SCRIP
CITELINE COMMERCIAL

12 Jan 2023 | **Analysis**

J.P. Morgan Day Four: Talking With Execs About BD Plans

Interviews With Lilly, Roche, Takeda And More

by Scrip Team

Daily notebook from the J.P. Morgan Healthcare Conference: Big pharma execs weigh in on business development strategy, Sage CEO Barry Green discusses how the Inflation Reduction Act should spur deal-making and bluebird talks about gene therapy commercialization plans.

Roche Exploring New Areas Of BD

Roche Holding AG global head of pharma partnering James Sabry told *Scrip* the company is exploring business development in new therapeutic areas outside of the ones it is best known for, like oncology, ophthalmology and neuroscience. It's all still in the exploratory stage, but the company is interested in bringing in some new science in areas like cardiometabolic disease and infectious disease, he said.

"We will start to evaluate this year other therapeutic areas that we historically may not have a footprint in right now, but we're curious," Sabry said. "The technology is getting so rich for identification of new medicines and new technologies that we'd like to look at more broadly, and so you'll start to see this with us this year."

He specifically highlighted the cardiometabolic space, which has gained renewed interest from big pharma recently given high unmet need in the therapeutic area and developments in the science.

"Cardiometabolic is a big one for us," he said, pointing out that Roche used to have a number of research programs in the area, though it never had a commercial footprint. Plus, he said the pharmaceutical team could leverage the diagnostic side of the business in the cardio space since the company does have some diagnostic tools in areas like heart failure and ischemia.

© Citeline 2024. All rights reserved.

Sabry said Roche's business development focus remains primarily in the earlier stages of drug development, including partnerships and alliances.

"Unlike many companies, we tend to do most of our alliances in the later stages of research and in the early stages of development," he said. "We have such a strong internal R&D capability." In the current environment, with some start-ups and early biotechs being more cash constrained, Sabry said Roche is seeing some companies looking to partner earlier.

"One trend that we're noticing is that companies are wanting to come and talk to us earlier in their development than they would have a year ago," he said. "That allows us to see things earlier, which is exciting for us to potentially develop alliances that are earlier stage."

Teva Will Return To Business Development With Smaller Deals

Brand new on the job, *Teva Pharmaceutical Industries Ltd.* CEO Richard Francis addressed J.P. Morgan on 11 January saying his 13 years at *Biogen, Inc.* – competing with Teva's Copaxone (glatiramer) in the multiple sclerosis space – and five years at direct competitor *Sandoz Inc.* give him a good head start in dealing with the complexities facing the Israeli firm, but that he is still learning. Case in point, chief financial officer Eli Kalif gave the principal address before the JPM Q&A session.

In terms of business development plans, Teva still faces limitations due to its debt situation and is still adjusting its business in hopes of having its free cash-flow run rate support its debt, which it has reduced significantly over multiple transactions since 2018, Kalif said. (Also see "*Teva Lowers Forecast As Q3 Revenues Decline Amid Growing Generic Competition*" - Scrip, 3 Nov, 2022.) Francis said Teva would offer some details about its business development plans at mid-year.

"Obviously, we have limitations with regard to the debt we have," the CEO said. "But, first and foremost, I think we've got to make some choices about what we want to invest in. And that means [determining] what we're going to have to stop investing in, because I do think we need to keep control on costs to make sure we can keep servicing the debt in the way we are and we have been."

The company's current capital constraints mean it likely will be focused, perhaps even limited to, licensing deals and small, targeted acquisitions when it resumes deal-making, Francis added. Teva should be seen as a partner of choice, he added, "because of our global capability."

Lilly's Focused On Deals It Wants To Do, Not That It Has To Do

Eli Lilly and Company chief science and medical officer and president of Lilly Research Laboratories Daniel Skovronsky sketched out the big pharma's enviable business development position in an interview with *Scrip* at J.P. Morgan.

© Citeline 2024. All rights reserved.

With five drug launches expected in 2023 and five candidates moving into Phase III development this year, and without a major drop in revenue coming this decade due to products losing patent exclusivity, Lilly can focus on the kinds of acquisitions and collaborations that it wants to do, not deals that it has to do to generate near-term product sales.

