Spectrum Pharmaceuticals Reports Fourth Quarter 2021 and Full Year 2021 Financial Results and Corporate Update

March 17, 2022

Eflapegrastim BLA resubmitted to FDA

Poziotinib NDA accepted for FDA review in previously treated patients with NSCLC harboring HER2 exon 20 insertion mutations, PDUFA date November 24, 2022

Positive poziotinib results in treatment naïve patients with NSCLC harboring HER2 exon 20 insertion mutations

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

HENDERSON, Nev.--(BUSINESS WIRE)--Mar. 17, 2022-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, announced today financial results for the three-month period and full year ended December 31, 2021.

"We have made significant progress against our core business objectives including the acceptance of the poziotinib NDA and resubmission of the eflapegrastim BLA to the FDA. We have also recently released positive data in front-line NSCLC patients harboring HER2 exon 20 insertion mutations," said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. "Additionally, we have strengthened our strategic corporate partnerships, restructured our operations, and are focused on advancing our mission."

Pipeline Updates

Eflapegrastim, a novel long-acting G-CSF

- The company has resubmitted the Biologics License Application (BLA) with an expected six-month review for eflapegrastim following remediation of manufacturing deficiencies. The FDA has indicated that a reinspection of the drug substance manufacturing facility in South Korea will be required.

Poziotinib, a Pan ErbB inhibitor targeting HER2 exon20 mutations

- The New Drug Application (NDA) was accepted for review by the FDA under a Fast Track designation. The NDA is based on the positive results of Cohort 2 in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 exon 20 insertion mutations. The agency has set a Prescription Drug User Fee Act (PDUFA) date of November 24, 2022. There is no FDA approved therapy for patients with NSCLC harboring HER2 exon 20 insertion mutations.

- Data from Cohort 4 of the ZENITH20 study in patients with treatment-naïve NSCLC harboring HER2 exon 20 insertion mutations were recently delivered in an oral presentation at the European Society for Medical Oncology Targeted Anticancer Therapies (ESMO TAT) Congress 2022. The results showed a confirmed objective response rate (ORR) of 41% (95% CI:30%-54%), as evaluated centrally by an independent image review committee using RECIST 1.1 criteria. The evaluable patient population showed an ORR of 50%. The study met its primary endpoint as the observed lower bound of 30% exceeded the pre-specified lower bound of 20%. The safety profile was consistent with the tyrosine kinase inhibitor (TKI) class. Notably, on-target AEs were reduced with BID dosing.

- Preclinical data showing synergy of poziotinib combined with KRAS inhibitors in $KRAS^{G12C}$ mutant specific cell lines, was presented in a poster titled "Pan-ErbB inhibition enhances activity of $KRAS^{G12C}$ inhibitors in preclinical models of $KRAS^{G12C}$ mutant cancers" at the International Conference on Molecular Targets and Cancer Therapeutics (AACR-NCI-EORTC). The data showed that inhibition of EGFR, HER2, HER3, and HER4 (Pan ErbB) signaling was synergistic when combined with $KRAS^{G12C}$ inhibitors.

Corporate Updates

- As of December 31, 2021, Tom Riga, who had been serving as Chief Commercial and Chief Operating Officer became President and Chief Executive Officer of Spectrum Pharmaceuticals and joined the Board of Directors. On February 23, 2022, Kurt Gustafson, Chief Financial Officer, provided notice of his resignation to pursue other professional opportunities. His last day at the company is March 18, 2022. The company has initiated a selection process to name a new chief financial officer.

- Hanmi Pharmaceutical completed a $20 million strategic equity investment in Spectrum in January 2022, which included revisions to the licensing agreement for eflapegrastim and poziotinib.
- Juhyun Lim was appointed to the company's Board of Directors. Ms. Lim currently serves as President, Global Strategy and Planning at Hanmi Science and Hanmi Pharmaceutical, where she leads the execution of corporate strategy and investment. She also serves as Director, Healthcare Investment at Hanmi Ventures.
- Strategic restructuring with a ~30% staff reduction and ~20-25% reduction in operating cash burn was announced in January 2022 to focus the company's development activities on late-stage assets, poziotinib and eflapegrastim. Further development activity for its early-stage pipeline have been deprioritized.

