



WHITE PAPER

What Lies Ahead for New Product Launches?

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What Lies Ahead for New Product Launches?

Trinity Life Sciences has been tracking and analyzing the challenges of commercialization and new product launches in the Biopharma industry for years (see our 2022 white paper, [Empowering the Next-Generation Launch Model](#)). One method we have leveraged to track the challenges in commercialization is new product launch performance, comparing first calendar year actual sales with consensus Wall Street analyst forecast estimates at time of launch for novel product (New Molecular Entities) launches within the U.S.

In this white paper, we explore historical launch performance trends to help predict where launches are headed and what the industry needs to be thinking about to improve commercialization success.

Examining Historical Trends in Launch Performance

In recent years the majority of new U.S. product launches have underperformed Wall Street revenue expectations in their first year:

- » 58% of launches since late 2019 (launching during the start of the COVID pandemic) through 2022 have underperformed
 - » Even in “post-COVID” 2022, this trend persisted as 62% of launches again underperformed
- » **Commercialization has been especially challenging for both first launch emerging companies and/or for products entering non-rare specialty and large disease category markets:**
 - » Between late 2019 and 2022, first launch companies are more likely to underperform (25 of 37 first launch companies; 68% of product launches) than companies with a commercial product already on the market (39 of 74 companies; 53% of product launches) (FIGURE 1). In the calendar year 2022 these trends continued, with 70% and 55% of first launch and non-first launch companies underperforming, respectively.
 - » Additionally, success has been elusive for those products entering non-rare, non-oncology specialty and large disease category markets: 77% of non-rare specialty & large market products underperformed vs 51% of rare disease market products and 38% of oncology market products (FIGURE 2). Again, for launches in calendar year 2022 these trends continued: 73% of non-rare specialty and large market, 67% of rare non-oncology, and 25% of oncology launches underperforming.

Performance of Product Launches by Company Type

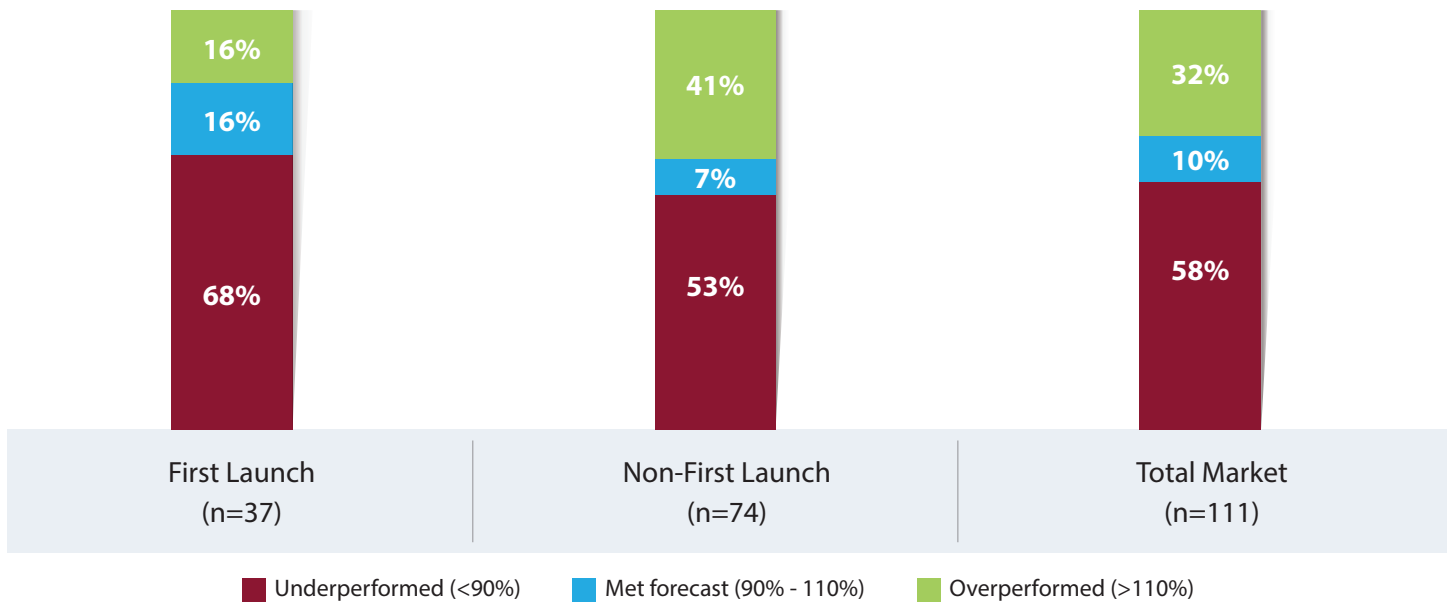


FIGURE 1 | Performance of recent new product launches by company type relative to first year forecast, for U.S. launches between September 2019 and December 2022

