (the "DC Participants"). DC Participants make annual elections to defer a portion of their eligible cash compensation which is then placed into their DC Plan accounts. We match a fixed percentage of these deferrals, and may make additional discretionary contributions. At September 30, 2018 and December 31, 2017, the aggregate value of this DC Plan liability totaled $6.5 million and $11.0 million, respectively, and is included within "accounts payable and other accrued liabilities" and "other long-term liabilities" in the accompanying Condensed Consolidated Balance Sheets.

(g) Litigation

We are involved from time-to-time with various legal matters arising in the ordinary course of business. These claims and legal proceedings are of a nature we believe are normal and incidental to a pharmaceutical business, and may include product liability, intellectual property, employment matters, and other general claims.

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 assessed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. Although the ultimate resolution of these various matters cannot be determined at this time, we do not believe that such matters, individually or in the aggregate, will have a material adverse effect on our consolidated results of operations, cash flows, or financial condition.

Stockholder Litigation

Olutayo Ayeni v. Spectrum Pharmaceuticals, Inc., et al. (Filed September 21, 2016 in the United States District Court, Central District of California; Case No. 2:16-cv-07074) (the "Ayeni Action") and Glen Hartsock v. Spectrum Pharmaceuticals, Inc., et al. (Filed September 28, 2016 in the United States District Court, District Court of Nevada Case; No. 2:16-cv-02279-RFB-GWF) (the "Hartsock Action"). On November 15, 2016, the Ayeni Action was transferred to the United States District Court for the District of Nevada. The parties have stipulated to a consolidation of the Ayeni Action with the Hartsock Action. These class action lawsuits allege that we and certain of our executive officers made false or misleading statements and failed to disclose material facts about our business and the prospects of approval for our NDA to the FDA for QAPZOLA in violation of Section 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Securities Exchange Act of 1934, as amended. The plaintiffs seek damages, interest, costs, attorneys' fees, and other unspecified equitable relief. We believe that these claims are without merit, and intend to vigorously defend against these claims. Furthermore, as of September 30, 2018, the value of a potential settlement cannot be reasonably estimated given its highly uncertain nature.

EVOMELA Litigation

We obtained global development and commercialization rights to EVOMELA from CyDex Pharmaceuticals, Inc., a wholly-owned subsidiary of Ligand Pharmaceuticals Incorporated, or CyDex, in March 2013. We thereafter assumed responsibility for completing its clinical trials and were responsible for filing the New Drug Application. Under our license agreement with CyDex, CyDex received a license fee and is eligible to receive milestone payments and royalties. On December 20, 2017, CyDex filed an action against Teva Pharmaceuticals USA, Inc., TEVA Pharmaceuticals Industries Ltd., and Actavis, LLC, together Teva, in the U.S. District Court for the District of Delaware, alleging patent infringement with respect to a paragraph IV certification, or an Abbreviated New Drug

Application (“ANDA”), filed with the FDA seeking approval to market a generic version of EVOMELA. CyDex brought suit against Teva to protect its intellectual property rights.”

Intellectual Property Litigation

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We and Onxeo received a Paragraph IV Notice Letter dated August 21, 2018, notifying us that Fresenius Kabi USA, LLC ("Fresenius") has submitted to the FDA, an ANDA seeking approval from the FDA to manufacture and market a generic version of BELEODAQ (belinostat) for injection in the U.S. We and Onxeo have filed a patent infringement lawsuit against Fresenius which triggered an automatic stay of this ANDA for 30 months. In addition, BELOEDAQ is protected from competition in the U.S. by an Orphan Drug Exclusivity indication until July 3, 2021.

16. INCOME TAXES

We apply an estimated annual effective tax rate ("ETR") approach for calculating a tax provision for interim periods, as required under GAAP. We recorded a provision for income taxes of $8 thousand and a benefit for income taxes of $1.4 million for the nine months ended September 30, 2018 and 2017, respectively. Our ETR differs from the U.S. federal statutory tax rate of 21% primarily as a result of nondeductible expenses, state income taxes, foreign income taxes, and the impact of a valuation allowance on our deferred tax assets.

Our provision for income taxes is computed using the asset and liability method, under which deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for the expected future tax benefit to be derived from tax loss and credit carryforwards. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction by jurisdiction basis, and includes a review of all available positive and negative evidence. We recognize the impact of a tax position in our financial statements only if that position is more likely than not to be sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense.

The intraperiod tax allocation rules require that we allocate the "(provision) benefit for income taxes" between continuing operations and other categories of earnings. In prior periods where we have a year-to-date pre-tax loss from continuing operations and year-to-date pre-tax income in other categories of earnings, such as other comprehensive income, ASC 740-20-45-7 requires that we allocate the income tax provision to other categories of earnings, and then record a related tax benefit in continuing operations. For the three and nine months ended September 30, 2017, we recognized net income from investments and currency transactions within "other comprehensive income" while sustaining losses from continuing operations. As a result of the required allocation under ASC 740-20-45-7, we recorded tax expense of $2.1 and $2.1 million in "other comprehensive income" on the accompanying Condensed Consolidated Statements of Comprehensive Loss, and a benefit for income taxes of $1.5 million and $1.4 million within "benefit for income taxes" on the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2017, respectively. Beginning January 1, 2018, as a result of the adoption of ASU 2016-01 Recognition and Measurement of Financial Assets and Liabilities, and related reclassification of gains on investments in equity securities to the Consolidated Statements of Operations, we have recognized currency translation losses in our Condensed Consolidated Statement of Comprehensive Income (Loss). Thus, during the three and nine months ended September 30, 2018, there has been no allocation of tax benefits to the Condensed Consolidated Statements of Operations pursuant to the required allocations under ASC 740-20-45-7.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). Changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning in 2018, the transition of U.S. international taxation from a worldwide tax system to a territorial system, which includes a new federal tax on global intangible low-taxed income (Global Minimum Tax, or GMT), and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017.

The SEC Staff issued SAB 118, which provides guidance on accounting for the tax effects of the Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the Tax Act for which the accounting under ASC 740 is complete. To the extent that a company's accounting for certain income tax effects of the Tax Act is incomplete but it is able to determine a reasonable estimate, it must record a provisional estimate in the financial statements. If a company cannot determine a provisional estimate to be included in the financial statements, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the Tax Act.

At December 31, 2017, we were able to make reasonable estimates of certain effects and, therefore, recorded provisional adjustments. The provisional amounts described below are subject to revisions as we complete our analysis of the Tax Act, collect data, and interpret any additional guidance issued by the U.S. Treasury Department, Internal Revenue Service, or IRS, FASB, and other standard-setting and regulatory bodies. Adjustments to the provisional amounts may materially impact our consolidated income tax provision (benefit) and effective tax rates in the period(s) in which such adjustments are made. Our accounting for the tax effects of the Tax Act will be completed during the one-year measurement period.