Three-Month Period Ended December 31, 2021 (All numbers are from Continuing Operations)

GAAP Results

Spectrum recorded net loss of $39.8 million, or $0.26 per basic and diluted share, in the three-month period ended December 31, 2021, compared to net loss of $49.9 million, or $0.36 per basic and diluted share, in the comparable period in 2020. Total research and development expenses were $18.0 million in the quarter, as compared to $47.2 million in the same period in 2020. Selling, general and administrative expenses were $18.9 million in the quarter, compared to $15.7 million in the same period in 2020.

Non-GAAP Results

Spectrum recorded non-GAAP net loss of $26.4 million, or $0.17 per basic and diluted share, in the three-month period ended December 31, 2021, compared to non-GAAP net loss of $28.9 million, or $0.20 per basic and diluted share, in the comparable period in 2020. Non-GAAP research and development expenses were $16.7 million, as compared to $17.1 million in the same period of 2020. Non-GAAP selling, general and administrative expenses were $10.2 million, as compared to $12.3 million in the same period in 2020.

Twelve-Month Period Ended December 31, 2021 (All numbers are from Continuing Operations)

GAAP Results

Spectrum recorded net loss of $158.4 million, or $1.02 per basic and diluted share, in the twelve-month period ended December 31, 2021, compared to net loss of $171.3 million, or $1.38 per basic and diluted share, in the comparable period in 2020. Total research and development expenses were $87.3 million for the year, as compared to $109.4 million in the same period in 2020. Selling, general and administrative expenses were $60.4 million for the year, compared to $60.4 million in the same period in 2020.

Non-GAAP Results

Spectrum recorded non-GAAP net loss of $120.7 million, or $0.78 per basic and diluted share, in the twelve-month period ended December 31, 2021, compared to non-GAAP net loss of $120.9 million, or $0.97 per basic and diluted share, in the comparable period in 2020. Non-GAAP research and development expenses were $79.2 million, as compared to $75.6 million in the same period of 2020. Non-GAAP selling, general and administrative expenses were $42.8 million, as compared to $47.2 million in the same period in 2020.

Cash Position and Guidance

Spectrum reported cash, cash equivalents, and marketable securities of approximately $100.6 million as of December 31, 2021, compared to $180 million at December 31, 2020. In January, the company received a $20 million strategic equity investment from Hanmi. The additional cash, combined with the restructuring, is expected to extend the company's cash runway into 2023.

Conference Call

Thursday, March 17, 2022 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 4573715
International: (973) 796-5077, Conference ID# 4573715

This conference call will also be webcast. Listeners may access the webcast, which will be available on the investor relations page of Spectrum Pharmaceuticals' website: http://investor.sppirx.com/events-and-presentations on March 17, 2022 at 4:30 p.m. Eastern/1:30 p.m. Pacific.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted oncology therapies. Spectrum has a strong track record of successfully executing across the biopharmaceutical business model, from in-licensing and acquiring differentiated drugs, clinically developing novel assets, successfully gaining regulatory approvals and commercializing in a competitive healthcare marketplace. Spectrum has a late-stage pipeline with novel assets that serve areas of unmet need. This pipeline has the potential to transform the company in the near future. For additional information on Spectrum Pharmaceuticals please visit www.sppirx.com.

About the ZENITH20 Clinical Trial

The ZENITH20 study consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) in previously treated NSCLC patients with exon 20 mutations and Cohort 3 (EGFR) in first-line patients have completed enrollment. Cohort 4 (HER2) in first-line NSCLC patients with exon 20 mutations is still enrolling patients. Cohorts 1- 4 are each independently powered for a pre-specified statistical hypothesis and the primary endpoint is objective response rate (ORR). Cohort 5 includes previously treated or treatment-naïve NSCLC patients with EGFR or HER2 exon 20 insertion mutations. Cohort 6 includes NSCLC patients with classical EGFR mutations who progressed while on treatment with first-line osimertinib and developed an additional EGFR mutation. Cohort 7 includes NSCLC patients with a variety of less common mutations in EGFR or HER2 exons 18-21

or the extracellular or transmembrane domains.

