

**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): May 9, 2023

SPECTRUM PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35006
(Commission
File Number)

93-0979187
(IRS Employer
Identification No.)

Pilot House-Lewis Wharf, 2 Atlantic Avenue
(Address of principal executive offices)

6th Floor Boston, MA

02110
(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 Capital 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 May 9, 2023, Spectrum Pharmaceuticals, Inc. issued a press release, which, among other matters, sets forth our results of operations for the quarter ended March 31, 2023. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 9, 2023
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

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: May 9, 2023

By: /s/ Nora E. Brennan

Name: Nora E. Brennan

Title: Executive Vice President and Chief Financial Officer



Spectrum Pharmaceuticals Reports First Quarter 2023 Financial Results and Corporate Update

— Q1 2023 net sales of \$15.6 million, an increase of 54% compared to Q4 2022 —

— Company to be acquired by Assertio Holdings, Inc., delivering value to stakeholders in an all stock and contingent value rights (CVR) transaction —

— Transaction expected to close in Q3 2023 —

BOSTON—(BUSINESS WIRE) — May 9, 2023— Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a commercial stage biopharmaceutical company focused on novel and targeted oncology therapies, announced today financial results for the three-month period ended March 31, 2023, and provided a corporate update.

First Quarter 2023 and Recent Business Update

- Net sales for Q1 2023 totaled \$15.6 million, an increase of 54% compared to Q4 2022.
- 172 targeted accounts purchased ROLVEDON™ (eflapegrastim-xnst) Injection during the quarter compared to 70 in Q4 2022, an increase of 145%.
- Permanent J-Code for ROLVEDON went into effect on April 1, facilitating more efficient and predictable reimbursement in the outpatient setting.
- On April 25, announced acquisition by Assertio Holdings, Inc. (Nasdaq: ASRT) (“Assertio”), a specialty pharmaceutical company offering differentiated products to patients, in an all-stock and CVR transaction which is expected to deliver immediate value to stockholders while providing the opportunity to share in future upside of ROLVEDON.
- Upfront consideration represents a premium of 65%, and the total potential consideration a premium of 94% to Spectrum’s closing price of \$0.69 on April 24, 2023.
- Following an anticipated Q3 2023 closing, Assertio stockholders will own approximately 65% of the combined company, and Spectrum stockholders will own approximately 35% of the combined company, on a fully diluted basis.

“Spectrum delivered a strong start to 2023 with outstanding execution in the launch of ROLVEDON. This success is demonstrated through significant quarter-over-quarter sales growth, account expansion, and continued customer receptivity to ROLVEDON’s value proposition,” said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. “Following the acquisition, we believe the combination of Spectrum’s commercial infrastructure and Assertio’s digital non-personnel resources will set the brand up for long-term success and accelerate the profitability of the combined company.”

Financial Results for the Quarter Ended March 31, 2023 (All numbers are from Continuing Operations)

Net sales for the first quarter of 2023 were \$15.6 million. During the fourth quarter of 2022 we began to sell our sole commercial product, ROLVEDON, which was approved by the FDA on September 9, 2022. We had no sales during the first quarter of 2022.

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Total cost of sales was \$1.1 million for the quarter ended March 31, 2023, and consisted primarily of royalties associated with net sales of ROLVEDON, stability testing and packaging costs. This figure did not include any direct costs associated with the manufacture of ROLVEDON, which were previously expensed as research and development expense. As we sell through certain inventory that was expensed prior to FDA approval of ROLVEDON, we expect the cost of sales to remain low through the first nine months of 2023 and to increase thereafter.

Selling, general and administrative expenses for the first quarter of 2023 increased by \$4.1 million to \$14.0 million as compared to the corresponding prior year period. The increase was due primarily to increased sales and marketing expenses to support the launch of ROLVEDON and an increase in legal and other fees incurred in connection with the pending acquisition by Assertio.

Research and development expenses increased for the three months ended March 31, 2023 by \$1.2 million to \$5.4 million as compared to the comparable period ended March 31, 2022. The current period had decreased personnel expenses of \$5.7 million related to the reduction in workforce during the strategic restructuring that began in January 2022 and decreased program activities of \$5.0 million for poziotinib. These period over period decreases were offset by the reversal of an \$11.2 million ROLVEDON drug substance accrual during the quarter ended March 31, 2022, which was a concession provided by Hanmi for drug substance which had been accrued during 2021 and is no longer payable.

