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J.P. Morgan Day One: Novartis Reveals Two Deals, Pfizer's Bad Year, Bristol's Wobbly Growth

Updates Also From Gilead, BioMarin, Bausch+Lomb

by Scrip Team

Daily notebook from the J.P. Morgan Healthcare Conference: Deal and strategy news from Novartis, BMS and Pfizer; Gilead talks lenacapavir PrEP launch plans; BioMarin's new CEO makes an appearance and Saunders explains the status at Bausch + Lomb.

Novartis Debuts Two Deals

While *Johnson & Johnson* had the day's largest acquisition with the $2bn offer for antibody-drug conjugate specialist *Ambrx, Inc.* (Also see "*J&J Makes Its Biggest Bet Yet On Antibody-Drug Conjugates With Ambrx Buyout*" - Scrip, 8 Jan, 2024.) and *Merck & Co., Inc.* made waves with its buyout of *Harpoon Therapeutics* for $680m (Also see "*Merck & Co. Spears Another Acquisition With Harpoon*" - Scrip, 8 Jan, 2024.), *Novartis AG* announced a pair of deals on the opening day of J.P. Morgan.

Just over a decade after *Calypso Biotech BV* was spun out from *Merck KGaA*, the firm is changing its tune as Novartis swooped in, paying $250m upfront for the firm with a potential $175m in development milestones. Calypso claims its interleukin-15 antibody CALY-002 is a pipeline-in-a-drug, with potential in a host of dermatological, gastrointestinal and rheumatic indications.

So far CALY-002 has only entered one Phase I study, comprising a single ascending dose (SAD) part in 95 healthy volunteers and subsequently a multiple ascending dosing (MAD) part in celiac patients undergoing a gluten challenge. The trial also includes open-label multiple dose expansion cohorts in eosinophilic esophagitis patients.

The SAD part of the study is complete; Calypso said CALY-002 was well tolerated and demonstrated IL-15 blockade by reducing the reduction of natural killer cells in patients' blood – which it claims is the first IL-15-specific antibody to show NK cell reduction in humans.

The MAD part of the study could yield data, including disease biomarkers and histology endpoints, imminently. It is not clear whether Novartis saw these results before opting to buy the firm. The Swiss giant said it would seek to put CALY-002 into trials in further autoimmune indications.

It lags behind *Amgen, Inc.*/*Sanofi*'s anti-IL-15 asset ordesekimab, which is in the Phase IIb PROACTIVE trial in celiac disease, and *Equillium, Inc.*'s EQ101, which inhibits IL-2, IL-9 and IL-15 and is in a 30-patient Phase II trial in alopecia. Data are due from both trials toward the end of 2024.

Novartis's second deal of the day was far more back-end loaded. The company licensed two unnamed RNAi therapeutics for cardiovascular conditions from Shanghai Argo Biopharmaceutical. The first is in Phase I trials, with Novartis gaining exclusive global development and commercialization rights, as well as a research collaboration and an option to license compounds directed against up to two further targets. The second deal nets Novartis an exclusive license outside China to develop and sell a product currently in Phase I/IIa trials.

Novartis paid $185m upfront across these two agreements, but the bio-buck value is an astonishing $4.2bn, with tiered royalties on top.

Pfizer's Bourla: '2023 Was Not A Good Year For Us'

Pfizer CEO Albert Bourla seems ready to welcome the new year and put 2023 in the rear view. During the company's presentation in the Grand Ballroom of the Westin on 8 January, the CEO admitted that 2023 was filled missteps, even when it came to one of the company's apparent bright spots – the launch of the vaccine Abrysvo for respiratory syncytial virus (RSV).

"Clearly, 2023 was not a good year for us," Bourla said. Not only did the company have to revise financial guidance late in the year, stemming primarily from lower-than-expected sales of its COVID-19 products, but other commercial products also under-performed, he said.

As Bourla described 2023, it was a year "to remember to never repeat again." He even sidestepped taking credit for strong sales of Abrysvo, which launched in September. Abrysvo generated $375m in the third quarter, a strong launch for any new product. (Also see "*Abrysvo Launch A Bright Spot For Pfizer In A Third Quarter Reset*" - Scrip, 31 Oct, 2023.) But the news was overshadowed by rival, GSK, which substantially outpaced Pfizer with its competing RSV vaccine Arexvy, which generated £700m ($806m) in the third quarter. (Also see "*A Stellar Launch For RSV Vaccine Arexvy Lifts GSK*" - Scrip, 1 Nov, 2023.)

Bourla acknowledged that the initial revenues surpassed internal expectations, but he said that was because the market was bigger than the company – or Wall Street analysts – had expected, not because of Pfizer's strengths.

"We have 35% market share. That's not Pfizer," Bourla said. "We need to fix it."