Reduction of U.S. Federal Corporate Tax Rate: For certain of our deferred tax assets and deferred tax liabilities, we have recorded a provisional decrease in net deferred tax assets of $38.9 million, with a corresponding decrease in the valuation allowance of $41.4 million and a benefit to income tax expense of $2.5 million for the year ended December 31, 2017. This provisional estimate may be affected by other analyses related to the Tax Act, including, but not limited to, the state tax effect of adjustments made to federal temporary differences.

Deemed Repatriation Transition Tax: Based upon our preliminary analysis, we have concluded that a net accumulated E&P deficit exists as of December 31, 2017 for our foreign subsidiaries. As a result, we did not accrue any provisional transition tax liabilities. We will continue to gather additional and perform additional analyses to more precisely determine past foreign earnings and related taxes and will update our provisional estimate with respect to the transition tax liability when such work is completed within the one-year measurement period.

Valuation Allowance: The Tax Act limits the amount taxpayers are able to deduct for net operating loss carryforwards generated in taxable years beginning after December 31, 2017 to 80% of the taxpayer’s taxable income. However, net operating loss carryforwards generated in taxable years ending after December 31, 2017 can be carried forward indefinitely. A taxable temporary difference associated with an indefinite-lived asset is generally considered to be a source of taxable income to support realization of a net operating loss with an unlimited carryforward period. Due to the restriction on the ability to use the net operating loss with unlimited carryforward periods arising in taxable years beginning after December 31, 2017, only 80% of the indefinite-lived taxable temporary difference would serve as a source of taxable income. As a result, the valuation allowance decreased by $2.9 million related to the 80% utilization of the indefinite-lived taxable temporary as a source of taxable income.

Under GAAP, we are allowed to make an accounting policy choice with respect to the GMT of either (1) treating taxes due on future U.S. inclusions in taxable income related to GMT as a current-period expense when incurred or (2) as a component of deferred income taxes. We will make our accounting policy election for this item when our analysis is complete, during the measurement period.

Due to the valuation allowance on our deferred tax assets, there was no net impact to the tax provision for income taxes arising from the Tax Act for the three and nine months ended September 30, 2018.

17. STOCKHOLDERS’ EQUITY

Sale of Common Stock Under ATM Agreements

In December 2015 and August 2017, we entered into collective at-market-issuance sales agreements with FBR Capital Markets & Co., MLV & Co. LLC, and H.C. Wainwright & Co., LLC. (the “December 2015 ATM Agreement” and the “August 2017 ATM Agreement”, respectively). These agreements allowed us to raise aggregate gross proceeds through these brokers of up to $250 million from the sale of our common stock on the public market.

Through September 30, 2018, we had raised aggregate gross net proceeds of $202.1 million through these at-market sales, of which $128.3 million was raised during the year ended December 31, 2017. We are using these proceeds to continue to develop our product pipeline and to provide additional capital structure flexibility.

We sold and issued shares of our common stock under both the December 2015 ATM Agreement and August 2017 ATM Agreement, summarized as follows:

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Description of Financing Transaction	No. of Common Shares Issued	Proceeds Received (Net of Broker Commissions and Fees)
Common shares issued pursuant to the December 2015 ATM Agreement during the year ended December 31, 2016	10,890,915	$ 73,869
Common shares issued pursuant to the December 2015 ATM Agreement between July 1, 2017 and July 31, 2017	3,243,882	$ 23,745
Common shares issued pursuant to the August 2017 ATM Agreement between August 1, 2017 and December 31, 2017	10,314,250	$ 104,527

There were no sales of our common stock under the August 2017 ATM Agreement during the nine months ended September 30, 2018.

18. IMMATERIAL RESTATEMENT OF PRIOR PERIOD FINANCIAL STATEMENTS FOR STOCK-BASED COMPENSATION

Subsequent to the issuance of our unaudited interim financial statements for the quarter and year-to-date periods ended September 30, 2017, our management identified certain immaterial errors within previously reported operating expense captions of “selling, general, and administrative” and “research and development” that solely relate to our stock-based compensation recognition (see Note 6). These errors were primarily the result of an improper system setting during our 2012 implementation of our then-new stock-based compensation software. Consequently, incremental expense for the reversal of previously applied forfeiture estimates was not timely recognized upon the full vesting of each award, as required; this error persisted through September 30, 2017. We considered these errors from a qualitative and quantitative perspective, and concluded they were not material to each prior period. However, we have restated our accompanying Condensed Consolidated Financial Statements to correct for these immaterial errors for the prior-year interim period presented.

Restated Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2017:

	Three Months Ended September 30, 2017		Nine Months Ended September 30, 2017	
	As Previously Reported	As Restated	As Previously Reported	As Restated
Operating costs and expenses:				
Selling, general and administrative	$18,880	$18,527	$54,595	$55,052
Research and development	13,878	13,815	43,670	43,760
Total operating costs and expenses	51,865	51,449	154,822	155,369
Loss from operations	(15,470)	(15,054)	(55,025)	(55,572)
Loss before income taxes	(20,175)	(19,759)	(63,556)	(64,103)
Net loss	$(18,709)	$(18,293)	$(62,144)	$(62,691)
Net loss per share:				
Basic	$(0.22)	$(0.22)	$(0.78)	$(0.78)
Diluted	$(0.22)	$(0.22)	$(0.78)	$(0.78)

Restated Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2017:

	Three Months Ended September 30, 2017		Nine Months Ended September 30, 2017	
	As Previously Reported	As Restated	As Previously Reported	As Restated
Net loss	$(18,709)	$(18,293)	$(62,144)	$(62,691)
Total comprehensive loss	$(13,257)	$(12,841)	$(56,892)	$(57,439)

Other than for the correction to net loss and stock-based compensation, the restatement adjustments had no impact on cash flows from operating, investing, or financing activities for the nine months ended September 30, 2017. Furthermore, such restatement adjustments had no impact to prior period total assets, total liabilities or total stockholders' equity.

19. NEW REVENUE RECOGNITION STANDARD

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As discussed in Note 2(i), Topic 606 became effective for us on January 1, 2018. We applied the "modified retrospective" transition method for the accounting of open contracts at implementation. This resulted in the recognition of an aggregate $4.7 million increase to our January 1, 2018 retained earnings (for the tax-effected cumulative impact of initially applying this new standard, with no adjustments to our prior period financial statements). Our prior periods continue to be presented in accordance with our historical revenue accounting practices under Topic 605.

