



## Spectrum Pharmaceuticals Reports Third Quarter 2019 Financial Results and Pipeline Update

November 7, 2019

*Topline data from Cohort 1 of ZENITH20 trial evaluating poziotinib for NSCLC expected in December*

*Basket trial initiated to study poziotinib in patients with EGFR or HER2 mutation-positive malignant solid tumors in an investigator-led study at The University of Texas MD Anderson Cancer Center*

*ROLONTIS®(eflapregrastim) Biologics License Application (BLA) submitted on October 24, 2019*

HENDERSON, Nev.--(BUSINESS WIRE)--Nov. 7, 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 September 30, 2019.

"Spectrum has an expanding pipeline, significant near-term milestones, solid capitalization and a highly focused team," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "In December, we look forward to results from Cohort 1 of our ZENITH20 study investigating poziotinib in lung cancer patients with hard-to-treat mutations. We recently submitted our BLA for ROLONTIS to the FDA, a key milestone, as we continue to execute on our strategic priorities."

### Pipeline Updates

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

- Topline results from the EGFR previously treated non-small cell lung cancer cohort (Cohort 1) in the ZENITH20 trial are expected in December. These data could potentially support a New Drug Application (NDA) filing with the FDA.
- The HER2 previously-treated non-small cell lung cancer cohort (Cohort 2) of the ZENITH20 trial is fully accrued and is expected to have topline results by mid-year 2020. This cohort also has the potential to support an NDA filing with the FDA in the future.
- A basket study has been initiated to investigate poziotinib in patients with EGFR or HER2 mutation-positive malignant solid tumors in an investigator-led study, with the first patient enrolled at The University of Texas MD Anderson Cancer Center.
- In September, new preclinical data from The University of Texas MD Anderson Cancer Center, was presented during the IASLC 2019 World Conference on Lung Cancer in Barcelona, Spain. These scientific data support the recently announced expansion of the ZENITH20 trial.

#### ***ROLONTIS (eflapregrastim), a novel long-acting GCSF***

- Spectrum submitted the ROLONTIS BLA to the FDA on October 24, 2019.
- In October, Spectrum presented a poster at the ASCO Supportive Care in Oncology Symposium in San Francisco, CA, highlighting 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.
- Integrated safety data from the ROLONTIS studies will be presented at the San Antonio Breast Cancer Symposium meeting in December.

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

##### **GAAP Results**

Spectrum recorded a loss of \$26.6 million, or \$0.24 loss per basic and diluted share, in the three-month period ended September 30, 2019, compared to net loss of \$69.2 million, or \$0.66 loss per basic and diluted share, in the comparable period in 2018. Total research and development expenses were \$17.2 million in the quarter, as compared to \$15.3 million in the same period in 2018. Selling, general and administrative expenses were \$13.1 million in the quarter, compared to \$13.1 million in the same period in 2018.

The company ended the quarter with cash, cash equivalents, restricted cash, and marketable securities of \$252 million.

##### **Non-GAAP Results**

Spectrum recorded a non-GAAP loss of \$24.5 million, or a non-GAAP loss of \$0.22 per basic and diluted share, in the three-month period ended September 30, 2019, compared to a non-GAAP loss of \$25.3 million, or a non-GAAP loss of \$0.24 per basic and diluted share, in the comparable period in 2018. Non-GAAP research and development expenses were \$16.1 million, as compared to \$14.7 million in the same period of 2018. Non-GAAP selling, general and administrative expenses were \$9.9 million, as compared to \$11.1 million in the same period in 2018.

##### **Conference Call:**

**Thursday, November 7, 2019 @ 4:30 p.m. Eastern/1:30 p.m. Pacific**

Domestic: (877) 837-3910, Conference ID# 1469173  
International: (973) 796-5077, Conference ID# 1469173

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 November 7, 2019 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](http://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). In July 2019, three new cohorts were added to the ZENITH20 study that are all currently enrolling patients. 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 company's ability to advance development of its late-stage pipeline assets, the ability of poziotinib to meet currently unaddressed medical needs and the size of the potential markets, the timing of the results of cohort 1 and cohort 2 in Spectrum's ZENITH20 study, the future potential of Spectrum's existing drug pipeline, the progression of the poziotinib 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 pre-clinical and clinical data, the possibility that Spectrum's new and existing drug candidates, including poziotinib, 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, 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues	\$ —	\$ —	\$ —	\$ —

Operating costs and expenses:

Selling, general and administrative	13,126	13,108	46,308	46,115
Research and development	17,167	15,314	56,035	45,274
Total operating costs and expenses	30,293	28,422	102,343	91,389
Loss from continuing operations before other income (expense) and income taxes (30,293 )	(28,422 )	(102,343 )	(91,389 )	
Other income (expense):				
Interest income (expense), net	1,521	(12 )	4,076	(484 )
Other income (expense), net	2,015	(40,880 )	(5,547 )	17,583
Total other income (expense)	3,536	(40,892 )	(1,471 )	17,099
Loss from continuing operations before income taxes	(26,757 )	(69,314 )	(103,814 )	(74,290 )
Benefit for income taxes from continuing operations	200	142	8,654	839
Loss from continuing operations	\$ (26,557 )	\$ (69,172 )	\$ (95,160 )	\$ (73,451 )
Income from discontinued operations, net of income taxes	572	454	21,625	2,659
Net loss	\$ (25,985 )	\$ (68,718 )	\$ (73,535 )	\$ (70,792 )
Basic and diluted loss per share:				
Loss per common share from continuing operations	\$ (0.24 )	\$ (0.66 )	\$ (0.86 )	\$ (0.72 )
Income per common share from discontinued operations	0.01	—	0.20	0.03
Net loss per common share	\$ (0.23 )	\$ (0.66 )	\$ (0.67 )	\$ (0.69 )
Weighted average shares outstanding:				
Basic	111,178,880	104,106,295	110,291,090	102,571,850
Diluted	111,178,880	104,106,295	110,291,090	102,571,850

