Evaluate Vantage

January 09, 2018

JP Morgan day one roundup – disappointments set the tone

Amy Brown

Investors marked yesterday's opening of biopharma's biggest beauty parade with a conspicuous snub – shares in the bellwether Nasdaq biotechnology index dropped 1.4%. But then the annual JP Morgan healthcare conference has become synonymous with dealmaking, and little of note was unveiled, leaving several disappointing strategy and pipeline updates to set the mood.

As torrential rain poured down on a soggy San Francisco, news of Celgene's swoop on Impact Biomedicines was not enough to lift the spirits of those hoping to see a pick-up in deal activity this year. Concerns around the Crispr stocks and confirmation of Axovant's demise added to the gloom; *EP Vantage* rounds up the other big news of the day.

Deal or no deal?

Given that companies typically chose to open the conference with deal news, it seems likely that Celgene's acquisition of Impact might be all the conference offers this year, in terms of larger acquisitions (*JP Morgan – Celgene makes an eve-of-meeting Impact, January 8, 2018*).

Other deals to emerge were technically no-deals – Shire's decision to hold on to its neuroscience unit for a while longer, and Novo Nordisk's snubbed approaches to Belgium's Ablynx.

Shire's decision was particularly disappointing for investors hoping to see a spin-out of the indebted UK company's ADHD business – some believe that this could in turn prompt a bid for its remaining rare disease assets. However in a strategy update management said they would delay any decisions on a sale or spin-off until the second half of 2018, and run the two divisions as distinct operating entities in the meantime.

Chief executive Flemming Ornskov made it clear that the neuroscience business would be broadened in the meantime, via M&A, to include neuropsychiatry. But investors do not like to be made to wait, and Shire shares dropped 5%, further dented by a substantial slice to 2020 revenue guidance announced at the same time.

While Shire's update was considered disappointing, deal watchers should keep an eye on the company's expansion plans – with one very obvious psychiatry player in Sage Therapeutics considered a highly attractive target, could Mr Ornskov be planning a big move?

Further takeover action also looks likely with Ablynx, whose Belgium shares climbed above the latest Novo Nordisk offer price this morning. A raised bid is widely expected from the diabetes giant (*Novo Nordisk turns the screw on Ablynx by making bid public, January 8, 2018*).

Deals announced elsewhere were of the licensing variety: Alnylam and Sanofi's asset swap, a research collaboration between Incyte and Syros Pharmaceuticals, and a BTK inhibitor deal between TG Therapeutics and Jiangsu Hengrui were all timed for the first day of the conference. China's Hengrui was one of the best-performing mid-cap biopharma stocks last year, and the company has remained active on the global scene since then (*Asia wins 2017's mid-cap race, January 8, 2018*).

On the down

Axovant provided investors the nastiest shock yesterday, revealing that it was canning intepirdine in its last potential use, Lewy body dementia, after flunking two phase II studies. The stock lost 56%; is it not quite clear why investors should have held out such hope for intepirdine, whose failure in Alzheimer's disease had caused a 70% share price crash in September.

Axovant's focus now turns to nelotanserin, a 5-HT2A inverse agonist licensed from Arena, plus anything else it might license in; the group had $235m in the bank at the end of September.

In a similar vein, Pfizer reportedly scrapped all further research into Alzheimer's and Parkinson's diseases, with the loss of 300 jobs, and entitled its JP Morgan presentation "A New Era of Pfizer R&D Productivity".

There was also bad news for Crispr stocks, which reacted late to a scientific paper published on Friday, suggesting that many people might be immune to the gene-editing technology. Intellia, Editas and Crispr Therapeutics fell 12%, 11% and 3% respectively.

Elsewhere at the conference...

Teva delivered little but bad news last year, and this year's JP Morgan presentation marked a substantial shift in tone, with an upbeat Kåre Schultz not afraid to crack a joke and openly admit to past mistakes. Comments from the new chief executive, who has already unveiled plans to integrate the company's three silos under one roof, point to how things went so wrong for the Israeli generics giant.

Outside of the boardroom no one was concerned about the overall group's profit and loss account, Mr Schultz told investors in a packed breakout session. "Teva used to focus on maximising revenue in its generics business, believing everything else would fall into place," he said, pledging to focus on profitability in the future.

