

# Spectrum Pharmaceuticals

A Biopharmaceutical Company Developing Targeted and Novel Therapies in Oncology

Tom Riga | CEO



### Safe Harbor Statement

This presentation contains 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 our business and its future, our strategy, the success of our drug candidates, the safety and efficacy of our drug products, product approvals, market potential, product sales, revenue, development, regulatory and approval timelines, product launches, product acquisitions, capital resources 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.

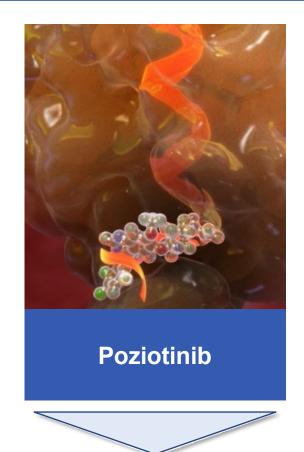
Risks that could cause actual results to differ include the possibility that our existing and new drug candidates may not prove safe or effective, the possibility that our existing and new drug candidates may not receive approval from the FDA and other regulatory agencies in a timely manner or at all, 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 price and other competitive pressures may make the marketing and sale of our drugs not commercially feasible, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our lack of sustained revenue history, our limited experience in establishing strategic alliances, our limited marketing experience, our customer concentration, the possibility for fluctuations in customer orders, evolving market dynamics, our dependence on third parties for clinical trials, manufacturing, distribution, information and quality control and other risks that are described in further detail in the Company's reports filed with the Securities and Exchange Commission. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this presentation except as required by law.



## Pipeline & Key Milestones







ODAC: September 22<sup>nd</sup> PDUFA: November 24<sup>th</sup>



## Poziotinib

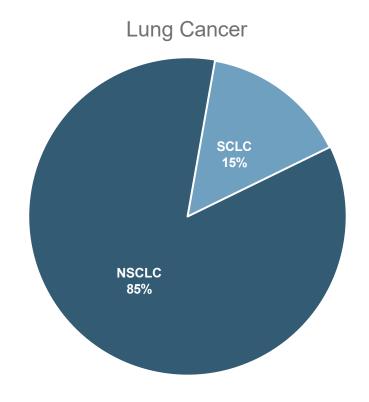


Pan ErbB inhibitor targeting mutations in lung cancer

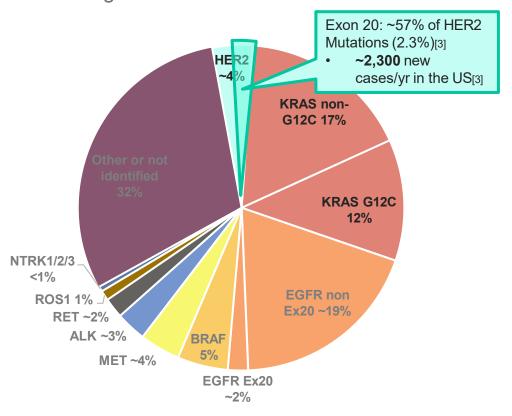
NDA submission based on positive study results in patients with previously treated metastatic NSCLC harboring HER2 exon 20 insertion mutations



## **NSCLC Mutations**



#### Oncogenetic driver mutations in NSCLC



- 1 Thai et al, Lancet 2021
- 2 Trinity, US Epi of NSCLC mutations
- 3 Robichaux 2019; Eng 2016; Patil 2020; Li 2018; Buttita 2006

## **ZENITH20 Registrational Cohorts**

#### Registrational Studies

### Cohort 1 (n=115)

Previously treated NSCLC with EGFR exon 20 insertions Fully Enrolled

## Cohort 2 (n=90)

Previously treated NSCLC with HER2 exon 20 insertions Fully Enrolled

#### **Primary Endpoint**

• Objective Response Rate

#### **Secondary Endpoints**

- Disease Control Rate
- Duration of Response
- Safety & Tolerability

#### **Key Eligibility Criteria**

- NSCLC EGFR or HER2 exon20 insertions
- Point mutations, including T790M, are not allowed
- · Brain mets are allowed if stable

