

Transformative Commercialization  
for New BioPharma Entrants:

# Ensuring Success with Capital and Time Efficiency

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Commercializing a new pharmaceutical product demands significant capital, extensive time and navigating numerous regulatory and commercial challenges. It is no surprise that first-time launchers often don't perform as well as those with prior launch experience.

This whitepaper aims to quantify some of the most significant commercialization challenges for pharmaceutical companies launching their first product and help them better understand the key challenges associated with launching using in-house capabilities. We outline what "good" looks like, leveraging the innovative EVERSANA's COMPLETE Commercialization® model, which is an end-to-end commercialization solution for manufacturers to maximize the value of their products and increase efficiencies by providing full-scale commercial strategy, operational excellence, and a success-share delivery platform that de-risks financial barriers, saves time, and allows manufacturers to keep the majority of their product's value. We draw parallels between our partnered launch model and Amazon's Marketplace Platform, where EVERSANA can serve as Amazon for first-time pharmaceutical launchers, cutting costs by 25% and launch prep time by 50% while reducing risk and ensuring launch success.<sup>1</sup>

## Background: The Power of the Amazon Platform for Emerging Businesses

Historically, traditional brick-and-mortar stores have dominated the retail landscape. With high overhead costs and limited reach for each individual store, a small company looking to reduce risk and increase the speed at which it could reach a broad consumer base would often turn to partnerships with big box retailers such as Walmart, Target, Kmart, or wholesalers. While brick-and-mortar retail still maintains a significant share of sales, e-commerce platforms have changed how small businesses can commercialize their products. Among these platforms, Amazon stands out as the leading e-commerce system due to its various benefits, including:

- ✓ **Increase likelihood of success:** Accounting for about 38% of all U.S. e-commerce sales<sup>2</sup>, Amazon ranked second in overall U.S. retail sales in 2023.<sup>3</sup> The Amazon model ensures that small businesses have the same chance for success as a large business with its review and recommendation driven model.
- ✓ **Lower capital investment:** Listing a product on Amazon typically requires less upfront investment compared to securing shelf space in a big box store, which often involves significant marketing and slotting fees that can add up to as much as \$1,000 per store.<sup>4</sup>
- ✓ **Save time:** Amazon has developed a straightforward platform for setting up an online store, complete with tools for inventory management, order processing, and customer service. This has reduced the time needed to build infrastructure in-house.
- ✓ **Reduce risk:** Amazon helps small businesses scale quickly with lower risk by providing access to a pre-existing customer base, global footprint, and a trusted and credible brand.

Retail transformation through e-commerce platforms such as Amazon illustrates how leveraging innovative infrastructure can significantly reduce costs, time to market and risk. Just as Amazon has enabled small businesses to achieve greater success with greater efficiencies, the pharmaceutical industry can benefit from similar strategies to overcome commercialization challenges with innovative partnership models. EVERSANA further differentiates itself by providing the benefits of scale and efficiencies and allowing for a custom approach with each partner, providing customer control, aligned incentives, and a dedicated team to drive success.



## The Hurdles for First-Time Launchers in Pharma

Commercializing pharmaceutical products for first-time launchers is expensive, time-consuming, high-risk, and often not as successful as experienced launchers. In this white paper, we explore four key factors that make commercialization difficult for first-time launchers and explain how EVERSANA is uniquely positioned to help our partners overcome these hurdles, summarized in Figure 1.

- Ineffective:** On average, first-time launchers generate three times less net revenue than experienced launchers. Additionally, only about one-third of launches achieve pre-launch forecast expectations, and most first-time launchers do not hit the same trajectories as experienced launchers.<sup>5-7</sup>
- Capital investment:** For first-time launchers, it costs approximately \$247 million cumulatively (max: \$1.1 billion, min: \$89 million) to bring a new drug to market over four years (the three years before launch and the launch year). This is supported by our prior analysis of cost to launch<sup>1</sup> and other

analyses finding that first-time launchers tend to spend more on Selling, General, and Administrative Expenses (SG&A) at launch than more experienced launchers.<sup>7</sup>

- Time intensive:** Successful first-time launchers must begin preparing more than 24+ months before launch.<sup>8</sup>
- High risk:** Seventy-eight percent of emerging pharma companies, defined as those with a market capitalization of less than \$300 million, received a delay or rejection from the U.S. Food and Drug Administration (FDA) over the past 10 years.<sup>9</sup>

While we will discuss these four key factors as independent challenges in the following sections, all should be seen as intertwined. A significant reason why launches are often ineffective is the failure to bring best-in-class capabilities at the right time. This failure is due to capital constraints and business choices that deprioritize certain commercial actions or rely on legacy commercialization principles that aren't compatible with the latest approaches to commercialization.

