# Midyear 2025 Biopharma Recap

H1 2025



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Tariffs, Market Access, Commercial Challenges, and more



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Based on region, therapeutic area, company size & phase of development



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Regional overview of upcoming trials

\*Plans disclosed in H1 2025 with start date after June 30, 2025



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Quarterly Comparison of Newly Launched Biotechs







## Introduction

The first half of 2025 presented a dual narrative for the biopharma sector. Internally, companies advanced clinical pipelines and executed on commercial strategies. Externally, however, the industry faced a complex operating environment marked by geopolitical pressures, shifting consumer sentiment, and an intricate regulatory landscape.

With new trade policies now taking effect, the impact of tariffs on supply chains and financial outlooks is moving from a hypothetical risk to a tangible reality. As these developments crystallize in the second half of the year, understanding the strategic responses will be critical for all industry stakeholders.

Fuelled by data directly sourced from Zymewire, this report delivers an inside look at the companies driving innovation in drug development. For the first time, this recap is enriched with direct executive commentary from Q2 earnings calls, a new layer of qualitative insight now integrated into our system.

By analyzing the trends shaping biopharma's future, we aim to provide sales and business development teams with the nuanced insights needed to navigate an industry that refuses to stand still. Let's dive in.



# Midyear 2025 Biopharma Recap

# Earnings Calls

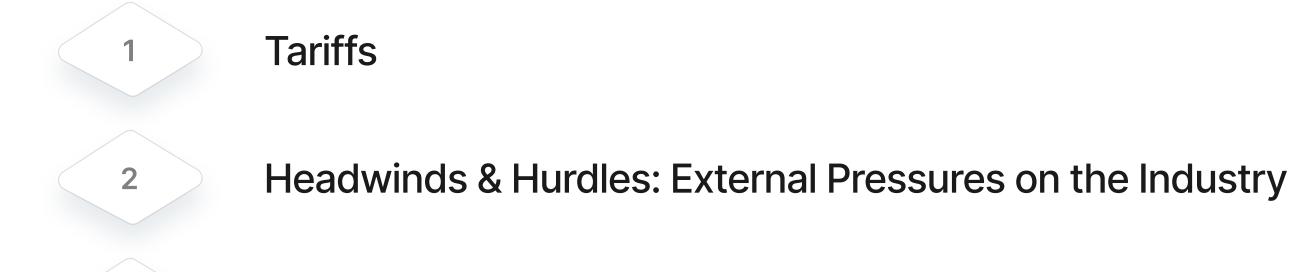




# From the Board: Unpacking Executive Commentary

For the first time, this report features insights pulled directly from biopharma executives themselves. This section leverages our newest data integration of Q2 earnings call transcripts to uncover the qualitative story behind the industry's strategic moves.

By analyzing the commentary of leaders on the front lines, we can add a crucial layer of context to the trends shaping the biopharma landscape. This unique perspective reveals not just what is happening, but why, providing a deeper understanding of the opportunities and challenges ahead.



The Financial Balancing Act

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## **Tariffs**

Geopolitical trade policies, particularly tariffs, have emerged as a significant factor creating both direct financial headwinds and strategic shifts in manufacturing and supply chain management.

- **Direct Financial Impact:** Several companies are now incorporating the direct cost of tariffs into their financial guidance. Bioventus has absorbed a \$5 million headwind from tariffs and foreign exchange, while Evolus has factored in a 15% tariff on its French-sourced Evolysse filler, noting the impact is manageable but real.
- **U.S. Manufacturing as a Strategic Advantage:** Companies with significant U.S.-based manufacturing are highlighting their resilience to tariffs. Amneal Pharmaceuticals notes it is "least impacted" due to its large domestic footprint, while Aquestive Therapeutics and Catalyst Pharmaceuticals view their U.S. operations as a key defense against supply chain disruptions and import duties.
- **Proactive Supply Chain Management:** The threat of tariffs is prompting companies to proactively manage inventory and supply chains. BioNTech, which manufactures KIMMTRAK in Europe, is mitigating potential immediate impact by holding 18 months of inventory in the United States.
- **Uncertainty and Near-Term Impact:** For many, the situation remains fluid and difficult to forecast, with Kyowa Kirin expressing it is having a "very difficult time" modeling the impact due to a lack of detail. This uncertainty is compounded by the timing of the financial effects; as Bioventus clarified, "most of the tariff headwinds will be in the back half of the year," suggesting the full financial impact for many companies will crystallize in the coming months. The broader strategic implication, as articulated by Amneal, is a push to bring critical drug manufacturing back to the U.S. for national security, a move that could reshape the industry's global footprint.

Tariffs have shifted from a hypothetical risk to a tangible line item impacting financial forecasts for the second half of the year. The industry is deploying a range of defensive strategies in response, from stockpiling inventory to highlighting the resilience of domestic manufacturing. More than just a near-term cost, these trade policies are acting as a catalyst, accelerating a strategic re-evaluation of global supply chains and the long-term value of onshoring critical manufacturing.





## **Tariffs**

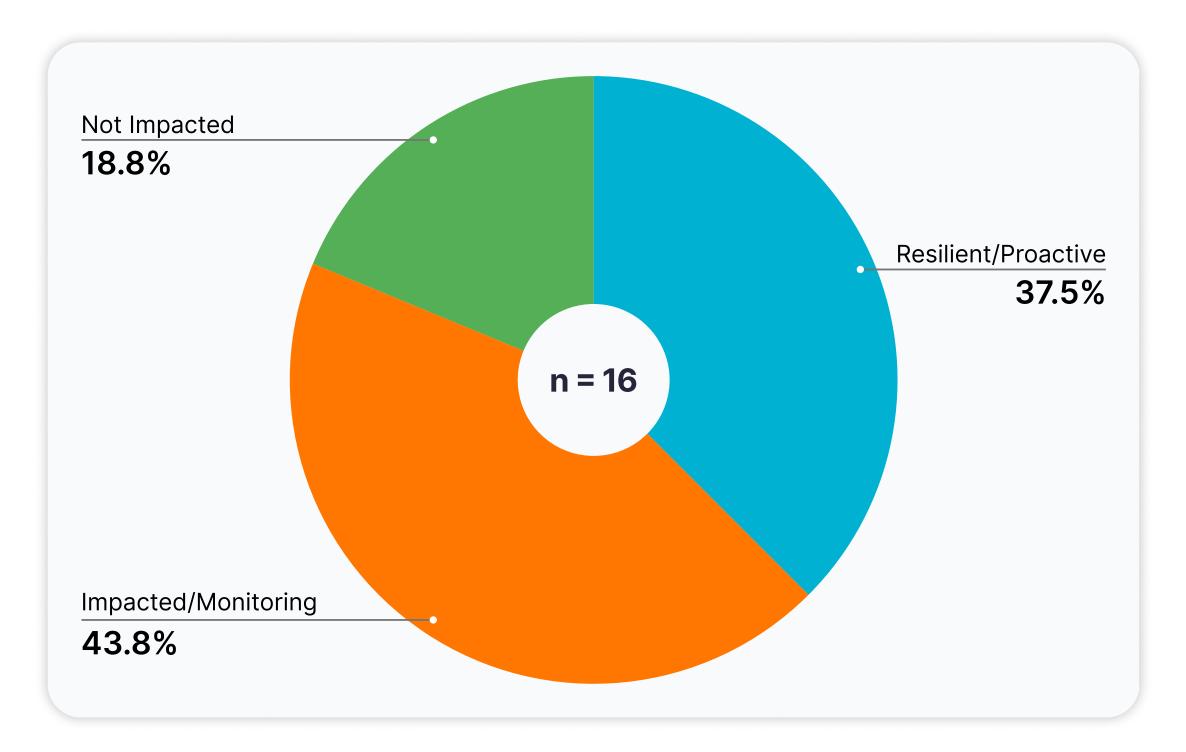
This chart provides a sentiment analysis of executive commentary on tariffs from Q2 earnings calls. Each company's stated position has been categorized based on their strategic response:

- Resilient/Proactive: Companies highlighting defensive strategies, such as domestic manufacturing or proactive supply chain management.
- Impacted/Monitoring: Companies acknowledging a direct financial impact or expressing uncertainty while actively monitoring the situation.
- Not Impacted: Companies stating they are not affected by current or proposed tariffs.

#### **Methodology Note**



→ Analysis is based on a random sample of 100 Q2 2025 earnings call transcripts. Of the companies sampled, **16** mentioned this topic.









# Headwinds & Hurdles: External Pressures on the Industry

The industry faces various external pressures, including shifts in consumer behavior, challenges in market access, and the impact of the broader geopolitical environment.

- **Consumer Sentiment in Aesthetics:** The U.S. aesthetic toxin market experienced a significant downturn, with Evolus's Jeuveau seeing its first year-over-year decrease due to a "sharp reduction in consumer sentiment" and "broad softness" across the market. This reflects broader macroeconomic pressures and consumer discretionary spending challenges, particularly for certain income brackets.
- **European Market Access**: European market access for advanced therapies remains a methodological challenge, with a "substantial proportion" of CAR T products not launched due to economic viability and uncertainties around regulatory processes.
- Competitive & Pricing Pressures: Companies are also adapting to competitive pricing pressures and the entry of generics, as seen with Amarin's VASCEPA, Assertio's Indocin, and Catalyst Pharma's FYCOMPA.
- **Restructuring and Geopolitical Strategy:** In response to a "challenging and extremely volatile macro environment," some companies like Hansa Biopharma have undertaken restructuring to reduce annual burn rates and streamline operations. Emergent highlights its North American-centric manufacturing model as a strategic advantage for a durable supply chain in the face of geopolitical shifts. NATO's decision to increase defense spending is seen as a positive signal for sustained demand for medical countermeasures.

Ultimately, these external factors are testing corporate agility. While some companies are directly impacted by consumer spending and market access hurdles, others are proactively restructuring and leveraging their operational footprint as a strategic shield. This highlights a clear trend towards building resilience in an unpredictable global environment.





## Headwinds & Hurdles: Macroeconomic Environment

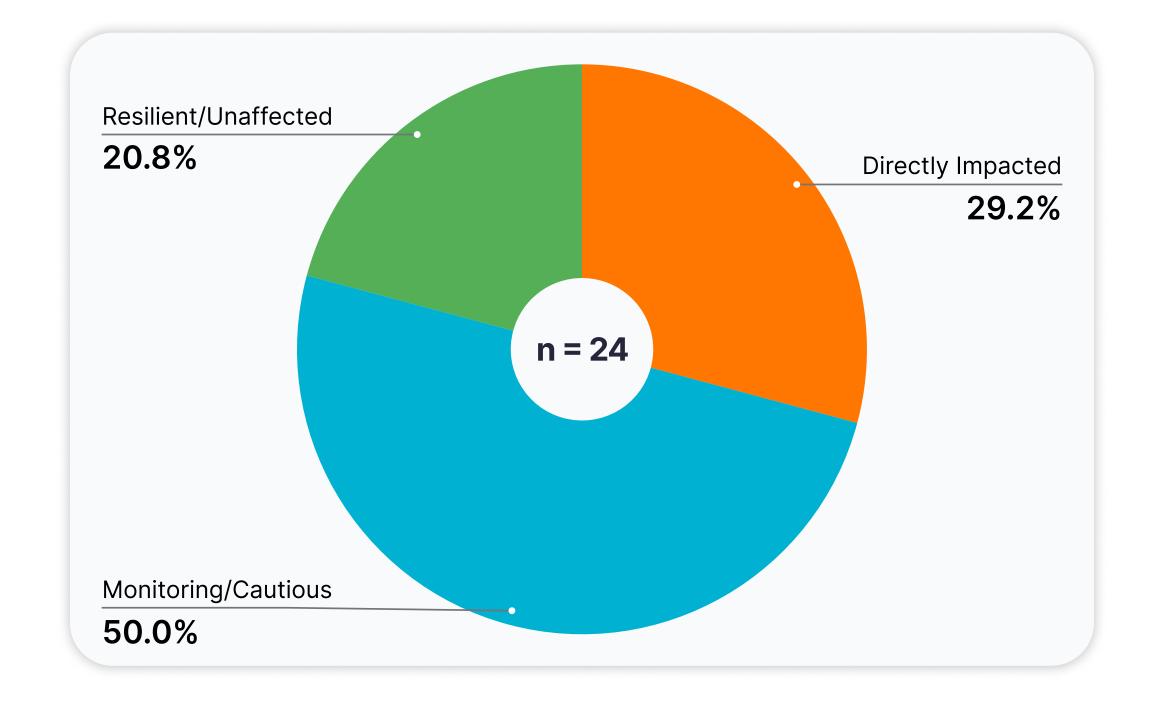
This chart provides an analysis of executive commentary on the macroeconomic environment from Q2 earnings calls. Each company's commentary has been categorized based on the described impact of these external pressures:

- Directly Impacted: Companies reporting a direct negative effect on sales, revenue, or patient volumes.
- Monitoring/Cautious: Companies discussing these pressures as a general business risk without citing a specific negative impact.
- Resilient/Unaffected: Companies stating their business is resilient or currently unaffected by these economic pressures.

