UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 12, 2022

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.)

11500 South Eastern Avenue	Suite 220	Henderson	Nevada	89052
(Address of principal executive offices)				(Zip Code)

Registrant's telephone number, including area code: **(702) 835-6300**

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 May 12, 2022, Spectrum Pharmaceuticals, Inc. issued a press release, which, among other matters, sets forth our results of operations for the quarter ended March 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 No.	Description
99.1	Press Release dated May 12, 2022
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: May 12, 2022

By: /s/ Thomas J. Riga

Thomas J.Riga President and Chief Executive Officer

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

Resubmitted eflapegrastim BLA accepted for review by the FDA, PDUFA date September 9, 2022

Poziotinib NDA under review by FDA with PDUFA date of November 24, 2022 and will be discussed at ODAC meeting in September

Positive poziotinib results in treatment naïve patients with NSCLC harboring HER2 exon 20 insertion mutations

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

HENDERSON, Nevada - May 12, 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 March 31, 2022 and provided a corporate update.

"We anticipate FDA approvals later this year for poziotinib and eflapegrastim. In the first quarter, we initiated a confirmatory study and presented additional positive scientific data for poziotinib. The resubmitted BLA for eflapegrastim was also accepted for review by the FDA," said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. "We are proud of the progress we've made toward our core business objectives and we remain dedicated to making a meaningful difference in the lives of cancer patients."

Pipeline Updates

Eflapegrastim, a novel long-acting G-CSF

- The U.S. Food and Drug Administration (FDA) has accepted Spectrum's resubmitted Biologics License Application (BLA) for eflapegrastim with a Prescription Drug User Fee Act (PDUFA) date of September 9, 2022. The company is working with its partner, Hanmi Pharmaceutical, to support the FDA regulatory review process.

Poziotinib, a Pan ErbB inhibitor targeting HER2 exon20 mutations

- The New Drug Application (NDA) for poziotinib is under active review at the FDA with Fast Track designation. The NDA is based on the positive results of Cohort 2 in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 exon 20 insertion mutations. The agency has set a PDUFA date of November 24, 2022. There is currently no FDA approved therapy for patients with NSCLC harboring HER2 exon 20 insertion mutations.

- A study for poziotinib has been initiated 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 will be Progression Free Survival.

- 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 fall ODAC meeting is being held September 22-23, 2022. 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 appropriate recommendations to the FDA. As usual, the final decision regarding the approval of the product is made by the FDA solely, and the recommendations by the panel are non-binding.

- Data from Cohort 4 of the ZENITH20 study in patients with treatment-naïve NSCLC harboring HER2 exon 20 insertion mutations were presented in an oral session at the European Society for Medical Oncology Targeted Anticancer Therapies (ESMO TAT) Congress 2022. The results showed a confirmed objective response rate (ORR) of 41%, as evaluated centrally by an independent image review committee using RECIST 1.1 criteria. The evaluable patient population showed an ORR of 50%. The study met its primary endpoint as the observed lower bound of 30% exceeded the pre-specified lower bound of 20%. The safety profile was consistent with the tyrosine kinase inhibitor (TKI) class. Notably, on-target adverse events (AEs) were meaningfully reduced with BID dosing.

- The company presented a poster on the predictive ability of circulating tumor DNA (ctDNA) in poziotinib-treated patients with NSCLC harboring HER2 exon 20 insertion mutations at the American Association for Cancer Research (AACR) Annual Meeting. 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. Additional data from this study will be presented at the 2022 ASCO Annual Meeting in early June.

Corporate Updates

- Nora E. Brennan was named Chief Financial Officer effective May 25, 2022. Ms. Brennan has served on Spectrum's Board of Directors since December 2020 and as Chair of the Audit Committee. She will relinquish her board duties to assume her new senior leadership role. Most recently, Ms. Brennan served as Chief Financial Officer of Fore Biotherapeutics, a developer of cancer therapies driven by functional genomics. Prior to Fore, she served as Chief Financial Officer at TELA Bio, Inc. and as Senior Vice President of Treasury and Investor Relations at Integra Life Sciences Holdings Corporation.

- Hanmi Pharmaceutical completed a $20 million strategic equity investment in Spectrum in January 2022, which included revisions to the licensing and supply agreements for eflapegrastim and poziotinib.

- Two new members of the Board of Directors have been named. In March, Juhyun Lim was appointed to the Board. Ms. Lim currently serves as President, Global Strategy and Planning at Hanmi Science and Hanmi Pharmaceutical, where she leads the execution of corporate strategy and investment. In May, Spectrum named Brittany Bradrick to the Board and she will succeed Ms. Brennan as Chair of the Audit Committee. Ms. Bradrick currently serves as Chief Financial Officer of Neurelis, Inc. Ms. Bradrick is a seasoned executive with 25 years of experience in the life sciences sector including in the areas of mergers and acquisitions, investment banking, finance, strategy and corporate development.

- A strategic restructuring with a ~30% staff reduction and ~20-25% reduction in operating cash burn was initiated in January 2022 to focus the company's development activities on its late-stage assets, poziotinib and eflapegrastim. Development activities for the early-stage pipeline has been deprioritized.

Three-Month Period Ended March 31, 2022 (All numbers are from Continuing Operations and are approximate)

GAAP Results

Spectrum recorded a net loss of $15.4 million, or a $0.09 loss per basic and diluted share, in the three-month period ended March 31, 2022, compared to a net loss of $35.7 million, or a $0.25 loss per basic and diluted share, in the comparable period in 2021. Total research and development expenses were $4.2 million in the quarter, as compared to $19.4 million in the same period in 2021. Selling, general and administrative expenses were $9.9 million in the quarter, compared to $14.3 million in the same period in 2021.

