EDISON

Edison Explains

Healthcare

Thoughts for a new year

What are Edison's thoughts on healthcare for a new year?

2020 was a busy year for global healthcare with unprecedented efforts to develop vaccines, treatments, and diagnostics for COVID-19.

Headline risks have subsided as the US presidential election unfolded, enabling both M&A and partnering deal flow to continue unabated into 2021 and driving biotech indexes to all-time highs in the US.

With respite from the annual healthcare meetings in San Francisco, which typically set the mood for the year ahead in the sector, we outline our thoughts on questions that could define the year ahead:

What will emerge from the COVID-19 fallout?

Healthcare industry players have sprinted along the vaccine development tightrope, surmounted regulatory hurdles and delivered solutions to a global pandemic in an unprecedented timeframe.

For us, a big takeaway from the pandemic has not just been the resurgent interest in anti-infectives and vaccines, but also diagnostics and manufacturing stepping out from the shadows as their importance has increasingly come into focus.

Collaboration has been key to this, and the newly formed alliances will likely strengthen in the near-term, potentially enabling further expansion of current partnerships.

- What is the market outlook for diagnostics and treatments if the pandemic subsides?
- Will the newly adopted dosing regimens for COVID-19 vaccines provide sufficient efficacy?
- What market will emerge for these COVID-19 vaccines once current supply agreements are fulfilled?
- How long can COVID-19 vaccine protection last and can you re-administer the same vaccine?
- Will these vaccines work against emergent strains or will annual reformulations be needed?

What is clear in our view, is that the status quo has been disrupted. The emergent vaccine platforms, such BioNTech's and Moderna's mRNA-based or Oxford University's AdV-based, will likely remain and challenge the incumbent platforms, which have failed to adapt in a timely manner.

Likewise, regulators will have learnt from the process and are likely to be re-evaluating their internal processes.

Are beta-amyloid Alzheimer's drugs back in vogue?

Before COVID-19 became the primary focus of 2020, a big talking point heading into the year was how the FDA might view Biogen's (BIIB) conflicting Phase III EMERGE and ENGAGE data for aducanumab, and whether the amyloid hypothesis could spring back to life in Alzheimer's disease research.

In our view this remains largely unanswered until the PDUFA decision date (7 March 2021), despite the negative outcome from the advisory committee (AdComm) meeting on 6 November 2020 where members voted against three key questions on whether these data are supportive of efficacy.

Although AdComm stances are typically upheld by the FDA these are non-binding, as highlighted with the controversial approval of Sarepta's Duchenne muscular dystrophy drug eteplirsen.

Edison Insight

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1) What will emerge from the COVID-19 fallout?

2) Are beta-amyloid Alzheimer's drugs back in vogue?

3) How long can deal momentum be sustained in the healthcare sector?

This leaves the door open for aducanumab being approved and would be a significant catalyst for Alzheimer's research more broadly. We await to see how the FDA finally decides to view the conflicting datasets in the face of a hugely under-treated patient population. The internal politics at the FDA on how the AdComm outcome will be treated is also of interest, particularly given Janet Woodcock seems likely to return to the regulator's helm in the coming weeks.

We note there has been significant investor interest in beta-amyloid-targeting drugs recently; Biogen gained and then lost c $15bn in market capitalisation prior to and as a result of the AdComm decision regarding aducanumab, with share price effects rippling across other companies with a focus on Alzheimer's.

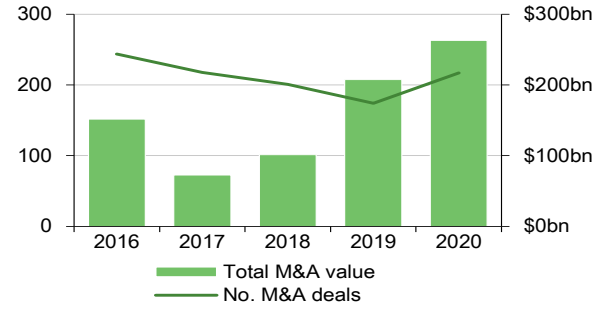
Furthermore, Eli Lilly announced positive headline data last week from the Phase II TRAILBLAZER-ALZ trial for donanemab, resulting in an increase of c $20bn in Lilly's market cap with positive effects again being reflected in other companies' share prices, including Biogen.

