Spectrum Pharmaceuticals Reports First Quarter 2020 Financial Results and Pipeline Update

May 7, 2020

BLA for ROLONTIS® (eflapegrastim) under active FDA review - PDUFA date on October 24, 2020

ROLONTIS same day dosing study initiated

Updated Poziotinib strategy implemented to include new dosing regimens

Poziotinib ZENITH20 Cohort 3 fully enrolled

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

HENDERSON, Nev.--(BUSINESS WIRE)--May 7, 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 March 31, 2020.

“The progress in our development pipeline speaks to the investigator interest and the commitment of our team during these unprecedented times,” said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. “The PDUFA date for ROLONTIS remains October 24, 2020 and our updated poziotinib strategy is well under way. We continue to drive the business forward and remain focused on achieving our milestones this year.”

Pipeline Updates

ROLONTIS (eflapegrastim), 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.
- Company-sponsored study evaluating the administration of ROLONTIS on the same day as chemotherapy, dosed its first patient. The trial will evaluate the duration of severe neutropenia when administered at three different time points on the same day following standard chemotherapy in patients with early stage breast cancer.

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

- Spectrum presented additional results for Cohort 1 from its Phase 2 clinical trial, ZENITH20, evaluating poziotinib in previously treated non-small cell lung cancer (NSCLC) patients with EGFR exon 20 insertion mutations at a plenary session of the virtual American Association for Cancer Research annual meeting on April 27, 2020. The podium presentation included additional safety and efficacy data. Although the results for Cohort 1 did not meet the primary endpoint, as previously announced, poziotinib demonstrated a 68.7% disease control rate.
- Spectrum provided an update on its ZENITH20 trial evaluating poziotinib in NSCLC patients with EGFR and HER2 exon 20 insertion mutations. The protocol has been amended to explore additional dosing regimens and the earlier use of corticosteroids in an effort to increase drug compliance.
- Cohort 2 of the ZENITH20 trial enrolling previously treated HER2 NSCLC patients is fully accrued as previously announced and is expected to have topline results released in mid-2020. Cohort 3 of the ZENITH20 trial enrolling first-line EGFR NSCLC patients is now fully enrolled and is expected to have topline results in the second half of 2020. Either cohort has the potential to support a future NDA submission.

Three-Month Period Ended March 31, 2020 (All numbers are from Continuing Operations and are approximate)

GAAP Results

Spectrum recorded a net loss of $40.6 million, or $0.36 loss per basic and diluted share, in the three-month period ended March 31, 2020, compared to net loss of $39.8 million, or $0.36 loss per basic and diluted share, in the comparable period in 2019. Total research and development expenses were $16.0 million in the quarter, as compared to $21.9 million in the same period in 2019. Selling, general and administrative expenses were $14.8 million in the quarter, compared to $16.0 million in the same period in 2019.

The company ended the quarter with cash, cash equivalents, and marketable securities of $177.8 million.

Non-GAAP Results

Spectrum recorded a non-GAAP net loss of $25.0 million, or $0.22 per basic and diluted share, in the three-month period ended March 31, 2020, compared to a non-GAAP net loss of $29.2 million, or $0.27 per basic and diluted share, in the comparable period in 2019. Non-GAAP research and development expenses were $14.6 million, as compared to $20.4 million in the same period of 2019. Non-GAAP selling, general and administrative expenses were $10.8 million, as compared to $10.7 million in the same period in 2019.

Conference Call and Webcast

Spectrum's management will host a webcast and conference call today, May 7, 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#: 8470139. 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.

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 company's ability to advance development of its late-stage pipeline assets and the potential of such assets to transform the company in the near future; the likelihood of the company achieving its milestones this year; the timing of the results of cohort 2 and cohort 3 in Spectrum's ZENITH20 study, and the potential of either cohort to support a future NDA submission; the timing and results of FDA decisions, including its approval of the ROLONTIS BLA; the ability of Spectrum's pipeline to serve areas of unmet medical need; the progression of the ROLONTIS and poziotinib 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 pre-clinical and clinical data, 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.

