Spectrum Pharmaceuticals Reports Fourth Quarter 2022 and Full Year 2022 Financial Results and Corporate Update

March 22, 2023

-- First launch quarter for ROLVEDON™ (eflapegrastim-xnst) injection --

-- Q4 and full year net sales of $10.1 million --

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

BOSTON--(BUSINESS WIRE)--Mar. 22, 2023-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, announced today financial results for the three-month period and full year ended December 31, 2022.

Fourth Quarter 2022 and Recent Business Update

- First launch quarter for ROLVEDON, with net sales for the quarter and year ended December 31, 2022, totaling $10.1 million.
- Operating expenses decreased 45% year-over-year as the Company streamlined operations while continuing to invest in core business objectives, including the commercialization of ROLVEDON.
- 70 targeted accounts purchased ROLVEDON during the launch quarter, including the top three community oncology networks, representing approximately 22% of the total clinic market.
- Received permanent J-Code, facilitating more efficient and predictable reimbursement in the outpatient setting.
- National Comprehensive Cancer Network® Supportive Care Guidelines (NCCN Guidelines) in oncology for Hematopoietic Growth Factors named ROLVEDON as an appropriate option for cancer patients who are at risk for febrile neutropenia.
- Cash, cash equivalents and marketable securities of $75.1 million at December 31, 2022, giving us an expected runway through 2024.

“It’s been a transformative year for Spectrum as we have become a commercially focused company. We’ve approached the launch of ROLVEDON with a disciplined strategy and an understanding that Spectrum’s long-term growth is dependent upon the product’s success. We’re off to a solid start and are encouraged by the initial customer receptivity to ROLVEDON,” said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. “Commercial success is foundational to the Company’s future and, with the right people in place, a lean infrastructure, and an ample cash runway, we have a tremendous opportunity moving forward.”

Financial Results for the Quarter and Year Ended December 31, 2022 (All numbers are from Continuing Operations)

Net sales for the quarter and year ended December 31, 2022 were $10.1 million as we began to sell our sole commercial product, ROLVEDON, which was approved by the FDA on September 9, 2022.

During the quarter and year ended December 31, 2022, the cost of sales was $1.8 million, consisting primarily of packaging costs, freight and royalties associated with the net sales of ROLVEDON and $1.1 million of start-up expenses associated with stability and bio-burden testing. This figure did not include any direct costs associated with the manufacture of ROLVEDON, which were previously expensed in research and development expense.

Selling, general and administrative expenses for the quarter and year ended December 31, 2022 were $11.3 million and $38.8 million, respectively, as compared to $18.9 million and $60.4 million for the comparable periods in 2021. The decrease was primarily due to lower costs associated with personnel related expenses associated with the reduction in workforce announced in January 2022 and decreases in professional services and other general expenses.

Total research and development expenses were $8.7 million and $42.2 million for the quarter and year ended December 31, 2022, respectively, as compared to $18.0 million and $87.3 million for the comparable periods in 2021. The decrease was due to decreased program activities for ROLVEDON, poziotinib, and early-stage compounds, personnel-related expenditures associated with the reduction in workforce during the strategic restructuring that began in January 2022, as well as a concession provided by Hanmi Pharmaceutical Co. Ltd. for drug substance which had been accrued during 2021 and is no longer payable by Spectrum.

Net loss was $11.7 million, or $0.06 per basic and diluted share, for the quarter ended December 31, 2022, compared to a net loss of $39.8 million, or $0.26 per basic and diluted share, for the comparable period in 2021. Net loss for the year ended December 31, 2022 was $78.1 million, or $0.43 per basic and diluted share, compared to net loss of $158.4 million, or $1.02 per basic and diluted share, for the comparable period in 2021.

The Company had a total cash, cash equivalents, and marketable securities balance of approximately $75.1 million at December 31, 2022.

