SPECTRUM PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

Filed 03/08/17 for the Period Ending 03/08/17

Address	11500 S. EASTERN AVE., SUITE 240 HENDERSON, NV 89052
Telephone	702-835-6300
CIK	0000831547
Symbol	SPPI
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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 8, 2017

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 S. Eastern Ave., Ste. 240, Henderson, NV	**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))

Item 2.02 Results of Operations and Financial Condition.

On March 8, 2017 , Spectrum Pharmaceuticals, Inc. issued a press release, which, among other matters, sets forth our results of operations for the quarter ended December 31, 2016 . 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 8, 2017

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 8, 2017

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 8, 2017.

COMPANY CONTACTS
Shiv Kapoor
Vice President, Strategic Planning & Investor Relations
702-835-6300
InvestorRelations@sppirx.com

Spectrum Pharmaceuticals Reports Fourth Quarter 2016 and Full Year 2016 Financial Results and Pipeline Update

- ROLONTIS™ (eflapegrastim) pivotal program is on track for Spectrum to file BLA next year.
- Poziotinib study in non-small cell lung cancer patients with EGFR Exon 20 insertion mutations, being run in partnership with The University of Texas MD Anderson Cancer Center, is expected to yield results before year end.
- Qapzola™ (apaziquone) receives a new Special Protocol Assessment (SPA) from the FDA that significantly reduces the number of patients required for NDA filing.
- Q4 revenues were $35.2 million , including $32.2 million in product sales.

HENDERSON, Nevada - March 8, 2017 - Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations with a primary focus in Hematology and Oncology, announced today financial results for the three-month period and year ended December 31, 2016 .

"We made significant advancements in our pipeline throughout 2016 and I believe we are well positioned for transformational growth," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "ROLONTIS is our highest priority drug and we are pleased that we remain on track for a BLA filing next year. Poziotinib, which is being developed for breast cancer has recently emerged as a potential treatment for a high unmet medical need in lung cancer. Data presented in December suggests that poziotinib has potential in lung cancer patients with certain genetic mutations that have poor prognosis and limited treatment options. An investigator sponsored trial of poziotinib in such patients with EGFR Exon 20 insertion mutations at MD Anderson Cancer Center could yield key results before year end. We have also obtained a new SPA for our late-stage bladder cancer drug Qapzola that significantly reduces the number of patients required for an NDA filing. Spectrum is in a unique position of having multiple opportunities to create value while benefiting patients."

Pipeline Update:

- **ROLONTIS (eflapegrastim), a novel long-acting GCSF:** A pivotal Phase 3 study was initiated under a SPA from the FDA in 2016 to evaluate ROLONTIS in the management of chemotherapy-induced neutropenia in patients with breast cancer. The Company is actively enrolling breast cancer patients in the current trial, expects to initiate an additional smaller Phase 3 trial, and continues to expect to file a BLA next year.

- **Poziotinib, a potential best-in-class, novel, pan-HER inhibitor** : In collaboration with The University of Texas MD Anderson Cancer Center, an investigator sponsored trial is being initiated in non-small cell lung cancer patients with EGFR Exon 20 insertion mutations. The study is expected to yield results before year end. Spectrum is also conducting a Phase 2 breast cancer trial in the U.S., based on promising Phase 1 efficacy data in breast cancer patients who had failed multiple other HER2-directed therapies. Further, multiple Phase 2 studies are being conducted in South Korea by Hanmi Pharmaceuticals and National OncoVenture to study additional cancer indications.

- **Qapzola, a potent tumor-activated drug being investigated for non-muscle invasive bladder cancer:** The Company received a new SPA from the FDA on a proposed Phase 3 study design. The Phase 3 study has been specifically designed to build on learnings from the previous studies, as well as recommendations from the FDA. Compared to the previous study, this study will use twice the dosage of Qapzola (8 mg), will evaluate approximately 70% fewer patients (n = 425), and will evaluate time-to-recurrence as the primary endpoint compared to recurrence at 2 years.

Three-Month Period Ended December 31, 2016 (All numbers are approximate)

GAAP Results

Total product sales were $32.2 million in the fourth quarter of 2016. Product sales in the fourth quarter included: FUSILEV ® (levoleucovorin) net sales of $4.3 million, FOLOTYN ® (pralatrexate injection) net sales of $10.7 million, ZEVALIN ® (ibritumomab tiuxetan) net sales of $2.5 million, MARQIBO ® (vinCRIStine sulfate LIPOSOME injection) net sales of $2.3 million, BELEODAQ ® (belinostat for injection) net sales of $3.0 million, and EVOMELA ® (melphalan) for injection net sales of $9.4 million.

