

Levers for Launch: How Five Analog Brands Used Positioning, Advocacy, Evidence, and Access Levers for Launch and Beyond

CASE STUDY - VOL. 3 OF 5: **REPATHA**



OVERVIEW

This case study is the third volume of a five-part series that distills the essence of what to do when launching a pharmaceutical product. We curated five analog products and analyzed how they deployed four launch levers: **Positioning Strategy, Advocacy and Guideline Inclusion, Evidence Generation, and Market Access**, to create traction and sustain growth. Each case is mapped to a launch archetype: **Paradigm Shaper, First Mover, Late Challenger, Opportunist** to clarify context and actions taken.

Who should read this: Commercial, medical, market access, and analytics leaders who are preparing to launch a brand or have recently launched one.

How to use this series: Identify your product archetype → review lever playbooks from the most relevant analogs → adapt actions for your product as appropriate.

Authors: Vaibhav Shrishail, William Sheehan, and Wes Yanowitch

INTRODUCTION

As referenced in the extended introduction provided in volume 1 of this case study series, this white paper series explores five examples of novel brands that shaped or reshaped their commercial trajectory through deliberate activation of key levers. Using a consistent framework, we examine each analog case through four strategic levers: **Positioning Strategy, Advocacy & Guideline Inclusion, Evidence Generation, and Market Access.**

Case Study 1 of 5 examined Entresto — a case where initial hesitation gave way to broad adoption after HCPs were

convinced on the “therapy switch moment” for patients, payer friction was resolved, and guideline language updates were incorporated.

Case Study 2 of 5 examined Nuplazid — a launch where early advocacy and dynamic positioning drove clinical entrenchment and commercial success despite community hesitations on safety profile.

FIGURE 1.

