# Spectrum Pharmaceuticals Reports Fourth Quarter 2018 and Full Year 2018 Financial Results and Pipeline Update

February 28, 2019

- Poziotinib enrollment completed in previously treated EGFR cohort (cohort 1) of ZENITH20 trial; topline results are expected in Q4 2019
- ROLONTIS® (eflapegrastim) Biologics License Application (BLA) was submitted to the FDA
- Q4 Revenues were $29.4 million, including $28.0 million in product sales; full year revenues were $109.3 million including $104.5 million in product sales

HENDERSON, Nev.--(BUSINESS WIRE)--Feb. 28, 2019-- Spectrum Pharmaceuticals, Inc. (NASDAQ-GS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, announced today financial results for the three-month period and year ended December 31, 2018.

“2018 was a very productive year for Spectrum in which our two promising pipeline products significantly progressed in clinical development," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "We begin 2019 with great momentum after meeting the enrollment target for the first cohort in our pivotal poziotinib study and submitting the BLA for ROLONTIS to the FDA at the end of 2018. In 2019, we are laser-focused on continuing to develop our two late-stage products, poziotinib and ROLONTIS, and looking for new opportunities that build upon these assets.”

***Pipeline update:***

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

- Enrollment in the EGFR, previously treated NSCLC cohort (cohort 1) in the ZENITH20 trial was completed; topline results are expected in Q4 2019.
- Enrollment in the HER2, previously treated NSCLC cohort (cohort 2) in the ZENITH20 trial is expected to be completed in Q4 2019.
- Initiation of pan-tumor and combination trials expected to be in H2 2019.

**ROLONTIS (eflapegrastim), a novel long-acting GCSF:**

- Spectrum submitted the BLA with the FDA in late December 2018. Due to the government shutdown, the file was officially received on January 28, 2019.

***Pipeline update continued:***

- Spectrum has begun launch readiness activities including inventory build and commercial preparedness.
- Data from the Phase 3 study (RECOVER) was presented in a poster session at the San Antonio Breast Cancer Symposium in December 2018. The RECOVER study was the second pivotal trial to meet all primary and secondary endpoints and demonstrated comparable safety and tolerability profiles to pegfilgrastim.

***2019 Guidance***

Assuming the previously announced divestiture transaction closes in March, we expect 2019 SG&A costs to decrease by approximately 30 percent relative to 2018. We expect 2019 R&D costs to increase nominally as reduced spending on the legacy assets is offset by the increased spending on pre-commercial supply and tech transfer activities for ROLONTIS and poziotinib. With the increase of cash from the sale of our commercial assets, we expect our cash balance to be sufficient to fund operations for at least three years.

***Three-Month Period Ended December 31, 2018 (All numbers are approximate)***

***GAAP Results***

Total product sales were $28.0 million in the fourth quarter of 2018. Product sales in the fourth quarter included: FOLOTYN® (pralatrexate injection) net sales of $12.2 million, EVOMELA® (melphalan) for injection net sales of $7.5 million, BELEODAQ® (belinostat) for injection net sales of $3.7 million, ZEVALIN® (ibritumomab tiuxetan) net sales of $0.9 million, MARQIBO® (vinCRIStine sulfate LIPOSOME injection) net sales of $2.3 million, KHAPZORY ™(levoleucovorin) net sales of $0.9 million, and FUSILEV® (levoleucovorin) net sales of $0.4 million.

Spectrum recorded net loss of $49.2 million, or $0.47 per basic and diluted share in the three-month period ended December 31, 2018, compared to net loss of $28.6 million, or $0.29 per basic and diluted share in the comparable period in 2017. Total research and development expenses were $34.5 million in the quarter, as compared to $22.1 million in the same period in 2017. Selling, general and administrative expenses were $23.3 million in the quarter, compared to $29.2 million in the same period in 2017.

The company ended the quarter with cash, cash equivalents and marketable securities of $204 million.

***Non-GAAP Results***

Spectrum recorded non-GAAP net loss of $32.1 million, or $0.30 per basic and diluted share in the three-month period ended December 31, 2018, compared to non-GAAP net loss of $22.8 million, or $0.23 per basic and diluted share in the comparable period in 2017. Non-GAAP research and development expenses were $33.6 million, as compared to $21.3 million in the same period of 2017. Non-GAAP selling, general and administrative expenses were $19.9 million, as compared to $19.1 million in the same period in 2017.

***Twelve-Month Period Ended December 31, 2018 (All numbers are approximate)***

***GAAP Results***

Total product sales were $104.5 million for the twelve months ended December 31, 2018. Total product sales decreased 10.1% from $116.2 million in the same period of 2017.