Spectrum recorded net loss of $17.4 million , or $0.22 per basic and diluted share in the three-month period ended December 31, 2016 , compared to net loss of $4.2 million , or $0.06 per basic and diluted share in the comparable period in 2015. Total research and development expenses were $15.9 million in the quarter, as compared to $15.4 million in the same period in 2015. Selling, general and administrative expenses were $18.3 million in the quarter, compared to $21.2 million in the same period in 2015.

During the quarter the Company purchased $10.0 million face value of its convertible debentures for $9.0 million. The Company ended the quarter with cash and cash equivalents of $158 million.

Non-GAAP Results

Spectrum recorded non-GAAP net loss of $8.1 million , or $0.10 per basic and diluted share in the three-month period ended December 31, 2016 , compared to non-GAAP net loss of $4.6 million , or $0.07 per basic and diluted share in the comparable period in 2015. Non-GAAP research and development expenses were $15.4 million , as compared to $14.8 million in the same period of 2015. Non-GAAP selling, general and administrative expenses were $15.6 million , as compared to $18.1 million in the same period in 2015.

Twelve-Month Period Ended December 31, 2016 (All numbers are approximate)

GAAP Results

Total product sales were $128.6 million for the twelve months ended December 31, 2016. Total product sales decreased 6% from $136.9 million in the same period of 2015.

Product sales in 2016 included: FUSILEV ® (levoleucovorin) net sales of $34.8 million , FOLOTYN ® (pralatrexate injection) net sales of $46.2 million , ZEVALIN ® (ibritumomab tiuxetan) net sales of $10.7 million , MARQIBO ® (vinCRIStine sulfate LIPOSOME injection) net sales of $7.2 million , BELEODAQ ® (belinostat) for injection net sales of $13.4 million , and EVOMELA ® (melphalan) for injection net sales of $16.2 million .

Spectrum recorded net loss of $68.5 million , or $0.94 per basic and diluted share in the twelve-month period ended December 31, 2016, compared to net loss of $50.8 million , or $0.78 per basic and diluted share in the comparable period in 2015. Total research and development expenses were $58.9 million for the year, as compared to $50.8 million in the same period in 2015. Selling, general and administrative expenses were $87.3 million for the year, compared to $86.5 million in the same period in 2015.

Non-GAAP Results

Spectrum recorded non-GAAP net loss of $16.8 million , or $0.23 per basic and diluted share in the twelve-month period ended December 31, 2016, compared to non-GAAP net loss of $17.6 million , or $0.27 per basic and diluted

share in the comparable period in 2015. Non-GAAP research and development expenses were $54.1 million , as compared to $45.7 million in the same period of 2015. Non-GAAP selling, general and administrative expenses were $64.1 million , as compared to $77.9 million in the same period in 2015.

Conference Call

Wednesday, March 8, 2017 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 67373281

International: (973) 796-5077, Conference ID# 67373281

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: www.sppirx.com on March 8, 2017 at 4:30 p.m. Eastern/1:30 p.m. Pacific.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing, and commercializing drug products, with a primary focus in Hematology and Oncology. Spectrum currently markets six hematology/oncology drugs, and has an advanced stage pipeline that has the potential to transform the Company. Spectrum's strong track record for in-licensing and acquiring differentiated drugs, and expertise in clinical development have generated a robust, diversified, and growing pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. More information on Spectrum is available at www.sppirx.com .

Forward-looking statement - This press release may contain forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially. These statements are based on management's current beliefs and expectations. These statements include, but are not limited to, statements that relate to Spectrum's business and its future, including certain company milestones, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, the timing and results of FDA decisions, and any statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact. Risks that could cause actual results to differ include the possibility that Spectrum's existing and new drug candidates may not prove safe or effective, the possibility that our existing and new applications to the FDA and other regulatory agencies may not receive approval in a timely manner or at all, the possibility that our existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our dependence on third parties for clinical trials, manufacturing, distribution and quality control and other risks that are described in further detail in the Company's reports filed with the Securities and Exchange Commission. The Company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.

