

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

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

(State or other jurisdiction of incorporation or organization)

93-0979187

(I.R.S. Employer Identification No.)

11500 South Eastern Avenue, Suite 240

Henderson, Nevada

(Address of principal executive offices)

(702) 835-6300

(Registrant's telephone number, including area code)

89052

(Zip Code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See 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   
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

As of October 31, 2015, 67,339,944 shares of the registrant's common stock were outstanding.

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 FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2015  
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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,<br>2015 | December 31,<br>2014 |
|---|-----------------------|----------------------|
| <b>ASSETS</b>   |                       |                      |
| 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           |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                       |                      |
| 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                  |

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|   |                  |                  |
|---|------------------|------------------|
| Common stock, \$0.001 par value; 175,000,000 shares authorized;<br>67,314,580 and 65,969,699 shares issued and outstanding at September 30,<br>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          |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>   | <b>\$447,661</b> | <b>\$490,033</b> |

See accompanying notes to these unaudited condensed consolidated financial statements.

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

(Unaudited)

|  | Three Months Ended |             | Nine Months Ended |             |
|--|--------------------|-------------|-------------------|-------------|
|  | September 30,      |             | 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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CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

|   | Three Months Ended |             | Nine Months Ended |             |
|---|--------------------|-------------|-------------------|-------------|
|   | September 30,      |             | 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<br>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    |

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|   |            |            |
|---|------------|------------|
| 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<br>(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 primary 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



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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)

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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Notes to Condensed Consolidated Financial Statements

(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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Notes to Condensed Consolidated Financial Statements

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

(Unaudited)

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





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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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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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**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”:

|  | Cost      | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses | Estimated<br>fair<br>Value | Cash and cash<br>equivalents | Marketable Securities |              |
|--|-----------|------------------------------|-------------------------------|----------------------------|------------------------------|-----------------------|--------------|
|  |           |                              |                               |                            |                              | Current               | Long<br>Term |
| <b>September 30, 2015</b>                            |           |                              |                               |                            |                              |                       |              |
| 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                 | \$—          |
| <b>December 31, 2014</b>                             |           |                              |                               |                            |                              |                       |              |
| 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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## 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, 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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## Notes to Condensed Consolidated Financial Statements

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## (f) Intangible Assets and Goodwill

“Intangible assets, net of accumulated amortization” consist of the following:

|  | September 30, 2015 |              |                         |            |            |                    | Full               | Remaining |
|--|--------------------|--------------|-------------------------|------------|------------|--------------------|--------------------|-----------|
|  | Historical         | Accumulated  | Foreign                 | Impairment | Net Amount | Amortization       | Amortization       |           |
|  | Cost               | Amortization | Currency<br>Translation |            |            | Period<br>(months) | Period<br>(months) |           |
| MARQIBO IPR&D<br>(NHL indication)        | \$ 17,600          | \$—          | \$—                     | \$—        | \$ 17,600  | n/a                | n/a                |           |
| EVOMELA IPR&D                            | 7,700              | —            | —                       | —          | 7,700      | n/a                | n/a                |           |
| BELEODAQ<br>distribution rights          | 25,000             | (2,344 )     | —                       | —          | 22,656     | 160                | 145                |           |
| MARQIBO distribution<br>rights           | 26,900             | (7,464 )     | —                       | —          | 19,436     | 81                 | 54                 |           |
| FOLOTYN distribution<br>rights           | 118,400            | (27,113 )    | —                       | —          | 91,287     | 152                | 116                |           |
| ZEVALIN distribution<br>rights – U.S.    | 41,900             | (29,740 )    | —                       | —          | 12,160     | 123                | 42                 |           |
| ZEVALIN distribution<br>rights – Ex-U.S. | 23,490             | (8,685 )     | (3,762 )                | —          | 11,043     | 96                 | 54                 |           |
| FUSILEV distribution<br>rights*          | 16,778             | (8,765 )     | —                       | (7,160 )   | 853        | 56                 | 3                  |           |
| FOLOTYN<br>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        | Accumulated  | Foreign                 | Impairment | Net Amount |
|                                | Cost              | Amortization | Currency<br>Translation |            |            |
| MARQIBO IPR&D (NHL indication) | \$ 17,600         | \$—          | \$—                     | \$—        | \$ 17,600  |
| EVOMELA IPR&D                  | 7,700             | —            | —                       | —          | 7,700      |

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|                                       |           |           |   |          |        |          |             |
|---------------------------------------|-----------|-----------|---|----------|--------|----------|-------------|
| 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                | 15,735    |
| 2021 and thereafter | 58,673    |
|                     | \$175,884 |

“Goodwill” is comprised of the following:

|  | September 30, 2015 | December 31, 2014 |
|--|--------------------|-------------------|
| Acquisition of Talon                               | \$10,526           | \$10,526          |
| Acquisition of ZEVALIN Ex-U.S. distribution rights | 2,525              | 2,525             |
| Acquisition of Allos                               | 5,346              | 5,346             |
| Foreign currency exchange translation effects      | (374               | ) (202            |
| Goodwill   | \$18,023           | \$18,195          |

(g) Other assets

“Other assets” are comprised of the following:

|   | September 30, 2015 | December 31, 2014 |
|---|--------------------|-------------------|
| Equity securities and secured promissory note - CASI (see Note 10)* | \$7,282            | \$8,501           |
| Supplies and deposits   | 185                | 234               |
| 2018 Convertible Notes issuance costs**                             | 1,650              | 2,171             |
| Executive officer life insurance – cash surrender value             | 8,725              | 6,958             |
| Other assets  | \$17,842           | \$17,864          |

\* These equity securities were excluded from “marketable securities” (see Note 3(a)) due to our intent to hold these securities for at least one year beyond September 30, 2015, as discussed in Note 10. Unrealized losses from these equity securities were recognized through “unrealized (loss) gain on available-for-sale securities” within the Condensed Consolidated Statements of Comprehensive Loss, and were \$0.9 million for the nine months ended September 30, 2015.

\*\* In April 2015, the FASB issued Accounting Standards Update 2015-03, Simplifying the Presentation of Debt Issuance Costs (“ASU 2015-03”). ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability. However, ASU 2015-03 does not impact the recognition and measurement guidance for debt issuance costs. ASU 2015-03 is effective for our annual and interim reporting periods beginning January 1, 2016. Accordingly, we will record a reclassification of our 2018 Convertible Notes issuance costs, from “other assets” to “convertible senior notes” within our Consolidated Balance Sheets, beginning January 1, 2016.

(h) Accounts payable and other accrued liabilities

“Accounts payable and other accrued liabilities” are comprised of the following:

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(Unaudited)

|  | September 30, 2015 | December 31, 2014 |
|--|--------------------|-------------------|
| Trade accounts payable and other accrued | \$30,764           | \$24,571          |
| Accrued rebates                          | 34,869             | 41,782            |
| Accrued product royalty                  | 3,694              | 5,182             |
| Allowance for returns                    | 1,610              | 1,135             |
| Accrued data and distribution fees       | 2,506              | 3,952             |
| Accrued GPO administrative fees          | 1,698              | 3,222             |
| Inventory management fee                 | 718                | 1,110             |
| Allowance for chargebacks                | 3,405              | 4,040             |
| Accounts payable and other accrued       | \$79,264           | \$84,994          |

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

| Description                          | Rebates and Chargebacks | Data and Distribution, GPO Fees, and Inventory Management Fees | Returns |
|--------------------------------------|-------------------------|--|---------|
| Balance as of December 31, 2013      | \$33,967                | \$5,373  | \$2,900 |
| Add: provisions (recovery)           | 76,636                  | 21,330   | (78)    |
| (Less): credits or actual allowances | (64,781)                | (18,419)   | (1,687) |
| Balance as of December 31, 2014      | 45,822                  | 8,284  | 1,135   |
| Add: provisions                      | 61,192                  | 13,041   | 1,144   |
| (Less): credits or actual allowances | (68,740)                | (16,403)   | (669)   |
| Balance as of September 30, 2015     | \$38,274                | \$4,922  | \$1,610 |

