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): March 30, 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))

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. ☐

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

Item 2.02 Results of Operations and Financial Condition.

On March 30, 2021, Spectrum Pharmaceuticals, Inc. issued a press release, which, among other matters, sets forth our results of operations for the quarter ended December 31, 2020. 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 March 30, 2021

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: March 30, 2021

By: /s/ Kurt A. Gustafson
Kurt A. Gustafson
Executive Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated March 30, 2021

Spectrum Pharmaceuticals Reports Fourth Quarter 2020 and Full Year 2020 Financial Results and Pipeline Update

Poziotinib receives Fast Track Designation from FDA

Preliminary safety and efficacy data for poziotinib twice daily dosing (BID) demonstrates improved anti-tumor activity and reduced toxicity relative to once daily dosing

FDA has scheduled the pre-approval inspection at the ROLONTIS® (eflapegrastim) manufacturing facility for May 2021

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

HENDERSON, Nevada – March 30, 2021 - 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, 2020.

“The Fast Track designation for poziotinib is a significant achievement towards an expedited review,” said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. “In addition, we are delighted that the FDA has scheduled the pre-approval inspection at the ROLONTIS manufacturing facility for May 2021. The company has made tremendous progress advancing our development programs and conducting our clinical trials, despite the challenges of the global pandemic. I am proud of our employees who demonstrated resiliency and creativity during these unprecedented times.”

Pipeline Updates

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

- Poziotinib received Fast Track designation from the FDA for the treatment of non-small cell lung cancer (NSCLC) in previously treated patients with HER2 exon 20 insertion mutations. Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious and life-threatening conditions and fill unmet medical needs.
- Spectrum is preparing a new drug application (NDA) for poziotinib in the treatment of patients with previously treated locally advanced or metastatic NSCLC with HER2 exon 20 insertion mutations after a successful pre-NDA meeting with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2020. Submission of the NDA based on the positive results of Cohort 2 from the ZENITH20 clinical trial is planned for later this year.
- Preliminary safety and efficacy data for poziotinib from Cohort 5 of the ZENITH20 clinical trial demonstrated improved tolerability with BID dosing, reduced dose interruption compared to once daily (QD) dosing, and a reduction in treatment emergent Grade 3 or higher adverse events. The preliminary data also demonstrated improved anti-tumor activity with 8mg BID dosing. These results were presented at the European Society for Medical Oncology Targeted Anticancer Therapies (ESMO TAT) Virtual Congress 2021 in early March. Spectrum will be presenting further data on BID dosing at the upcoming AACR Annual Meeting 2021.

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

- The FDA's pre-approval inspection of the ROLONTIS manufacturing facility has been scheduled for May 2021. In October 2020, the FDA deferred its action on the Biologics License Application (BLA) for ROLONTIS due to an inability to inspect the drug substance manufacturing facility, citing travel restrictions related to the COVID-19 pandemic.

IGN002, interferon/CD20 monoclonal antibody fusion protein

- Anti-CD20-IFNα, an antibody-interferon fusion molecule directed against CD20 has two sites open for enrollment in a Phase 1 study for treating relapsed or refractory non-Hodgkin's lymphoma patients, including diffuse large B-cell lymphoma.

Three-Month Period Ended December 31, 2020 (All numbers are from Continuing Operations)

GAAP Results

Spectrum recorded net loss of $49.9 million, or $0.36 per basic and diluted share, in the three-month period ended December 31, 2020, compared to net loss of $40.2 million, or $0.36 per basic and diluted share, in the comparable period in 2019. Total research and development expenses were $47.2 million in the quarter, as compared to $23.3 million in the same period in 2019. Selling, general and administrative expenses were $15.7 million in the quarter, compared to $15.1 million in the same period in 2019.

