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): August 12, 2021

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 240	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 August 12, 2021, Spectrum Pharmaceuticals, Inc. issued a press release, which, among other matters, sets forth our results of operations for the quarter ended June 30, 2021. 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 August 12, 2021
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: August 12, 2021

By: /s/ Kurt A. Gustafson

Kurt A. Gustafson
Executive Vice President and Chief Financial Officer

Spectrum Pharmaceuticals Reports Second Quarter 2021 Financial Results and Corporate Update

Submission of poziotinib NDA on track for later in 2021 under a Fast Track designation

The company is requesting a meeting with the FDA to clarify the remediation timelines regarding the Complete Response Letter (CRL) for ROLONTIS® (eflapegrastim)

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

HENDERSON, Nevada – August 12, 2021 - Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced financial results for the three-month period ended June 30, 2021 and provided a corporate update.

“Momentum continues to build with poziotinib and the submission of the NDA later this year is our top corporate priority,” said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. “We are also seeking clarification on the recent CRL for ROLONTIS and are planning to have a Type A meeting with the FDA as soon as possible.”

Pipeline Updates

Poziotinib, an irreversible tyrosine kinase inhibitor targeting EGFR and HER2 mutations

- Preparation is continuing for the poziotinib new drug application (NDA) seeking an indication for the use of poziotinib in patients with previously treated locally advanced or metastatic NSCLC with HER2 exon 20 insertion mutations. Submission of the NDA, based on the positive results of Cohort 2 from the ZENITH20 clinical trial, is planned for later this year.
- Clinically meaningful data for poziotinib was presented in June at the American Society of Clinical Oncology (ASCO) Annual Meeting that showed its CNS activity in patients with NSCLC with EGFR or HER2 exon 20 mutations. These data were based on Cohorts 1-3 and included three patients achieving intracranial complete responses.
- Enrollment for Cohort 4 of first-line patients with NSCLC HER2 exon 20 mutations is continuing in the ZENITH20 clinical trial. Poziotinib is currently being administered at a dose of 8mg BID in first line treatment.
- Patient enrollment is also continuing in Cohort 5 which is now dosing exclusively at 8mg BID.

ROLONTIS (eflapegrastim), a novel long-acting G-CSF

- Received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) in connection with the biologics license application (BLA) for ROLONTIS. The CRL cited deficiencies related to manufacturing and a reinspection will be necessary. The company is seeking further clarification from the FDA and plans to meet with the agency as soon as possible.

Three-Month Period Ended June 30, 2021 (All numbers are from Continuing Operations and are approximate)

GAAP Results

Spectrum recorded a net loss of $49.9 million, or $0.32 loss per basic and diluted share, in the three-month period ended June 30, 2021, compared to a net loss of $32.2 million, or $0.29 loss per basic and diluted share, in the comparable period in 2020. Total research and development expenses were $29.1 million in the quarter, as compared to $21.7 million in the same period in 2020. Selling, general and administrative expenses were $15.0 million in the quarter, compared to $14.7 million in the same period in 2020.

The company ended the quarter with cash, cash equivalents, and marketable securities of $158.8 million.

Non-GAAP Results

Spectrum recorded a non-GAAP net loss of $39.3 million, or $0.25 loss per basic and diluted share, in the three-month period ended June 30, 2021, compared to a non-GAAP net loss of $31.8 million, or $0.28 loss per basic and diluted share, in the comparable period in 2020. Non-GAAP research and development expenses were $27.8 million, as compared to $20.6 million in the same period of 2020. Non-GAAP selling, general and administrative expenses were $11.9 million, as compared to $11.8 million in the same period in 2020.

Conference Call

Thursday, August 12, 2021 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910

International: (973) 796-5077

Conference ID#: 2398834

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 12, 2021 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 ZENITH20

The ZENITH20 study consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) have completed enrollment of previously treated NSCLC patients with exon 20 mutations. Cohorts 3