GSK essentially beat Pfizer in the retail market, he acknowledged. "We came later and GSK had already signed contracts and we missed the opportunity to sign the contracts that we should have," Bourla said. "Every year, it's a clean slate, so now we will see how the contracting will go this year." While Pfizer was behind in the retail setting, he said the company performed better in physician's offices.

In December, with the closing of Pfizer's $43bn acquisition of Seagen, Pfizer reorganized its commercial organization, culminating in the departure of chief commercial officer and biopharmaceuticals president Angela Hwang. (Also see "*With Seagen Integration In Sight, Pfizer Reorganizes Commercial And R&D*" - Scrip, 13 Dec, 2023.)

Bristol CEO Boerner Outlines Wobbly Growth Path

Bristol Myers Squibb Company CEO Chris Boerner, now two months into his tenure at the helm of the organization, outlined a path to growth through the rest of this decade that will come with multiple bumps in the road. The company revised its mid-term guidance in October, noting that its portfolio of nine new launches expected to generate $10bn-$13bn in revenue by 2025 would now achieve $10bn-plus in 2026, and BMS maintained that guidance at the J.P. Morgan Healthcare Conference. (Also see "*Bristol's New Launches Hit Reality As New Product Portfolio Forecast Is Revised*" - Scrip, 26 Oct, 2023.)

"First, we exist in an evolving, increasingly complicated regulatory and market access environment that includes, but is not limited to, the impact of [Inflation Reduction Act (IRA)] in the US," Boerner told the J.P. Morgan crowd. "Second, virtually all aspects of our business are becoming intensely competitive. And while both of these factors impact all companies to a certain extent in our sector, our situation is magnified by a third factor, namely, we face losses of exclusivity for a number of key products."

BMS already is working through the loss of exclusivity and staggered release of generics for its multiple myeloma blockbuster Revlimid (lenalidomide) and its anticoagulant Eliquis (apixaban) and PD-1 inhibitor Opdivo (nivolumab) will go off patent later in this decade, among other products.

"These are meaningful revenue losses and these factors require that we have a plan and that we execute that plan exquisitely well," Boerner said.

The CEO said BMS will navigate the dynamics impacting its portfolio through the rest of this decade in three distinct periods.

“Between now and the middle of the decade, the focus will be on growth and maximizing the opportunity that we have with our launched and soon-to-launch growth portfolio,” Boerner said. “We then have to navigate a couple of years starting in 2026 where we are at the height of our LOE exposure, and the focus here will be on shortening this period as much as possible by accelerating our R&D programs. And then importantly, emerging in the last part of the decade, 2028 and beyond, as a company with sustainable top-tier growth.”

The company has invested heavily in its pipeline, announcing several new early-stage programs at an R&D day in September. (Also see "*BMS Revs R&D Engine To Advance 10 New Drug Candidates Annually*" - Scrip, 15 Sep, 2023.) And at the end of December, BMS made two big purchases, including one with a near-term product approval – schizophrenia drug maker *Karuna Therapeutics, Inc.* for $14bn – and one with a potentially differentiated radiopharmaceutical portfolio, *RayzeBio, Inc.* for $4.1bn. (Also see "*BMS Makes Second Big Buy Of December, Pays $4.1bn For RayzeBio*" - Scrip, 27 Dec, 2023.)

Gilead Prepping For Twice-Yearly Lenacapavir Launch

Gilead Sciences, Inc. will deliver an important proof point for its long-acting injectable strategy in HIV during the second half of 2024 when it expects to report results from the Phase III PURPOSE-1 clinical trial of lenacapavir in pre-exposure prophylaxis (PrEP). The capsid inhibitor is approved in the US and EU as Sunlenca for heavily treatment-experienced adults with multidrug-resistant HIV, but the company sees great potential for the product in PrEP as a twice-yearly injectable option. (Also see "*Gilead Keeps Focus On HIV, Long-Acting Drugs And Growth Through Oncology*" - Scrip, 31 Jan, 2023.)

Gilead CEO Daniel O’Day noted during the company’s J.P. Morgan presentation that it is preparing for up to five new launches in the HIV space by the end of 2030, beginning with lenacapavir for PrEP in late 2025. Gilead already sells the once-daily oral product Descovy (emtricitabine and tenofovir alafenamide [TAF]), which has a market-leading 43% share of the PrEP market.

“The [PrEP] market's been growing at about 15% or so year-on-year, and we expect that to continue,” chief commercial officer Johanna Mercier added. “With new entrants, such as lenacapavir twice-yearly injection, that market should actually be accelerated.”

Mercier noted that about 33% of the population who could benefit from PrEP are currently treated with prevention medicines. “We believe that number will be well over 50% as lenacapavir subcutaneous formulation twice a year will come to market,” she said.

