Spectrum Pharmaceuticals Reports First Quarter 2021 Financial Results and Corporate Update

May 13, 2021

Poziotinib NDA on track for 2021 submission

New poziotinib twice daily dosing (BID) data presented at AACR demonstrated improved anti-tumor activity and better tolerance

FDA pre-approval inspection at the ROLONTIS® manufacturing facility scheduled for May 2021

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

HENDERSON, Nev.--(BUSINESS WIRE)--May 13, 2021-- 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 March 31, 2021 and provided a corporate update.

“Our top priority is submission of the NDA to the FDA for poziotinib based on the positive data from Cohort 2 of the ZENITH20 clinical trial,” said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. “The additional data on twice daily dosing presented at AACR has the potential to significantly expand the value of poziotinib. We also look forward to the FDA’s pre-approval inspection of the ROLONTIS manufacturing facility which has been scheduled for later this month.”

Pipeline Updates

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

- Spectrum is actively working on its new drug application (NDA) for the use of poziotinib in patients with previously treated locally advanced or metastatic NSCLC with HER2 exon 20 insertion mutations. Submission of the NDA, based on the positive results of Cohort 2 from the ZENITH20 clinical trial, is planned for later this year.
- New data was presented at the American Association for Cancer Research (AACR) Virtual Annual Meeting 2021 from ZENITH20 Cohort 5 which demonstrated improved efficacy and tolerability for twice daily (BID) dosing. In the 38 patients, with EGFR or HER2 exon 20 insertion mutations, who received 16mg per day and randomized either to poziotinib 16mg once daily (QD) or 8mg BID in Cohort 5, improved responses were observed in the BID arm with 31.6% of patients reaching a partial response, and Grade 3 or higher related adverse events were reduced by approximately 60%. Additionally, the BID dosing allowed for an improved rate of dose reductions and interruptions relative to the QD dose.
- Faster enrollment is expected in Cohort 5 which is now dosing exclusively at 8mg BID.
- Enrollment of first-line patients with NSCLC HER2 exon 20 mutations is continuing for Cohort 4 of the ZENITH20 clinical trial. Poziotinib is being administered at a dose of 8mg BID in first line treatment.
- A poster titled “CNS activity of poziotinib in NSCLC with exon 20 insertion mutations” based on data from Cohorts 1-3 has been accepted for presentation at ASCO.

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

- The FDA’s pre-approval inspection of the ROLONTIS manufacturing facility has been scheduled for later this month and pre-commercial preparation activities are underway.

Three-Month Period Ended March 31, 2021 (All numbers are from Continuing Operations and are approximate)

GAAP Results

Spectrum recorded a net loss of $35.7 million, or $0.25 loss per basic and diluted share, in the three-month period ended March 31, 2021, compared to a net loss of $40.6 million, or $0.36 loss per basic and diluted share, in the comparable period in 2020. Total research and development expenses were $19.4 million in the quarter, as compared to $16.0 million in the same period in 2020. Selling, general and administrative expenses were $14.3 million in the quarter, compared to $14.8 million in the same period in 2020.

The company ended the quarter with cash, cash equivalents, and marketable securities of $162.9 million.

Non-GAAP Results

Spectrum recorded a non-GAAP net loss of $29.4 million, or $0.20 loss per basic and diluted share, in the three-month period ended March 31, 2021, compared to a non-GAAP net loss of $25.0 million, or $0.22 loss per basic and diluted share, in the comparable period in 2020. Non-GAAP research and development expenses were $18.0 million, as compared to $14.6 million in the same period of 2020. Non-GAAP selling, general and administrative expenses were $11.5 million, as compared to $10.8 million in the same period in 2020.