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,	
	2016	**2015**	**2016**	**2015**
Revenues:				
Product sales, net	$ 32,195	$ 34,837	$ 128,596	$ 136,851
License fees and service revenue	3,041	15,494	17,848	25,705
Total revenues	$ 35,236	$ 50,331	$ 146,444	$ 162,556
Operating costs and expenses:				
Cost of product sales (excludes amortization and impairment charges of intangible assets)	9,238	6,181	27,953	27,689
Cost of service revenue	2,174	—	7,890	—
Selling, general and administrative	18,300	21,218	87,347	86,514
Research and development	15,899	15,433	58,936	50,766
Amortization and impairment charges of intangible assets	6,894	10,462	25,946	38,319
Total operating costs and expenses	52,505	53,294	208,072	203,288
Loss from operations	(17,269)	(2,963)	(61,628)	(40,732)
Other (expense) income:				
Interest expense, net	(2,348)	(2,314)	(9,435)	(9,074)
Change in fair value of contingent consideration related to acquisitions	600	1,241	(649)	676
Other (expense) income, net	(102)	251	887	(1,249)
Total other expenses	(1,850)	(822)	(9,197)	(9,647)
Loss before income taxes	(19,119)	(3,785)	(70,825)	(50,379)
Benefit (provision) for income taxes	1,677	(369)	2,313	(406)
Net loss	$ (17,442)	$ (4,154)	$ (68,512)	$ (50,785)
Net loss per share:				
Basic and diluted	$ (0.22)	$ (0.06)	$ (0.94)	$ (0.78)
Weighted average shares outstanding:				
Basic and diluted	78,401,381	65,370,371	72,824,070	64,882,417

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

	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 158,222	$ 139,741
Marketable securities	247	245
Accounts receivable, net of allowance for doubtful accounts of $88 and $120, respectively	39,782	30,384
Other receivables	5,754	12,572
Inventories	8,715	4,176
Prepaid expenses and other assets	3,930	3,507
Total current assets	216,650	190,625
Property and equipment, net of accumulated depreciation	449	918
Intangible assets, net of accumulated amortization and impairment charges	164,234	190,335
Goodwill	17,886	17,960
Other assets	29,549	19,211
Total assets	$ 428,768	$ 419,049
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 52,483	$ 56,539
Accrued payroll and benefits	8,981	8,188
Deferred revenue	3,188	6,130
Drug development liability	861	259
Acquisition-related contingent obligations	—	5,227
Total current liabilities	65,513	76,343
Drug development liability, less current portion	12,269	14,427
Deferred revenue, less current portion	323	383
Acquisition-related contingent obligations, less current portion	1,315	1,439
Deferred tax liability	6,675	6,779
Other long-term liabilities	9,604	7,444
Convertible senior notes	97,043	99,377
Total liabilities	192,742	206,192
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized	—	—
Series B Junior Participating Preferred Stock, $0.001 par value; 1,500,000 shares authorized; no shares issued and outstanding	—	—
Series E Convertible Voting Preferred Stock, $0.001 par value and $10,000 stated value; 2,000 shares authorized; 0 and 20 shares issued and outstanding at December 31, 2016 and 2015, respectively (the presented 2015 balance relates to 20 shares of preferred stock which were converted into 40,000 shares of common stock in 2016)	—	123
Common stock, $0.001 par value; 175,000,000 shares authorized; 80,466,735 and 68,228,935 issued and outstanding at December 31, 2016 and 2015, respectively	80	68
Additional paid-in capital	640,166	552,108
Accumulated other comprehensive loss	(1,579)	(5,319)
Accumulated deficit	(402,641)	(334,123)
Total stockholders' equity	236,026	212,857
Total liabilities and stockholders' equity	$ 428,768	$ 419,049

Non-GAAP Financial Measures

In this press release, Spectrum reports certain historical "non-GAAP financial measures," as defined in Regulation G of the Securities Exchange Act of 1934. Non-GAAP financial measures differ from financial statements reported in conformity to U.S. generally accepted accounting principles ("GAAP"). In accordance with Regulation G, we reconciled each non-GAAP financial measure to its most directly comparable GAAP measure. Management uses non-GAAP financial measures to assess our company's performance and allocate company resources, and believes that providing these non-GAAP financial measures allows investors to view the Company's financial results in the way that management views the financial results. We believe non-GAAP disclosures also provide investors with information used generally in our industry for evaluating operating results. Investors should not place undue reliance on non-GAAP financial measures, nor should investors consider non-GAAP financial measures as more meaningful than, or as substitutes or replacements for, 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.