Had we continued to apply Topic 605 for our revenue recognition for the three and nine months ended September 30, 2018, the "pro forma" impact to our Condensed Consolidated Statements of Operations is presented in the table below:

	Three Months Ended September 30, 2018		
	As Reported Under Topic 606	Adjustments	If Reported Under Topic 605
Revenue:			
Product sales, net	$24,556	$ 424	$24,980
License fees and service revenue	712	(241)	471
Total revenues	$25,268	$ 183	$25,451
Loss from operations	(29,024)	183	(28,841)
Loss before income taxes	(68,716)	183	(68,533)
Net income	$(68,718)	$ 183	$(68,535)
Net income per share:			
Basic	$(0.66)	$ —	$(0.66)
Diluted	$(0.66)	$ —	$(0.66)

	Nine Months Ended September 30, 2018		
	As Reported Under Topic 606	Adjustments	If Reported Under Topic 605
Revenue:			
Product sales, net	76,419	1,985	78,404
License fees and service revenue	3,511	(177)	3,334
Total revenues	79,930	1,808	81,738
Loss from operations	(88,600)	1,808	(86,792)
Loss before income taxes	(70,784)	1,808	(68,976)
Net loss	(70,792)	1,808	(68,984)
Net loss per share:			
Basic	$(0.69)	$ 0.02	$ (0.67)
Diluted	$(0.69)	$ 0.02	$ (0.67)

Had we continued to apply Topic 605 for our revenue recognition for the three and nine months ended September 30, 2018, the “pro forma” impact to our Condensed Consolidated Balance Sheets as of September 30, 2018 is presented in the table below.

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Notes to Condensed Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)
(Unaudited)

	September 30, 2018		
	As Reported Under Topic 606	Adjustments	If Reported Under Topic 605
Current assets:			
Accounts receivable, net of allowance for doubtful accounts	29,485	(216)	29,269
Total current assets	$267,450	$ (216)	$267,234
Total assets	$412,627	$ (216)	$412,411
Current liabilities:			
Deferred revenue	—	1,885	1,885
Total current liabilities	$100,945	$ 1,885	$102,830
Deferred revenue, less current portion	—	267	267
Total liabilities	$125,849	$ 2,152	$128,001
Stockholders' equity:			
Accumulated deficit	(550,667)	(2,368)	(553,035)
Total stockholders' equity	286,778	(2,368)	284,410
Total liabilities and stockholders' equity	$412,627	$ (216)	$412,411

Had we continued to apply Topic 605 for our revenue recognition for the nine months ended September 30, 2018, the "proforma" impact to our Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 is presented in the table below:

	September 30, 2018		
	As Reported Under Topic 606	Adjustments	If Reported Under Topic 605
Net loss	$(70,792)	$ 1,808	$(68,984)
Changes in operating assets and liabilities:			
Accounts receivable, net	3,252	216	3,468
Deferred revenue	—	(2,024)	(2,024)

20. SUBSEQUENT EVENT

FDA Approval of KHAPZORY

On October 23, 2018, we obtained FDA approval to commercialize KHAPZORY (levoleucovorin) for injection, a folate analog for three indications: (i) rescue after high-dose methotrexate therapy in patients with isteosarcoma; (ii) diminishing the toxicity associated with overdosage of folic acid antagonists or impaired methotrexate elimination; and (iii) the treatment of patients with metastatic colorectal cancer in combination with fluorouracil. We completed a contractually-required licensor payment of $2.7 million for this milestone achievement that will be included within "intangible assets, net of accumulated depreciation" on our Consolidated Balance Sheets at December 31, 2018.

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ITEM 2.
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, statements regarding our future product development activities and costs, the revenue potential (licensing, royalty and sales) of our products and product candidates, the success, safety and efficacy of our drug products, revenues, development timelines, product acquisitions, accounting principles, litigation expenses, liquidity and capital resources and trends, and other statements containing forward-looking words, such as, "believes," "may," "could," "will," "expects," "intends," "estimates," "anticipates," "plans," "continues," or the negative thereof or variation thereon or similar terminology (although not all forward-looking statements contain these words). Such forward-looking statements are based on the reasonable beliefs of our management as well as assumptions made by and information currently available to our management. Readers should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in our periodic reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, as well as those discussed elsewhere in this Quarterly Report on Form 10-Q, and the following factors:

- our ability to successfully develop, obtain regulatory approval for and market our products;
- our ability to continue to grow sales revenue of our marketed products;
- risks associated with doing business internationally;
- our ability to generate and maintain sufficient cash resources to fund our business;
- our ability to enter into strategic alliances with partners for manufacturing, development and commercialization;
- efforts of our development partners;
- the ability of our manufacturing partners to meet our timelines;
- our ability to timely deliver product supplies to our customers;
- our ability to identify new product candidates and to successfully integrate those product candidates into our operations;
- the timing and/or results of pending or future clinical trials, and our reliance on contract research organizations;
- reports of adverse events or safety concerns involving each of our products;
- our ability to protect our intellectual property rights;
- competition in the marketplace for our drugs;
- delay in approval of our products or new indications for our products by the United States ("U.S.") Food and Drug Administration (the "FDA");
- the impact of legislative or regulatory reform on the pricing for pharmaceutical products;
- actions by the FDA and other regulatory agencies, including international agencies;
- securing positive reimbursement for our products;
- the impact of any product liability, or other litigation to which we are, or may become a party;
- the impact of legislative or regulatory reform of the healthcare industry and the impact of recently enacted healthcare reform legislation;
- the availability and price of acceptable raw materials and components from third-party suppliers, and their ability to meet our demands;

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- our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards, and the application and interpretation of those laws, regulations and standards, that govern or affect the pharmaceutical and biotechnology industries, the non-compliance with which may delay or prevent the development, manufacturing, regulatory approvals and sale of our products;
- defending against claims relating to improper handling, storage or disposal of hazardous chemical, radioactive or biological materials which could be time consuming and expensive;
- our ability to maintain the services of our key executives and technical and sales and marketing personnel;
- the difficulty in predicting the timing or outcome of product development efforts and regulatory approvals; and
- demand and market acceptance for our approved products.

All subsequent written and oral forward-looking statements attributable to us or by persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. We expressly disclaim any intent or obligation to update information contained in any forward-looking statement after the date thereof to conform such information to actual results or to changes in our opinions or expectations.