	INEFFECTIVE	CAPITAL INTENSIVE	TIME INTENSIVE	HIGH RISK
Challenge	First-time launchers generate on average <b>3x less net revenue</b> than experienced launchers	Average total in-house drug launch costs are <b>~\$247M</b> from three years prior to launch through the launch year	<b>~24 months</b> are typically required for launch preparation	<b>78%</b> of companies with a market cap <\$300M receive a delay or rejection
Solution	<ul style="list-style-type: none"> <li>Team with experience across 500+ launches</li> <li>End-to-end capabilities and innovation</li> </ul>	<ul style="list-style-type: none"> <li>Lower cost to launch overall by 23% with prebuilt infrastructure</li> <li>Co-financing model to reduce pre-launch investments further</li> </ul>	<ul style="list-style-type: none"> <li>Preexisting launch capabilities, infrastructure and ready-to-deploy teams reduce time to market by 50%</li> </ul>	<ul style="list-style-type: none"> <li>Contractual flexibility and agility to ramp up and down cost-efficiently in &lt;10 days</li> </ul>
Outcome	<ul style="list-style-type: none"> <li>Launched in six months, while exceeding forecast by 7% for first-time launcher in oncology with a mildly differentiated product</li> </ul>	<ul style="list-style-type: none"> <li>Reduced commercial spend by ~\$63M over five years for a first-time launcher in cardiology</li> </ul>	<ul style="list-style-type: none"> <li>Achieved launch readiness for a first-time launcher in rare disease in eight months</li> </ul>	<ul style="list-style-type: none"> <li>Paused commercial preparations after partner received a CRL in five days, avoiding &gt;\$10M in costs of down- and up-sizing</li> </ul>

Figure 1: Four key factors make commercialization challenging for first-time launchers, but our innovative partnership model is uniquely positioned to help our partners overcome these obstacles



## Solving for These Commercialization Hurdles

### Ineffective

#### The Challenge

One of the most significant and all-encompassing challenges in pharmaceutical launches is achieving success, especially for first-time launchers who often do not achieve the same trajectory as experienced launchers, as shown in Figure 2. Analyzing FDA-categorized novel products with reported U.S. net sales data, we examined drugs launched from 2015 to 2023. Our findings revealed that 186 launches by experienced companies achieved an average of \$604 million in net sales by the fourth year post-launch compared to \$187 million for first-time launch companies – a three-fold difference in revenue generation!

Several forces are at play against first-time launchers, including the investment and time needed to prepare for successful commercialization to sufficiently conduct pre-launch disease education, engage customers, and overcome market access and adherence barriers. First-time launchers need an Amazon-like partner to level the playing field and help them achieve a product's true potential.

Additionally, according to multiple studies, most launches fail to meet their first-year forecasts.<sup>5</sup> Specifically, 66% of launches fall short of their initial projections, 8% meet or are close to their forecasts, and only 26% exceed expectations.<sup>5</sup> First-time launchers achieve just 63% of their forecasted targets.<sup>6</sup>

#### The Solution

Several factors contribute to struggling to achieve launch success, including setting unrealistic expectations, inadequate market shaping, underestimating market access issues, leaky funnels with insufficient fills and adherence, poor customer engagement, and misaligned incentives with vendors. Understanding and addressing these challenges is crucial for improving launch success rates. Our expertise in understanding these issues through experience across more than 500 launches allows us to focus on the key leverage points across the journey, including diagnosis, prescribing, access, onboarding, and adherence. Further, we provide innovative solutions such as:

- Precise targeting of physicians and health systems with appropriate patients, access, and readiness to adopt leveraging real-world data and predictive models.
- Modern engagement methodologies, such as the creation of patient communities and omnichannel orchestration to target the right stakeholders with the right messages and right channels at the right time.
- Direct-to-patient approaches to improve time to diagnosis and therapy, overcome access barriers, enhance fills at the pharmacy and promote adherence.
- AI-enabled tools, such as MLR process automation, digital KOLs, a health concierge, and app-enabled diagnosis.

