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15 Feb 2021 |

Scrip Asks…What Does 2021 Hold For Biopharma? Part 5: Business Environment And Strategy

Bullish Sector Outlook As Technological Progress Drives Growth

by Eleanor Malone

A strong year is predicted for biopharma business with investment and deal making set to continue apace. Executives across industry share their forecasts for the year ahead.

Industry leaders and experts envisage positive change in the biopharma sector over the coming year, fueled by advances in science and data processing. The application of artificial intelligence will improve and make more efficient activities across the business continuum, from drug discovery to manufacturing, while genomics will offer even more fruitful avenues for the development of much-need therapeutics.

Last year was strong for both financing and deal making, reflecting the global investment in life sciences in the face of the COVID-19 pandemic as well as the continuation of the positive trend for those developing cutting edge technologies in fields such as immuno-

SCRIP ASKS…What Does 2021 Hold For Biopharma?

A broad survey of the industry's expectations for the year to come.

Every December, *Scrip* asks industry leaders and experts to share their expectations for the year to come. With responses from more than 200 professionals, Scrip Asks…What Does 2021 Hold For Biopharma? provides an unprecedented insight into the biopharma universe's collective crystal ball.

The full list of installments:

oncology and gene therapy. The consensus opinion is that the funds will continue to flow in 2021, and the appetite for deal making will not abate.

Some observers wondered how Democrat President Joe Biden's administration would address the thorny question of drug pricing in the US, although there was a feeling that this would not be tackled while the country remained in the grip of the pandemic crisis.

- *Tackling COVID-19*
- *COVID-19 Shock Waves And Silver Linings*
- *Patient Access To Health Care*
- *Technology And Disease*
- Business Environment And Strategy

In our fifth and final installment of *Scrip Asks…What Does 2021 Hold For Biopharma*, executives from companies large and small share their expectations around the business environment for the coming year.

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Investment

"I expect capital to continue to flow into biotech and biopharma," Jim Woody, CEO of inflammation-focused drug developer 180 Life Sciences, told *Scrip*, although he caveated his prediction: "But then I am always a pathologic optimist." 180 Life Sciences completed a public market listing in November 2020 using the increasingly popular SPAC (special purpose acquisition company) route, via which it was acquired by a listed "blank check" company set up by investors looking to invest in target companies and realize a gain.

Pathologic optimist or not, Woody was in good company among those who offered a view on investment in the sector in 2021.

"We expect investors to remain focused on the impressive performance of biotech capital markets, where funding reached record levels in 2020 and is likely to remain strong in 2021," wrote SVBLeerink biopharma research analysts Geoffrey Porges and Charles Song in their December report on the outlook for the sector in 2021. "We believe depressed biopharma multiples could recover in 2H 2021 as investor concerns about major disruption to the economics of the biopharma industry, largely propagated by a minority of Democratic policymakers, are diminished."

Lisa Anson, CEO of the UK's *Redx Pharma Plc*, also foresaw an ongoing appetite among investors for companies in biopharma after their major contribution to guiding the world out of the COVID-19 pandemic. "2020 saw a much increased focus on the sector. In 2021, we will see biopharma leveraging that increased public profile and capital investment appetite," she said.

This was a view shared by James Graham, managing director and CEO of Australian anti-infectives developer *Recce Pharmaceuticals Ltd.* "From an investor standpoint, the potential of biotech and pharma companies responding to global health crisis like antibiotic-resistant infections or COVID-19 is being recognized and will continue to spark interest within the investor community – a trend I believe we'll continue to see next year and excited to be a part of it," he said.

Philip Astley-Sparke, CEO and co-founder of oncolytic immunotherapy developer *Replimune Group Inc.*, thought the ongoing boom in investment would be no flash in the pan, because of the potential for further meaningful advances. "Despite the elevated valuations of late, the fundamentals for the future for biopharma are bright," he said.

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"The sector has reached critical mass while at the same time we are only in the early innings of properly understanding the immune system and the nervous system. The onion will continue to be pulled back in 2021 in the areas where the potential for new and breakthrough interventions are vast."

Robert Fallon, president, CEO and co-founder of *Phosplatin Therapeutics*, thought the positive investment environment would also be driven by external economic factors. "Investor and stock market bullishness in biotech and life sciences companies will likely continue as stock market liquidity burgeons due to the low interest rate erosion of core attributes of fixed-income investments," he noted.