He also insisted that major acquisitions and major divestments were off the table, stressing that the key focuses this year were creating synergies from the existing business and executing important drug launches. Mr Schultz was guarded on certain details of the portfolio and his outlook, and investors will be keenly awaiting the company's official guidance for 2018 numbers, due to come alongside annual results in February.

Moderna's sessions were also standing room only, unsurprising given that the private RNA player is one of the most successful fund-raisers of recent times. Investors are keen to see whether all this cash can be turned into viable projects, and chief executive Stephane Bancel delivered a robust defence of the company's progress to date.

With a very broad but still early-stage pipeline – Moderna now boasts of 19 mRNA drug candidates – it can be tricky to dig out new or notable developments from the company. However, Mr Bancel was keen to stress the impending start of Moderna's first phase II study, with the Astrazeneca-partnered project AZD8601, a new development candidate in a rare liver disease that works by directing the expression of a deficient enzyme, and the filing of an IND for a KRAS cancer vaccine.

Mr Bancel promised to start several other phase II trials this year and next – with a $5bn private valuation and talk of an IPO in the next few years Moderna needs to keep up the pace.

Regeneron execs took a walk down memory lane, but the company needs to find a replacement for Eylea if it is to have a rosy future, and it highlighted its anti-PD-1 asset cemiplimab as a way of doing so.

Apparently undeterred by the prospect of this becoming the sixth PD-(L)1 agent to hit the market, the company plans US and EU filngs this year – an amazingly fast development timeline. This will be helped by an increased funding commitment along with its partner Sanofi, with the planned initial use being cutaneous squamous cell carcinoma (CSCC), a unique indication for this class of agents.

Another latecomer to the checkpoint party, Novartis's PDR001, is in pivotal melanoma trials, having been fast-tracked internally, and is the cornerstone of the Swiss firm's combo effort. Yesterday Regeneron played up CSCC as a tumour setting not explored by others, but its chief executive, Len Schleifer, admitted that there were "no shortcuts in this business".

Better than expected guidance for 2018 sales and an incredibly upbeat presentation from management failed to set **Sarepta's** stock alight yesterday. True, the company's shares are trading close to a record high, but it is also becoming apparent that subdued investors need something very special to get excited during this washout JP Morgan conference.

Chief executive Doug Ingram modestly described 2017 as a prelude to Sarepta's "moment of inflection" in 2018, highlighting an imminent meeting with the FDA to determine whether its follow-on Duchenne muscular dystrophy therapy golodirsen can be fast-tracked to market, and a decision on Exondys 51 from European regulators, due mid-year.

Mr Ingram also said mid-2018 could see early data from three DMD patients treated with its micro-dystrophin gene therapy project, and investors were left with no illusion about the company's ambitions here. "If we see positive signals we're going to lean in with gene therapy. We'll go beyond DMD and do it rapidly – I don't mean five years from now," he proclaimed.

Gilead's JP Morgan breakout highlighted the company's high hopes for the anti-HIV triple bictegravir/F/TAF, which will see US regulatory action next month. As the group gets set for more HIV battles against Glaxosmithkline its vice-president of commercial operations, Jim Meyers, said doctors saw the triple as a near-ideal regimen, with patients able to start immediately after diagnosis.

Much of the discussion focused on CAR-T, after last year's $11.9bn takeout of Kite Pharma. Gilead did not disclose how many patients had been treated commercially with Yescarta so far – reports suggest a very low number – but said uptake and Medicare reimbursement were "playing out how we thought". Management

called the recent ICER assessment of CAR-T therapies very positive, but accepted that risk-based pricing models would become the norm here.

And Gilead's chief executive, John Milligan, whetted deal bankers' appetites by saying M&A and building pipeline were key priorities – in cell therapy and beyond. Celgene made similar comments during its presentation, with chairman Bob Hugin describing business development as the company's "number-one strategic priority".

The desire of large companies to do deals is incontrovertible. The more pertinent question for assembled investors in San Francisco is whether asset values are palatable.

An EP Vantage staff report, with reporting by Madeleine Armstrong in San Francisco. For live updates from the JP Morgan healthcare conference in San Francisco on January 9-12 follow @ByMadeleineA on Twitter. To contact the writers of this story email news@epvantage.com.

See our full coverage from the JP Morgan conference here.