SPECTRUM PHARMACEUTICALS INC
Form 10-Q
November 06, 2015
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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, 2015

.. 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes ý No ¨

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

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

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

As of October 31, 2015, 67,339,944 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, 2015
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Item 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, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$136,527	$129,942
Marketable securities	245	3,306
Accounts receivable, net of allowance for doubtful accounts of $131 and $120, respectively	48,150	70,758
Other receivables	13,495	5,489
Inventories	7,071	9,200
Prepaid expenses	3,963	3,774
Deferred tax assets	82	—
Total current assets	209,533	222,469
Property and equipment, net of accumulated depreciation	1,079	1,405
Intangible assets, net of accumulated amortization	201,184	230,100
Goodwill	18,023	18,195
Other assets	17,842	17,864
Total assets	$447,661	$490,033
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$79,264	$84,994
Accrued payroll and benefits	7,140	8,444
Deferred revenue	9,990	9,959
Drug development liability	573	1,141
Acquisition-related contingent obligations	5,373	4,901
Total current liabilities	102,340	109,439
Drug development liability, less current portion	13,827	14,644
Deferred revenue, less current portion	407	—
Acquisition-related contingent obligations, less current portion	2,534	2,441
Deferred tax liability	6,659	6,569
Other long-term liabilities	6,963	6,088
Convertible senior notes	100,192	96,298
Total liabilities	232,922	235,479
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized:		
Series B junior participating preferred stock, $0.001 par value; 1,500,000 shares authorized; no shares issued and outstanding	—	—
Series E Convertible Voting Preferred Stock, $0.001 par value and $10,000 stated value; 2,000 shares authorized; 20 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively (convertible into 40,000 shares of common stock, with aggregate liquidation value of $240)	123	123

Common stock, $0.001 par value; 175,000,000 shares authorized; 67,314,580 and 65,969,699 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	66	66
Additional paid-in capital	548,232	538,553
Accumulated other comprehensive loss	(3,712)	(850)
Accumulated deficit	(329,970)	(283,338)
Total stockholders' equity	214,739	254,554
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$447,661	$490,033

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,	
	2015	2014	2015	2014
Revenues:				
Product sales, net	$28,457	$47,916	$102,014	$134,867
License fees and service revenue	170	74	10,212	102
Total revenues	$28,627	$47,990	$112,226	$134,969
Operating costs and expenses:				
Cost of product sales (excludes amortization of intangible assets)	8,447	6,530	21,508	18,964
Selling, general and administrative	19,411	24,125	65,297	72,927
Research and development	9,924	14,420	35,333	55,252
Amortization and impairment of intangible assets	6,919	7,042	27,857	17,763
Total operating costs and expenses	44,701	52,117	149,995	164,906
Loss from operations	(16,074)	(4,127)	(37,769)	(29,937)
Other expenses:				
Interest expense, net	(2,274)	(2,361)	(6,760)	(6,404)
Change in fair value of contingent consideration related to acquisitions	81	(181)	(565)	(1,910)
Other expense, net	(535)	(1,393)	(1,501)	(2,238)
Total other expenses	(2,728)	(3,935)	(8,826)	(10,552)
Loss before income taxes	(18,802)	(8,062)	(46,595)	(40,489)
Benefit (provision) for income taxes	78	(3,477)	(37)	(2,254)
Net loss	$(18,724)	$(11,539)	$(46,632)	$(42,743)
Net loss per share:				
Basic and diluted	$(0.28)	$(0.18)	$(0.71)	$(0.66)
Weighted average shares outstanding:				
Basic and diluted	65,855,727	64,765,072	65,457,060	64,369,466