Performance of Product Launches by Category

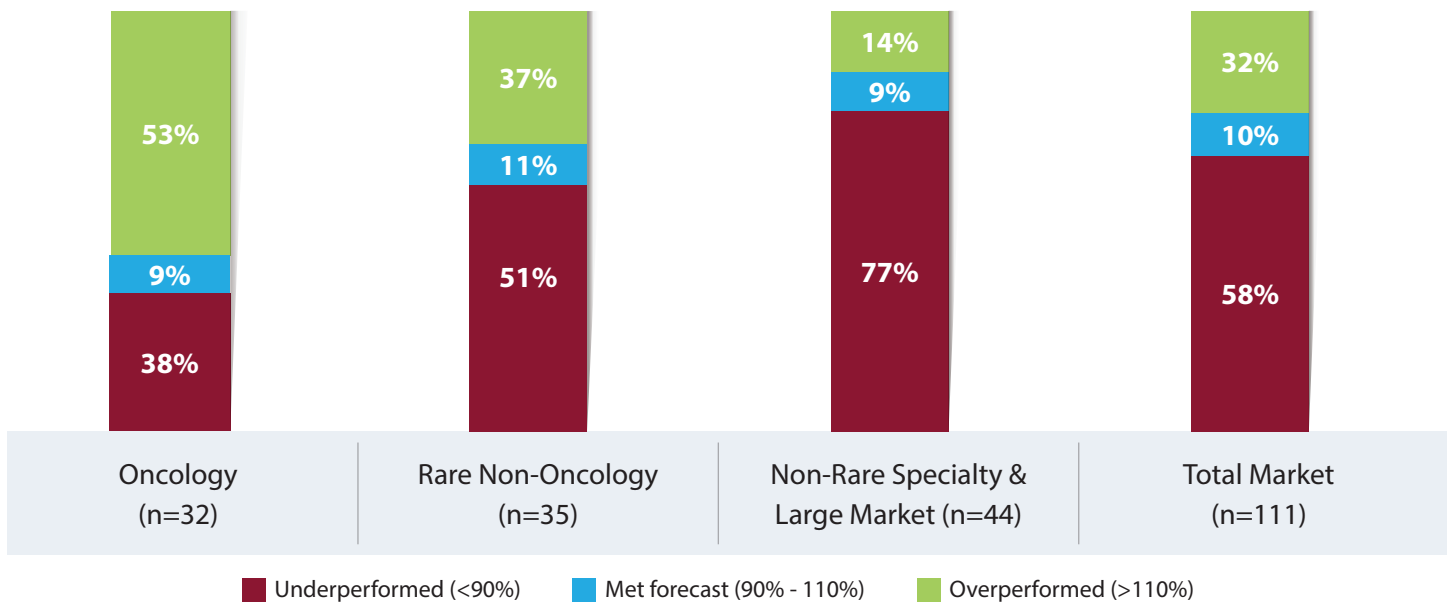


FIGURE 2 | Performance of recent product launches by category relative to first year forecast, for U.S. launches between September 2019 and December 2022

Source: Analyst consensus forecast (reported from EvaluatePharma & Analyst Reports) & Company Reported Sales Performance is measured by comparing reported first calendar year sales against pre-launch forecasted first calendar sales from Evaluate pharma or analyst reports. Performance data are limited by the availability of full year sales in the calendar year of launch and the availability of a pre-launch forecast.

We have seen dramatic swings and the impact of externalities (e.g., COVID) on the market in the last three years, which has continued post-COVID. Even with the large number of biopharma company financings in 2020 that supported 2021 and 2022 launches, it has been difficult to meet Wall Street revenue expectations for the launch of new products. **The first year of launch is not the financial “welcome party” it used to be given the increasing hurdles to gaining favorable reimbursement and market access in the first few months of launch.** While there will always be the handful of success stories (even for first launch companies and/or products in large/non-rare specialty markets; FIGURE 3), commercial performance is rarely a given and can be challenging to predict.