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 reported under 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. The non-GAAP financial measures presented by the Company may be different from the non-GAAP financial measures used by other companies.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
(1) GAAP product sales, net & license fees and service revenue	**$ 35,236**	**$ 50,331**	**$ 146,444**	**$ 162,556**
Non-GAAP adjustments to product sales, net & license fees and service revenue:	—	(15,000)	(6,000)	(24,681)
Non-GAAP product sales, net & license fees and service revenue	**$ 35,236**	**$ 35,331**	**$ 140,444**	**$ 137,875**
(2) GAAP selling, general and administrative expenses	**$ 18,300**	**$ 21,218**	**$ 87,347**	**$ 86,514**
Non-GAAP adjustments to SG&A:				
Stock-based compensation	(2,201)	(2,928)	(10,410)	(10,049)
Litigation expenses	(387)	(15)	(12,333)	(7)
Insurance reimbursement under D&O policy	—	—	—	2,111
Depreciation expense	(103)	(170)	(535)	(691)
Non-GAAP selling, general and administrative	**$ 15,609**	**$ 18,105**	**$ 64,069**	**$ 77,878**
(3) GAAP research and development	**$ 15,899**	**$ 15,433**	**$ 58,936**	**$ 50,766**
Non-GAAP adjustments to R&D:				
Stock-based compensation	(457)	(666)	(2,002)	(2,035)
Depreciation expense	(3)	(3)	(11)	(18)
Other R&D milestone payments	—	—	(2,826)	(3,000)
Non-GAAP research and development	**$ 15,439**	**$ 14,764**	**$ 54,097**	**$ 45,713**
(4) GAAP net loss	**$ (17,442)**	**$ (4,154)**	**$ (68,512)**	**$ (50,785)**
Non-GAAP adjustments to net loss:				
Adjustments to product sales, net & license fees and service revenue, SG&A, and R&D as noted above	3,151	(11,218)	22,117	(10,992)
Amortization and impairment charges of intangible assets	6,894	10,462	25,946	38,319
Adjustments to other (expense) income	959	(46)	6,011	5,463
Adjustments to benefit (provision) for income taxes	(1,677)	369	(2,313)	406
Non-GAAP net loss	**$ (8,115)**	**$ (4,587)**	**$ (16,751)**	**$ (17,589)**
(5) GAAP loss per share (Basic and Diluted)	$ (0.22)	$ (0.06)	$ (0.94)	$ (0.78)
Non-GAAP loss per share (Basic and Diluted)	$ (0.10)	$ (0.07)	$ (0.23)	$ (0.27)
Weighted average shares outstanding:				
Basic and Diluted	78,401,381	65,370,371	72,824,070	64,882,417

(1) Non-GAAP product sales, net & license fees and service revenue: These amounts reflect adjustments to reverse revenue recognition for upfront revenue from out-licenses and revenue from milestone achievement(s) that do not consistently recur. The resulting non-GAAP revenue solely consists of our (i) product sales, (ii) percentage-based royalties from our licensees' sales, and (iii) on-going service revenue. We believe this measure of non-GAAP revenue is more indicative of the period-over-period success of our core ongoing product sales and service revenue.

(2) Non-GAAP selling, general and administrative: 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 irregular operating expense items such as non-recurring legal fees and settlements. We believe the resulting non-GAAP SG&A value is more indicative of the period-over-period success of our administrative expense control, and more reflective of our normalized SG&A expense trends.

(3) Non-GAAP research and development: 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 R&D milestone achievements that we record to expense for our in-licenses. We believe the resulting non-GAAP R&D value is more reflective of our true R&D expense

trends.

(4) Non-GAAP net loss: These amounts reflect all non-GAAP adjustments described in (1) through (3) above, plus other non-cash and/or non-recurring items, including: (i) adjustments to reverse cost of service expense recognition for certain service arrangements that do not consistently recur (which corresponds with our non-GAAP reversal of license and contract revenue, as discussed in (1) above); (ii) adjustments to reverse operating expenses for non-cash amortization and impairment of intangible assets (the reversal of these non-cash expenses allows for a clearer representation of the period-over-period success of our overall financial results and future working capital requirements); (iii) adjustments to reverse the impact of income taxes; and (iv) adjustments to reverse the impact of mark-to-market contingent consideration (although our contingent consideration results from prior acquisitions and is a part of our business strategy, these adjustments through earnings typically result from variables other than our current commercial activity or other operating performance measures that are a focus of our management), (v) reversal of foreign exchange gains and losses (non-cash), and (vi) debt discount accretion expense (non-cash) for our convertible notes.

(5) Non-GAAP loss per share: These amounts reflect all non-GAAP adjustments in (1) through (4) above to present our overall non-GAAP financial results for each period on a per-share basis.