Conference Call

As previously announced, management will host a conference call as follows:

Date:	Wednesday, March 22, 2023
Time:	8:30 AM ET
Register:	Click Here
Webcast (Audio Only):	Click Here

The webcast will be archived under the "Events and Presentations" section of the Company's investor relations website.

About ROLVEDON™

ROLVEDON™ (eflapegrastim-xnst)injection is a long-acting granulocyte colony-stimulating factor (G-CSF) with a novel formulation. Spectrum has received an indication to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. ROLVEDON is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. The BLA for ROLVEDON was supported by data from two identically designed Phase 3, randomized, open-label, noninferiority clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of ROLVEDON in 643 early-stage breast cancer patients for the management of neutropenia due to myelosuppressive chemotherapy. In both studies, ROLVEDON demonstrated the pre-specified hypothesis of non-inferiority (NI) in mean duration of severe neutropenia (DSN) and a similar safety profile to pegfilgrastim. ROLVEDON also demonstrated non-inferiority to pegfilgrastim in the mean DSN across all four cycles (all NI $p<0.0001$) in both trials.

Please see the Important Safety Information below and the full prescribing information for ROLVEDON at www.rolvedon.com.

Indications and Usage

ROLVEDON is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.

Limitations of Use

ROLVEDON is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Important Safety Information

Contraindications

- ROLVEDON is contraindicated in patients with a history of serious allergic reactions to eflapegrastim, pegfilgrastim or filgrastim products. Reactions may include anaphylaxis.

Warnings and Precautions

Splenic Rupture

- Splenic rupture, including fatal cases, can occur following the administration of recombinant human granulocyte colony-stimulating factor (rhG-CSF) products. Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.

Acute Respiratory Distress Syndrome (ARDS)

- ARDS can occur in patients receiving rhG-CSF products. Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue ROLVEDON in patients with ARDS.

Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis, can occur in patients receiving rhG-CSF products. Permanently discontinue ROLVEDON in patients who experience serious allergic reactions.

Sickle Cell Crisis in Patients with Sickle Cell Disorders

- Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving rhG-CSF products. Discontinue ROLVEDON if sickle cell crisis occurs.

Glomerulonephritis

- Glomerulonephritis has occurred in patients receiving rhG-CSF products. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved

after dose-reduction or discontinuation. Evaluate and consider dose reduction or interruption of ROLVEDON if causality is likely.

Leukocytosis

- White blood cell (WBC) counts of 100 x 10^9/L or greater have been observed in patients receiving rhG-CSF products. Monitor complete blood count (CBC) during ROLVEDON therapy. Discontinue ROLVEDON treatment if WBC count of 100 x 10^9/L or greater occurs.

Thrombocytopenia

- Thrombocytopenia has been reported in patients receiving rhG-CSF products. Monitor platelet counts.

Capillary Leak Syndrome

- Capillary leak syndrome has been reported after administration of rhG-CSF products and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency and severity and may be life-threatening if treatment is delayed. If symptoms develop, closely monitor and give standard symptomatic treatment, which may include a need for intensive care.

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

- The granulocyte colony-stimulating factor (G-CSF) receptor through which ROLVEDON acts has been found on tumor cell lines. The possibility that ROLVEDON acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which ROLVEDON is not approved, cannot be excluded.

Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer

- MDS and AML have been associated with the use of rhG-CSF products in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.

Aortitis

- Aortitis has been reported in patients receiving rhG-CSF products. It may occur as early as the first week after start of therapy. Consider aortitis in patients who develop generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count) without known etiology. Discontinue ROLVEDON if aortitis is suspected.

Nuclear Imaging

- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone imaging results.

Adverse Reactions

- The most common adverse reactions (≥20%) were fatigue, nausea, diarrhea, bone pain, headache, pyrexia, anemia, rash, myalgia, arthralgia, and back pain.
- Permanent discontinuation due to an adverse reaction occurred in 4% of patients who received ROLVEDON. The adverse reaction requiring permanent discontinuation in 3 patients who received ROLVEDON was rash.

