



## Spectrum Pharmaceuticals Reports Second Quarter 2020 Financial Results and Corporate Update

August 10, 2020

*Recently announced positive topline results in HER2 exon 20 insertion mutations from Cohort 2 of the poziotinib ZENITH20 trial*

*Company is in process of requesting a pre-NDA meeting with the FDA seeking an indication for second-line NSCLC patients with HER2 exon 20 insertion mutations*

*BLA for ROLONTIS® (eflapragrastim) under active FDA review - PDUFA date of October 24, 2020*

*Management to host webcast and conference call today at 4:30 p.m. ET / 1:30 p.m. PT*

HENDERSON, Nev.--(BUSINESS WIRE)--Aug. 10, 2020-- 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, 2020.

"The recently announced positive results from Cohort 2 are a meaningful development for patients with NSCLC HER2 exon 20 insertion mutations for which there is no approved therapy," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "We are in the process of requesting a pre-NDA meeting with the FDA and look forward to reviewing this data with the agency. In addition, the BLA for ROLONTIS is under active FDA review with a PDUFA date of October 24, 2020. We are in a strong capital position to fund our ongoing development and commercialization of our late stage assets."

### Pipeline Updates

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

- Poziotinib met the pre-specified primary endpoint for Cohort 2 in the ZENITH20 Phase 2 clinical trial evaluating previously treated non-small cell lung cancer (NSCLC) patients with HER2 exon 20 insertion mutations. Cohort 2 of the ZENITH20 clinical trial enrolled a total of 90 patients who received an oral, once daily dose of 16 mg/day of poziotinib. All responses were read independently and confirmed by a central imaging laboratory using RECIST criteria. The intent-to-treat analysis demonstrated a confirmed objective response rate (ORR) of 27.8% (95% Confidence Interval (CI) 18.9%-38.2%). Based on the pre-specified statistical hypothesis for the primary endpoint, the observed lower bound of 18.9% exceeded the pre-specified lower bound of 17% in this heavily pre-treated population.
- The median duration of response was 5.1 (range 1 to >12.3) months, with a median follow up of 8.3 months. The disease control rate (DCR) was 70% and the median progression free survival was 5.5 months.
- Spectrum plans to present additional results from Cohort 2 at a medical meeting later in the year.
- The company is in the process of requesting a pre-NDA meeting with the FDA based on the positive results from Cohort 2 to seek an indication for the treatment of patients with previously treated locally advanced or metastatic NSCLC with HER2 exon 20 insertion mutations.
- Cohort 3 of the ZENITH20 trial in first-line EGFR NSCLC patients is fully enrolled and topline results are expected by year-end 2020.

#### **ROLONTIS (eflapragrastim), 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 is October 24, 2020.

#### **Three-Month Period Ended June 30, 2020 (All numbers are from Continuing Operations and are approximate)**

##### **GAAP Results**

Spectrum recorded a net loss of \$32.2 million, or \$0.29 loss per basic and diluted share, in the three-month period ended June 30, 2020, compared to a net loss of \$28.8 million, or \$0.26 loss per basic and diluted share, in the comparable period in 2019. Total research and development expenses were \$21.7 million in the quarter, as compared to \$17.0 million in the same period in 2019. Selling, general and administrative expenses were \$14.7 million in the quarter, compared to \$17.2 million in the same period in 2019.

The company ended the quarter with cash, cash equivalents, and marketable securities of \$156.5 million. The quarter-end cash balance does not include aggregate net proceeds of \$82.1 million, after deducting underwriting discounts and commissions, from our recent underwritten public offering and sales under our at-the-market sales agreement.

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

Spectrum recorded a non-GAAP net loss of \$31.8 million, or \$0.28 per basic and diluted share, in the three-month period ended June 30, 2020,

compared to a non-GAAP net loss of \$25.2 million, or \$0.23 per basic and diluted share, in the comparable period in 2019. Non-GAAP research and development expenses were \$20.6 million, as compared to \$13.2 million in the same period of 2019. Non-GAAP selling, general and administrative expenses were \$11.8 million, as compared to \$13.7 million in the same period in 2019.