(EGFR) and 4 (HER2) are currently enrolling first-line NSCLC patients with exon 20 mutations. 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, the timing of an NDA submission for poziotinib based on the positive results of Cohort 2 from the ZENITH20 clinical trial, the ability for poziotinib to treat patients with CNS disease, the timing and outcome of the company’s meeting with the FDA to gain clarification on the recent CRL for ROLONTIS, the future potential of Spectrum’s existing drug pipeline, the progression of the poziotinib and ROLONTIS development programs 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 possibility that the different methodologies, assumptions and applications the company utilizes to assess particular safety or efficacy parameters may yield different statistical results, and even if the company believes the data collected from the clinical trials of its product candidates, including poziotinib, are positive, these data may not be sufficient to support approval by the FDA; the possibility that success in early clinical trials, especially if based on a small patient sample, might not result in success in later clinical trials, and other unforeseen events during clinical trials which could cause delays or other adverse consequences; other uncertainties inherent in new product development; 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; the company’s ability to remediate the deficiencies cited in the CRL for ROLONTIS in a timely manner, if at all; 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, 2020, 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues	$ —	$ —	$ —	$ —
Operating costs and expenses:				
Selling, general and administrative	14,957	14,744	29,272	29,538
Research and development	29,114	21,746	48,485	37,739
Total operating costs and expenses	44,071	36,490	77,757	67,277
Loss from continuing operations before other income (expense) and income taxes	(44,071)	(36,490)	(77,757)	(67,277)
Other income (expense):				
Interest income, net	26	325	110	1,029
Other income (expense), net	(5,876)	3,945	(7,957)	(6,589)
Total other income (expense)	(5,850)	4,270	(7,847)	(5,560)
Loss from continuing operations before income taxes	(49,921)	(32,220)	(85,604)	(72,837)
Provision for income taxes from continuing operations	(16)	(9)	(9)	(9)
Loss from continuing operations	$ (49,937)	$ (32,229)	$ (85,613)	$ (72,846)
Income (loss) from discontinued operations, net of income taxes	(195)	144	(216)	189
Net loss	$ (50,132)	$ (32,085)	$ (85,829)	$ (72,657)
Basic and diluted loss per share:				
Loss from continuing operations	$ (0.32)	$ (0.29)	$ (0.57)	$ (0.65)
Income (loss) from discontinued operations	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Net loss per share, basic and diluted	$ (0.32)	$ (0.28)	$ (0.57)	$ (0.65)
Weighted average shares outstanding, basic and diluted	155,243,402	112,615,744	150,334,548	112,199,229

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 114,573	$ 46,009
Marketable securities	44,244	134,016
Accounts receivable, net	—	67
Other receivables	3,532	2,394
Prepaid expenses and other current assets	3,357	4,161
Total current assets	165,706	186,647
Property and equipment, net	3,580	3,577
Facility and equipment under lease	1,432	2,247
Other assets	4,327	4,327
Total assets	$ 175,045	$ 196,798
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 50,295	$ 43,771
Accrued payroll and benefits	6,404	9,375
Total current liabilities	56,699	53,146
Other long-term liabilities	9,758	9,409
Total liabilities	66,457	62,555
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; 164,106,060 and 146,083,110 issued and outstanding at June 30, 2021 and December 31, 2020, respectively	164	146
Additional paid-in capital	1,082,875	1,021,221
Accumulated other comprehensive loss	(3,327)	(1,829)
Accumulated deficit	(971,124)	(885,295)
Total stockholders' equity	108,588	134,243
Total liabilities and stockholders' equity	$ 175,045	$ 196,798

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, 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 June 30,		CONTINUING OPERATIONS ONLY Six Months Ended June 30,	
		2021	2020	2021	2020
(1)	**GAAP selling, general and administrative**	**$ 14,957**	**$ 14,744**	**$ 29,272**	**$ 29,538**
	Non-GAAP adjustments to SG&A:				
	Stock-based compensation expense	(3,005)	(2,877)	(5,803)	(6,755)
	Depreciation expense	(71)	(112)	(134)	(218)
	Lease expense	26	5	49	14
	Non-GAAP selling, general and administrative	**$ 11,907**	**$ 11,760**	**$ 23,384**	**$ 22,579**
(2)	**GAAP research and development**	**$ 29,114**	**$ 21,746**	**$ 48,485**	**$ 37,739**
	Non-GAAP adjustments to R&D:				
	Stock-based compensation expense	(1,355)	(1,110)	(2,769)	(2,508)
	Depreciation expense	(2)	(31)	(4)	(65)
	Non-GAAP research and development	**$ 27,757**	**$ 20,605**	**$ 45,712**	**$ 35,166**
(3)	**GAAP net loss from continuing operations**	**$ (49,937)**	**$ (32,229)**	**$ (85,613)**	**$ (72,846)**
	Non-GAAP adjustments to net loss from continuing operations:				
	Adjustments to SG&A and R&D, as noted above	4,407	4,125	8,661	9,532
	Adjustments to other income (expense)	6,197	(3,667)	8,569	6,582
	Adjustments to provision for income taxes	16	9	9	9
	Non-GAAP net loss from continuing operations	**$ (39,317)**	**$ (31,762)**	**$ (68,374)**	**$ (56,723)**
(4)	**GAAP net loss from continuing operations - per basic and diluted share**	**$ (0.32)**	**$ (0.29)**	**$ (0.57)**	**$ (0.65)**
	Non-GAAP net loss from continuing operations - per basic and diluted share	**$ (0.25)**	**$ (0.28)**	**$ (0.45)**	**$ (0.51)**
	Weighted average shares outstanding, basic and diluted	155,243,402	112,615,744	150,334,548	112,199,229

(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. 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. 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.