## (i) Deferred revenue

Deferred revenue (including current and long-term) is comprised of the following:

|   | September 30, 2015 | December 31, 2014 |
|---|--------------------|-------------------|
| CASI out-license (see Note 10)                | \$—                | \$9,959           |
| FUSILEV deferred revenue*                     | 9,941              | —                 |
| Dr. Reddy's out-license (see Note 13(b)(iii)) | 456                | —                 |
| Deferred revenue                              | \$10,397           | \$9,959           |

\* In the third quarter 2015, we deferred revenue recognition for \$9.9 million related to certain FUSILEV product shipments that did not meet our revenue recognition criteria (see Note 2(i)(a)). Specifically, this deferral is a result of our current inability to estimate future rebate values (with requisite precision) offered to our customers in order to compete with generic products.

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## (j) Other long-term liabilities

Other long-term liabilities are comprised of the following:

|   | September 30, 2015 | December 31, 2014 |
|---|--------------------|-------------------|
| Accrued executive deferred compensation | \$5,965            | \$4,694           |
| Deferred rent (non-current portion)     | 261                | 364               |
| Business acquisition liability          | —                  | 300               |
| Other tax liabilities                   | 737                | 730               |
| Other long-term liabilities             | \$6,963            | \$6,088           |

## 4. GROSS-TO-NET PRODUCT SALES

The below table presents a GTN product sales reconciliation for the accompanying Condensed Consolidated Statement of Operations:

|  | Three Months Ended |          | Nine Months Ended |           |
|--|--------------------|----------|-------------------|-----------|
|  | September 30,      |          | September 30,     |           |
|  | 2015               | 2014     | 2015              | 2014      |
| Gross product sales                            | \$44,713           | \$75,331 | \$160,111         | \$205,158 |
| Rebates and chargebacks                        | (12,515)           | (21,495) | (44,364)          | (56,215)  |
| Data, distribution and GPO administrative fees | (3,503)            | (5,707)  | (12,709)          | (15,123)  |
| Prompt pay discounts                           | (15)               | (2)      | (16)              | (7)       |
| Product returns allowance                      | (223)              | (211)    | (1,008)           | 1,054     |
| Product sales, net                             | \$28,457           | \$47,916 | \$102,014         | \$134,867 |

## 5. NET PRODUCT SALES BY GEOGRAPHIC REGION AND PRODUCT LINE

The below table presents our net product sales by geography for the three and nine months ended September 30, 2015 and 2014:

|                                   | Three Months Ended |       |   | Nine Months Ended |       |   |
|-----------------------------------|--------------------|-------|---|-------------------|-------|---|
|                                   | September 30,      |       |   | September 30,     |       |   |
|                                   | 2015               | 2014  | % | 2015              | 2014  | % |
| United States                     | \$26,262           | 92.3  | % | \$46,382          | 96.8  | % |
| International:                    |                    |       |   |                   |       |   |
| Europe (ZEVALIN and FOLOTYN only) | 709                | 2.5   | % | 849               | 1.8   | % |
| Asia Pacific (ZEVALIN only)       | 1,486              | 5.2   | % | 685               | 1.4   | % |
| Total international               | 2,195              | 7.7   | % | 1,534             | 3.2   | % |
| Product sales, net                | \$28,457           | 100.0 | % | \$47,916          | 100.0 | % |
|                                   | \$96,546           | 94.6  | % | \$128,380         | 95.2  | % |
|                                   | \$102,014          | 100.0 | % | \$134,867         | 100.0 | % |

The below table presents our net product sales by product line for the three and nine months ended September 30, 2015 and 2014:



|                    | Three Months Ended<br>September 30, |       |      |          | Nine Months Ended<br>September 30, |   |           |       |   |           |       |   |
|--------------------|-------------------------------------|-------|------|----------|------------------------------------|---|-----------|-------|---|-----------|-------|---|
|                    | 2015                                |       | 2014 |          | 2015                               |   | 2014      |       |   |           |       |   |
| FUSILEV            | \$11,101                            | 39.0  | %    | \$26,883 | 56.1                               | % | \$45,597  | 44.7  | % | \$75,630  | 56.1  | % |
| FOLOTYN            | 8,722                               | 30.6  | %    | 12,677   | 26.5                               | % | 30,261    | 29.7  | % | 35,332    | 26.2  | % |
| ZEVALIN            | 4,762                               | 16.7  | %    | 4,585    | 9.6                                | % | 13,784    | 13.5  | % | 17,221    | 12.8  | % |
| MARQIBO            | 1,316                               | 4.6   | %    | 1,793    | 3.7                                | % | 5,290     | 5.2   | % | 4,706     | 3.5   | % |
| BELEODAQ           | 2,556                               | 9.0   | %    | 1,978    | 4.1                                | % | 7,082     | 6.9   | % | 1,978     | 1.5   | % |
| Product sales, net | \$28,457                            | 100.0 | %    | \$47,916 | 100.0                              | % | \$102,014 | 100.0 | % | \$134,867 | 100.0 | % |

## 6. STOCK-BASED COMPENSATION

We classify 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 department to which the recipient belongs. Stock-based compensation expense included within "Total operating costs and expenses" for the three and nine months ended September 30, 2015 and 2014 was as follows:

|                                     | Three Months Ended<br>September 30, |         | Nine Months Ended<br>September 30, |         |
|-------------------------------------|-------------------------------------|---------|------------------------------------|---------|
|                                     | 2015                                | 2014    | 2015                               | 2014    |
| Cost of product sales               | \$21                                | \$—     | \$43                               | \$—     |
| Research and development            | 474                                 | 411     | 1,326                              | 1,366   |
| Selling, general and administrative | 2,005                               | 2,653   | 7,121                              | 7,223   |
| Total stock-based compensation      | \$2,500                             | \$3,064 | \$8,490                            | \$8,589 |

## 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, 2015 and 2014:

|   | Three Months Ended<br>September 30, |            | Nine Months Ended<br>September 30, |            |
|---|-------------------------------------|------------|------------------------------------|------------|
|   | 2015                                | 2014       | 2015                               | 2014       |
| Net loss                                    | \$(18,724)                          | \$(11,539) | \$(46,632)                         | \$(42,743) |
| Weighted average shares – basic and diluted | 65,855,727                          | 64,765,072 | 65,457,060                         | 64,369,466 |
| Net loss per share – basic and diluted      | \$(0.28)                            | \$(0.18)   | \$(0.71)                           | \$(0.66)   |

The below outstanding securities were excluded from the above calculation of net loss per share because their impact would have been anti-dilutive due to net loss per share in the three and nine months ended September 30, 2015 and 2014, as summarized below:

|                         | Three Months Ended<br>September 30, |            | Nine Months Ended<br>September 30, |            |
|-------------------------|-------------------------------------|------------|------------------------------------|------------|
|                         | 2015                                | 2014       | 2015                               | 2014       |
| 2018 Convertible Notes  | 11,401,284                          | 11,401,284 | 11,401,284                         | 11,401,284 |
| Common stock options    | 1,591,709                           | 2,173,016  | 1,507,700                          | 2,256,053  |
| Restricted stock awards | 1,457,232                           | 972,881    | 1,457,232                          | 972,881    |
| Common stock warrants   | 59,853                              | 121,741    | 45,121                             | 126,909    |
| Preferred stock         | 40,000                              | 40,000     | 40,000                             | 40,000     |
| Total                   | 14,550,078                          | 14,708,922 | 14,451,337                         | 14,797,127 |



