



Spectrum Pharmaceuticals Reports Fourth Quarter 2019 and Full Year 2019 Financial Results and Pipeline Update

February 27, 2020

BLA for ROLONTIS® (eflapegrastim) accepted for FDA review - PDUFA date on October 24, 2020

Data from poziotinib Cohort 1 of ZENITH20 accepted for podium presentation on March 18 at 11th Annual Congress on Pulmonary and Respiratory Medicine in Amsterdam

Spectrum plans to hold a conference call following the data presentation to review the data and strategy of the program

HENDERSON, Nev.--(BUSINESS WIRE)-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, announced today financial results for the three-month period and year ended December 31, 2019.

"ROLONTIS is in active review by the FDA and we are preparing to launch shortly following approval," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "We believe this market represents a significant commercial opportunity and our prelaunch activities are well underway. We have a podium presentation on poziotinib in a few short weeks, we have taken steps to adjust our strategy and we have multiple data catalysts in 2020. I look forward to updating you on our progress throughout the year."

Pipeline Updates

ROLONTIS (eflapegrastim), a novel long-acting G-CSF

- FDA is actively reviewing the BLA for ROLONTIS for the treatment of chemotherapy-induced neutropenia. The PDUFA target action date for the ROLONTIS BLA has been set for October 24, 2020.
- In October 2019, Spectrum presented a poster at the ASCO Supportive Care in Oncology Symposium in San Francisco. The poster highlighted integrated efficacy data from the Phase 3 ROLONTIS clinical trials, ADVANCE and RECOVER, which studied more than 600 patients combined and met all primary and secondary endpoints.
- An abstract reporting preclinical data on eflapegrastim or pegfilgrastim using "same day dosing" as chemotherapy has been accepted for presentation at the AACR meeting April 24-29 in San Diego.

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

- The pre-specified primary endpoint in a Phase 2 clinical trial (ZENITH20) evaluating poziotinib in previously treated non-small cell lung cancer (NSCLC) patients with EGFR exon 20 insertion mutations was not achieved in Cohort 1.
- Data from Cohort 1 will be presented in a podium presentation at the 11th Annual Congress on Pulmonary and Respiratory Medicine in Amsterdam on March 18th.
- Cohort 2 of the ZENITH20 trial enrolling previously treated HER2 non-small cell lung cancer patients is fully accrued and is expected to have topline results by mid-year 2020. Cohort 3 of the ZENITH20 trial enrolling first-line EGFR NSCLC patients is expected to have topline results by year-end 2020. Either cohort has the potential to support a future NDA submission.

Three-Month Period Ended December 31, 2019 (All numbers are from Continuing Operations)

GAAP Results

Spectrum recorded net loss of \$40.2 million, or \$0.36 per basic and diluted share, in the three-month period ended December 31, 2019, compared to net loss of \$53.1 million, or \$0.50 per basic and diluted share, in the comparable period in 2018. Total research and development expenses were \$23.3 million in the quarter, as compared to \$29.9 million in the same period in 2018. Selling, general and administrative expenses were \$15.1 million in the quarter, compared to \$16.6 million in the same period in 2018.

Non-GAAP Results

Spectrum recorded non-GAAP net loss of \$33.4 million, or \$0.30 per basic and diluted share, in the three-month period ended December 31, 2019, compared to non-GAAP net loss of \$43.4 million, or \$0.41 per basic and diluted share, in the comparable period in 2018. Non-GAAP research and development expenses were \$22.4 million, as compared to \$29.2 million in the same period of 2018. Non-GAAP selling, general and administrative expenses were \$11.6 million, as compared to \$14.0 million in the same period in 2018.

Twelve-Month Period Ended December 31, 2019 (All numbers are from Continuing Operations)

GAAP Results

Spectrum recorded net loss of \$135.4 million, or \$1.22 per basic and diluted share, in the twelve-month period ended December 31, 2019, compared to net loss of \$126.7 million, or \$1.23 per basic and diluted share, in the comparable period in 2018. Total research and development expenses were \$79.3 million for the year, as compared to \$75.2 million in the same period in 2018. Selling, general and administrative expenses were \$61.4 million for the year, compared to \$62.7 million in the same period in 2018.

Non-GAAP Results

Spectrum recorded non-GAAP net loss of \$111.9 million, or \$1.01 per basic and diluted share, in the twelve-month period ended December 31, 2019, compared to non-GAAP net loss of \$124.3 million, or \$1.20 per basic and diluted share, in the comparable period in 2018. Non-GAAP research and development expenses were \$72.0 million, as compared to \$72.1 million in the same period of 2018. Non-GAAP selling, general and administrative expenses were \$45.5 million, as compared to \$53.2 million in the same period in 2018.

