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10 Jan 2023 | **News**

J.P. Morgan Day One: Biopharma Braces For Headwinds Ahead

by Scrip Team

Daily notebook from the J.P. Morgan Healthcare Conference: Turbulent weather matches sentiment about the year ahead, with investors looking for reassurance on the IRA, deal-making and growth strategy from big pharma. Updates from J&J, Biogen, BMS, Merck and more.

J&J Didn't Really Want Horizon

Johnson & Johnson CEO Joaquin Duato took time during the firm's 9 January J.P. Morgan Healthcare Conference presentation in the Westin Grand Ballroom to clarify that the company wasn't interested in acquiring *Horizon Therapeutics plc*, even though J&J was named in a press release as one of several drug makers pursuing the company in December. *Amgen, Inc.* ultimately sealed a deal to buy Horizon for $27.8bn. (Also see "*Amgen To Enhance Rare Disease Franchise With $27.8bn Horizon Takeover*" - Scrip, 12 Dec, 2022.)

"I think it's important for investors to understand that Horizon Therapeutics was not a company that was in the sweet spot of our strategic criteria," he said.

J&J was named as a potential acquirer because of certain takeover disclosure regulations, he said. "I want to explain to you what we did there. We attended a market presentation," he said. "Now, after attending the market presentation, we subsequently decided that the acquisition did not meet our strategic criteria, and as a consequence, we never entered into diligence, never put in a bid for Horizon Therapeutics."

The CEO sought to clarify the company's current thinking on M&A, which he said remains focused mainly on early- to mid-stage deals. J&J's most successful business development deals have been ones around assets that are immediately after proof-of-concept or just before, Duato said.

"Now does that mean that we are against other types of M&A opportunities? No, we are not."

However, he said, "we have a disciplined capital allocation strategy and disciplined metrics in order to evaluate those opportunities, and normally these companies ... do have a fair valuation from the Street and it's more challenging and they have a higher bar."

Viehbacher Debuts As Biogen's New CEO

Newly installed *Biogen, Inc.* CEO Christopher Viehbacher, the former *Sanofi* CEO who left behind his more recent career in biopharma investing to take the helm at the troubled company, did not pull any punches about the challenges ahead during his J.P. Morgan Healthcare Conference fireside chat. (Also see "*Biogen Lures Viehbacher Back From Venture Capital As CEO*" - Scrip, 10 Nov, 2022.)

Viehbacher noted that Biogen has been "a very narrowly focused company on multiple sclerosis and very successful. But of course, that is now something we're calling basically a melting iceberg. It's not a patent cliff, but it's not got growth perspectives. And my job, as I see it, is to restore the company to sustainable growth."

The launch of Alzheimer's drug Aduhelm (aducanumab) was expected to deliver a blockbuster for Biogen's declining commercial portfolio, but generated only a few million dollars in sales under prior CEO Michel Vounatsos. (Also see "*How Biogen's Aduhelm Bet Became A Commercial Bust*" - Scrip, 6 Jun, 2022.)

Viehbacher noted he joined Biogen at a time when the company has two potential blockbuster launches within the same year – the newly approved *Eisai Co., Ltd.*-partnered Alzheimer's drug Leqembi (lecanemab) and the *Sage Therapeutics, Inc.*-partnered depression drug zuranolone. (Also see "*Sage/Biogen See Big Potential Market For Zuranolone In PPD*" - Scrip, 1 Jun, 2022.)

Viehbacher confirmed that Eisai is leading the Leqembi launch in every way, from negotiating for Medicare coverage of the amyloid protofibril-clearing antibody to the initial commercialization activities in the US, including preparing health care providers to identify appropriate patients for treatment and monitor them for amyloid-related imaging abnormalities (ARIA).

Eisai/Biogen's Leqembi Will Launch Below Aduhelm At $26,500 Per Year

By Mandy Jackson

06 Jan 2023

With accelerated approval granted and a supplemental filing for full approval in the FDA's hands, Eisai set a price it says is below the "societal value" its Alzheimer's drug provides as it prepares to seek Medicare coverage. Labeling notably comes with no black box warning or safety restrictions despite various concerns.