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

(Unaudited)

## 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 three fair value measurement categories:

|  | September 30, 2015      |          |          |          |
|--|-------------------------|----------|----------|----------|
|  | Fair Value Measurements |          |          |          |
|  | Level 1                 | Level 2  | Level 3  | Total    |
| Assets:  |                         |          |          |          |
| Bank certificates of deposits  | \$—                     | \$245    | \$—      | \$245    |
| Money market currency funds  | —                       | 80,086   | —        | 80,086   |
| Equity securities  | 5,784                   | —        | —        | 5,784    |
| Deferred compensation investments, including life insurance cash surrender value | —                       | 8,725    | —        | 8,725    |
|  | \$5,784                 | \$89,056 | \$—      | \$94,840 |
| Liabilities:   |                         |          |          |          |
| Deferred executive compensation liability  | \$—                     | \$5,965  | \$—      | \$5,965  |
| Drug development liability   | —                       | —        | 14,400   | 14,400   |
| Ligand Contingent Consideration  | —                       | —        | 5,373    | 5,373    |
| Talon CVR  | —                       | —        | 2,472    | 2,472    |
| Corixa Liability   | —                       | —        | 62       | 62       |
|  | \$—                     | \$5,965  | \$22,307 | \$28,272 |
|  |                         |          |          |          |
|  | December 31, 2014       |          |          |          |
|  | Fair Value Measurements |          |          |          |
|  | Level 1                 | Level 2  | Level 3  | Total    |
| Assets:  |                         |          |          |          |
| Bank certificates of deposits  | \$—                     | \$244    | \$—      | \$244    |
| Money market currency funds  | —                       | 66,945   | —        | 66,945   |
| Equity securities  | 7,191                   | —        | —        | 7,191    |
| Mutual funds   | —                       | 3,062    | —        | 3,062    |
| Deferred compensation investments, including life insurance cash surrender value | —                       | 6,958    | —        | 6,958    |
|  | \$7,191                 | \$77,209 | \$—      | \$84,400 |
| Liabilities:   |                         |          |          |          |
| Deferred executive compensation liability  | \$—                     | \$4,694  | \$—      | \$4,694  |
| Deferred development costs   | —                       | —        | 15,785   | 15,785   |
| Ligand Contingent Consideration  | —                       | —        | 4,901    | 4,901    |
| Talon CVR  | —                       | —        | 2,379    | 2,379    |
| Corixa Liability   | —                       | —        | 62       | 62       |
|  | \$—                     | \$4,694  | \$23,127 | \$27,821 |

We did not have any transfers between Levels 1 and 2 for all periods presented. The following presents a roll forward of our liabilities for which we utilize Level 3 inputs in determining period-end value. These liabilities are included on our Condensed Consolidated Balance Sheets within “acquisition-related contingent obligations” and “drug development liability”. The basis of the various Level 3 valuation inputs are discussed in the Notes to these accompanying

Condensed Consolidated Financial Statements.

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.

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

(Unaudited)

|   | Fair Value Measurements of<br>Unobservable Inputs (Level 3) |
|---|---|
| Balance at December 31, 2013                    | \$26,071  |
| Transfers in (out) of Level 3                   | —   |
| Deferred development costs                      | (1,957 )  |
| Ligand Contingent Consideration                 | 901   |
| Talon CVR                                       | (1,950 )  |
| Corixa Liability                                | 62  |
| Balance at December 31, 2014                    | 23,127  |
| Transfers in (out) of Level 3                   | —   |
| Deferred development costs (see Note 12)        | (1,385 )  |
| Ligand Contingent Consideration (see Note 9(b)) | 472   |
| Talon CVR (see Note 9(a))                       | 93  |
| Corixa Liability (see Note 13(b)(i))            | —   |
| Balance at September 30, 2015**                 | \$22,307  |

\*\* This amount is comprised of current and long-term portion of “drug development liability” and “acquisition-related contingent obligations” on our accompanying Condensed Consolidated Balance Sheets.

## 9. BUSINESS COMBINATIONS AND CONTINGENT CONSIDERATION

## (a) Acquisition of Talon Therapeutics, Inc. and Related Contingent Consideration

## 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 comprised of (i) an aggregate upfront cash amount of \$11.3 million, (ii) issuance of 3.0 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 contingent value rights (“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 \$195.0 million if all sales and regulatory approval milestones are achieved, as summarized below:

- \$5.0 million upon the achievement of net sales of MARQIBO in excess of \$30.0 million in any calendar year
- \$10.0 million upon the achievement of net sales of MARQIBO in excess of \$60.0 million in any calendar year
- \$25.0 million upon the achievement of net sales of MARQIBO in excess of \$100.0 million in any calendar year
- \$50.0 million upon the achievement of net sales of MARQIBO in excess of \$200.0 million in any calendar year
- \$100.0 million upon the achievement of net sales of MARQIBO in excess of \$400.0 million in any calendar year
- \$5.0 million upon receipt of marketing authorization from the FDA regarding Menadione Topical Lotion

## Talon CVR Fair Value as of September 30, 2015 and December 31, 2014

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<br>of Talon<br>CVR |
|--|-------------------------------|
| December 31, 2014  | \$2,379                       |
| Fair value adjustment for the nine months ended September 30, 2015 | 93                            |
| September 30, 2015   | \$2,472                       |

## (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 recently branded as “EVOMELA”) for use as a conditioning treatment prior to autologous stem cell transplant for patients with multiple myeloma. We acquired these rights from CyDex Pharmaceuticals, Inc. a wholly-owned subsidiary of Ligand Pharmaceuticals Incorporated (“Ligand”) for an initial license fee of \$3.0 million.

We accounted for this transaction as a business combination, which requires 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 \$66.0 million, upon the achievement of certain regulatory milestones and net sales thresholds, and we also assumed full financial responsibility for its ongoing clinical and regulatory development program. We also must pay royalties in the range of 20% on our future net sales of EVOMELA in all territories.

## 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 closing date. The allocation of the total purchase price to the net assets acquired is as follows:

|                      |         |
|----------------------|---------|
| IPR&D EVOMELA 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 amounts to a single present amount (discounted). Our measurement is based on the value indicated by current market expectations about those future amounts. The fair value estimate took into account our estimates of future incremental earnings that may be achieved upon regulatory approval, promotion, and distribution associated with the rights, and included estimated cash flows of approximately 10 years and a discount rate of approximately 25%.

The fair value of the contingent consideration liability assumed was determined using the probability of success and the discounted cash flow method of the income approach (representing unobservable inputs and are therefore represent Level 3 values - see Note 2(xiii)), which assumed that FDA approval of EVOMELA will occur on or about December 31, 2015. Upon receipt of FDA approval, we are contractually obligated to make payment in full within 30 days of \$6.0 million to Ligand (“Ligand Contingent Consideration”).

Ligand Contingent Consideration Fair Value as of September 30, 2015 and December 31, 2014



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The Ligand Contingent Consideration fair value will continue to be evaluated on a quarterly basis. Any changes in its fair value results from the likelihood and timing of milestone achievement and/or the corresponding discount rate applied thereon. Adjustments to Ligand Contingent Consideration fair value are recognized within "change in fair value of contingent consideration related to acquisitions" in the accompanying Condensed Consolidated Statements of Operations.

|  | Fair Value of<br>Ligand<br>Contingent<br>Consideration |
|--|--|
| December 31, 2014  | \$4,901  |
| Fair value adjustment for the nine months ended September 30, 2015 | 472  |
| September 30, 2015   | \$5,373  |

## (c) Allos Acquisition

We acquired Allos Therapeutics, Inc. ("Allos") on September 5, 2012, which was accounted for as a business combination. Our total cash consideration for this acquisition was \$205.2 million, through which we acquired FOLOTYN distribution rights. We have no contingent consideration obligations as part of this transaction.

