



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

November 4, 2020

*FDA deferred action on the BLA for ROLONTIS® (eflapregrastim) due to inability to conduct inspection of the manufacturing facility citing COVID-19 related travel restrictions*

*Pre-NDA meeting with FDA is scheduled for poziotinib in NSCLC HER2 exon-20 insertion mutations in previously treated patients*

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

HENDERSON, Nev.--(BUSINESS WIRE)--Nov. 4, 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 September 30, 2020.

"The third quarter was marked by significant progress in our drug development programs and a strengthened financial position," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "Our team is preparing for the upcoming pre-NDA meeting with the FDA for poziotinib and actively working to obtain an approval for ROLONTIS as soon as possible."

### Pipeline Updates

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

- Spectrum has a pre-NDA meeting with the FDA to review the positive results from Cohort 2 and the path forward for poziotinib registration for the treatment of patients with previously treated locally advanced or metastatic NSCLC with HER2 exon 20 insertion mutations.
- Spectrum presented the results from Cohort 2 at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 in September. This marked the first presentation to the medical and scientific community of the positive results from this registrational cohort from the ZENITH20 clinical trial.
- Spectrum expects to provide poziotinib update, including dosing strategy and topline results from Cohort 3 of the ZENITH20 trial in first-line EGFR NSCLC patients, by year-end 2020.

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

- The FDA deferred its action on the BLA for ROLONTIS, due to an inability to inspect the Hanmi Bioplant in South Korea citing travel restrictions related to the COVID-19 pandemic.
- Spectrum has confirmed with the FDA that the deferral is not a Complete Response Letter (CRL). The company is actively working to find a way to expedite the plant inspection.

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

##### **GAAP Results**

Spectrum recorded a net loss of \$48.5 million, or \$0.37 loss per basic and diluted share, in the three-month period ended September 30, 2020, compared to a net loss of \$26.6 million, or \$0.24 loss per basic and diluted share, in the comparable period in 2019. Total research and development expenses were \$24.5 million in the quarter, as compared to \$17.2 million in the same period in 2019. Selling, general and administrative expenses were \$15.1 million in the quarter, compared to \$13.1 million in the same period in 2019.

The company ended the quarter with cash, cash equivalents, and marketable securities of \$198.3 million.

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

Spectrum recorded a non-GAAP net loss of \$35.2 million, or \$0.27 loss per basic and diluted share, in the three-month period ended September 30, 2020, compared to a non-GAAP net loss of \$24.5 million, or \$0.22 per basic and diluted share, in the comparable period in 2019. Non-GAAP research and development expenses were \$23.3 million, as compared to \$16.1 million in the same period of 2019. Non-GAAP selling, general and administrative expenses were \$12.3 million, as compared to \$9.9 million in the same period in 2019.

##### **Conference Call and Webcast**

Spectrum's management will host a webcast and conference call today, November 4, 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#: 1281757. A live webcast of the call will be available from the Investor Relations section of the company's website at <http://investor.sppix.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 outcome of the upcoming 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 the timing of the FDA’s inspection of the Hanmi Bioplant in South Korea and its action on the ROLONTIS BLA; the timing of the poziotinib update, including dosing strategy and topline results from Cohort 3; the overall progression of the poziotinib and ROLONTIS development programs; 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 ongoing effects of the COVID-19 pandemic, including the duration of travel restrictions related thereto; 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	\$ —	\$ —	\$ —	\$ —
Operating costs and expenses:				
Selling, general and administrative	15,116	13,126	44,654	46,308

Research and development	24,453	17,167	62,192	56,035
Total operating costs and expenses	39,569	30,293	106,846	102,343
Loss from continuing operations before other income (expense) and income taxes	(39,569 )	(30,293 )	(106,846 )	(102,343 )
Other income (expense):				
Interest income, net	188	1,521	1,217	4,076
Other income (expense), net	(9,131 )	2,015	(15,720 )	(5,547 )
Total other income (expense)	(8,943 )	3,536	(14,503 )	(1,471 )
Loss from continuing operations before income taxes	(48,512 )	(26,757 )	(121,349 )	(103,814 )
(Provision) benefit for income taxes from continuing operations	(6 )	200	(15 )	8,628
Loss from continuing operations	\$ (48,518 )	\$ (26,557 )	\$ (121,364 )	\$ (95,186 )
Income from discontinued operations, net of income taxes	66	572	255	21,547
Net loss	\$ (48,452 )	\$ (25,985 )	\$ (121,109 )	\$ (73,639 )
Basic and diluted loss per share:				
Loss from continuing operations	\$ (0.37 )	\$ (0.24 )	\$ (1.02 )	\$ (0.86 )
Income from discontinued operations	\$ 0.00	\$ 0.01	\$ 0.00	\$ 0.20
Net loss per share, basic and diluted	\$ (0.37 )	\$ (0.23 )	\$ (1.02 )	\$ (0.67 )
Weighted average shares outstanding, basic and diluted	131,455,727	111,178,880	118,664,914	110,291,090