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As far as adding other products and R&D programs to Biogen's portfolio, Viehbacher said he does not anticipate that the company will veer too far from its neurology focus and will look to build in areas where it is already growing, such as psychiatry with zuranolone and Alzheimer's disease with Leqembi.

"I'm going to focus on getting really things right within the company sort of the first half of this year," he said. "I do think we'll have to turn our attention to some external growth in the second half."

While he said he wouldn't shy away from an acquisition, big purchases come with a different risk profile than partnerships, Viehbacher noted, saying that Biogen has proven to be a good partner to a lot of companies, including Ionis Pharmaceutical Inc., the company's partner on spinal muscular atrophy therapy Spinraza (nusinersen).

IRA Looms Large Over J.P. Morgan

Policies under the Inflation Reduction Act (IRA) that will allow Medicare to negotiate drug prices have been an overhang for the otherwise celebratory start of J.P. Morgan. The IRA is expected to be a hot topic at the meeting, with one of the keynote spots dedicated to the new law's impact on innovation.

The IRA was passed in August, and since then industry leaders have been hard at work strategizing how to adjust to the first introduction of Medicare price negotiation, while waiting for specifics on which products will be affected and how the program will work. (Also see "*Medicare Price 'Negotiation' Process Gets Broad Brush Treatment In New Law*" - Pink Sheet, 16 Aug, 2022.)

At the time, Pharmaceutical Research and Manufacturers of America (PhRMA) CEO Stephen Ubl issued a statement saying: "The President signed into law a partisan set of policies that will lead to fewer new treatments and doesn't do nearly enough to address the real affordability problems facing patients at the pharmacy. We will explore every opportunity to mitigate the harmful impacts from the unprecedented government price setting system being put in place by this law. We will continue to advocate for policies that give patients better and more affordable access to lifesaving treatments and for a system that supports

Eisai Pricing For Lecanemab Reflects Concern With Medicare 'Sustainability,' 'Giving Back,' Firm Says

By Cathy Kelly

06 Jan 2023
Despite internal modeling indicating lecanemab offers a 'societal value' of around $37,600 per year, the company has decided on a list price of around $26,500 annually to moderate the impact on Medicare and patients.

Read the full article here

innovation."

For its part, PhRMA has pushed reforming PBMs and the 340B discount program to create a more sustainable health care system in the US. While those arguments weren't enough to stop a Democratic Congress from enacting the drug pricing legislation, they could find more purchase now that Republicans control the House. (Also see "*Republican Leaders In Congress Want To Undercut Drug Pricing Law: What's The Opportunity?*" - Pink Sheet, 8 Nov, 2022.)

The J.P. Morgan stage is usually used for executives to weigh in on how they seen political trends affecting the industry, and set the tone for the year ahead.

At the start of the meeting, one big pharma CEO noted that the priority throughout the year will be how to ensure the IRA does not limit innovation in small molecules and new technologies. Several industry leaders have spoken out about how they see the IRA incentivizing biologics and broadly discouraging research and development. (Also see "*US Pricing Reform Puts Cancer Drug Innovation At Risk, Drug Leaders Warn*" - Scrip, 2 Nov, 2022.)

The legislation already appears to be impacting mergers and other deal-making. (Also see "*Amgen, Takeda Acquisition Targets Involve Limited Exposure To Medicare – And Price Controls*" - Pink Sheet, 27 Dec, 2022.) On 5 January at the Goldman Sachs Healthcare CEOs Unscripted Conference, *Merck & Co., Inc.* CEO Rob Davis explained how the IRA factored into the firm's acquisition of Imago. (Also see "*IRA Already Impacting Merck & Co. BD Decisions, CEO Davis Says*" - Scrip, 5 Jan, 2023.)

"It's going to change how you think about strategically bringing assets forward," Davis said of the IRA. "I think it will change the way we assess assets in the business development context."