Non-GAAP Results

Spectrum recorded non-GAAP net loss of $28.9 million, or $0.20 per basic and diluted share, in the three-month period ended December 31, 2020, compared to non-GAAP net loss of $33.4 million, or $0.30 per basic and diluted share, in the comparable period in 2019. Non-GAAP research and development expenses were $17.1 million, as compared to $22.4 million in the same period of 2019. Non-GAAP selling, general and administrative expenses were $12.3 million, as compared to $11.6 million in the same period in 2019.

Twelve-Month Period Ended December 31, 2020 (All numbers are from Continuing Operations)

GAAP Results

Spectrum recorded net loss of $171.3 million, or $1.38 per basic and diluted share, in the twelve-month period ended December 31, 2020, compared to net loss of $135.4 million, or $1.22 per basic and diluted share, in the comparable period in 2019. Total research and development expenses were $109.4 million for the year, as compared to $79.3 million in the same period in 2019. Selling, general and administrative expenses were $60.4 million for the year, compared to $61.4 million in the same period in 2019.

Non-GAAP Results

Spectrum recorded non-GAAP net loss of $120.9 million, or $0.97 per basic and diluted share, in the twelve-month period ended December 31, 2020, compared to non-GAAP net loss of $111.9 million, or $1.01 per basic and diluted share, in the comparable period in 2019. Non-GAAP research and development expenses were $75.6 million, as compared to $72.0 million in the same period of 2019. Non-GAAP selling, general and administrative expenses were $47.2 million, as compared to $45.5 million in the same period in 2019.

Cash Position and Guidance

Spectrum reported cash, cash equivalents, and marketable securities of approximately $180.0 million as of December 31, 2020, compared to $224 million at December 31, 2019.

Conference Call

Tuesday, March 30, 2021 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 3577235

International: (973) 796-5077, Conference ID# 3577235

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: http://investor.sppirx.com/events-and-presentations on March 30, 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. Cohort 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, given its Fast Track designation and the significance of such designation, the timing of an NDA submission for poziotinib based on the positive results of Cohort 2 from the ZENITH20 clinical trial, whether the final safety and efficacy data for poziotinib from Cohort 5 of the ZENITH20 clinical trial will continue to demonstrate similar results to the preliminary data, the content of the company’s presentation at the AACR Annual Meeting 2021, the company’s ability to advance development of its late-stage

pipeline assets, the ability of such assets to meet currently unaddressed medical needs, the future potential of Spectrum's existing drug pipeline, the progression of the poziotinib, ROLONTIS and Anti-CD20-IFNα 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 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, the possibility that the FDA postpones its pre-approval inspection of the ROLONTIS manufacturing facility past May 2021 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 per share amounts)
(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Revenues	$ —	$ —	$ —	$ —
Operating costs and expenses:				
Selling, general and administrative	15,703	15,065	60,357	61,373
Research and development	47,185	23,290	109,377	79,325
Total operating costs and expenses	62,888	38,355	169,734	140,698
Loss from continuing operations before other income (expense) and income taxes	(62,888)	(38,355)	(169,734)	(140,698)
Other income (expense):				
Interest income (expense), net	125	920	1,342	4,996
Other (expense) income, net	12,780	(3,345)	(2,940)	(8,892)
Total other (expense) income	12,905	(2,425)	(1,598)	(3,896)
Loss from continuing operations before income taxes	(49,983)	(40,780)	(171,332)	(144,594)
Benefit for income taxes from continuing operations	75	579	60	9,208
Loss from continuing operations	$ (49,908)	$ (40,201)	$ (171,272)	$ (135,386)
Income from discontinued operations, net of income taxes	10,149	1,150	10,404	22,697
Net loss	$ (39,759)	$ (39,051)	$ (160,868)	$ (112,689)
Basic and diluted loss per share:				
Loss per common share from continuing operations	$ (0.36)	$ (0.36)	$ (1.38)	$ (1.22)
Income per common share from discontinued operations	$ 0.07	$ 0.01	$ 0.08	$ 0.21
Net loss per common share, basic and diluted	$ (0.29)	$ (0.35)	$ (1.29)	$ (1.02)
Weighted average shares outstanding, basic and diluted	141,432,302	111,355,254	124,386,545	110,585,768