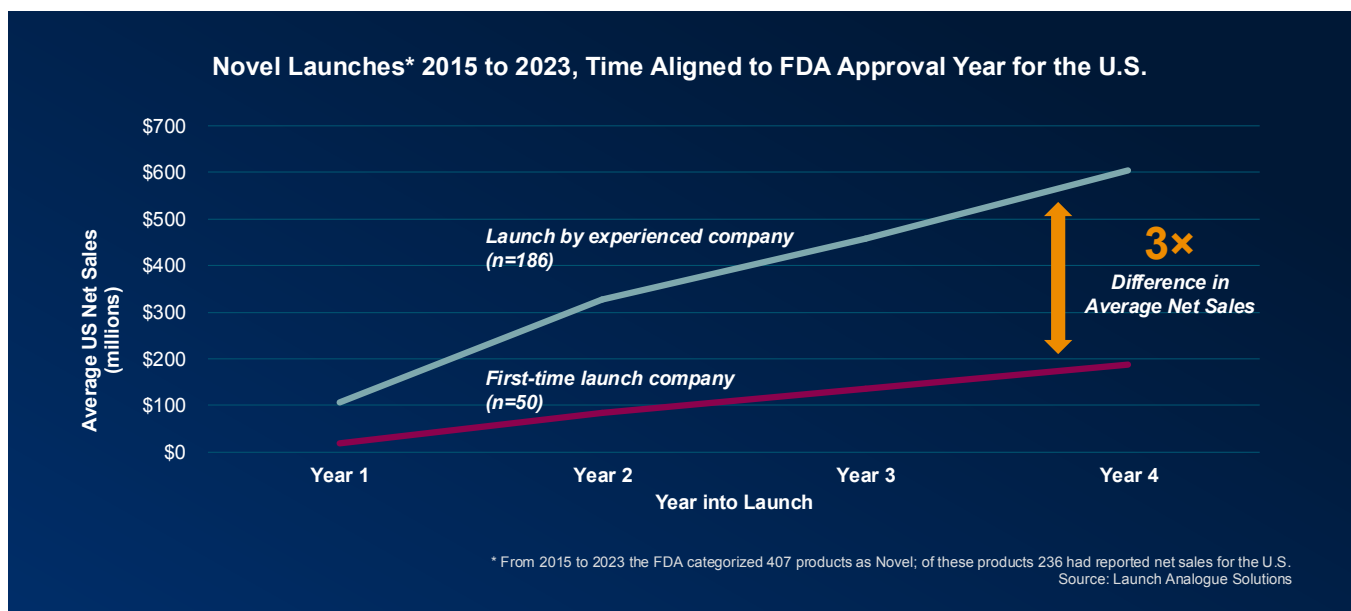


Figure 2: Four years into launch, products launched by companies with launch experience outpaced first-time launches by three-fold in terms of net sales.



# Launch Excellence

*An emerging biotech in oncology needed help preparing for a launch in six months while achieving success with a later line product*

## OUTCOME

Through our COMPLETE partnership with this biotech, a team of over 80 members was brought in to help the company become launch-ready within six months.

Additionally, the launch investments were significantly reduced, and the promotional model was adapted to start with access, then move to in-person promotion, and finally pivot to non-personal promotion to maximize profitability.

# 6 months

from partnership kickoff to being launch ready

# 7%

performance exceeding forecast, even after pulling out the sales team

### The Outcome: Exceeding Forecast in Oncology Launch Challenge

An emerging biotech in oncology required assistance preparing for a product launch within only six months. EVERSANA assembled a team of over 80 members across various functions to develop and execute a launch plan to ensure launch readiness within this time frame. Additionally, EVERSANA significantly reduced launch investment needs and dynamically flexed the promotional model, starting with a focus on market access and then shifting to an in-person promotional model before finally pivoting to a non-personal promotional model to maximize profitability. As a result, the partner biotech outperformed the forecast by 7% while improving its profitability significantly by transitioning to non-personal promotion later in the launch.