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,	
	2015	2014	2015	2014
Net loss	$(18,724)	$(11,539)	$(46,632)	$(42,743)
Other comprehensive (loss) income, net of income tax:				
Unrealized (loss) gain on available-for-sale securities	(3,934)	706	(949)	1,364
Adjustment for realized loss on available-for-sale securities, and included in net income	—	(2,217)	—	(2,217)
Foreign currency translation adjustments	387	897	(1,913)	1,080
Other comprehensive (loss) income	(3,547)	(614)	(2,862)	227
Total comprehensive loss	$(22,271)	$(12,153)	$(49,494)	$(42,516)

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,	
	2015	2014
Cash Flows From Operating Activities:		
Net loss	$(46,632)	$(42,743)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21,235	18,692
Stock-based compensation	8,490	8,589
Accretion of debt discount, recorded to interest expense on 2018 Convertible Notes (Note 11)	3,895	3,556
Amortization of deferred financing costs, recorded to interest expense on 2018 Convertible Notes (Note 11)	493	443
Bad debt (recovery) expense	11	(46)
Impairment of intangible assets (Note 3(f))	7,160	—
Unrealized foreign currency exchange loss	435	4,469
Research and development expense recognized for the value of stock issued in connection with BELEODAQ in-license milestone achievement (Note 13(b)(x))	—	7,790
Change in fair value of contingent consideration related to Talon and EVOMELA acquisitions (Note 9)	565	1,910
Changes in operating assets and liabilities:		
Accounts receivable, net	22,537	(10,556)
Other receivables	(8,008)	(1,809)
Inventories	2,127	3,576
Prepaid expenses	(133)	(1,292)
Deferred tax assets	(147)	1,521
Intangible assets, net	—	(25,000)
Other assets	(1,398)	(13,803)
Accounts payable and other accrued obligations	(5,638)	21,964
Accrued payroll and benefits	(1,286)	(9)
Drug development liability	(1,385)	(1,340)
Deferred revenue	359	9,803
Deferred tax liability	89	(179)
Other long-term liabilities	874	(179)
Net cash provided by (used in) operating activities	3,643	(14,643)
Cash Flows From Investing Activities:		
Proceeds from sale of available-for-sale securities	3,061	4,093
Purchases of property and equipment	(212)	(808)
Net cash provided by investing activities	2,849	3,285
Cash Flows From Financing Activities:		
Proceeds from exercise of stock options	1,482	1,460
Proceeds from sale of stock under employee stock purchase plan	335	348
Purchase and retirement of restricted stock to satisfy employee tax liability at vesting	(629)	(684)
Net cash provided by financing activities	1,188	1,124
Effect of exchange rates on cash and equivalents	(1,095)	(1,838)

Net increase (decrease) in cash and cash equivalents	6,585	(12,072)
Cash and cash equivalents—beginning of period	129,942	156,306
Cash and cash equivalents—end of period	$136,527	$144,234
Supplemental disclosure of cash flow information:		
Out-license proceeds for MARQIBO, ZEVALIN, and EVOMELA in China territory (Note 10) included in other assets	$—	$9,959
In-license payment for BELEODAQ (Note 13(b)(x))	$—	$25,000
Cash paid for income taxes	$332	$329
Cash paid for interest	$1,650	$1,588

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 biotechnology company, with a prima focus on oncology and hematology. Our strategy is comprised of the (i) commercialization of cancer therapeutics through our U.S. direct sales force and our international licensees and distributors, (ii) completion of clinical studies for new indications of our marketed products, and (iii) acquisition, development, and marketing of a broad and diverse pipeline of late-stage clinical and commercial drug compounds.

We currently market five intravenous drug products for cancer treatment:

- FUSILEV® injection for patients with advanced metastatic colorectal cancer and to counteract certain effects of methotrexate therapy;
- ZEVALIN® injection for patients with follicular non-Hodgkin's lymphoma;
- FOLOTYN® injection for patients with relapsed or refractory peripheral T-cell lymphoma;
- MARQIBO® injection for patients with Philadelphia chromosome–negative acute lymphoblastic leukemia; and
- BELEODAQ® injection for patients with relapsed or refractory peripheral T-cell lymphoma

We also have ongoing indication expansion clinical studies with some of our marketed products, and have a diversified pipeline of product candidates in Phase 2 and Phase 3 clinical studies.