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

	December 31,	
	2020	**2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,009	$ 64,418
Marketable securities	134,016	159,455
Accounts receivable, net	67	441
Other receivables	2,394	9,558
Prepaid expenses and other current assets	4,161	10,148
Total current assets	186,647	244,020
Property and equipment, net	3,577	11,607
Facility and equipment under lease	2,247	3,806
Other assets	4,327	4,000
Total assets	$ 196,798	$ 263,433
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 43,771	$ 54,284
Accrued payroll and benefits	9,375	7,686
Total current liabilities	53,146	61,970
Other long-term liabilities	9,409	11,070
Total liabilities	62,555	73,040
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; 146,083,110 and 113,299,612 issued and outstanding at December 31, 2020 and 2019, respectively	146	113
Additional paid-in capital	1,021,221	918,205
Accumulated other comprehensive loss	(1,829)	(3,498)
Accumulated deficit	(885,295)	(724,427)
Total stockholders' equity	134,243	190,393
Total liabilities and stockholders' equity	$ 196,798	$ 263,433

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Non-GAAP Financial Measures

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 from continuing operations and non-GAAP net loss per share from continuing operations. 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 from continuing operations in its evaluation of the company's core 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, expect per share amounts)

	CONTINUING OPERATIONS ONLY Three Months Ended December 31,		CONTINUING OPERATIONS ONLY Twelve Months Ended December 31,	
	2020	2019	2020	2019
(1) GAAP selling, general and administrative	**$ 15,703**	**$ 15,065**	**$ 60,357**	**$ 61,373**
Non-GAAP adjustments to SG&A:				
Stock-based compensation expense	(3,354)	(3,393)	(13,127)	(13,822)
Depreciation expense	(55)	(96)	(130)	(276)
Lease expense	23	(25)	69	(282)
Severance expense	—	—	—	(1,515)
Non-GAAP selling, general and administrative	**$ 12,317**	**$ 11,551**	**$ 47,169**	**$ 45,478**
(2) GAAP research and development	**$ 47,185**	**$ 23,290**	**$ 109,377**	**$ 79,325**
Non-GAAP adjustments to R&D:				
Stock-based compensation expense	(1,094)	(882)	(4,692)	(4,254)
Depreciation expense	(33)	(36)	(131)	(81)
Impairment of second source manufacturer	(28,197)	—	(28,197)	—
Other R&D milestone payments	(750)	—	(750)	(2,751)
Severance expense	—	—	—	(260)
Non-GAAP research and development	**$ 17,111**	**$ 22,372**	**$ 75,607**	**$ 71,979**
(3) GAAP net loss from continuing operations	**$ (49,908)**	**$ (40,201)**	**$ (171,272)**	**$ (135,386)**
Non-GAAP adjustments to net loss from continuing operations:				
Adjustments to SG&A and R&D as noted above	33,460	4,432	46,958	23,241
Adjustments to other (income) expense	(12,379)	2,969	3,521	9,418
Adjustments to benefit for income taxes	(75)	(579)	(60)	(9,208)
Non-GAAP net loss from continuing operations	**$ (28,902)**	**$ (33,379)**	**$ (120,853)**	**$ (111,935)**
(4) GAAP net loss from continuing operations - per basic and diluted share	$ (0.35)	$ (0.36)	$ (1.38)	$ (1.22)
Non-GAAP net loss from continuing operations - per basic and diluted share	$ (0.20)	$ (0.30)	$ (0.97)	$ (1.01)
Weighted average shares outstanding, basic and diluted	141,432,302	111,355,254	124,386,545	110,585,768

(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 non-recurring severance expenses, other R&D milestone achievement payments, and impairment of second source manufacturer that we record to this expense caption. 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) and (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 from continuing operations - per basic and diluted share: 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.