Mercier pointed out that with daily oral regimens, individuals often take PrEP medicines on demand, rather than every day. “What will happen is they might take it a couple of days over a weekend if their social agenda demands it and then be off the drug for another week or so, so compliance is really iffy versus HIV treatment,” she said. “It'll be really important to make sure that people are compliant with the twice-yearly, but we believe that in light of the fact that sexual health visits are actually every six months, this coincides incredibly well for their lenacapavir injections as well.”

Gilead has been in pre-launch mode for lenacapavir PrEP “for some time now” with an expected US launch possible in late 2025. “We will be more than ready and we think the uptake will happen very quickly,” Mercier said. “There's a demand out there in the community. People are talking about it already without us having any input to that. People are excited about what lenacapavir twice yearly can offer and so I think the uptake will be quite rapid.”

BioMarin’s CEO Hardy Makes His Debut

BioMarin’s new CEO Alexander Hardy spoke publicly to investors for the first time at J.P. Morgan after succeeding the company’s longtime CEO Jean-Jacques Bienamé at the start of the year. The former Genentech CEO used the conference as an opportunity to outline his early vision for leading the rare disease specialist, but he didn’t provide 2024 financial guidance or long-term expectations for the launch of the company’s new gene therapy for hemophilia A, Roctavian.

“I am enormously excited about where BioMarin is and its potential,” he said. “Being located here in the Bay Area for many years, Biomarin was on my radar screen, and I was watching – under the vision and leadership of JJ – the company become more and more successful.”

Hardy’s primary focus initially is on driving growth of Voxzogo (vosoritide) for achondroplasia and other indications, as investors would expect, as it is the company’s primary near-term growth driver. (Also see "*BioMarin’s Next Chapter: ‘A Financial Growth Story’*" - Scrip, 13 Sep, 2023.)

As for Roctavian, Hardy cautioned investors that the launch trajectory is expected to grow slowly over time.

“We’ve got to establish the Roctavian opportunity. We made important progress in market access and readiness, but 2024 and 2025 are going to actually inform what that uptake curve is,” he said. “We’re going to let the results do the talking for Roctavian and let that guide our outlook and our communications with the market.”

The company announced in December that it dosed its first patient in the US with the gene therapy.

“The reality is this is a highly disruptive therapy in a very complex market,” Hardy said. “You have to have a highly motivated patient. You have to have a supportive payer, and you have to have a treatment site and a physician who’s willing and able to use this product.”

Saunders: Bausch + Lomb Spinout Just A Matter Of ‘When And How’

Bausch Health Companies Inc. first announced its plan to spin out ophthalmology-centric *Bausch + Lomb Inc.* in August 2020, but the separation still is not complete, even though B+L grossed $630m in a May 2022 initial public offering. (Also see "*Bausch Investors Initially Pessimistic Following B+L Spinout*" - Scrip, 10 May, 2022.) Addressing the J.P. Morgan Healthcare Conference audience for the first time since returning as B+L’s CEO last February, Brent Saunders said he is not worried about the transaction being finalized; it would be a greater challenge to try to put all the pieces back together. (Also see "*Bausch + Lomb Taps A Familiar Face, Brent Saunders, As Next CEO*" - Scrip, 15 Feb, 2023.)

“It's a BHC decision [and] I don't think there's really any situation where it doesn't happen,” Saunders told the conference on 8 January. “It's just a question of when and how.”

Within its pharmaceutical portfolio, B+L intends to lead in the dry eye disease space. Saunders reported that Miebo (perfluorohexyloctane), approved by the US Food and Drug Administration last May for DED that directly targets tear evaporation, partnered with *Novaliq GmbH*, is off to a solid launch entering its first full year on the market.

In addition, B+L acquired established DED therapy Xiidra (lifitegrast) last June from Novartis AG. (Also see "*Novartis Eyes Leaner Ophthalmic Business In Xiidra Deal With Bausch + Lomb*" - Scrip, 30 Jun, 2023.) Saunders called Xiidra the best therapy for inflammatory DED and predicted that marketing two products would help expand the market, noting that that is what happened when *Shire Pharmaceuticals Group PLC*first launched Xiidra to compete with Allergan’s Restasis (cyclosporine emulsion) back in 2016.

“When you put [Miebo and Xiidra] together and have a sales rep talking to a physician, [that is] a real therapeutic approach to the disease,” Saunders said. “It's not about a hammer looking for a nail. It's about ‘let's really treat the etiology of this disease with the appropriate treatment,’ whether it be an anti-inflammatory or an evaporative drug.” Historically, DED is a “promotionally sensitive” indication whose market grows when there is strong commercial support behind one or more products, he added.