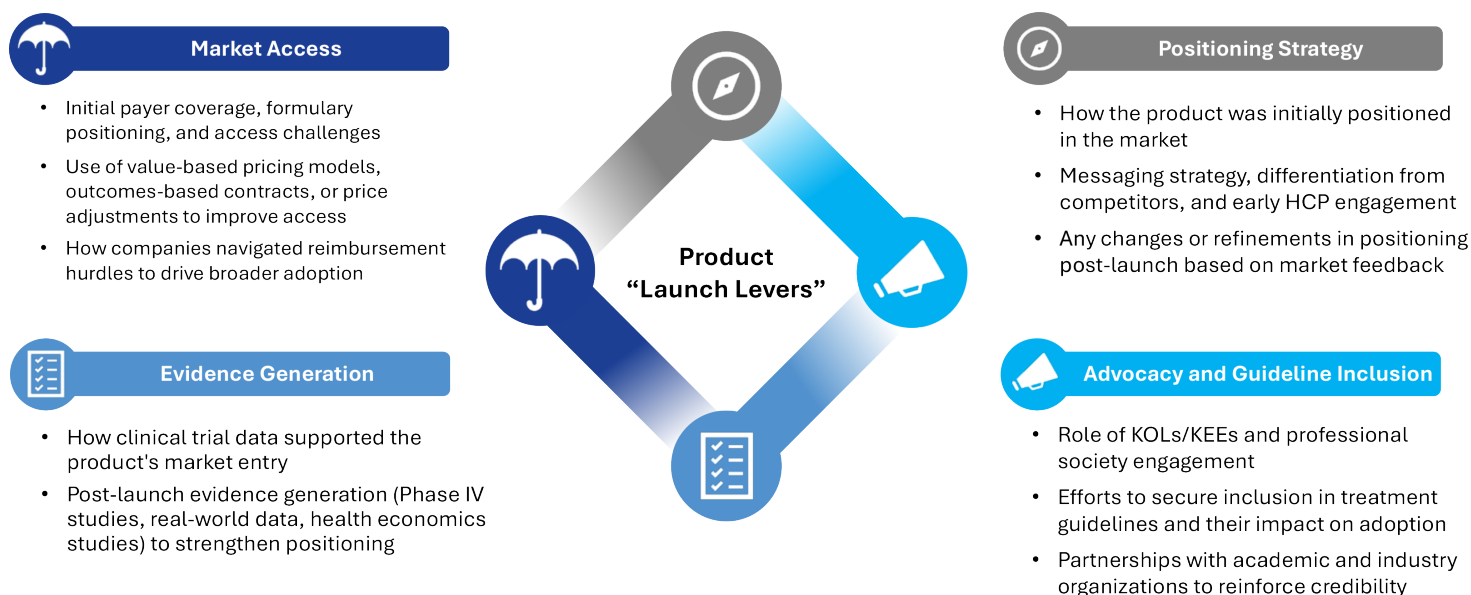


Figure 1. Overview of product “Launch Lever” categories in preparation for, at launch, and following launch.

The five analog case studies featured in this series are categorized into distinct launch archetypes based on market maturity and product differentiation, providing additional context for the strategic levers activated at each stage of commercial evolution. By first identifying where