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BIO 2022 Notebook: Staying Afloat In Rough Waters

by Scrip Team

News and views from day two of the BIO annual meeting include reflections on the ups and downs of the financing environment, Cerevance CEO Craig Thomson on the challenges of raising VC funds right now, and Bayer business development exec Marianne de Backer explains that it's not a good strategy to buy things just because they are on sale.

As 2022 proves to be a year of missed predictions and uncertainty, we are using this year's BIO notebook to provide additional context by reviewing different industry metrics to provide more perspective to the comments coming from the meeting.

The State Of The Financing Environment

Biotechnology stock valuations are down 30%-50% over the past year, depending on which index you track, impacting the ability of private drug developers to go public and for public companies to raise cash in follow-on offerings, so companies are looking for alternative strategies for managing their operations and keeping R&D programs on track, whether through financing, deals or cost-cutting. Ways to navigate these rough waters is a key focus at BIO.

The Next Big Patent Cliff Is Coming, And Time Is Running Out To Pad The Fall

By Jessica Merrill

04 Apr 2022

There were only nine initial public offerings by biopharmaceutical companies in the US during the first quarter of 2022 versus 32 in the first quarter of 2021, with IPO proceeds totaling just $807m in Q1 of this year versus $5.2bn in Q1 of last year, according to *Scrip*'s tally. (Also see "*Finance Watch: Q1 Biopharma IPOs Shrink To A Fraction Of 2021 Total*" - Scrip, 8 Apr, 2022.) As a result, venture capital fundraising totaled just $9.5bn in

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the first three months of 2022 compared to $10.8bn in the same period of 2021, but it was 53% of the Q1 total this year versus 32% in Q1 of last year, according to Biomedtracker. (Also see "*Finance Watch: Venture Capital Dominates Biopharma Funding So Far In 2022*" - Scrip, 3 Jun, 2022.)

Blockbusters like Stelara, Eliquis, Prolia and Ibrance are poised to lose US exclusivity over the next five years; pressure is mounting for industry to replenish the portfolio with the next high-growth brands.

Read the full article here

With funding down across the board, cost-cutting will be required, as many companies have found this year. (Also see "*Finance Watch: More Job Cuts As Companies Prioritize Cash Conservation*" - Scrip, 18 May, 2022.) However, big pharma and specialty pharmaceutical firms are hungry for deals to fill their pipelines as key products face generic competition over the next decade, so collaborations, licensing agreements and acquisitions could be a life preserver for companies struggling to stay afloat.

Cerevance Confident Of Edge In Tough Fundraising Market

Cerevance Inc. is preparing to initiate a pivotal trial for its first-in-class Parkinson's disease drug in the first quarter of 2023, but first the company needs to raise a series C venture capital round.

CEO Craig Thompson told *Scrip* in an interview at the BIO meeting that it is a challenging time to be out raising VC funding since the upheaval in the public markets is being felt by private biopharma firms as well, but the company feels confident about its chances to raise cash because of the positive Phase II results it reported for lead drug candidate CVN424, a GPR6 inverse agonist, in March.

Cerevance's First-In-Class Parkinson's Candidate Shows Phase II Promise

By Andrew McConaghie

31 Mar 2022

Promising results from a small Phase II study will now propel the company's CVN424 into pivotal trials, though its optimum dose is still unclear.

Read the full article here

"Currently, we're looking to raise a series C," Thompson said. "We also have the opportunity with our early platform in our discussions with pharmaceutical companies on doing some target discovery for them, which could bring in some non-dilutive funding as well."

Every company is finding the financial markets difficult because of the turmoil being experienced on a macro scale, he noted.

"I think what differentiates our platform versus a lot of other companies is that we're doing interesting biology and we have the tech angle with machine learning, and then we've been able to validate that platform with our lead compound," Thompson noted. "It's, I think, one of the few cases where you have a platform company that has a validated platform."

Those factors have contributed to a wide variety of investors showing interest in Cerevance's programs, which includes two clinical programs – CVN424 and CVN766, an orexin 1 inhibitor in Phase I that is expected to move into a Phase IIa proof-of-concept trial for the treatment of negative symptoms of schizophrenia in late 2022 or early 2023 – and several preclinical and discovery stage assets.

"Investors overall been receptive to the story just given we have the breadth of the pipeline, and we can appeal to investors who want to be a late-stage player," Thompson said. "Those that are interested in early-stage, we kind of check that box as well. And machine learning or kind of more tech-savvy investors, we also cover that bucket as well.

