Spectrum Pharmaceuticals Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 11, 2022

Eflapegrastim BLA under FDA review; PDUFA date September 9, 2022

FDA completes re-inspection of drug substance manufacturing facility for eflapegrastim

Poziotinib NDA under FDA review with ODAC meeting on September 22, 2022

Management to host webcast and conference call today at 8:30 a.m. ET / 5:30 a.m. PT

BOSTON--(BUSINESS WIRE)--Aug. 11, 2022-- 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, 2022 and provided a corporate update.

"The completion of the FDA re-inspection of the drug substance facility for eflapegrastim is a critical step in the regulatory review process. With this hurdle behind us, we have turned our focus to our potential approval and commercialization," said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. "Additionally, our team is engaged in extensive preparations ahead of poziotinib's ODAC review in September, and we look forward to moving a step closer to bringing this therapy to patients."

Pipeline Updates

Eflapegrastim, a novel long-acting G-CSF

- The Biologics License Application (BLA) for eflapegrastim is under active review at the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) date of September 9, 2022. The pre-approval inspection of the drug substance manufacturing facility has been completed by the FDA. The company anticipates an FDA decision by the PDUFA date and is actively preparing for the potential commercial launch.

Poziotinib, a Pan ErbB inhibitor targeting HER2 exon 20 mutations

- The New Drug Application (NDA) for poziotinib is under active review at the FDA with Fast Track designation and a PDUFA date of November 24, 2022. The NDA is based on the positive results of Cohort 2 from the ZENITH20 clinical trial in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 exon 20 insertion mutations. There is currently no FDA approved therapy for patients with NSCLC harboring HER2 exon 20 insertion mutations.
- An abstract showing a high level of activity for poziotinib in patients with a G778_P780dup mutation, the second most prevalent mutation in HER2 exon 20 NSCLC, has been accepted for presentation at ESMO 2022 being held September 9-13 in Paris. The data comes from Cohorts 2 and 4 of the ZENITH20 clinical trial.
- A study for poziotinib is in progress to confirm the clinical benefit seen in Cohort 2, as required for an accelerated approval. The trial, Study SPI-POZ-301 (PINNACLE), is designed to enroll 268 patients with previously treated NSCLC harboring HER2 exon 20 mutations. Patients are being randomized 2-to-1 into one of two treatment arms using 8mg of poziotinib orally administered BID (twice daily) versus 75mg/m^2 of docetaxel administered intravenously every three weeks. The primary endpoint is progression free survival.
- The FDA's Oncologic Drugs Advisory Committee (ODAC) is scheduled to review poziotinib for the treatment of patients with previously treated locally advanced or metastatic NSCLC harboring HER2 exon 20 insertion mutations. The poziotinib ODAC review is scheduled for September 22, 2022 at 9 a.m. ET. ODAC is an independent panel of experts that evaluates data concerning the efficacy and safety of marketed and investigational products for use in the treatment of cancer and makes non-binding recommendations to the FDA. The final decision regarding the approval of the product is made solely by the FDA.
- The company presented data on the predictive ability of circulating tumor DNA (ctDNA) in poziotinib treated patients with NSCLC harboring HER2 exon 20 insertion mutations at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting in June. Preliminary results suggest that decreases in plasma ctDNA during poziotinib therapy correlate with clinical response in patients with advanced NSCLC with HER2 exon 20 insertion mutations.

Three-Month Period Ended June 30, 2022 (All numbers are from Continuing Operations)

Spectrum recorded a net loss of $29.0 million, or a $0.17 loss per basic and diluted share, in the three-month period ended June 30, 2022, compared to a net loss of $49.9 million, or a $0.32 loss per basic and diluted share, in the comparable period in 2021. Total research and development expenses

were $16.0 million in the quarter, as compared to $29.1 million in the same period in 2021. Selling, general and administrative expenses were $9.4 million in the quarter, compared to $15.0 million in the same period in 2021.