your own product sits among the four archetypes, you will have appropriate context for how each upcoming case study, based on the archetype, can be considered as an analog.

FIGURE 2.

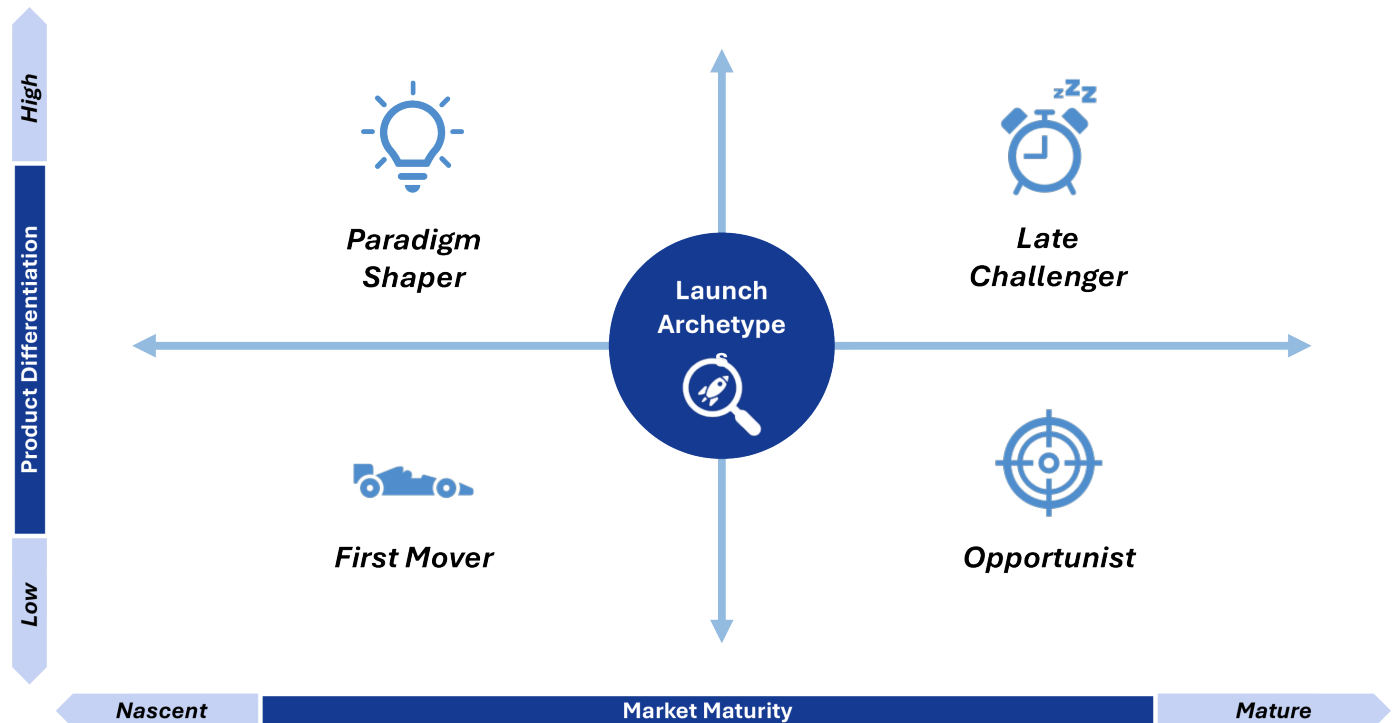


Figure 2. Illustrates four launch archetypes defined by the intersection of product differentiation and market maturity, highlighting the strategic contexts in which potential launch strategies may emerge