But, industry leaders also acknowledge that the biopharma industry can rise to meet the challenges of the IRA as it has adapted to shifting policies in the past – dating back to the establishment of the Food, Drug and Cosmetic Act, the Hatch-Waxman Act and the creation of Medicare Part D.

The IRA is just the latest set of circumstances for industry to adapt to.

[Editor's note: This article has been updated to remove quotes from an off-the-record event, but retains the intention of the comments.]

Merck Eager To Build Its Pipeline With Help From Partners

Merck & Co., Inc. CEO Rob Davis and president of Merck Research Laboratories Dean Li made it clear during their J.P. Morgan presentation that the big pharma is pushing business development.

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With $45.5bn in revenue through third quarter 2022 excluding sales of the COVID-19 treatment Lagevrio (molnupiravir), representing 29% growth, Davis said Merck is going to leverage its strong cash flow to build the pipeline internally and externally. The company spent $36.5bn on business development during the last five years – including mergers and acquisitions as well as fees paid under licensing and collaboration agreements – with about 90 transactions per year. That has brought Merck 16 mid- to late-stage programs, plus several earlier-stage programs.

“That continues to be an important priority,” Davis said. The CEO has also spoken out about how the IRA is affecting BD, but at J.P. Morgan the execs laid out more of what they are looking for. (Also see "*IRA Already Impacting Merck & Co. BD Decisions, CEO Davis Says*" - Scrip, 5 Jan, 2023.)

“Where science and value align, we will act. But what's also important is that we're not desperate. We're disciplined, we're focused,” Davis said. “We're in a position where we can be selective, we can look for the best science, but when we see it, we will move.”

And Davis said Merck is increasingly confident it is preparing to make up for the loss of exclusivity for its top-selling product – Keytruda (pembrolizumab) – in 2028. “We're starting to talk less about 2028,” he said. “We're talking about do we have a sustainable engine? And if you have a sustainable engine, 2028 will take care of itself.” He noted “we are starting to really build that engine ... and so as we sit here today, I'm feeling good.”

CMO Eliav Barr On Merck & Co.'s Post-Keytruda Game Plan

By Jessica Merrill

25 Nov 2022
Merck & Co. chief medical officer Eliav Barr talks with *Scrip* about the generational leadership change under way at the company, Merck's next oncology plays and its bold plan to rebuild a cardiovascular franchise.

Read the full article here

Li added that “we are here because we are looking for partners that we have been successful at working with and we encourage all these partners to come see us because we're open for business and we're interested in advancing our pipeline with you.”

In an interview with *Scrip*, Li said he is somewhat agnostic about therapeutic area and modality when evaluating partnerships, but he is focused on the science and whether he has gotten to know the teams involved in a potential partner.

“I do care about therapeutic areas, I do think about modalities, I do think about biology, technology, clinical, commercial,” Li said, “but the [partnerships] that are most productive are the ones where I actually know the people and know who I'm working with, and not them in a peripheral sense, but we have both put our hands in the batter.”

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Bristol Outlines Another $10bn+ In New Product Sales

Bristol Myers Squibb Company chief commercialization officer Chris Boerner – standing in for CEO Giovanni Caforio, who is recovering from COVID-19 – outlined another $10bn-plus in annual sales from new product launches on top of guidance for the current decade the company has given during the past two years.

This is on top of the more than $25bn in new annual revenue by 2029 that the company will bring in from nine recent launches, including three products launched in 2022 – Camzyos (mavacamten) for obstructive hereditary cardiomyopathy, Opdualag (nivolumab and relatlimab) for melanoma and Sotyktu (deucravacitinib) for psoriasis. (Also see "*BMS Does Not Think Pricing Or Monitoring Will Limit Camzyos Use*" - Scrip, 29 Apr, 2022.) Boerner said use of Sotyktu is rapidly increasing in the first month and a half since its launch. (Also see "*BMS Aims To Unseat Otezla In Psoriasis With US FDA-Approved Sotyktu*" - Scrip, 9 Sep, 2022.)