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

## Overview of CASI Out-License

On September 17, 2014, we executed three product out-license agreements with a perpetual term (collectively, the "CASI Out-License") with CASI Pharmaceuticals, Inc. ("CASI"), a publicly-traded biopharmaceutical company (NASDAQ: CASI) with a primary focus on the China market. Under the CASI Out-License, we granted CASI the exclusive rights to distribute two of our commercialized oncology drugs, ZEVALIN and MARQIBO, and our Phase 3 drug candidate, EVOMELA ("CASI Out-Licensed Products") in greater China (which includes Taiwan, Hong Kong and Macau). In return, we received CASI equity for the rights related to ZEVALIN and EVOMELA and a secured promissory note for the rights related to MARQIBO. Additionally, under certain conditions which generally expire on September 17, 2019, we have a right to receive additional CASI common stock in order to maintain our post-investment ownership percentage if CASI issues additional securities.

CASI will be responsible for the development and commercialization of these three 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.

## Proceeds Received in the Quarter Ended September 30, 2014

The proceeds we received, 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 due March 17, 2016 (since extended to March 17, 2017), 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) |

Value 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. Our current intention is to hold these securities on a long-term basis. Accordingly, we have presented its \$5.8 million value as of September 30, 2015 within "other assets" (rather than (a) "marketable securities") on our accompanying Condensed Consolidated Balance Sheets. The change in fair value of these securities is reported within "unrealized (loss) gain on available-for-sale securities" on the Condensed Consolidated Statements of Comprehensive Loss.

(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. The face value of the promissory note as of September 30, 2015 is included within "other assets" on the accompanying Condensed Consolidated Balance Sheets.

(c) Presented within "license fees and service revenue" in the accompanying Condensed Consolidated Statement of Operations for the nine months ended September 30, 2015 (see below).

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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.

Recognition of Proceeds – License Fee Revenue in 2015

The \$9.7 million value (undiscounted, and net of certain foreign exchange adjustments) of the upfront proceeds that we received from CASI were recognized in the second quarter of 2015 within “license fees and service revenue” through our Condensed Consolidated Statements of Operations. The timing of this revenue recognition corresponds with the execution of 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 their supply.

## 11. CONVERTIBLE SENIOR NOTES

### Overview

On December 17, 2013, we entered into an agreement for the sale of \$120 million aggregate principal amount of 2.75% Convertible Senior Notes due December 2018 (the “2018 Convertible Notes”). The 2018 Convertible Notes are convertible into shares of our common stock at a conversion rate of 95 shares per \$1,000 principal amount of the 2018 Convertible Notes, equating to 11.4 million common shares if fully converted. 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 our net proceeds were \$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 “Note Hedge”). We recorded the Note 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 Note Hedge transaction is not expected to be marked-to-market through earnings or comprehensive income in future reported periods.

### Conversion Hedge

We entered into Note Hedge transactions 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, matching the 11.4 million common shares the 2018 Convertible Notes may be converted into. 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.

### Conversion Events

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. Prior to June 15, 2018, holders may convert all or a portion of their 2018 Convertible Notes only under any of the following circumstances: (1) during any fiscal quarter (and only during such fiscal quarter), if, for at least 20 trading days (whether or not consecutive) during the 30 consecutive trading day period ending on the last trading day of the immediately preceding fiscal quarter, the last reported sale price of our common stock on such trading day is greater than or equal to 130% of the Notes' conversion price on such trading day; (2) during the five consecutive business day period immediately following any five consecutive trading day period in which, for each trading day of that measurement period, the trading price per \$1,000 principal amount of 2018 Convertible Notes for such trading day

was less than 98% of the product of (i) the last reported sale price of our common stock on such trading day and (ii) the Notes' conversion rate on such trading day; (3) upon the occurrence of certain corporate transactions; and (4) at any time prior to our stockholders' approval to settle the 2018 Convertible Notes in our common shares and/or cash.

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As of September 30, 2015, the 2018 Convertible Notes are not eligible to be converted into our common stock, as none of the above elements (1) through (4) were met. Our stockholders' approval of "flexible settlement" occurred at our Annual Meeting of Shareholders on June 29, 2015. As a result, we may (at our election) settle any future conversions of the 2018 Convertible Notes by paying or delivering cash, shares of our common stock, or a combination of cash and shares of our common stock. However, if the holders of the Convertible Notes do not elect any conversion into our common stock, our December 2018 obligation to repay the principal amount of \$120 million in cash, plus any accrued and unpaid interest, is unchanged.

## Carrying Value and Fair Value

The carrying value of the 2018 Convertible Notes as of September 30, 2015 is summarized as follows:

|   |            |   |
|---|------------|---|
| Principal amount  | \$ 120,000 |   |
| (Less): Unamortized debt discount (amortized through December 2018) | (19,808    | ) |
| September 30, 2015  | \$ 100,192 |   |

As of September 30, 2015 and December 31, 2014, the estimated aggregate fair value of the 2018 Notes is \$106.2 million and \$113.2 million, respectively. These fair value estimates are less than the principal amount of \$120 million, largely since the conversion feature of the 2018 Notes was, and remains, out-of-the-money. 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

The following table sets forth the components of net interest expense (partially offset by interest income of \$0.5 million) recognized in the accompanying Condensed Consolidated Statements of Operations for the 2018 Convertible Notes for the nine months ended September 30, 2015:

|                                     |         |   |
|-------------------------------------|---------|---|
| Contractual coupon interest expense | \$2,475 |   |
| Amortization of debt issuance costs | 493     |   |
| Accretion of debt discount          | 3,895   |   |
| Total                               | \$6,863 |   |
| Effective interest rate             | 8.66    | % |

## 12. MUNDIPHARMA AGREEMENT

As the result of our acquisition of Allos Therapeutics, Inc. on September 5, 2012 (through which we obtained distribution rights for FOLOTYN), we assumed its obligations under an active strategic collaboration agreement with a third-party, Mundipharma (the "Mundipharma Collaboration Agreement"). Under the Mundipharma Collaboration Agreement, 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 (the "Mundipharma Territories").

On May 29, 2013, the Mundipharma Collaboration Agreement was amended and restated (the "Amended Mundipharma Collaboration Agreement"), 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 Amended 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 Amended 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, (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 bear our own FOLOTYN development costs.

On May 29, 2015 and effective as of May 1, 2015, we entered into an amendment to the Amended Mundipharma Collaboration Agreement (the "Amendment"). Pursuant to the Amendment, among other things, the parties revised the

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conditions to our exercise of the option to gain commercialization rights in Switzerland from Mundipharma, and also revised tiered double digit royalties payable by Mundipharma on net sales in Switzerland.

The fair value of this liability is included in the current and long-term portions of “drug development liability” within the accompanying Condensed Consolidated Balance Sheets, and it includes our assumptions about personnel needed to perform these research and development activities, third party costs for projected clinical trial enrollment, and patient treatment-related follow up through approximately 2031.

The fair value of our “drug development liability” within our accompanying Condensed 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, (ii) estimates of expected cash outflows to third parties for 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.