Recent Select Overperforming Launches

Asset	Company	Indication	Category	First Launch	Performance	Launch Year Revenue (\$M)	Forecasted Revenue (\$M)
Fotivda	Aveo	R/R advanced renal cell carcinoma	Oncology	Yes	418%	\$46	\$11
Mounjaro	Eli Lilly	Diabetes, type 2	Non-Rare Specialty and Large Market	No	466%	\$367	\$79
Vyvgart	Argenx	Myasthenia Gravis	Rare (Non-Oncology)	Yes	335%	\$378	\$113
Vabysmo	Roche	Wet age-related macular degeneration (AMD)	Non-Rare Specialty and Large Market	No	382%	\$544	\$143

FIGURE 3 | Notable recent examples of companies demonstrating successful commercial performance, based on actual revenue relative to first year forecast

Potential Drivers of Launch Performance

Trinity assessed various metrics to determine if any were potential drivers that could help explain (or potentially predict) industry-wide launch performance. Some of the metrics that we analyzed included the number of FDA approvals and filings, biotech companies announcing layoffs and FDA Complete Response Letters (CRLs). Trends from the last few years, as shown in FIGURE 4, indicate that in 2022:

- » Approvals are lower (a high of 71 in 2021 vs. 50 in 2022)
- » Filings have stayed relatively steady, with a slight dip (a high of 73 in 2019 vs. 67 in 2022)
- » CRLs have been on the rise in the last few years (9 and 11 in 2019 and 2020 respectively vs. 18 and 16 in 2021 and 2022 respectively)
- » The economic downturn woes led to a wave of layoffs (119 in 2022) ([Fierce Biotech Layoff Tracker¹](#))

¹ Armstrong A, Masson G, Bayer M. Fierce Biotech Layoff Tracker 2023: Biogen begins 1K layoff wave; Bayer-bought BlueRock makes cuts. Fierce Biotech. 18 August 2023. <https://www.fiercebiotech.com/biotech/fierce-biotech-layoff-tracker-2023>

Trends in Approvals, Filings and Complete Response Letters (2019 – 2022)

