

WHEN A CURVEBALL THREATENS YOUR PRODUCT'S LAUNCH

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EVERYONE KNOWS BIOPHARMA IS A HIGH-STAKES GAME THAT CAN BE AS RISKY AS IT IS REWARDING.

Consider three potential strikes that could send your product back to the bench:

- 1 Your FDA approval doesn't go as planned.
- 2 Uncertain market conditions adversely affect your ability to raise — or re-raise — capital.
- 3 A legal, manufacturing, compliance or other operational issue catches your team off guard.

But these common and often very disruptive scenarios don't have to threaten your launch. At EVERSANA, we can help you de-risk the game while you maintain full control of your product – and YES, overcome these scenarios that can be fatal to your product and/or company.

1 Your FDA approval doesn't go as planned.

In 2019, the FDA approved several drugs (including those for rare diseases) months ahead of their Prescription Drug User Fee Act (PDUFA) goal dates, boosting their companies' share prices. This year alone, the FDA has fast-tracked about 20 drugs, including those for cancer.

But many drugs aren't as lucky. In a typical year, at least one-third of drugs from emerging pharma firms are delayed or rejected. Of course, this isn't a typical year. The FDA has had to focus on evaluating COVID-19 therapies and has warned the industry to expect delays. What if your drug is one that gets delayed? Realistically, you must

be prepared if the FDA delays your approval. And working with a **COMPLETE COMMERCIALIZATION** partner balances the uncertainty about your drug's commercial potential.

And worse yet, nothing is as disruptive as having the FDA reject your submission, which can substantially cut the value of your company's shares and unmotivated key internal stakeholders. A rejection often requires a new wave of investment to restart and realign your entire commercialization plan, and that new wave is happening at the worst possible time to raise additional funds. The water has been muddied. Additionally, rejection threatens the stability of your C-suite – what if they begin to look outside the company for greater odds?

Delays and rejections also can deal a blow to your company's culture, especially if you must go through a round of costly layoffs — only to rehire your team in 9 to 12 months. The other option — keeping your staff intact but not fully productive during this waiting period — is expensive and inefficient.

Even if your company submitted a 505(b)(2) for a drug that isn't a new chemical entity, you should be prepared for the unexpected, as using this pathway is not a guarantee for a smooth approval. If you overestimate your chances for approval, you could be unprepared for a potential delay or even rejection.

How COMPLETE COMMERCIALIZATION by EVERSANA can help: To mitigate the risks of drug development across the entire life cycle, EVERSANA has developed the **COMPLETE COMMERCIALIZATION** model. We help your company reduce its financial exposure upfront, while you still maintain full ownership so you can capture the full revenue potential of your products.



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According to Jim Lang, CEO, “When you work with EVERSANA, you don’t have to worry about quickly building your infrastructure when your product gets the green light sooner than expected — or the time and expense needed to rebuild your infrastructure after a delay or rejection. We have everything you need, as soon as you need it, to increase the likelihood of commercialization without the additional cost to restart the process.” The short story is this: Leverage our infrastructure as your own — when and how you need it. It offers you the ability to speed up, slow down or scale up at the exact moment you need to do so.

2 Uncertain market conditions adversely affect your ability to raise — or re-raise — capital.

Like uncertain weather patterns in a game, changes in the economic and political landscape can dampen investors’ appetite for risk and make it much more difficult for your team to execute your strategy as planned. At the same time, health policies on drugs are always evolving, threatening to change the game for companies expecting a robust ROI from their breakthrough products.

An inability to raise or re-raise capital because of market conditions can be especially damaging for emerging companies with just one or two products in development. For them, a lack of investor confidence can put them out of the game for good.

How COMPLETE COMMERCIALIZATION by EVERSANA can help: We have made and continue to make \$500M+ investments in the industry’s first and only full-scale product commercialization model. Together, we will enhance your portfolio strategy by optimizing your valuable capital and advancing pipelines without increasing development expenses.

“Our team also has the experience to anticipate these curveballs as well as the playbook to build a more agile commercialization strategy so you can bring your critical therapies to market.”
— Jim Lang

Our proprietary model helps protect your upfront investment and provides your company with direct access to additional capital when you need it most. With **COMPLETE**, you don’t have to raise money when the market conditions aren’t optimal because you will have already protected those same investments using our already-in-place infrastructure. And you don’t have to hire more expertise to build your internal team: We have experienced advisors available to help you quickly respond to changing conditions.

3 A legal, manufacturing, compliance or other operational issue catches your team off guard.

When bringing a new product to market, you need to expect the unexpected. This could be a competitor’s lawsuit, a manufacturing issue or a compliance concern that demands your team’s immediate attention and money. Any one of these scenarios can require significant investments that drain critical resources needed to commercialize your product.



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How COMPLETE COMMERCIALIZATION by EVERSANA can help: Our model helps shield your company from these unwelcome surprises by reducing your financial exposure and creating a more stable and flexible launch operation. You can worry less about uncertainty potentially derailing your launch. We protect your momentum so you can keep your team focused on your key objectives and let us work together to quickly respond to these surprises, so your commercialization plan stays on track.

"Our team also has the experience to anticipate these curveballs as well as the playbook to build a more agile commercialization strategy so you can bring your critical therapies to market," says Jim Lang, CEO. "And because you still maintain full ownership, you can fully reap the rewards once your product has received approval. It's a home run for you and us."

Protecting Your Investments

COMPLETE COMMERCIALIZATION by EVERSANA allows you to stay in control while protecting your upfront investments. We can respond quickly because we wholly own all the components rather than using thin partnerships. Our proven industry leaders understand the complexities of successful launches and have the therapeutic and functional expertise needed to guide your product to commercial success. This includes the full range of marketing, market access, distribution, sales force deployment, reimbursement and patient support services needed to fully optimize your brand's performance at each stage of launch and thereafter.

By choosing EVERSANA, you can be sure that you have your bases covered.

About EVERSANA™



EVERSANA is the leading independent provider of global services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product lifecycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies, to advance life science solutions for a healthier world. To learn more about EVERSANA, visit EVERSANA.COM or connect through [LinkedIn](#) and [Twitter](#).

