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BIO Notebook: Amgen CEO Blasts IRA, Novo Nordisk Stays Cautious On BD, And More

by Scrip Team

Insights from Day Three of the BIO International Convention in San Diego include Amgen CEO Bob Bradway taking aim at the "Innovation Reduction Act," Novo Nordisk's business development head talking about spending its semaglutide bounty, Roivant's long view on BD prospects for Immunovant's FcRn inhibitor, and more regulatory concerns around artificial intelligence.

Amgen's Bradway Decries 'Innovation Reduction Act'

Amgen, Inc. CEO Bob Bradway has reiterated his concerns about the Inflation Reduction Act and the damaging effect it will have on biotech innovation.

Speaking at the BIO International Convention 5 June, he noted that in an industry where on average, drugmakers spend $2.5bn and 10-15 years to get the approval stage, "the risks and the stakes are high [and] we have a narrow window to earn a return from that innovation ... there's a degree of complexity there that's not shared by other industries."

The IRA timeframe for small molecules (nine years versus 13 for biologics) makes it unrealistic to make that return on investment and in oncology in particular, nine years may not be enough time to get from a metastatic to a curative setting, Bradway said. Labeling it the "Innovation Reduction Act," he said: "I would venture to guess that none of the legislators who advocated for that legislation recognize what the long term effects will be on research in this country, which is a shame because we're at an extraordinary moment in time where technology and biology are coming together to enable us to move confidently and more quickly with innovation."

As a result of the IRA, Bradway added that Amgen had to make tough decisions on the

reallocation of capital "and like everybody else we had to adjust our thinking accordingly." Some promising small molecules for cancer that may not see the light of day, he claimed, and while "we have to adapt to the circumstances that we operate in ... we shouldn't pretend it won't have consequences on innovation or have an immediate effect on behaviors."

Bradway said the IRA had done very little to address the affordability and access issues in the US and the problems of a health care system that spends heavily to fix what is broken but when it comes to prevention, "so it doesn't have to break in the first place, we struggle with that." The technologies exist to predict who is at risk of a major adverse cardiac event or postmenopausal osteoporotic fractures but "there is no economic system" to support preventative therapies, he said, concluding that "there are lots of ways for us to do better when it comes to health care in the US."

- *Kevin Grogan*

Lack Of Opportunities, Not Cash, Is Only Limit To Novo's BD Plans

Novo Nordisk A/S may be awash with cash following the spectacular commercial success of its semaglutide-based blockbusters (the obesity drug Wegovy and the type 2 diabetes therapy Ozempic), which together delivered $5.4bn in sales for the first quarter of this year alone, but observers should not expect any mega M&A deals from the Danish group.

Speaking to *Scrip*'s Mandy Jackson at a fireside chat at BIO, John McDonald, Novo's global head of business development and M&A, acknowledged that the firm is in an enviable position on the financial front, noting that "there is absolutely no budget restriction whatsoever for BD." The "sole limit" is the fact that there are "not enough good opportunities out there to just spend."

Novo has stepped up its BD activities of late, not least in upping its production capacity through the recent acquisition of three manufacturing facilities from *Catalent, Inc* for $11bn as demand for semaglutide continues to outstrip supply. The company also opened its bulging wallet in March to acquire Germany's *Cardior Pharmaceuticals GmbH*, boosting its cardiovascular pipeline through a deal worth up to €1.03bn. (Also see "*Novo Pumps Up Heart Failure Prospects With Cardior Purchase*" - Scrip, 25 Mar, 2024.)

However, McDonald said that he preferred

Novo Splashes Out Again To Solve Semaglutide Supply Problem

By Kevin Grogan

05 Feb 2024

Novo Nordisk is buying three manufacturing facilities for $11bn from Catalent, which has just been acquired by the former's main shareholder Novo Holdings, in its latest bid to meet surging demand for its semaglutide-based diabetes and obesity drugs.

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"partnering versus buying" because in the former situation, "the company makes its money by working with you and the talent stay to work on the asset." If the biotech is bought, there is a risk of a brain drain because "these people are just naturally small company people and think 'I'm gonna get out of here and go to the next opportunity.'"

Read the full article here

In terms of the size of any future acquisition, he reminded the audience at BIO that the firm is owned by the century-old Novo Nordisk Foundation, which is bigger than the Wellcome and the Bill & Melinda Gates Foundations with €108bn in total assets. "We have this great moral obligation to other shareholders ... so going out and buying a company for $50bn-$100bn could put at risk over 100 years" of the foundation's philanthropic and innovative research projects, McDonald added. (Also see "*Novo Nordisk Foundation Strengthens Ties With Gates*" - Scrip, 6 May, 2024.)