#### Cohort 3 (n=79)

First-line NSCLC with **EGFR** exon 20 insertions **Fully Enrolled** 

#### Cohort 4 (n=70)

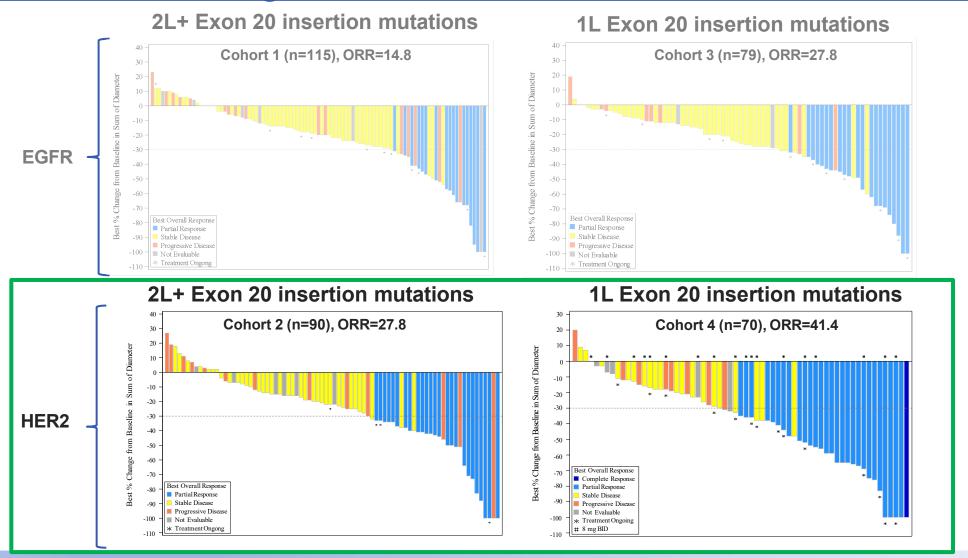
First-line NSCLC with **HER2** exon 20 insertions 16mg QD/8mg BID **Fully Enrolled** 

#### **Exploratory cohorts:**

- Cohort 5: Dose exploration of poziotinib in patients with previously-treated or treatment-naïve NSCLC with EGFR or HER2 mutations randomized to either QD or BID dosing
- Cohort 6: Patients with acquired EGFR mutations who progressed on first-line osimertinib
- Cohort 7: Patients with atypical EGFR or HER2 activating mutations



# Poziotinib has Demonstrated Clinical Activity Across ZENITH20 Registrational Cohorts





## NDA Submission Based on Positive Cohort 2 Results

	Intent to treat (N=90) N (%)
Objective Response Rate (ORR) 95% Confidence Interval	27.8% (18.9 – 38.2%)
Disease Control Rate (DCR=CR+PR+SD)	70%
Duration of Response, Median (months)	5.1
Progression-free Survival, Median (months)	5.5

Cohort 2 met Primary Efficacy Endpoint: Observed lower bound of 18.9% exceeded the pre-specified lower bound of 17%



## Safety Profile for Cohort 2 In-line with TKIs

- Cohort 2 starting dose 16 mg QD
- Safety profile was in-line with the type of adverse events seen with other second-generation EGFR TKIs
- Grade 3 incidence of rash was 30%
- Grade 3 incidence of diarrhea was 26%
- > 11 patients (12%) permanently discontinued study due to adverse events



## Exposure and Safety of HER2 First-line

	QD (n=48)	BID (n=22)	Total (N=70)
Drug interruption, n (%)	43 (90%)	15 (68%)	58 (83%)
Median days to first interruption	19	26	23
Dose reduction, n (%)	38 (79%)	14 (64%)	52 (74%)
Median days to first reduction	36	33	36
Grade ≥3 TRAEs of special			
interest, n (%)			
Diarrhea	7 (15%)	3 (14%)	10 (14%)
Rash	17 (35%)	4 (18%)	21 (30%)
Stomatitis / Mucosal	10 (21%)	3 (14%)	13 (19%)
Inflammation			
Paronychia	4 (8%)	1 (5%)	5 (7%)
Pneumonitis	1 (2%)	1 (5%)	2 (3%)