#### **Methodology Note**



→ Analysis is based on a random sample of 100 Q2 2025 earnings call transcripts. Of the companies sampled, **24** mentioned this topic.







# Headwinds & Hurdles: Restructuring and Cost-Saving

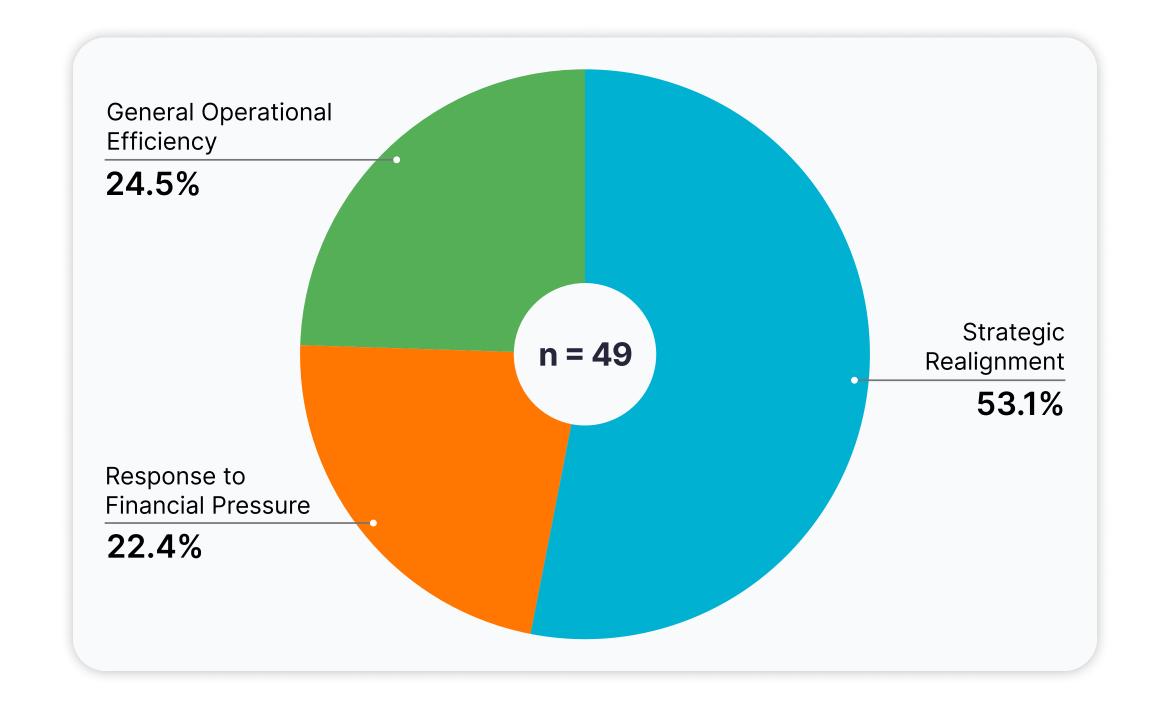
This chart analyzes the primary drivers behind restructuring and cost-saving initiatives discussed during Q2 earnings calls. Each company's actions have been categorized based on their stated strategic purpose:

- Strategic Realignment: Efforts to focus the pipeline, integrate acquisitions, or pivot corporate strategy.
- Response to Financial Pressure: Measures explicitly taken to extend cash runway or react to market and economic conditions.
- General Operational Efficiency: General business improvements mentioned without a specific external trigger.

#### **Methodology Note**



→ Analysis is based on a random sample of 100 Q2 2025 earnings call transcripts. Of the companies sampled, **49** mentioned this topic.







# Headwinds & Hurdles: Commercial Challenges

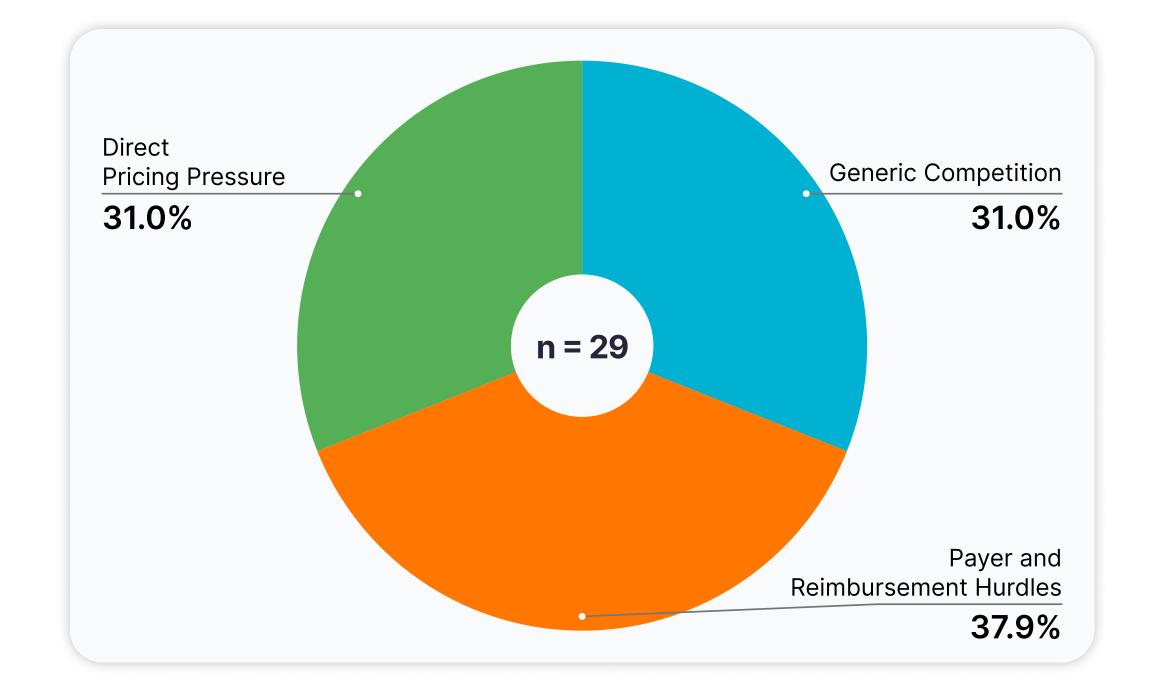
This chart breaks down the primary commercial challenges discussed by executives during Q2 earnings calls. Each company's commentary has been categorized based on the specific pressure addressed:

- Generic Competition: Discussions centered on the impact of generic or biosimilar entry and loss of exclusivity.
- Payer and Reimbursement Hurdles: Challenges related to securing favorable coverage, formulary placement, and navigating payer negotiations.
- Direct Pricing Pressure: Commentary on external pressures from drug pricing legislation or market demands for lower costs.

#### **Methodology Note**



→ Analysis is based on a random sample of 100 Q2 2025 earnings call transcripts. Of the companies sampled, **29** mentioned this topic.







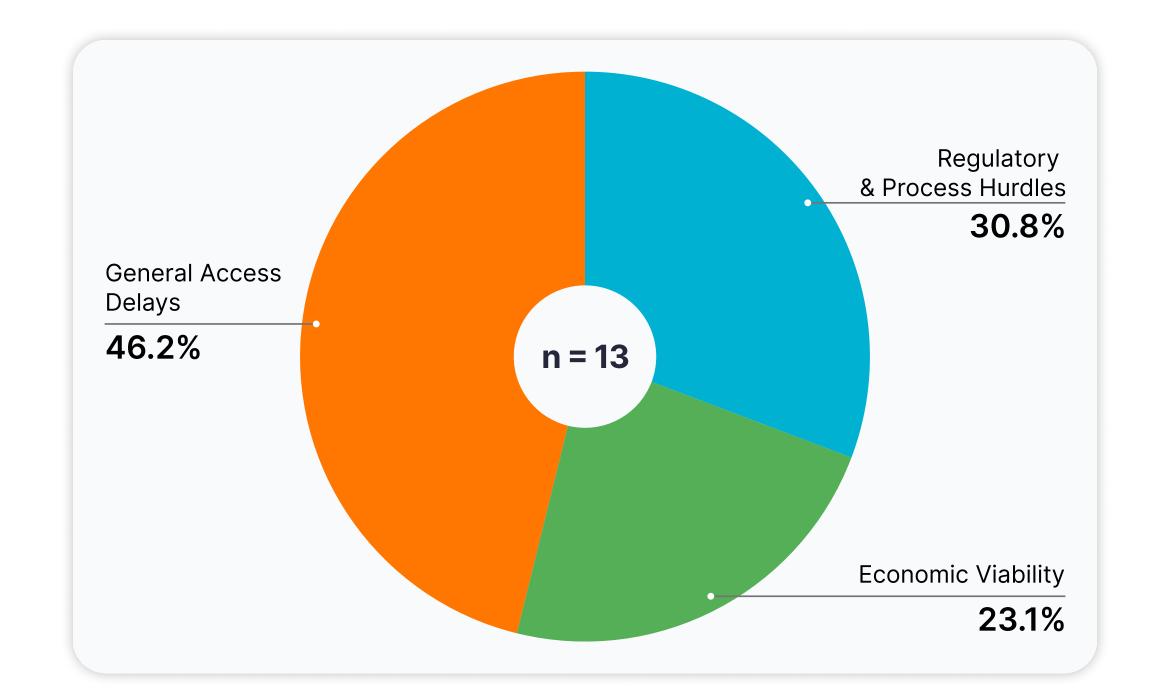
# Headwinds & Hurdles: European Market Access

This chart provides an analysis of executive commentary on European market access challenges from Q2 earnings calls. Each company's commentary has been categorized based on the primary hurdle discussed:

- Regulatory & Process Hurdles: Challenges related to the structure of the European review process, such as specific clinical data requirements.
- Economic Viability: Challenges related to pricing negotiations and whether reimbursement levels make a commercial launch feasible.
- General Access Delays: Mentions of general delays in securing market access without a specific underlying cause cited.

#### **Methodology Note**

→ Analysis is based on a random sample of 100 Q2 2025 earnings call transcripts. Of the companies sampled, **13** mentioned this topic.







