



## Spectrum Pharmaceuticals Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 12, 2022

*Resubmitted eflapegrastim BLA accepted for review by the FDA, PDUFA date September 9, 2022*

*Pozitotinib NDA under review by FDA with PDUFA date of November 24, 2022 and will be discussed at ODAC meeting in September*

*Positive pozitotinib 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)--May 12, 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 ended March 31, 2022 and provided a corporate update.

"We anticipate FDA approvals later this year for pozitotinib and eflapegrastim. In the first quarter, we initiated a confirmatory study and presented additional positive scientific data for pozitotinib. The resubmitted BLA for eflapegrastim was also accepted for review by the FDA," said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. "We are proud of the progress we've made toward our core business objectives and we remain dedicated to making a meaningful difference in the lives of cancer patients."

### Pipeline Updates

#### ***Eflapegrastim, a novel long-acting G-CSF***

- The U.S. Food and Drug Administration (FDA) has accepted Spectrum's resubmitted Biologics License Application (BLA) for eflapegrastim with a Prescription Drug User Fee Act (PDUFA) date of September 9, 2022. The company is working with its partner, Hanmi Pharmaceutical, to support the FDA regulatory review process.

#### ***Pozitotinib, a Pan ErbB inhibitor targeting HER2 exon20 mutations***

- The New Drug Application (NDA) for pozitotinib is under active review at the FDA with 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 PDUFA date of November 24, 2022. There is currently no FDA approved therapy for patients with NSCLC harboring HER2 exon 20 insertion mutations.
- A study for pozitotinib has been initiated to confirm the clinical benefit seen in Cohort 2, as required for an accelerated approval. The trial, Study SPI-POZ-301 (PINNACLE), is designed to enroll 268 patients with previously treated NSCLC harboring HER2 exon 20 mutations. Patients are being randomized 2-to-1 into one of two treatment arms using 8mg of pozitotinib orally administered BID (twice daily) versus 75mg/m<sup>2</sup> of docetaxel administered intravenously every three weeks. The primary endpoint will be Progression Free Survival.
- FDA's Oncologic Drugs Advisory Committee (ODAC) is scheduled to review pozitotinib for the treatment of patients with previously treated locally advanced or metastatic NSCLC harboring HER2 exon 20 insertion mutations. The fall ODAC meeting is being held September 22-23, 2022. ODAC is an independent panel of experts that evaluates data concerning the efficacy and safety of marketed and investigational products for use in the treatment of cancer and makes appropriate recommendations to the FDA. As usual, the final decision regarding the approval of the product is made by the FDA solely, and the recommendations by the panel are non-binding.
- Data from Cohort 4 of the ZENITH20 study in patients with treatment-naïve NSCLC harboring HER2 exon 20 insertion mutations were presented in an oral session 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%, 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 adverse events (AEs) were meaningfully reduced with BID dosing.
- The company presented a poster on the predictive ability of circulating tumor DNA (ctDNA) in pozitotinib-treated patients with NSCLC harboring HER2 exon 20 insertion mutations at the American Association for Cancer Research (AACR)

Annual Meeting. Preliminary results suggest that decreases in plasma ctDNA during poziotinib therapy correlate with clinical response in patients with advanced NSCLC with HER2 exon 20 insertion mutations. Additional data from this study will be presented at the 2022 ASCO Annual Meeting in early June.