He argued that buying assets that are in Phase III or are on the market do not provide a great return to shareholders compared with acquiring products earlier, adding that any purchases would probably be "in the single digits of billions." Novo can comfortably go into the double digits, McDonald said, "but how high, I don't know, we haven't had the opportunity to take a look at those but I'd be surprised."

- *Kevin Grogan*

Roivant In No Hurry To Sell Immunovant's FcRn Candidate

Roivant Sciences Ltd. CEO Matt Gline said during a fireside chat at BIO that it is in no hurry to make a big-money deal for its subsidiary company *Immunovant Inc.*'s neonatal fragment crystallizable receptor (FcRn) inhibitor IMVT-1402, similar to the fast turnaround disposition of its TL1A inhibitor RVT-3101 in a $7.1bn deal with *Roche Holding AG* last year.

Immunovant announced a comprehensive clinical trial plan at the end of May across multiple IgG-driven diseases for the closely watched IMVT-1402, which the company believes to be a best-in-class FcRn inhibitor, a drug mechanism that quickly turned *argenx N.V.*'s Vyvgart (efgartigimod) for myasthenia gravis into a blockbuster product. (Also see "*Immunovant Swaps Out Lead Assets*" - Scrip, 30 May, 2024.)

FcRn inhibition is "a popular area and we know that much of big pharma is tracking it as a target," Gline said. He added that Roivant and Immunovant have many incoming questions from outside parties interested in the companies' plans for IMVT-1402, including whether they plan to keep the asset or seek a partner or buyer for it.

"We've demonstrated through the TL1A situation that we're open to those conversations, but

we're really excited about the biology in FcRn," Gline said.

And because of the cash the transaction with Roche generated, Roivant has the capital to fund Immunovant's clinical trial plan for IMVT-1402. That means, in terms of a future deal for the asset, "we have sufficient capital so that we will make that decision from a position of strength," Gline said.

Roivant received $5.32bn from the RVT-3101 transaction with Roche in October 2023. The other $1.78bn went to *Pfizer Inc.*, from which the company previously acquired rights to the TL1A inhibitor. (Also see "*Roivant/Roche: Did Pfizer Miss Out?*" - Scrip, 23 Oct, 2023.) Roivant had $6.6bn in cash on its balance sheet as of 31 March, largely as a result of that deal.

– *Mandy Jackson*

AI Experts Discuss Regulatory Considerations For The Field

Chris Hart, partner at Foley Hoag LLP, indicated during a BIO session that regulatory approaches for artificial intelligence vary widely globally. US AI regulation tends to be very fragmented, sectoral and evolving compared to the European Union, which has comprehensive privacy legislation that applies across sectors and companies of all sizes.

Mida Pezeshkian, founder of the boutique advisory firm STEMA.cg, said AI regulation in health care, including using AI tools in electronic medical records, falls under the jurisdiction of the US Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC), which also continues to evolve and is highly fragmented.

"The structure of the data, the format of the data, the quality of the data, these are all challenges," Pezeshkian said. "We need to have better data, we need to structure and format it better, but we also need our information systems to talk to each other."

Alex Zhavronokov, CEO of *Insilico Medicine*, which uses generative AI to accelerate drug discovery, praised the US Food and Drug Administration for being extremely efficient.

"Once you are going [into] clinical [trials], there are all the barriers that you need in place to protect the consumer, to protect the patient and enable fast drug discovery," Zhavronokov said.

The EU has established a common regulatory and legal framework called the EU Artificial Intelligence Act, as well as the Cyber Resilience Act. (Also see "*EU AI Act Regulatory Overlap "Likely To Persist": Expert Presents Solutions For Dual Conformity*" - Medtech Insight, 10 Jan, 2024.) The UK government also adopted an AI regulatory framework. (Also see "*MedTech Europe Calls For Swift Answers In Areas Where AI Act Threatens MedTech*" - Medtech Insight, 15 Mar, 2024.)

One of the biggest challenges when it comes to using generative AI is hallucinations, which is when the chatbot gives false or misleading information. However, one audience member said that based on his conversations with AI leaders, the hallucinations problem is inherent with large language models and unlikely to be solved.

Zhavronokov argued that continued benchmarking and other measures can address the issue.

"I think we are all in … agreement that hallucinations are not going to go away," Brandon Rice, chief product officer for Weave Bio, said during the session. "Humans are also not perfect."

Rice said the answer will be a composite of people, algorithms and organizations working together.

– *Marion Webb*