### Capital Intensive

#### The Challenge

Commercializing products is capital-intensive, particularly for first-time launchers and smaller biotech companies. Our analysis of 17 first-time launchers of FDA-categorized novel products revealed that the average SG&A over a four-year period, spanning from three years before launch through the launch year, was \$247 million, as shown in Figure 3A. There is a broad

range of cumulative SG&A costs over the four-year period across the 17 companies analyzed, with the highest SG&A of \$1.1B and the lowest of \$89M, reflective of the very different needs and associated budgets required to launch different products.

This analysis considers products that launched in 2017 or later, were publicly traded, and were only source of product revenue upon launch. The SG&A figures exclude R&D costs and any other costs the company incurred prior to the three years leading up to launch. In other words, most first-time launchers must spend nearly \$250 million building up commercial capabilities before reaching their first full year of revenue generation. Our analysis is also consistent with other industry reports investigating launch costs.<sup>7,10</sup>

Further, even when companies can secure the necessary resources to launch a product, first-time launchers face profitability issues. For the same 17 first-time launchers, we also examined SG&A ratios for the four years following launch, shown in Figure 3B. For reference, large pharma SG&A ratios are typically in the range of 15% to 40%. Based on this analysis, it typically takes two full years of revenue before revenues exceed SG&A (i.e., SG&A ratio <100%), and even after four full years in the market, most first-time launchers are still operating on limited to negative cash flow once other costs are considered.



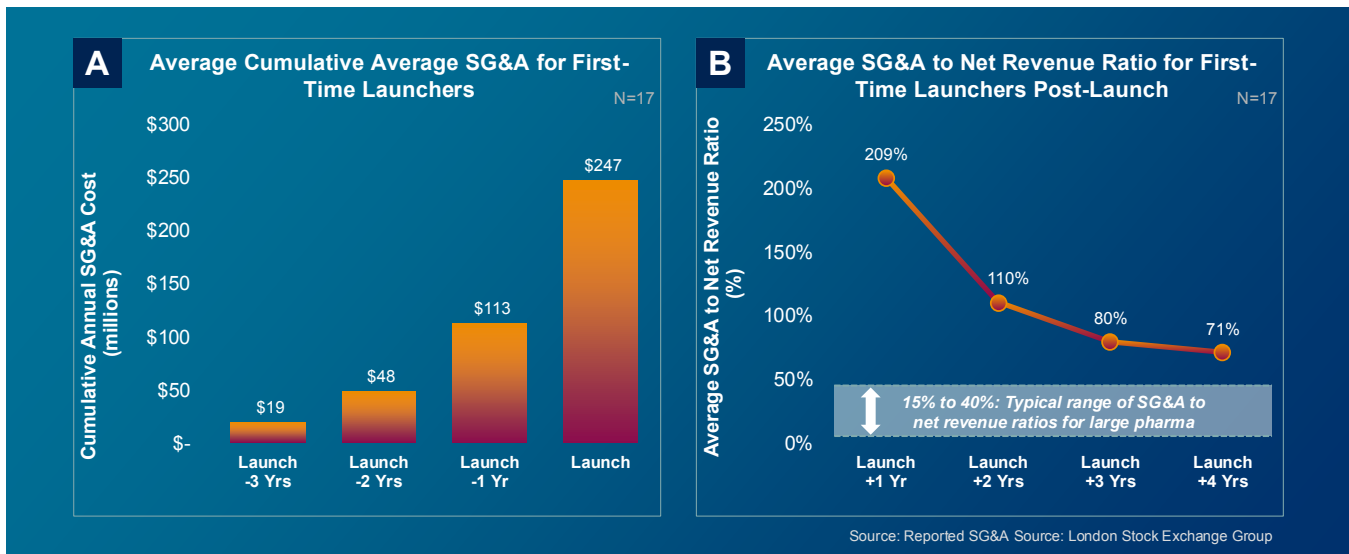


Figure 3: A) Cumulative SG&A for first-time launchers over a four-year period from three years prior to launch to year of launch; B) Average SG&A to net revenue ratio for first-time launchers for the five years post-launch. Criteria for products included in the analysis: First-time launcher, launched between Jan 2017 – December 2021, publicly available financial data (i.e., revenue, SG&A), single source of product revenue is the launched asset.