Company Overview

Spectrum Pharmaceuticals, Inc. (“Spectrum”, the “Company”, “we”, “our”, or “us”) is a biopharma company, with a primary strategy comprised of acquiring, developing, and commercializing a broad and diverse pipeline of clinical and commercial products. We have an in-house clinical development organization with regulatory and data management capabilities, in addition to commercial infrastructure and a field-based sales force for our marketed products. Currently, we have six approved oncology/hematology products (FUSILEV, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA) that target different types of cancer including: non-Hodgkin’s lymphoma, advanced metastatic colorectal cancer, acute lymphoblastic leukemia, and multiple myeloma.

We also have two drugs in mid-to-late stage development (in Phase 2 or Phase 3 clinical trials):

- Poziotinib, a novel pan-HER inhibitor used in the treatment of patients with a variety of solid tumors, including breast and lung cancer; and
- ROLONTIS for chemotherapy-induced neutropenia.

See Item 1. Business of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, for a discussion of:

- Company Overview
- Cancer Background and Market Size
- Product Portfolio
- Manufacturing
- Sales and Marketing
- Customers
- Competition
- Research and Development

Recent Highlights of Product Development Initiatives

We continued to make meaningful progress in the advancement of our product pipeline during 2018, as summarized below:

- poziotinib, an irreversible tyrosine kinase inhibitor:

Non-small cell lung cancer (“NSCLC”) tumors with EGFR or HER2 exon 20 insertion mutations are rare, and have generally not been responsive to several other tyrosine kinase inhibitors (“TKIs”). Consequently, there are no drugs currently approved to treat patients with these mutations, who have a poor prognosis of approximately two

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months of progression-free survival. However, poziotinib, due to its unique chemical structure and characteristics, is believed to inhibit cell growth of tumors with EGFR or HER2 exon 20 insertion mutations.

poziotinib use in Treatment of Lung Cancer

In collaboration with The University of Texas MD Anderson Cancer Center ("MD Anderson"), an investigator-sponsored Phase 2 trial was initiated in NSCLC patients with EGFR or HER2 exon 20 mutations. The EGFR cohort of 50 patients has completed enrollment; the enrollment of the HER2 cohort of 30 patients is ongoing.

The poziotinib NSCLC clinical program for patients with EGFR or HER2 exon 20 insertion mutations currently consists of this Phase 2 investigator-initiated study at MD Anderson and a Phase 2 pivotal, Spectrum-sponsored, multi-center, global study ("ZENITH20") with active sites in the U.S. and future centers planned in Canada and Europe. The overall poziotinib clinical development program is focused on four pillars, including previously treated NSCLC, first-line treatment of NSCLC, combination therapy and treatment of other solid tumors.

On April 23, 2018, poziotinib data was published in Nature Medicine from the ongoing study led by MD Anderson, which provided an update on the preliminary clinical data of poziotinib dosing on the 11 NSCLC patients previously reported at World Lung Conference on Lung Cancer in October 2017. This publication summarized the current preclinical and clinical data with poziotinib for EGFR and HER2 exon 20 mutations. MD Anderson utilized in silico, in vitro, and in vivo testing to model structural alterations induced by exon 20 mutations and identify potentially effective inhibitors. 3-D modeling indicated alterations restricted the size of the drug binding pocket, limiting the binding of large, rigid inhibitors. It was found that poziotinib, due to its small size and flexibility, can circumvent these steric changes, and is a potent inhibitor of the most common EGFR and HER2 exon 20 mutants. Poziotinib demonstrated greater activity than approved EGFR TKIs in vitro and in EGFR or HER2 exon 20 mutant patient-derived xenograft models, and genetically engineered mouse models of NSCLC.

MD Anderson reported an interim Phase 2 analysis at the World Conference on Lung Cancer on September 24, 2018 in Toronto, Canada, as follows:

- In evaluable patients with EGFR exon 20 mutations, the confirmed overall response rate (ORR) was 43% and disease control rate was 90%. Median progression free survival (PFS) was 5.5 months (ITT).
- In evaluable patients with HER2 exon 20 mutations, the confirmed overall response rate (ORR) was 42% and disease control rate was 83%. Median progression free survival (PFS) was 5.1 months (ITT).
- EGFR-related toxicities (including rash, diarrhea, and paronychia) were manageable and required dose reductions in 60% of patients. Discontinuation due to poor tolerance was rare (approximately 3% of patients).

We submitted a request for Breakthrough Therapy Designation for poziotinib in previously treated metastatic NSCLC with EGFR exon 20 mutations and we expect a response from the FDA by the end of 2018. Our ZENITH20 trial is well underway and enrolling in four distinct cohorts.

- First-line cohorts in both EGFR and HER2 were initiated in the third quarter of 2018.
- Enrollment in the EGFR, previously treated cohort is expected to be completed by the first quarter of 2019.

poziotinib use in Treatment of Breast Cancer

We are also currently enrolling patients in a Phase 2 breast cancer trial for poziotinib. The Phase 2 study is an open-label study that will enroll approximately 75 patients with HER2 positive metastatic breast cancer, who have failed at least two HER2 directed therapies. Additionally, we have recently opened a Phase 1b study that will test the combination of poziotinib and ado-trastuzumab emtansine (T-DM1) in patients with metastatic breast cancer.

- ROLONTIS, a novel long-acting G-CSF:

A pivotal Phase 3 study (ADVANCE study, or SPI-GCF-301) was initiated to evaluate ROLONTIS as a treatment for chemotherapy-induced neutropenia. The ADVANCE study is being conducted under a special protocol assessment ("SPA") with the FDA. On June 29, 2018, we announced that the ADVANCE study met the non-inferiority of ROLONTIS to pegfilgrastim endpoint in the Duration of Severe Neutropenia ("DSN") across all 4 cycles (all $p<0.0001$).

We initiated a second pivotal Phase 3 study (RECOVER study, or SPI-GCF-302), and as also announced on June 29, 2018, had met its primary efficacy endpoint of non-inferiority in DSN between ROLONTIS and pegfilgrastim.

We had a productive pre-Biologics License Application ("BLA") meeting with the FDA for ROLONTIS and we expect to file our BLA in the fourth quarter of 2018.

Data from our RECOVER study will be presented in a poster session at the San Antonio Breast Cancer Symposium in early December 2018.

