ConnectA
STRATEGIC SOLUTIONS GROUP

The Real Impact of Drug Launch Failures

Why Launch Planning Is Keeping Life-Improving Drugs From the Patients That Need It Most

The Background

As the world evolves into a new post-pandemic space, the efficacy of new drugs has become a hot topic among both patients and researchers. And, with the Nasdaq Biotechnology Index rising over 600% since 2005 the stage is being set for a host of medical breakthroughs to revolutionize healthcare for billions of people worldwide.

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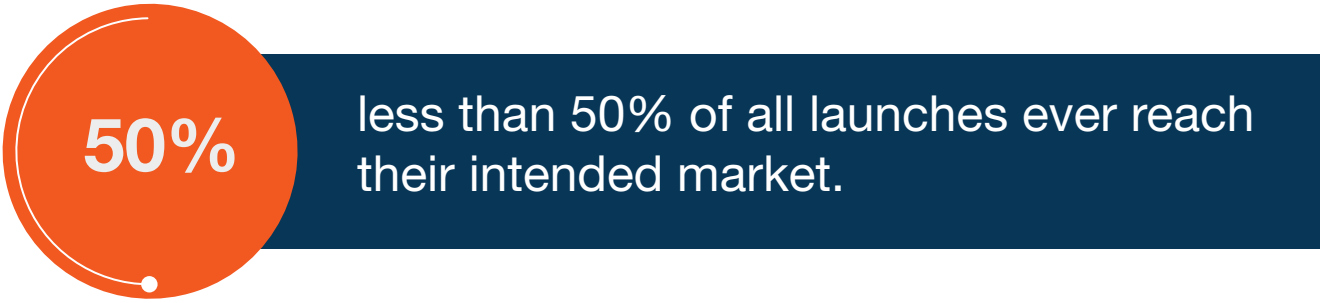
Yet, despite the growth indicators of the market pointing to the potential (and growing need) for a novel, blockbuster drug, less than 50% of all launches ever reach their intended market. Pharmaceutical researchers have traced the failure of these drugs often not back to lapses in FDA approval, but, instead to glaring gaps in product launch strategy.



Because without the right team in place, that is equipped with a resilient mindset, and a solid product launch strategy, 48% of all newly-released drugs fail to hit their financial expectations even three years after launch. One such example, to illustrate the importance of taking a holistic approach to launch strategy can be seen with the continued failure of the PCSK9 inhibitor alirocumab, sold as Praluent.

This paper serves to analyze the 2015 Praluent launch and its subsequent 2018 and 2021 rebrandings to pinpoint key breakdown points that must be considered for successful product launches.

The Case

Marketed, originally, as a once-a-month, **injectable PCSK9** inhibitor designed to reduce **low-density lipoprotein cholesterol (LDL-C)** or bad cholesterol in adults – Praluent had an intended large market for distribution. With relatively mild side effects reported during clinical trials that ranged from muscle cramps, to itching at the injection site, to occasional body chills, analysts expected the drug to be a blockbuster hit. Especially because it helped to address a largely unmet clinical need in patients with an inherited disorder called **"familial hypercholestrolemia" (FH).** Patients with this disorder have abnormally high LDL levels that are not usually effectively treated by traditional statins.

So, Praluent represented a possible medical solution for over 31 million people worldwide (prevalence of 1 in every 250 people). According to the July 2015 FDA approval, Praluent was found to reduce LDL among those with this unique disorder by up to 59%.

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However, despite it's documented benefits – even for a subset of the general population – the 2015 launch was a marked failure. In 2015, after 5 months of being on the market, Praluent only generated a startling low **$11 million in sales revenue**. The drug has since been remarketed in 2018 and again in January 2021 as more research has been completed on its wider range of health benefits and effectiveness.