Note: Market maturity is defined by the degree of branded and generic competition within an indication

We selected brands that (1) faced meaningful early adoption barriers, (2) executed targeted beachhead strategies, and (3) left a visible trail of levers used (positioning, advocacy/guidelines, evidence, access) that launch teams can adapt. The set spans cardiovascular, oncology, CNS, and rare disease to ensure breadth across therapeutic areas.

FIGURE 3.

Product	Disease Area	Mechanism of Action	Launch Archetype	Product Launch Overview
 Entresto™ sacubitril/valsartan	HFrEF/HFpEF	ARNI	<i>Paradigm Shaper</i>	Entresto is a product in the cardiovascular space with a dual ARNI mechanism, representing a strong acceleration of market access and clinical uptake driven by extensive evidence generation, real-world validation, and targeted market-shaping initiatives
 NUPLAZID™ (pimavanserin) tablets	PD Psychosis	Selective 5-HT _{2A} inverse agonist	<i>First Mover</i>	Nuplazid is a therapy in the Parkinson's disease psychosis space with a selective 5-HT _{2A} inverse agonist mechanism, representing a differentiated CNS launch that overcame early resistance through focused clinical education and advocacy-driven market engagement
 Repatha™ (evolocumab)	LDL-C	PCSK9 inhibitor mAb	<i>Late Challenger</i>	Repatha is a therapy in the cardiovascular space with a PCSK9-inhibiting mechanism, representing a clinically differentiated but access-sensitive launch that was repositioned successfully through outcomes validation and strategic pricing realignment
 Vyndamax™ (tafamidis) orally dissolving tablets	ATTR-CM	TTR Stabilizer	<i>Paradigm Shaper</i>	Vyndaquel/Vyndamax is a therapy in the rare disease cardiovascular space with a transthyretin-stabilizing mechanism, representing a market-shaping breakthrough that turned a once-invisible disease into a defined, treatable condition through focused clinical education and advocacy-driven market engagement
 Kadcyla	HER2+ breast cancer	HER2+ ADC	<i>Late Challenger</i>	Kadcyla is a therapy in the breast cancer space with a HER2+ antibody-drug conjugate mechanism, representing a case of functional innovation that required post-launch evidence and strategic repositioning to unlock its full commercial potential

Figure 3. Provides an overview of the five analog products analyzed in this series, highlighting their therapeutic area, mechanism of action, launch archetype, and a brief launch overview

Note: The five analog products featured in the table above are categorized using launch archetypes, which help frame each asset's initial market context.

CASE STUDY 3: REPATHA

FIGURE 4.



Product Overview

- Repatha (evolocumab), launched by Amgen in 2015 as one of the first FDA-approved PCSK9 inhibitors for hypercholesterolemia and cardiovascular risk reduction
 - It was positioned as a breakthrough biologic for patients with familial hypercholesterolemia or established atherosclerotic CV disease who remained uncontrolled on statins, offering unprecedented LDL-C lowering and CV benefits
- Despite clear unmet need, Repatha’s early adoption was constrained by payer restrictions and cost-effectiveness debates that limited patient access
 - By aligning evidence, access, and advocacy, Repatha stabilized its trajectory and established itself as the market-leading PCSK9 inhibitor, now embedded in guidelines as standard of care for high-risk patients

Market Phases: Repatha’s performance in the market from launch in 2015 to present can be segmented into four phases:

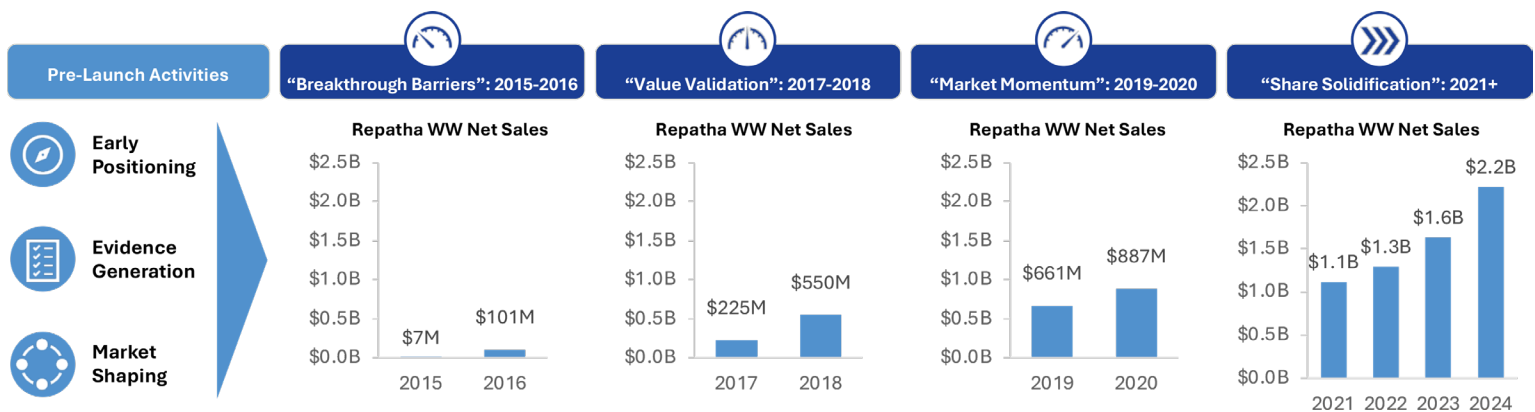
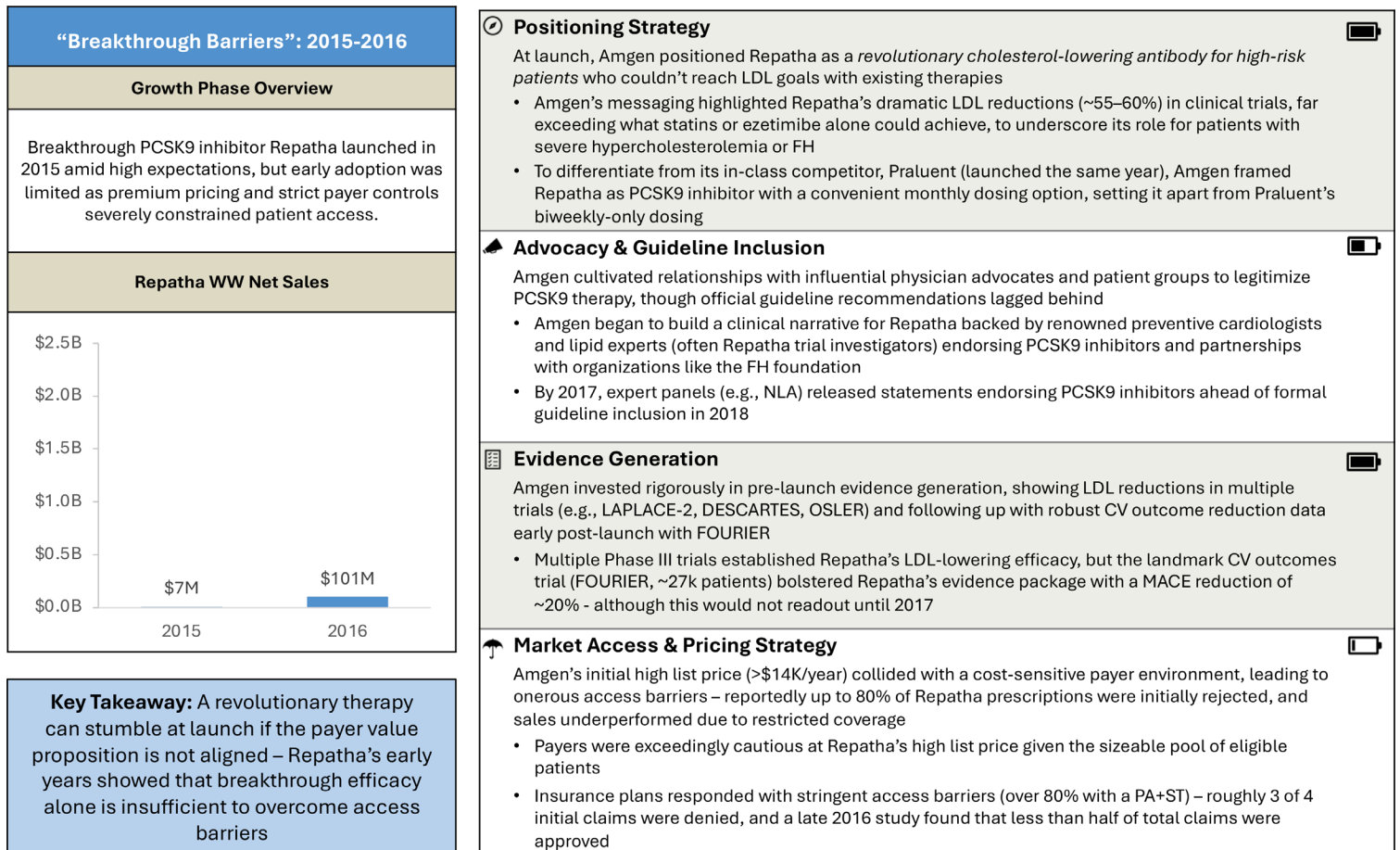