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CHARACTERISTICS OF OUR REVENUE AND EXPENSES

See Item 7. Characteristics of Our Revenue and Expenses of our Annual Report on Form 10-K for the year ended December 31, 2017, for a discussion of the nature of our revenue and operating expense line items within our accompanying Condensed Consolidated Statements of Operations.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

See Item 7. Critical Accounting Policies and Estimates of our Annual Report on Form 10-K for the year ended December 31, 2017, for a discussion of significant estimates and assumptions as part of the preparation of our accompanying Condensed Consolidated Financial Statements. These critical accounting policies and estimates arise in conjunction with the following accounts:

- Revenue recognition (see Note 2(i) to our accompanying Condensed Consolidated Financial Statements for discussion regarding our January 1, 2018 adoption of the new revenue recognition standard)
- Inventories – lower of cost or market
- Fair value of acquired assets and assumed liabilities
- Goodwill and intangible assets – impairment evaluations
- Income taxes
- Stock-based compensation
- Litigation accruals (as required)

RESULTS OF OPERATIONS

Operations Overview – Three and Nine Months Ended September 30, 2018 and 2017

	Three Months Ended September 30,						Nine Months Ended September 30,					
	2018			2017			2018			2017		
	($ in thousands)						($ in thousands)					
Total revenues	$25,268	100.0	%	$36,395	100.0	%	$79,930	100.0	%	$99,797	100.0	%
Operating costs and expenses:												
Cost of sales (excludes amortization of intangible assets)	6,472	25.6	%	12,179	33.5	%	19,891	24.9	%	31,618	31.7	%
Cost of service revenue	—	—	%	—	—	%	—	—	%	4,221	4.2	%
Selling, general and administrative	19,837	78.5	%	18,527	50.9	%	67,393	84.3	%	55,052	55.2	%
Research and development	21,060	83.3	%	13,815	38.0	%	60,442	75.6	%	43,760	43.8	%
Amortization of intangible assets	6,923	27.4	%	6,928	19.0	%	20,804	26.0	%	20,718	20.8	%
Total operating costs and expenses	54,292	214.9	%	51,449	141.4	%	168,530	210.8	%	155,369	155.7	%
Loss from operations	(29,024)	(114.9)%		(15,054)	(41.4)%		(88,600)	(110.8)%		(55,572)	(55.7)%	
Interest expense, net	(12)	—	%	(2,014)	(5.5)%		(484)	(0.6)%		(6,196)	(6.2)%	
Change in fair value of contingent consideration related to acquisitions	1,200	4.7	%	(2,942)	(8.1)%		717	0.9	%	(3,236)	(3.2)%	
Other (expense) income, net	(40,880)	(161.8)%		251	0.7	%	17,583	22.0	%	901	0.9	%
Loss before income taxes	(68,716)	(271.9)%		(19,759)	(54.3)%		(70,784)	(88.6)%		(64,103)	(64.2)%	
(Provision) benefit for income taxes	(2)	—	%	1,466	4.0	%	(8)	—	%	1,412	1.4	%
Net loss	$(68,718)	(272.0)%		$(18,293)	(50.3)%		$(70,792)	(88.6)%		$(62,691)	(62.8)%	

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THREE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017

Total Revenues

	Three months ended September 30, 2018	2017	$ Change	% Change
	($ in millions)			
Product sales, net:				
FOLOTYN	$11.3	$11.6	$ (0.3)	(2.6)%
EVOMELA	6.9	10.5	(3.6)	(34.3)%
BELEODAQ	3.2	3.4	(0.2)	(5.9)%
ZEVALIN	1.5	2.7	(1.2)	(44.4)%
MARQIBO	1.1	1.2	(0.1)	(8.3)%
FUSILEV	0.6	1.8	(1.2)	(66.7)%
Total Product sales, net	$24.6	$31.2	$ (6.6)	(21.2)%
License fees and service revenue	0.7	5.2	(4.5)	(86.5)%
Total revenues	$25.3	$36.4	$ (11.1)	(30.5)%

Product sales, net. To derive net product sales, gross product revenues in each period are reduced by management's latest estimated provisions for (i) product returns, (ii) government chargebacks, (iii) prompt pay discounts, (iv) commercial rebates, (v) Medicaid rebates, and (vi) distribution, data, and group purchasing organization ("GPO"), administrative fees. Our management considers various factors in the determination of these provisions, which are described within Note 2(i)(a) to our accompanying Condensed Consolidated Financial Statements.

FOLOTYN revenue decreased $0.3 million as a result of a decrease in the number of units sold, partially offset by an increase in the average net sales price per unit in the current period.

EVOMELA revenue decreased $3.6 million as a result of both the decrease in the number of units sold and our average net sales price per unit in the current period.

BELEODAQ revenue decreased $0.2 million as a result of a decrease in the number of units sold, partially offset by an increase in the net average sales price per unit in the current period.

ZEVALIN revenue decreased $1.2 million as a result of both the decrease in the number of units sold and our average net sales price per unit in the current period.

MARQIBO revenue decreased $0.1 million as a result of a decrease in the number of units sold, partially offset by an increase in our average net sales price per unit in the current period.

FUSILEV revenue decreased $1.2 million as a result of both the decrease in the number of units sold and our average net sales price per unit, due to the competitive generic levo-leucovorin products, beginning in April 2015 (see Note 3(f) to our accompanying Condensed Consolidated Financial Statements).

License fees and service revenue. Our license fees and service revenue in the current period decreased by $4.5 million. This is due to $5 million recognized in the prior-year period for contractual milestone achievements, related to the non-recurrence of $5 million of regulatory and commercial milestone achievements of our licensee within Japan (see Note 15(b)(vii) to our accompanying Condensed Consolidated Financial Statements). This decrease was partially offset by $0.6 million increase in royalties related to our out-license of FOLOTYN (see Note 14 to our accompanying Condensed Consolidated Financial Statements).

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Operating Expenses

	Three months ended September 30,			
	2018	2017	$ Change	% Change
	($ in millions)			
Operating costs and expenses:				
Cost of sales (excludes amortization of intangible assets)	$6.5	$12.2	$ (5.7)	(46.7)%
Selling, general and administrative	19.8	18.5	1.3	7.0 %
Research and development	21.1	13.8	7.3	52.9 %
Amortization of intangible assets	6.9	6.9	—	— %
Total operating costs and expenses	$54.3	$51.4	$ 2.9	5.6 %

Cost of Sales. Cost of sales decreased $5.7 million in the current period primarily due to our net product revenue decrease, as well as our product sales mix in each period.

Selling, General and Administrative. Selling, general and administrative expenses increased $1.3 million in the current period primarily due to increases in personnel-related and employee development costs to support our current operations and future growth.

Research and Development. Research and development expenses increased by $7.3 million in the current period due to a number of factors, including: (i) $3.5 million increase in clinical and development initiatives related to poziotinib; (ii) $1.3 million increase in manufacturing costs associated with KHAPZORY (see Note 20 to our accompanying Condensed Consolidated Financial Statements); (iii) $1.2 million increase of FDA validation costs for EVOMELA production; (iv) $0.5 million increase in our development of MARQIBO single-vial formulation; and (iv) $1.9 million increase in personnel-related costs to drive these product development initiatives. These increases were partially offset by a $0.9 million decrease in expenses associated with ROLONTIS, as both the ADVANCE and RECOVER clinical studies have completed enrollment and associated costs are down as compared to the prior year period.

