Spectrum Pharmaceuticals Reports Second Quarter 2019 Financial Results and Pipeline Update

August 8, 2019

HENDERSON, Nev.--(BUSINESS WIRE)--Aug. 8, 2019-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, announced today financial results for the three-month period ended June 30, 2019.

"We've made significant progress on our pipeline in the last few months," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "Most notably, we completed enrollment in our first two poziotinib cohorts in the ZENITH20 study and expect to see results from cohort 1 in the fourth quarter. Based on strong science, we've expanded the poziotinib development program to include additional areas of high unmet medical need in lung cancer. We also had a productive meeting with the FDA and expect to submit the ROLONTIS BLA in the fourth quarter."

Pipeline Overview:

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

- The cornerstone poziotinb ZENITH20 trial currently consists of seven cohorts of patients with non-small cell lung cancer (NSCLC).
  - Cohorts Fully Enrolled
    - Cohort 1: Previously treated patients with EGFR exon 20 insertion mutation; topline results expected in the fourth quarter 2019
    - Cohort 2: Previously treated patients with HER2 exon 20 insertion mutation; topline results expected in mid-2020
  - Cohorts Currently Enrolling
    - Cohort 3: Treatment naïve patients with EGFR exon 20 insertion mutation
    - Cohort 4: Treatment naïve patients with HER2 exon 20 insertion mutation
    - Cohort 5: Previously treated or treatment naïve patients with EGFR or HER2 exon 20 insertion mutation
    - Cohort 6: Previously treated first-line osimertinib patients with acquired EGFR mutations
    - Cohort 7: Previously treated patients with atypical EGFR or HER2 mutation
- Spectrum expects to initiate a basket study in H2 2019.

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

- Integrated data from both Phase 3 ROLONTIS clinical trials with 643 patients were presented in a poster session at American Society of Clinical Oncology 2019 annual meeting.
  - The analysis found that integrated efficacy and safety data from the two identically designed Phase 3 trials - ADVANCE and RECOVER - were consistent with results from the individual trials, demonstrating that ROLONTIS was non-inferior to pegfilgrastim in the reduction of duration of severe neutropenia (DSN) in all four cycles of treatment.
- Spectrum met with the FDA and expects to submit the ROLONTIS BLA in the fourth quarter of 2019.

Business Development

- In May 2019, Spectrum completed an asset purchase and license agreement with ImmunGene, Inc., a privately held biotechnology company.
  - The deal includes an exclusive license for the intellectual property related to the FIT antibody-interferon fusion technology drug delivery platform and two innovative early-stage drug candidates derived from the platform.
  - Originally developed by scientists at UCLA, the FIT platform fuses interferon with a monoclonal antibody providing a mechanism for targeting many different tumor antigens and has the potential for broad application in oncology.

Three-Month Period Ended June 30, 2019 (All numbers are from Continuing Operations and are approximate)

GAAP Results

Spectrum recorded a loss of $28.8 million, or a loss of $0.26 per basic and diluted share, in the three-month period ended June 30, 2019, compared to income of $14.9 million, or $0.15 income per basic share and $0.14 per diluted share, in the comparable period in 2018. Total research and development expenses were $17.0 million in the quarter, as compared to $16.6 million in the same period in 2018. Selling, general and administrative expenses were $17.2 million in the quarter, compared to $16.4 million in the same period in 2018.

The company ended the quarter with cash, cash equivalents, restricted cash, and marketable securities of $282 million.

Non-GAAP Results

Spectrum recorded a non-GAAP loss of $25.2 million, or a non-GAAP loss of $0.23 per basic and diluted share, in the three-month period ended June 30, 2019, compared to a non-GAAP loss of $28.8 million, or a non-GAAP loss of $0.28 per basic and diluted share, in the comparable period in 2018. Non-GAAP research and development expenses were $13.2 million, as compared to $15.4 million in the same period of 2018. Non-GAAP selling, general and administrative expenses were $13.7 million, as compared to $13.8 million in the same period in 2018.

Conference Call:

Thursday, August 8, 2019 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 5378656
International: (973) 796-5077, Conference ID# 5378656

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: http://investor.sppirx.com/events-and-presentations on August 8, 2019 at 4:30 p.m. Eastern/1:30 p.m. Pacific.

AboutSpectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted drug products, with a primary focus in hematology and oncology. Spectrum has a strong track record of successfully executing across the biopharmaceutical business model, from in-licensing and acquiring differentiated drugs, clinically developing novel assets, successfully gaining regulatory approvals and commercializing in a competitive healthcare marketplace. Spectrum has a late-stage pipeline with novel assets that serve areas of unmet need. This pipeline has the potential to transform the company in the near future. More information on Spectrum is available at www.sppirx.com.

Notice Regarding Forward-looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These forward-looking statements relate to a variety of matters, including, without limitation, statements that relate to Spectrum's business and its future, the Company's ability to execute its long-term strategy, the timing of the BLA filing for ROLONTIS, the timing of the topline results from the poziotinib EGFR previously treated and HER2 previously treated non-small cell lung cancer cohort in the ZENITH20 trial, the potential for the two poziotinib cohorts to support an NDA filing with the FDA, the potential clinical applications for the FIT therapies, its potential for treating both solid and hematologic malignancies, the ability of the FIT therapies to meet currently unaddressed medical needs and the size of potential markets, the future potential of Spectrum's existing drug pipeline, and any other statements that are not purely statements of historical fact. These forward-looking statements are based on management's current beliefs, expectations and assumptions and are subject to significant risks and uncertainties. Investors are cautioned not to place undue reliance on any such forward-looking statements. All such forward-looking statements speak only as of the date they are made, and Spectrum undertakes no obligation to update or revise these statements, whether as a result of new information, future events or otherwise. Although Spectrum believes that the expectations reflected in these forward-looking statements are reasonable, these statements involve many risks and uncertainties that may cause actual results to differ materially from what may be expressed or implied in these forward-looking statements, including, without limitation, the uncertainties inherent in new product development, including clinical trial results and additional analysis of existing clinical data, the possibility that Spectrum's applications to the FDA and other regulatory agencies may not receive approval in a timely manner or at all, the possibility that Spectrum's existing and new drug candidates, including poziotinib, ROLONTIS and the FIT therapies, may not be more effective, safer or more cost efficient than competing drugs, and Spectrum's dependence on third parties for clinical trials, manufacturing and quality control. For a further discussion of risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Spectrum in general, see the risk disclosures in the Annual Report on Form 10-K of Spectrum for the year ended December 31, 2018, and in subsequent reports on Forms 10-Q and 8-K and other filings made with the SEC by Spectrum.

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SPECTRUM PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**

Revenues (*Note 1(b)*)	$ —	$ —	$ —	$ —
Operating costs and expenses:				
Selling, general and administrative	17,230	16,391	33,182	33,007
Research and development	16,982	16,595	38,868	29,960
Total operating costs and expenses	34,212	32,986	72,050	62,967
Loss from continuing operations	(34,212)	(32,986)	(72,050)	(62,967)
Other income (expense):				
Interest income (expense), net	1,495	(242)	2,556	(473)
Other income (expense), net	3,722	48,492	(7,563)	58,463
Total other income (expense)	5,217	48,250	(5,007)	57,990
(Loss) income from continuing operations before income taxes	(28,995)	15,264	(77,057)	(4,977)
Benefit (provision) for income taxes from continuing operations	212	(370)	8,454	698
(Loss) income from continuing operations	$ (28,783)	$ 14,894	$ (68,603)	$ (4,279)
Income (loss) from discontinued operations, net of income taxes	388	(1,150)	21,053	2,205
Net (loss) income	$ (28,395)	$ 13,744	$ (47,550)	$ (2,074)
Basic (loss) income per share:				
(Loss) income per common share from continuing operations	$ (0.26)	$ 0.15	$ (0.63)	$ (0.04)
Income (loss) per common share from discontinued operations	—	(0.01)	0.19	0.02
Net (loss) income per common share	$ (0.26)	$ 0.14	$ (0.44)	$ (0.02)
Diluted (loss) income per share:				
(Loss) income per common share from continuing operations	$ (0.26)	$ 0.14	$ (0.63)	$ (0.04)
Income (loss) per common share from discontinued operations	—	(0.01)	0.19	0.02
Net (loss) income per common share	$ (0.26)	$ 0.13	$ (0.44)	$ (0.02)
Weighted average shares outstanding:				

Basic	110,345,135	102,597,059	109,744,405	101,747,416
Diluted	110,345,135	112,617,150	109,744,405	101,747,416

SPECTRUM PHARMACEUTICALS, INC.