Figure 4. Overview of Repatha’s commercial performance, segmented by revenue growth phases

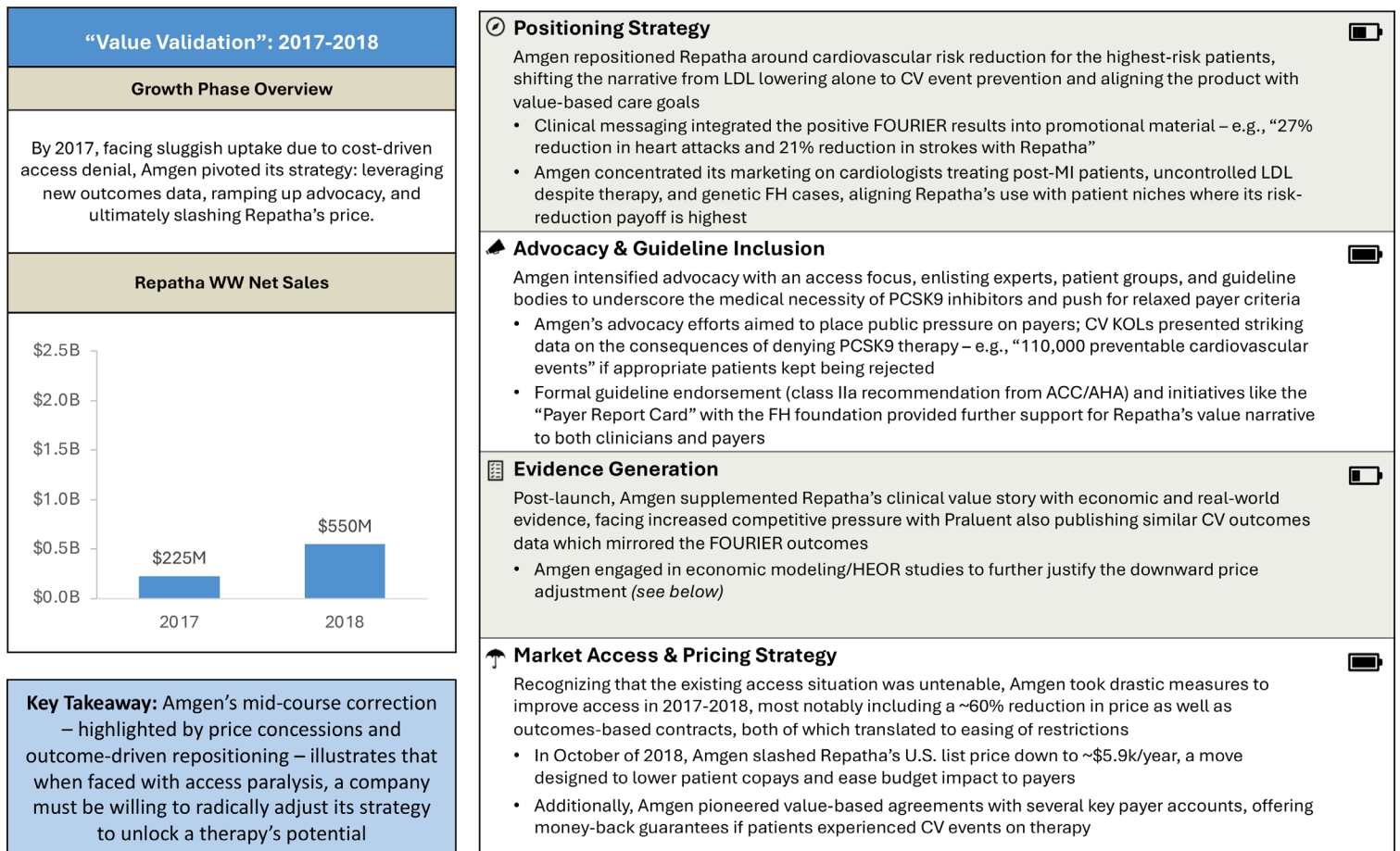
FIGURE 5.



