Evaluate Vantage

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Merck cements its novel drug approval dominance

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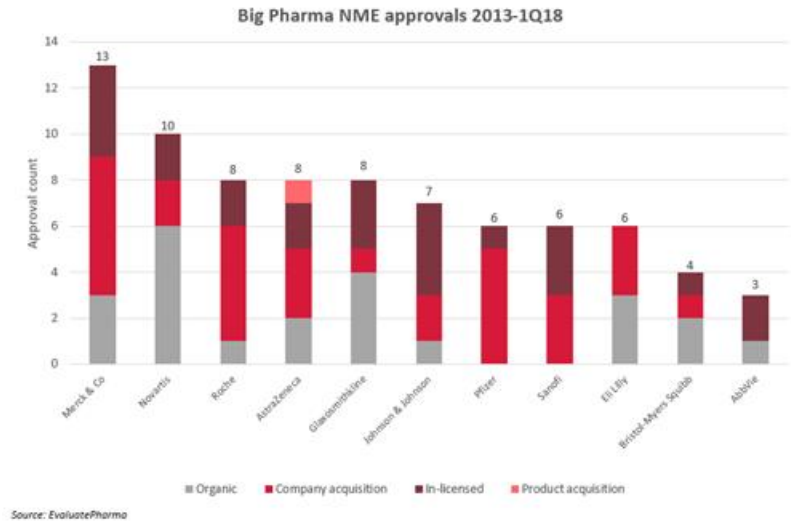
When it comes to getting products to market, size is not everything. Merck & Co has once again beaten its bigger rivals in terms of the number of new drug approvals in the past five years (see charts below).

However, the latest analysis of this indicator of biopharma productivity makes unhappy reading for Merck's mid-sized peer, Abbvie – as their pipline looks lacklustre.



The near term, however, looks less bleak for Abbvie, which has three potential blockbusters nearing the market in the form of elagolix, upadacitinib and risankizumab. Still, the company took a big knock recently with the late-stage failure of Rova-T.

Still, there is much to do to catch up with Merck, which had 13 NMEs approved by the FDA between 2013 and the first quarter of 2018, ahead of the next most prolific company, Novartis.

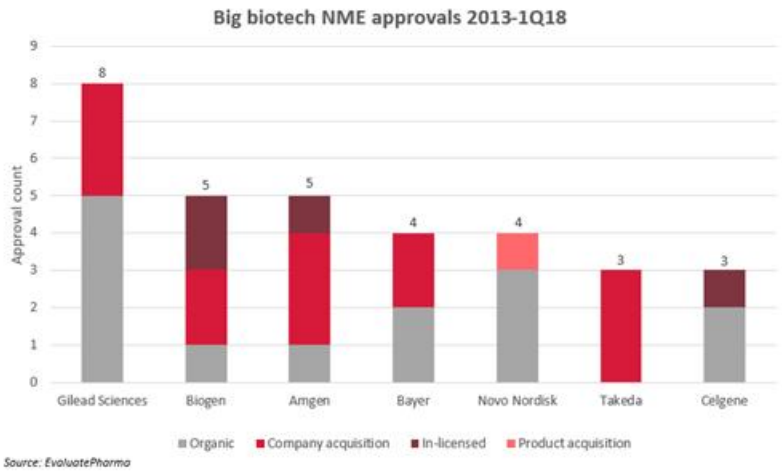
Buying in

Shepherding an asset through regulation, however, is not the same as company R&D productivity. In most cases the drugs approved came from an external source – being acquired or licensed before approval.

Novartis is the notable exception to this trend, with over half of its approvals being for in-house assets, including some of the Swiss company's big hitters such as the IL-17 MAb Cosentyx and the congestive heart failure treatment Entresto – forecast by *EvaluatePharma* sellside consensus to make over $3bn and $4bn respectively in 2024.

Still, buying in assets is no bad thing, illustrated by the fact that the drugs in this analysis with the biggest forecasts originated from outside sources. This includes Merck's Keytruda, which came courtesy of its takeover of Schering-Plough and Bristol-Myers Squibb's rival PD-1 inhibitor Opdivo, via a deal with Ono Pharmaceuticals.

A similar analysis of the big biotech players highlights several differences between these groups and their big pharma brethren – one being that biotech companies have focused more on organic development or company acquisitions, and less on licensing products and taking them through approval.