Notice Regarding Forward-looking statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These forward-looking statements relate to a variety of matters, including, without limitation, statements that relate to Spectrum's business and its future, including the likelihood and timing of the FDA approval of poziotinib, including the results of the FDA's review of the NDA submission for poziotinib, the significance of the results from Cohort 4 of the ZENITH20 clinical trial and the pre-clinical data showing the synergistic impact of poziotinib when combined with KRAS inhibitors, the outcome of the company's resubmission of its BLA for eflapegrastim, as well as the results of the reinspection of Hanmi's manufacturing facility, the outcome of the company's restructuring efforts, the future potential of Spectrum's existing drug pipeline, the progression of the poziotinib and eflapegrastim development programs and other statements that are not purely statements of historical fact. These forward-looking statements are made on the basis of the current beliefs, expectations, and assumptions of the management of Spectrum and are subject to significant risks and uncertainties that could cause actual results to differ materially from what may be expressed or implied in these forward-looking statements. Risks that could cause actual results to differ include, but are not limited to, the possibility that the different methodologies, assumptions and applications the company utilizes to assess particular safety or efficacy parameters may yield different statistical results, and even if the company believes the data collected from the clinical trials of its product candidates, including poziotinib, are positive, these data may not be sufficient to support approval by the FDA; the possibility that success in early clinical trials, especially if based on a small patient sample, might not result in success in later clinical trials, and other unforeseen events during clinical trials which could cause delays or other adverse consequences; other uncertainties inherent in new product development; the possibility that Spectrum's new and existing drug candidates, if approved, may not be more effective, safer, or more cost-efficient than competing drugs; the company's ability to remediate the deficiencies cited in the CRL for eflapegrastim; and other risks that are described in further detail in the company's reports filed with the Securities and Exchange Commission. The company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law. For a further discussion of risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Spectrum in general, see the risk disclosures in the Annual Report on Form 10-K of Spectrum for the year ended December 31, 2021, 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,	
	2021	**2020**	**2021**	**2020**
Operating costs and expenses:				
Selling, general and administrative	18,891	15,703	60,406	60,357
Research and development	17,962	47,185	87,297	109,377
Total operating costs and expenses	36,853	62,888	147,703	169,734
Loss from continuing operations before other income (expense) and income taxes	(36,853)	(62,888)	(147,703)	(169,734)
Other income (expense):				
Interest income (expense), net	41	125	163	1,342
Other (expense) income, net	(2,943)	12,780	(10,892)	(2,940)

Total other (expense) income	(2,902)	12,905	(10,729)	(1,598)
Loss from continuing operations before income taxes	(39,755)	(49,983)	(158,432)	(171,332)
(Provision) benefit for income taxes from continuing operations	5	75	(4)	60
Loss from continuing operations	$ (39,750)	$ (49,908)	$ (158,436)	$ (171,272)
Income from discontinued operations, net of income taxes	36	10,149	(192)	10,404
Net loss	$ (39,714)	$ (39,759)	$ (158,628)	$ (160,868)
Basic and diluted loss per share:				
Loss per common share from continuing operations	$ (0.26)	$ (0.36)	$ (1.02)	$ (1.38)
Income per common share from discontinued operations	$ 0.00	$ 0.07	$ —	$ 0.08
Net loss per common share, basic and diluted	$ (0.26)	$ (0.29)	$ (1.02)	$ (1.29)
Weighted average shares outstanding, basic and diluted	154,680,363	141,432,302	154,861,704	124,386,545

SPECTRUM PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

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

	December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 88,539	$ 46,009
Marketable securities	12,108	134,016
Accounts receivable, net	—	67
Other receivables	1,028	2,394
Prepaid expenses and other current assets	2,277	4,161
Total current assets	103,952	186,647

Property and equipment, net	455	3,577
Facility and equipment under lease	2,505	2,247
Other assets	4,636	4,327
Total assets	$ 111,548	$ 196,798
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 41,258	$ 43,771
Accrued payroll and benefits	11,971	9,375
Total current liabilities	53,229	53,146
Other long-term liabilities	10,766	9,409
Total liabilities	63,995	62,555
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; 164,502,013 and 146,083,110 issued and outstanding at December 31, 2021 and 2020, respectively	165	146
Additional paid-in capital	1,094,353	1,021,221
Accumulated other comprehensive loss	(3,042)	(1,829)
Accumulated deficit	(1,043,923)	(885,295)
Total stockholders' equity	47,553	134,243
Total liabilities and stockholders' equity	$ 111,548	$ 196,798

Non-GAAP Financial Measures

In this press release, Spectrum reports certain historical results that have not been prepared in accordance with generally accepted accounting principles (GAAP), including non-GAAP selling, general and administrative expenses, non-GAAP research and development expenses, non-GAAP net loss from continuing operations and non-GAAP net loss per share from continuing operations. Non-GAAP financial measures are reconciled to the most directly comparable GAAP financial measures in the tables of this press release and the accompanying footnotes. The non-GAAP financial measures contained herein are a supplement to the corresponding financial measures prepared in accordance with GAAP. The non-GAAP financial measures presented exclude the items summarized in the below table.