“I think it's hard for any company to create value through business development by being the top bidder on obvious assets, but yet many companies are in a position where they have to be the top bidder on obvious assets,” Skovronsky said. “I don't think that's going to be our strategy. We have to see value where others don’t or take risk by going earlier. We can afford to do that because we can wait and we can add value to molecules. We don't need things that are launching next year that are going to drive our revenue or fill a revenue gap.”

He noted that 2023 will be “an incredible year” for Lilly with five big launches, including four brand new medicines and a major new indication for a drug first approved in 2022 – the type 2 diabetes drug tirzepatide could possibly see an FDA decision on an obesity claim before the end of 2023. (Also see "*Lilly’s Mounjaro Diabetes Approval Is First Challenge To Novo’s GLP-1 Franchise*" - Scrip, 13 May, 2022.)

The other four launches expected this year are anti-amyloid antibody donanemab for Alzheimer's disease, pirtobrutinib for B-cell malignancies, lebrikizumab for atopic dermatitis and mirikizumab for ulcerative colitis. (Also see "*Lilly Does Not Expect A Quick Medicare Coverage Decision For Donanemab*" - Scrip, 15 Dec, 2022.) The five candidates entering Phase III are a weekly insulin product, the next-generation subcutaneously administered anti-amyloid Alzheimer's drug remternetug, the oral selective estrogen receptor degrader (SERD) imlunestrant and two diabetes/obesity candidates – the oral GLP-1 agonist orforglipron and GLP-1, GIP and glucagon (GGG) agonist retatrutide. (Also see "*Lilly Revenue Guidance Rises Along With Diabetes, Obesity Investments*" - Scrip, 14 Dec, 2022.)

Sage CEO Barry Greene Sees Some Lemonade In IRA Lemon

Sage Therapeutics, Inc. CEO Barry Greene was slated to be part of a keynote panel discussion on the Inflation Reduction Act (IRA) with Lilly CEO David Ricks at J.P. Morgan, but Ricks was unable to attend the meeting so the discussion didn’t take place. Instead, *Scrip* met with Greene and asked for his perspective on the law passed last year, which allows Medicare to negotiate drug prices nine years after US Food and Drug Administration approval and 13 years after approval for biologics. (Also see "*Medicare Drug Pricing Casts A Cloud Over J.P. Morgan’s Opening Day*" - Pink Sheet, 9 Jan, 2023.)

“I think the IRA is a bad law,” he said. “Fundamentally, government picking a price for a medicine, given the current health care system is just not a good idea and it can be a stunter of innovation. Now, for those companies that had long-range plans that were growth through price increases or growth through multiple indications for a drug on the market for 10 or 15 years,

© Citeline 2024. All rights reserved.

they're in trouble."

Greene went on to say that "the lemonade I see in this kind of lemon of a law" is that biopharmaceutical companies with novel medicines could benefit from increased interest in mergers and acquisitions and other deal-making. In addition to the upcoming patent cliff that many big pharmas are facing later in this decade, the impending likelihood that sales of key products will decline sooner than anticipated due to Medicare price negotiations means that firms have even more need to add new products to their portfolios. (Also see "*The Next Big Patent Cliff Is Coming, And Time Is Running Out To Pad The Fall*" - Scrip, 4 Apr, 2022.)

"IRA for big pharma should spur more M&A, more licensing deals because they need more products to fill that revenue growth curve, and that should be beneficial for companies like us or other companies out there," Greene said.

In terms of the impact of the IRA for Sage, he said the company's strategy all along has been growth through innovation. Sage has built "a true product engine capable of producing many, many medicines." Each one will have one or a limited number of indications, so that the company is not dependent on revenue from a single product across multiple indications for its sales growth.

Takeda Focused On Early Collaborations, Single-Asset Deals

Takeda Pharmaceutical Co. Ltd. president of research and development Andy Plump described the company's business development intentions for *Scrip* in an interview at J.P. Morgan, noting that the strategy starts with a focus on four core therapeutic areas – gastrointestinal diseases, oncology, neuroscience and a broader category that includes rare and genetic diseases and hematology.

"Secondly, as we have for the past eight years, we continue to be very proactive in early-stage research, platform-based partnerships – that's fundamental to our innovation model," Plump said. "We've fully bought into the fact that we have really great labs, but even with our great labs, the majority of what we'll eventually bring to patients will come through our partners and that's what the industry has taught us over decades and decades."