# The Financial Balancing Act

Reflecting a cautious outlook on the broader economy, biopharma companies are strategically shifting focus to financial resilience. The priority is clear: build a substantial cash cushion through cost reductions and capital management to navigate uncertainty and fund operations through critical inflection points.

#### Securing the Future: Cash Runways Extended to 2027-2028:

- Multiple companies, including Absci, ADC Therapeutics, and Arcturus, have secured funding into 2028.
- A broad cohort including Avir, Intellia, CytomX, and Biolinerx now have cash runways extending deep into 2027.

#### Streamlining Operations: Aggressive Cost-Cutting Underway

- Widespread restructuring is freeing up capital for core priorities.
- Assertio is targeting \$70M in operating expense savings.
- 23andMe announced a 40% workforce reduction.
- AYTU BioScience shuttered its clinical development program, saving \$20-\$30M in R&D.

#### Fortifying the Balance Sheet: Strategic Capital Management

- Companies are actively refinancing debt, raising capital, and generating positive cash flow.
- Amneal refinanced \$2.7B in debt, extending maturities to 2032.
- Emergent boosted its liquidity by \$297M.
- Avadel is now generating sustainable positive cash flow.

Ultimately, this financial discipline is about controlling the controllables. In a cloudy economic environment, companies are aggressively managing costs and capital to create a stable foundation, ensuring their progress is dictated by clinical data and commercial execution, less so by market volatility."





# The Financial Balancing Act: Cash Runways

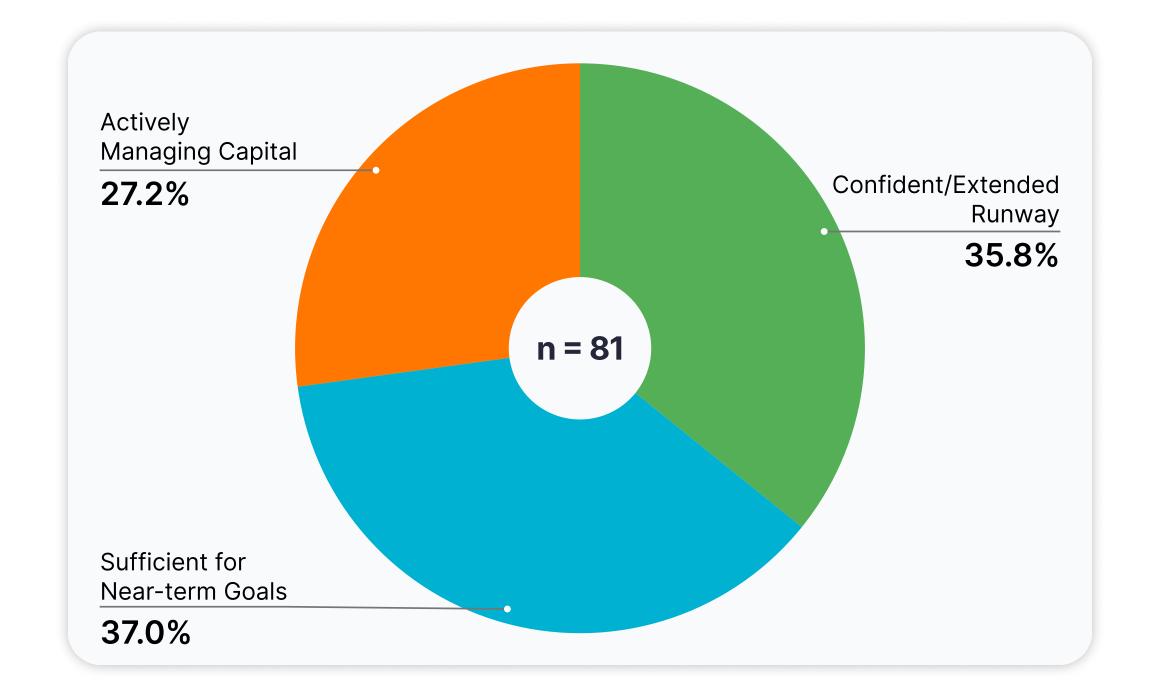
This chart analyzes executive sentiment regarding their company's cash runway from Q2 earnings calls. Commentary has been categorized based on the projected duration and confidence level:

- Confident/Extended Runway: Stating a runway into 2027 or beyond.
- Sufficient for Near-Term Goals: Funded through specific upcoming milestones.
- Actively Managing Capital: Commentary focused on careful burn management or future capital needs.

#### **Methodology Note**



→ Analysis is based on a random sample of 100 Q2 2025 earnings call transcripts. Of the companies sampled, **81** mentioned this topic.







# The Financial Balancing Act: Cost-Saving

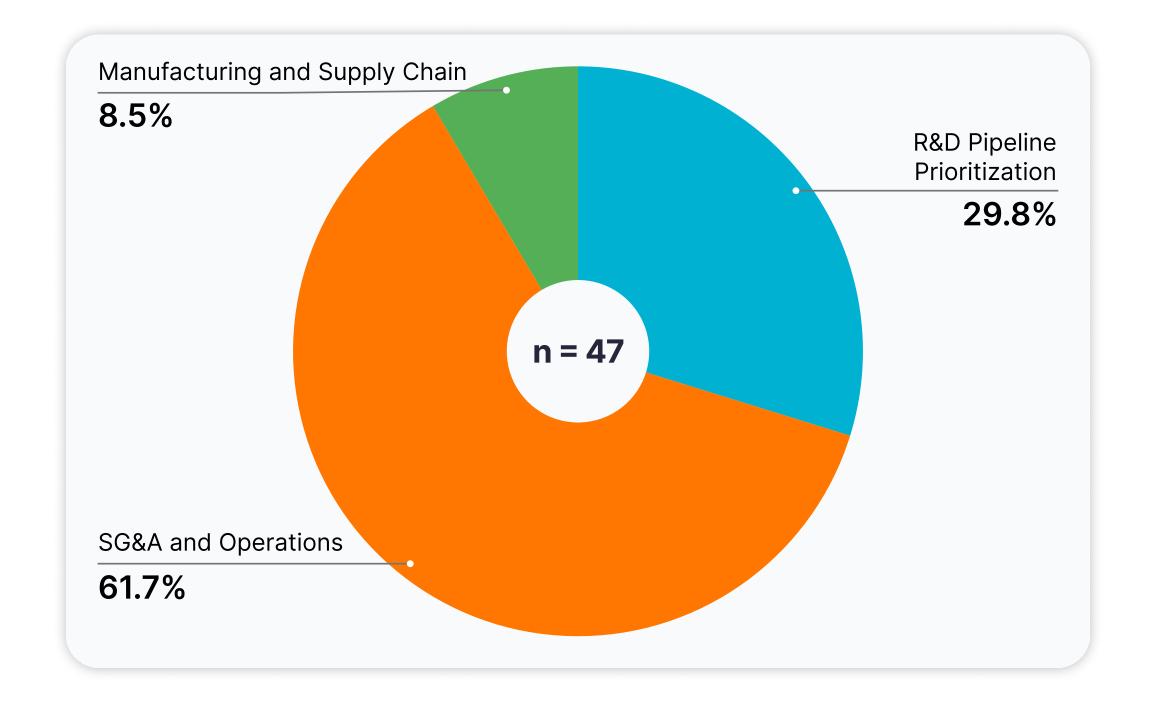
This chart breaks down the primary focus of cost-saving initiatives discussed during Q2 earnings calls. Each company's efforts have been categorized based on the main operational area targeted:

- R&D Pipeline Reprioritization: Pausing or discontinuing clinical programs.
- SG&A and Operations: Reductions in sales, general, and administrative staff and expenses.
- Manufacturing and Supply Chain: Optimizing production or closing facilities.

#### **Methodology Note**



→ Analysis is based on a random sample of 100 Q2 2025 earnings call transcripts. Of the companies sampled, **47** mentioned this topic.









# The Financial Balancing Act: Fortifying the Balance Sheet

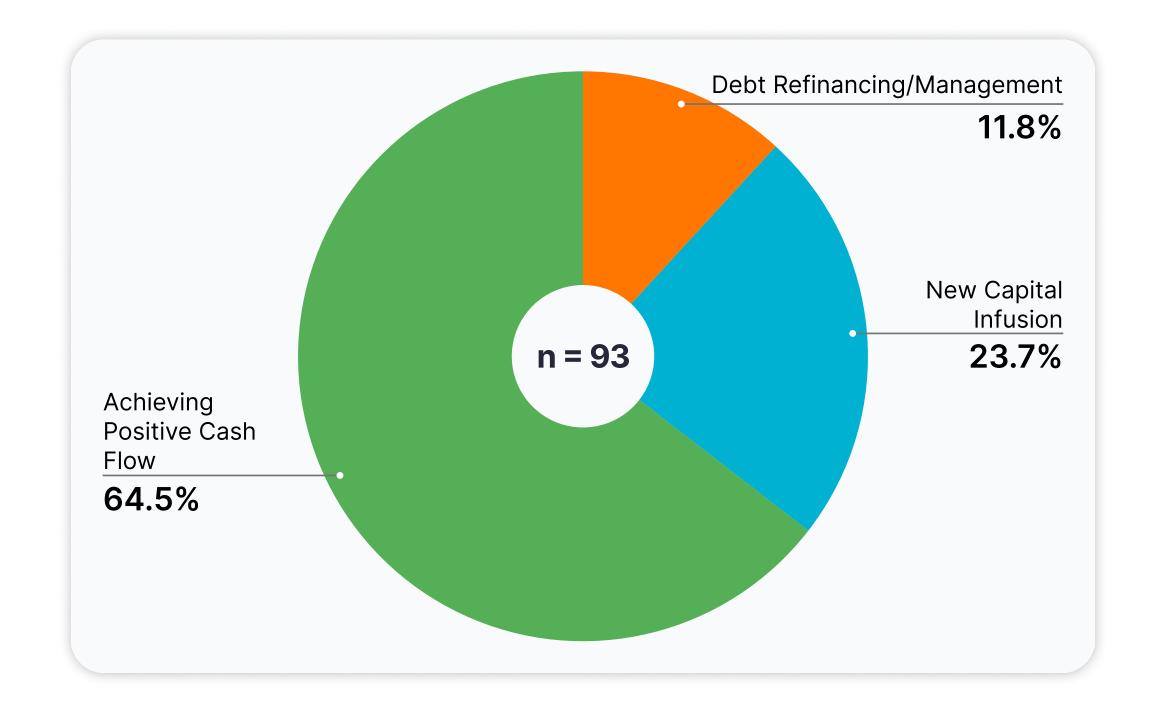
This chart quantifies the primary balance sheet strategies discussed by executives during Q2 earnings calls. Each company's approach has been categorized based on the main tactic emphasized:

- **Debt Refinancing/Management:** Restructuring or paying down existing debt.
- New Capital Infusion: Raising new funds through equity or other financing.
- Achieving Positive Cash Flow: Reaching or sustaining operational profitability.

#### **Methodology Note**



→ Analysis is based on a random sample of 100 Q2 2025 earnings call transcripts. Of the companies sampled, **93** mentioned this topic.





# Midyear 2025 Biopharma Recap

# Funding





# Methodology

At Zymewire, we focus on capturing financial events that directly contribute to a company's ability to advance its research, development, and operations. This means we record amounts that a company is **sure to receive** or **has already received**. This approach allows us to provide a clear picture of the financial landscape which ultimately directs outsourcing demands. All funding numbers are presented in \$USD unless specified otherwise.

