

SPECTRUM PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 11/02/17 for the Period Ending 11/02/17

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|-------------|----------------------------------------------------------|
| 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): November 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))

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 November 2, 2017, Spectrum Pharmaceuticals, Inc. issued a press release, which, among other matters, sets forth our results of operations for the quarter ended September 30, 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 November 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: November 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 November 2, 2017](#)

COMPANY CONTACTS

Shiv Kapoor

Vice President, Strategic Planning & Investor Relations

702-835-6300

InvestorRelations@sppirx.com

Spectrum Pharmaceuticals Reports Third Quarter 2017 Financial Results and Pipeline Update

- **Poziotinib:**
 - **Objective Response Rate of 73% was observed in preliminary analysis from an ongoing Phase 2 study conducted by MD Anderson Cancer Center in Non-Small-Cell Lung Cancer (NSCLC) patients with EGFR exon 20 insertion mutations.**
 - **The Company has initiated a multicenter clinical trial to expedite the development of poziotinib in lung cancer patients with exon 20 insertion mutations.**
- **ROLONTIS™ (eflapegrastim):**
 - **Topline results expected in Q1 2018 from the fully enrolled ADVANCE Study under a Special Protocol Assessment (SPA) from the FDA.**
 - **RECOVER, a second smaller Phase 3 study, is enrolling patients internationally.**
 - **BLA filing expected in Q4 2018.**
- **QAPZOLA®:**
 - **Phase 3 study under an SPA is currently enrolling patients.**
- **Financials:**
 - **Q3 revenues were \$36.4 million, including \$31.2 million in product sales.**

HENDERSON, Nevada - November 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 September 30, 2017.

"We have been focused on developing our late-stage pipeline and I am proud of our progress," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "Encouraging data from the Phase 2 lung cancer study from poziotinib was presented at the World Conference on Lung Cancer in Japan two weeks ago. We remain very excited about poziotinib's prospects in lung cancer as well as other solid tumors. We also look forward to receiving top-line results from ROLONTIS's ADVANCE registrational Phase 3 study in the first quarter of 2018. We are enthusiastic about developing our pipeline strategically and expeditiously."

Pipeline Update:

- **Poziotinib, an irreversible tyrosine kinase inhibitor:** Three Phase 2 studies evaluating poziotinib in lung cancer and breast cancer are currently enrolling patients in the U.S.
 - An investigator sponsored trial is currently enrolling at the University of Texas MD Anderson Cancer Center in non-small cell lung cancer patients with exon 20 insertion mutations in EGFR or HER2. The study yielded preliminary results demonstrating evidence of significant antitumor activity in NSCLC patients with EGFR exon 20 insertion mutations, with preliminary data showing an Objective Response Rate of 73%. Toxicities have included rash, diarrhea, paronychia, and mucositis consistent with those previously described for poziotinib and other TKIs, which led to dose reduction in 55% of the patients.
 - In consultation with the FDA, the Company has initiated a multicenter study. This trial will enroll up to 87 patients with EGFR exon 20 insertion mutations and up to 87 patients with HER2 exon 20 insertion

mutations at several leading cancer institutions. The study will evaluate objective response rate (ORR) as the primary endpoint, and disease control rate (DCR), duration of response (DOR), and safety as secondary endpoints.

- Spectrum is also conducting a Phase 2 breast cancer study in the third-line setting in the U.S.
- **ROLONTIS (eflapegrastim), a novel long-acting GCSF:** A registrational Phase 3 study ADVANCE was initiated under an SPA with the FDA last year to evaluate ROLONTIS in the management of chemotherapy-induced neutropenia. The Company has completed enrollment in the ADVANCE study with 406 patients randomized and expects to report topline data in Q1 2018. To strengthen the regulatory package in Europe and the U.S., the Company is currently enrolling the 218-patient international RECOVER study, which has a similar design. The Company expects to file the BLA in Q4 2018.
- **QAPZOLA, a potent tumor-activated drug for bladder cancer is being investigated for low and intermediate risk non-muscle invasive bladder cancer:** The Company has an SPA from the FDA and is currently enrolling patients in a Phase 3 study. The Phase 3 study has incorporated learnings from the previous studies, as well as recommendations from the FDA. The Phase 3 study will enroll approximately 425 evaluable patients, using a single dose of 8 mg, and will evaluate time-to-recurrence as the primary endpoint.