Conference Call

Thursday, May 13, 2021 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 1373243
International: (973) 796-5077, Conference ID# 1373243

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 May 13, 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 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. 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 potential for an increase in the value of poziotinib using BID dosing, the speed of enrollment in Cohort 5, the timing of the FDA's pre-approval inspection of the ROLONTIS manufacturing facility, whether the final safety and efficacy data for poziotinib from Cohort 5 of the ZENITH20 clinical trial will continue to demonstrate similar results to the preliminary data, 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 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 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, the possibility that the FDA postpones its pre-approval inspection of the ROLONTIS manufacturing facility past May 2021 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, 2021, 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 March 31,	
	2021	**2020**

Revenues	$ —	$ —
Operating costs and expenses:		
Selling, general and administrative	14,315	14,794
Research and development	19,371	15,993
Total operating costs and expenses	33,686	30,787
Loss from continuing operations before other income (expense) and income taxes	(33,686)	(30,787)
Other income (expense):		
Interest income, net	84	704
Other expense, net	(2,081)	(10,534)
Total other expense	(1,997)	(9,830)
Loss from continuing operations before income taxes	(35,683)	(40,617)
Benefit for income taxes from continuing operations	7	—
Loss from continuing operations	$ (35,676)	$ (40,617)
(Loss) income from discontinued operations, net of income taxes	(21)	45
Net loss	$ (35,697)	$ (40,572)
Basic and diluted loss per share:		
Loss from continuing operations	$ (0.25)	$ (0.36)
(Loss) income from discontinued operations	$ 0.00	$ 0.00
Net loss per share, basic and diluted	$ (0.25)	$ (0.36)
Weighted average shares outstanding, basic and diluted	145,371,657	111,780,571

SPECTRUM PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share and par value amounts)

(Unaudited)

	March 31, 2021	**December 31, 2020**

ASSETS		
Current assets:		
Cash and cash equivalents	$ 69,521	$ 46,009
Marketable securities	93,336	134,016
Accounts receivable, net	64	67
Other receivables	2,795	2,394
Prepaid expenses and other current assets	3,491	4,161
Total current assets	169,207	186,647
Property and equipment, net	3,613	3,577
Facility and equipment under lease	1,824	2,247
Other assets	4,363	4,327
Total assets	$ 179,007	$ 196,798
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 42,412	$ 43,771
Accrued payroll and benefits	4,967	9,375
Total current liabilities	47,379	53,146
Other long-term liabilities	9,189	9,409
Total liabilities	56,568	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; 153,728,336 and 146,083,110 issued and outstanding at March 31, 2021 and December 31, 2020, respectively	154	146
Additional paid-in capital	1,046,784	1,021,221
Accumulated other comprehensive loss	(3,507)	(1,829)
Accumulated deficit	(920,992)	(885,295)

Total stockholders' equity	122,439	134,243
Total liabilities and stockholders' equity	$ 179,007	$ 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)

		CONTINUING OPERATIONS ONLY Three Months Ended March 31,	
		2021	**2020**
(1)	**GAAP selling, general and administrative**	**$ 14,315**	**$ 14,794**
	Non-GAAP adjustments to SG&A:		
	Stock-based compensation expense	(2,799)	(3,878)
	Depreciation expense	(63)	(106)
	Lease expense	23	9
	Non-GAAP selling, general and administrative	**$ 11,476**	**$ 10,819**
(2)	**GAAP research and development**	**$ 19,371**	**$ 15,993**
	Non-GAAP adjustments to R&D:		
	Stock-based compensation expense	(1,414)	(1,398)

	Depreciation expense	(2)	(33)
	Non-GAAP research and development	**$ 17,955**	**$ 14,562**
(3)	**GAAP net loss from continuing operations**	**$ (35,676)**	**$ (40,617)**
	Non-GAAP adjustments to net loss from continuing operations:		
	Adjustments to SG&A and R&D, as noted above	4,255	5,406
	Adjustments to other expense	2,072	10,249
	Adjustments to benefit for income taxes	(7)	—
	Non-GAAP net loss from continuing operations	**$ (29,356)**	**$ (24,962)**
(4)	**GAAP net loss from continuing operations - per basic and diluted share**	**$ (0.25)**	**$ (0.36)**
	Non-GAAP net loss from continuing operations - per basic and diluted share	**$ (0.20)**	**$ (0.22)**
	Weighted average shares outstanding, basic and diluted	145,371,657	111,780,571

(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 and depreciation. 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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