Cash Position and Guidance

The company's cash, cash equivalents and marketable securities balance was approximately $68 million at June 30, 2022, which provides for a cash runway into 2023.

Conference Call

Thursday, August 11, 2022 @ 8:30 a.m. Eastern/5:30 a.m. Pacific

To access the live call by phone, please go to this link (registration link), and you will be provided with dial in details. To avoid delays, participants are encouraged to dial into the conference call fifteen minutes ahead of the scheduled start time.

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 August 11, 2022 at 8:30 a.m. Eastern/5:30 a.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.

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 and eflapegrastim, if FDA approval is received, the success and timing of the company's commercialization efforts, the results of the confirmatory study for poziotinib, the results of the ODAC's review of poziotinib and related recommendation to the FDA, the speed of enrollment in the company's remaining ZENITH20 Cohorts, whether additional data for poziotinib-treated patients with NSCLC harboring HER2 exon 20 insertion mutations will continue to demonstrate similar results to the preliminary data suggesting the predictive ability of circulating tumor DNA (ctDNA), the future potential of Spectrum's existing drug pipeline, the results of the company's strategic restructuring, the length of the company's cash runway 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 and other risks that are described in further detail in the company's reports filed with the Securities and Exchange Commission (SEC). 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating costs and expenses:				

Selling, general and administrative	$ 9,385	$ 14,957	$ 19,255	$ 29,272
Research and development	16,007	29,114	20,200	48,485
Total operating costs and expenses	25,392	44,071	39,455	77,757
Loss from continuing operations before other income (expense) and income taxes	(25,392)	(44,071)	(39,455)	(77,757)
Other income (expense):				
Interest income, net	117	26	128	110
Other expense, net	(3,757)	(5,876)	(5,091)	(7,957)
Total other expense	(3,640)	(5,850)	(4,963)	(7,847)
Loss from continuing operations before income taxes	(29,032)	(49,921)	(44,418)	(85,604)
Provision for income taxes from continuing operations	(13)	(16)	(29)	(9)
Loss from continuing operations	(29,045)	(49,937)	(44,447)	(85,613)
Loss from discontinued operations, net of income taxes	(3)	(195)	(43)	(216)
Net loss	$ (29,048)	$ (50,132)	$ (44,490)	$ (85,829)
Basic and diluted loss per share:				
Loss from continuing operations	$ (0.17)	$ (0.32)	$ (0.26)	$ (0.57)
Loss from discontinued operations	$ (0.00)	$ (0.00)	$ (0.00)	$ (0.00)
Net loss per share, basic and diluted	$ (0.17)	$ (0.32)	$ (0.26)	$ (0.57)
Weighted average shares outstanding, basic and diluted	175,566,757	155,243,402	172,558,831	150,334,548

SPECTRUM PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share and par value amounts)

(Unaudited)

	June 30, 2022	**December 31, 2021**
ASSETS		
Current assets:		

Cash and cash equivalents	$ 25,512	$ 88,539
Marketable securities	42,447	12,108
Other receivables	608	1,028
Prepaid expenses and other current assets	5,012	2,277
Total current assets	73,579	103,952
Property and equipment, net	347	455
Facility and equipment under lease	1,703	2,505
Other assets	3,800	4,636
Total assets	$ 79,429	$ 111,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 33,123	$ 41,258
Accrued payroll and benefits	7,918	11,971
Total current liabilities	41,041	53,229
Other long-term liabilities	4,946	10,766
Total liabilities	45,987	63,995
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; 184,870,273 and 164,502,013 issued and outstanding at June 30, 2022 and December 31, 2021, respectively	185	165
Additional paid-in capital	1,124,625	1,094,353
Accumulated other comprehensive loss	(2,955)	(3,042)
Accumulated deficit	(1,088,413)	(1,043,923)
Total stockholders' equity	33,442	47,553
Total liabilities and stockholders' equity	$ 79,429	$ 111,548

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