#### What We Consider "Funding"

- Royalty Payments
- Grants
- Financing
  - Underwritten offerings, amounts raised in Form D filings, Series funding rounds, and closings of public offerings

#### What We Do NOT Consider "Funding"

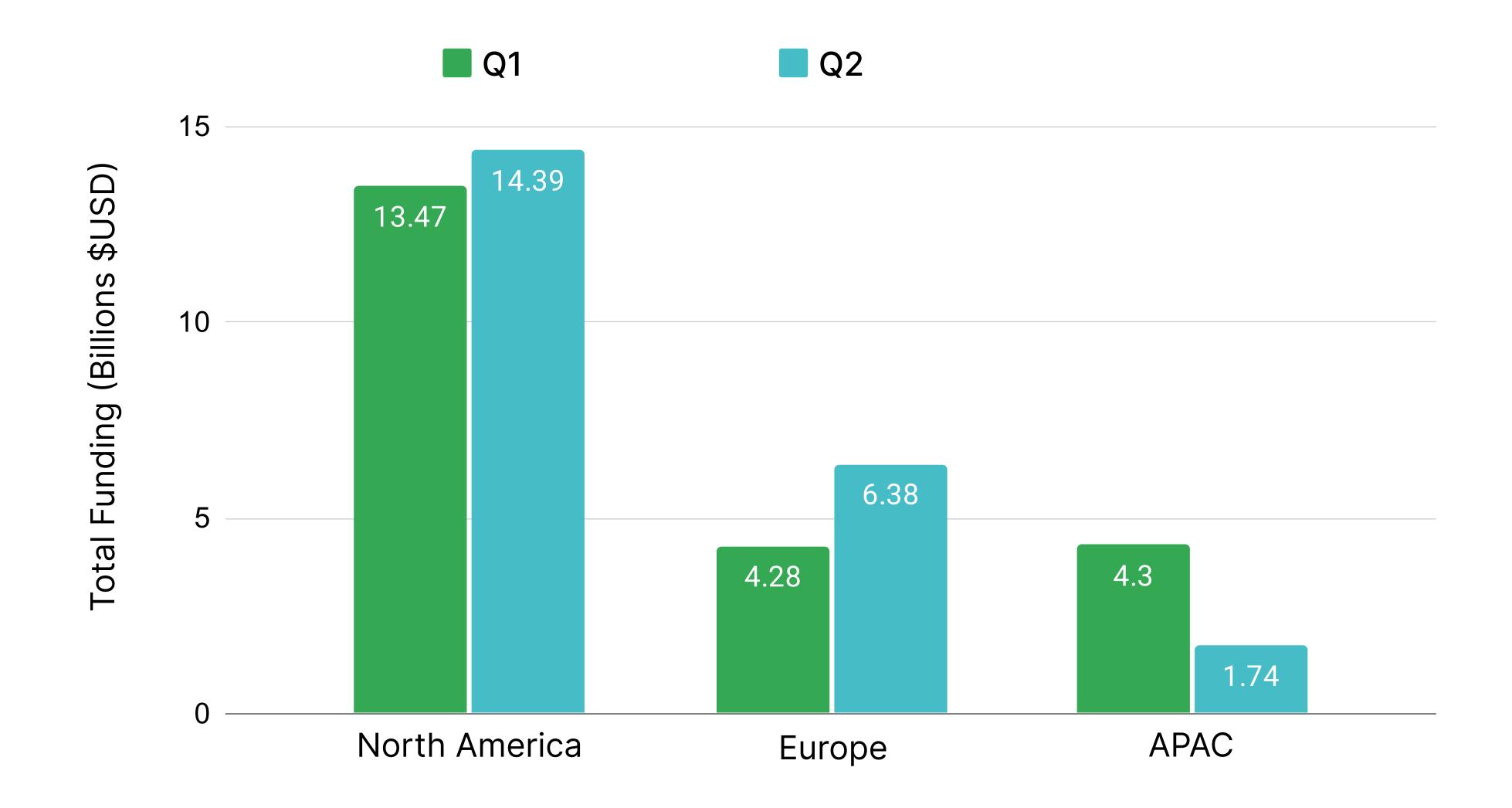
- Revenue
- Intended or "planned" funding
- Loans withdrawn over time
- Amendments to previous loans
  - Unless new money is being received
- Units for Debt Settlement
- Company filing for or announcing public offering
  - Amount recorded once offering is closed



Figure 1:
Global Funding Diverges as Europe Surges and APAC Falters in Q2

16

Total funding received by biopharma companies in North America, Europe, and APAC during the first and second quarters of 2025, presented in billions of USD.





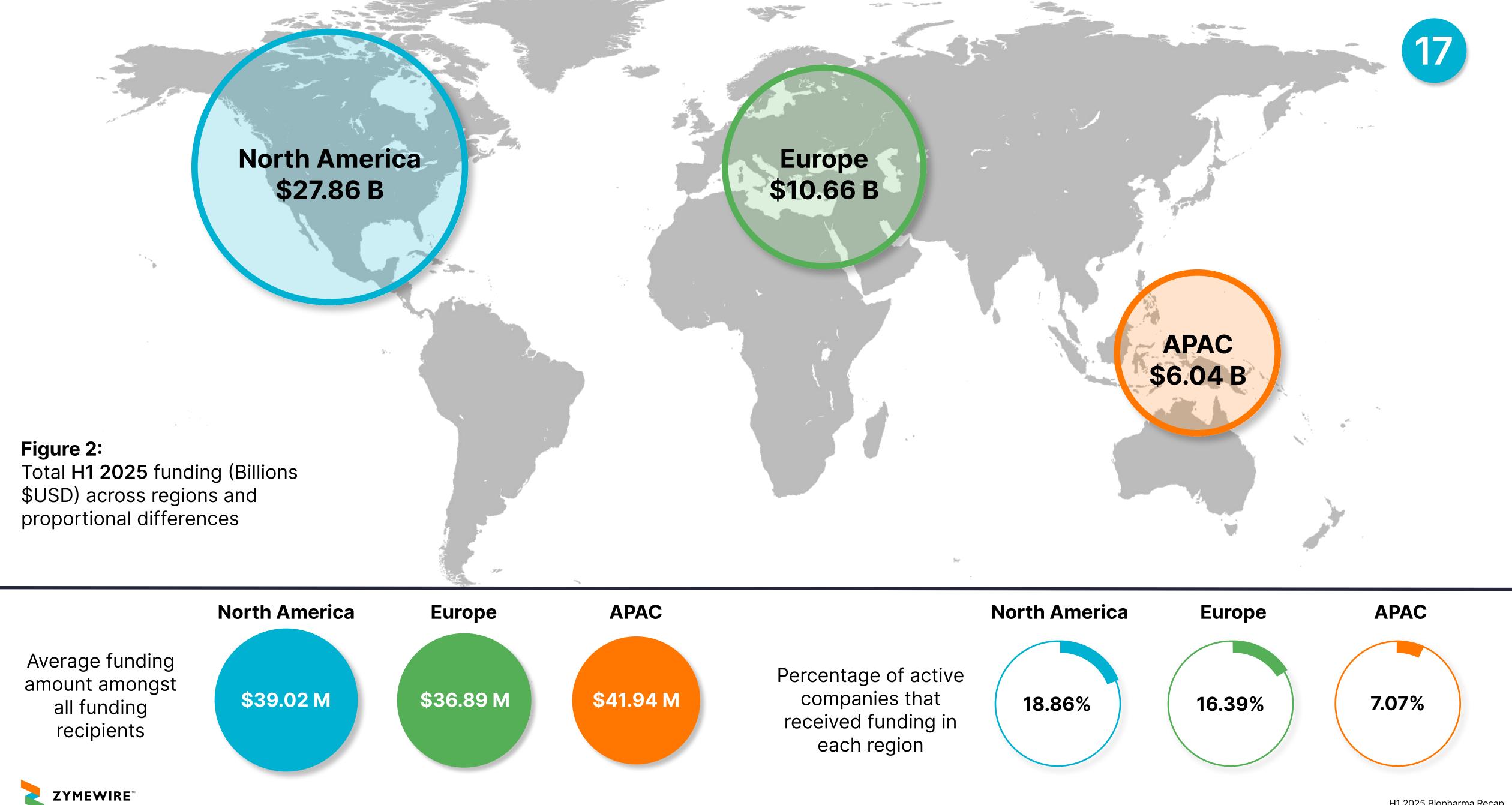


Figure 3:
As Grant Funding Tightens for Small Biotechs, Investment Pivots to Mid-Sized Companies
Total funding received in H1 2025, segmented by the size of the recipient company based on employee count, presented in billions of USD.



\$20.56 B 20.0 B 17.5 B \$USD) 15.0 B Total Funding (Billions 12.5 B 10.0 B \$8.00 B 7.5 B \$5.65 B \$5.02 B 5.0 B \$2.91 B \$2.48 B 2.5 B 0.0 B 11-50 51-100 1-10 101-500 501-1000 1000+



Figure 4:
The Final Hurdle: Capital-Intensive Phase 3 Trials Command Lion's Share of Funding
Total funding received in H1 2025, segmented by the highest phase of clinical development mentioned by the