Not only is the cost of launching a product high, but raising capital has also become more difficult. While both venture capital (VC) investments and life sciences IPOs are rebounding from drops in 2022 and 2023, both lag behind pre-2022 investment levels. Additionally, interest rates remain high for debt financing.

This analysis reveals that first-time launchers need to be extremely capital sensitive and seize all opportunities to become capital efficient. With EVERSANA's innovative partnership model, first-time launchers can achieve 25% to 50% capital efficiency.

The Solution

Similar to the Amazon Marketplace platform, which can reduce capital investment requirements, partnered launches with EVERSANA cost less year-over-year

compared to launching in-house, as the model eliminates the need to build extensive infrastructure. EVERSANA has successfully launched 12 products across various therapy areas, with companies demonstrating an average of 23% cost savings.<sup>1</sup> Additionally, EVERSANA offers co-financing, which significantly reduces pre-launch capital needs.

These cost savings can be achieved through leveraging EVERSANA's pre-built infrastructure and single-partner model across insights, strategy, and execution, which results in seamless connectivity between workstreams and cost efficiencies. We can offer capital efficiencies by leveraging just-in-time deployment of experienced teams, pre-built infrastructure and improved resource utilization, reduced project management requirements, and acceleration of launch preparation, as detailed in Figure 4.



Figure 4: Summary of significant capital efficiencies that can be realized by adopting a partnered, innovative commercial model



# Capital-Efficient Launches

An analysis of 10 early-stage companies demonstrated that the **EVERSANA COMPLETE Commercialization®** model yielded savings of ~25% over companies that launched on their own

## OUTCOME

Through our support in commercialization preparations, we are able to reduce our emerging biotech partner's overall launch costs and investment needs by 25% using our integrated prebuilt infrastructure. Additionally, we can lower pre-launch costs through a co-financing partnership.

~25%

estimated savings  
in pre-launch spend

### The Outcome: Capital Efficient Cardiology Launch

EVERSANA's ready-to-deploy model helped a cardiology company reduce required launch investments from \$248 million over five years from pre- to post-launch by \$63 million. This was achieved through SG&A savings and the partnership's ability to offer co-financing for the launch.

### **Time Intensive**

#### The Challenge

Time is another challenge, with launch preparations typically taking more than 24 months. Pharma companies need to begin planning well in advance of a Prescription Drug User Fee Act (PDUFA) date to ensure all necessary resources and strategies are in place for a successful launch. Sometimes, first-time launchers wait for favorable partnerships or out-licensing deals because they don't have the resources to launch themselves; therefore, they miss out on the critical launch window, potentially decreasing the time to loss of exclusivity (LOE) or causing suspicion among HCPs as to why the product isn't on the market. In Figure 5, we have summarized two recent examples of products that were approved, but the manufacturers were not launch-ready and experienced significant delays in commercialization:

- **ACCRUFER®:** Shield Therapeutics received FDA approval for ACCRUFER in July 2019 but waited 18 months to launch, intending to find a suitable licensing partner to optimize the product's commercial prospects. Ultimately, Shield launched independently in 2021 with a relatively small field team, and by the second year of launch it reached only 40% of covered lives. In December 2022, Shield partnered with Viartis and achieved a four-fold growth in sales. In 2025, ACCRUFER continues to grow, with an estimated peak-year revenue of \$450 million, which likely could have been achieved earlier had the right partner been available. This example demonstrates how optimizing a launch requires early planning of resources and partnerships.
- **IBSRELA®:** Ardelyx received FDA approval for IBSRELA in September 2019 but delayed the launch of IBSRELA by over two years to focus on continued clinical development and prioritize another pipeline asset, XPHOZAH. Having multiple priorities can be difficult for first-time launchers, with Ardelyx waiting until 2024 to expand its salesforce for IBSRELA, potentially delaying the achievement of opportunity. The example shows how waiting to launch alone can delay net sales and how selecting a partner earlier in the commercialization process can help capture the opportunity sooner.