Income from Discontinued Operations, net of Income Taxes

(In thousands)

(Unaudited)

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2019	**2018**	**2019**	**2018**
Product sales, net***	$ (1,245)	$ 23,753	$ 12,938	$ 51,863
License fees and service revenue	—	415	290	2,799
Total revenues	$ (1,245)	$ 24,168	$ 13,228	$ 54,662
Operating costs and expenses:				
Cost of sales (excluding amortization of intangible assets)	433	6,606	3,601	13,420
Selling, general and administrative	(61)	7,060	5,890	14,549
Research and development	255	4,893	2,791	9,422
Amortization of intangible assets	—	6,934	1,248	13,880
Restructuring - employee severance****	(2,439)	—	3,858	—
Total operating costs and expenses	$ (1,812)	$ 25,493	$ 17,388	$ 51,271
Income (loss) from discontinued operations	$ 567	$ (1,325)	$ (4,160)	$ 3,391
Other (expense) income:				
Change in fair value of contingent consideration	—	(192)	(1,478)	(483)
Gain on sale of Commercial Product Portfolio*	—	—	33,644	—
Total other (expense) income	$ —	$ (192)	$ 32,166	$ (483)
Income (loss) from discontinued operations before income taxes	567	(1,517)	28,006	2,908
(Provision) benefit for income taxes from discontinued operations**	(179)	367	(6,953)	(703)
Income (loss) from discontinued operations, net of income taxes	$ 388	$ (1,150)	$ 21,053	$ 2,205

*This pre-tax gain on sale represents the $158.8 million proceeds from the Commercial Product Portfolio Transaction *less* our $121.2 book value of transferred net assets (inclusive of assumed liabilities) to Acrotech on the March 1, 2019 closing date, and after legal and banker transaction expenses

for the three months ended March 31, 2019 that aggregated $3.9 million.

**This income tax provision (benefit) represents an allocation of taxes as required under the intraperiod allocation guidance. Due to our aggregate net operating loss-carryforwards, nofederal or state income tax payments are expected to be made relating to our current year activity, inclusive of our gain on sale of the Commercial Product Portfolio.

***The “Product sales, net” is inclusive of our commercial product sales for January and February 2019, as well as recognized EVOMELA product sales during the second quarter of 2019 to a single customer under an active contract that was not yet assumed by Acrotech. The negative revenue value reflects actual government chargeback claims received during the three months ended June 30, 2019 that were in excess of current period revenue for this interim EVOMELA supply arrangement and our then-existing allowance for government chargebacks.

****The “Restructuring - employee severance” negative value in the second quarter of 2019 reflects a current period reclassification to continuing operations “selling, general and administrative” and “research and development” expenses. This $2.4 million amount was previously included within “income (loss) from discontinued operations, net of income taxes” in the first quarter of 2019.

SPECTRUM PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands, expect per share and par value amounts)

(Unaudited)

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 118,251	$ 157,480
Restricted cash	4,020	—
Marketable securities	160,134	46,508
Accounts receivable, net of allowance for doubtful accounts of $67 and $67, respectively	2,542	29,873
Other receivables	10,229	3,698
Prepaid expenses and other assets	10,839	7,574
Discontinued operations, current assets	—	5,555
Total current assets	306,015	250,688
Property and equipment, net of accumulated depreciation	4,534	385
Other assets	8,277	7,188
Facility and equipment under lease	3,842	—
Discontinued operations, non-current assets	—	132,625
Total assets	$ 322,668	$ 390,886
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		

Accounts payable and other accrued liabilities	$ 44,455	$ 69,460
Accrued payroll and benefits	5,262	9,853
Contract liabilities	7,245	4,850
Discontinued operations, current liabilities	—	2,311
Total current liabilities	56,962	86,474
Deferred tax liabilities	—	1,469
Other long-term liabilities	10,923	5,650
Discontinued operations, non-current liabilities	—	14,031
Total liabilities	67,885	107,624
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; 112,684,387 and 110,525,141 issued and outstanding at June 30, 2019 and December 31, 2018, respectively	112	110
Additional paid-in capital	905,871	886,740
Accumulated other comprehensive loss	(3,764)	(3,702)
Accumulated deficit	(647,436)	(599,886)
Total stockholders’ equity	254,783	283,262
Total liabilities and stockholders’ equity	$ 322,668	$ 390,886

Non-GAAP Financial Measures (from Continuing Operations)