Biotech Rollercoaster Will Rise Again

While many investors and companies are not enjoying the rollercoaster ride that biotech is on and are worried that it may crash into the ground rather than climb again, there are plenty of reasons for optimism about the sector.

So said McKinsey partner Lydia The at a 14 June panel discussion entitled "Funding Transformational Platforms: Sustaining Development of Next Generation Medicines in a Challenging Market." She said that the rollercoaster is indeed "very scary in this uncertain period" but insisted that the consulting giant was "unabashedly optimistic" for start-ups that can offer cutting-edge platform technologies.

The noted that despite recent dips in the valuations of newly public companies and a slight decline in venture capital funding over the past four quarters, VCs continue to plough money into biotech. McKinsey research has shown that they invested in 2,200 biotech start-ups worldwide in 2016 and by 2021, that number had grown to 3,100.

From 2019 to 2021, VCs invested more than $52bn in therapeutic-based biotechs globally and two-thirds of that went to start-ups with platform technologies, she noted. The platforms creating most excitement are those that offer tailored treatments that can be delivered accurately to the target site such as cell and gene therapy, as well as drug discovery enabled by machine learning and approaches to tackle "undruggable" targets, The said.

She added that despite all the concerns the public markets have about the sector, the fundamentals remain the same, given the "regulatory clarity and commercial viability for innovative therapies." The also pointed out that many VCs have funds they need to deploy "although the bar maybe higher" and noted that "large pharma dry powder" stands at around

$320bn which is good news for the most innovative firms looking for partnerships, representing a sum that's "enough to buy all of the small-cap biotechs."

Bayer's Wishlist Not Determined By Biotech Bargains

Speaking to *Scrip* at BIO on 14 June, Marianne de Backer, *Bayer AG*'s head of strategy, business development, licensing and open innovation, said that while the price of biotech assets have come down, "just because things are on sale, you don't want to just buy them."

De Backer joined Bayer in September 2019 from *Johnson & Johnson* and was tasked with replenishing the pipeline through external innovation. Since her arrival, numerous deals have been inked, notably the acquisitions of *KaNDy Therapeutics Ltd.* and its promising non-hormonal menopause drug, the gene therapy specialist AskBio and *Vividion Therapeutics, Inc.*, which has a pipeline of precision therapeutics targeting traditionally undruggable targets in oncology and immunology. (Also see "*The Inside Story On How Bayer Swooped On NASDAQ-Bound Vividion*" - Scrip, 5 Aug, 2021.)

She added that the prices paid for Vividion and the other buys were secondary considerations when it came to making those acquisitions which are examples of Bayer's innovative "arm's length" approach, which allows acquired companies to largely maintain their independence and keep their entrepreneurial culture. De Backer declared: "We have a strategy, we really know what we want in each of those areas and we know that it has to come through external innovation, largely."

She acknowledged that "valuations have dropped quite significantly, which will allow us to potentially do more than we had originally anticipated with the same firepower, but it is not that we're going to buy all sorts of things because they're cheaper. We continue to be very disciplined."

Harsh Reality: 'There Will Be Consolidation'

Panelists during a 14 June session titled "How to Survive a Stormy Biotech Season: Thriving in a Challenging Market" addressed strategies that they have employed or that they recommend for peers who are struggling. They also acknowledged that a reckoning is coming, as has happened in prior economic downturns.

Silverback Therapeutics, Inc. CEO Laura Shawver noted that she has been in the biopharma business since 1989 and "I've seen this movie before," in 2008. "We will come out on the other side," Shawver said. "Not all companies will survive."

Silverback had a big setback in the clinic in April with its lead drug candidate and decided to discontinue development of the drug and its second most-advanced drug, focusing on a preclinical hepatitis B candidate and other early-stage programs going forward. The company also instituted layoffs to extend its cash balance of more than $300m.

But even companies without a setback are considering their options to ensure that in this difficult financial market their existing cash will last long enough to get lead programs to key inflection points that will support attractive financings or deals later on.

Julie Eastland, president and CEO of *Harpoon Therapeutics*, said she is thinking about how to shape Harpoon's story to be attractive to investors while also considering whether there are programs that should be put on hold or cut altogether to make sure lead programs that have already shown promising results can get to the next steps in their development. Execution of the story that companies tell investors will help keep them interested when it is time to raise money again, but if times remain tough, cuts may have to be made, she advised.

The key is managing that balance before it is too late, but not every company will heed that advice.

"I think there will be some consolidation," *Apellis Pharmaceuticals, Inc.* co-founder and CEO Cedric Francois said. "I'm optimistic. I think we will look back and say it was painful, but it was a good reality check."