To report SUSPECTED ADVERSE REACTIONS, contact Spectrum Pharmaceuticals, Inc. at 1-888-713-0688 or FDA at 1800FDA1088 or www.fda.gov/medwatch

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals, Inc. is a commercial stage 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. For additional information on Spectrum please visit www.sppirx.com.

Notice Regarding Forward-looking Statements

This press release may contain forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially. These statements are based on management's current beliefs and expectations. These statements include, but are not limited to, statements that relate to Spectrum's fourth quarter and full year financial performance, including Spectrum's expected net sales, expected cash runway, the future success of Spectrum's commercial launch of ROLVEDON, and any other statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact. Risks that could cause actual results to differ include the possibility that Spectrum's existing and new drug candidates may not prove safe or effective, the

possibility that our existing and new applications to the FDA and other regulatory agencies may not receive approval in a timely manner or at all, the possibility that our existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our dependence on third parties for clinical trials, manufacturing, distribution and quality control, the impact of the COVID-19 pandemic, geopolitical issues and inflation on our business and operations, supply chain and labor force 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.

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SPECTRUM PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	**2021**	**2022**	**2021**
Net sales	$ 10,114	$ —	$ 10,114	$ —
Expenses:				
Cost of sales	1,792	—	1,792	—
Selling, general and administrative	11,298	18,891	38,816	60,406
Research and development	8,669	17,962	42,203	87,297
Total expenses	21,759	36,853	82,811	147,703
Loss from continuing operations before other income (expense) and income taxes	(11,645)	(36,853)	(72,697)	(147,703)
Other income (expense):				
Interest income	615	45	968	215
Interest expense	(901)	(4)	(998)	(52)
Other expense, net	202	(2,943)	(5,331)	(10,892)
Total other expense	(84)	(2,902)	(5,361)	(10,729)
Loss from continuing operations before income taxes	(11,729)	(39,755)	(78,058)	(158,432)
Benefit (provision) for income taxes from continuing operations	—	5	(46)	(4)

Loss from continuing operations	$ (11,729)	$ (39,750)	$ (78,104)	$ (158,436)
Income (loss) from discontinued operations, net of income taxes	2,742	36	2,703	(192)
Net loss	$ (8,987)	$ (39,714)	$ (75,401)	$ (158,628)
Basic and diluted loss per share:				
Loss per common share from continuing operations	$ (0.06)	$ (0.26)	$ (0.43)	$ (1.02)
Income per common share from discontinued operations	$ 0.01	$ —	$ 0.01	$ —
Net loss per common share, basic and diluted	$ (0.05)	$ (0.26)	$ (0.41)	$ (1.02)
Weighted average shares outstanding, basic and diluted	199,539,109	154,680,363	183,237,200	154,861,704

SPECTRUM PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

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

	December 31,	
	2022	**2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 40,368	$ 88,539
Marketable securities	34,728	12,108
Accounts receivable, net	12,996	—
Other receivables	617	1,028
Inventories	9,230	—
Prepaid expenses and other current assets	3,072	2,277
Total current assets	101,011	103,952
Property and equipment, net	476	455
Facility and equipment under lease	1,694	2,505
Other assets	157	4,636

Total assets	$ 103,338	$ 111,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 38,105	$ 41,258
Accrued payroll and benefits	4,580	11,971
Total current liabilities	42,685	53,229
Loan payable, long-term	28,666	—
Other long-term liabilities	4,099	10,766
Total liabilities	75,450	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; 202,827,831 and 164,502,013 issued and outstanding at December 31, 2022 and 2021, respectively	203	165
Additional paid-in capital	1,149,926	1,094,353
Accumulated other comprehensive loss	(2,917)	(3,042)
Accumulated deficit	(1,119,324)	(1,043,923)
Total stockholders' equity	27,888	47,553
Total liabilities and stockholders' equity	$ 103,338	$ 111,548

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