

SPECTRUM PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 05/02/17 for the Period Ending 05/02/17

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): May 2, 2017

SPECTRUM PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-35006

(Commission
File Number)

93-0979187

(IRS Employer
Identification No.)

11500 S. Eastern Ave., Ste. 240, Henderson, NV

(Address of Principal Executive Offices)

89052

(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 May 2, 2017, Spectrum Pharmaceuticals, Inc. issued a press release, which, among other matters, sets forth our results of operations for the quarter ended March 31, 2017. 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 2, 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: May 2, 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 May 2, 2017

COMPANY CONTACTS

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

Spectrum Pharmaceuticals Reports First Quarter 2017 Financial Results and Pipeline Update

- **ROLONTIS™ (eflapegrastim):**
 - Phase 3 ADVANCE Pivotal study: Number of evaluable patients reduced to 400 from 580, per an amended Special Protocol Assessment (SPA) received from the FDA.
 - ADVANCE study is 75% enrolled and the Company expects to complete enrollment in the second half of this year.
 - To strengthen the regulatory package in the U.S. and Europe, the Company has initiated an international 218-patient RECOVER study and first patient enrollment is imminent.
 - The Company continues to expect to file a BLA next year.
- **Poziotinib :**
 - Phase 2 study in non-small cell lung cancer patients with EGFR exon 20 insertion mutations was recently initiated at The University of Texas MD Anderson Cancer Center.
 - Interim results are expected before year end.
- **QAPZOLA™:**
 - Phase 3 study is expected to start enrolling patients in the third quarter.
 - The current study based on a new SPA from the FDA, is required to enroll 425 evaluable patients compared to 1,557 in the previous SPA.
- Q1 revenues were \$29.1 million , including \$25.8 million in product sales.

HENDERSON, Nevada - May 2, 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 ended March 31, 2017 .

"We remain focused on our advanced stage pipeline and look forward to several important milestones in the near future," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "Based on the preclinical results and clinical data from the first compassionate-use patient, treated at MD Anderson Cancer Center by Dr. John Heymach under a compassionate-use protocol approved by the FDA, enthusiasm is building in the scientific community about the potential of poziotinib in non-small cell lung cancer patients with exon 20 insertion mutations. There is immense need for effective therapies in this disease as the current progression free survival is under 2 months. In addition, I am delighted with the recent pace of enrollment of the ROLONTIS Phase 3 program. Since the beginning of this year, we have enrolled over 135 patients in the pivotal trial. We are looking forward to Phase 3 results and a BLA filing next year. With three advanced stage drugs being studied in multiple tumors, I believe Spectrum is poised for transformational growth."

Pipeline Update:

- **ROLONTIS (eflapegrastim), a novel long-acting GCSF:** A pivotal Phase 3 study (ADVANCE) was initiated under a SPA from the FDA in 2016 to evaluate ROLONTIS in the management of chemotherapy-induced neutropenia. Based on the amended SPA, the size of the ADVANCE study was reduced to 400 from 580 evaluable patients. The ADVANCE study is now 75% enrolled and the Company expects to complete

enrollment in the second half of this year. To strengthen the regulatory package in the U.S. and Europe, the Company has initiated the 218-patient RECOVER study, which is expected to include sites not only from the U.S., but also from Europe, Canada and South Korea. For the RECOVER Study, sites have been initiated and first patient enrollment is imminent. The Company continues to expect to file the BLA next year.