Product sales in 2018 included: FOLOTYN® (pralatrexate injection) net sales of $48.0 million, EVOMELA® (melphalan) for injection net sales of $28.3 million, BELEODAQ® (belinostat) for injection net sales of $12.3 million, ZEVALIN® (ibritumomab tiuxetan) net sales of $7.0 million, MARQIBO® (vinCRIStine sulfate LIPOSOME injection) net sales of $5.5 million, KHAPZORY ™(levoleucovorin) net sales of $0.9 million, and FUSILEV® (levoleucovorin) net sales of $2.4 million. Spectrum recorded net loss of $120.0 million, or $1.16 per basic and diluted share in the twelve-month period ended December 31, 2018, compared to net loss of $91.2 million, or $1.07 per basic and diluted share in the comparable period in 2017. Total research and development expenses were $95.0 million for the year, as compared to $65.9 million in the same period in 2017. Selling, general and administrative expenses were $90.7 million for the year, compared to $84.3 million in the same period in 2017.

***Non-GAAP Results***

Spectrum recorded non-GAAP net loss of $86.8 million, or $0.84 per basic and diluted share in the twelve-month period ended December 31, 2018, compared to non-GAAP net loss of $52.1 million, or $0.61 per basic and diluted share in the comparable period in 2017. Non-GAAP research and development expenses were $91.0 million, as compared to $63.4 million in the same period of 2017. Non-GAAP selling, general and administrative expenses were $76.5 million, as compared to $65.4 million in the same period in 2017.

**Conference Call**

**Thursday, February 28, 2019 @ 4:30 p.m. Eastern/1:30 p.m. Pacific**

Domestic: (877) 837-3910, Conference ID# 2797623

International: (973) 796-5077, Conference ID# 2797623

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 February 28, 2019 at 4:30 p.m. Eastern/1:30 p.m. Pacific.

**About Spectrum**

Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted drug products, with a primary focus in hematology and oncology. 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 that has the potential to transform the company in the near future. More information on Spectrum is available at www.sppirx.com.

***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 role of poziotinib in treating NSCLC patients with EGFR and HER2 exon 20 mutations and the advancement in treatment of such patients, the treatment potential of poziotinib to consistently deliver high response and disease control rates for NSCLC patients with EGFR and HER2 exon 20 mutations, the likelihood and timing of receiving the FDA's approval of the BLA for ROLONTIS®, Spectrum's ability to expand the poziotinib clinical program to explore poziotinib in new areas, including pan-tumor and combination therapies, the timing of enrollment for the poziotinib HER2, previously treated cohort in the ZENITH20 trial, the timing of the initiation of the pan-tumor and combination therapies trial, the timing of the release of the results from the poziotinib EGFR, previously treated cohort in the ZENITH20 trial, the timing and likelihood of the closing of the previously announced divestiture of Spectrum's hematology/oncology products, the expected reduction in SG&A and R&D costs resulting from the divestiture, the future potential of Spectrum's existing drug pipeline, and any other statements that are not purely statements of historical fact.These forward-looking statements are based on management's current beliefs, expectations and assumptions and are subject to significant risks and uncertainties. Investors are cautioned not to place undue reliance on any such forward-looking statements. All such forward-looking statements speak only as of the date they are made, and Spectrum undertakes no obligation to update or revise these statements, whether as a result of new information, future events or otherwise. Although Spectrum believes that the expectations reflected in these forward-looking statements are reasonable, these statements involve many risks and uncertainties that may cause actual results to differ materially from what may be expressed or implied in these forward-looking statements, including, without limitation, the uncertainties inherent in new product development, including clinical trial results and additional analysis of existing clinical data, the possibility that Spectrum's existing and new drug candidates, including poziotinib and ROLONTIS® , may not ultimately prove to be safe or effective, the possibility that Spectrum's 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 Spectrum's existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, Spectrum's ability to complete the divestiture of its hematology/oncology products on a timely basis, or at all, and Spectrum's dependence on third parties for clinical trials, manufacturing, distribution*

*and quality control. 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, 2018, as amended, and in subsequent reports on Forms 10-Q and 8-K and other filings made with the SEC by Spectrum.*