> ***BMS Projects 2022 Growth Even With $3bn Hit From Revlimid, Abraxane Generics***
>
> By Mandy Jackson
>
> 10 Jan 2022
> Bristol executives reiterated the company's aggressive revenue growth expectations while outlining the impact Revlimid generics will have in Europe, Japan and – to a limited extent – in the US.
>
> *Read the full article here*

"Over a quarter of all new oral scripts in psoriasis are going to Sotyktu," he said. "We're sourcing patients evenly across naïve patients, as well as those patients who are experienced on Otezla or a biologic, which confirms physicians' willingness to use Sotyktu across multiple patient types, and that's important. And we've seen good momentum in terms of new volume month over month."

The six products expected to bring in greater than $10bn in new revenue on top of those first nine new launches include the Factor XIa inhibitor milvexian, which BMS hopes will generate similar efficacy and a better safety profile than its blockbuster anticoagulant Eliquis (apixaban) across three indications moving into Phase III clinical trials in 2023. These indications – secondary stroke prevention, atrial fibrillation and acute coronary syndrome – should add up to $5bn-plus in sales, Boerner said. (Also see "*BMS/Janssen Will Begin Phase III For Factor XIa Inhibitor Milvexian By Year-End*" - Scrip, 28 Aug, 2022.)

The other five products in the next wave of new launches later in this decade include the cereblon modulators (CELMoDs) iberdomide and mezigdomide in Phase III for multiple myeloma, the oral LPA1 antagonist BMS-986278 entering Phase III in 2023 for lung fibrosis, the

interleukin-13 inhibitor cendakimab in Phase III for eosinophilic esophagitis and the ROS1/NTRK inhibitor repotrectinib expected to launch this year. BMS purchased repotrectinib in its mid-2022 acquisition of *Turning Point Therapeutics Inc.* for $4.1bn. (Also see "*BMS Hopes Turning Point Buyout Will Fare Better Than Roche's Ignyta Acquisition*" - Scrip, 3 Jun, 2022.)

"We think repotrectinib has the potential to be a best-in-class ROS1 inhibitor based on the compelling efficacy data as well as particularly compelling duration of response data," Boerner said. "Currently, the ROS1 market is about a $500m to $600m annual market. We believe, based on the profile we've seen with repotrectinib, we have the potential to possibly double the size of that market."

Ipsen CEO Outlines Benefits Of Albireo Buy

Ipsen SA CEO David Loew was an early riser in San Francisco as he filled in analysts on the French firm's acquisition of *Albireo Ltd.* and its lead asset Bylvay, which is approved for progressive familial intrahepatic cholestasis. (Also see "*Ipsen Eyes Opportunity In Rare Liver Diseases With Albireo Buy*" - Scrip, 9 Jan, 2023.)

However, much of the value from Bylvay could come from two other rare liver disease indications, namely Alagille syndrome, for which the drug has been filed on both sides of the Atlantic, and biliary atresia. Loew noted that with Alagille, there is already a rival on the market in the shape of Mirum's same-class offering Livmarli (maralixibat) but said that while the profiles "are pretty similar regarding efficacy, perhaps there is a safety advantage for Bylvay ... because there is less diarrhea," though he acknowledged that given the very low numbers of patients involved in the firms' respective trials, "one needs to be super careful when looking at cross-study comparisons." (Also see "*Mirum Targets $500m Sales For Just-Approved Rare Liver Disorder Drug*" - Scrip, 30 Sep, 2021.)

He said: "Where we do see a differentiation is clearly on the dosing," as Bylvay is available in both capsule and pellets, with the latter particularly convenient when treating a baby or toddler. "You can sprinkle the pellets over an apple sauce or a chocolate pudding and babies usually like that," Loew quipped.

There is no late-stage competition for Bylvay in the biliary atresia space, he noted, adding that if all goes well in the clinic, the latter indication would make up about 50% of Ipsen's peak sales forecast of $800m for the drug.