Evaluate Vantage

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Blockbuster approvals line up for biopharma in 2018

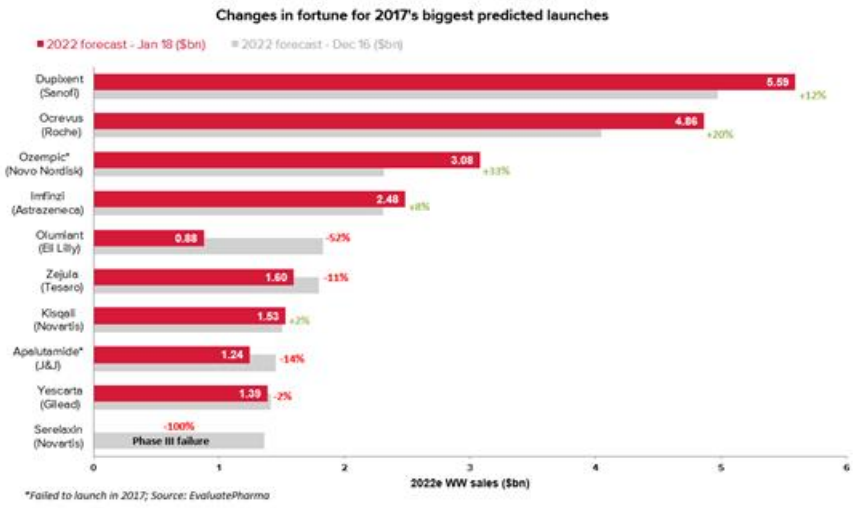
Amy Brown

2018 shaping up to be a bumper approval year, as Juno Therapeutics, Epizyme and Avexis line up to launch potential blockbusters.

The year might not have opened with the bang that many were hoping for on the deal front, but in terms of drug launches 2018 should deliver some big splashes. Nine of the 10 most promising projects nearing the market are expected to generate blockbuster sales by 2022, according to *EvaluatePharma*.

And should three companies catch a strong tailwind this year's record could look even better - Juno Therapeutics, Epizyme and Avexis are all tantalizingly close to achieving 2018 launches for their lead assets. Trip ups are always possible, of course, but in general biopharma looks set for another productive year (see tables below).

Looking at the fate of 2017's predicted biggest launches shows how even the most highly rated of the industry's pipeline is open to setbacks. The most damaging delays of 2017 included Eli Lilly's RA candidate Olumiant, which was held back by the FDA on safety concerns, and the failure of Novartis's heart drug serelaxin in phase III.



Ozempic and apalutimide were in part casualties of over-optimistic time-lines, and both now feature in this year's rankings.

Ozempic, Novo Nordisk's new once-weekly diabetes medicine, is due to hit the shelves in the US this quarter, and in Europe later this year. *EvaluatePharma's* consensus of sellside forecasts put it as the second biggest launch this year, behind Gilead's latest HIV combination therapy.

Number three and four in the below analysis are far more contentious, and still need to deliver phase III data to justify these sales forecasts. Incyte's epacadostat is one of the most closely-watched immuno-oncology assets in the industry's pipeline; pivotal data from the Echo-301 trial due in the coming months is arguably one of the important read outs for the sector this year.

Hopes for Rova-T have dimmed somewhat, if only because of advances elsewhere, but the results are still important for Abbvie's oncology ambitions (*Why the Rova-T delay is anything but irrelevant, 30 October 2017*).

The remaining assets in the list have already delivered data packages to the FDA – in Portola's case launch of Bevyxxa is about to commence – so should be safer bets. Particularly interesting to watch will be the fate of GW Pharmaceuticals' refractory epilepsy treatment Epidiolex. The UK company is the smallest drug maker among this group and approval for its cannabis-based product would be a huge coup.

2018's biggest potential launches

Product	Company	2022e Sales ($bn)	Next Event
Bictegravir/F/TAF	Gilead	5.05	PDUFA February 12/CHMP Q2
Ozempic	Novo Nordisk	3.08	Approved US, launch due Q1
Epacadostat	Incyte	1.94	Phase III data due H1
Rova-T	Abbvie	1.44	Phase III data due Q2
Ozanimod	Celgene	1.27	US approval Q3'18/EU filing due
Apalutamide	Johnson & Johnson	1.24	PDUFA April
Elagolix	Abbvie	1.21	PDUFA May 4
Lanadelumab	Shire	1.13	US approval H2
Epidiolex	GW Pharma	1.04	PDUFA June 27/CHMP Q3
Bevyxxa	Portola	0.80	Approved US, launch due January

Source:EvaluatePharma

Of course the potential for a positive surprise also exists in biopharma, and the three companies below are among those most likely to deliver this in the coming months. To launch their respective therapies in 2018 all would have to progress with astonishing speed and development and regulatory work proceed without a hitch – but this cannot be entirely ruled out.

Avexis for example is due to meet with the FDA around mid-year to discuss a BLA based on phase I data for its spinal muscular atrophy gene therapy, AVXS-101. Should the regulator give the go-ahead for an accelerated filing, bulls maintain that approval could come before the end of the year. A $400m fundraising, announced today, will help it on its way.

Epizyme meanwhile is pushing forward fast with tazemetostat, a novel epigenetic approach being trialled in both blood cancers and solid tumours. A phase II study in INI1 negative epithelioid sarcoma is due to read out in the coming months and could form the basis of an accelerated approval, while some analysts believe a filling in follicular lymphoma could also happen this year.

Finally, Juno has said it should complete the BLA for JCAR017, its lead CAR-T asset, in the second half of 2018.

In all likelihood, these projects look more likely to be notable 2019 launches. And at the end of the day, winning the approval in the first place is far more important than what month it falls in. But for these small drug developers and their investors the next few months will be critical, and their performance could help decide just how impressive a year 2018 turns out to be.

Will they, won't they?		
Product	**Company**	**2022e Sales ($m)**
AVXS-101	Avexis	1,135
Tazemetostat	Epizyme	858
JCAR017	Juno Therapeutics	828
Source:EvaluatePharma		

To contact the writers of this story email Amy Brown or Edwin Elmhirst in London at news@epvantage.com or follow @ByAmyBrown or @EdwinElmhirst on Twitter.