(b) Basis of Presentation

Interim Financial Statements

The interim financial data as of September 30, 2015 and 2014 is unaudited and is not necessarily indicative of our 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, 2015 and 2014. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") have been condensed or omitted pursuant to U.S. Securities and Exchange Commission ("SEC") rules and regulations relating to interim financial statements. The December 31, 2014 balances reported herein are derived from the audited Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2014. The accompanying Condensed Consolidated Financial Statements should be read in conjunction with our audited Consolidated Financial Statements and Notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on March 13, 2015.

Principles of Consolidation

The accompanying Condensed Consolidated Financial Statements have been prepared in accordance with GAAP and under 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 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 Spectrum Pharma Canada ("SPC"), a legal entity organized in Quebec, Canada in January 2008. Certain of our drug clinical studies are conducted through this "variable interest entity" (as defined under applicable GAAP) and we fund all of SPC's operating costs. Since we carry the full risks and rewards of SPC, we meet the applicable GAAP

criteria as being its "primary beneficiary." 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

We operate in one reportable operating segment that is focused exclusively on developing and commercializing oncology and hematology drug products. For the three and nine months ended September 30, 2015 and 2014, all of our revenue and related expenses were solely attributable to these activities. Substantially all of our assets (excluding our cash held in certain foreign bank accounts and our ZEVALIN distribution rights for the Ex-U.S. territory) 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 the reported amounts of assets, liabilities, revenues, and expenses. However, actual values may materially differ, since estimates are inherently uncertain. On an on-going basis, our management evaluates its 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 inventories can be recovered; (v) the fair value of goodwill and intangible assets; (vi) the realization of tax assets and estimates of tax liabilities; (vii) the likelihood of payment and value of contingent liabilities; (viii) the fair value of investments; (ix) the valuation of stock options and the periodic expense recognition of stock-based compensation; and (x) the potential outcome of ongoing or threatened litigation.

The estimates and assumptions that most significantly impact the presented amounts within these accompanying Condensed Consolidated Financial Statements are further described below:

(i) Revenue Recognition

(a) Product Sales: We sell our products to 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 when title and risk of loss have transferred to our customer, and the following additional criteria are met:

(1) appropriate evidence of a binding arrangement exists with our customer;
(2) price is substantially fixed and determinable;
(3) collection from our customer is reasonably assured;
(4) our customer's obligation to pay us is not contingent on resale of the product;
(5) we do not have significant continued performance obligations to our customer; and
(6) we have a reasonable basis to estimate returns.

Our gross revenue is reduced by our gross-to-net ("GTN") estimates each period, resulting in our reported "product sales, net" in the accompanying Condensed Consolidated Statements of Operations. We defer revenue recognition in full if these estimates are not reasonably determinable at the time of sale. These estimates are based upon information received from external sources (such as written and oral information obtained from our customers with respect to their period-end inventory levels, and their sales to end-users during the period), in combination with management's informed judgments. Due to the inherent uncertainty of estimates, the actual amount we incur may be materially different than our GTN estimates, and require prospective revenue adjustments in periods after the initial sale was recorded.

Our GTN estimates are comprised of the following categories:

Product Returns Allowances: Our FUSILEV, MARQIBO, and BELEODAQ customers are permitted to return purchased product beginning at its expiration date, and within six months thereafter. Returned product is generally not resold. Returns for expiry of ZEVALIN and FOLOTYN are not contractually, or customarily, allowed. We estimate expected returns based on our historical return rates.

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(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)
(Unaudited)

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 product 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 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: We recognize revenue for our licensing of intellectual property to third-parties (out-licenses), based on the contractual terms of each agreement and our application of pertinent GAAP. This revenue may be associated with upfront license fees, milestone payments from our licensees' sales or regulatory achievements, and royalties from our licensees' sales in applicable territories.