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source: www.fiercepharma.com/pharma/half-drugs-launched-last-15-years-failed-to-meet-wall-street-s-expectations-report#
www.fiercepharma.com/pharma/half-drugs-launched-last-15-years-failed-to-meet-wall-street-s-expectations-report
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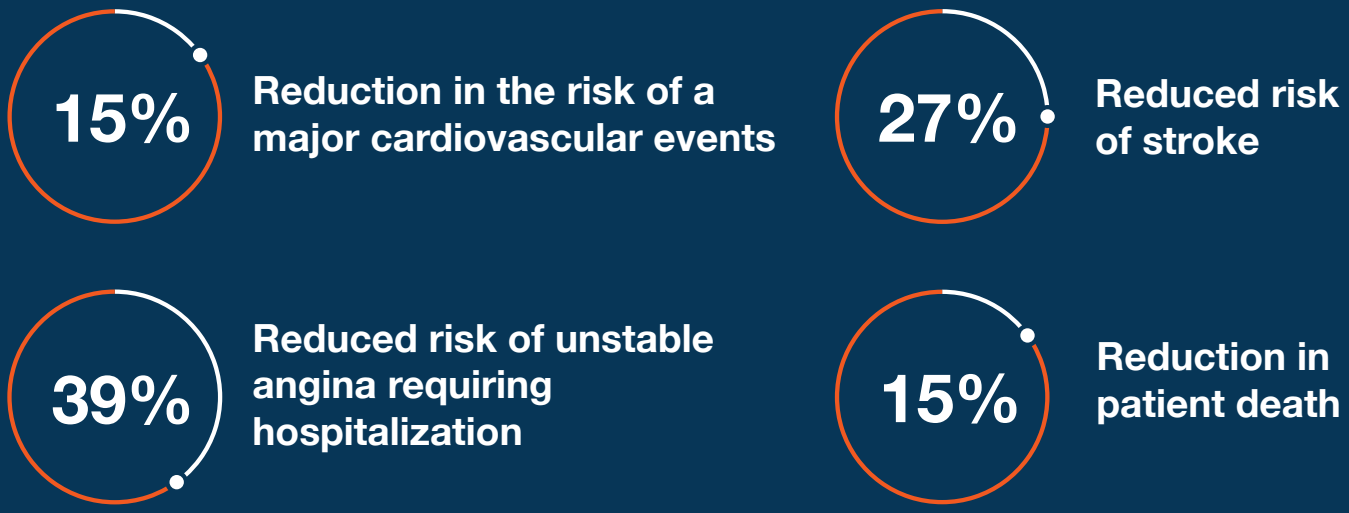
www.mmm-online.com/home/channel/features/can-the-third-pcsk9-drug-succeed-where-the-first-two-failed/

One such finding emerged from a November 2018 study, published in the New England Journal of Medicine that found that Praluent, resulted in a **15% reduction in the risk of a major cardiovascular events, 27% reduced risk of stroke, 39% reduced risk of unstable angina requiring hospitalization, and a 15% reduction in patient death.** This represented a significant opportunity for the drug to re-enter the market and positively impact the lives of so many more patients. However, to date, sales have continued to be disappointing at best, with Praluent falling short of expectations.



So, the question ultimately becomes...

For such a life-saving drug, why has it not been able to gain traction, even among those patients who need it the most?

The Analysis

On paper, Praluent had the makings of becoming one of the biggest cardio injectable drugs in a decade. However, in practice, it's fallen into obscurity. From a drug launch perspective, there were a number of breakdowns in the launch strategy that led to the lower-than-expected market performance.

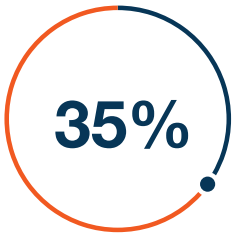
1 Failed Pricing & Competitor Assessment

The largest challenge Praluent faced is standing out in an already saturated cardiovascular market. Add to that the presence of a direct competitor, Repatha – a rival therapy from pharmaceutical giant, Amgen. From the initial launch the two drugs were in a pricing war that ultimately priced both drugs out of the market. **At launch in July 2015, with a list price of $14,625 and with little, if any real medical evidence to prove it's effectiveness, Praluent was too expensive for most.**

2 Incomplete Go-To-Market Strategy

Launch teams were dependent on a handful of short-term scientific studies to use as marketing material to justify driving patients to want to ask their doctors for Praluent. However, when the drug was launched, its ability to lower LDL was still in question. The more detailed study, examining the heart benefits was just initiated, and it can be assumed that there was limited buy-in within the market prior to launch. Coupled with the mountain of paperwork that patients had to complete to get Praluent's high cost covered, this further disincentivized patients from requesting the novel medication. According to research by **Duke Clinical Research Institute, of patients given a prescription for Praluent in its first year, only 47% received insurance approval, and of those, 35% never filled the prescription due to the high out-of-pocket costs.**

Received insurance approval.