Amortization of Intangible Assets. Amortization expense remained consistent compared to the prior year period.

Total Other Expense

	Three months ended September 30,			
	2018	2017	$ Change	% Change
	($ in millions)			
Total other expense	$(39.7)	$(4.7)	$ (35.0)	(744.7)%

Total other expense. Total other expense increased by $35.0 million primarily due to $40.9 million increase in unrealized loss on our CASI Pharmaceuticals, Inc. equity securities, which are now recorded within “other (expense) income, net” rather than “other comprehensive (loss) income” due to our adoption of ASU 2016-01 (see Note 3(a) to our accompanying Condensed Consolidated Financial Statements). This increase was partially offset by (i) $4.1 million decrease in the fair value of contingent consideration related to our MARQIBO product (see Note 9(a) to our accompanying Condensed Consolidated Financial Statements), and (ii) $2 million decrease in interest expense on our 2.75% Convertible Senior Notes due December 2018 (the “2018 Convertible Notes”) as a result of our October 2017 repurchase of $69.5 million of principal value (see Note 13 to our accompanying Condensed Consolidated Financial Statements).

(Provision) Benefit for Income Taxes

	Three months ended

	September 30, 2018	2017	$ Change	% Change
	($ in millions)			
(Provision) benefit for income taxes	$ —	$ 1.5	$ (1.5)	(100.0)%

For the three months ended September 30, 2018, there was nominal domestic provision for income taxes due to our pre-tax loss from operations. A $2 thousand tax provision for foreign taxes was recorded within “(provision) benefit for income

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taxes" on our Condensed Consolidated Statements of Operations for the three months ended September 30, 2018. Due to a required intraperiod allocation of tax expense for the three months ended September 30, 2017 we recorded a benefit for income taxes of $1.5 million in continuing operations as a result of unrealized gains recognized in "other comprehensive (loss) income" on our Condensed Consolidated Statements of Comprehensive Loss. As a result of the unrealized gains, we recorded $2 million of tax expense within "other comprehensive (loss) income" on our Condensed Consolidated Statements of Comprehensive Loss for the three months ended September 30, 2017.

NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017

Total Revenues

	Nine months ended September 30, 2018	2017	$ Change	% Change
	($ in millions)			
Product sales, net:				
FOLOTYN	35.7	32.0	$ 3.7	11.6 %
EVOMELA	20.8	26.9	$ (6.1)	(22.7)%
BELEODAQ	8.6	9.7	$ (1.1)	(11.3)%
ZEVALIN	6.1	7.9	$ (1.8)	(22.8)%
MARQIBO	3.2	5.4	$ (2.2)	(40.7)%
FUSILEV	$2.0	$6.4	$ (4.4)	(68.8)%
Total Product sales, net	$76.4	$88.3*	$ (11.9)	(13.5)%
License fees and service revenue	3.5	11.6	(8.1)	(69.8)%
Total revenues	$79.9	$99.9*	$ (20.0)	(20.0)%

* Does not agree to the face of the accompanying Condensed Consolidated Statements of Operations for the nine months ended September 30, 2018 by an immaterial amount due to rounding.

Product sales, net. To derive net product sales, gross product revenues in each period are reduced by management's latest estimated provisions for (i) product returns, (ii) government chargebacks, (iii) prompt pay discounts, (iv) commercial rebates, (v) Medicaid rebates, and (vi) distribution, data, and GPO administrative fees. Our management considers various factors in the determination of these provisions, which are described within Note 2(i)(a) to our accompanying Condensed Consolidated Financial Statements.

FOLOTYN revenue increased $3.7 million due to an increase in our average net sales price per unit, partially offset by a decrease in units sold during the period.

EVOMELA revenue decreased $6.1 million due to a decrease in our average net sales price per unit.

BELEODAQ revenue decreased $1.1 million due to a decrease in units sold during the period, partially offset by an increase in our average net sales price per unit.

ZEVALIN revenue decreased $1.8 million due to a decrease in units sold in the U.S. territory, partially offset by an increase in product sales to Mundipharma for end-users in Japan (see Note 11).

MARQIBO revenue decreased $2.2 million due to a decrease in units sold during the period, partially offset by an increase in our average net sales price per unit.

FUSILEV revenue decreased $4.4 million as a result of both the decrease in the number of units sold and our average net sales price per unit, due to the competitive generic levo-leucovorin products, beginning in April 2015 (see Note 3(f)) to our accompanying Condensed Consolidated Financial Statements).

License fees and service revenue. Our license fees and service revenue in the current period decreased by $8.1 million primarily due to the following: (i) $4 million decrease in FOLOTYN royalties, primarily related to the non-recurrence of $5 million of regulatory and commercial milestone achievements of our licensee within Japan (see Note 15(b)(vii) to our accompanying Condensed Consolidated Financial Statements); and (ii) $4.7 million of non-recurring service revenue from our expired co-promotion arrangement with Eagle Pharmaceuticals, Inc. (see Note 12 to our

accompanying Condensed Consolidated Financial Statements), partially offset by a $0.8 million increase in ZEVALIN license fees.

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Operating Expenses

	Nine months ended September 30,			
	2018	2017	$ Change	% Change
	($ in millions)			
Operating costs and expenses:				
Cost of sales (excludes amortization of intangible assets)	$19.9	$31.6	$ (11.7)	(37.0)%
Cost of service revenue	—	4.2	(4.2)	(100.0)%
Selling, general and administrative	67.4	55.1	12.3	22.3 %
Research and development	60.4	43.8	16.6	37.9 %
Amortization of intangible assets	20.8	20.7	0.1	0.5 %
Total operating costs and expenses	$168.5	$155.4	$ 13.1	8.4 %

Cost of Sales. Cost of sales decreased $11.7 million in the current period primarily due to our net product revenue decrease, as well as our product sales mix in each period.

Cost of Service Revenue. Cost of service revenue relates to our allocated commercial and marketing expenses (from “selling, general, and administrative” expenses) for the fee-based promotion and sale of Eagle Pharmaceuticals, Inc.’s products by our sales force. Our cost of service revenue decreased by the full $4.2 million incurred in the prior period, as we ceased marketing these products as of July 1, 2017 (see Note 12 to our accompanying Condensed Consolidated Financial Statements).