**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, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Revenues: | | | | |
| Product sales, net | $ 28,047 | $ 27,942 | $ 104,466 | $ 116,178 |
| License fees and service revenue | 1,356 | 627 | 4,867 | 12,189 |
| Total revenues | $ 29,403 | $ 28,569 | $ 109,333 | $ 128,367 |
| Operating costs and expenses: | | | | |
| Cost of sales (excludes amortization of intangible assets) | 6,865 | 11,241 | 26,756 | 42,859 |
| Cost of service revenue | — | 138 | — | 4,359 |
| Selling, general and administrative | 23,307 | 29,214 | 90,700 | 84,267 |
| Research and development | 34,514 | 22,134 | 94,956 | 65,895 |
| Amortization of intangible assets | 7,294 | 6,929 | 28,098 | 27,647 |
| Total operating costs and expenses | 71,980 | 69,656 | 240,510 | 225,027 |
| Loss from operations | (42,577) | (41,087) | (131,177) | (96,660) |
| Other income (expense): | | | | |
| Interest income (expense), net | 143 | (602) | (340) | (6,798) |
| Change in fair value of contingent consideration related to acquisitions | 1,210 | (1,721) | 1,927 | (4,957) |
| Other (expense) income, net | (8,003) | (512) | 9,580 | 389 |
| Total other (expense) income | (6,650) | (2,835) | 11,167 | (11,366) |
| Loss before income taxes | (49,227) | (43,922) | (120,010) | (108,026) |
| Benefit (provision) for income taxes | 7 | 15,366 | (1) | 16,778 |
| Net loss | $ (49,220) | $ (28,556) | $ (120,011) | $ (91,248) |
| Net loss per share: | | | | |
| Basic and diluted | $ (0.47) | $ (0.29) | $ (1.16) | $ (1.07) |
| Weighted average shares outstanding: | | | | |
| Basic and diluted | 105,633,296 | 98,366,416 | 103,305,911 | 85,115,592 |

**SPECTRUM PHARMACEUTICALS, INC.**
**Condensed Consolidated Balance Sheets**

(In thousands, expect per share and par value amounts)

| | December 31, | |
|---|---|---|
| | **2018** | **2017** |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 157,480 | $ 227,323 |
| Marketable securities | 46,508 | 248 |
| Accounts receivable, net of allowance for doubtful accounts of $67 and $71, respectively | 29,873 | 32,260 |
| Other receivables | 3,698 | 2,133 |
| Inventories | 3,550 | 5,715 |

| | | |
|---|---|---|
| Prepaid expenses and other assets | 9,579 | 10,067 |
| Total current assets | 250,688 | 277,746 |
| Property and equipment, net of accumulated depreciation | 385 | 589 |
| Intangible assets, net of accumulated amortization | 111,594 | 137,159 |
| Goodwill | 18,061 | 18,162 |
| Other assets | 10,158 | 53,783 |
| Total assets | $ 390,886 | $ 487,439 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and other accrued liabilities | $ 69,460 | $ 58,117 |
| Accrued payroll and benefits | 9,853 | 9,261 |
| Contract liabilities | 4,850 | — |
| Deferred revenue | — | 3,872 |
| FOLOTYN development liability | 2,311 | 275 |
| Convertible senior notes | — | 38,224 |
| Total current liabilities | 86,474 | 109,749 |
| FOLOTYN development liability, less current portion | 9,686 | 12,111 |
| Deferred revenue, less current portion | — | 315 |
| Acquisition-related contingent obligations | 4,345 | 6,272 |
| Deferred tax liabilities | 1,469 | 1,438 |
| Other long-term liabilities | 5,650 | 6,215 |
| Total liabilities | 107,624 | 136,100 |
| 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; 110,525,141 and 100,742,735 issued and outstanding at December 31, 2018 and 2017, respectively | 110 | 100 |
| Additional paid-in capital | 886,740 | 837,347 |
| Accumulated other comprehensive (loss) income | (3,702) | 15,999 |
| Accumulated deficit | (599,886) | (502,107) |
| Total stockholders' equity | 283,262 | 351,339 |
| Total liabilities and stockholders' equity | $ 390,886 | $ 487,439 |

***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 product sales, net and license fees and service revenue, non-GAAP selling, general and administrative expenses, non-GAAP research and development expenses, non-GAAP net loss and non-GAAP net loss per share. Non-GAAP financial measures are reconciled to the most directly comparable GAAP financial measures in the tables of this press release and the accompanying footnotes. The non-GAAP financial measures contained herein are a supplement to the corresponding financial measures prepared in accordance with GAAP. The non-GAAP financial measures presented exclude the items summarized in the below table.