He noted that partnering earlier in the research and development process brings a less expensive upfront cost than a later-stage collaboration, but also "they help our own scientists evolve and grow. And we're starting to see success from that strategy now and we continue to do that."

In addition, Takeda is interested in targeted asset acquisitions or licensing deals across its four core therapeutic areas, such as the deal it announced in December with *Nimbus Therapeutics, Inc.* to acquire the Phase III-ready TYK2 inhibitor NDI034858 for $4bn up front. (Also see "*Takeda Aims At BMS's Sotyktu In $4bn Deal For Nimbus's TYK2 Inhibitor*" - Scrip, 13 Dec, 2022.) Plump

© Citeline 2024. All rights reserved.

also pointed to Takeda's collaboration announced in October with Dr. Falk Pharma GmbH for TAK-227, a transglutaminase 2 inhibitor in Phase IIb for celiac disease, as a recent example of the single-asset part of the company's business development strategy. (Also see "*Asia Deal Watch: Astellas Invests In Taysha, Gets Rights To Two AAV Gene Therapies*" - Scrip, 25 Oct, 2022.)

"We don't emphasize one [type of deal] over the other," he said. "We're looking for the best opportunities. It's quite hard to find really compelling assets in late stage and when you do, like the Nimbus program, they are very competitive. There just aren't that many out there."

Sofinnova Achieves Another Big Cardiovascular Exit With CinCor Deal

Scrip met up with Sofinnova Partners managing partner Graziano Seghezzi to talk about the firm's strategy and outlook for 2023, and caught the venture capitalist in a celebratory mood. One of the three billion-dollar deals announced at the start of the meeting was Sofinnova portfolio company *CinCor Pharma, Inc.*'s acquisition by *AstraZeneca PLC* for $1.3bn up front – a 121% premium to the hypertension drug developer's last closing stock price.

Seghezzi said CinCor is a "great story" that validates Sofinnova's two strategies for company creation. The first is building companies around technology emerging from academia and the second – the strategy used for CinCor – is building companies around assets spun out of big pharma. In this case, CinCor's lead drug candidate for hypertension, the aldosterone synthase inhibitor baxdrostat (CIN-107), originated from Roche.

"It just happens that Sofinnova is pretty good when it comes to cardiovascular investments," Seghezzi said. "We have a very strong track record both on the drug side and on the devices side."

One recent exit in particular was fortuitous for the VC firm and for CinCor – the 2020 sale of *Corvidia Therapeutics* to *Novo Nordisk A/S* for $725m up front freed up the ideal CEO for CinCor.

AstraZeneca Nabs CinCor's Hypertension Asset In $1.3bn Acquisition

By Ayisha Sharma

09 Jan 2023

The UK major is acquiring CinCor in a deal that could be worth up to $1.8bn, in return getting hold of its Phase II hypertension candidate, baxdrostat, which offers combination potential with Farxiga.

Read the full article here

"In order to transform a nascent company like a spin-off into a major opportunity, you need to make sure that you have the right leadership," Seghezzi explained. And Corvidia CEO Mark de

© Citeline 2024. All rights reserved.

Garidel, who previously was the chairman and CEO of *Ipsen SA*, was the right leader for CinCor, he said.

“For us, it's a great story because not only do we revalidate the fact that spinoffs are a core part of our strategy, but we also revalidate another key aspect of our strategy, which is we don't invest only in science, we actually invest in people,” Seghezzi said.

Arm's-Length Approach Paying Off For Bayer

As well as turning the spotlight on its new launched drugs Nubeqa and Kerendia, plus the late-stage candidates asundexian and elinzanetant, *Bayer AG* devoted a fair chunk of its J.P. Morgan presentation to advances being made at some of its acquired platform companies, notably *BlueRock Therapeutics LP*, *Asklepios BioPharmaceutical, Inc.* (AskBio) and *Vividion Therapeutics, Inc.*. (Also see "*Bullish Bayer Highlights Four Future Blockbusters*" - Scrip, 11 Jan, 2023.)