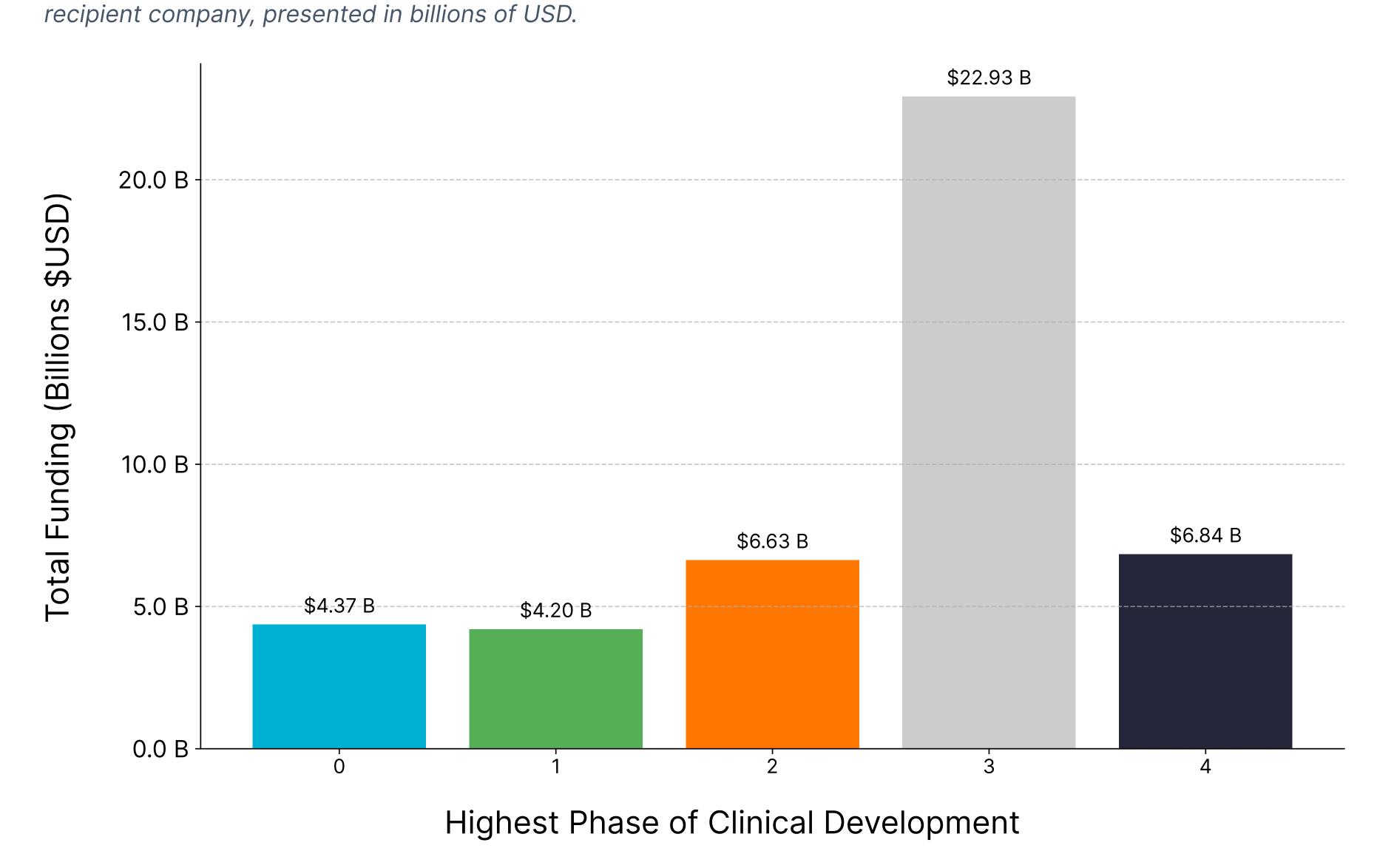
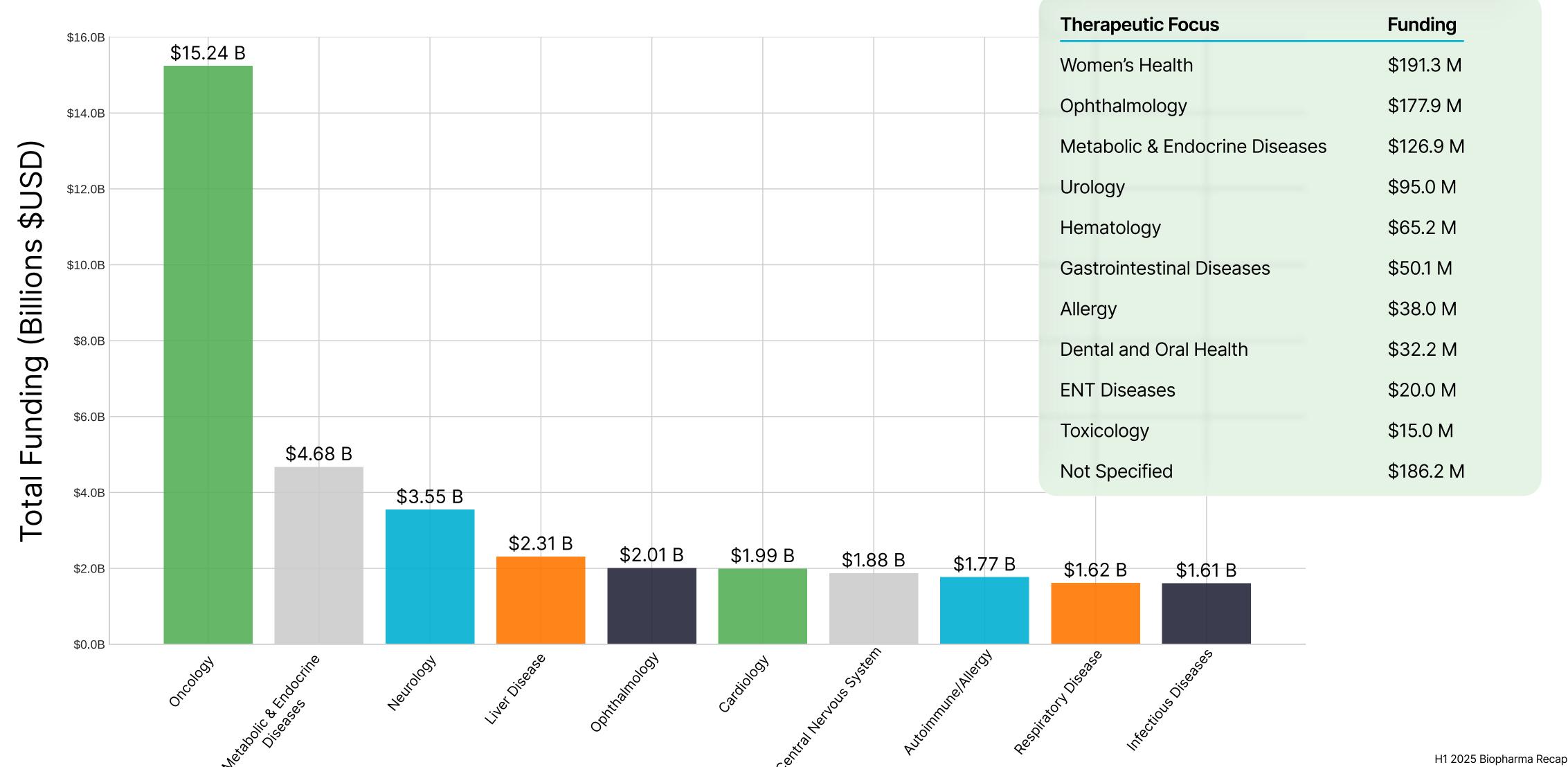




Figure 5: Investment Priorities Broaden as Metabolic and Neurology Carve Out Significant Share



Total funding received in H1 2025, segmented by the primary therapeutic area focus (TAFS™) of the recipient company, presented in billions of USD.





# Midyear 2025 Biopharma Recap

# Upcoming Clinical Trials





# A Look Ahead: Mapping the Future Clinical Trial Landscape

Zymewire uniquely tracks forward-looking clinical trial plans, offering a window into the future of biopharma activity.

To understand where the biopharma pipeline is heading, we analyzed planned trial disclosures captured during the first half of 2025. This forward-looking data provides a unique snapshot of the clinical studies scheduled to begin in the third quarter of 2025 and beyond.

The following slides break down this future activity, offering a glimpse into the strategic priorities of the industry. We will explore where the science is focused with a breakdown by therapeutic area, a regional analysis of planned trials by phase, and a focused look at the evolving pipelines for next-generation modalities like cell and gene therapy. We also segment this data by the clinical stage of the companies themselves, using our 'Highest Phase' metric to provide another layer of analysis.

**Planned Trial =** Newly Disclosed clinical trial plan captured by Zymewire during H1 2025, with an anticipated start date of H2 or later.



Figure 6: A Snapshot of the Global Pipeline: Q1 2025 Disclosures by Region



Total planned trial disclosures captured during Q1 2025, segmented by region and clinical phase.

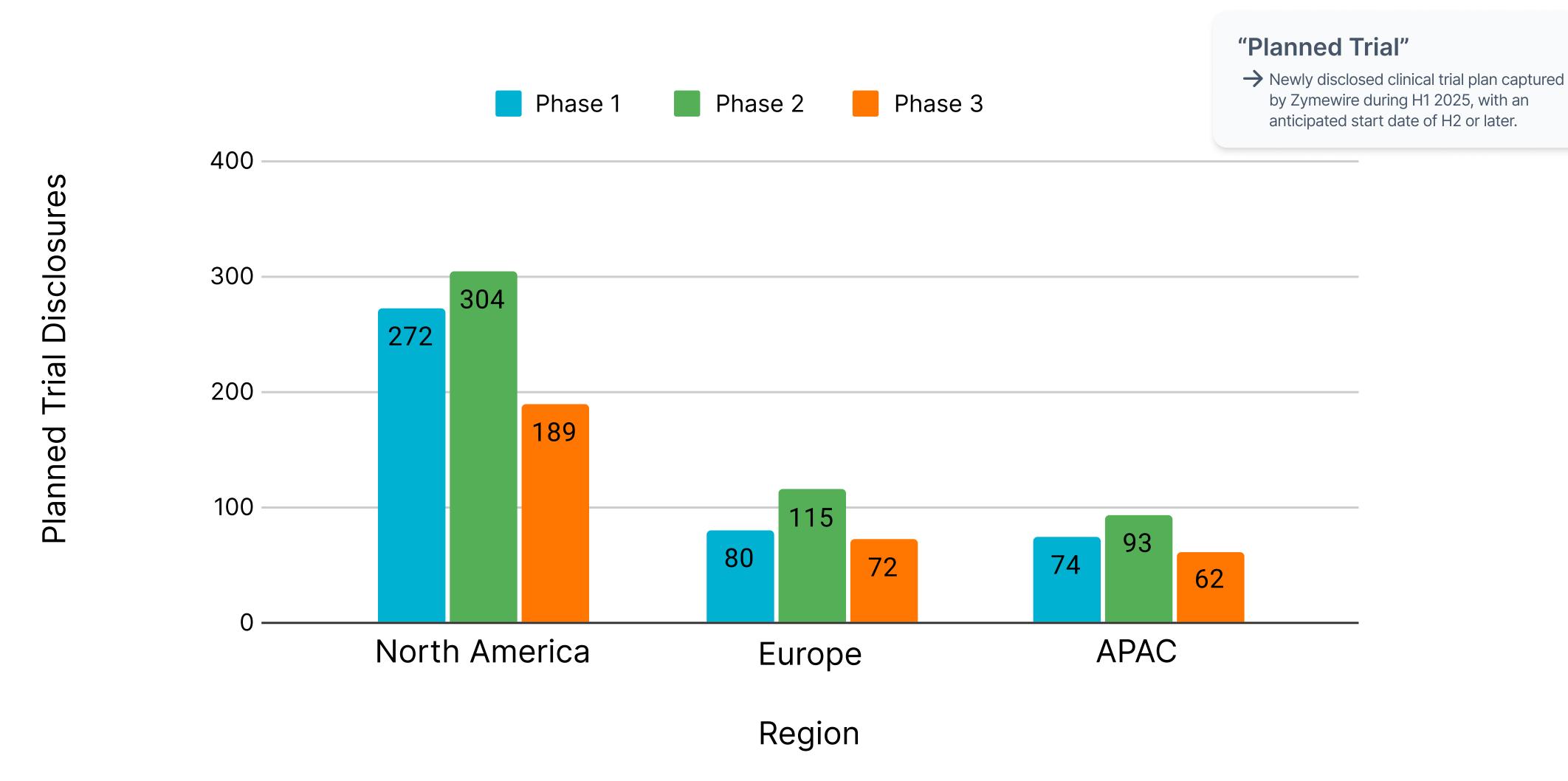
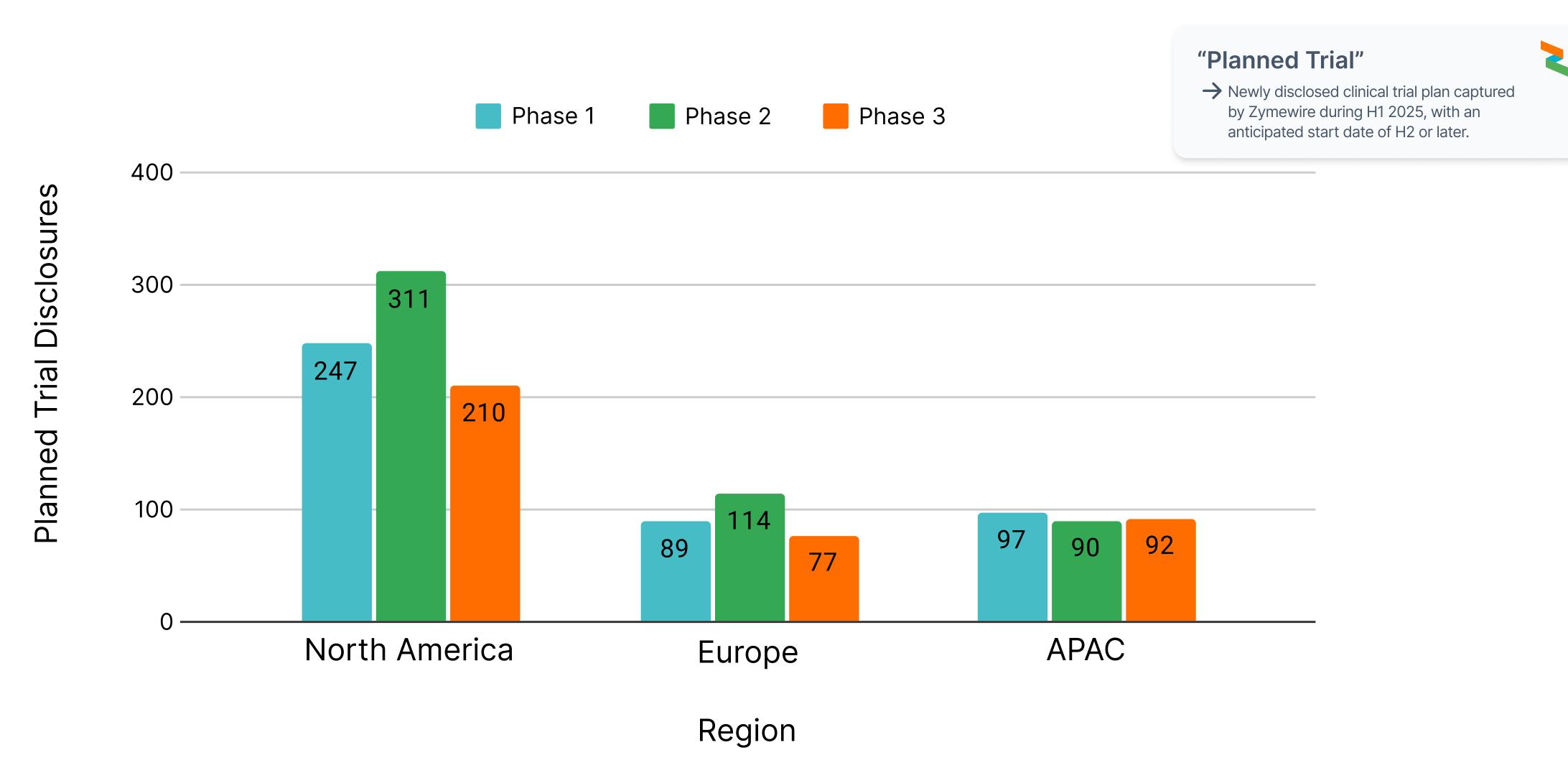