SPECTRUM PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Revenues	$ —	$ —
Operating costs and expenses:		

Selling, general and administrative	14,794	15,952
Research and development	15,993	21,886
Total operating costs and expenses	30,787	37,838
Loss from continuing operations before other expense and income taxes	(30,787)	(37,838)
Other (expense) income:		
Interest income, net	704	1,061
Other expense, net	(10,534)	(11,285)
Total other expense	(9,830)	(10,224)
Loss from continuing operations before income taxes	(40,617)	(48,062)
Benefit for income taxes from continuing operations	—	8,216
Loss from continuing operations	$ (40,617)	$ (39,846)
Income from discontinued operations, net of income taxes	45	20,587
Net loss	$ (40,572)	$ (19,259)
Basic and diluted loss per share:		
Loss per common share from continuing operations	$ (0.36)	$ (0.36)
Income per common share from discontinued operations	—	0.19
Net loss per common share	$ (0.36)	$ (0.18)
Weighted average shares outstanding:		
Basic	111,780,571	109,552,602
Diluted	111,780,571	109,552,602

SPECTRUM PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

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

(Unaudited)

	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,352	$ 64,418
Marketable securities	107,441	159,455
Accounts receivable, net of allowance for credit losses of $43 and $43, respectively	435	441
Other receivables	8,789	9,558
Prepaid expenses and other assets	10,263	10,148
Total current assets	197,280	244,020
Property and equipment, net of accumulated depreciation	12,058	11,607
Other assets	3,187	4,000
Facility and equipment under lease	3,467	3,806
Total assets	$ 215,992	$ 263,433
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 49,130	$ 54,284
Accrued payroll and benefits	4,568	7,686
Total current liabilities	53,698	61,970
Other long-term liabilities	8,526	11,070
Total liabilities	62,224	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; 114,774,079 and 113,299,612 issued and outstanding at March 31, 2020 and December 31, 2019, respectively	114	113
Additional paid-in capital	923,480	918,205
Accumulated other comprehensive loss	(4,827)	(3,498)

Accumulated deficit	(764,999)	(724,427)
Total stockholders' equity	153,768	190,393
Total liabilities and stockholders' equity	$ 215,992	$ 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, expect per share amounts)

		CONTINUING OPERATIONS ONLY	
		Three Months Ended	
		March 31,	
		2020	**2019**
(1)	**GAAP selling, general and administrative**	**$ 14,794**	**$ 15,952**
	Non-GAAP adjustments to SG&A:		
	Stock-based compensation expense	(3,878)	(3,450)
	Depreciation expense	(106)	(66)
	Lease expense	9	(129)
	Severance expense	—	(1,641)
	Non-GAAP selling, general and administrative	**$ 10,819**	**$ 10,666**
(2)	**GAAP research and development**	**$ 15,993**	**$ 21,886**

	Non-GAAP adjustments to R&D:			
	Stock-based compensation expense	(1,398)	(908)	
	Depreciation expense	(33)	(2)	
	Severance expense	—	(547)	
	Non-GAAP research and development	**$ 14,562**	**$ 20,429**	
(3)	**GAAP net loss from continuing operations**	**$ (40,617)**	**$ (39,846)**	
	Non-GAAP adjustments to net loss from continuing operations:			
	Adjustments to SG&A and R&D, as noted above	5,406	6,743	
	Adjustments to other expense	10,249	12,140	
	Adjustments to benefit for income taxes	—	(8,216)	
	Non-GAAP net loss from continuing operations	**$ (24,962)**	**$ (29,179)**	
(4)	**GAAP net loss from continuing operations - per basic and diluted share**	$ (0.36)	$ (0.36)	
	Non-GAAP net loss from continuing operations - per basic and diluted share	$ (0.22)	$ (0.27)	
	Weighted average shares outstanding:			
	Basic	111,780,571	109,552,602	
	Diluted	111,780,571	109,552,602	

(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. 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); and (iii) reversal of the mark-to-market adjustment (non-cash) on our equity securities 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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