(c) Service Revenue: We receive fees from third-parties under certain arrangements for our research and development activities, clinical trial management, and supply chain services. Payment may be triggered by the successful completion of a phase of development, results from a clinical trial, regulatory approval events, or completion of product delivery in our capacity as an agent in such arrangement. We recognize revenue when the corresponding milestone is achieved, or the revenue is otherwise earned and due to us through our on-going activities.

(d) New Revenue Recognition Standard: On April 1, 2015, the FASB voted for a one-year deferral of the effective date of the new revenue recognition standard, ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"). ASU 2014-09 is now effective for us beginning January 1, 2018, requiring revenue recognition in a manner that reasonably reflects the delivery of our goods or services to customers in return for expected consideration. To achieve this core principle, the guidance provides the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

We continue to evaluate the impact of ASU 2014-09 to our current revenue recognition models for product sales, license fees, and service revenue, as described above.

(ii) Cash and Equivalents

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

(iii) Marketable Securities

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Our marketable securities consist of our holdings in mutual funds and bank certificates of deposit. Since we classify these securities as “available-for-sale” under applicable GAAP, any unrealized gains or losses from their change in value is reflected in “unrealized gain on available-for-sale securities” on the accompanying Condensed Consolidated Statements of Comprehensive Loss. Realized gains and losses on available-for-sale securities are included in “other expense, net” on the accompanying Condensed Consolidated Statements of Operations.

(iv) Accounts Receivable

Our accounts receivables are derived from our product sales, license fees, and service revenue, 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 current market value. Inventory cost is determined on the first-in, first-out method (FIFO). 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.

Direct and indirect manufacturing costs related to the production of inventory prior to U.S. Food and Drug Administration ("FDA") approval are expensed through “research and development,” rather than being capitalized to inventory cost.

(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 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

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 (by termination of employment or

service) prior to vesting. We use the Black-Scholes option pricing model to determine the fair value of stock options (as of the date of grant) which carry service conditions for vesting. We use the Monte Carlo valuation model to value equity awards (as of the date of grant) which carry combined market conditions and service conditions for vesting. The calculation of the fair value of stock options and the recognition of stock-based compensation expense requires uncertain assumptions, including (a) the pre-vesting forfeiture rate of the award, (b) the expected term of the stock option, (c) the stock price volatility over the term of the stock option, and (d) the risk-free interest rate over the term of the stock option.

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 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. Treasury yields in effect at award grant, for a period equaling the stock options' expected term.

(ix) Foreign Currency Transactions and Translation

We translate the assets and liabilities of our foreign subsidiaries that are stated in their functional currencies (i.e., local operating currencies), 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 the translation of our subsidiaries' financial statements (that are initially denominated in the corresponding functional currency) are included as a separate component of "accumulated other comprehensive loss" in the Condensed Consolidated Balance Sheets.

We record foreign currency transactions, when initially denominated in a currency other than the respective functional currency of our subsidiary, at the prevailing exchange rate on the date of the transaction. Resulting unrealized foreign exchange gains and losses from transactions with third parties are included in "accumulated other comprehensive loss" in the Condensed Consolidated Balance Sheets.

Beginning April 1, 2015, all unrealized foreign exchange gains and losses associated with our intercompany loans were included in "accumulated other comprehensive loss" in the Condensed Consolidated Balance Sheets, as these loans with our foreign subsidiaries are no longer expected to be settled in the "foreseeable future." For the period January 1, 2015 through March 31, 2015, unrealized foreign exchange gains and losses associated with our intercompany loans were included in "accumulated other comprehensive loss" in the Condensed Consolidated Balance Sheets and in "other expense, net" in the Condensed Consolidated Statements of Operations. In periods prior to January 1, 2015, all unrealized foreign exchange gains and losses associated with intercompany loans were included in "other expense, net" in the Condensed Consolidated Statements of Operations.