Figure 7:
Phase 2 Planning Represents Peak Activity in North America and Europe for Q2
Total planned trial disclosures captured during Q2 2025, segmented by region and clinical phase.







#### Figure 8:

## Where the Science is Focused: A Look at the Top Priorities in Clinical Development

Regional breakdown of planned trial disclosures from H1 2025 by therapeutic area. Only includes trials with a specified therapeutic area.

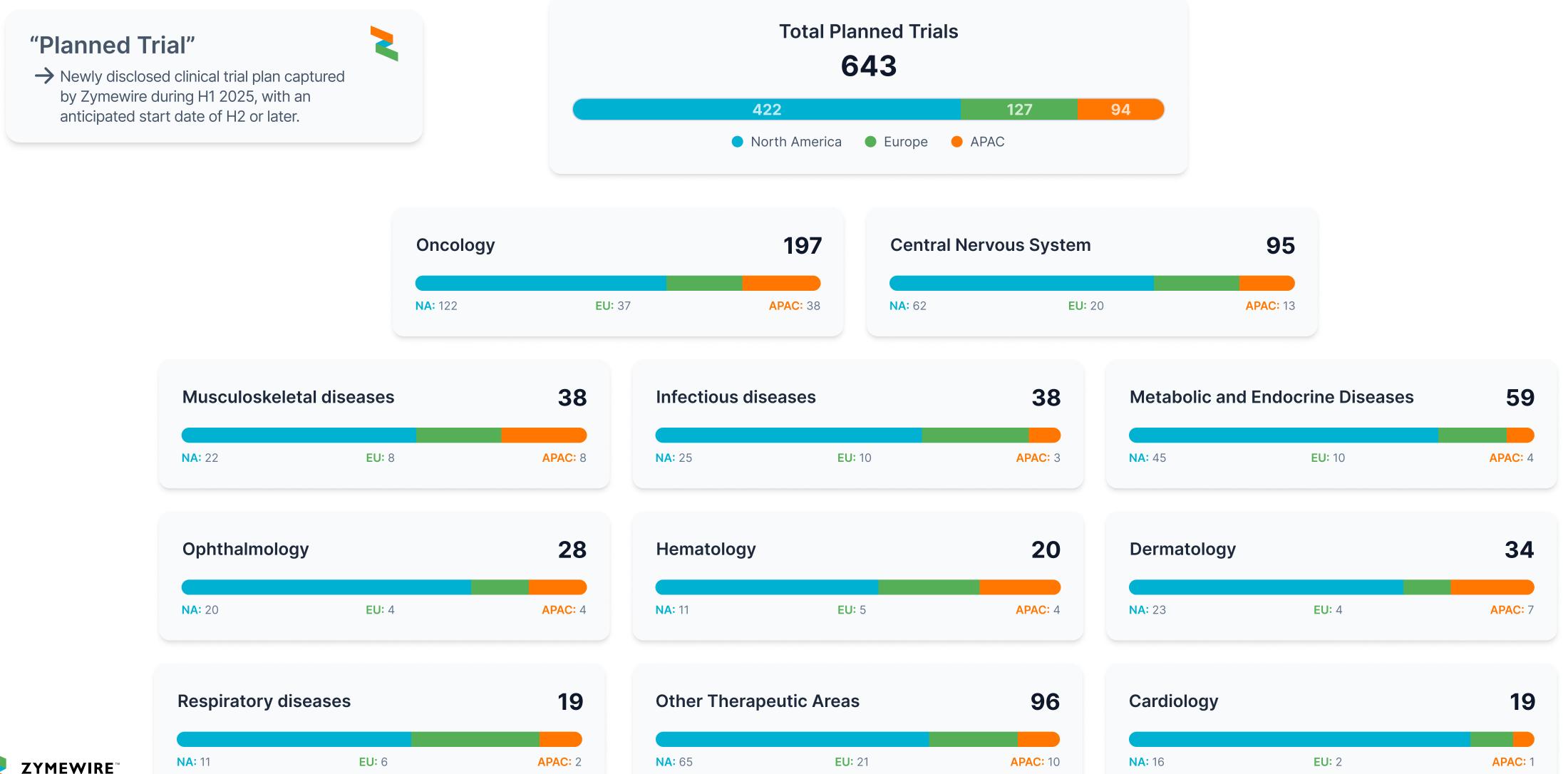




Figure 9:
A Snapshot of ATMP Trial Planning: Cell Therapies

A comparison of planned trial disclosures for cell therapies in H1 2024 versus H1 2025, segmented by clinical phase.

#### "Planned Trial"

→ Newly disclosed clinical trial plan captured by Zymewire during H1 2025, with an anticipated start date of H2 or later.



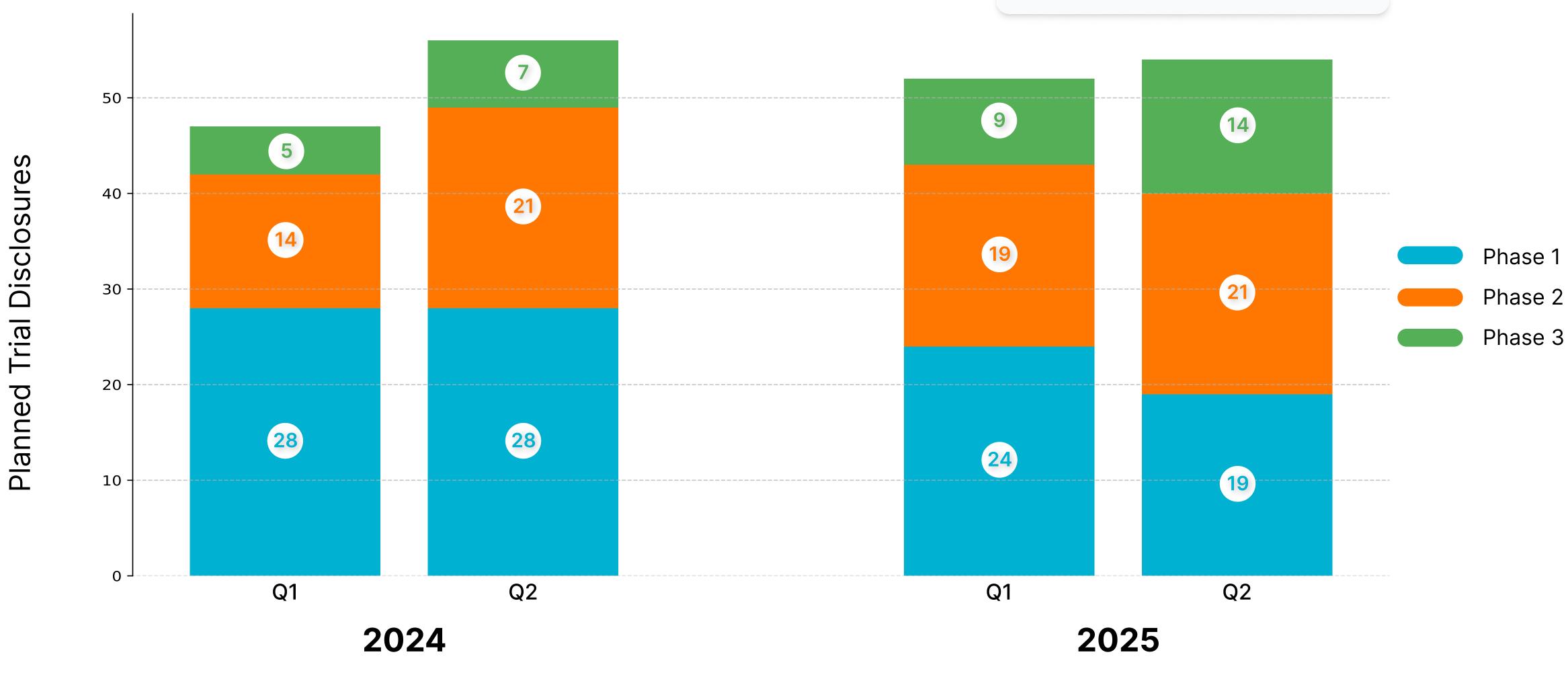


Figure 10:
Regulatory Headwinds and Selective Funding Cool the Start of New Gene Therapy Trials
A comparison of planned trial disclosures for gene therapies in H1 2024 versus H1 2025, segmented by clinical phase.







Figure 11:
A Cautious Turn: North American Trial Planning Moderates in Q2

27

Total planned trial disclosures in North America during H1 2025, segmented by the highest phase of clinical development of the sponsoring company.