#### **Corporate Updates**

- Nora E. Brennan was named Chief Financial Officer effective May 25, 2022. Ms. Brennan has served on Spectrum's Board of Directors since December 2020 and as Chair of the Audit Committee. She will relinquish her board duties to assume her new senior leadership role. Most recently, Ms. Brennan served as Chief Financial Officer of Fore Biotherapeutics, a developer of cancer therapies driven by functional genomics. Prior to Fore, she served as Chief Financial Officer at TELA Bio, Inc. and as Senior Vice President of Treasury and Investor Relations at Integra Life Sciences Holdings Corporation.
- Hanmi Pharmaceutical completed a \$20 million strategic equity investment in Spectrum in January 2022, which included revisions to the licensing and supply agreements for eflapegrastim and poziotinib.
- Two new members of the Board of Directors have been named. In March, Juhyun Lim was appointed to the Board. 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. In May, Spectrum named Brittany Bradrick to the Board and she will succeed Ms. Brennan as Chair of the Audit Committee. Ms. Bradrick currently serves as Chief Financial Officer of Neurelis, Inc. Ms. Bradrick is a seasoned executive with 25 years of experience in the life sciences sector including in the areas of mergers and acquisitions, investment banking, finance, strategy and corporate development.
- A strategic restructuring with a ~30% staff reduction and ~20-25% reduction in operating cash burn was initiated in January 2022 to focus the company's development activities on its late-stage assets, poziotinib and eflapegrastim. Development activities for the early-stage pipeline has been deprioritized.

#### ***Three-Month Period Ended March 31, 2022 (All numbers are from Continuing Operations and are approximate)***

##### **GAAP Results**

Spectrum recorded a net loss of \$15.4 million, or a \$0.09 loss per basic and diluted share, in the three-month period ended March 31, 2022, compared to a net loss of \$35.7 million, or a \$0.25 loss per basic and diluted share, in the comparable period in 2021. Total research and development expenses were \$4.2 million in the quarter, as compared to \$19.4 million in the same period in 2021. Selling, general and administrative expenses were \$9.9 million in the quarter, compared to \$14.3 million in the same period in 2021.

##### **Non-GAAP Results**

Spectrum recorded a non-GAAP net loss of \$9.6 million, or a \$0.06 non-GAAP loss per basic and diluted share, in the three-month period ended March 31, 2022, compared to a non-GAAP net loss of \$29.4 million, or a \$0.20 non-GAAP loss per basic and diluted share, in the comparable period in 2021. Non-GAAP research and development expenses were \$2.1 million, as compared to \$18.0 million in the same period of 2021. Non-GAAP selling, general and administrative expenses were \$7.5 million, as compared to \$11.5 million in the same period in 2021.

##### **Cash Position and Guidance**

In January, the company received a \$20 million strategic equity investment from Hanmi Pharmaceutical. Together with this strategic investment, Spectrum ended the quarter with cash, cash equivalents, and marketable securities of approximately \$89.2 million. The additional cash, combined with the restructuring, is expected to extend the company's cash runway into 2023.

##### **Conference Call**

Thursday, May 12, 2022 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 2863606

International: (973) 796-5077, Conference ID# 2863606

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: <https://investor.sppirx.com/events-and-presentations> on May 12, 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](http://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. Cohort 3 (EGFR) in first-line patients and Cohort 4 (HER2) in first-line NSCLC patients with exon 20 mutations have completed enrollment. 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 and eflapegrastin, the results of the confirmatory study for poziotinib, the results of the ODAC’s review of poziotinib and related recommendation to the FDA, the speed of enrollment in the company’s remaining ZENITH20 Cohorts, whether additional data for poziotinib-treated patients with NSCLC harboring HER20 exon 20 insertion mutations will continue to demonstrate similar results to the preliminary data suggesting the predictive ability of circulating tumor DNA (ctDNA), the future potential of Spectrum’s existing drug pipeline, the results of the company’s strategic restructuring, the length of the company’s cash runway 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 uncertainties inherent in new product development, including clinical trial results and additional analysis of existing preclinical and clinical data, the possibility that Spectrum’s new and existing drug candidates, including poziotinib, may not ultimately prove to be safe or effective, 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 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.® is a registered trademark of Spectrum Pharmaceuticals, Inc and its affiliates. REDEFINING CANCER CARE™ and the Spectrum Pharmaceuticals’ logos are trademarks owned by Spectrum Pharmaceuticals, Inc. Any other trademarks are the property of their respective owners.*

© 2022 Spectrum Pharmaceuticals, Inc. All Rights Reserved

**SPECTRUM PHARMACEUTICALS, INC.**

**Condensed Consolidated Statements of Operations**

(In thousands, except share and per share amounts)