We assess this liability at each reporting date and record its adjustment through “research and development” expense in our accompanying Condensed Consolidated Statements of Operations.

|  | Drug<br>Development<br>Liability,<br>Current –<br>FOLOTYN | Drug<br>Development<br>Liability,<br>Long Term –<br>FOLOTYN | Total Drug<br>Development<br>Liability –<br>FOLOTYN |
|--|---|---|---|
| Balance at December 31, 2014               | \$1,141   | \$14,644  | \$15,785  |
| Transfer from long-term to current in 2015 | 817   | (817)   | —   |
| (Less): Expenses incurred in 2015          | (1,385)   | —   | (1,385)   |
| Balance at September 30, 2015              | \$573   | \$13,827  | \$14,400  |

## 13. COMMITMENTS AND CONTINGENCIES

## (a) Facility Leases

We lease our principal executive office in Henderson, Nevada under a non-cancelable operating lease expiring May 31, 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) Licensing Agreements, Co-Development Agreements, and Milestone Payments

Our drug candidates are being developed pursuant to license agreements that provide us with territory-specific rights to its manufacture, sublicense, and sale. We are generally responsible for all development costs, patent filings and maintenance costs, sales and marketing costs, and liability insurance costs. We are also obligated to make certain milestone payments to third parties upon the achievement of regulatory and sales milestones that are specified in these license agreements. We estimate and present a corresponding liability on our Condensed Consolidated Balance Sheets when amounts are probable and reasonably estimable. In addition, we are obligated to pay royalties based on our current and future net sales of in-licensed products.

Our most significant of these agreements are listed and summarized below:

## (i) ZEVALIN U.S.: In-Licensing and Development in the U.S.

In December 2008, we acquired rights to commercialize and develop ZEVALIN in the U.S. as the result of a transaction with Cell Therapeutics, Inc. (“CTI”) through our subsidiary, RIT Oncology LLC (“RIT”). We assumed certain agreements with various third parties related to ZEVALIN intellectual property for its manufacture, use, and sale in

the U.S.

In accordance with the terms of assumed contracts, we are required to meet specified payment obligations, including a milestone payment to Corixa Corporation of \$5 million based on ZEVALIN sales in the U.S. (the “Corixa Liability”).

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milestone has not yet been met, and \$0.1 million for this potential milestone achievement is included within “acquisition-related contingent obligations” in our accompanying Condensed Consolidated Balance Sheet as of September 30, 2015 and December 31, 2014, respectively. Our U.S. net sales-based royalties are in the low to mid-single digits to Genentech, Inc. and mid-teens to Biogen.

(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 the acquisition of licensing rights to market ZEVALIN outside of the U.S. from Bayer Pharma AG (“Bayer”). ZEVALIN is currently approved in approximately 40 countries outside the U.S. for the treatment of B-cell non-Hodgkin lymphoma, including countries in Europe, Latin America, and Asia.

In consideration for the rights granted under the agreement, concurrent with the closing, we paid Bayer a one-time fee of €19 million. Our ex-U.S. net sales-based royalty to Bayer ranges between the single digits to mid-teens. Unless earlier terminated, the term of the agreement continues until the expiration of the last-to-expire patent covering the sale of a licensed product in the relevant country, or 15 years from the date of first commercial sale of the licensed product in such country, whichever is longer.

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

Effective June 27, 2014, we executed an exclusive License Agreement with Dr. Reddy’s Laboratories Ltd. (“Dr. Reddy’s”), for the distribution rights of ZEVALIN within India. The agreement term is 15 years from the receipt of pending approval of ZEVALIN from the Drug Controller General of India. On December 17, 2014, upon the execution of a supply agreement, an upfront and non-refundable payment of \$0.5 million was triggered and was paid to us in February 2015. The recognition of this upfront payment is reported on a straight-line basis within “license fee and service revenue” on the Condensed Consolidated Statements of Operations over a 10 year term through December 2024. Additionally, sales and regulatory milestones (aggregating \$3 million) will become payable to us when achieved by Dr. Reddy’s, as well as a 20% royalty on net sales of ZEVALIN in India.

(iv) 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. Pursuant to the license agreement with Merck, we obtained the exclusive license to use regulatory filings related to FUSILEV and a non-exclusive license under certain patents and know-how to develop, manufacture, use, and sell FUSILEV in the field of oncology in North America in return for a royalty percentage (in the mid-single digits) of net sales. Merck is eligible to receive a \$0.2 million payment from us upon the achievement of a FDA approval of an oral form of FUSILEV. This milestone has not yet been met, and no amounts have been accrued in our accompanying Condensed Consolidated Balance Sheets for its potential achievement.

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

In December 2002, Allos entered into the FOLOTYN License Agreement with Sloan-Kettering Institute for Cancer Research, SRI International, and Southern Research Institute. As a result of Allos becoming our wholly owned subsidiary in September 2012, we are bound by the FOLOTYN License Agreement under which we obtained exclusive worldwide rights to a portfolio of patents and patent applications related to FOLOTYN and its uses. Under the terms of the FOLOTYN License Agreement, we are required to fund all development programs and will have sole responsibility for all commercialization activities. In addition, we pay graduated royalties to our licensors based on our (including sub licensees) worldwide annual net sales of FOLOTYN. 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.

(vi) EVOMELA: In-License Agreement with Cydex Pharmaceuticals, Inc.

In March 2013, we completed the acquisition of exclusive global development and commercialization rights to EVOMELA from Ligand (see Note 9(b)). We filed an NDA with the FDA in December 2014 for its use as a conditioning treatment prior to autologous stem cell transplant for patients with multiple myeloma, and received a Complete Response Letter from the FDA in October 2015 (see Note 15).

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

(Unaudited)

We are required to pay Ligand additional amounts of up to \$66 million, upon achievement of certain regulatory milestones and net sales thresholds, which we have valued at \$5.4 million and \$4.9 million within “acquisition-related contingent obligations” in our accompanying Condensed Consolidated Statements of Operations as of September 30, 2015 and December 31, 2014, respectively. We will also pay royalties of 20% on our net sales of licensed products in all territories.

(vii) MARQIBO: Contingent Consideration Agreement with Talon Therapeutics, Inc.

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, we issued the former Talon stockholders contingent value rights (“CVR”) that we have valued and presented on our accompanying Condensed Consolidated Balance Sheets as a \$2.5 million and \$2.4 million liability within “acquisition-related contingent obligations” as of September 30, 2015 and December 31, 2014, respectively. The CVR has a maximum payout value of \$195 million if all sales and regulatory approval milestones are achieved.

(viii) APAZQUONE: License Agreements with Allergan, Inc. and NDDO Research Foundation

In October 2008, we entered into an exclusive development and commercialization collaboration agreement with Allergan for APAZQUONE. Pursuant to the terms of the agreement, Allergan paid us an up-front non-refundable fee of \$41.5 million at closing (which we amortized through revenue within “license fees and service revenue” in full as of December 31, 2013). In October 2008, pursuant to a letter agreement with NDDO Research Foundation (“NDDO”), we agreed to pay NDDO the following in relation to APAZQUONE milestones: (a) upon FDA acceptance of the NDA, the issuance of 25,000 of our common shares and (b) upon FDA approval of the drug, a one-time payment of \$0.3 million.

In January 2013, we entered into a second amendment to the license, development, supply and distribution agreement with Allergan to amend the agreement and reacquire the rights originally licensed to Allergan in the U.S., Europe, and other territories in exchange for a tiered single-digit royalty on certain products containing APAZQUONE, and relieved Allergan of its development and commercialization obligations.

(ix) APAZQUONE: 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 APAZQUONE in Asia, except North and South Korea (the “Nippon Kayaku Territory”). In addition, Nippon Kayaku received exclusive rights to APAZQUONE for the treatment of non-muscle invasive bladder cancer in Asia (other than North and South Korea), including Japan and China. Nippon Kayaku will conduct APAZQUONE 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 APAZQUONE in the Nippon Kayaku Territory.