Net loss from continuing operations was \$5.0 million, or \$0.02 per basic and diluted share, for the quarter ended March 31, 2023, compared to a net loss of \$15.4 million, or \$0.09 per basic and diluted share, for the comparable period in 2022.

The Company had a total cash, cash equivalents, and marketable securities balance of approximately \$56.1 million as of March 31, 2023.

About ROLVEDON™

ROLVEDON™ (eflapregastim-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 similarly 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 treatment 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.

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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 $100 \times 10^9/L$ 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 $100 \times 10^9/L$ 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 ($\geq 20\%$) 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 is a commercial stage biopharmaceutical company, with a strategy of acquiring, developing, and commercializing novel and targeted oncology therapies. We have an in-house clinical development organization with regulatory and data management capabilities, in addition to commercial infrastructure and a field based sales force for our marketed product, ROLVEDON™ (eflapegrastim-xnst) Injection. For additional information on Spectrum please visit www.sppirx.com.

About Assertio

Assertio is a specialty pharmaceutical company offering differentiated products to patients utilizing a non-personal promotional model. We have built and continue to build our commercial portfolio by identifying new opportunities within our existing products as well as acquisitions or licensing of additional approved products. To learn more about Assertio, visit www.assertiotx.com.

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Notice Regarding Forward-looking Statements

This communication contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Generally, the words “anticipate,” “estimate,” “expect,” “project,” “intend,” “plan,” “contemplate,” “predict,” “forecast,” “likely,” “believe,” “target,” “will,” “could,” “would,” “should,” “potential,” “may” and similar expressions or their negative, may, but are not necessary to, identify forward-looking statements. Such forward-looking statements, including those regarding the timing, and consummation and anticipated benefits of the transaction described herein, involve risks and uncertainties. Assertio’s and Spectrum’s experience and results may differ materially from the experience and results anticipated in such statements. The accuracy of such statements is subject to a number of risks, uncertainties and assumptions including, but are not limited to, the following factors: the risk that the conditions to the closing of the transaction are not satisfied, including the risk that required approvals of the transaction from the stockholders of Assertio or stockholders of Spectrum or from regulators are not obtained; litigation relating to the transaction; uncertainties as to the timing of the consummation of the transaction and the ability of each party to consummate the transaction; risks that the proposed transaction disrupts the current plans or operations of Assertio or Spectrum; the ability of Assertio and Spectrum to retain and hire key personnel; competitive responses to the proposed transaction; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to relationships with customers, suppliers, distributors and other business partners resulting from the announcement or completion of the transaction; the combined company’s ability to achieve the synergies expected from the transaction, as well as delays, challenges and expenses associated with integrating the combined company’s existing businesses; 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 overall industry and general economic conditions, including inflation, interest rates and related monetary policy by governments in response to inflation; geopolitical events, including the war between Russia and Ukraine, and regulatory, economic and other risks associated therewith; and continued uncertainty around the ongoing impacts of the COVID-19 pandemic, as well as broader macroeconomic conditions. Other factors that might cause such a difference include those discussed in Assertio’s and Spectrum’s filings with the SEC, which include their Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and in the joint proxy statement/prospectus on Form S-4 to be filed in connection with the proposed transaction. For more information, see the section entitled “Risk Factors” and the forward looking statements disclosure contained in Assertio’s and Spectrum’s Annual Reports on Form 10-K and in other filings. All forward-looking statements made herein are based on information currently available to Spectrum as of the date of this communication. Spectrum undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Additional Information and Where to Find It

In connection with the proposed transaction, Assertio intends to file with the SEC a registration statement on Form S-4 that will include a joint proxy statement of Spectrum and Assertio and that also constitutes a prospectus of the Assertio. Each of Spectrum and Assertio may also file other relevant documents with the SEC regarding the proposed transaction. This document is not a substitute for the joint proxy statement/prospectus or registration statement or any other document that Spectrum or Assertio may file with the SEC. The definitive joint proxy statement/prospectus (if and when available) will be mailed to stockholders of Spectrum and Assertio. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE REGISTRATION STATEMENT, JOINT PROXY STATEMENT/PROSPECTUS AND ANY OTHER RELEVANT DOCUMENTS THAT MAY BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY IF AND WHEN THEY BECOME AVAILABLE BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Investors and security holders will be able to obtain free copies of the registration statement and joint proxy statement/prospectus (if and when available) and other documents containing important information about Spectrum, Assertio and the proposed transaction, once such documents are filed with the SEC through the website maintained by the SEC at <http://www.sec.gov>. Copies of the documents filed with the SEC by Assertio are also available free of charge on Assertio's internet website at www.assertiotx.com or by contacting Assertio Investor Relations Department through investor@assertiotx.com. Copies of the documents filed with the SEC by Spectrum will be available free of charge Spectrum's internet website at www.sppirx.com or by contacting Spectrum's Investor Relations Department ir@sppirx.com.