### **Conference Call and Webcast**

Spectrum's management will host a webcast and conference call today, August 10, 2020, at 4:30 p.m. ET / 1:30 p.m. PT to discuss the financial results and provide a corporate update. The live call may be accessed by dialing (877) 837-3910 for domestic callers and (973) 796-5077 for international callers and entering the conference ID#: 4093736. A live webcast of the call will be available from the Investor Relations section of the company's website at <http://investor.sppirx.com/events-and-presentations> and will be archived there shortly after the live event.

### **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) has completed enrollment and Cohort 4 (HER2) is 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 significance of Cohort 2's reported results; the availability, timing and outcome of a potential pre-NDA meeting with the FDA regarding poziotinib and the FDA's determination of a path forward for poziotinib; poziotinib's potential to significantly advance the treatment of NSCLC patients with HER2 exon 20 insertion mutations; the timing and results of future FDA decisions, including with respect to the ROLONTIS BLA; the timing of the topline results of Cohort 3; the overall progression of the poziotinib and ROLONTIS development programs; the company's plans to present additional study results from Cohort 2 at a medical meeting later in the year; the company's ability to advance and fund the development and commercialization of its late-stage pipeline assets and such assets' ability to serve areas of unmet need; the future potential of the company's existing drug pipeline and its ability to transform the company in the near future; 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 possibility that the different methodologies, assumptions and applications the company utilizes to assess particular safety or efficacy parameters may yield different statistical results, and even if the company believes the data collected from the clinical trials of its product candidates, including poziotinib, are positive, these data may not be sufficient to support approval by the FDA; the possibility that success in early clinical trials, especially if based on a small patient sample, might not result in success in later clinical trials, and other unforeseen events during clinical trials which could cause delays or other adverse consequences; other uncertainties inherent in new product development; the possibility that Spectrum's new and existing drug candidates, including ROLONTIS and 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, 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 share and per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues	\$ —	\$ —	\$ —	\$ —
Operating costs and expenses:				
Selling, general and administrative	14,744	17,230	29,538	33,182
Research and development	21,746	16,982	37,739	38,868
Total operating costs and expenses	36,490	34,212	67,277	72,050
Loss from continuing operations before other expense and income taxes	(36,490 )	(34,212 )	(67,277 )	(72,050 )
Other income (expense):				
Interest income, net	325	1,495	1,029	2,556
Other income (expense), net	3,945	3,722	(6,589 )	(7,563 )
Total other income (expense)	4,270	5,217	(5,560 )	(5,007 )
Loss from continuing operations before income taxes	(32,220 )	(28,995 )	(72,837 )	(77,057 )
(Provision) benefit for income taxes from continuing operations	(9 )	212	(9 )	8,428
Loss from continuing operations	\$ (32,229 )	\$ (28,783 )	\$ (72,846 )	\$ (68,629 )
Income from discontinued operations, net of income taxes	144	388	189	20,975
Net loss	\$ (32,085 )	\$ (28,395 )	\$ (72,657 )	\$ (47,654 )
Basic and diluted loss per share:				
Loss per common share from continuing operations	\$ (0.29 )	\$ (0.26 )	\$ (0.65 )	\$ (0.63 )
Income per common share from discontinued operations	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.19
Net loss per common share, basic and diluted	\$ (0.28 )	\$ (0.26 )	\$ (0.65 )	\$ (0.43 )
Weighted average shares outstanding, basic and diluted	112,615,744	110,345,135	112,199,229	109,744,405

**SPECTRUM PHARMACEUTICALS, INC.**

**Condensed Consolidated Balance Sheets**

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

(Unaudited)

