UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 31, 2023

SPECTRUM PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-35006**	**93-0979187**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
Pilot House-Lewis Wharf, 2 Atlantic Avenue 6th Floor Boston, MA		**02110**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: (617) 586-3900

Not Applicable
(Former name or former address if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	SPPI	The NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On January 31, 2023, Spectrum Pharmaceuticals, Inc. issued a press release, which, among other matters, sets forth certain estimated preliminary unaudited financial results for the quarter and year ended December 31, 2022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The foregoing information, including Exhibit 99.1, is being furnished under Item 2.02 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated January 31, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SPECTRUM PHARMACEUTICALS, INC.

Date: January 31, 2023

By: /s/ Nora E. Brennan
Nora E. Brennan
Executive Vice President and Chief Financial Officer

Spectrum Pharmaceuticals Provides Update on ROLVEDON™ (eflapegrastim-xnst) Injection and Announces Unaudited Fourth Quarter 2022 Financial Results

— Preliminary unaudited Q4 2022 net sales expected to be approximately $10 million —
— Cash, cash equivalents and marketable securities of $75 million at 12/31/2022, which is expected to extend cash runway through 2024 —

Boston, MA, January 31, 2023 – Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology today announced business highlights and preliminary ROLVEDON net sales for the quarter and year ended December 31, 2022.

Business Highlights and Preliminary, Unaudited Financial Results

- Preliminary unaudited net sales for the quarter ending December 31, 2022 are expected to be approximately $10 million
- ROLVEDON was launched in the U.S. on October 18, 2022 with a comprehensive strategy to address community oncology, 340B and non-340B hospitals
- 70 targeted accounts purchased ROLVEDON during the launch quarter
- The top three community oncology networks, representing approximately 22% of the total clinic market, have begun utilizing ROLVEDON
- Cash, cash equivalents and marketable securities of $75 million at 12/31/2022

“I am pleased with the early receptivity to ROLVEDON from our oncology customers in the first quarter of our launch,” said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. “The commercial team is implementing our launch strategy and are committed to disciplined execution over time. The energy and enthusiasm within our company is high as we look to establish a strong launch trajectory with our novel product in this highly competitive, yet attractive market.”

The Company intends to provide a detailed operational and financial update during its fourth quarter and full-year 2022 earnings call in March 2023. Closing procedures for the fiscal quarter and year ended December 31, 2022, are not yet complete. The preliminary unaudited financial information presented in this press release reflects the Company’s current estimates based on information available as of the date of this press release and is subject to change as a result of the completion of the Company’s financial and operating closing procedures, customary audit procedures, and other developments that may occur before the completion of these procedures. Accordingly, you should not place undue reliance on this preliminary financial information, which may differ materially from actual results. See “Notice Regarding Forward-looking Statements” below for a discussion of certain factors that could result in differences between the estimated unaudited financial information reported in this press release and actual results.

This update does not present all necessary information for an understanding of Spectrum's financial condition as of the date of this release, or its results of operations for the fourth quarter or full year of 2022. As Spectrum completes its quarter- and year-end close process and finalizes its financial statements for the fourth quarter and full year of 2022, the Company will be required to make judgements in a number of areas. It is possible that Spectrum may identify items that require the Company to make adjustments to the preliminary selected financial information set forth above and those adjustments could be material. Except as set forth above, Spectrum does not intend to update any financial information prior to the release of its final fourth quarter and full year 2022 financial statements in March 2023.

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 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 and cash burn rate for the quarter and expected cash on hand at December 31, 2022, the future success of Spectrum's commercial launch of ROLVEDON, including the aggregate size of the LA-GCSF market and Spectrum's ability to generate future sales into the community oncology clinic segment, 340B and non-340B hospitals and other systems within the market, the ability of Spectrum's pricing strategy to deliver near- and long-term value to clinics it serves, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, 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 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.

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