Cash Position and Guidance

Spectrum reported cash, cash equivalents, restricted cash, and marketable securities of approximately \$224 million as of December 31, 2019, compared to \$204 million at December 31, 2018. Based on current operating plans, Spectrum expects that SG&A expense will increase in the second half of this year as we scale up our commercial operations in preparation to launch ROLONTIS.

Conference Call

Thursday, February 27, 2020 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 4475135

International: (973) 796-5077, Conference ID# 4475135

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 February 27, 2020 at 4:30 p.m. Eastern/1:30 p.m. Pacific.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted oncology therapies. 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. For additional information on Spectrum Pharmaceuticals please visit www.sppirx.com.

About ZENITH20

The ZENITH20 study consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) have completed enrollment of previously treated NSCLC patients with exon 20 mutations. Cohort 3 (EGFR) and 4 (HER2) are currently enrolling first-line NSCLC patients with exon 20 mutations. Cohorts 1- 4 are each independently powered for a pre-specified statistical hypothesis and the primary endpoint is objective response rate (ORR). Cohort 5 includes previously treated or treatment-naïve NSCLC patients with EGFR or HER2 exon 20 insertion mutations. Cohort 6 includes NSCLC patients with classical EGFR mutations who progressed while on treatment with first-line osimertinib and developed an additional EGFR mutation. Cohort 7 includes NSCLC patients with a variety of less common mutations in EGFR or HER2 exons 18-21 or the extracellular or transmembrane domains.

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, including the likelihood and timing of FDA approval of ROLONTIS, the size of the potential market for ROLONTIS and the timing of its commercial launch, the company's ability to advance development of its late-stage pipeline assets, the ability of such assets to meet currently unaddressed medical needs, the timing of the results of cohort 2 and cohort 3 in Spectrum's ZENITH20 study and their potential to support future NDA submissions, the future potential of Spectrum's existing drug pipeline, the progression of the pozitotinib development program and other statements that are not purely statements of historical fact. These forward-looking statements are made on the basis of the current beliefs, expectations, and assumptions of the management of Spectrum and are subject to significant risks and uncertainties that could cause actual results to differ materially from what may be expressed or implied in these forward-looking statements. Risks that could cause actual results to differ include, but are not limited to, the uncertainties inherent in new product development, including clinical trial results and additional analysis of existing preclinical and clinical data, the possibility that Spectrum's new and existing drug candidates, including pozitotinib, may not ultimately prove to be safe or effective, the possibility that Spectrum's new and existing drug candidates, if approved, may not be more effective, safer, or more cost efficient than competing drugs, 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. 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, 2019, 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 December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Revenues	\$ —	\$ —	\$ —	\$ —
Operating costs and expenses:				
Selling, general and administrative	15,065	16,575	61,373	62,690
Research and development	23,290	29,883	79,325	75,157
Total operating costs and expenses	38,355	46,458	140,698	137,847
Loss from continuing operations before other (expense) income and income taxes	(38,355)	(46,458)	(140,698)	(137,847)
Other (expense) income :				
Interest income (expense), net	920	143	4,996	(340)
Other (expense) income, net	(3,345)	(8,003)	(8,892)	9,580
Total other (expense) income	(2,425)	(7,860)	(3,896)	9,240
Loss from continuing operations before income taxes	(40,780)	(54,318)	(144,594)	(128,607)
Benefit for income taxes from continuing operations	579	1,201	9,208	1,901
Loss from continuing operations	\$ (40,201)	\$ (53,117)	\$ (135,386)	\$ (126,706)
Income from discontinued operations, net of income taxes	1,150	4,974	22,697	5,965
Net loss	\$ (39,051)	\$ (48,143)	\$ (112,689)	\$ (120,741)
Basic and diluted loss per share:				
Loss per common share from continuing operations	\$ (0.36)	\$ (0.50)	\$ (1.22)	\$ (1.23)
Income per common share from discontinued operations	\$ 0.01	\$ 0.05	\$ 0.21	\$ 0.06

Net loss per common share	\$ (0.35)	\$ (0.46)	\$ (1.02)	\$ (1.17)
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Weighted average shares outstanding:

Basic	111,355,254	105,633,296	110,585,768	103,305,911
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Diluted	111,355,254	105,633,296	110,585,768	103,305,911
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SPECTRUM PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