Perceived Effort Level: High High-mod Mod-low Low

Figure 5. Overview of Repatha’s commercial performance “Breakthrough Barriers” phase

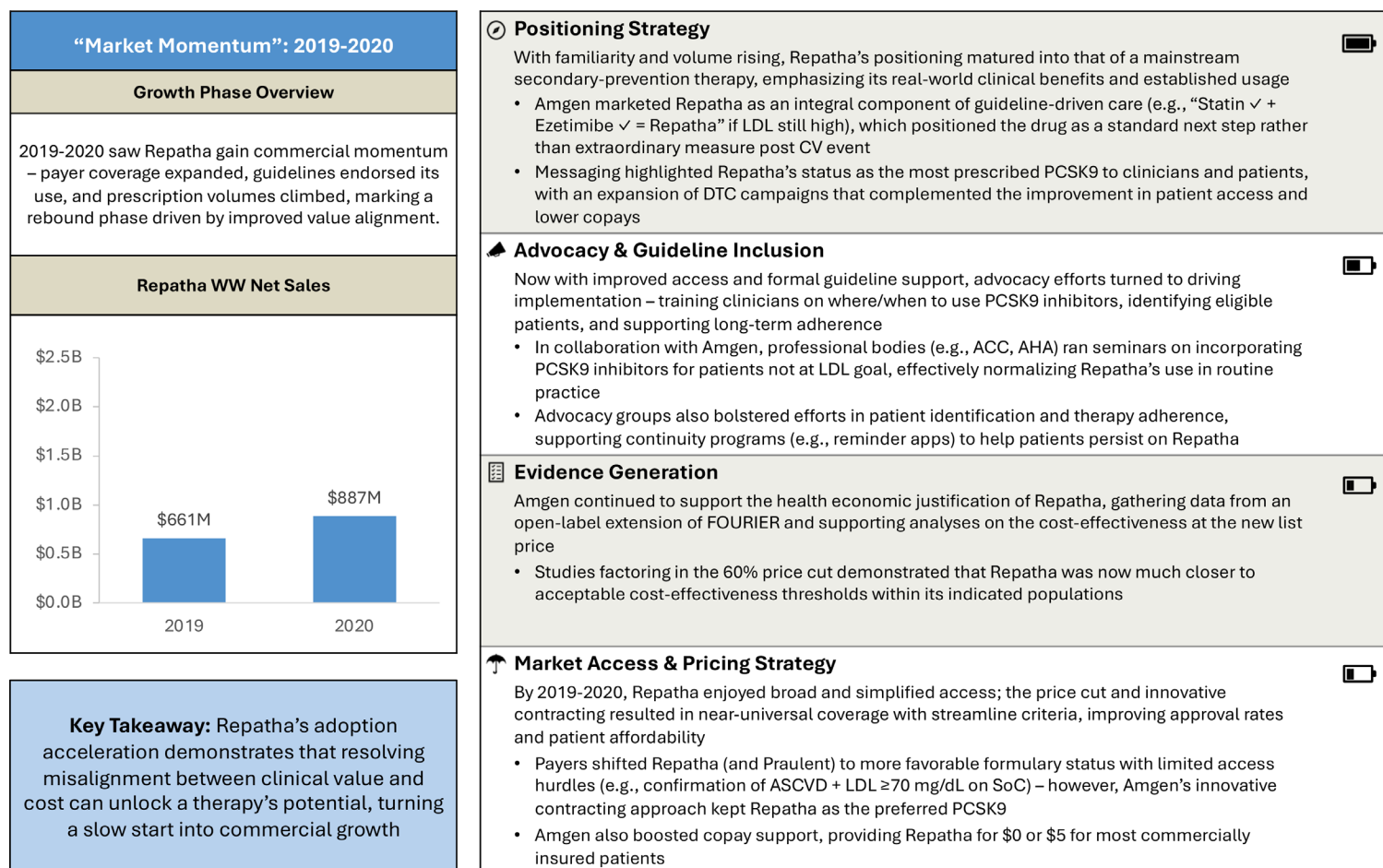
FIGURE 6.