Non-GAAP Results

Spectrum recorded a non-GAAP net loss of $9.6 million, or a $0.06 non-GAAP loss per basic and diluted share, in the three-month period ended March 31, 2022, compared to a non-GAAP net loss of $29.4 million, or a $0.20 non-GAAP loss per basic and diluted share, in the comparable period in 2021. Non-GAAP research and development expenses were $2.1 million, as compared to $18.0 million in the same period of 2021. Non-GAAP selling, general and administrative expenses were $7.5 million, as compared to $11.5 million in the same period in 2021.

Cash Position and Guidance

In January, the company received a $20 million strategic equity investment from Hanmi Pharmaceutical. Together with this strategic investment, Spectrum ended the quarter with cash, cash equivalents, and marketable securities of approximately $89.2 million. The additional cash, combined with the restructuring, is expected to extend the company’s cash runway into 2023.

Conference Call

Thursday, May 12, 2022 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 2863606
International: (973) 796-5077, Conference ID# 2863606

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 May 12, 2022 at 4:30 p.m. Eastern/1:30 p.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.

About the ZENITH20 Clinical Trial

The ZENITH20 study consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) in previously treated NSCLC patients with exon 20 mutations. Cohort 3 (EGFR) in first-line patients and Cohort 4 (HER2) in first-line NSCLC patients with exon 20 mutations have completed enrollment. 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 likelihood and timing of the FDA approval of poziotinib and eflapegrastin, 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 HER20 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. 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
Redefining Cancer Care

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

	Three Months Ended March 31,	
	2022	**2021**
Operating costs and expenses:		
Selling, general and administrative	$ 9,870	$ 14,315
Research and development	4,193	19,371
Total operating costs and expenses	14,063	33,686
Loss from continuing operations before other income (expense) and income taxes	(14,063)	(33,686)
Other income (expense):		
Interest income, net	11	84
Other expense, net	(1,334)	(2,081)
Total other expense	(1,323)	(1,997)
Loss from continuing operations before income taxes	(15,386)	(35,683)
Benefit for income taxes from continuing operations	(16)	7
Loss from continuing operations	$ (15,402)	$ (35,676)
Loss from discontinued operations, net of income taxes	(40)	(21)
Net loss	$ (15,442)	$ (35,697)
Basic and diluted loss per share:		
Loss from continuing operations	$ (0.09)	$ (0.25)
Loss from discontinued operations	$ 0.00	$ 0.00
Net loss per share, basic and diluted	$ (0.09)	$ (0.25)
Weighted average shares outstanding, basic and diluted	169,735,019	145,371,657

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

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

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 78,679	$ 88,539
Marketable securities	10,535	12,108
Other receivables	639	1,028
Prepaid expenses and other current assets	3,328	2,277
Total current assets	93,181	103,952
Property and equipment, net	418	455
Facility and equipment under lease	2,107	2,505
Other assets	4,348	4,636
Total assets	$ 100,054	$ 111,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 32,575	$ 41,258
Accrued payroll and benefits	6,633	11,971
Total current liabilities	39,208	53,229
Other long-term liabilities	5,590	10,766
Total liabilities	44,798	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; 178,827,485 and 164,502,013 issued and outstanding at March 31, 2022 and December 31, 2021, respectively	179	165
Additional paid-in capital	1,117,350	1,094,353
Accumulated other comprehensive loss	(2,908)	(3,042)
Accumulated deficit	(1,059,365)	(1,043,923)
Total stockholders' equity	55,256	47,553
Total liabilities and stockholders' equity	$ 100,054	$ 111,548

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

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 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
Redefining Cancer Care

SPECTRUM PHARMACEUTICALS, INC.
Reconciliation of Non-GAAP Adjustments for Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)

		CONTINUING OPERATIONS ONLY Three Months Ended March 31,	
		2022	2021
(1)	**GAAP selling, general and administrative**	**$ 9,870**	**$ 14,315**
	Non-GAAP adjustments to SG&A:		
	Stock-based compensation expense	(1,905)	(2,799)
	Depreciation expense	(71)	(63)
	Lease expense	39	23
	Severance expense	(408)	—
	Non-GAAP selling, general and administrative	**$ 7,525**	**$ 11,476**
(2)	**GAAP research and development**	**$ 4,193**	**$ 19,371**
	Non-GAAP adjustments to R&D:		
	Stock-based compensation expense	(1,090)	(1,414)
	Depreciation expense	(2)	(2)
	Severance expense	(1,040)	—
	Non-GAAP research and development	**$ 2,061**	**$ 17,955**
(3)	**GAAP net loss from continuing operations**	**$ (15,402)**	**$ (35,676)**
	Non-GAAP adjustments to net loss from continuing operations:		
	Adjustments to SG&A and R&D, as noted above	4,477	4,255
	Adjustments to other expense	1,329	2,072
	Adjustments to benefit for income taxes	16	(7)
	Non-GAAP net loss from continuing operations	**$ (9,580)**	**$ (29,356)**
(4)	**GAAP net loss from continuing operations - per basic and diluted share**	**$ (0.09)**	**$ (0.25)**
	Non-GAAP net loss from continuing operations - per basic and diluted share	**$ (0.06)**	**$ (0.20)**
	Weighted average shares outstanding, basic and diluted	169,735,019	145,371,657

(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); (iii) reversal of the mark-to-market adjustment (non-cash) on our equity securities holdings; and (iv) reversal of realized gain recorded on the sales of our equity 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.