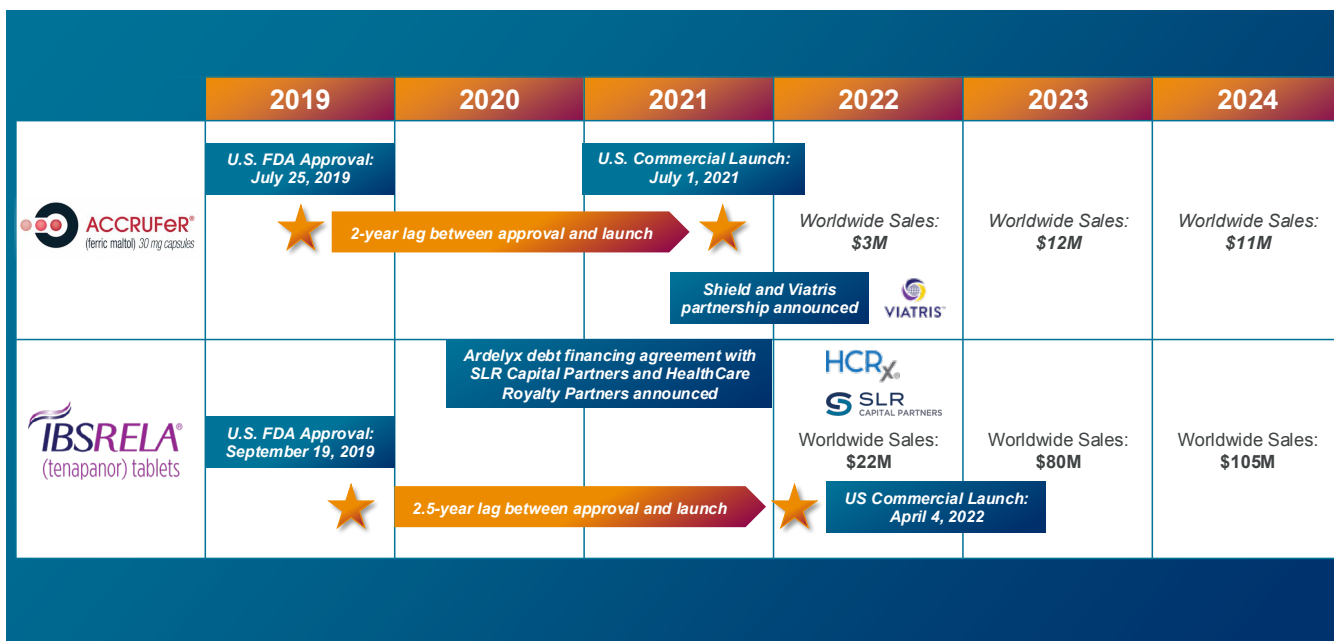


Figure 5: Two examples of products that experienced delayed commercial launches post-approval by the FDA.

Delays to launch are often driven by hiring functional area or business unit leads, setting up operations, building infrastructure and onboarding vendors.<sup>8</sup> Timing a launch can be critical for pharma companies, especially first-time launchers, as delays can mean reduced time of exclusivity in the market, delays in revenue generation, and reduced ability to capitalize on the positive momentum of the news of an FDA approval.

#### The Solution

EVERSANA is equipped to reduce the time to launch by 50% or more, from 24 months to 12 months or fewer, by activating the right functions at the right time. Key tactics to save time include a phased deployment of teams, leveraging pre-built launch kits for different launch archetypes that can be customized within a few weeks, utilizing EVERSANA's ready-to-deploy teams that have already worked together successfully on other launches, and having access to a single partner across all functions that starts execution from day 1, with no wasted time in a request for proposal (RFP) process.

#### The Outcome: Expedited Ultra-Rare Disease Launch for First-in-Class Therapy

A small pharmaceutical company in the ultra-rare disease space, where the team had only a pre-existing brand plan and some medical affairs materials, needed help preparing for launch in a short time frame. With EVERSANA's partnership model in place, we were able to focus on data infrastructure, developing marketing materials, and strategy development for medical affairs, market access, and marketing. As a result, the company was able to prepare for launch within eight months from partnership kick-off to PDUFA date and reduced launch costs. Similar to how the Amazon Marketplace platform provides companies with a readily available marketplace with a large customer base, EVERSANA's unique platform can save companies time through its pre-existing relationships, processes, infrastructure, and launch model.

**EVERSANA is equipped to reduce the time to launch by 50% or more, from 24 months to 12 months or fewer.**



# Launch Readiness

An emerging rare disease company needed help preparing for launch in an expedited fashion

## OUTCOME

Through our partnership with this rare disease company, we built 50+ capabilities across 8 functions with 100+ EVERSANA team members to help company be launch ready.

