Biopharma in 2019 - navigating choppy waters

Vantage publishes its annual look ahead to 2019, examining the trends and issues that will shape biopharma in the coming year.

Amid a turbulent period for global stock markets biopharma heads into 2019 on a shaky footing. Investors are taking little comfort from the fact that the turmoil has largely been triggered by fears from beyond the sector, and most agree that a more volatile year is approaching.

At this stage, financing options are not expected to dry up completely, though those looking to raise funds will probably have to work a bit harder next year. After a record-breaking 2018 for venture financing, firms are expected to start investing more prudently, while the public markets are already showing a diminishing appetite for new issues.

It is always hard to forecast how much further markets might fall, or when a rebound will occur. Our annual preview attempts to identify swing factors specific to biopharma that could help improve sentiment or damage it further over the course of the year.

Pluses and minuses

Excitement about new technologies that are delivering real breakthroughs remains palpable, but most are in launch phase or approaching commercialisation. The harsh realities of the market are already being felt by some, like Spark and Alnylam, and further struggles could provide investors with another reason to retreat.

Expectations are low for substantial progress in immuno-oncology next year, so a surprise win here would lift spirits. Huge optimism prevails around cell therapy and related techniques, however, and it is in this realm that valuations remain testing.

The extent to which companies with unproven technologies can maintain their billion-dollar-plus valuations next year will signal the depths of any downturn; these include Allogene, which is working on allogeneic CAR-T therapies, those pursuing gene editing like Crispr Therapeutics, and of course the newly public mRNA researcher Moderna.

The fact that many of these cash-hungry firms are valued more highly than those with products on the market suggests that the sector is some way from the bottom. A serious setback in one of these rock-star segments would be very destabilising.

M&A boost?
If dented valuations tempt buyers back into the market M&A could give biopharma a boost; the takeout of Tesaro suggests that this might already be happening. However, the appalling track record of many high-profile takeovers of the past few years could persuade business development teams to sit on their hands for a while longer.

A string of opportunistic moves could actually damage the sector in the longer term, some investors fear. Still, deal-making is expected from big cap biotechs, many of which have fallen out of favour with investors after failing to replace ageing blockbusters. The absence of significant late-stage assets in the pipelines of these big beasts of the sector is notable.

Nash is an exception here, and this therapy area will see several important readouts in 2019, from the likes of Gilead and Intercept. Clinical wins could give investors a new disease area to get excited about.

<table>
<thead>
<tr>
<th>Product</th>
<th>Company</th>
<th>Consensus NPV ($bn)</th>
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<tbody>
<tr>
<td>VX-659 + tezacaftor + ivacaftor</td>
<td>Vertex</td>
<td>14.4</td>
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<tr>
<td>JCAR017</td>
<td>Celgene</td>
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<tr>
<td>Semaglutide oral</td>
<td>Novo Nordisk</td>
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<tr>
<td>Aducanumab</td>
<td>Biogen</td>
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<tr>
<td>ARGX-113/efgartigimod</td>
<td>Argenx</td>
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<tr>
<td>NKTR-214</td>
<td>Nektar Therapeutics</td>
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<tr>
<td>Elafibranor</td>
<td>Genfit</td>
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<td>Glaxosmithkline</td>
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<td>DS-8201</td>
<td>Daiichi Sankyo</td>
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<tr>
<td>Valoctocogene roxaparvec</td>
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<td>Voxelotor</td>
<td>Global Blood Therapeutics</td>
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<td>bb2121</td>
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<td>Gilead Sciences/Galapagos</td>
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<td>Pamrevlumab</td>
<td>Fibrogen</td>
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<td>Madrigal Pharmaceuticals</td>
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<tr>
<td>ARGX-110</td>
<td>Argenx</td>
<td>3.0</td>
</tr>
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Source: EvaluatePharma.

On the plus side, for groups with late-stage assets like those listed above, the US FDA looks like it will remain one of biopharma’s best friends. The influential regulator’s willingness to speed novel therapies to market on controversially slim evidence has emboldened companies and investors to take ever-greater risks.

Perhaps herein lies another red flag. Should the agency alter its stance, the sector would have a real reason for an existential crisis.

The implications of a shift in power in the US are also something to watch. Rhetoric around US drug prices could well ramp up again as re-invigorated Democrats attempt to make their mark on healthcare policy. What they can realistically achieve remains to be seen.
Overall, biopharma is not expected to generate a year of record-breaking numbers in 2019. But neither is a serious retrenchment widely expected, at this stage at least. Many fear that things will have to get worse before they can get better again, however.

Ultimately, drug developers thrive or die by the advances they make. It seems highly unlikely that rising stock market tides will buoy the life science sector next year. Innovation needs to be delivered. Over to you, biopharma.

For a fuller discussion of these issues, interviews with investors and many more data tables, download a free copy of the full report here.