(x) Basic and Diluted Net (Loss) Income per Share

We calculate basic and diluted net (loss) income 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 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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(Unaudited)

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 “benefit (provision) for income taxes” within the Condensed Consolidated Statements of Operations in the period the notice was received.

(xii) Research and Development Costs

Our research and development costs are expensed as incurred, or as certain milestone payments become due, generally triggered by 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. The fair value hierarchy gives the lowest priority to Level 3 inputs.

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(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)
(Unaudited)

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, 2015 and December 31, 2014, our holdings included within “cash and cash equivalents” and “marketable securities” were at major financial institutions.

Our investment policy requires that investments in marketable securities be in only highly-rated instruments, which are primarily U.S. treasury bills or U.S. treasury-backed securities, and limited investments in securities of any single issuer. We maintain cash balances in excess of federally insured limits with reputable financial institutions. To a limited degree, the Federal Deposit Insurance Corporation (FDIC) 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 on our portfolio by investing in highly liquid, highly rated instruments, and limit investing in long-term maturity instruments.

The carrying amount of our equity securities, money market funds, bank certificate of deposits, and mutual funds 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 “cash and cash equivalents” and “marketable securities”:

						Marketable Securities	
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated fair Value	Cash and cash equivalents	Current	Long Term
September 30, 2015							
Bank deposits	$56,441	$—	$—	$56,441	$56,441	$—	$—
Money market funds	80,086	—	—	80,086	80,086	—	—
Bank certificates of deposits	245	—	—	245	—	245	—
Mutual funds	—	—	—	—	—		—
Total cash and equivalents and marketable securities	$136,772	$—	$—	$136,772	$136,527	$245	$—
December 31, 2014							
Bank deposits	$62,997	$—	$—	$62,997	$62,997	$—	$—
Money market funds	66,945	—	—	66,945	66,945	—	—
Bank certificates of deposits	244	—	—	244	—	244	—
Mutual funds	3,062	—	—	3,062	—	3,062	—
Total cash and equivalents and marketable securities	$133,248	$—	$—	$133,248	$129,942	$3,306	$—

As of September 30, 2015, none of these securities had been in a continuous unrealized loss position longer than one year.

(b) Property and Equipment

“Property and equipment, net of accumulated depreciation” consist of the following:

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	September 30, 2015	December 31, 2014
Computer hardware and software	$3,822	$3,616
Laboratory equipment	609	643
Office furniture	348	344
Leasehold improvements	2,872	2,847
Property and equipment, at cost	7,651	7,450
(Less): Accumulated depreciation	(6,572)	(6,045)
Property and equipment, net of accumulated depreciation	$1,079	$1,405

Depreciation expense (included within “total operating costs and expenses” in the accompanying Condensed Consolidated Statements of Operations) for the nine months ended September 30, 2015 and 2014, was $0.5 million and $0.9 million, respectively.

(c) Inventories
“Inventories” consist of the following:

	September 30, 2015	December 31, 2014
Raw materials	$1,057	$1,507
Work-in-process*	4,001	3,979
Finished goods	2,013	3,714
Inventories	$7,071	$9,200

*We have contractual commitments to receive $6.4 million of raw materials for the future manufacture of ZEVALIN (representing strategic long-term supply), with expected delivery in full by January 2016. During the third quarter of 2015, we received $2.4 million of this product, which was fully consumed in quality testing and recognized through "cost of product sales (excludes amortization of intangible assets)" within the Condensed Consolidated Statements of Operations. Our work-in-process inventory at September 30, 2015 includes $0.8 million of packaged, but unlabeled ZEVALIN vials with expiry in December 2017. We expect to sell our existing and committed ZEVALIN inventory over the next few years. However, if our forecasted ZEVALIN sales or production strategy changes, it could result in a charge in that period to “cost of product sales (excludes amortization of intangible assets)” within the Condensed Consolidated Statements of Operations.