Meanwhile, Ken Krisko, a US-based partner in the life sciences corporate partnering and licensing group at law firm Cooley LLP, pointed to how sustained US investor appetite along with the trend for companies to access public markets via SPAC transactions as an alternative to the more arduous IPO route would continue to benefit companies across the Atlantic. "The seemingly insatiable appetite of US investors (hopefully) continues to support growth in the sector, particularly in Europe. The flow of the public market cash firehouse hasn't ebbed. Companies with platform potential and high differentiation continue to attract investors. SPACs are the life science industry's "bellbottoms" attracting new money and companies – a unique opportunity for UK and European companies that opt not to pursue the crossover route to US public market financing," he said.

Off the back of the ongoing investments, Pam Contag, CEO and co-founder of *BioEclipse Therapeutics, Inc.*, expected that: "We will move forward to apply both private and public funding to create a broader fundamental science framework that will support many new discoveries."

Simba Gill, president and CEO of *Evelo Biosciences, Inc.*, had a similar view. "2021 will be a year of focus on fundamental platform biotech companies. 2020 has shown the importance of biotech to solving critical unmet and growing healthcare needs in global societies. The general retail sector will start to see biotech platform companies in a similar way to tech in terms of growth and valuation," he forecast, adding: "Two key areas will become for the first time mainstream topics and areas of attention: the central role of the gut and microbes [and] from this the ability to transform medicine; and the importance of developing affordable medicines in an interconnected global society." Evelo is focused on discovering and developing drugs that act on cells in the small intestine to have a systemic effect in inflammatory disease and oncology.

Sounding a rare note of caution among the leaders we surveyed was *Aridis Pharmaceuticals, Inc* founder and CEO Vu Truong, who said: "One of the biggest changes I'd expect to see in 2021 is increased selectivity in life sciences investments. In 2020, we saw an unusual uptick in investments that were not driven by fundamentals, higher-than-normal M&As or key innovations in a particular space… While the pandemic did stimulate a little more focus on infectious diseases and vaccines, it would appear that this focus was driven mainly by viral infections and zoonotic pathogens that could cause the next pandemic, rather than on antimicrobials and antimicrobial resistance (AMR)."

Aridis is working on developing monoclonal antibodies and other novel drugs for infectious diseases to overcome the threat of AMR and viral pandemic. "The best hope for a renewed interest in investments in antimicrobials will have to be driven by innovations and clinical data from innovative, novel mechanism anti-infectives. Some of the pull mechanisms that governmental agencies are injecting to the antibiotics will likely keep certain companies relevant, but they are unlikely sufficient to create another renaissance in the infectious disease space," said Truong. But while he doubted the likelihood of sustained investment at a scale sufficient to address the need for new antibiotics and antifungals, he did see some spin-off benefits from the interest generated by the pandemic: "The successes of the *Pfizer Inc.* and *Moderna, Inc.* RNA vaccines are expected to create more enthusiasm in the use of RNA for vaccines and other therapies."

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Deal Making

The broad view is that 2021 will be an active year for deal making.

Gil Van Bokkelen, CEO of *Athersys, Inc.*, predicted both "consolidation as larger companies make strategic acquisitions" and "high value partnerships in select areas."

"In 2021 I see the continuation of the marked increase in M&A activity that we saw in the fourth quarter of 2020," said Annalisa Jenkins, board member of Milken Institute's FasterCures center and chair of the Court of London School of Hygiene and Tropical Medicine. "Pharma is back out on the hunt for innovation to fill their pipelines and they have the cash along with very low cost of capital for a shopping spree."

In particular, Jenkins expected "continued significant interest in cell and gene therapies seeking cures" which would lead to "a move by pharma to acquire these platforms and bring them in

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house in order to accelerate and scale."

San Diego-based cancer therapy developer *VelosBio Inc.*'s chief financial officer Enoch Kariuki agreed about pharma's appetite for deals. "Pharma companies will continue to be aggressive with BD [business development] and M&A as they seek to shore up their franchises, some of which will soon be facing meaningful patent expirations," he said.

Joe Wiley, CEO of rare disease-focused *Amryt Pharma*, pointed out that: "One of the key learnings from 2020 is that there is no need to have boots on the ground to strike a deal, and I expect that to continue into 2021. There are always opportunities for licensing and M&A and we have not seen COVID-19 diminish this. Naturally, we would still prefer to see each other in person. However, the last year has proved we can adapt."