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

The non-GAAP financial measures presented herein have certain limitations in that they do not reflect all of the costs associated with the operations of

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

SPECTRUM PHARMACEUTICALS, INC.

Reconciliation of Non-GAAP Adjustments for Condensed Consolidated Statements of Operations

(In thousands, expect per share amounts)

	CONTINUING OPERATIONS ONLY		CONTINUING OPERATIONS ONLY	
	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
(1) GAAP selling, general and administrative	**$ 18,891**	**$ 15,703**	**$ 60,406**	**$ 60,357**
Non-GAAP adjustments to SG&A:				
Stock-based compensation expense	(3,676)	(3,354)	(12,405)	(13,127)
Depreciation expense	(72)	(55)	(278)	(130)
Lease expense	(65)	23	(49)	69
Severance expense	(4,861)	—	(4,861)	—
Non-GAAP selling, general and administrative	**$ 10,217**	**$ 12,317**	**$ 42,813**	**$ 47,169**
(2) GAAP research and development	**$ 17,962**	**$ 47,185**	**$ 87,297**	**$ 109,377**
Non-GAAP adjustments to R&D:				
Stock-based compensation expense	(1,241)	(1,094)	(5,197)	(4,692)
Depreciation expense	(2)	(33)	(8)	(131)
Impairment of second source manufacturer	—	(28,197)	(2,912)	(28,197)
Other R&D milestone payments	—	(750)	—	(750)
Non-GAAP research and development	**$ 16,719**	**$ 17,111**	**$ 79,180**	**$ 75,607**
(3) GAAP net loss from continuing operations	**$ (39,750)**	**$ (49,908)**	**$ (158,436)**	**$ (171,272)**
Non-GAAP adjustments to net loss from continuing operations:				
Adjustments to SG&A and R&D as noted above	9,917	33,460	25,710	46,958

Adjustments to other (income) expense	3,389	(12,379)	12,052	3,521
Adjustments to benefit for income taxes	(5)	(75)	4	(60)
Non-GAAP net loss from continuing operations	**$ (26,449)**	**$ (28,902)**	**$ (120,670)**	**$ (120,853)**
(4) GAAP net loss from continuing operations - per basic and diluted share	$ (0.26)	$ (0.35)	$ (1.02)	$ (1.38)
Non-GAAP net loss from continuing operations - per basic and diluted share	$ (0.17)	$ (0.20)	$ (0.78)	$ (0.97)
Weighted average shares outstanding, basic and diluted	154,680,363	141,432,302	154,861,704	124,386,545

(1) Non-GAAP selling, general and administrative expenses (from continuing operations): These amounts reflect adjustments to reverse allocated operating expenses for certain non-cash items (including stock-based compensation, depreciation, lease and severance expense). We believe the resulting non-GAAP SG&A value is reflective of the period-over-period success of our administrative expense control and more indicative of our normalized SG&A expense trends.

(2) Non-GAAP research and development expenses (from continuing operations): These amounts reflect adjustments to reverse allocated operating expenses for certain non-cash items (including stock-based compensation and depreciation), as well as other R&D milestone achievement payments, and impairment of second source manufacturer that we record to this expense caption. We believe this resulting non-GAAP R&D value is more indicative of our normalized R&D expense trends.

(3) Non-GAAP net loss from continuing operations: These amounts reflect all non-GAAP adjustments described in (1) and (2) above, plus other non-cash and/or non-recurring items, including: (i) adjustments to reverse the impact of income taxes; (ii) reversal of foreign exchange gains and losses (non-cash); (iii) reversal of the mark-to-market adjustment (non-cash) on our equity securities holdings; and (iv) reversal of realized gain recorded on the sales of our equity holdings.

(4) Non-GAAP net loss from continuing operations - per basic and diluted share: These amounts reflect all non-GAAP adjustments in (1) through (3) above to present our overall non-GAAP financial results for each period on a per-share basis.

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