Under the terms of this agreement, Nippon Kayaku paid us an upfront fee of \$15 million (which we have amortized through revenue within “license fees and service revenue” in full as of December 31, 2013). Nippon Kayaku is also obligated to make additional payments to us based on the achievement of certain development, regulatory and commercialization milestones. Under the terms of the agreement, we are entitled to payment of \$10 million and \$126 million upon achievement of certain regulatory and commercialization milestones, respectively. Also, Nippon Kayaku has agreed to pay us royalties based on a percentage of net sales of the subject products in the defined territory in the mid-teen digits.

(x) BELEODAQ: In-License and Collaboration Agreement with TopoTarget

In February 2010, we entered into a licensing and collaboration agreement with TopoTarget A/S (now Onxeo DK) (“TopoTarget”), as amended in October 2013, for the development and commercialization of BELEODAQ. The agreement provides that we have the exclusive right to manufacture, develop, and commercialize BELEODAQ in North America and India, with an option for China. Pursuant to the terms of this agreement, we paid TopoTarget an

upfront fee of \$30 million in 2010.

Under continuing terms, all development, including studies, will be conducted under a joint development plan, which we will fund 70% of such costs, and TopoTarget will fund 30%. We have final decision-making authority for all developmental activities in North America and India (and China upon exercise of its option). TopoTarget has final decision-making authority

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

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for all developmental activities in all other jurisdictions. In February 2014, upon FDA acceptance of our new drug application, we issued one million shares of our common stock, and made a \$10 million milestone payment to TopoTarget. The aggregate payout value of this first milestone at achievement was \$17.8 million, and was recognized within “research and development” on the accompanying Condensed Consolidated Statement of Operations during 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 paid a second milestone payment to TopoTarget of \$25 million in November 2014, which we capitalized as an amortizable intangible asset. Other potential milestone payments due upon BELEODAQ regulatory achievements and sales thresholds (aggregating up to \$278 million) are not included within “total liabilities” in our accompanying Condensed Consolidated Balance Sheets.

We will pay TopoTarget future royalties in the mid-teen digits based on net sales of BELEODAQ. The agreement will continue until the expiration of the last royalty payment period in the last country in the defined territory with certain provisions surviving, unless earlier terminated in accordance with its terms.

(xi) SPI-2012: Co-Development and Commercialization Agreement with Hanmi Pharmaceutical Company

In January 2012 (and as amended in March 2014 and October 2014), we entered into a License, Development, and Supply Agreement with Hanmi Pharmaceutical Company, Ltd. (“Hanmi”), for SPI-2012, formerly known as “LAPS-GCSF”, a drug based on Hanmi’s proprietary LAPSCOVERY™ technology for the treatment of chemotherapy induced neutropenia. Under the terms of the agreement, as amended, we have primary financial responsibility for the SPI-2012 development plan. We have worldwide rights for SPI-2012, except for Korea, China, and Japan. We will also be responsible for milestone payments related to SPI-2012 Phase 3 clinical trial commencement, regulatory approvals, and sales thresholds (aggregating \$238 million), which are not included within “total liabilities” in our Condensed Consolidated Balance Sheets. We will pay Hanmi royalties in the mid-teen digits on our net sales of SPI-2012.

(xiii) POZIOTINIB: In-License Agreement with Hanmi

In February 2015, we executed an in-license agreement with Hanmi Pharmaceutical Co., Ltd for POZIOTINIB, a pan-HER inhibitor in Phase 2 clinical trials, requiring our upfront payment for these rights. This drug has shown single agent activity in the treatment of various cancer types during Phase I studies, including breast, gastric, colorectal, and lung cancers.

Under the terms of this agreement, we received the exclusive rights to commercialize POZIOTINIB globally, excluding Korea and China. Hanmi, and its development partners, will bear full responsibility for completion of on-going Phase 2 trials in Korea. We will bear full financial responsibility for all other clinical studies. The agreement includes future regulatory and sales-dependent milestones payments (aggregating \$358 million), 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.

(c) Service Agreements

In connection with the research and development of our drug products, we have entered into contracts with numerous third party service providers, such as radio-pharmacies, distributors, clinical trial centers, clinical research organizations, data monitoring centers, and with drug formulation, development and testing laboratories. The financial terms of these agreements are varied and generally obligate us to pay in stages, depending on achievement of certain events specified in the agreements, such as contract execution, reservation of service or production capacity, actual performance of service, or the successful accrual and dosing of patients.

At each period end, we accrue for all services received, with such accruals based on factors such as estimates of work performed, patient enrollment, completion of patient 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 be limited to the extent of the work

completed. Generally, we are able to terminate these contracts due to the discontinuance of the related project(s) and thus avoid paying for the services that have not yet been rendered.

(d) Supply Agreements

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(Unaudited)

We have entered into certain supply agreements, or have issued purchase orders, which require us to make minimum purchases from vendors for the manufacture of our products. These commitments do not exceed our planned commercial requirements, and the contracted prices do not exceed their fair market value.

(e) Employment Agreement

We have entered into an employment agreement with our Chief Executive Officer under which cash compensation and benefits would become payable 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.

(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 deferred compensation benefits for a select group of our employees (the “DC Participants”). Under the DC Plan, we provide the DC Participants with the opportunity to make annual elections to defer up to a specified amount or percentage of their eligible cash compensation, and we have the option to make discretionary contributions. At September 30, 2015 and December 31, 2014, the aggregate DC Plan deferrals by employees and our discretionary contributions totaled \$6.0 million and \$4.7 million, respectively, and are included within “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.

We are presently responding to Abbreviated New Drug Applications (“ANDAs”) filed by companies seeking to market generic forms of FOLOTYN. We are also responding to certain shareholder suits that purportedly stem from our March 12, 2013 press release, in which we announced anticipated changes in customer ordering patterns of FUSILEV. These complaints allege that, as a result of this press release, our stock price declined.

FUSILEV ANDA Litigation

On January 20, 2012, March 2, 2012, June 18, 2014, January 23, 2015, July 17, 2015 and September 3, 2015 respectively, we filed suit against Sandoz Inc., Innopharma Inc., Ben Venue Laboratories, Inc., Amneal Pharmaceuticals, Inc., and Actavis LLC. respectively, following Paragraph IV certifications in connection with their filing separate ANDAs, to manufacture a generic version of FUSILEV. We filed the lawsuits in the U.S. District Court for the Districts of Nevada and Delaware seeking to enjoin the approval of their ANDAs plus recovery of our litigation fees and costs incurred in such matters. On December 9, 2013, three Mylan entities collaborating with Innopharma were joined to Innopharma case. On November 24, 2014 the complaint in the Ben Venue case was amended to substitute the original defendant Ben Venue Laboratories, Inc. with successors West-Ward Pharmaceutical Corp. and Eurohealth International SARRL.

A trial took place in the Sandoz case from January 12, 2015 through January 20, 2015 in the U.S. District Court for the District of Nevada and on February 20, 2015 the district court found certain of the asserted claims of the patent covering FUSILEV invalid. On February 27, 2015, we filed our Notice of Appeal. On August 4, 2015 the Delaware

district court ordered that judgment be entered for Innopharma and Mylan due to the Nevada district court judgment in the Sandoz action. On October 2, 2015, the U.S. Court of Appeals for the Federal Circuit affirmed the previously reported judgment from the U.S. District Court for the District of Nevada in favor of Sandoz Inc.

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(Unaudited)

On April 27, 2015, we filed suit in the U.S. District Court for the District of Columbia against the FDA seeking a temporary restraining order or preliminary injunction to suspend FDA approval of Sandoz's ANDA. The Company contends that Sandoz's ANDA should not have been approved until the expiry of the Company's Orphan Drug Exclusivity on April 29, 2018. On April 29, 2015, the court denied the temporary restraining order and on May 27, 2015, the court entered summary judgment in favor of the FDA et al. On June 5, 2015, we filed our Notice of Appeal. Oral argument was held October 22, 2015. The ultimate outcome of this proceeding is uncertain.

