Spectrum Pharmaceuticals Reports Third Quarter 2021 Financial Results and Corporate Update

November 10, 2021

Poziotinib NDA is on track for submission in 2021 under a Fast Track designation

Positive front line poziotinib data presented at ESMO Congress 2021 from Cohort 4 of the ZENITH20 clinical trial

Preclinical data presented at 2021 AACR-NCI-EORTC (Triple) conference demonstrated the synergistic impact of poziotinib when combined with KRAS inhibitors in KRAS^{G12C} mutant specific cell line

ROLONTIS® (eflapegrastim) CRL manufacturing deficiencies expected to be remediated by the end of the year

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

HENDERSON, Nev.--(BUSINESS WIRE)--Nov. 10, 2021-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced financial results for the three-month period ended September 30, 2021 and provided a corporate update.

"The submission of the poziotinib NDA this quarter remains our top corporate priority. The front line data presented at ESMO and the preclinical combination data with KRAS inhibitors at the Triple meeting has the potential to significantly expand the poziotinib opportunity," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "Following a productive Type A meeting with the FDA on ROLONTIS, we anticipate the remediation efforts at Hanmi to be completed by the end of the year and would expect to resubmit our BLA for ROLONTIS shortly thereafter."

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

- Submission of the NDA, based on the positive results of Cohort 2 in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) with HER2 exon 20 insertion mutations is on track for this year under a Fast Track designation. There is currently no treatment specifically approved for this indication.
- Encouraging results from Cohort 4 of the ZENITH20 clinical trial were presented at the European Society of Medical (ESMO) Congress 2021. The primary endpoint of objective rate of response (ORR) was 44% (95% CI:29.5-58.8%) in the first 48 treated patients including one complete response. 88% of patients showed tumor reduction with a disease control rate of 75%. Median duration of response was 5.4 months (range 2.8-19.1+). Median progression free survival was 5.6 months (range 0-20.2+). The most common treatment related Grade ≥ 3 adverse effects (AEs) were rash, stomatitis, diarrhea, and paronychia. In addition, only one patient experienced Grade ≥ 3 pneumonitis. Poziotinib demonstrated clinically meaningful anti-tumor activity in newly diagnosed NSCLC patients with HER2 exon 20 mutations with 16mg QD dosing. The safety profile was manageable and similar to those observed in previous studies and other second-generation tyrosine kinase inhibitors.
- Preclinical data showed the synergistic impact of poziotinib when combined with KRAS inhibitors in KRAS^{G12C} mutant specific cell lines. Jacqulyne Robichaux, Ph.D., Assistant Professor, University of Texas, MD Anderson Cancer Center presented a poster titled "Pan-ErbB inhibition enhances activity of KRAS ^{G12C} inhibitors in preclinical models of KRAS^{G12C} mutant cancers" at the Virtual International Conference on Molecular Targets and Cancer Therapeutics hosted by the American Association for Cancer Research (AACR), the National Cancer Institute (NCI), and the European Organization for Research and Treatment of Cancer (EORTC). The preclinical data showed that inhibition of EGFR, HER2, HER3, and HER4 signaling was synergistic when combined with KRAS^{G12C} inhibitors. These results highlight the importance of a pan inhibitor of the Erb family of proteins.

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

- The company held a Type A meeting with the U.S. Food and Drug Administration (FDA) to better understand the issues identified in the Complete Response Letter (CRL). At that meeting, the company learned that the deficiencies at the fill finish site have been adequately addressed. Remediation of deficiencies at the drug substance facility are well under way and expected to be completed by the end of the year. The FDA confirmed that the reinspection of the drug substance facility would be in-person.

Three-Month Period Ended September 30, 2021 (All numbers are from Continuing Operations and are approximate)

GAAP Results

Spectrum recorded a net loss of $33.1 million, or $0.21 loss per basic and diluted share, in the three-month period ended September 30, 2021,

compared to a net loss of $48.5 million, or $0.37 loss per basic and diluted share, in the comparable period in 2020. Total research and development expenses were $20.9 million in the quarter, as compared to $24.5 million in the same period in 2020. Selling, general and administrative expenses were $12.2 million in the quarter, compared to $15.1 million in the same period in 2020.

The company ended the quarter with cash, cash equivalents, and marketable securities of $133.6 million.

Non-GAAP Results

Spectrum recorded a non-GAAP net loss of $25.8 million, or $0.16 loss per basic and diluted share, in the three-month period ended September 30, 2021, compared to a non-GAAP net loss of $35.2 million, or $0.27 loss per basic and diluted share, in the comparable period in 2020. Non-GAAP research and development expenses were $16.7 million, as compared to $23.3 million in the same period of 2020. Non-GAAP selling, general and administrative expenses were $9.2 million, as compared to $12.3 million in the same period in 2020.

Conference Call

Wednesday, November 10, 2021 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910
International: (973) 796-5077
Conference ID#: 6579214

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 https://investor.sppirx.com/events-and-presentations on November 10, 2021 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 the ZENITH20 Clinical Trial

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. Cohorts 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 the FDA approval of poziotinib, the timing of an NDA submission for poziotinib based on the positive results of Cohort 2 from the ZENITH20 clinical trial, the significance of the results from Cohort 4 of the ZENITH20 clinical trial, the synergistic impact of poziotinib when combined with KRAS inhibitors, the timing and outcome of the remediation efforts at the Hanmi Pharmaceutical, Inc. manufacturing facility and the company’s resubmission of its BLA for ROLONTIS, the future potential of Spectrum’s existing drug pipeline, the progression of the poziotinib and ROLONTIS development programs 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, if approved, may not be more effective, safer, or more cost-efficient than competing drugs; the company’s ability to remediate the deficiencies cited in the CRL for ROLONTIS in a timely manner, if at all; 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, 2020, and in subsequent reports on Forms 10-Q and 8-K and other filings made with the SEC by Spectrum.