Participants in the Solicitation

Spectrum and Assertio and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from their respective stockholders in respect of the proposed transactions contemplated by the joint proxy statement/prospectus. Information regarding the persons who are, under the rules of the SEC, participants in the solicitation of the stockholders of Spectrum and Assertio in connection with the proposed transactions, including a description of their direct or indirect interests, by security holdings or otherwise, will be set forth in the joint proxy statement/prospectus when it is filed with the SEC. Information regarding Spectrum's directors and executive officers, including a description of their direct and indirect interests, by security holdings or otherwise, is available in its Annual Report on Form 10-K for the year ended December 31, 2022 and its Proxy Statement on Schedule 14A, dated April 27, 2022, which are filed with the SEC. Information regarding Assertio's directors and executive officers, including a description of their direct and indirect interests, by security holdings or otherwise, is available in Assertio's Annual Report on Form 10-K for the year ended December 31, 2022 and its Proxy Statement on Schedule 14A, dated April 3, 2023, which are filed with the SEC. Other information regarding the participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the joint proxy statement/prospectus and other relevant materials to be filed with the SEC regarding the proposed transaction when such materials become available. Investors should read the joint proxy statement/prospectus carefully when it becomes available before making any voting or investment decisions. You may obtain free copies of these documents from Spectrum or Assertio using the sources indicated above.



No Offer or Solicitation

This communication is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made, except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended.

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SPECTRUM PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Net sales	\$ 15,615	\$ —
Expenses:		
Cost of sales	1,063	—
Selling, general and administrative	13,998	9,870
Research and development	5,424	4,193
Total expenses	20,485	14,063
Loss from continuing operations before other income (expense) and income taxes	(4,870)	(14,063)
Other income (expense):		
Interest income	559	13
Interest expense	(943)	(2)
Other income (expense), net	248	(1,334)
Total other expense	(136)	(1,323)
Loss from continuing operations before income taxes	(5,006)	(15,386)
Provision for income taxes from continuing operations	—	(16)
Loss from continuing operations	(5,006)	(15,402)
Loss from discontinued operations, net of income taxes	(1)	(40)
Net loss	\$ (5,007)	\$ (15,442)
Basic and diluted loss per share:		
Loss from continuing operations	\$ (0.02)	\$ (0.09)
Loss from discontinued operations	\$ —	\$ —
Net loss, basic and diluted	\$ (0.02)	\$ (0.09)
Weighted average shares outstanding, basic and diluted	201,918,066	169,735,019

SPECTRUM PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and par value amounts)
(Unaudited)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 52,373	\$ 40,368
Marketable securities	3,763	34,728
Accounts receivable, net	32,755	12,996
Other receivables	883	617
Inventories	12,862	9,230
Prepaid expenses and other current assets	2,742	3,072
Total current assets	105,378	101,011
Property and equipment, net	534	476
Facility and equipment under lease	1,518	1,694
Other assets	245	157
Total assets	\$ 107,675	\$ 103,338
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 35,379	\$ 38,105
Accrued payroll and benefits	3,502	4,580
Total current liabilities	38,881	42,685
Loan payable, long-term	28,840	28,666
Other long-term liabilities	13,149	4,099
Total liabilities	80,870	75,450
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; 205,284,506 and 202,827,831 issued and outstanding at March 31, 2023 and December 31, 2022, respectively	205	203
Additional paid-in capital	1,153,818	1,149,926
Accumulated other comprehensive loss	(2,887)	(2,917)
Accumulated deficit	(1,124,331)	(1,119,324)
Total stockholders' equity	26,805	27,888
Total liabilities and stockholders' equity	\$ 107,675	\$ 103,338