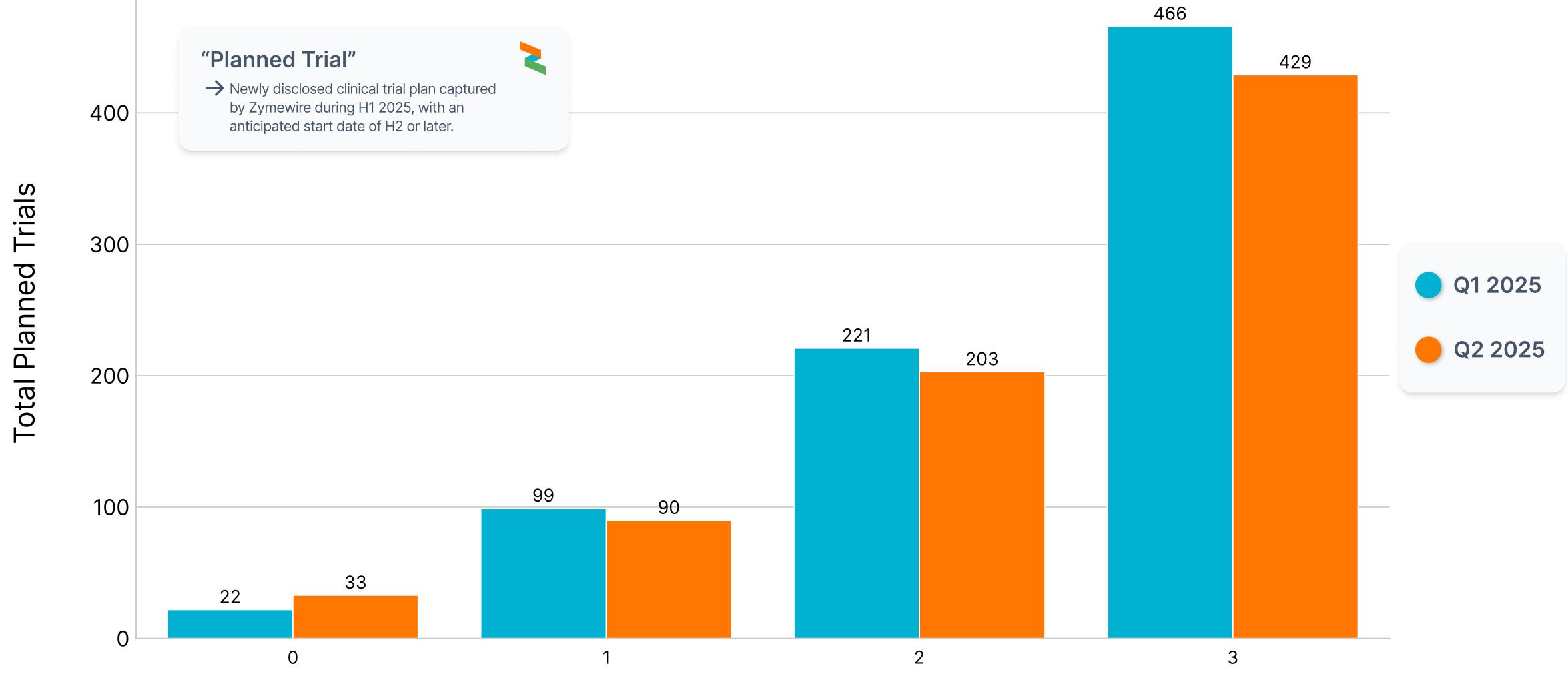




Figure 12: Consistency in a Shifting Landscape: European Trial Planning Remains Stable



Total planned trial disclosures in Europe during H1 2025, segmented by the highest phase of clinical development of the sponsoring company.

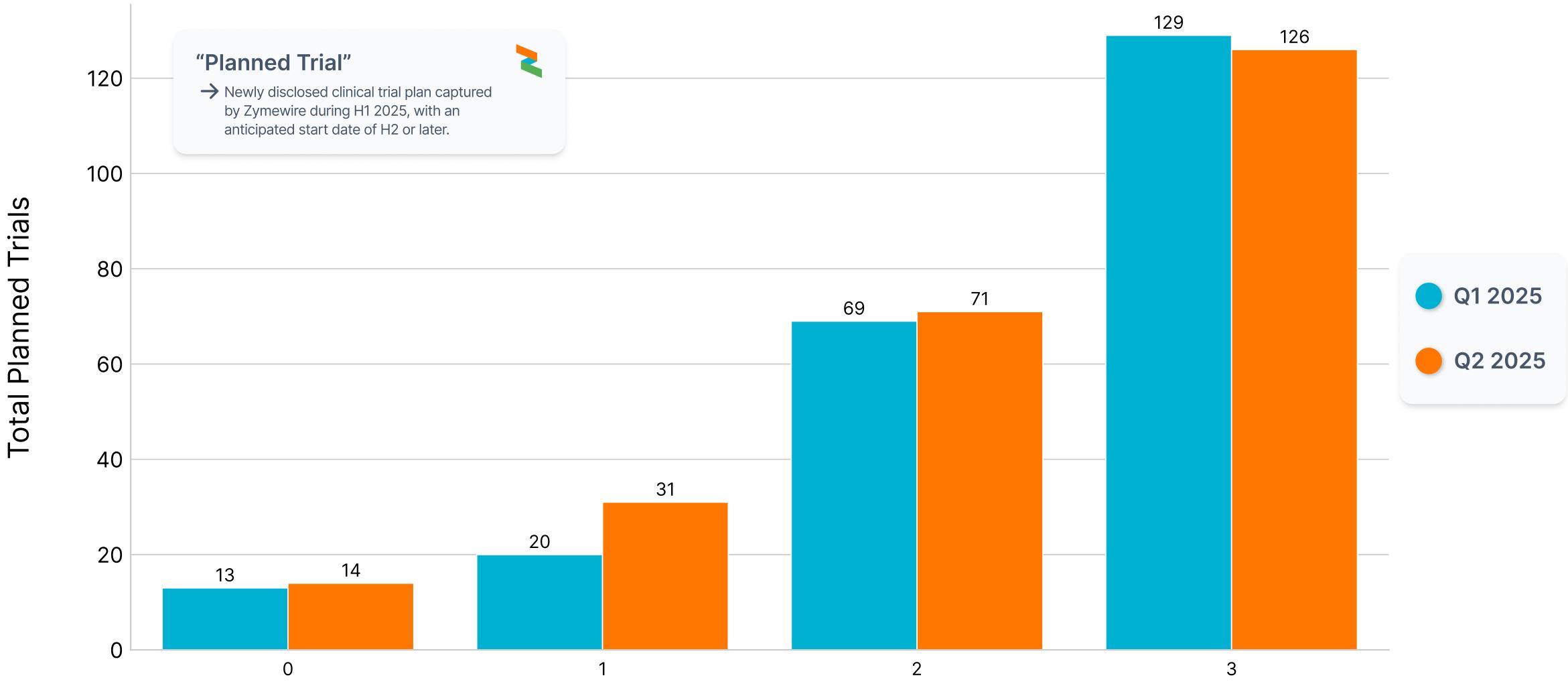
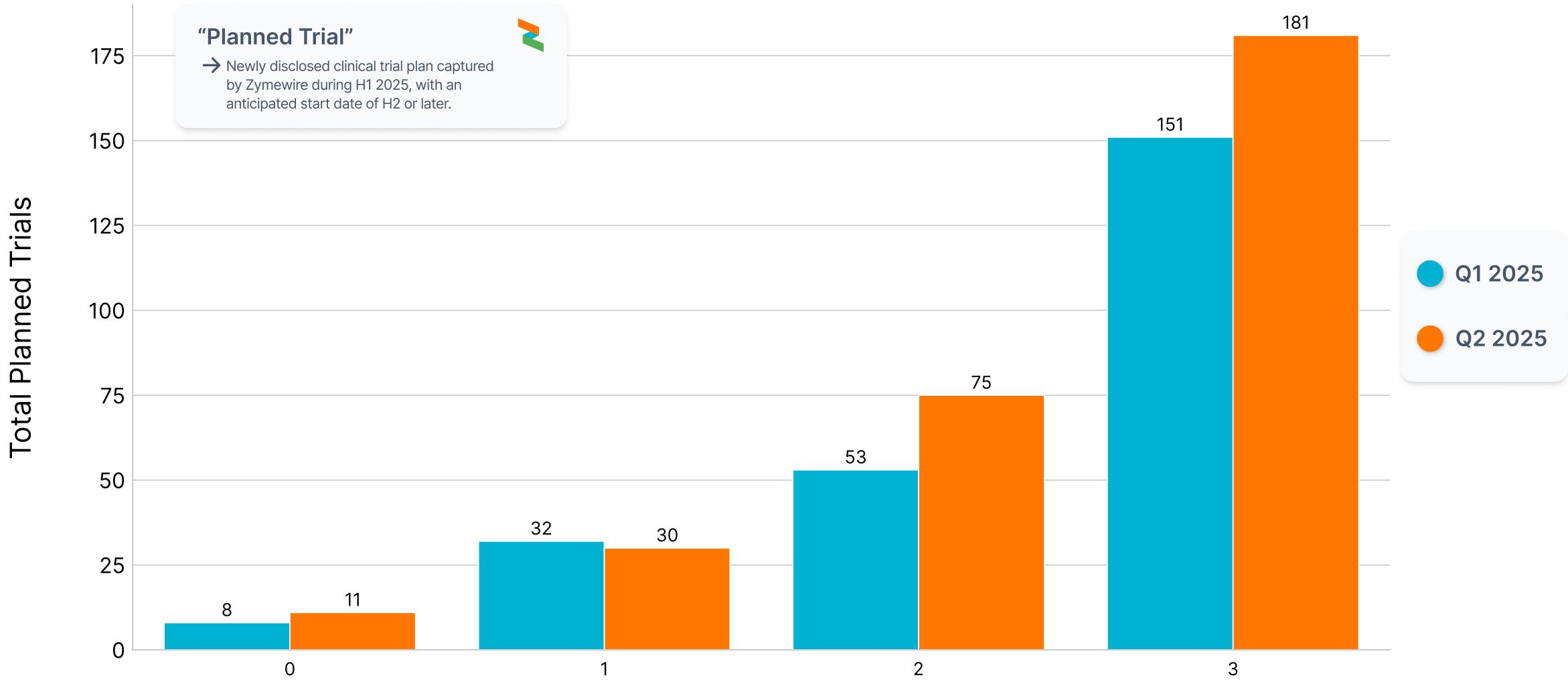




Figure 13:
APAC's Clinical Ambitions Grow, Challenging Europe as Trial Activity Accelerates



Total planned trial disclosures in APAC during H1 2025, segmented by the highest phase of clinical development of the sponsoring company.





# Midyear 2025 Biopharma Recap

# Study Initiations & Closeouts





# Initiations & Closeouts: The Pulse of Clinical Opportunities



#### **Study Initiations:**

Monitoring study starts provides a crucial early advantage. The launch of a new clinical trial is a clear indicator of upcoming opportunities. Even for services focused on later stages, identifying a study at its beginning allows for strategic tracking. When positive results are announced, you are already prepared to engage with sponsors and establish yourself as the ideal partner for their subsequent phases.

#### **Study Closeouts:**

The end of one trial often signals the start of another, particularly after positive findings. By closely following study completions, you can foresee a sponsor's next move before it becomes public knowledge. Successful outcomes frequently pave the way for subsequent trials, presenting a prime window for timely outreach. Keeping a pulse on trial completions and their results positions you to capture new opportunities the moment they arise.