Perceived Effort Level: High High-mod Mod-low Low

Figure 6. Overview of Repatha commercial performance “Value Validation” phase

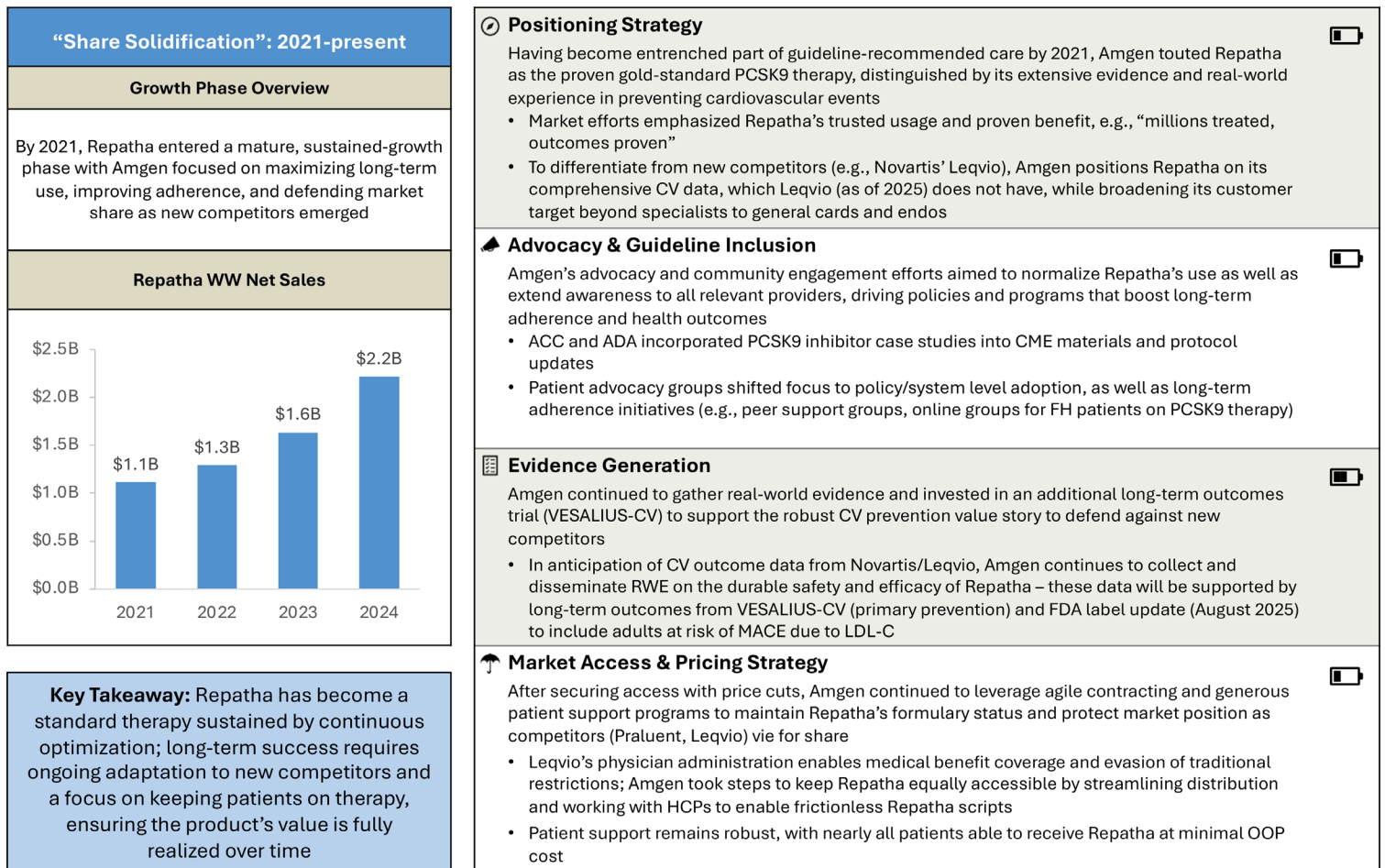
FIGURE 7.



Perceived Effort Level:  High  High-mod  Mod-low  Low

Figure 7. Overview of Repatha’s commercial performance “Market Momentum” phase

FIGURE 8.



Perceived Effort Level: High High-mod Mod-low Low

Figure 8. Overview of Repatha’s commercial performance “Share Solidification” phase

CLOSING

What to consider for your product based on learnings from Repatha:

1. Price with Purpose

If aiming for immediate traction, set launch pricing in a way that reflects payer-perceived value and budget impact. If a therapy's price is not aligned with the value perceived by payers, access will be restricted, and adoption will stall in the short term.

2. Transform the Narrative with Early Outcomes Data

Invest early in outcomes and health economics evidence to defend clinical value while proactively addressing cost-effectiveness challenges and payer skepticisms before they stall uptake. Clear, durable clinical outcomes will boost provider confidence and drive preferred access among competitive therapies.

3. Advocacy to Drive Utilization and Access

Engage KOLs and patient groups not only to endorse the therapy but to publicly challenge restrictive payer practices preventing access; coordinated advocacy can both legitimize the product and pressure payers to ease access.

4. Send Clear Credibility Signals

Market confidence requires more than clinical trial evidence; it demands bold signals. Demonstrate commitment and instill confidence by taking direct action in communicating new evidence, pricing resets, and community engagement that show stakeholders the therapy is not only viable, but clinically imperative.

5. Defend and Deepen Market Share

Even after access improves, growth is not automatic. Actively reinforce long-term success by bolstering payer partnerships, investing in continued evidence generation, and defending share against new entrants to ensure sustained patient use as the market crowds.

SERIES SEGUE

This wraps Case Study 3 of 5 (Repatha) — a product scenario which began as an access-constrained launch but was repositioned through outcomes validation and strategic pricing adjustments to unlock broader adoption.

Case Study 4 will examine Vyndamax, a market-shaping breakthrough that turned a once-invisible disease into a defined, treatable condition through focused clinical education and advocacy-driven market engagement.