Selling, General and Administrative. Selling, general and administrative expenses increased by $12.3 million in the current period primarily due to (i) the non-recurrence of certain sales and marketing costs in the prior period, aggregating $4.2 million, that were allocated from this account to “cost of service revenue” (see above); (ii) $3.2 million increase in personnel-related costs largely attributed to increased stock-based compensation expense of $2.1 million, and $1.0 million of Nevada payroll tax expense related to stock option exercises by our former chief executive officer; (iii) $3 million increase in litigation expenses primarily associated with the termination of our former chief executive officer in December 2017; (iv) $1.2 million increase in consulting expenses, given our key initiatives, including the expected commercial launch of ROLONTIS in late 2019, and our ongoing clinical trials for poziotinib; and (v) $0.7 million increase in various other costs to support our current operations and planned growth.

Research and Development. Research and development expenses increased by $16.6 million in the current period due to a number of factors, including (i) $11.4 million increase in clinical and development initiatives largely related to poziotinib; (ii) $3.8 million increase in personnel-related costs to drive our product development; (iii) $2.8 million increase in the development of KHAPZORY (primarily due to a $1.2 million FDA filing fee for its NDA, a corresponding $0.3 million milestone payment to a licensor, and associated manufacturing costs) (see Note 20 our accompanying Condensed Consolidated Financial Statements); (iv) $0.8 million in technical transfer costs associated with ZEVALIN production; and (v) $0.6 million increase in new contract manufacturer validation for EVOMELA. These increases were partially offset by a $3.3 million decrease in clinical trial expenses associated with ROLONTIS, as both the ADVANCE and RECOVER studies have completed enrollment and associated costs are significantly reduced as compared to the prior year period.

Amortization and Impairment Charges of Intangible Assets. Amortization expense remained consistent compared to the prior year period.

Total Other Income (Expense)

	Nine months ended September 30,			
	2018	2017	$ Change	% Change

	($ in millions)			
Total other income (expense)	$17.8	$(8.5)	$ 26.3	309.4 %

Total other income (expense). Total other income (expense) increased by $26.3 million primarily due to (i) $17.7 million increase in unrealized gain on our CASI Pharmaceuticals, Inc. equity securities, which are now recorded within “other (expense) income, net” rather than “other comprehensive (loss) income” due to our adoption of ASU 2016-01 (see Note 3(a) to our accompanying Condensed Consolidated Financial Statements); (ii) $5.7 million decrease in interest expense primarily due to our 2018 Convertible Notes as a result of our October 2017 repurchase of $69.5 million of principal value (see Note 13 to our

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accompanying Condensed Consolidated Financial Statements); and (iii) $3.9 million decrease in the fair value of contingent consideration related to our MARQIBO product (see Note 9(b) to our accompanying Condensed Consolidated Financial Statements), partially offset by $0.9 million increase in executive deferred compensation as a result of decreases in fair value of corresponding plan assets (see Note 15(f) to our accompanying Condensed Consolidated Financial Statements).

(Provision) benefit for Income Taxes

	Nine months ended September 30, 2018	2017	$ Change	% Change
	($ in millions)			
(Provision) benefit for income taxes	$ —	$ 1.4	$ (1.4)	100.0 %

Our provision for income taxes of $8 thousand for the nine months ended September 30, 2018, is primarily due to increases in our deferred tax liabilities associated with indefinite lived assets which in turn result in an increased valuation allowance on our deferred tax assets. For the nine months ended September 30, 2017 we recorded a benefit for income taxes of $1.4 million within our Condensed Consolidated Statements of Operations due to a required intraperiod allocation of tax expense, resulting in unrealized gains within “other comprehensive (loss) income” on our Condensed Consolidated Statements of Comprehensive Loss. As a result of the unrealized gains, we recorded $2 million of tax expense within “other comprehensive (loss) income” on our Condensed Consolidated Statements of Comprehensive Loss for the nine months ended September 30, 2017.

LIQUIDITY AND CAPITAL RESOURCES

	September 30, 2018	December 31, 2017	September 30, 2017
	(in thousands, except financial metrics data)		
Cash, cash equivalents, and marketable securities*	$ 220,555	$ 227,571	$ 247,716
Accounts receivable, net	$ 29,485	$ 32,260	$ 37,767
Total current assets	$ 267,450	$ 277,746	$ 303,299
Total current liabilities	$ 100,945	$ 109,749	$ 60,207
Working capital surplus (a)	$ 166,505	$ 167,997	$ 243,092
Current ratio (b)	2.6	2.5	5.0

* Beginning March 31, 2018, we prospectively reclassified our presentation of equity holdings in CASI (see Note 3(a) and Note 10 to our accompanying Condensed Consolidated Financial Statements) from the caption of “other assets” to “marketable securities.”

(a) Total current assets at period end minus total current liabilities at period end.
(b) Total current assets at period end divided by total current liabilities at period end.

Net Cash Used In Operating Activities

Net cash used in operating activities was $50.1 million for the nine months ended September 30, 2018, as compared to $26 million in the prior year period. For the nine months ended September 30, 2018 and 2017, our cash collections from customers totaled $91.9 million and $119.1 million, respectively, representing 115.0% and 121.8% of reported net revenue for the same nine-month periods. For the nine months ended September 30, 2018 and 2017, cash payments for products, services, chargebacks, and rebates to our employees, vendors, and product end-users totaled $153.5 million and $149.7 million, respectively.

Net Cash Provided by (Used In) Investing Activities

Net cash provided by investing activities was $4.1 million for the nine months ended September 30, 2018, as compared to $1 million of cash used in investing activities during the prior year period. The cash provided by investing activities for the nine months of 2018 primarily relates to $4.1 million of proceeds received from the redemption of our corporate-owned life insurance policy.

Net Cash (Used In) Provided by Financing Activities

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Net cash used in financing activities was $14.5 million for the nine months ended September 30, 2018, as compared to $115.9 million provided by financing activities in the prior year period. Our cash used in financing activities during the first nine months of 2018 primarily relates to our $27.7 million of aggregate payments to federal and state tax authorities related to our employees' tax liabilities at the time of stock vestings and exercises. We made these payments in return for an equivalent value of surrendered shares by our employees. This outflow was partially offset by: (i) $4.6 million of proceeds received from employees related to remittances to federal and state tax authorities for taxes due at vesting/exercise of equity awards, (ii) $7.8 million of proceeds as a result of the exercise of employee stock options, and (iii) $0.7 million of proceeds from the sale of equity under our employee stock purchase plan.

