Spectrum Pharmaceuticals Reports Second Quarter 2018 Financial Results and Pipeline Update

August 9, 2018

- An oral presentation of updated Phase 2 poziotinib data including EGFR and HER2 patients with exon 20 mutations will occur on September 24 at the World Conference on Lung Cancer in Toronto
- Spectrum's current poziotinib Phase 2 study is viewed as the pivotal registrational trial following recent conversations with the FDA
- Both Phase 3 ROLONTIS® (eflapegrastim) studies, RECOVER and ADVANCE, have met the primary efficacy endpoint; Spectrum is preparing for a pre-BLA meeting with the FDA in the third quarter
- Q2 revenues were $24.2 million, including $23.8 million in product sales

HENDERSON, Nev.--(BUSINESS WIRE)--Aug. 9, 2018-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations with a primary focus in hematology and oncology, announced today financial results for the three-month period ended June 30, 2018.

"The second quarter marked significant progress and data milestones for our two lead programs poziotinib and ROLONTIS, moving us closer to our ultimate goal of delivering targeted and novel therapies to cancer patients," said Joe Turgeon, President and Chief Executive Officer of Spectrum Pharmaceuticals. "We have strong momentum going into the second half of the year as we aggressively broaden our poziotinib clinical program and continue to gain additional regulatory clarity."

Clinical Program Overview:

Poziotinib, an irreversible tyrosine kinase inhibitor targeting EGFR and HER2 mutations:

- Updated data from the MD Anderson Phase 2 trial in non-small cell lung cancer with exon 20 mutations will be presented at the World Conference on Lung Cancer in Toronto on September 24. Updated data will include EGFR and HER2 patients with exon 20 mutations. The abstract will be released online on September 5.
- Spectrum recently had a meeting with the FDA regarding poziotinib to gain clarity on the regulatory pathway. Based on that conversation, Spectrum views the current poziotinib phase 2 study as the pivotal registrational trial needed for the Agency's review.
- Data published in Nature Medicine from the first 11 NSCLC patients with EGFR exon 20 mutations receiving poziotinib in MD Anderson's Phase 2 clinical trial demonstrated a confirmed objective response rate of 64 percent. The median progression-free survival had not been reached, with a median follow up of 6.6 months. The safety profile was consistent with what has been previously described for poziotinib and other TKIs with the two most common adverse events being known EGFR inhibitor-related toxicities: skin rash and diarrhea.
- Data presented at AACR demonstrated that HER2 exon 20 mutations were prevalent across multiple solid tumors.

ROLONTIS (eflapegrastim), a novel long-acting GCSF:

- Spectrum plans to conduct a pre-BLA meeting in the third quarter to ensure alignment with the FDA in preparation for a planned BLA filing in the fourth quarter of 2018.
- Top line data from RECOVER, the second Phase 3 ROLONTIS study, demonstrated that the study met the primary efficacy endpoint of non-inferiority in the duration of severe neutropenia (DSN) between ROLONTIS and pegfilgrastim. Both Phase 3 ROLONTIS clinical trials, ADVANCE and RECOVER which studied more than 600 patients combined, have met the primary efficacy endpoint. Additional RECOVER data will be released at a future medical meeting.
- ADVANCE data released as part of ASCO 2018 demonstrated that ROLONTIS was non-inferior to pegfilgrastim in the reduction of duration of severe neutropenia (DSN) in all four cycles of the study. Mean DSN±SD was 0.19±0.478 days for ROLONTIS and 0.34±0.668 days for pegfilgrastim, demonstrating non-inferiority with 95 percent confidence interval (CI) of DSN: [-0.260, -0.035]; $p<0.0001$) in Cycle 1. There were no statistically significant differences in all secondary endpoints in Cycle 1. The adverse event profiles were similar across groups. The most common treatment emergent adverse events in both treatment arms were fatigue, nausea, neutropenia, and lymphopenia.
- In an oral presentation at MASCC 2018, data from the ADVANCE Phase 3 study demonstrated an absolute risk reduction of severe neutropenia of 8.5 percent (95% CI: 0.2%, 16.2%) versus pegfilgrastim in Cycle 1. Absolute risk reduction was defined as the difference in percentage of patients experiencing no severe neutropenia (ROLONTIS 84.2 percent; pegfilgrastim 75.7 percent).