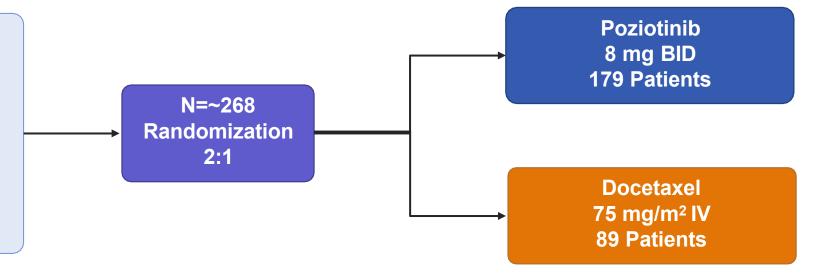
Grade 4 TRAEs were reported in 2 patients in the BID cohort (*hypokalemia*, *hyponatremia*). MedDRA preferred terms shown.



## Global Confirmatory Study Initiated (PINNACLE)

Phase 3, randomized, two-arm, active-control, open label, global-multicenter study

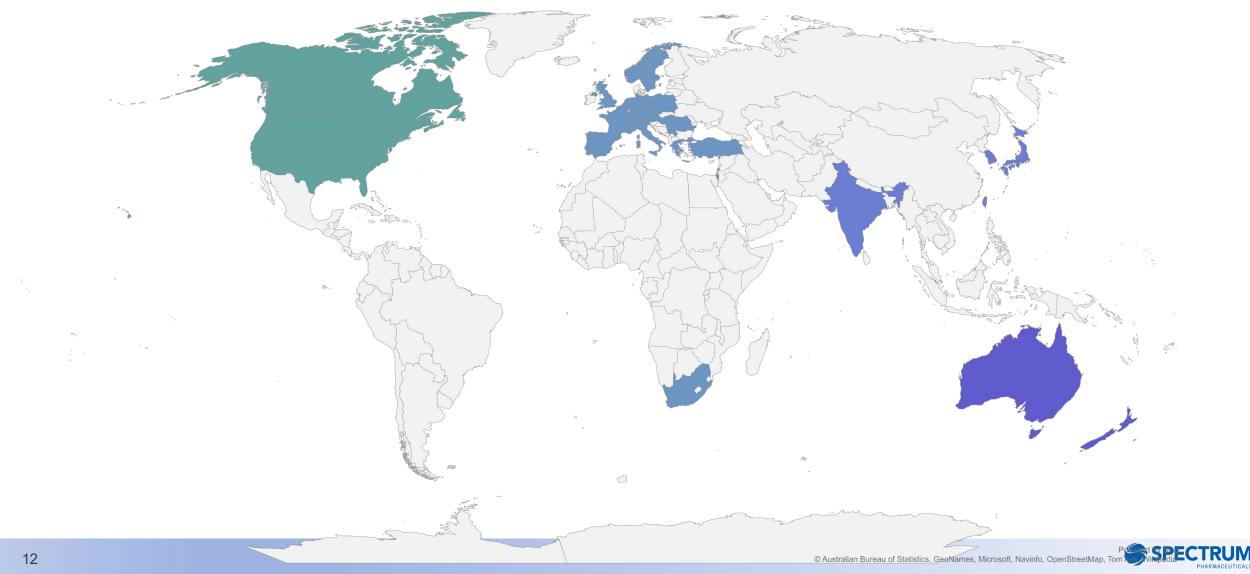
- Advanced or metastatic NSCLC
   harboring HER2 Exon 20 mutations
- Baseline imaging
- Genotyping Report from either tissue or plasma