In this press release, Spectrum reports certain historical results that have not been prepared in accordance with generally accepted accounting principles (GAAP), including non-GAAP selling, general and administrative expenses, non-GAAP research and development expenses, non-GAAP net loss and non-GAAP net loss per share. Non-GAAP financial measures are reconciled to the most directly comparable GAAP financial measures 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 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 these non-GAAP financial measures are useful to investors in providing greater transparency to the information used by management in its operational decision-making. Management believes that the use of these non-GAAP financial measures also facilitates a comparison of the Company’s underlying operating performance with that of other companies in its industry, which use similar non-GAAP measures to supplement their GAAP 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. In addition, other companies, including other companies in our industry, may calculate non-GAAP financial measures differently than we do, limiting their usefulness as a comparative tool. Investors and potential investors are encouraged to review the reconciliation of our non-GAAP financial measures contained within this news release with our GAAP financial results.

SPECTRUM PHARMACEUTICALS, INC.

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

(In thousands, expect per share amounts)

		CONTINUING OPERATIONS ONLY		CONTINUING OPERATIONS ONLY	
		Three Months Ended		Six Months Ended	
		June 30,		June 30,	
		2019	2018	2019	2018
(1)	**GAAP selling, general and administrative**	**$ 17,230**	**$ 16,391**	**$ 33,182**	**$ 33,007**
	Non-GAAP adjustments to SG&A:				
	Stock-based compensation expense	(3,555)	(2,531)	(7,030)	(4,784)
	Depreciation expense	(56)	(61)	(122)	(108)
	Lease expense	—	—	(129)	—
	Severance expense	126	—	(1,515)	—
	Non-GAAP selling, general and administrative	**$ 13,745**	**$ 13,799**	**$ 24,386**	**$ 28,115**
(2)	**GAAP research and development**	**$ 16,982**	**$ 16,595**	**$ 38,868**	**$ 29,960**
	Non-GAAP adjustments to R&D:				
	Stock-based compensation expense	(1,344)	(650)	(2,227)	(1,281)
	Depreciation expense	(13)	(2)	(15)	(5)
	Severance expense	286	—	(260)	—
	R&D milestones and in-license upfront fees	(2,751)	(500)	(2,751)	(500)
	Non-GAAP research and development	**$ 13,160**	**$ 15,443**	**$ 33,615**	**$ 28,174**
(3)	**GAAP net (loss) income from continuing operations**	**$ (28,783)**	**$ 14,894**	**$ (68,603)**	**$ (4,279)**
	Non-GAAP adjustments to net (loss) income from continuing operations:				
	Adjustments to SG&A and R&D as noted above	7,307	3,744	14,049	6,678
	Adjustments to other (income) expense	(3,477)	(47,789)	8,428	(57,333)
	Adjustments to (benefit) provision for income taxes	(212)	370	(8,454)	(698)
	Non-GAAP net loss from continuing operations	**$ (25,165)**	**$ (28,781)**	**$ (54,580)**	**$ (55,632)**

(4)	**GAAP net (loss) income from continuing operations - per basic share**	$ (0.26)	$ 0.15	$ (0.63)	$ (0.04)
	GAAP net (loss) income from continuing operations - per diluted share	$ (0.26)	$ 0.14	$ (0.63)	$ (0.04)
	Non-GAAP net loss from continuing operations - per basic and diluted share	$ (0.23)	$ (0.28)	$ (0.50)	$ (0.55)
	Weighted average shares outstanding:				
	Basic	110,345,135	102,597,059	109,744,405	101,747,416
	Diluted	110,345,135	112,617,150	109,744,405	101,747,416

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

(2) Non-GAAP research and development expenses (from continuing operations): 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 severance expenses and R&D milestone achievements and upfront in-license fees that we record to this expense caption. We believe this resulting non-GAAP R&D value is more indicative of our normalized R&D expense trends.

(3) Non-GAAP net loss (from continuing operations): These amounts reflect all non-GAAP adjustments described in (1) through (2) above, plus other non-cash and/or non-recurring items, including: (i) adjustments to reverse the impact of income taxes; (ii) reversal of foreign exchange gains and losses (non-cash); (iii) reversal of debt discount accretion expense (non-cash) for our convertible notes during the prior year period; and (iv) reversal of the mark-to-market adjustment (non-cash) on our equity securities holdings.

(4) Non-GAAP net loss per share (from continuing operations): These amounts reflect all non-GAAP adjustments in (1) through (3) above to present our overall non-GAAP financial results for each period on a per-share basis.

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