Financial Guidance

Spectrum's 2018 revenue guidance remains between $95 to $115 million. Additionally, Spectrum anticipates current cash and marketable securities will be sufficient to fund operations into 2020.

Three-Month Period Ended June 30, 2018 (All numbers are approximate)

GAAP Results

Total product sales were $23.8 million in the second quarter of 2018. Product sales in the second quarter included: FOLOTYN® (pralatrexate injection) net sales of $11.7 million, EVOMELA® (melphalan) for injection net sales of $5.8 million, BELEODAQ® (belinostat) for injection net sales of $2.7 million, ZEVALIN® (ibritumomab tiuxetan) net sales of $1.6 million, MARQIBO® (vinCRIStine sulfate LIPOSOME injection) net sales of $1.1 million, and FUSILEV® (levoleucovorin) net sales of $0.8 million.

Spectrum recorded net income of $13.7 million, or $0.13 income per basic share and $0.13 per diluted share in the three-month period ended June 30, 2018, compared to net loss of $(20.9) million, or $(0.27) loss per basic and diluted share in the comparable period in 2017. Total research and development expenses were $21.5 million in the quarter, as compared to $15.2 million in the same period in 2017. Selling, general and administrative expenses were $23.5 million in the quarter, compared to $17.4 million in the same period in 2017.

Non-GAAP Results

Spectrum recorded non-GAAP net loss of $(21.6) million, or $(0.21) loss per basic and diluted share in the three-month period ended June 30, 2018, compared to non-GAAP net loss of $(8.6) million, or $(0.11) loss per basic and diluted share in the comparable period in 2017. Non-GAAP research and development expenses were $20.1 million, as compared to $14.6 million in the same period of 2017. Non-GAAP selling, general and administrative expenses were $19.6 million, as compared to $14.5 million in the same period in 2017.

Conference Call

Thursday, August 9, 2018 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic:	(877) 837-3910	Conference ID# 9084737
International:	(973) 796-5077	Conference ID# 9084737

This conference call will also be webcast. Listeners may access the webcast, which will be available on the investor relations page of Spectrum Pharmaceuticals' website: www.sppirx.com on August 9, 2018 at 4:30 p.m. Eastern/1:30 p.m. Pacific.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing, and commercializing drug products, with a primary focus in hematology and oncology. Spectrum currently markets six hematology/oncology drugs, and has an advanced stage pipeline that has the potential to transform the company. Spectrum's strong track record for in-licensing and acquiring differentiated drugs, and expertise in clinical development have generated a robust, diversified, and growing pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. More information on Spectrum is available at www.sppirx.com.

Forward-looking statement - This press release may contain forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially.These statements are based on management's current beliefs and expectations.These statements include, but are not limited to, statements that relate to Spectrum's business and its future, including certain company milestones, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, the timing and results of FDA decisions, and any statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact.Risks that could cause actual results to differ include the possibility that Spectrum's existing and new drug candidates may not prove safe or effective, the possibility that our existing and new applications to the FDA and other regulatory agencies may not receive approval in a timely manner or at all, the possibility that our existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our dependence on third parties for clinical trials, manufacturing, distribution and quality control and other risks that are described in further detail in the company's reports filed with the Securities and Exchange Commission.The company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.

SPECTRUM PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended	Six Months Ended

	June 30, 2018	2017	June 30, 2018	2017
Revenues:				
Product sales, net	$ 23,753	$ 31,156	$ 51,863	$ 57,001
License fees and service revenue	415	3,145	2,799	6,401
Total revenues	$ 24,168	$ 34,301	$ 54,662	$ 63,402
Operating costs and expenses:				
Cost of sales (excludes amortization of intangible assets)	6,606	11,303	13,420	19,439
Cost of service revenue	—	2,118	—	4,221
Selling, general and administrative	23,451	17,421	47,556	36,525
Research and development	21,488	15,167	39,382	29,945
Amortization of intangible assets	6,934	6,901	13,880	13,790
Total operating costs and expenses	58,479	52,910	114,238	103,920
Loss from operations	(34,311)	(18,609)	(59,576)	(40,518)
Other income (expense):				
Interest expense, net	(242)	(2,131)	(472)	(4,182)
Change in fair value of contingent consideration related to acquisitions	(192)	(97)	(483)	(294)
Other income, net	48,492	240	58,463	650
Total other income (expense)	48,058	(1,988)	57,508	(3,826)
Income (loss) before income taxes	13,747	(20,597)	(2,068)	(44,344)
Provision for income taxes	(3)	(255)	(6)	(54)
Net income (loss)	$ 13,744	$ (20,852)	$ (2,074)	$ (44,398)
Net income (loss) per share:				
Basic	$ 0.13	$ (0.27)	$ (0.02)	$ (0.57)
Diluted	$ 0.13	$ (0.27)	$ (0.02)	$ (0.57)
Weighted average shares outstanding:				
Basic	102,597,059	78,576,260	101,747,416	78,366,610
Diluted	112,617,150	78,576,260	101,747,416	78,366,610