- **Poziotinib, a potential best-in-class, novel, pan-HER inhibitor** : An investigator sponsored trial has been initiated at the University of Texas MD Anderson Cancer Center in non-small cell lung cancer patients with EGFR exon 20 insertion mutations. The study is expected to yield interim results before year end. Spectrum is also conducting a Phase 2 breast cancer study in the U.S., based on promising Phase 1 study efficacy data in breast cancer patients who had failed multiple HER2-directed therapies. Further, multiple Phase 2 studies are being conducted in South Korea by Hanmi Pharmaceuticals and National OncoVenture to study breast, lung, head-and-neck and gastric cancer indications.
- **QAPZOLA, a potent tumor-activated drug being investigated for low and intermediate risk non-muscle invasive bladder cancer:** The Company received a new SPA from the FDA for a new Phase 3 study incorporating learnings from the previous studies, as well as recommendations from the FDA. Compared to the previous program, this new Phase 3 study will include fewer evaluable patients (n=425 versus 1,557 patients), use a higher dosage of QAPZOLA (8 mg versus 4 mg), and will evaluate time-to-recurrence as the primary endpoint. The Phase 3 trial is expected to start enrolling patients in the third quarter.

Three-Month Period Ended March 31, 2017 (All numbers are approximate)

GAAP Results

Total product sales were \$25.8 million in the first quarter of 2017 . Product sales in the first quarter included: FUSILEV[®] (levoleucovorin) net sales of \$2.6 million , FOLOTYN[®] (pralatrexate injection) net sales of \$9.3 million , ZEVALIN[®] (ibritumomab tiuxetan) net sales of \$2.8 million , MARQIBO[®] (vinCRISTine sulfate LIPOSOME injection) net sales of \$2.0 million , BELEODAQ[®] (belinostat) for injection net sales of \$2.9 million , and EVOMELA[®] (melphalan) for injection net sales of \$6.3 million .

Spectrum recorded net loss of \$23.0 million , or \$0.29 per basic and diluted share in the three-month period ended March 31, 2017 , compared to net loss of \$9.3 million , or \$0.14 per basic and diluted share in the comparable period in 2016 . Total research and development expenses were \$14.7 million in the quarter, as compared to \$15.5 million in the same period in 2016 . Selling, general and administrative expenses were \$18.6 million in the quarter, compared to \$22.0 million in the same period in 2016 .

The Company ended the quarter with Cash and Cash Equivalents of \$137 million .

Non-GAAP Results

Spectrum recorded non-GAAP net loss of \$11.4 million , or \$0.14 per basic and diluted share in the three-month period ended March 31, 2017 , compared to non-GAAP net income of \$0.3 million , or \$0.01 per basic share and less than \$0.01 per diluted share in the comparable period in 2016 . Non-GAAP research and development expenses were \$14.3 million , as compared to \$13.0 million in the same period of 2016 . Non-GAAP selling, general and administrative expenses were \$15.7 million , as compared to \$16.7 million in the same period in 2016 .

Conference Call

Tuesday, May 2, 2017 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 5573704

International: (973) 796-5077, Conference ID# 5573704



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 May 2, 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.®, FUSILEV®, FOLOTYN®, ZEVALIN®, MARQIBO®, BELEODAQ®, and EVOMELA® are registered trademarks of Spectrum Pharmaceuticals, Inc. and its affiliates. REDEFINING CANCER CARE™, ROLONTIS™, QAPZOLA™ and the Spectrum Pharmaceuticals' logos are trademarks owned by Spectrum Pharmaceuticals, Inc. Any other trademarks are the property of their respective owners.

© 2017 Spectrum Pharmaceuticals, Inc. All Rights Reserved

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

	Three Months Ended March 31,	
	2017	2016
Revenues:		
Product sales, net	\$ 25,845	\$ 35,241
License fees and service revenue	3,256	8,625
Total revenues	<u>29,101</u>	<u>43,866</u>
Operating costs and expenses:		
Cost of product sales (excludes amortization and impairment charges of intangible assets)	8,135	5,604
Cost of service revenue	2,103	1,282
Selling, general and administrative	18,607	21,962
Research and development	14,696	15,462
Amortization and impairment charges of intangible assets	6,889	5,839
Total operating costs and expenses	<u>50,430</u>	<u>50,149</u>
Loss from operations	<u>(21,329)</u>	<u>(6,283)</u>
Other (expense) income:		
Interest expense, net	(2,052)	(2,340)
Change in fair value of contingent consideration related to acquisitions	(197)	(1,042)
Other income, net	410	278
Total other expenses	<u>(1,839)</u>	<u>(3,104)</u>
Loss before income taxes	<u>(23,168)</u>	<u>(9,387)</u>
Benefit for income taxes	201	66
Net loss	<u>\$ (22,967)</u>	<u>\$ (9,321)</u>
Net loss per share:		
Basic and diluted	<u>\$ (0.29)</u>	<u>\$ (0.14)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>78,523,023</u>	<u>65,597,261</u>