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,	
	2021	**2020**	**2021**	**2020**
Revenues	$ —	$ —	$ —	$ —
Operating costs and expenses:				
Selling, general and administrative	12,243	15,116	41,515	44,654
Research and development	20,850	24,453	69,335	62,192
Total operating costs and expenses	33,093	39,569	110,850	106,846
Loss from continuing operations before other income (expense) and income taxes	(33,093)	(39,569)	(110,850)	(106,846)
Other income (expense):				
Interest income, net	11	188	121	1,217
Other income (expense), net	9	(9,131)	(7,948)	(15,720)
Total other income (expense)	20	(8,943)	(7,827)	(14,503)
Loss from continuing operations before income taxes	(33,073)	(48,512)	(118,677)	(121,349)
Provision for income taxes from continuing operations	—	(6)	(9)	(15)
Loss from continuing operations	$ (33,073)	$ (48,518)	$ (118,686)	$ (121,364)
Income (loss) from discontinued operations, net of income taxes	(11)	66	(227)	255
Net loss	$ (33,084)	$ (48,452)	$ (118,913)	$ (121,109)
Basic and diluted loss per share:				
Loss from continuing operations	$ (0.21)	$ (0.37)	$ (0.77)	$ (1.02)
Income (loss) from discontinued operations	$ (0.00)	$ 0.00	$ (0.00)	$ 0.00
Net loss per share, basic and diluted	$ (0.21)	$ (0.37)	$ (0.78)	$ (1.02)
Weighted average shares outstanding, basic and diluted	159,261,818	131,455,727	153,341,854	118,664,914

Condensed Consolidated Balance Sheets

(In thousands, except share and par value amounts)

(Unaudited)

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 107,435	$ 46,009
Marketable securities	26,160	134,016
Accounts receivable, net	—	67
Other receivables	3,863	2,394
Prepaid expenses and other current assets	2,540	4,161
Total current assets	139,998	186,647
Property and equipment, net	507	3,577
Facility and equipment under lease	2,881	2,247
Other assets	4,415	4,327
Total assets	$ 147,801	$ 196,798
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 48,982	$ 43,771
Accrued payroll and benefits	8,290	9,375
Total current liabilities	57,272	53,146
Other long-term liabilities	11,065	9,409
Total liabilities	68,337	62,555
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; 163,957,900 and 146,083,110 issued and outstanding at September 30, 2021 and December 31, 2020, respectively	164	146
Additional paid-in capital	1,086,989	1,021,221
Accumulated other comprehensive loss	(3,481)	(1,829)
Accumulated deficit	(1,004,208)	(885,295)
Total stockholders' equity	79,464	134,243
Total liabilities and stockholders' equity	$ 147,801	$ 196,798

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 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 share and per share amounts)

(Unaudited)

		CONTINUING OPERATIONS ONLY Three Months Ended September 30,		**CONTINUING OPERATIONS ONLY Nine Months Ended September 30,**	
		2021	**2020**	**2021**	**2020**
(1)	**GAAP selling, general and administrative**	**$ 12,243**	**$ 15,116**	**$ 41,515**	**$ 44,654**
	Non-GAAP adjustments to SG&A:				
	Stock-based compensation expense	(2,927)	(3,018)	(8,730)	(9,773)
	Depreciation expense	(72)	144	(206)	(74)
	Lease expense	(33)	23	16	47

	Non-GAAP selling, general and administrative	**$ 9,211**	**$ 12,265**	**$ 32,595**	**$ 34,854**
(2)	**GAAP research and development**	**$ 20,850**	**$ 24,453**	**$ 69,335**	**$ 62,192**
	Non-GAAP adjustments to R&D:				
	Stock-based compensation expense	(1,187)	(1,090)	(3,956)	(3,598)
	Depreciation expense	(2)	(33)	(6)	(98)
	Loss on disposal of manufacturing equipment	(2,912)	—	(2,912)	—
	Non-GAAP research and development	**$ 16,749**	**$ 23,330**	**$ 62,461**	**$ 58,496**
(3)	**GAAP net loss from continuing operations**	**$ (33,073)**	**$ (48,518)**	**$ (118,686)**	**$ (121,364)**
	Non-GAAP adjustments to net loss from continuing operations:				
	Adjustments to SG&A and R&D, as noted above	7,133	3,974	15,794	13,496
	Adjustments to other income (expense)	94	9,317	8,663	15,899
	Adjustments to provision for income taxes	—	6	9	15
	Non-GAAP net loss from continuing operations	**$ (25,846)**	**$ (35,221)**	**$ (94,220)**	**$ (91,954)**
(4)	**GAAP net loss from continuing operations - per basic and diluted share**	**$ (0.21)**	**$ (0.37)**	**$ (0.77)**	**$ (1.02)**
	Non-GAAP net loss from continuing operations - per basic and diluted share	**$ (0.16)**	**$ (0.27)**	**$ (0.61)**	**$ (0.77)**
	Weighted average shares outstanding, basic and diluted	159,261,818	131,455,727	153,341,854	118,664,914

(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. 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, depreciation expense and loss on disposal of manufacturing equipment. We believe the 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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