For Ken Krisko at law firm Cooley LLP, COVID-19 will be actually be a catalyst for deal making in 2021. "Pandemic mitigation and control efforts remain a dominant focus and drive deal making as the more traditional industry engine of drug discovery, development and commercialization accelerates," he said.

"Market indicators also point to a brisk pace for acquisition and collaboration deal making," Krisko continued. "The drive toward public market financing and acquisition means that many companies with cash will look less to asset dilutive transactions and more toward a later value inflection. Companies will continue to search for value earlier with discovery collaboration deals back in vogue. Novel technologies accelerate these trends and sustain value for acquisition opportunities. Larger companies continue to hunt for partners to solve nagging problems and present new modalities, such as gene therapy vectors, protein folding, precision oncology and mRNA." He concluded: "A fluid year is an understatement, perhaps."

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Ken Krisko, Cooley LLP

"M&As should continue to keep pace in 2021 that is driven mainly by pending key late-stage data in cell therapies, cancer vaccines and RNA-focused therapies," noted Aridis Pharmaceuticals' CEO, Vu Truong.

SVBLeerink analysts Geoffrey Porges and Charles Song also expected big pharma to continue with significant investments, even if they did not give such moves a ringing endorsement. In their 2021 outlook report from mid-December they wrote: " We believe that investors should also

be attentive to large biopharma capital allocation strategies in 2021 – historically poor success rates and marginal returns have contributed to the underperformance of large cap stocks compared to their emerging company peers, but these chunky M&A and licensing investments are likely to continue, in our view. Biopharma management teams tend to be incentivized to pursue growth regardless of cost, and because internally developed mega-blockbusters are rarely replicable, management teams look to M&A to fortify pipelines, typically at excessive premiums."

Meanwhile, Robert Armstrong, CEO and co-founder of *Boston Pharmaceuticals Inc.*, expected to see new trends in the ongoing activity. "In 2021, we expect to see new transaction structures and business models that shift the interplay between biotech and pharma," he told *Scrip*. "While we will continue to see pharma interest in later stage programs or companies, we are already seeing the shift to earlier stage or preclinical companies as they seek value inflection points, such as *Bayer AG*'s multiple deals with emerging gene and cell therapy companies, *AbbVie Inc.*'s partnership with *Frontier Medicines Corp.*, and *Eli Lilly and Company*'s recent foray into gene therapy via *Prevail Therapeutics Inc.* We expect to see new transaction types, such as program specific investments and de-SPACing transactions."

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Growth

The sector has enjoyed much investment in recent years, and the available capital plus rapid technological advances offer long-term growth prospects for the biopharma industry.

"Despite business disruptions due to COVID in 2020, biotech had a strong year as evidenced by a record number of IPOs. Coming off of a strong 2020 for the sector, and with the expected availability of COVID vaccines, I expect to see continued momentum for the sector in 2021," said Enoch Kariuki, chief financial officer of VelosBio. "The amount of capital in biotech has increased significantly, and there has been a strong trend in financings (both private and public) in the sector."

"Outside of the pandemic, immune-oncology will continue as the major driver of growth in this sector," specified Jennifer Buell, president and chief operating officer of *Agenus Inc.*, a company in the IO space. "The record number of biotech IPOs emphasize this trend. Agile innovators will drive progress and build on the trend for more partnerships over M&A to drive innovation and speed."

Dave Lennon, president, of *Novartis Gene Therapies*, foresaw expansion in gene therapy. “2020 was the year we saw the opportunity with gene therapy really go global with our approvals in EU, Japan, Brazil, Israel and Canada, “ he said. “In 2021, I expect [we will] collectively improve our understanding of how gene therapy can be applied to more diseases. In addition, we will start to see the investments in manufacturing buildouts come to fruition with next generation engineering advances improving the industry’s capacity to reach patients and deliver on the promise of gene therapy.”

“Commercially, pharma performed with remarkable resilience during 2020 without large revisions to financial guidances, despite reduced patient mobility and healthcare capacity through much of the year,” said Dan Chancellor, director of thought leadership at *Informa Pharma Intelligence*’s *Datamonitor Healthcare*.

"This augurs well for 2021 once pre-pandemic patient engagement levels are reached, added to a vaccines/therapeutics boost worth several tens of billions of dollars. Any potential pain as a result of the pandemic will be tied to the wider global economic recovery and ability of governments/payers to maintain healthcare budgets, and so will be realized slowly over many years," Chancellor predicted.