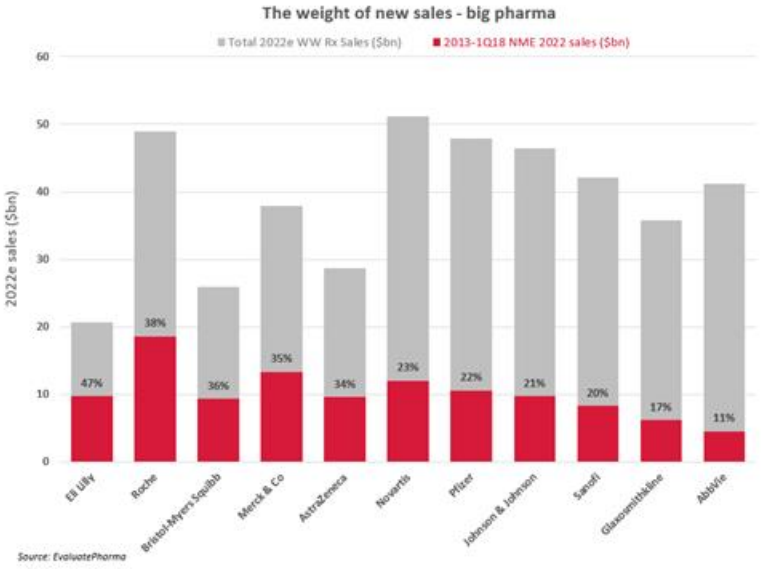


Of this cohort Gilead was by far and away the winner in terms of approval numbers, with eight NMEs over the five-year period, rivalling some of the more successful big pharma companies. With the dwindling of Gilead's hepatitis C franchise, a wave of new approvals is a good sign.

Meanwhile, Celgene's lack of success in getting new molecules approved shows again just how reliant the company remains on Revlimid.

Selling out

Although the regulatory success of new treatments is something to be celebrated this is only the first step, and subsequent sales are also important. The following analysis looks at the relative contribution of the NMEs approved in the same timeframe to a company's total forecast 2022 prescription sales.



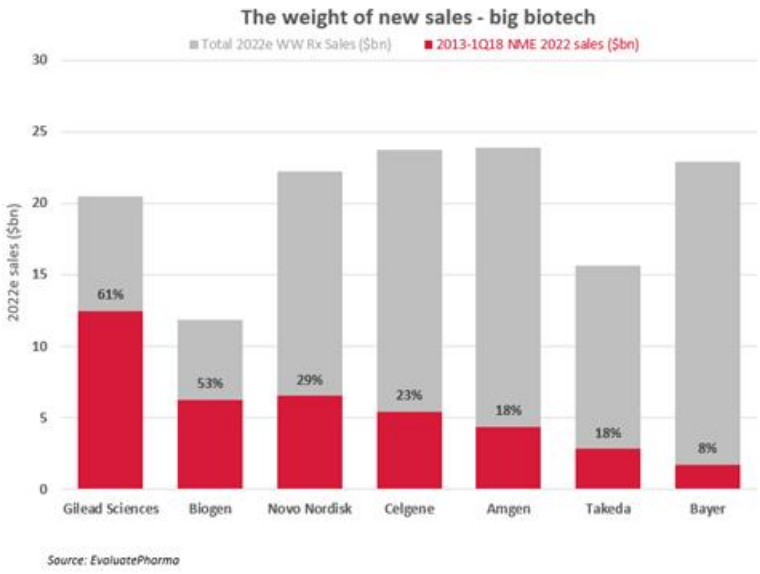
Eli Lilly is the most reliant on its newer products, with the lion's share of its 2022 revenues set to come from the companies frontrunning blockbusters Trulicity and Taltz.

Things are not a bleak as the graph make them seem with some truely giant products having fallen just oustide the range of 2013. In the case of Bristol if one were to include the blood-thinner Eliquis, approved in the last few days of 2012, the total contribution of new sales jumps to 71%.

And unsurprisingly Abbvie, whose fortunes still largely hinge on its ageing giant Humira, is expected to have the smallest contribution from new products. It will be interesting to see how much this changes if any of the company's late-stage candidates get the green light, and also factoring in biosimilar Humira competition, which is expected in the US in 2023.

In biotech Gilead is expected to benefit most from new products, but there are still questions marks over some of these. The new HIV triplet Biktarvy disappointed in the first quarter, but Gilead pointed out that it had only been on the market for six weeks.

And the group's bet on CAR-T might still end up being an expensive mistake in a nascent sector where commercial success is not guaranteed – but for now Gilead is celebrating first-quarter sales well ahead of expectations.



Still, the $12bn that Gilead spent on Yescarta's developer, Kite Pharma, is dwarfed by Takeda's recent £46bn ($62bn) merger with Shire – and the tiny contribution from new products illustrates why the Japanese company was so desperate to strike a deal.

Others with similar problems might soon also be forced into M&A, but will no doubt want to get the balance right. As shown above, buying in growth is an important part of biopharma's strategy, but there is always the risk of overpaying.

This story has been updated to reflect a correction to the data.

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