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source: www.drugs.com/newdrugs/fda-approves-praluent-alirocumab-certain-patients-cholesterol-4236.html
www.investor.regeneron.com/news-releases/news-release-details/regeneron-reports-fourth-quarter-and-full-year-2015-financial
www.drugs.com/newdrugs/fda-approves-praluent-alirocumab-prevent-heart-attack-stroke-unstable-angina-requiring-4955.html
www.biopharmadive.com/news/praluents-lower-list-price-isnt-yielding-better-sales-yet/553560/

3 Lack of Integration Between Scientific Findings & Marketing Strategy.

It wasn't until April 2019 (4 years after launch), that Praluent was finally approved to add a heart benefit to its label. However, now **7 years post-launch**, and with a host of new competitors in this space, **Praluent has been forced to cut their prices by 60%**, during a recent rebranding, to attempt to salvage sales. This launch breakdown could point to a failure in properly integrating the scientific studies (that were still in their infancy when the product was prematurely launched) with a detailed marketing strategy that would generate solid physician and insurer buy-in.

The Emerging Importance of Mental Resilience For Launch Teams

When the details of the launch are further analyzed, it also becomes apparent that there was not just miscommunication that riddled the ultimate failure of the launch, but also a lack of mindset or resiliency training.

Drug and product launches are demanding and rather grueling multi-year endeavors that require a high level of mental and emotional endurance to be able to manage stress, anxiety, and overwhelm. As Tony Robbins acknowledges, 80% of any success is rooted in psychology and only 20% of the success we achieve comes from the strategies we use and the skills we have. This is also true for life-improving drug and product launches. Because if the team leaders do not develop mental resilience, then the launch team's strategy will still be ineffective or never executed properly at all.

Coupling the length of the launch cycle with having to navigate various stakeholder expectations – in a global arena – creates a very challenging environment to perform, even for the most experienced launch teams. However, if mental resilience and team dynamics support are not provided during the often grueling 24-month launch process, these lapses in communication, information sharing, and collaboration can easily lead to all of the above highly-avoidable launch failures.

Had the launch team considered the pricing objections by insurance companies, Praluent would have met expectations. Had the launch team sought to secure physician relationships to help boost patient awareness, Praluent may have reached its launch goals. Likewise, had the launch team been supported to fully integrate the scientific findings into a cohesive marketing strategy, Praluent's reach would have been much greater.

Because, at the end of the day, the group that is always most affected when drug launches fail are not just the pharmaceutical and life science companies, but rather the patients who are in need of these life-improving medications and treatments.

The Company Behind The Report

Welcome to **ConnectA Strategic Solutions**

Founded on one simple principle: People first, people always – ConnectA Strategic Solutions has an unwavering commitment to help midsize life science companies do what they do best: change the lives of the patients they serve.

With an intense focus not solely on providing product and drug launch teams with winning launch strategies, ConnectA infuses a highly tailored and unique mental resilience approach to ensure that team leaders have the mindset tools, the team dynamics training, and the leadership development they need to thrive.

It is from this authentic space of supporting the whole team, by uplifting the leader that ConnectA has been able to successfully reduce communication disconnects, increase team collaboration, and lead launch teams to 10-figure results.

To R.A.M.P. Up to Launch, Leaders Must Start with Resilience

Meet Lynn Donaldson,
Founder & CEO of
ConnectA Strategic Solutions

Hi, my name is Lynn Donaldson. As the Founder & CEO of ConnectA Strategic Solutions, our proprietary R.A.M.P. methodology first develops the mental resilience among your top performers, so you can effectively expand product launch team synergy, identify innovative and proven launch strategies, and ensure flawless, results-driven execution.

Our A-team brings over 180+ years of combined subject matter expertise, helping launch teams seamlessly navigate marketing, commercial, and regulatory areas that often derail product launch success. The power of starting with mental resilience first – in your product launch – has enabled our clients to achieve up to 80% higher product launch revenues with 80% fewer delays, and empowering them to transform the lives of their patients.

If you'd like to learn more about who we are and why we're different, please visit our website at **www.connectastrategy.com.**

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