Three-Month Period Ended September 30, 2017 (All numbers are approximate)

GAAP Results

Total product sales were \$31.2 million in the third quarter of 2017 . Product sales in the third quarter included: FUSILEV[®] (levoleucovorin) net sales of \$1.8 million , FOLOTYN[®] (pralatrexate injection) net sales of \$11.6 million , ZEVALIN[®] (ibrutinomab tiuxetan) net sales of \$2.7 million , MARQIBO[®] (vinCRISTine sulfate LIPOSOME injection) net sales of \$1.2 million , BELEODAQ[®] (belinostat) for injection net sales of \$3.4 million , and EVOMELA[®] (melphalan) for injection net sales of \$10.5 million .

Spectrum recorded a net loss of \$18.7 million , or \$0.22 per basic and diluted share in the three-month period ended September 30, 2017 , compared to a net loss of \$17.5 million , or \$0.22 per basic and diluted share in the comparable period in 2016 . Total research and development expenses were \$13.9 million in the quarter, as compared to \$13.3 million in the same period in 2016 . Selling, general and administrative expenses were \$18.9 million in the quarter, compared to \$19.5 million in the same period in 2016 .

Our September 30, 2017 cash and equivalents balance is \$248 million .

Non-GAAP Results

Spectrum recorded non-GAAP net loss of \$9.2 million , or \$0.11 per basic and diluted share in the three-month period ended September 30, 2017 , compared to non-GAAP net loss of \$5.3 million , or \$0.07 per basic share and diluted share in the comparable period in 2016 . Non-GAAP research and development expenses were \$13.2 million , as compared to \$12.8 million in the same period of 2016 . Non-GAAP selling, general and administrative expenses were \$16.1 million , as compared to \$15.6 million in the same period in 2016 .

Conference Call

Thursday, November 2, 2017 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 7488227

International: (973) 796-5077, Conference ID# 7488227



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 November 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®, EVOMELA® and QAPZOLA® are registered trademarks of Spectrum Pharmaceuticals, Inc. and its affiliates. REDEFINING CANCER CARE™, ROLONTIS™, and the Spectrum Pharmaceuticals' logos are trademarks owned by Spectrum Pharmaceuticals, Inc. Any other trademarks are the property of their respective owners.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|-----------------------------------------------------------------------------------|-------------------------------------|-------------|------------------------------------|-------------|
| | 2017 | 2016 | 2017 | 2016 |
| Revenues: | | | | |
| Product sales, net | \$ 31,234 | \$ 30,272 | \$ 88,235 | \$ 96,401 |
| License fees and service revenue | 5,161 | 3,121 | 11,562 | 14,807 |
| Total revenues | 36,395 | 33,393 | 99,797 | 111,208 |
| Operating costs and expenses: | | | | |
| Cost of sales (excludes amortization and impairment charges of intangible assets) | 12,179 | 7,503 | 31,618 | 18,715 |
| Cost of service revenue | — | 2,221 | 4,221 | 5,716 |
| Selling, general and administrative | 18,880 | 19,465 | 54,595 | 69,047 |
| Research and development | 13,878 | 13,293 | 43,670 | 43,037 |
| Amortization and impairment charges of intangible assets | 6,928 | 6,907 | 20,718 | 19,052 |
| Total operating costs and expenses | 51,865 | 49,389 | 154,822 | 155,567 |
| Loss from operations | (15,470) | (15,996) | (55,025) | (44,359) |
| Other (expense) income: | | | | |
| Interest expense, net | (2,014) | (2,373) | (6,196) | (7,087) |
| Change in fair value of contingent consideration related to acquisitions | (2,942) | 78 | (3,236) | (1,249) |
| Other income, net | 251 | 372 | 901 | 990 |
| Total other expenses | (4,705) | (1,923) | (8,531) | (7,346) |
| Loss before income taxes | (20,175) | (17,919) | (63,556) | (51,705) |
| Benefit for income taxes | 1,466 | 464 | 1,412 | 635 |
| Net loss | \$ (18,709) | \$ (17,455) | \$ (62,144) | \$ (51,070) |
| Net loss per share: | | | | |
| Basic and diluted | \$ (0.22) | \$ (0.22) | \$ (0.78) | \$ (0.73) |
| Weighted average shares outstanding: | | | | |
| Basic and diluted | 83,463,153 | 79,303,380 | 80,177,370 | 70,437,885 |