**SPECTRUM PHARMACEUTICALS, INC.**

**Condensed Consolidated Balance Sheets**

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

(Unaudited)

**September 30, 2019**      **December 31, 2018**

**ASSETS**

## Current assets:

Cash and cash equivalents	\$ 124,598	\$ 157,480
Restricted cash	4,040	—
Marketable securities	123,164	46,508
Accounts receivable, net of allowance for doubtful accounts of \$67 and \$67, respectively	483	29,873
Other receivables	7,752	3,698
Prepaid expenses and other assets	12,680	7,574
Discontinued operations, current assets	—	5,555
Total current assets	272,717	250,688
Property and equipment, net of accumulated depreciation	8,965	385
Other assets	8,613	7,188
Facility and equipment under lease	3,531	—
Discontinued operations, non-current assets	—	132,625
Total assets	\$ 293,826	\$ 390,886

**LIABILITIES AND STOCKHOLDERS' EQUITY**

## Current liabilities:

Accounts payable and other accrued liabilities	\$ 39,959	\$ 69,460
Accrued payroll and benefits	6,475	9,853
Contract liabilities	1,360	4,850
Discontinued operations, current liabilities	—	2,311
Total current liabilities	47,794	86,474
Deferred tax liabilities	—	1,469
Other long-term liabilities	11,313	5,650
Discontinued operations, non-current liabilities	—	14,031
Total liabilities	59,107	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; 112,988,706 and 110,525,141 issued and outstanding at September 30, 2019 and December 31, 2018, respectively	113	110
Additional paid-in capital	912,558	886,740
Accumulated other comprehensive loss	(4,531	) (3,702
Accumulated deficit	(673,421	) (599,886
Total stockholders' equity	234,719	283,262
Total liabilities and stockholders' equity	\$ 293,826	\$ 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, except per share amounts)

	<b>CONTINUING OPERATIONS ONLY</b>		<b>CONTINUING OPERATIONS ONLY</b>	
	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
<b>(1) GAAP selling, general and administrative</b>	<b>\$ 13,126</b>	<b>\$ 13,108</b>	<b>\$ 46,308</b>	<b>\$ 46,115</b>
Non-GAAP adjustments to SG&A:				
Stock-based compensation expense	(3,155	) (1,902	) (10,254	) (6,686

Depreciation expense	(58	) (83	) (180	) (190	)
Lease expense	—	—	(129	) —	
Severance expense	—	—	(1,515	) —	
<b>Non-GAAP selling, general and administrative</b>	<b>\$ 9,913</b>	<b>\$ 11,123</b>	<b>\$ 34,230</b>	<b>\$ 39,239</b>	
<b>(2) GAAP research and development</b>	<b>\$ 17,167</b>	<b>\$ 15,314</b>	<b>\$ 56,035</b>	<b>\$ 45,274</b>	
Non-GAAP adjustments to R&D:					
Stock-based compensation expense	(1,030	) (603	) (3,190	) (1,885	)
Depreciation expense	(30	) (2	) (45	) (7	)
Severance expense	—	—	(260	) —	
R&D milestones and in-license upfront fees	—	—	(2,751	) (500	)
<b>Non-GAAP research and development</b>	<b>\$ 16,107</b>	<b>\$ 14,709</b>	<b>\$ 49,789</b>	<b>\$ 42,882</b>	
<b>(3) GAAP net loss from continuing operations</b>	<b>\$ (26,557</b>	<b>) \$ (69,172</b>	<b>) \$ (95,160</b>	<b>) \$ (73,451</b>	<b>)</b>
Non-GAAP adjustments to net loss from continuing operations:					
Adjustments to SG&A and R&D as noted above	4,273	2,590	18,324	9,268	
Adjustments to other (income) expense	(1,979	) 41,426	6,449	(15,904	)
Adjustments to benefit for income taxes	(200	) (142	) (8,654	) (839	)
<b>Non-GAAP net loss from continuing operations</b>	<b>\$ (24,463</b>	<b>) \$ (25,298</b>	<b>) \$ (79,041</b>	<b>) \$ (80,926</b>	<b>)</b>
<b>(4) GAAP net loss from continuing operations - per basic and diluted share</b>	<b>\$ (0.24</b>	<b>) \$ (0.66</b>	<b>) \$ (0.86</b>	<b>) \$ (0.72</b>	<b>)</b>
<b>Non-GAAP net loss from continuing operations - per basic and diluted share</b>	<b>\$ (0.22</b>	<b>) \$ (0.24</b>	<b>) \$ (0.72</b>	<b>) \$ (0.79</b>	<b>)</b>
<b>Weighted average shares outstanding:</b>					
Basic	111,178,880	104,106,295	110,291,090	102,571,850	
Diluted	111,178,880	104,106,295	110,291,090	102,571,850	

**(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 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 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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