FOLOTYN ANDA Litigation

On June 19, 2014, we filed a lawsuit against five parties resulting from Paragraph IV certifications in connection with four separate ANDAs to manufacture a generic version of FOLOTYN: (1) Teva Pharmaceuticals USA, Inc., (2) Sandoz Inc., (3) Fresenius Kabi USA, LLC, (4) Dr. Reddy's Laboratories, Ltd., and (5) Dr. Reddy's Laboratories, Inc. We filed the lawsuit in the U.S. District Court for the District of Delaware seeking to enjoin the approval of their ANDAs plus recovery of our litigation fees and costs. The litigation is stayed with respect to the Dr. Reddy's entities pending resolution of the case against the other FOLOTYN ANDA filers. A trial date of September 12, 2016 has been set in the FOLOTYN lawsuit in the U.S. District Court for the District of Delaware. While we believe our patent rights are strong, the ultimate outcome of such action is uncertain.

Shareholder Litigation

John Perry v. Spectrum Pharmaceuticals, Inc. et al. (Filed March 14, 2013 in United States District Court, District of Nevada; Case Number 2:2013-cv-00433-LDG-CWH). This putative consolidated class action raises substantially identical claims and allegations against defendants Spectrum Pharmaceuticals, Inc., Dr. Rajesh C. Shrotriya, Brett L. Scott, and Joseph Kenneth Keller. The alleged class period is August 8, 2012 to March 12, 2013. The lawsuits allege a violation of Section 10(b) of the Securities Exchange Act of 1934 against all defendants and control person liability, as a violation of Section 20(b) of the Securities Exchange Act of 1934, against the individual defendants. The claims purportedly stem from the Company's March 12, 2013 press release, in which it announced that it anticipated a change in ordering patterns of FUSILEV. The complaints allege that, as a result of the March 12, 2013 press release, the Company's stock price declined. The complaints further allege that during the putative class period certain defendants made misleadingly optimistic statements about FUSILEV sales, which inflated the trading price of Company stock. The lawsuits seek relief in the form of monetary damages, costs and fees, and any other equitable or injunctive relief that the court deems appropriate. On March 21, 2014, the Court entered an order appointing Arkansas Teacher Retirement System as lead plaintiff. On May 20, 2014, Arkansas Teacher Retirement System filed a consolidated amended class action complaint. On July 18, 2014, we filed a motion to dismiss the consolidated amended class action complaint. On March 26, 2015, the court denied the motion to dismiss. On June 15, 2015, the Court ordered a stay of the proceedings pending the outcome of mediation between the parties. On October 27, 2015, we reached a \$7 million settlement in principle with the lead plaintiff (which involved our insurance carrier, as the reimbursing party in full), subject to preliminary and final court approval. We have included this settlement amount, along with \$1.1 million of reimbursable legal expenses for this matter, on our accompanying Condensed Consolidated Balance Sheets as of September 30, 2015 within "other receivables" and "accounts payable and other accrued liabilities."

Timothy Fik v. Rajesh C. Shrotriya, et al. (Filed April 11, 2013 in United States District Court, District of Nevada; Case Number 2:2013-cv-00624-JCM-CWH); Christopher J. Watkins v. Rajesh C. Shrotriya, et al. (Filed April 22, 2013 in United States District Court, District of Nevada; Case Number 2:2013-cv-00684-JCM-VCF); and Stefan Muenchhagen v. Rajesh C. Shrotriya, et al. (Filed May 28, 2013; Case Number 2:2013-cv-00942-APG-PAL). These derivative complaints are brought by the respective purported shareholders on behalf of nominal plaintiff Spectrum against certain current and former directors and officers. The complaints generally allege breaches of fiduciary based on conduct relating to the events alleged in the consolidated Perry action. The complaints seek compensatory damages, corporate governance reforms, restitution and disgorgement of defendants' alleged profits, and costs and fees. These actions are stayed pending resolution of the federal securities class action. Settlement discussions are

ongoing, and accordingly, no agreement has yet been reached to resolve these derivative complaints. If a settlement were reached, it would be reimbursable by our insurance carrier. However, the value of a potential settlement cannot be reasonably estimated given its highly uncertain nature.

Hardik Kakadia v. Rajesh C. Shrotriya, et al. (Filed April 23, 2013 in the Eighth Judicial District Court of the State of Nevada in and for Clark County; Case Number A-13-680643-B); and Joel Besner v. Rajesh C. Shrotriya, et al. (Filed May 31, 2013; Case Number A-13-682668-C) (collectively the “State Derivative Actions”). These consolidated State Derivative Actions are brought by the respective purported shareholders on behalf of nominal plaintiff Spectrum Pharmaceuticals, Inc. and are substantially similar to the consolidated federal derivative actions. These actions are stayed pending resolution of the federal

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securities class action. Settlement discussions are ongoing, and accordingly, no agreement has yet been reached to resolve these derivative complaints. If a settlement were reached, it would be reimbursable by our insurance carrier. However, the value of a potential settlement cannot be reasonably estimated given its highly uncertain nature.

(h) SEC Subpoena

On April 1, 2013, we received a subpoena from the SEC for documents pursuant to a formal order of investigation. The subpoena followed our March 12, 2013 announcement that we anticipated a change in customer ordering patterns of FUSILEV. We continue to cooperate with this SEC investigation, though we cannot predict its outcome, or the timing of resolution.

(i) Notice from HRSA

We received a notice on October 10, 2014 from the U.S. Health Resources and Services Administration, Office of Pharmacy Affairs (“HRSA”). In this notice HRSA asserted that, for at least one of our products with an “orphan drug” designation under section 526 of the Federal Food, Drug, and Cosmetic Act, we did not make the product(s) available for purchase by certain categories of providers at the applicable 340B price. The 340B price is a discounted price for covered outpatient drugs that manufacturers participating in Medicaid (which includes us) agree to make available to providers that participate in the 340B drug pricing program (“Covered Entities”). HRSA’s notice asserted that, by not selling our product(s) to certain categories of Covered Entities at 340B prices, we were overcharging them, and that we owed certain undefined refunds to those Covered Entities based on our previously made and reported product sales.

On October 14, 2015, the U.S. District Court for the District of Columbia issued a decision in the case of Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services, et al., invalidating HRSA’s July 21, 2014 “interpretive rule” relating to orphan drug pricing under the 340B drug pricing program. Because HRSA’s October 10, 2014 notice to us reflected the same interpretation of relevant orphan drug pricing statutes as the interpretation overturned by the District Court in the Pharmaceutical Research and Manufacturers of America decision, we believe the decision supports the propriety of our pricing to Covered Entities. Since we only make provisions for liabilities when it is both probable that a liability has been incurred, and the amount can be reasonably estimated, we have not recorded a liability for this pending matter as of September 30, 2015 or any earlier period.

#### 14. 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 \$37 thousand and \$2.3 million for the nine months ended September 30, 2015 and 2014, respectively. Our ETR differs from the U.S. federal statutory tax rate of 35% 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 excess tax benefits associated with share-based compensation to stockholders' equity only when realized. When assessing whether excess tax benefits relating to share-based compensation have been realized, we follow the with-and-without approach, excluding any indirect effects of the excess tax deductions. Under this approach, excess tax benefits related to share-based compensation are not deemed to be realized until after the utilization of all other tax benefits available to us. We recognize the impact of a tax position in our financial statements only if that position is more likely than not of being 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.