Management believes that adjustments for these items assist investors in making comparisons of period-to-period operating results and that these items are not indicative of the company's on-going core operating performance. Management uses non-GAAP net income (loss) in its evaluation of the company's core after-tax results of operations and trends between fiscal periods and believes that these measures are important components of its internal performance measurement process. Management believes that these non-GAAP financial measures are useful to investors in providing greater transparency to the information used by management in its operational decision-making. Management believes that the use of these non-GAAP financial measures also facilitates a comparison of the Company's underlying operating performance with that of other companies in its industry, which use similar non-GAAP measures to supplement their GAAP results.

The non-GAAP financial measures presented herein have certain limitations in that they do not reflect all of the costs associated with the operations of the company's business as determined in accordance with GAAP. Therefore, investors should consider non-GAAP financial measures in addition to, and not as a substitute for, or as superior to, measures of financial performance prepared in accordance with GAAP. In addition, other companies, including other companies in our industry, may calculate non-GAAP financial measures differently than we do, limiting their usefulness as a comparative tool. Investors and potential investors are encouraged to review the reconciliation of our non-GAAP financial measures contained within this news release with our GAAP financial results.

**SPECTRUM PHARMACEUTICALS, INC.**
**Reconciliation of Non-GAAP Adjustments for Condensed Consolidated Statements of Operations**

(In thousands, expect per share amounts)

| | **Three Months Ended December 31,** | **Twelve Months Ended December 31,** |
|---|---|---|

| | | 2018 | 2017 | 2018 | 2017 |
|---|---|---|---|---|---|
| (1) | **GAAP product sales, net & license fees and service revenue** | **$ 29,403** | **$ 28,569** | **$ 109,333** | **$ 128,367** |
| | Non-GAAP adjustments to product sales, net & license fees and service revenue: | (999) | — | (3,000) | (5,000) |
| | **Non-GAAP product sales, net & license fees and service revenue** | **$ 28,404** | **$ 28,569** | **$ 106,333** | **$ 123,367** |
| (2) | **GAAP selling, general and administrative expenses** | **$ 23,307** | **$ 29,214** | **$ 90,700** | **$ 84,267** |
| | Non-GAAP adjustments to SG&A: | | | | |
| | Stock-based compensation | (3,337) | (2,997) | (14,010) | (11,521) |
| | Depreciation expense | (22) | (76) | (213) | (316) |
| | Severance and legal expenses | — | (7,080) | — | (7,080) |
| | **Non-GAAP selling, general and administrative** | **$ 19,948** | **$ 19,061** | **$ 76,477** | **$ 65,350** |
| (3) | **GAAP research and development** | **$ 34,514** | **$ 22,134** | **$ 94,956** | **$ 65,895** |
| | Non-GAAP adjustments to R&D: | | | | |
| | Stock-based compensation | (949) | (557) | (3,473) | (2,235) |
| | Depreciation expense | (2) | (2) | (9) | (9) |
| | Other R&D milestone payments | — | (250) | (500) | (250) |
| | **Non-GAAP research and development** | **$ 33,563** | **$ 21,325** | **$ 90,974** | **$ 63,401** |
| (4) | **GAAP net loss** | **$ (49,220)** | **$ (28,556)** | **$ (120,011)** | **$ (91,248)** |
| | Non-GAAP adjustments to net loss: | | | | |
| | Adjustments to product sales, net & license fees and service revenue, SG&A, and R&D as noted above | 3,311 | 10,962 | 15,205 | 16,411 |
| | Adjustment to cost of sales | 22 | — | 89 | 1,000 |
| | Amortization of intangible assets | 7,294 | 6,929 | 28,098 | 27,647 |
| | Adjustments to other (expense) income | 6,454 | 3,258 | (10,168) | 10,914 |
| | Adjustments to (benefit) provision for income taxes | (7) | (15,366) | 1 | (16,778) |
| | **Non-GAAP net loss** | **$ (32,146)** | **$ (22,773)** | **$ (86,786)** | **$ (52,054)** |
| (5) | **GAAP loss per share (Basic and Diluted)** | $ (0.47) | $ (0.29) | $ (1.16) | $ (1.07) |
| | **Non-GAAP loss per share (Basic and Diluted)** | $ (0.30) | $ (0.23) | $ (0.84) | $ (0.61) |
| | **Weighted average shares outstanding:** | | | | |
| | Basic and Diluted | 105,633,296 | 98,366,416 | 103,305,911 | 85,115,592 |

**(1) Non-GAAP product sales, net and 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) 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 expenses:** 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, settlements and severance. 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. 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 expenses:** 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; (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); (vi) reversal of debt discount accretion expense (non-cash) for our convertible notes; and (vii) reversal of the mark-to-market adjustment on our equity securities.

**(5) Non-GAAP net 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.

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Source: Spectrum Pharmaceuticals, Inc.

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