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"We expect the biopharma sector to gradually return to trend growth over 2021, with post-COVID budget constraints accelerating the uptake of cost-efficient solutions and new technology, including AI."

Ningfeng Fiona Li, VasoDynamics

"We expect the biopharma sector to gradually return to trend growth over 2021, with post-COVID budget constraints accelerating the uptake of cost-efficient solutions and new technology, including AI [artificial intelligence]," said Ningfeng Fiona Li, CEO of VasoDynamics.

There was a also a view that China would grow in R&D-based biopharma this year. "We are seeing Chinese biopharma coming of age with companies maturing into engines for global research, innovation, and eventually commercialization. This is being accelerated by greater access to capital and a resurgence of sector investment due to regulatory reforms in China and to a lesser extent the global impact of COVID-19," said Christian Hogg, CEO of *Hutchison China MediTech Limited*. "In 2021, I think we will see leading China-based biotechs kicking into gear and delivering a stream of new medicines, particularly in the oncology space, across the globe."

Robert Armstrong, CEO of Boston Pharmaceuticals, agreed. "We expect to see reverse China trade with China accelerating its first-in-class drug development," he said.

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Business Models And Operational Evolution

Life sciences are undergoing a maelstrom of change, with new insights from diverse fields like artificial intelligence and genomics offering multiple new avenues for product development – and business transformation. Predictions from several executives reflected these opportunities.

"Sophisticated medical approaches and AI technologies, such as the protein structure at DeepMind [the UK artificial intelligence company owned by Google], will continue to impact research in a meaningful way," predicted Lisa Anson, CEO of UK oncology drug developer Redx Pharma.

"The future of biopharma will be significantly impacted by greater and more sophisticated use of data and technology. Advanced analysis of historical clinical trial data allows for real-time optimization of industrial processes and personalized treatments. Combining data like these with those from the complex multi-omics that represent the total physiology of a human will lead to increasingly more precise tools, enabling greater discovery of new therapeutic targets and more possibilities of precision intervention," said Mimi Keshani, vice president of operations at deep tech startup Hadean. "These innovative solutions are also contributing towards the wider influence of preventative methods. With more vaccines and curative therapies available, drugs used in the treatment of these diseases will in turn be less in demand in the future and forward-looking firms will already be looking to adapt their business models."

Pratap Khedkar, principal at professional services firm ZS Associates, also suggested that business models would need to change with the next generation of therapeutics. "The business model of cures is different than treatments: cell and gene therapies are really multiplying in number and having impact that is qualitatively different," he said. "Cures don't just have a pricing challenge, but it's a new business model: you need supportive care and new provider partnerships and supply chains to administer these drugs, and there is a range of disease areas where these are starting to emerge – not just oncology."

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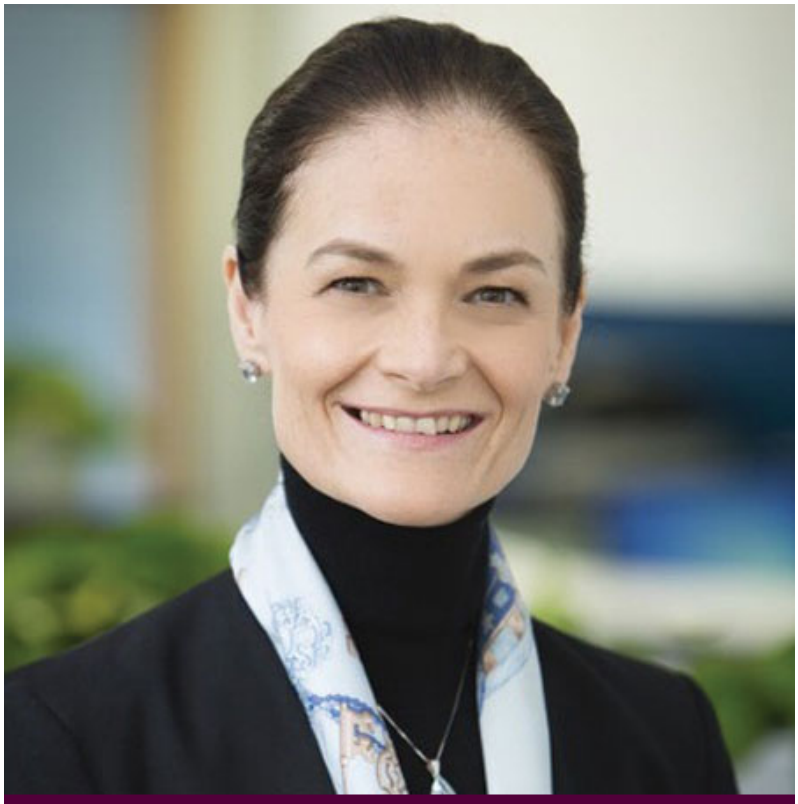
One recurring theme was the idea that change would create both opportunity and threat. "The big data AI/ML [machine learning] boom will continue to impact across the R&D and market access continuum, gathering momentum and disrupting the traditional approaches, creating leaders and laggards," said FasterCures' Annalisa Jenkins.