*We've been able to get launch ready **in record time** due to our partnership with EVERSANA.*

—Chief Commercial Officer,  
Emerging Rare Disease Company

# 8 months

from partnership kickoff  
to being launch-ready

# >1,000

Executed activities  
in eight months

## High Risk

### The Challenge

The third key launch challenge is risk. An analysis of delays and rejections over the past 10 years shows that a company with a market cap of less than \$300 million had a 78% chance of a delay or rejection, whereas companies with a greater than \$300 million market cap had a 47% chance of a delay or rejection.<sup>9</sup> When a complete response letter (CRL) is received, it usually takes at least 18 months or longer to resolve, refile, and gain approval, and company leadership must keep millions of dollars tied up or disband the entire commercial team only to rehire them again in 9-12 months.<sup>9</sup>

### The Solution

Similar to the Amazon Marketplace platform, leveraging an innovative partnership model reduces risk by using an innovative commercialization model that has been proven and tested by other companies. EVERSANA offers flexibility based on regulatory actions and has the ability to quickly dial up and down commercial efforts while minimizing financial strain and execution risk and eliminating the need to hire or fire team members internally. Partnerships with EVERSANA can even include innovative financial structures that further reduce the risk and capital needed for launch.

### The Outcome: Downsizing and Upsizing for an Anti-Infective Product Launch After a CRL

A small pharma company developing an anti-infective faced a significant setback when it received a CRL from the FDA. To navigate this uncertainty, EVERSANA quickly downsized the launch operations in five days, minimizing costs and preserving resources. Once the company received FDA approval two years later, EVERSANA seamlessly scaled up operations with the same launch team, ensuring the retention of key knowledge and allowing for a rapid launch within six months. As a result of this partnership, the pharma company avoided an estimated \$10 million in costs had it downsized and upsized on its own without EVERSANA.

**As a result of this partnership, the pharma company avoided an estimated \$10 million in costs had it downsized and upsized on its own without EVERSANA.**



# Flexibility

*A small pharma anti-infectives company needed help preparing for launch after receiving a CRL from the FDA*

## OUTCOME

EVERSANA quickly downsized operations within five days of the company receiving a CRL.

Now the has received an FDA approval two years later, EVERSANA is ready to scale back up and launch within six months.

*You've been a **great partner** through the ups and downs and worked so hard on our behalf. It's greatly appreciated.*

*—CEO, Emerging Anti-Infectives Company*

# 5 days

time to pause operations

# >\$10M

estimated savings by avoiding downsizing and then upsizing on its own

## Concluding Thoughts

### Transformative Commercialization: Leveraging Strategic Partnerships for First-Time Launch Success

Commercial partnerships can significantly enhance drug launches by providing companies with specialized expertise, accelerating time to market, mitigating risks and achieving cost efficiencies.

In conclusion, EVERSANA is uniquely positioned to serve as the “Amazon platform” for first-time launchers by offering cost and time-efficient commercialization while reducing costs.

Partnering with EVERSANA offers immediate access to subject matter experts and their extensive experience. Additionally, companies benefit from EVERSANA’s established infrastructure, networks and relationships, which expedite the launch process. EVERSANA also

assists in identifying potential risks and developing strategies to mitigate them, allowing companies to focus on other priorities. Finally, EVERSANA provides flexible and scalable support tailored to each company’s unique needs.

Through EVERSANA’s “commercialization as a service” model, we offer a platform that functions as a configurable, turnkey solution that combines operations, technology, and cross-functional subject matter experts. This turnkey solution can be instantly configured for a launch and is flexible enough to allow modifications during and after launch. Further, layered on top of this turnkey solution is a financial construct that enhances the commercial outcomes of the products EVERSANA launches in partnership with companies. This novel approach to commercialization yields greater top- and bottom-line results and is the transformative model for pharma commercialization.



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EVERSANA is the leading provider of global commercialization services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, providers, channel partners and payers. The company serves more than 650 organizations, including innovative start-ups and established pharmaceutical companies, to advance life sciences services for a healthier world. To learn more about EVERSANA, visit [EVERSANA.COM](https://EVERSANA.COM) or connect through [LinkedIn](#) and [X](#).