Figure 14:
APAC's Momentum Continues, Leading Broad-Based Growth in New Trial Initiations



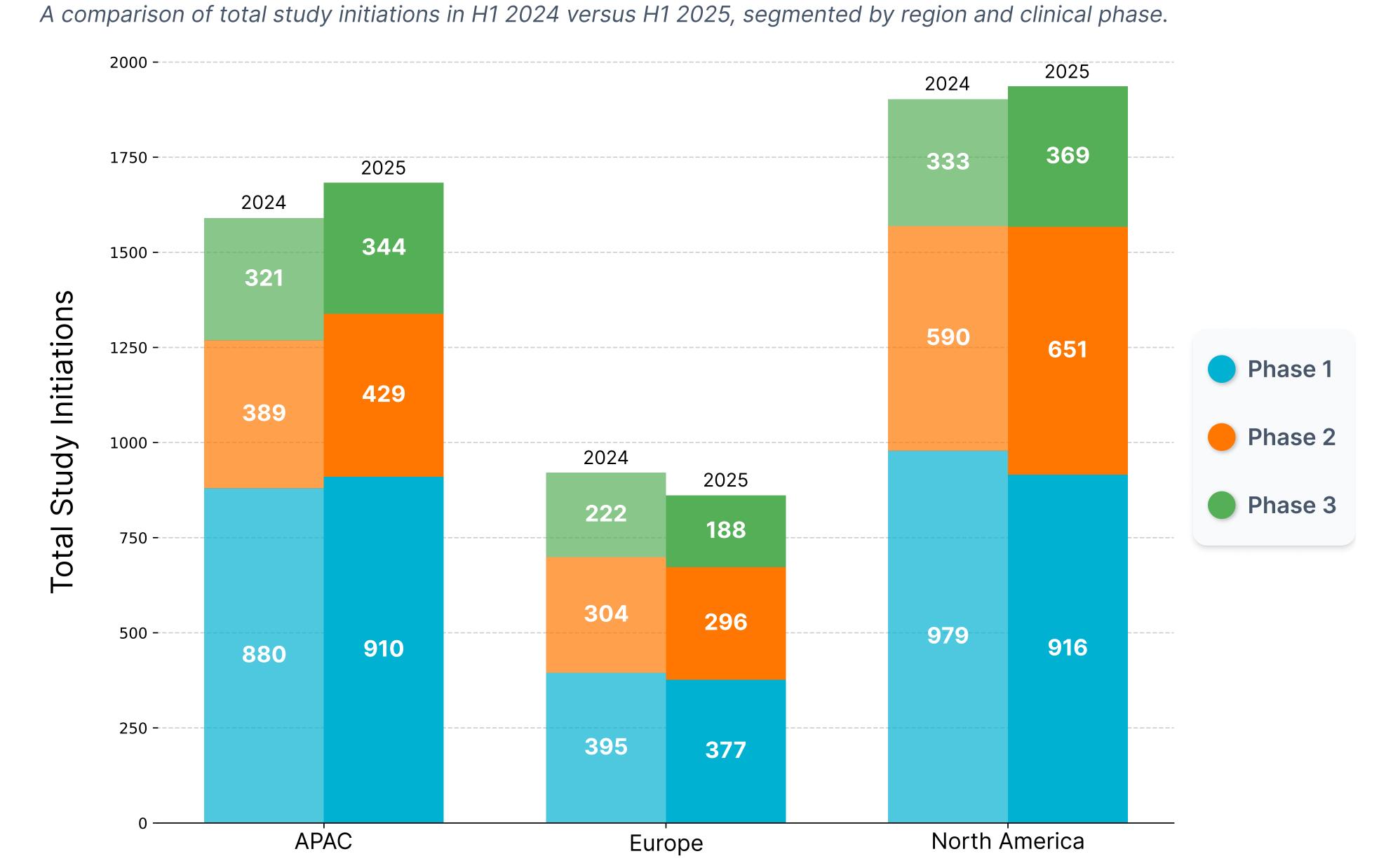
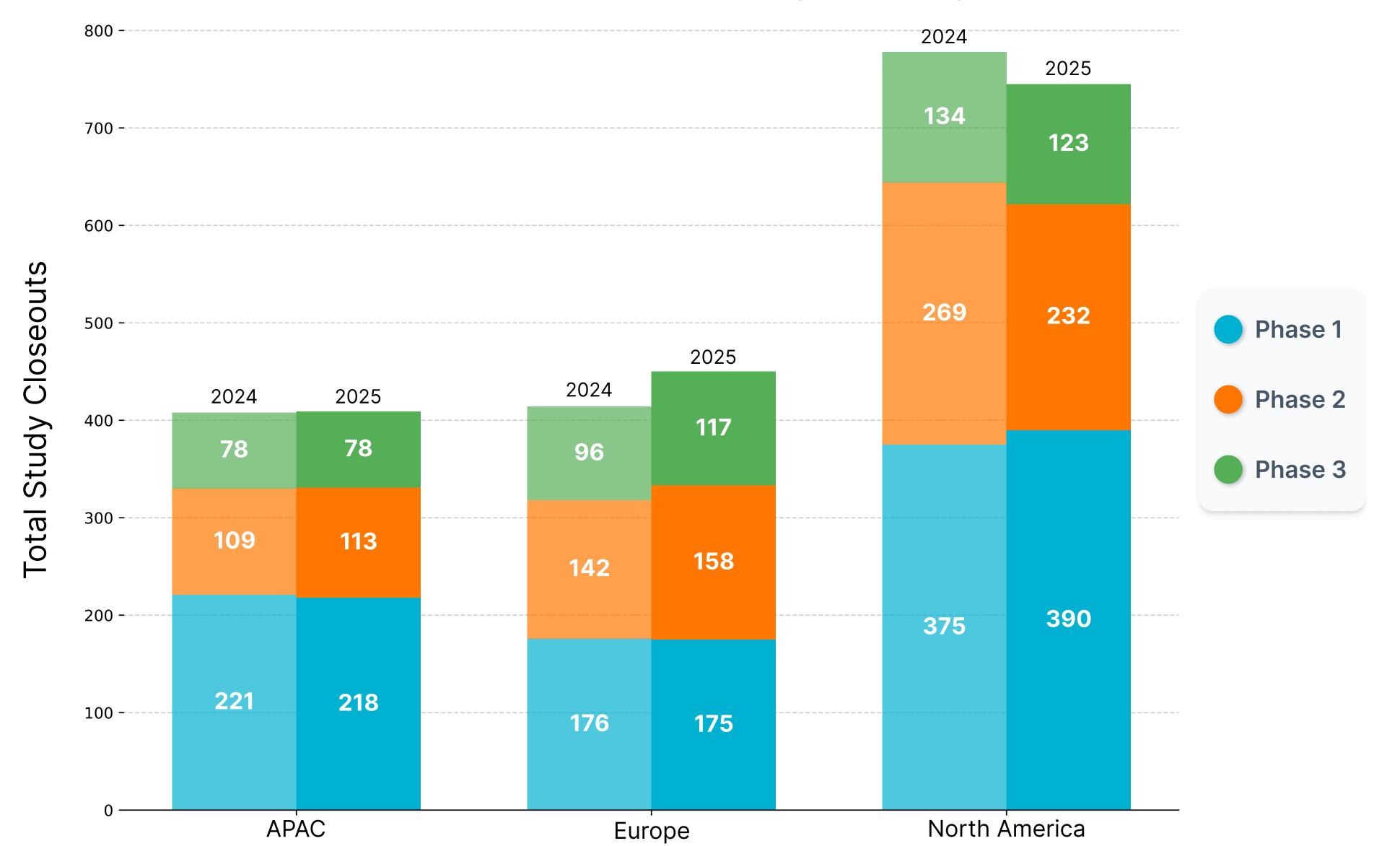


Figure 15: How the Global Pipeline Matured in H1: A Look at Study Closeouts

32

A comparison of total study closeouts in H1 2024 versus H1 2025, segmented by region and clinical phase.



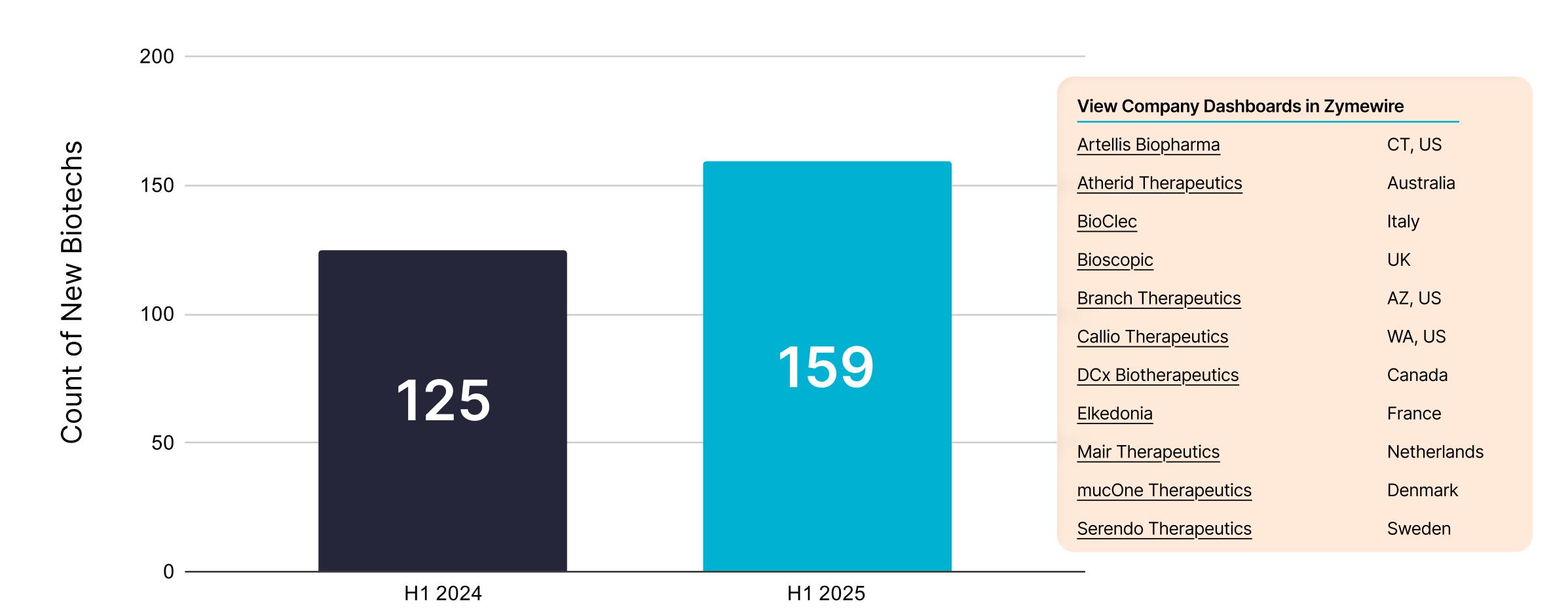
# Midyear 2025 Biopharma Recap

Newcomers



Figure 16:
A Promising Surge in New Biotech Creation Marked H1, Despite Grant Freezes
Companies newly identified by Zymewire as organizations conducting novel drug development activities.









# The Data Tells the Story. Zymewire Helps You Act On It.

The clinical trial landscape is constantly shifting... New biotech entrants, evolving outsourcing demands, and changing study volumes across all phases. Keeping up isn't just about seeing the trends; it's about knowing what to do next.

Biopharma's landscape is constantly shifting. New players are emerging, funding is flowing into different regions and therapeutic areas, and clinical trials are evolving phase by phase. These aren't just numbers; they're signals of where outsourcing demand is headed and where the next opportunities lie.

Understanding these trends is the first step; translating them into strategic action is what drives success. Whether it's engaging with newly funded biotechs, positioning your team for upcoming trials, or tracking where studies are wrapping up, being proactive, not reactive, is key. Zymewire is built to help you do exactly that.

The question isn't whether the opportunities are there, it's about whether or not you're equipped to find them.

ZYMEWIRE"

Demo Zymewire