	June 30, 2020	December 31, 2019
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 85,126	\$ 64,418
Marketable securities	71,390	159,455
Accounts receivable, net of allowance for credit losses of \$43 and \$43, respectively	441	441
Other receivables	6,294	9,558
Prepaid expenses and other current assets	11,789	10,148
Total current assets	175,040	244,020
Property and equipment, net	12,547	11,607
Facility and equipment under lease	3,068	3,806
Other assets	3,598	4,000
Total assets	\$ 194,253	\$ 263,433
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 49,684	\$ 54,284
Accrued payroll and benefits	5,874	7,686
Total current liabilities	55,558	61,970
Other long-term liabilities	8,098	11,070
Total liabilities	63,656	73,040
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; 117,823,973 and 113,299,612 issued and outstanding at June 30, 2020 and December 31, 2019, respectively	118	113
Additional paid-in capital	930,817	918,205
Accumulated other comprehensive loss	(3,254 )	(3,498 )

Accumulated deficit	(797,084 )	(724,427 )
Total stockholders' equity	130,597	190,393
Total liabilities and stockholders' equity	\$ 194,253	\$ 263,433

### **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)

	CONTINUING OPERATIONS ONLY		CONTINUING OPERATIONS ONLY	
	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
<b>(1) GAAP selling, general and administrative</b>	<b>\$ 14,744</b>	<b>\$ 17,230</b>	<b>\$ 29,538</b>	<b>\$ 33,182</b>
Non-GAAP adjustments to SG&A:				
Stock-based compensation expense	(2,877 )	(3,555 )	(6,755 )	(7,030 )
Depreciation expense	(112 )	(56 )	(218 )	(122 )
Lease expense	5	—	14	(129 )
Severance expense	—	126	—	(1,515 )
<b>Non-GAAP selling, general and administrative</b>	<b>\$ 11,760</b>	<b>\$ 13,745</b>	<b>\$ 22,579</b>	<b>\$ 24,386</b>
<b>(2) GAAP research and development</b>	<b>\$ 21,746</b>	<b>\$ 16,982</b>	<b>\$ 37,739</b>	<b>\$ 38,868</b>

Non-GAAP adjustments to R&D:					
Stock-based compensation expense	(1,110	) (1,344	) (2,508	) (2,227	)
Depreciation expense	(31	) (13	) (65	) (15	)
Severance expense	—	286	—	(260	)
R&D milestones and in-license upfront fees	—	(2,751	) —	(2,751	)
<b>Non-GAAP research and development</b>	<b>\$ 20,605</b>	<b>\$ 13,160</b>	<b>\$ 35,166</b>	<b>\$ 33,615</b>	
<b>(3) GAAP net loss from continuing operations</b>	<b>\$ (32,229</b>	<b>) \$ (28,783</b>	<b>) \$ (72,846</b>	<b>) \$ (68,629</b>	<b>)</b>
Non-GAAP adjustments to net loss from continuing operations:					
Adjustments to SG&A and R&D, as noted above	4,125	7,307	9,532	14,049	
Adjustments to other expense	(3,667	) (3,477	) 6,582	8,428	
Adjustments to provision (benefit) for income taxes	9	(212	) 9	(8,428	)
<b>Non-GAAP net loss from continuing operations</b>	<b>\$ (31,762</b>	<b>) \$ (25,165</b>	<b>) \$ (56,723</b>	<b>) \$ (54,580</b>	<b>)</b>
<b>(4) GAAP net loss from continuing operations - per basic and diluted share</b>	<b>\$ (0.29</b>	<b>) \$ (0.26</b>	<b>) \$ (0.65</b>	<b>) \$ (0.63</b>	<b>)</b>
<b>Non-GAAP net loss from continuing operations - per basic and diluted share</b>	<b>\$ (0.28</b>	<b>) \$ (0.23</b>	<b>) \$ (0.51</b>	<b>) \$ (0.50</b>	<b>)</b>
Weighted average shares outstanding, basic and diluted	112,615,744	110,345,135	112,199,229	109,744,405	

**(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 the reversal of non-recurring severance expenses and R&D milestone achievements and in-license upfront 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; and (iv) reversal of realized gain recorded on the sales of our equity holdings during the current year.

**(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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