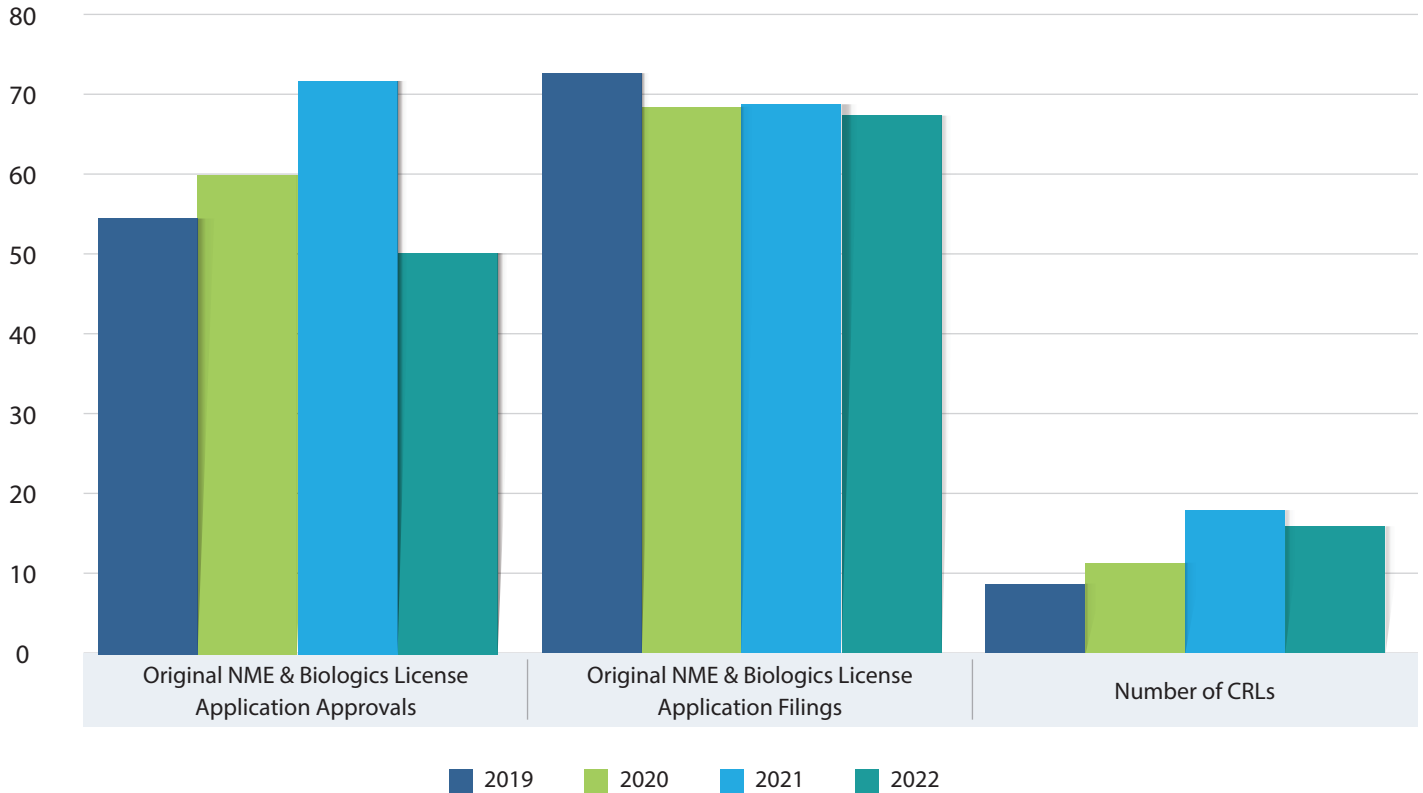


FIGURE 4 | Original NME and Biologics License Application approvals, original NME and Biologics License Application filings and number of CRLs based on the year announced

Most metrics did not have a strong relationship with launch performance data. However, we found an interesting correlation: Over the past three years, a **higher number of approvals has been strongly correlated with underperformance** (FIGURE 5). This correlation does not exist when looking at approvals relative to overperformance or those meeting forecast expectations.

Why might this correlation exist? Our hypothesis is that increasing approvals could potentially indicate a higher number of suboptimal products coming to market. The influx of cash from company financing in 2020-2021 could have encouraged spending on products and strategies that were not the right fit for the needs of the market. More product launches can also be distracting, create noise and make it more challenging for companies to compete for prescriber and payer attention.

Launch Performance Relative to Approvals (2019 – 2022)