(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2022</b>	<b>2021</b>
Operating costs and expenses:		
Selling, general and administrative	\$ 9,870	\$ 14,315
Research and development	4,193	19,371
Total operating costs and expenses	14,063	33,686
Loss from continuing operations before other income (expense) and income taxes	(14,063 )	(33,686 )
Other income (expense):		
Interest income, net	11	84

Other expense, net	(1,334	)	(2,081	)
Total other expense	(1,323	)	(1,997	)
Loss from continuing operations before income taxes	(15,386	)	(35,683	)
Benefit for income taxes from continuing operations	(16	)	7	
Loss from continuing operations	\$ (15,402	)	\$ (35,676	)
Loss from discontinued operations, net of income taxes	(40	)	(21	)
Net loss	\$ (15,442	)	\$ (35,697	)

Basic and diluted loss per share:

Loss from continuing operations	\$ (0.09	)	\$ (0.25	)
Loss from discontinued operations	\$ 0.00		\$ 0.00	
Net loss per share, basic and diluted	\$ (0.09	)	\$ (0.25	)

Weighted average shares outstanding, basic and diluted	169,735,019	145,371,657
--	-------------	-------------

**SPECTRUM PHARMACEUTICALS, INC.**

**Condensed Consolidated Balance Sheets**

(In thousands, except share and par value amounts)

(Unaudited)

	<b>March 31, 2022</b>	<b>December 31, 2021</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 78,679	\$ 88,539
Marketable securities	10,535	12,108
Other receivables	639	1,028
Prepaid expenses and other current assets	3,328	2,277
Total current assets	93,181	103,952
Property and equipment, net	418	455

Facility and equipment under lease	2,107	2,505
Other assets	4,348	4,636
Total assets	\$ 100,054	\$ 111,548

#### LIABILITIES AND STOCKHOLDERS' EQUITY

##### Current liabilities:

Accounts payable and other accrued liabilities	\$ 32,575	\$ 41,258
Accrued payroll and benefits	6,633	11,971
Total current liabilities	39,208	53,229

Other long-term liabilities	5,590	10,766
-----------------------------	-------	--------

Total liabilities	44,798	63,995
-------------------	--------	--------

##### 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; 178,827,485 and 164,502,013 issued and outstanding at March 31, 2022 and December 31, 2021, respectively	179	165
Additional paid-in capital	1,117,350	1,094,353
Accumulated other comprehensive loss	(2,908 )	(3,042 )
Accumulated deficit	(1,059,365 )	(1,043,923 )
Total stockholders' equity	55,256	47,553
Total liabilities and stockholders' equity	\$ 100,054	\$ 111,548

#### **Non-GAAP Financial Measures (from Continuing Operations)**

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 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 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, except share and per share amounts)

	<b>CONTINUING OPERATIONS ONLY</b>	
	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>(1) GAAP selling, general and administrative</b>	<b>\$ 9,870</b>	<b>\$ 14,315</b>
Non-GAAP adjustments to SG&A:		
Stock-based compensation expense	(1,905 )	(2,799 )
Depreciation expense	(71 )	(63 )
Lease expense	39	23
Severance expense	(408 )	—
<b>Non-GAAP selling, general and administrative</b>	<b>\$ 7,525</b>	<b>\$ 11,476</b>
<b>(2) GAAP research and development</b>	<b>\$ 4,193</b>	<b>\$ 19,371</b>
Non-GAAP adjustments to R&D:		
Stock-based compensation expense	(1,090 )	(1,414 )
Depreciation expense	(2 )	(2 )
Severance expense	(1,040 )	—
<b>Non-GAAP research and development</b>	<b>\$ 2,061</b>	<b>\$ 17,955</b>
<b>(3) GAAP net loss from continuing operations</b>	<b>\$ (15,402 )</b>	<b>\$ (35,676 )</b>
Non-GAAP adjustments to net loss from continuing operations:		
Adjustments to SG&A and R&D, as noted above	4,477	4,255
Adjustments to other expense	1,329	2,072
Adjustments to benefit for income taxes	16	(7 )
<b>Non-GAAP net loss from continuing operations</b>	<b>\$ (9,580 )</b>	<b>\$ (29,356 )</b>