- Primary Objective: PFS
- Secondary Objectives: OS, ORR, DCR, Safety & tolerability
- Exploratory Objective: Circulating ctDNA in subset of patients



## Global Confirmatory Study with 100-150 Sites



## Poziotinib Summary



Review is under a Fast-Track Designation



NDA accepted based on the positive results in previously treated NSCLC patients harboring HER2 exon 20 insertion mutations



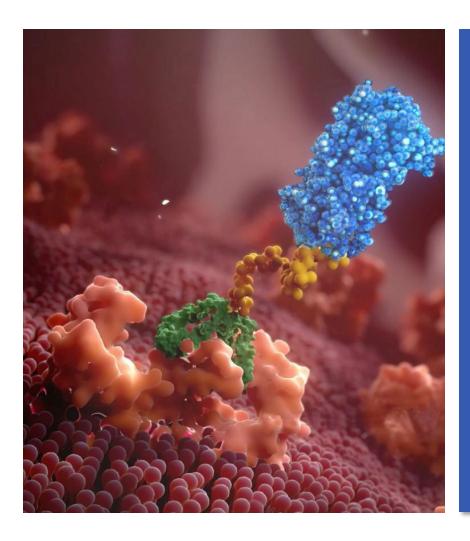
ODAC Meeting September 22, 2022



PDUFA date November 24, 2022



## Eflapegrastim

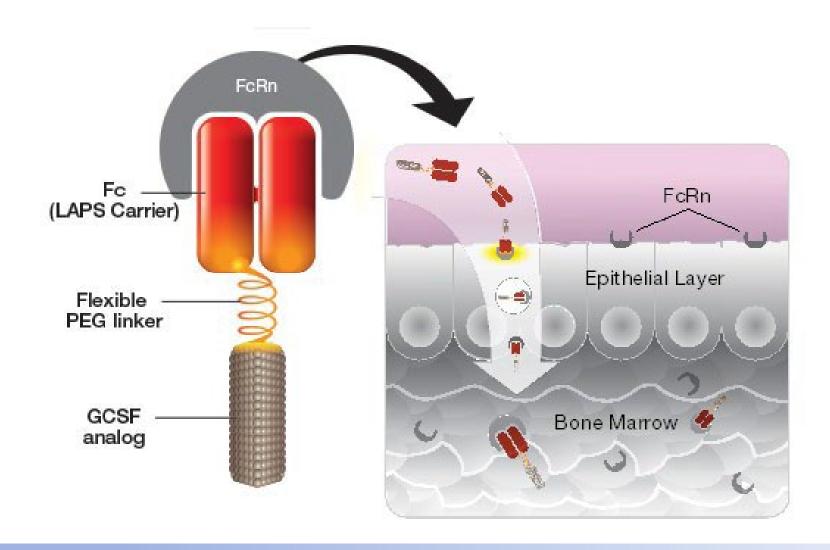


Novel LA-GCSF developed with proprietary LAPSCOVERY technology

BLA submission based on two large phase 3 head-to-head non-inferiority studies vs. pegfilgrastim (n=643)



# Eflapegrastim is a Novel Product with Unique Molecular Structure





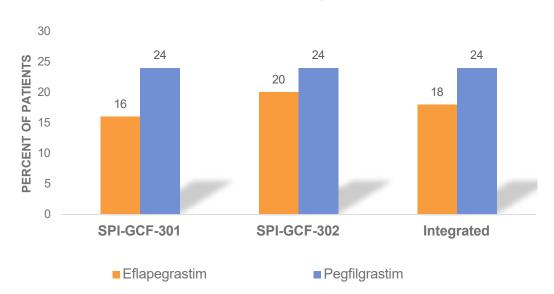
# Eflapegrastim Demonstrated an Effect on Incidence and Duration of Severe Neutropenia

Two Phase 3 Fixed Dose Non-inferiority Studies with Eflapegrastim and Pegfilgrastim:

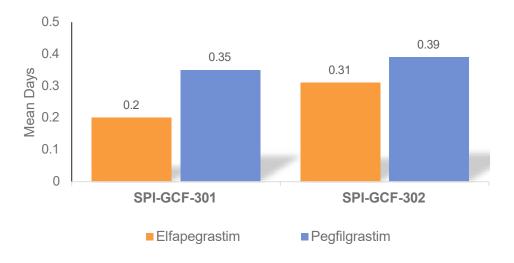
ADVANCE-301 (N=406) & RECOVER-302 (N=237)

**Primary Endpoint: Duration of Severe Neutropenia** 

#### Incidence of SN in Cycle 1

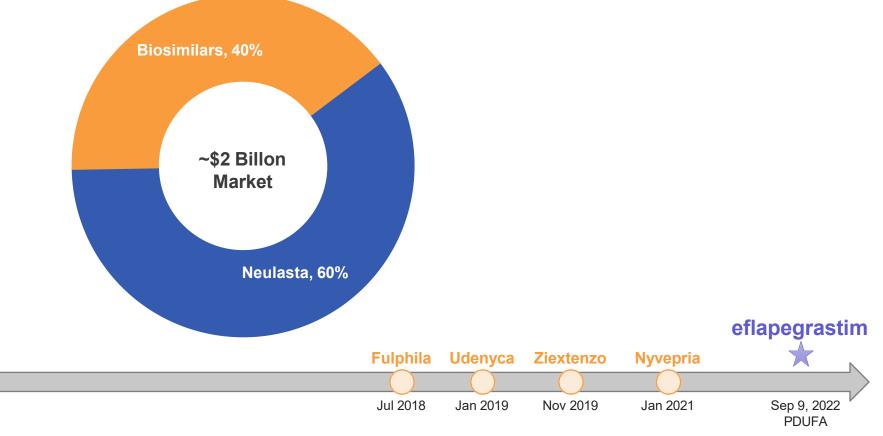


#### **Duration of SN in Cycle 1**



# The LA-GCSF Market Presents a Compelling Opportunity

Eflapegrastim will be the first new novel LA-GCSF in more than 20 years



Product Launch

Neulasta

Feb 2002

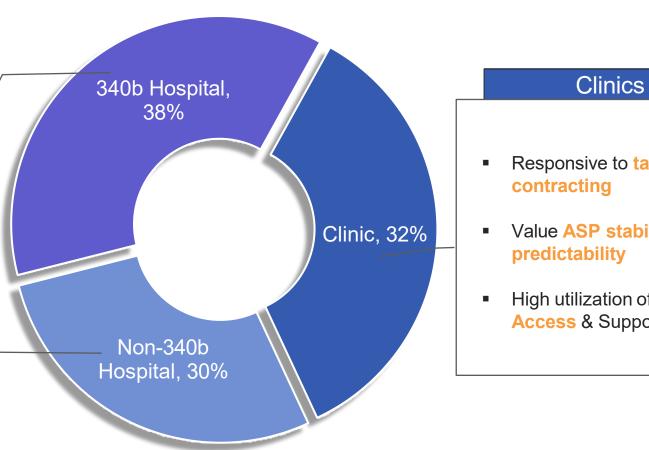
## LA-GCSF Business Segmentation

#### 340b Hospitals

- Pass through status impacts 340b reimbursement
  - ASP + 6% vs. ASP 22.5%

#### Non-340b Hospitals

Largely acquisition cost sensitive



- Responsive to tailored
- Value ASP stability &
- High utilization of Patient **Access** & Support Programs



### Commercial Effectiveness

## Efficacious & Safe



Unique clinical profile with proven safety and efficacy

# Compelling Value Proposition



**Tailored** contracting & **independent** reimbursement

# Access and Reimbursement



Prepared to partner with providers to ensure eflapegrastim is an available option

# **Exceptional Customer Support**



Best in class support programs with fully integrated field team



## Cash Runway into 2023

Cash and marketable securities as of June 30, 2022:

\$68M

Q2 2022 Operating Expenses:

\$25.4M

Q2 2022 Net Loss:

(\$29M)

Weighted Average Shares Outstanding as of June 30, 2022:

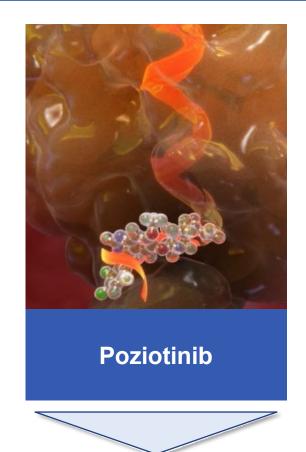
175.6M



## Pipeline & Key Milestones







ODAC: September 22<sup>nd</sup>
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#### SPECTRUM PHARMACEUTICALS, INC.

#### **Condensed Consolidated Statements of Operations**

(In thousands, except share and per share amounts) (Unaudited)

	Three Months Ended June 30.			Six Months Ended June 30.				
		2022		2021		2022		2021
Operating costs and expenses:								
Selling, general and administrative	\$	9,385	\$	14,957	\$	19,255	\$	29,272
Research and development		16,007		29,114		20,200		48,485
Total operating costs and expenses		25,392		44,071		39,455		77,757
Loss from continuing operations before other income (expense) and income taxes		(25,392)		(44,071)		(39,455)		(77,757)
Other income (expense):								
Interest income, net		117		26		128		110
Other expense, net		(3,757)		(5,876)	_	(5,091)		(7,957)
Total other expense		(3,640)		(5,850)	_	(4,963)	_	(7,847)
Loss from continuing operations before income taxes		(29,032)		(49,921)		(44,418)		(85,604)
Provision for income taxes from continuing operations		(13)		(16)		(29)	_	(9)
Loss from continuing operations		(29,045)		(49,937)		(44,447)		(85,613)
Loss from discontinued operations, net of income taxes		(3)		(195)		(43)		(216)
Net loss	\$	(29,048)	\$	(50,132)	\$	(44,490)	\$	(85,829)
Basic and diluted loss per share:								
Loss from continuing operations	\$	(0.17)	\$	(0.32)	\$	(0.26)	\$	(0.57)
Loss from discontinued operations	\$	(0.00)	\$	(0.00)	\$	(0.00)	\$	(0.00)
Net loss per share, basic and diluted	\$	(0.17)	\$	(0.32)	\$	(0.26)	\$	(0.57)
Weighted average shares outstanding, basic and diluted		175,566,757		155,243,402		172,558,831		150,334,548

#### SPECTRUM PHARMACEUTICALS, INC.

#### Condensed Consolidated Balance Sheets

(In thousands, except share and par value amounts)  $(\mbox{Unaudited})$ 

		June 30, 2022	December 31, 2021		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	25,512	\$	88,539	
Marketable securities		42,447		12,108	
Other receivables		608		1,028	
Prepaid expenses and other current assets		5,012		2,277	
Total current assets		73,579		103,952	
Property and equipment, net		347		455	
Facility and equipment under lease		1,703		2,505	
Other assets		3,800		4,636	
Total assets	\$	79,429	\$	111,548	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable and other accrued liabilities	s	33.123	s	41.258	
Accrued payroll and benefits		7,918		11,971	
Total current liabilities		41,041		53,229	
Other long-term liabilities		4,946		10,766	
Total liabilities		45.987		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; 184,870,273 and 164,502,013 issued and outstanding at June 30, 2022 and December 31, 2021, respectively		185		165	
Additional paid-in capital		1,124,625		1,094,353	
Accumulated other comprehensive loss					
Accumulated deficit		(2,955)		(3,042)	
		(1,088,413)		(1,043,923)	
Total stockholders' equity		33,442		47,553	
Total liabilities and stockholders' equity	\$	79,429	\$	111,548	