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

	March 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 137,196	\$ 158,222
Marketable securities	247	247
Accounts receivable, net of allowance for doubtful accounts of \$88, respectively	39,488	39,782
Other receivables	5,948	5,754
Inventories	10,388	8,715
Prepaid expenses and other assets	3,726	3,930
Total current assets	196,993	216,650
Property and equipment, net of accumulated depreciation	493	449
Intangible assets, net of accumulated amortization and impairment charges	157,419	164,234
Goodwill	17,917	17,886
Other assets	30,684	29,549
Total assets	\$ 403,506	\$ 428,768
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 48,228	\$ 52,483
Accrued payroll and benefits	5,174	8,981
Deferred revenue	2,922	3,188
Drug development liability	861	861
Acquisition-related contingent obligations	—	—
Total current liabilities	57,185	65,513
Drug development liability, less current portion	11,910	12,269
Deferred revenue, less current portion	316	323
Acquisition-related contingent obligations, less current portion	1,512	1,315
Deferred tax liabilities	6,749	6,675
Other long-term liabilities	9,874	9,604
Convertible senior notes	98,590	97,043
Total liabilities	186,136	192,742
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
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; no shares issued and outstanding.	—	—
Common stock, \$0.001 par value; 175,000,000 shares authorized; 80,423,844 and 80,466,735 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	80	80
Additional paid-in capital	642,518	640,166
Accumulated other comprehensive income (loss)	380	(1,579)
Accumulated deficit	(425,608)	(402,641)
Total stockholders' equity	217,370	236,026
Total liabilities and stockholders' equity	\$ 403,506	\$ 428,768

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 March 31,	
	2017	2016
(1) GAAP product sales, net & license fees and service revenue	\$ 29,101	\$ 43,866
Non GAAP adjustments to product sales, net & license fees and service revenue:	—	(6,000)
Non-GAAP product sales, net & license fees and service revenue	\$ 29,101	\$ 37,866
(2) GAAP selling, general and administrative expenses	\$ 18,607	\$ 21,962
Non GAAP adjustments to SG&A:		
Stock-based compensation	(2,741)	(2,769)
Litigation expenses	(116)	(2,295)
Depreciation expense	(90)	(166)
Non-GAAP selling, general and administrative	\$ 15,660	\$ 16,732
(3) GAAP research and development	\$ 14,696	\$ 15,462
Non-GAAP adjustments to R&D:		
Stock-based compensation	(399)	(407)
Depreciation expense	(3)	(3)
Other R&D milestone payments	—	(2,056)
Non-GAAP research and development	\$ 14,294	\$ 12,996
(4) GAAP net loss	\$ (22,967)	\$ (9,321)
Non-GAAP adjustments to net loss:		
Adjustments to product sales, net & license fees and service revenue, SG&A, and R&D as noted above	3,349	1,696
Amortization and impairment charges of intangible assets	6,889	5,839
Adjustments to other expense (income)	1,573	2,200
Adjustments to (benefit) provision for income taxes	(201)	(66)
Non-GAAP net loss	\$ (11,357)	\$ 348
(5) GAAP loss per share (Basic and Diluted)	\$ (0.29)	\$ (0.14)
Non-GAAP loss per share (Basic and Diluted)		
Basic	\$ (0.14)	\$ 0.01
Diluted	\$ (0.14)	\$ 0.00
Weighted average shares outstanding:		
Basic	78,523,023	65,597,261
Diluted	78,523,023	80,613,907

(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 (noncash), 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.