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## 15. SUBSEQUENT EVENTS

### Co-Promotion Agreement with Eagle Pharmaceuticals, Inc.

On November 4, 2015, we executed an agreement with Eagle Pharmaceuticals, Inc. ("Eagle") whereby designated members of our sales force will concurrently market up to six of Eagle's pharmaceutical products along with our products, in return for fixed monthly payments over the initial 18 month contract term through June 30, 2017, aggregating \$12.8 million (the "Eagle Agreement"). We are also eligible to receive milestone payments of up to \$5 million for sales made in 2016 that exceed certain thresholds, and up to \$4 million for sales made in the first half 2017 that exceed certain thresholds. In addition, for performance above such sales thresholds in 2016, and in the first half of 2017, we are eligible to receive certain further payments if specified targets for annual net sales of Eagle's products are exceeded.

Eagle may extend the initial term of this agreement by six months to December 31, 2017 at its sole election. Any extensions after December 31, 2017 require mutual consent and will be for six months per extension. The Eagle Agreement may be terminated by either party for uncured material breaches and certain other events following a change of control or insolvency of either party, and solely by Eagle for convenience with 60 days written notice, subject to an established termination fee, as calculated within the Eagle Agreement.

The foregoing description of this contract does not purport to be complete and is qualified in its entirety by the Eagle Agreement, which will be filed as an exhibit to our 2015 Annual Report on Form 10-K.

### Complete Response Letter from the FDA for EVOMELA

On October 23, 2015, we received a Complete Response Letter ("CRL") from the FDA for our EVOMELA New Drug Application ("NDA"). In the letter, the FDA did not identify any clinical deficiency in our NDA package. EVOMELA is intended for use as a conditioning treatment prior to autologous stem cell transplant for patients with multiple myeloma. A CRL is a standard communication from the FDA that informs companies that an application cannot be approved in its present form. We are presently working with the FDA to address this CRL.

### Shareholder Litigation

On November 3, 2015, Ira Gains v. Spectrum Pharmaceuticals, Inc. and Rajesh C. Shrotriya was filed in the United States District Court, District of Nevada. This putative class action is brought against us and our CEO. The alleged class period is May 7, 2015 to October 23, 2015. The complaint alleges a violation of Section 10(b) of the Securities Exchange Act of 1934 against us and our CEO, and a violation of Section 20(a) of the Securities Exchange Act of 1934 against our CEO. The claims purportedly stem from our October 23, 2015 press release in which we announced that the FDA issued a CRL indicating that the FDA would not approve our NDA for EVOMELA in its present form. The complaint alleges that, as a result of the October 23, 2015 press release, our stock price declined. The complaint further alleges that during the putative class period, we and certain of our officers and/or directors made misleadingly optimistic statements about the progress of the NDA for EVOMELA with the FDA, our expectations regarding FDA approval of the NDA, and EVOMELA's potential as a future driver of our revenue, which inflated the trading price of our stock. The complaint seeks relief in the form of monetary damages, costs and fees, and any other relief that the Court deems appropriate. We believe this claim is without merit and we are in process of responding to it.

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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or 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, liquidity and capital resources and trends, and other statements containing forward-looking words, such as, "believes," "may," "could," "will," "expects," "intends," "estimates," "anticipates," "plans," "seeks," "continues," or the negative 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 Securities and Exchange Commission, or the SEC, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, 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;
- the 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;
- 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 U.S. Food and Drug Administration ("FDA");
- 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;
- 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

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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

We are a biotechnology company with fully integrated commercial and drug development operations, with a primary 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 distributors, (ii) completion of 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 side 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 relapsed 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 studies with some of our marketed products, and have a diversified pipeline of product candidates in Phase 2 and Phase 3 clinical studies.

### Business Strategy

Our business strategy is comprised of the following three initiatives:

Maximize the revenue potential of our five currently-marketed drugs for the treatment of cancer.

Our near-term outlook largely depends on sales and marketing success of our five marketed drugs. It is this "base business" that provides the requisite working capital to operate our daily operations, and for opportunistic acquisitions and licensing arrangements.

Develop and commercialize drugs for the treatment of cancer within our pipeline.

Our focus is on drugs in the late-stages of development. We strive to timely complete clinical studies in order to obtain regulatory approval expeditiously. Upon obtaining approval, our sales, marketing, and medical affairs functions educate physicians on the safety and effectiveness of the drug in treating cancer patients for the approved indication(s).

Expand our pipeline of development-stage and commercial-stage drugs, while also pursuing out-licensing opportunities.

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We are constantly seeking strategic opportunities that complement our current product portfolio. We will continue to explore collaborations with third parties for cancer drugs that are in the clinical trial phase of development, as well as the acquisition of the rights to cancer drugs that have significant growth potential. To maximize revenue potential, we also pursue strategic out-license opportunities for our drugs in specific territories.

See Item 1. of our Annual Report on Form 10-K for the year ended December 31, 2014, "Business" section for a discussion of our:

Company Overview

Cancer Background and Market Size

Product Portfolio

Manufacturing

Sales and Marketing

Customers

Competition

Research and Development

Recent Highlights in Our Business, Product Development Initiatives, and Regulatory Approvals

During the nine months ended September 30, 2015 and through the filing date of this quarterly report, we accomplished various critical business objectives, which included:

Sales and Marketing:

Sales Force Contracting Arrangement: On November 4, 2015, we executed a contract with Eagle Pharmaceuticals, Inc. ("Eagle") whereby designated members of our sales force will concurrently market (beginning January 2016) up to six of Eagle's pharmaceutical products, along with our products, in return for aggregate fixed proceeds of \$12.8 million that will be paid over the 18-month service period. We are also eligible to receive variable, performance-based payments for sales of Eagle's products that exceed certain thresholds.

Business Development:

POZIOTINIB: In February 2015, we executed an in-license with Hanmi Pharmaceutical Co., Ltd for POZIOTINIB, a pan-HER inhibitor in Phase 2 clinical trials, for an upfront payment and future regulatory and sales-dependent milestone payments. POZIOTINIB has shown single agent activity in the treatment of various cancer types, including breast, gastric, colorectal and lung cancers. Under the terms of this agreement, we received the exclusive rights to commercialize this drug globally, excluding Korea and China.

Medical:

APAZIQUONE: In August 2015, we reached agreement with the FDA on the Special Protocol Assessment (SPA) of the planned Phase 3 clinical trial of our novel, potent pro-drug, APAZIQUONE. This trial commenced with its first patient dosing in October 2015, and is designed to evaluate the intravesical use of this drug for the treatment of patients with non-muscle invasive bladder cancer (NMIBC) as one or two instillations, immediately following transurethral resection of bladder tumor (TURBT). Due to the high rate of recurrence for NMIBC, there is a significant unmet medical need and the overall cost of bladder cancer treatment in the U.S. is \$3.4 billion annually, most of which is related to the direct treatment of this disease. Accordingly, this drug represents much-needed therapy for patients and provides a meaningful opportunity to reduce overall medical costs.

EVOMELA: On October 23, 2015, we received a Complete Response Letter ("CRL") from the FDA for our EVOMELA New Drug Application ("NDA"). EVOMELA is intended for use as a conditioning treatment prior to autologous stem cell transplant for patients with multiple myeloma. A CRL is a standard communication from the FDA that informs companies that an application cannot be approved in its present form. Nonclinical deficiencies were identified, however, the FDA did not identify any clinical deficiencies for this drug in the CRL. We have a meeting scheduled with the FDA to address this CRL and related comments on November 6, 2015. We continue to expect FDA approval of EVOMELA in the near future.

CHARACTERISTICS OF OUR REVENUE AND EXPENSES



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See Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2014, Characteristics of Our Revenue and Expenses 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 of our Annual Report on Form 10-K for the year ended December 31, 2014,