**SPECTRUM PHARMACEUTICALS, INC.**

**Condensed Consolidated Balance Sheets**

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

(Unaudited)

	<b>September 30, 2020</b>	<b>December 31, 2019</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 77,132	\$ 64,418
Marketable securities	121,179	159,455

Accounts receivable, net of allowance for credit losses of \$43 and \$43, respectively	453	441
Other receivables	3,186	9,558
Prepaid expenses and other current assets	10,876	10,148
Total current assets	212,826	244,020
Property and equipment, net	18,456	11,607
Facility and equipment under lease	2,662	3,806
Other assets	3,994	4,000
Total assets	\$ 237,938	\$ 263,433

#### **LIABILITIES AND STOCKHOLDERS' EQUITY**

##### Current liabilities:

Accounts payable and other accrued liabilities	\$ 52,985	\$ 54,284
Accrued payroll and benefits	8,113	7,686
Total current liabilities	61,098	61,970
Other long-term liabilities	8,480	11,070
Total liabilities	69,578	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; 145,931,172 and 113,299,612 issued and outstanding at September 30, 2020 and December 31, 2019, respectively	146	113
Additional paid-in capital	1,016,474	918,205
Accumulated other comprehensive loss	(2,724 )	(3,498 )
Accumulated deficit	(845,536 )	(724,427 )
Total stockholders' equity	168,360	190,393
Total liabilities and stockholders' equity	\$ 237,938	\$ 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		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
<b>(1) GAAP selling, general and administrative</b>	<b>\$ 15,116</b>	<b>\$ 13,126</b>	<b>\$ 44,654</b>	<b>\$ 46,308</b>
Non-GAAP adjustments to SG&A:				
Stock-based compensation expense	(3,018 )	(3,155 )	(9,773 )	(10,254 )
Depreciation expense	144	(58 )	(74 )	(180 )
Lease expense	23	—	47	(129 )
Severance expense	—	—	—	(1,515 )
<b>Non-GAAP selling, general and administrative</b>	<b>\$ 12,265</b>	<b>\$ 9,913</b>	<b>\$ 34,854</b>	<b>\$ 34,230</b>
<b>(2) GAAP research and development</b>	<b>\$ 24,453</b>	<b>\$ 17,167</b>	<b>\$ 62,192</b>	<b>\$ 56,035</b>
Non-GAAP adjustments to R&D:				
Stock-based compensation expense	(1,090 )	(1,030 )	(3,598 )	(3,190 )
Depreciation expense	(33 )	(30 )	(98 )	(45 )
Severance expense	—	—	—	(260 )
R&D milestones and in-license upfront fees	—	—	—	(2,751 )
<b>Non-GAAP research and development</b>	<b>\$ 23,330</b>	<b>\$ 16,107</b>	<b>\$ 58,496</b>	<b>\$ 49,789</b>

<b>(3) GAAP net loss from continuing operations</b>	<b>\$ (48,518 )</b>	<b>\$ (26,557 )</b>	<b>\$ (121,364 )</b>	<b>\$ (95,186 )</b>
Non-GAAP adjustments to net loss from continuing operations:				
Adjustments to SG&A and R&D, as noted above	3,974	4,273	13,496	18,324
Adjustments to other (income) expense	9,317	(1,979 )	15,899	6,449
Adjustments to provision (benefit) for income taxes	6	(200 )	15	(8,628 )
<b>Non-GAAP net loss from continuing operations</b>	<b>\$ (35,221 )</b>	<b>\$ (24,463 )</b>	<b>\$ (91,954 )</b>	<b>\$ (79,041 )</b>
<b>(4) GAAP net loss from continuing operations - per basic and diluted share</b>	<b>\$ (0.37 )</b>	<b>\$ (0.24 )</b>	<b>\$ (1.02 )</b>	<b>\$ (0.86 )</b>
<b>Non-GAAP net loss from continuing operations - per basic and diluted share</b>	<b>\$ (0.27 )</b>	<b>\$ (0.22 )</b>	<b>\$ (0.77 )</b>	<b>\$ (0.72 )</b>
Weighted average shares outstanding, basic and diluted	131,455,727	111,178,880	118,664,914	110,291,090

**(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.

**(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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