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

	December 31,	
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 64,418	\$ 157,480
Marketable securities	159,455	46,508
Accounts receivable, net of allowance for doubtful accounts of \$43 and \$67, respectively	441	29,873
Other receivables	9,558	3,698
Prepaid expenses and other assets	10,148	7,574
Discontinued operations, current assets	—	5,555
Total current assets	244,020	250,688
Property and equipment, net of accumulated depreciation	11,607	385
Other assets	4,000	7,188
Facility and equipment under lease	3,806	—
Discontinued operations, non-current assets	—	132,625
Total assets	\$ 263,433	\$ 390,886
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 54,284	\$ 81,312

Accrued payroll and benefits	7,686	9,853
Contract liabilities	—	4,850
Discontinued operations, current liabilities	—	2,311
Total current liabilities	61,970	98,326
Deferred tax liabilities, net	—	1,469
Other long-term liabilities	11,070	5,650
Discontinued operations, non-current liabilities	—	14,031
Total liabilities	73,040	119,476
Commitments and contingencies (<i>Note 10</i>)		
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; 113,299,612 and 110,525,141 issued and outstanding at December 31, 2019 and 2018, respectively	113	110
Additional paid-in capital	918,205	886,740
Accumulated other comprehensive loss	(3,498)	(3,702)
Accumulated deficit	(724,427)	(611,738)
Total stockholders' equity	190,393	271,410
Total liabilities and stockholders' equity	\$ 263,433	\$ 390,886

Non-GAAP Financial Measures

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 from continuing operations and non-GAAP net loss per share from continuing operations. 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 loss from continuing operations in its evaluation of the company's core 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.

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

(In thousands, except per share amounts)

	CONTINUING OPERATIONS ONLY		CONTINUING OPERATIONS ONLY	
	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
(1) GAAP selling, general and administrative	\$ 15,065	\$ 16,575	\$ 61,373	\$ 62,690
Non-GAAP adjustments to SG&A:				
Stock-based compensation expense	(3,393)	(2,582)	(13,822)	(9,268)
Depreciation expense	(96)	(22)	(276)	(213)
Lease expense	(25)	—	(282)	—
Severance expense	—	—	(1,515)	—
Non-GAAP selling, general and administrative	\$ 11,551	\$ 13,971	\$ 45,478	\$ 53,209
(2) GAAP research and development	\$ 23,290	\$ 29,883	\$ 79,325	\$ 75,157
Non-GAAP adjustments to R&D:				
Stock-based compensation expense	(882)	(681)	(4,254)	(2,566)
Depreciation expense	(36)	(2)	(81)	(9)
Severance expense	—	—	(260)	—
Other R&D milestone payments	—	—	(2,751)	(500)
Non-GAAP research and development	\$ 22,372	\$ 29,200	\$ 71,979	\$ 72,082
(3) GAAP net loss from continuing operations	\$ (40,201)	\$ (53,117)	\$ (135,386)	\$ (126,706)
Non-GAAP adjustments to net loss from continuing operations:				
Adjustments to SG&A and R&D as noted above	4,432	3,287	23,241	12,556
Adjustments to other expense (income)	2,969	7,664	9,418	(8,241)
Adjustments to benefit for income taxes	(579)	(1,201)	(9,208)	(1,901)
Non-GAAP net loss from continuing operations	\$ (33,379)	\$ (43,367)	\$ (111,935)	\$ (124,292)
(4) GAAP net loss from continuing operations - per basic and diluted share	\$ (0.36)	\$ (0.50)	\$ (1.22)	\$ (1.23)

Non-GAAP net loss from continuing operations - per basic and diluted share \$ (0.30) \$ (0.41) \$ (1.01) \$ (1.20)

Weighted average shares outstanding:

Basic	111,355,254	105,633,296	110,585,768	103,305,911
Diluted	111,355,254	105,633,296	110,585,768	103,305,911

(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) and (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 the mark-to-market adjustment (non-cash) on our equity securities holdings; (iv) reversal of the realized gain on the sale of our equity securities holdings; and (v) reversal of debt discount accretion expense (non-cash) for our convertible notes during the prior year period.

(4) Non-GAAP net loss from continuing operations - per basic and diluted share: 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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Robert Uhl
 Managing Director, Westwicke ICR
 858.356.5932
robert.uhl@westwicke.com

Kurt Gustafson
 Chief Financial Officer
 949.788.6700
InvestorRelations@sppirx.com

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