(d) Prepaid expenses
“Prepaid expenses” consist of the following:

	September 30, 2015	December 31, 2014
Prepaid operating expenses	$3,273	$3,112
Short term debt issuance costs	690	662
Prepaid expenses	$3,963	$3,774

(e) Other receivables
“Other receivables” consist of the (i) amounts we expect to be refunded from taxing authorities, primarily relating to income taxes paid for fiscal year 2012, (ii) insurance carrier proceeds relating to the settlement of shareholder litigation and related attorney fees (see Note 13(g)), and (iii) amounts we expect to be reimbursed from certain third-parties for incurred research and development expenses.

	September 30, 2015	December 31, 2014
Income tax receivable	$1,749	$1,387
Insurance receivable	8,148	—
Research and development expenses - reimbursements due	3,598	4,102
Other receivables	$13,495	$5,489

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(f) Intangible Assets and Goodwill
"Intangible assets, net of accumulated amortization" consist of the following:

	September 30, 2015						
	Historical Cost	Accumulated Amortization	Foreign Currency Translation	Impairment	Net Amount	Full Amortization Period (months)	Remaining Amortization Period (months)
MARQIBO IPR&D (NHL indication)	$17,600	$—	$—	$—	$17,600	n/a	n/a
EVOMELA IPR&D	7,700	—	—	—	7,700	n/a	n/a
BELEODAQ distribution rights	25,000	(2,344)	—	—	22,656	160	145
MARQIBO distribution rights	26,900	(7,464)	—	—	19,436	81	54
FOLOTYN distribution rights	118,400	(27,113)	—	—	91,287	152	116
ZEVALIN distribution rights – U.S.	41,900	(29,740)	—	—	12,160	123	42
ZEVALIN distribution rights – Ex-U.S.	23,490	(8,685)	(3,762)	—	11,043	96	54
FUSILEV distribution rights*	16,778	(8,765)	—	(7,160)	853	56	3
FOLOTYN out-license**	27,900	(8,428)	—	(1,023)	18,449	110	82
Total intangible assets	$305,668	$(92,539)	$(3,762)	$(8,183)	$201,184		

* On February 20, 2015, the U.S. 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 $7.2 million impairment charge (non-cash) in the first quarter of 2015. We accelerated amortization expense recognition for the remaining net book value of FUSILEV distribution rights.

** 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 an impairment charge (non-cash) of $1.0 million in the second quarter of 2013.

	December 31, 2014				
	Historical Cost	Accumulated Amortization	Foreign Currency Translation	Impairment	Net Amount
MARQIBO IPR&D (NHL indication)	$17,600	$—	$—	$—	$17,600
EVOMELA IPR&D	7,700	—	—	—	7,700

BELEODAQ distribution rights	25,000	(937)	—	—	24,063
MARQIBO distribution rights	26,900	(4,225)	—	—	22,675
FOLOTYN distribution rights	118,400	(20,030)	—	—	98,370
ZEVALIN distribution rights – U.S.	41,900	(27,134)	—	—	14,766
ZEVALIN distribution rights – Ex-U.S.	23,490	(7,402)	(2,162)	—	13,926
FUSILEV distribution rights	16,778	(6,270)	—	—	10,508
FOLOTYN out-license	27,900	(6,385)	—	(1,023)	20,492
Total intangible assets	$305,668	$(72,383)	$(2,162)	$(1,023)	$230,100

Intangible asset amortization and impairment expense recognized during the nine months ended September 30, 2015 and 2014 was $27.9 million, of which $20.7 million relates to current period amortization expense and $7.2 million relates to the impairment of the FUSILEV distribution rights, compared to $17.8 million of amortization expense, respectively.

Estimated intangible asset amortization expense (excluding incremental amortization from the reclassification of IPR&D to developed technology) for the remainder of 2015 and the five succeeding fiscal years and thereafter is as follows:

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Years Ending December 31,	
Remainder of 2015	$6,926
2016	24,289
2017	24,289
2018	24,289
2019	21,683
2020	