SPECTRUM PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets
(In thousands, expect per share and par value amounts)
(Unaudited)

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 174,371	$ 227,323
Marketable securities	95,287	248
Accounts receivable, net of allowance for doubtful accounts of $70 and $71, respectively	27,658	32,260
Other receivables	2,915	2,133
Inventories	4,520	5,715
Prepaid expenses and other assets	4,769	10,067
Total current assets	309,520	277,746
Property and equipment, net of accumulated depreciation	523	589
Intangible assets, net of accumulated amortization	123,214	137,159
Goodwill	18,106	18,162
Other assets	13,159	53,783
Total assets	$ 464,522	$ 487,439
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 49,886	$ 58,117
Accrued payroll and benefits	4,946	9,261
Deferred revenue	—	3,872
FOLOTYN development liability	211	275
Convertible senior notes	39,427	38,224
Total current liabilities	94,470	109,749
FOLOTYN development liability, less current portion	11,980	12,111
Deferred revenue, less current portion	—	315
Acquisition-related contingent obligations	6,755	6,272

Deferred tax liabilities	1,447	1,438
Other long-term liabilities	5,751	6,215
Total liabilities	120,403	136,100
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized; 105,130,603 and 100,742,735 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	103	100
Additional paid-in capital	829,052	837,347
Accumulated other comprehensive (loss) income	(3,088)	15,999
Accumulated deficit	(481,948)	(502,107)
Total stockholders' equity	344,119	351,339
Total liabilities and stockholders' equity	$ 464,522	$ 487,439

Non-GAAP Financial Measures

In this press release, Spectrum reports certain historical and expected non-GAAP results. Non-GAAP financial measures are reconciled to the most directly comparable GAAP financial measure in the tables of this press release and the accompanying footnotes. The non-GAAP financial measures contained herein are a supplement to the corresponding financial measures prepared in accordance with generally accepted accounting principles (GAAP). The non-GAAP financial measures presented exclude the items summarized in the below table. Management believes that adjustments for these items assist investors in making comparisons of period-to-period operating results and that these items are not indicative of the company's on-going core operating performance.

Management uses non-GAAP net income (loss) in its evaluation of the company's core after-tax results of operations and trends between fiscal periods and believes that these measures are important components of its internal performance measurement process. Management believes that providing these non-GAAP financial measures allows investors to view the company's financial results in the way that management views the financial results.

The non-GAAP financial measures presented herein have certain limitations in that they do not reflect all of the costs associated with the operations of the company's business as determined in accordance with GAAP. Therefore, investors should consider non-GAAP financial measures in addition to, and not as a substitute for, or as superior to, measures of financial performance prepared in accordance with GAAP. The non-GAAP financial measures presented by the company may be different from the non-GAAP financial measures used by other companies.

SPECTRUM PHARMACEUTICALS, INC.

Reconciliation of Non-GAAP Adjustments for Condensed Consolidated Statements of Operations

(In thousands, expect per share amounts)