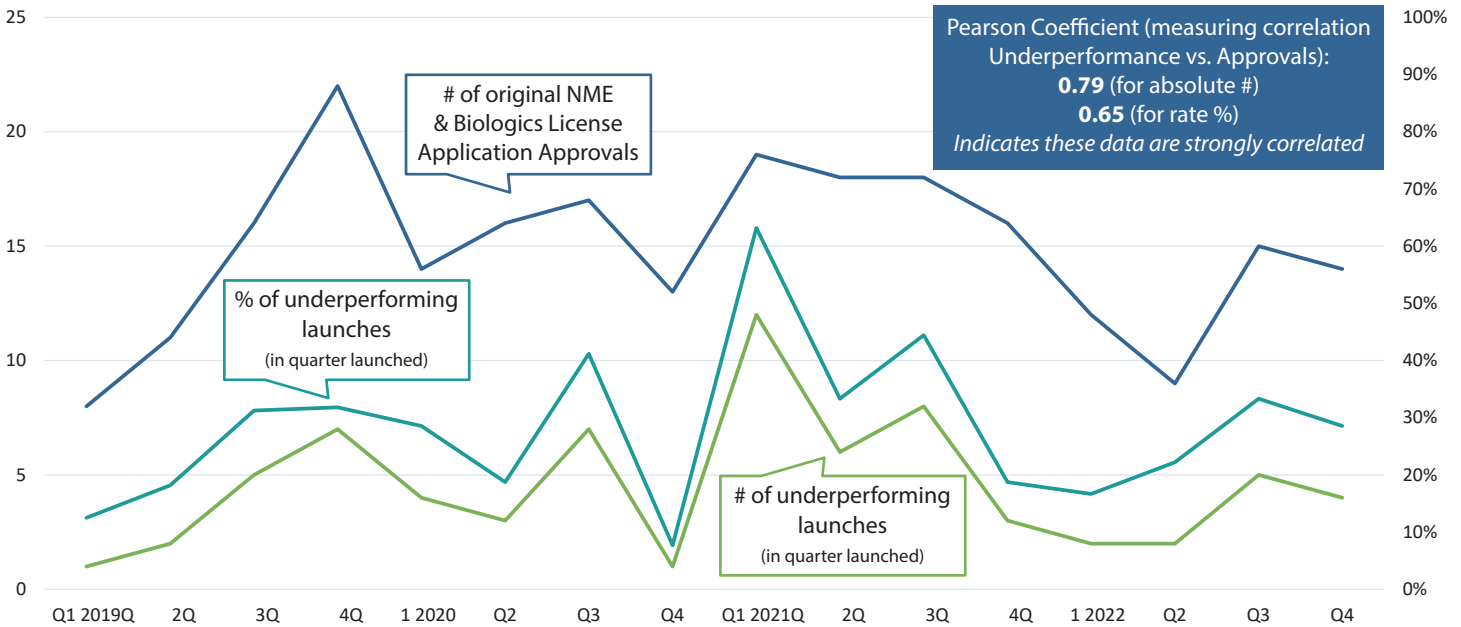


FIGURE 5 | Comparison of the number of original NME and Biologics License Application approvals relative to the percentage and number of underperforming launches in the quarter launched between 2019 and 2022

Predictions for 2023 Launch Performance

Looking forward with this historical context in mind, we are predicting that overall 2023 launch performance will match the patterns that we have seen since 2020. **We expect 2023 launches to face the same challenges in the face of continued payer hurdles and limited commercial innovation.** For 2023 relative to 2022:

- » Approvals are trending higher (28 in 1H '23 vs. 21 in 1H '22), which has historically correlated with underperformance
- » Tough market conditions persist, including with increased layoffs (93 in 1H '23 vs. 60 in 1H '22)¹
- » 57% of year-to-date 2023 approvals are within non-rare specialty and large disease population markets a category that has historically underperformed at a disproportionately higher rate (FIGURE 6)

2023 Year-to-Date Approvals by Category

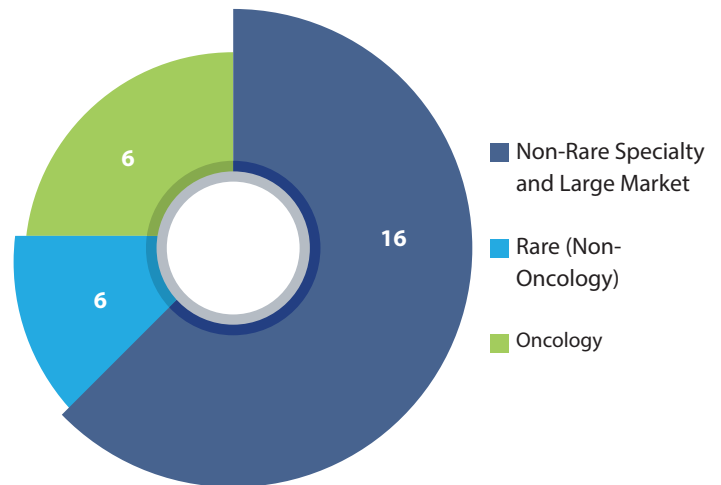


FIGURE 6 | Number of novel Biologics License Application & NME approvals in the first half of 2023 by category

¹ Armstrong A, Masson G, Bayer M. Fierce Biotech Layoff Tracker 2023: Biogen begins 1K layoff wave; Bayer-bought BlueRock makes cuts. Fierce Biotech. 18 August 2023. <https://www.fiercebiotech.com/biotech/fierce-biotech-layoff-tracker-2023>

Trinity's Perspective

To invert these trends, we need commercial innovation and improved customer engagement models that are data-driven and right-sized to the opportunity. Future forecasts also need to take into account the new market realities and expectations. **Given the lower filings in 2023 to date, perhaps the industry will see less approvals in 2024, but better performance in the products that do come to market.** While the funding days of 2020-2021 perhaps shepherded in less-than-stellar products, the industry may now be shifting towards right-sizing with more focused investment on the right products, leading to stronger launches in the future. Looking towards the future, the industry can rise to meet these challenges and bend the curve with an improved rate of successful launches.



Launch Excellence

Trinity's Launch Excellence engagements help companies effectively and efficiently prepare for successful commercialization tailored to their market and situation. No matter where you are on the path to launch, Trinity works with you to define, execute and optimize your commercialization readiness. We directly support >30 companies annually in their launch journeys – strategy, planning and management – across dozens of therapeutic areas, from first-launch emerging biotech to the largest global pharma leaders.

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