2018 Convertible Notes

In December 2013, we entered into an agreement for the sale of our 2018 Convertible Notes in the aggregate amount of $120 million. The 2018 Convertible Notes bear interest at a rate of 2.75% per year, payable semiannually in arrears on June 15 and December 15 of each year. The 2018 Convertible Notes will mature and become payable on December 15, 2018, subject to earlier conversion into common stock at the holders' option. As of September 30, 2018 and December 31, 2017, an aggregate amount of $35.8 million and $40.6 million of principal of the 2018 Convertible Notes remained outstanding, respectively, due to our open market purchases of these instruments in December 2016 and October 2017, as well as $4.7 million of principal value, converted by a holder in July 2018 into 451,300 common shares (see Note 13 to our accompanying Condensed Consolidated Financial Statements).

The 2018 Convertible Notes are convertible into shares of our common stock at a current conversion rate of 95 shares per $1,000 principal amount of the 2018 Convertible Notes, or a conversion price of approximately $10.53 per common share. Our stockholders' approved "flexible settlement" at our Annual Meeting of Stockholders on June 29, 2015, though on September 27, 2018, we elected to exclusively settle any and all conversions with our common stock. As a result, a maximum of approximately 3.4 million common shares would have been issued if the 2018 Convertible Notes had been converted in full on September 30, 2018. If the holders of our 2018 Convertible Notes do not elect to convert, our December 2018 obligation to repay the remaining principal amount of $35.8 million in cash, plus any accrued and unpaid interest, will remain unchanged.

Sale of Common Stock Under ATM Agreements

In December 2015 and August 2017, we entered into collective at-market-issuance sales agreements with FBR Capital Markets & Co., MLV & Co. LLC, and H.C. Wainwright & Co., LLC. These agreements allowed us to raise aggregate gross proceeds through these brokers of up to $250 million from the sale of our common stock on the public market.

Through September 30, 2018, we had raised aggregate gross net proceeds of $202.1 million through these at-market sales, of which $128.3 million was raised during the year ended December 31, 2017. We had no sales under the ATM during the nine months ended September 30, 2018. We are using these proceeds to continue to develop our product pipeline and to provide additional capital structure flexibility.

Future Capital Requirements

We believe that the future growth of our business will depend on our ability to successfully develop and acquire new drugs for the treatment of cancer and successfully bring these drugs to market.

The timing and amount of our future capital requirements will depend on many factors, including:

- the need for additional capital to fund future development programs;
- the need for additional capital to fund strategic acquisitions;
- the need for additional capital to fund licensing arrangements;
- our requirement for additional information technology infrastructure and systems; and
- adverse outcomes from potential litigation and the cost to defend such litigation.

We believe that our $221 million in aggregate cash and equivalents and marketable securities as of September 30, 2018 will allow us to fund our current and planned operations into 2020. However, we may seek additional capital through the sale of debt or equity securities, if necessary, especially in conjunction with opportunistic acquisitions or licensing arrangements. We may be unable to obtain such additional capital on terms favorable to us or our current stockholders and convertible senior note holders, if at all.

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Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements (except for operating leases) that provide financing, liquidity, market or credit risk support, or involve derivatives. In addition, we have no arrangements that may expose us to liability that are not expressly reflected in the accompanying Condensed Consolidated Financial Statements and/or notes thereto. As of September 30, 2018, we did not have any relationships with unconsolidated entities or financial partnerships, often referred to as "structured finance" or "special purpose entities," established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not subject to any material financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the normal course of business, our operations are exposed to risks associated with fluctuations in interest rates, credit ratings and foreign currency exchange rates.

The primary objective of our investment activities is to preserve principal, while at the same time maximizing yields without significantly increasing risk. We do not utilize hedging contracts or similar instruments, except with respect to the 2018 Convertible Notes (see Note 13 to our accompanying Condensed Consolidated Financial Statements). Because of our ability to generally redeem these investments at par at short notice and without penalty, changes in interest rates would have an immaterial effect on the fair value of these investments. If a 10% change in interest rates were to have occurred on September 30, 2018, any decline in the fair value of our investments would not be material in the context of our accompanying Condensed Consolidated Financial Statements. In addition, we are exposed to certain market risks associated with credit ratings of corporations whose corporate bonds we may purchase from time to time. If these companies were to experience a significant detrimental change in their credit ratings, the fair market value of such corporate bonds may significantly decrease. If these companies were to default on these corporate bonds, we may lose part or all of our principal. We believe that we effectively manage this market risk by diversifying our investments, and investing in highly-rated securities.

We are exposed to foreign currency exchange rate fluctuations relating to payments we make to vendors, suppliers and license partners in Euros (and other currencies to a lesser extent). We mitigate such risk by maintaining a limited portion of our cash in Euros.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. These include controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our chief executive officer and chief financial officer concluded that, as of that date, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the third fiscal quarter of 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations of the Effectiveness of Internal Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the internal control system are met. Because of inherent limitations in any control systems, no

evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. We continuously seek to improve the efficiency and effectiveness of our operations and of our internal controls.

PART II. OTHER INFORMATION

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ITEM 1. LEGAL PROCEEDINGS

We are involved from time-to-time with various legal matters arising in the ordinary course of business. These claims and legal proceedings are of a nature we believe are normal and incidental to a pharmaceutical business, and may include product liability, intellectual property, employment matters, and other general claims. We may also be subject to derivative lawsuits from time to time.

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 assessed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. Although the ultimate resolution of these various matters cannot be determined at this time, we do not believe that such matters, individually or in the aggregate, will have a material adverse effect on our consolidated results of operations, cash flows, or financial condition.

Certain of the legal proceedings in which we are involved are discussed in Note 15, “Financial Commitments & Contingencies and License Agreements,” to our accompanying Condensed Consolidated Financial Statements, and are hereby incorporated by reference.

ITEM 1A. RISK FACTORS

As of the date of this filing, there have been no material changes to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on March 7, 2018.

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ITEM 6. EXHIBITS

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation of Spectrum Pharmaceuticals, Inc.	8-K	001-35006	3.1	6/18/18	
3.2	Third Amended and Restated Bylaws of Spectrum Pharmaceuticals, Inc.	8-K	001-35006	3.2	3/29/18	
10.1	Amended and Restated Spectrum Pharmaceuticals, Inc. 2009 Employee Stock Purchase Plan					X
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) promulgated under the Securities Exchange Act of 1934.					X
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a) promulgated under the Securities Exchange Act of 1934.					X
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b)/15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.					X
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b)/15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.					X
101.INS	XBRL Instance Document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

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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.

SPECTRUM PHARMACEUTICALS, INC.

Date: November 8, 2018 By: /s/ Kurt A. Gustafson
Kurt A. Gustafson
Executive Vice President and Chief Financial Officer
(Authorized Signatory and Principal Financial and Accounting Officer)