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

| | September 30, 2017 | December 31, 2016 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 247,468 | \$ 158,222 |
| Marketable securities | 248 | 247 |
| Accounts receivable, net of allowance for doubtful accounts of \$88 and \$88, respectively | 37,767 | 39,782 |
| Other receivables | 5,876 | 5,754 |
| Inventories | 8,983 | 8,715 |
| Prepaid expenses and other assets | 2,957 | 3,930 |
| Total current assets | 303,299 | 216,650 |
| Property and equipment, net of accumulated depreciation | 615 | 449 |
| Intangible assets, net of accumulated amortization and impairment charges | 144,036 | 164,234 |
| Goodwill | 18,131 | 17,886 |
| Other assets | 35,736 | 29,549 |
| Total assets | \$ 501,817 | \$ 428,768 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable and other accrued liabilities | \$ 49,635 | \$ 52,483 |
| Accrued payroll and benefits | 7,636 | 8,981 |
| Deferred revenue | 2,783 | 3,188 |
| FOLOTYN development liability | 153 | 861 |
| Total current liabilities | 60,207 | 65,513 |
| FOLOTYN development liability, less current portion | 12,273 | 12,269 |
| Deferred revenue, less current portion | 324 | 323 |
| Acquisition-related contingent obligations | 4,551 | 1,315 |
| Deferred tax liabilities | 6,829 | 6,675 |
| Other long-term liabilities | 11,127 | 9,604 |
| Convertible senior notes | 101,770 | 97,043 |
| Total liabilities | 197,081 | 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; 94,061,740 and 80,466,735 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively | 94 | 80 |
| Additional paid-in capital | 765,754 | 640,166 |
| Accumulated other comprehensive income (loss) | 3,673 | (1,579) |
| Accumulated deficit | (464,785) | (402,641) |
| Total stockholders' equity | 304,736 | 236,026 |
| Total liabilities and stockholders' equity | \$ 501,817 | \$ 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, except per share amounts)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------------------------------------------------------------------------------------------|-------------------------------------|-------------------|------------------------------------|-------------------|
| | 2017 | 2016 | 2017 | 2016 |
| (1) GAAP product sales, net & license fees and service revenue | \$ 36,395 | \$ 33,393 | \$ 99,797 | \$ 111,208 |
| Non GAAP adjustments to product sales, net & license fees and service revenue: | (5,000) | — | (5,000) | (6,000) |
| Non-GAAP product sales, net & license fees and service revenue | <u>\$ 31,395</u> | <u>\$ 33,393</u> | <u>\$ 94,797</u> | <u>\$ 105,208</u> |
| (2) GAAP selling, general and administrative expenses | \$ 18,880 | \$ 19,465 | \$ 54,595 | \$ 69,047 |
| Non GAAP adjustments to SG&A: | | | | |
| Stock-based compensation | (2,750) | (2,650) | (8,066) | (8,209) |
| Litigation expenses | — | (1,133) | — | (11,946) |
| Depreciation expense | (75) | (103) | (241) | (432) |
| Non-GAAP selling, general and administrative | <u>\$ 16,055</u> | <u>\$ 15,579</u> | <u>\$ 46,288</u> | <u>\$ 48,460</u> |
| (3) GAAP research and development | \$ 13,878 | \$ 13,293 | \$ 43,670 | \$ 43,037 |
| Non-GAAP adjustments to R&D: | | | | |
| Stock-based compensation | (660) | (500) | (1,588) | (1,545) |
| Depreciation expense | (2) | (3) | (6) | (9) |
| Other R&D milestone payments | — | — | — | (2,826) |
| Non-GAAP research and development | <u>\$ 13,216</u> | <u>\$ 12,790</u> | <u>\$ 42,076</u> | <u>\$ 38,657</u> |
| (4) GAAP net loss | \$ (18,709) | \$ (17,455) | \$ (62,144) | \$ (51,070) |
| Non-GAAP adjustments to net loss: | | | | |
| Adjustments to product sales, net & license fees and service revenue, SG&A, and R&D as noted above | (1,513) | 4,389 | 4,901 | 18,967 |
| Adjustment to cost of sales | 1,000 | — | 1,000 | — |
| Amortization and impairment charges of intangible assets | 6,928 | 6,907 | 20,718 | 19,052 |
| Adjustments to other expense, net | 4,557 | 1,358 | 7,655 | 5,052 |
| Adjustments to provision (benefit) for income taxes | (1,466) | (464) | (1,412) | (635) |
| Non-GAAP net loss | <u>\$ (9,203)</u> | <u>\$ (5,265)</u> | <u>\$ (29,282)</u> | <u>\$ (8,634)</u> |
| (5) GAAP loss per share (Basic and Diluted) | \$ (0.22) | \$ (0.22) | \$ (0.78) | \$ (0.73) |
| Non-GAAP loss per share (Basic and Diluted) | | | | |
| Basic and diluted | <u>\$ (0.11)</u> | <u>\$ (0.07)</u> | <u>\$ (0.37)</u> | <u>\$ (0.12)</u> |
| Weighted average shares outstanding: | | | | |
| Basic and diluted | <u>83,463,153</u> | <u>79,303,380</u> | <u>80,177,370</u> | <u>70,437,885</u> |

(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 royalty expense on receipts from regulatory and sales milestone achievements; (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.