In recent years, the company has invested more than $7bn in biotech acquisitions and managed 60 strategic and ongoing alliances. Marianne de Backer, Bayer's head of strategy, business development, licensing and open innovation, who presented at J.P. Morgan, noted that these partnerships "reflect our focus on collaborating rather than integrating and thereby preserving the partner’s entrepreneurial culture and talent base," adding that by "maintaining independence through an arm’s length operational model, we experience accelerated drug development programs results.” (Also see "*Bayer Spend On Start-Ups Growing By Leaps And Bounds*" - Scrip, 4 Apr, 2022.)

BlueRock’s lead asset, BRT-DA01, is being developed for the treatment of Parkinson’s disease. It is comprised of pluripotent stem cell-derived dopaminergic neurons that are implanted in the brain, targeting the root cause of the disease, and enrollment of a Phase I study has been completed, with data expected in the second half of 2023.

As for Vividion, the chemoproteomics specialist acquired in August 2021 for $1.5bn upfront, its first two programs "addressing high profile cancer targets" are expected to reach the investigational new drug application stage in 2023. AskBio has five assets in Phase I for Parkinson’s, multiple system atrophy, Huntington‘s, Pompe disease and congestive heart failure, which is one of the broadest pipelines in AAV-based gene therapies, the company claimed. (Also see "*Bayer's High Hopes For Huntington's Gene Therapy As Novartis’s Branaplam Stumbles*" - Scrip, 24 Aug, 2022.) (Also see "*The Inside Story On How Bayer Swooped On NASDAQ-Bound Vividion*" - Scrip, 5 Aug, 2021.)

AskBio kicked off J.P. Morgan week by inking a collaboration with *ReCode Therapeutics* to develop a platform for full gene insertion by single vector delivery of gene editing and DNA cargoes. In June last year, ReCode closed a $200m series B extension financing co-led by Leaps by Bayer, the Leverkusen-headquartered firm's venture arm.

© Citeline 2024. All rights reserved.

SCRIP
CITELINE COMMERCIAL

Zynteglo Launch Progress Should Benefit Lovo-Cel Plans, Bluebird Says

The launch of Zynteglo, *bluebird bio*'s gene therapy for beta thalassemia, is off to a strong start, CEO Andrew Obenshain said 12 January at J.P. Morgan, and that success should read through to the expected approval and rollout of lovotibeglogene autotemcel (lovo-cel) for sickle cell disease.

The biotech, which restructured in April 2022 due to financial difficulties and development setbacks, has two of the five approved gene therapy products in the US – Zynteglo (betibeglogene autotemcel) and Skysona (elivaldogene autotemcel) for the ultra-rare disorder cerebral adrenoleukodystrophy – and anticipates its first commercial patients for both this quarter, Obenshain said. (Also see "*Bluebird Bio Restructures Amid Financial Woes, But Will It Fly?*" - Scrip, 5 Apr, 2022.)

Bluebird Confident In Financial Runway For Skysona Launch

By Alaric DeArment

19 Sep 2022 The $3m gene therapy for the rare disease cerebral adrenoleukodystrophy marks bluebird's second approval in just under a month.
Read the full article here

The Zynteglo launch will be built upon three pillars – patient interest, a network of qualified treatment centers and early progress on access and reimbursement, he said, and bluebird will be able to rely upon the same physicians and treatment centers for the lovo-cel launch if that product clears the FDA. To propel use of Zynteglo, the company is offering outcomes-based reimbursement that would return 80% of the product's $2.8m upfront cost if the patient does not achieve transfusion independence within two years of beginning treatment.

Obenshain said he anticipates that about 50% patients on Zynteglo will access the drug under the outcomes-based treatment plan. The company is optimistic that it won't need to pay out many rebates since 90% of patients in Zynteglo trials achieved transfusion independence and 100% of those patients maintained that status, he added.

"We believe about 50% of our patients will be treated under an outcomes-based agreement," Obenshain told the meeting. "The outcomes-based agreement was really a tool or a mechanism to help us achieve both rapid access, but also access consistent with our label in clinical trials. So, we feel that was a great accomplishment for us to achieve access so quickly, and very consistent with our clinical trials and label."

Right now, about 70%-75% of beta-thal patients have commercial insurance, the exec noted, and with agreements in place with three of the largest pharmacy benefit managers, bluebird estimates that roughly 190 million US patients potentially have coverage for Zynteglo. There have been no ultimate denials of coverage so far, he added.

© Citeline 2024. All rights reserved.

© Citeline 2024. All rights reserved.