		Three Months Ended June 30,		Six Months Ended June 30,	
		2018	**2017**	**2018**	**2017**
(1)	**GAAP product sales, net & license fees and service revenue**	**$ 24,168**	**$ 34,301**	**$ 54,662**	**$ 63,402**
	Non-GAAP adjustments to product sales, net & license fees and service revenue:	—	—	(2,001)	—
	Non-GAAP product sales, net & license fees and service revenue	**$ 24,168**	**$ 34,301**	**$ 52,661**	**$ 63,402**
(2)	**GAAP selling, general and administrative expenses**	**$ 23,451**	**$ 17,421**	**$ 47,556**	**$ 36,525**
	Non-GAAP adjustments to SG&A:				
	Stock-based compensation	(3,832)	(2,888)	(7,522)	(6,126)
	Depreciation expense	(61)	(76)	(108)	(166)
	Non-GAAP selling, general and administrative	**$ 19,558**	**$ 14,457**	**$ 39,926**	**$ 30,233**
(3)	**GAAP research and development**	**$ 21,488**	**$ 15,167**	**$ 39,382**	**$ 29,945**
	Non-GAAP adjustments to R&D:				
	Stock-based compensation	(902)	(599)	(1,689)	(1,081)
	Depreciation expense	(2)	(2)	(5)	(5)
	Other R&D milestone payments	(500)	—	(500)	—
	Non-GAAP research and development	**$ 20,084**	**$ 14,566**	**$ 37,188**	**$ 28,859**
(4)	**GAAP net income (loss)**	**$ 13,744**	**$ (20,852)**	**$ (2,074)**	**$ (44,398)**
	Non-GAAP adjustments to net income (loss):				
	Adjustments to product sales, net & license fees and service revenue, SG&A, and R&D as noted above	5,297	3,565	7,823	7,378
	Amortization of intangible assets	6,934	6,901	13,880	13,790
	Adjustments to other (expense) income	(47,596)	1,525	(56,847)	3,098
	Adjustments to provision for income taxes	3	255	6	54
	Non-GAAP net loss	**$ (21,618)**	**$ (8,606)**	**$ (37,212)**	**$ (20,078)**
(5)	**GAAP income (loss) per share (Basic)**	$ 0.13	$ (0.27)	$ (0.02)	$ (0.57)
	GAAP income (loss) per share (Diluted)	$ 0.13	$ (0.27)	$ (0.02)	$ (0.57)

Non-GAAP loss per share (Basic and Diluted)	$ (0.21)	$ (0.11)	$ (0.37)	$ (0.26)
Weighted average shares outstanding:				
Basic	102,597,059	78,576,260	101,747,416	78,366,610
Diluted	112,617,150	78,576,260	101,747,416	78,366,610

(1) Non-GAAP product sales, net & license fees and service revenue: These amounts reflect adjustments to reverse revenue recognition for upfront revenue from out-licenses and revenue from milestone achievement(s) that do not consistently recur. The resulting non-GAAP revenue solely consists of our (i) product sales, (ii) percentage-based royalties from our licensees' sales, and (iii) on-going service revenue. We believe this measure of non-GAAP revenue is more indicative of the period-over-period success of our core ongoing product sales and service revenue.

(2) Non-GAAP selling, general and administrative: These amounts reflect adjustments to reverse allocated operating expenses for certain non-cash items (including stock-based compensation and depreciation). We believe the resulting non-GAAP SG&A value is more indicative of the period-over-period success of our administrative expense control, and more reflective of our normalized SG&A expense trends.

(3) Non-GAAP research and development: These amounts reflect adjustments to reverse allocated operating expenses for certain non-cash items (including stock-based compensation and depreciation), as well as non-recurring R&D milestone achievements that we record to expense for our in-licenses. We believe the resulting non-GAAP R&D value is more reflective of our true R&D expense trends.

(4) Non-GAAP net loss: These amounts reflect all non-GAAP adjustments described in (1) through (3) above, plus other non-cash and/or non-recurring items, including: (i) adjustments to reverse sales milestone achievements; (ii) adjustments to reverse operating expenses for non-cash amortization and impairment of intangible assets (the reversal of these non-cash expenses allows for a clearer representation of the period-over-period success of our overall financial results and future working capital requirements); (iii) adjustments to reverse the impact of income taxes; (iv) adjustments to reverse the impact of mark-to-market contingent consideration (although our contingent consideration results from prior acquisitions and is a part of our business strategy, these adjustments through earnings typically result from variables other than our current commercial activity or other operating performance measures that are a focus of our management), (v) reversal of foreign exchange gains and losses (non-cash), (vi) reversal of debt discount accretion expense (non-cash) for our convertible notes, and (vii) reversal of the mark-to-market adjustment on our equity securities.

(5) Non-GAAP loss per share: These amounts reflect all non-GAAP adjustments in (1) through (4) above to present our overall non-GAAP financial results for each period on a per-share basis.

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