How long can deal momentum be sustained?

Deal flow in the sector continued to gain momentum in 2020, with M&A transactions and product licensing deals totalling five-year highs as large-cap pharma sought to bolster top-lines and expand into new therapeutic areas.

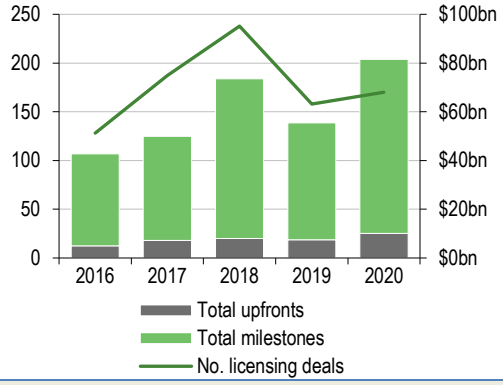
With business development occurring virtually in the pandemic, negotiations that would have taken weeks with face-to-face meetings and travel, have been able to take place in days. Will this trend continue during 2021 given the usual West Coast congregation that acts as a melting pot of introductions has not occurred in the same way this year?

Exhibit 1: Five-year M&A deal flow



Source: Evaluate Pharma, Edison Investment Research

Exhibit 2: Five-year drug licensing deal flow



Source: Evaluate Pharma, Edison Investment Research

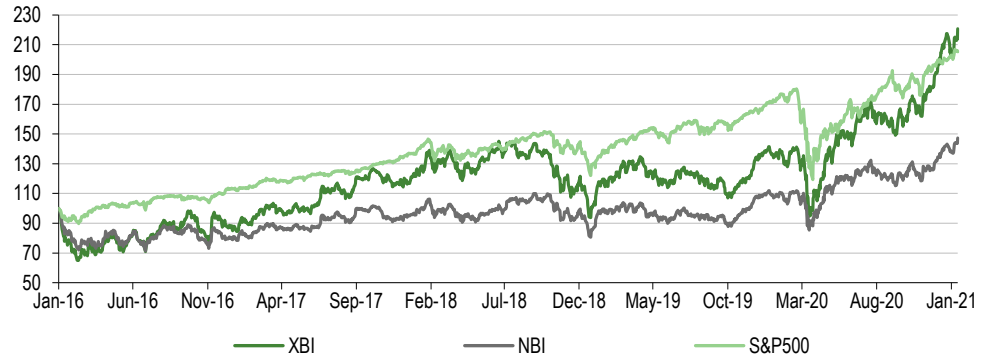
Our expectations for deal flow remain positive in 2021 following some big moves in Q420, including: AstraZeneca expanding its rare-disease offering through the proposed c $39bn acquisition of Alexion, likely for its burgeoning franchise of C5-complement inhibitors (Soliris and Ultomiris); and Bayer's acquisition of Asklepios for $4bn as it steps up its aspirations in cell and gene therapies.

Several notable deals occurred last week from Sanofi, including its proposed c $1.5bn acquisition of Kymab primarily for its Phase II OX40-targeting antibody and its licensing deal with Biond Biologics worth up to c $1.1bn, for a ILT2-targeting antibody that is currently preclinical.

Novartis's licensing deal with BeiGene last week is also notable, with Novartis paying $650m upfront for select commercial rights to Beigene's PD-1 tislelizumab, with milestones of up to $1.6bn. Combined with the c $1bn deal signed in August 2020 between Eli Lilly and Innovent for the latter's PD-1 Tyvyt, we view these deals as strong validations for some of the Chinese-developed drugs.

With the IPO window still seemingly strong also, invariably there will continue to be a trade-off between companies raising additional capital and progressing projects internally to retain economic value, versus out-licensing to larger external partners. Combined with US biotech indices being valued at all-time highs, it will be interesting to see if sector deal flow continues in 2021.

Exhibit 3: Five-year sector performance for US biotech



Source: Refinitiv, Edison Investment Research; Note: rebased to 100.

In association with the London Stock Exchange Group, Edison is hosting its first Global Healthcare Open House between 26–28 January. We look forward welcoming you to our virtual home.