Robert Armstrong, CEO of Boston Pharmaceuticals, thought that change would be driven by challenges: "We would potentially see new business models evolve that look to overcome current industry challenges, including resource availability and drug pricing," he told *Scrip*.

Armstrong was not the only executive to flag up the risk of resource limitations. Winston Black, chairman and CEO of healthcare-focused finance company SWK Holdings, warned: "The COVID-19 pandemic and the race to develop and approve a vaccine have overshadowed two important issues that could have a major impact on 2021.

"First, with the record-breaking amount of capital formation in the biopharmaceutical industry this year, the stage is set for a research bottle neck next year as the demand for contract research organization services likely will, in turn, follow the capital raises.



"The big data AI/ML boom will continue to impact across the R&D and market access continuum, gathering momentum and disrupting the traditional approaches, creating leaders and laggards."

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Annalisa Jenkins, FasterCures

"Second is the disruption to the global biopharmaceutical supply chain caused by COVID-19,

which is continuing as we speak, particularly as shut-downs resume across the globe. The need to reduce reliance on overseas markets for key materials and manufacturing has surprisingly disappeared from the national discourse during the past six months, and could, in my opinion, be another wildcard in 2021."

Some companies are protecting themselves from this manufacturing capacity risk by building their own. Jennifer Buell, president and chief operating officer of immuno-oncology firm Agenus, which recently announced it was expanding its GMP production capacity to support its own programs and accelerate partnered programs, said: "Manufacturing and supply chain independence will be critical. Production space is at a premium and independence here will be coveted."

Mahesh Veerina, CEO of Cloudleaf, which provides digital tracking services for pharma supply chains, also considered global manufacturing upheaval. "In 2021, the near-shore regionalization of APIs [active pharmaceutical ingredients] will cause a long-term policy shift throughout the global supply chain, fueling changes in supply chain behavior such as the creation of a larger, connected ecosystem within the supply chain. This ecosystem will result in the building of new partnerships between not only drug manufacturers and API suppliers, but also logistics providers, vendors and other organizations throughout the supply chain. As supply chain entities work to quickly form these new partnerships, the element of 'blind trust' between long-time business partners will no longer be a factor and organizations will look to adopt new solutions that provide real-time visibility into a product's location – reassuring both parties that each other is on track."

Matthew Durdy, CEO of the UK's Cell and Gene Therapy Catapult, focused on the importance of strategic support from government to harness the opportunity for growth in the advanced therapy sector. "In the space of a few years, the area around Stevenage has developed into the largest cell and gene therapy cluster outside the US, with a whole ecosystem around it. It is important that we now look to continue to develop the UK cell and gene therapy industry further by harnessing the academic and industry resources across the country."

Durdy underlined the ongoing maturation of the sector in the UK as it moves towards commercialization: "Based upon the CGT Catapult's recent manufacturing report, the cell and gene therapy industry is clearly moving towards commercialization and maturing, with now 96% of the gene therapy space being commercially owned, a shift towards expansion of manufacturing facilities, rather than new MHRA licensed facilities coming on line, and 10 companies now delivering their own GMP pipelines."

With this in mind, he hoped for strategic support to help equip the burgeoning sector with the talent it needs in the UK: "There is a critical need for upskilling that will continue to be addressed into 2021. The CGT Catapult 2019 Skills Demand Survey identified that the cell and

gene therapy workforce is expected to double to more than 6,000 by 2024, with a widening skill gaps in training and experience for which educational programs across the industry are needed."

Marcio Souza, president and CEO of *Praxis Precision Medicines, Inc.*, which develops CNS therapies, offered a fitting summary of the pervasive spirit of optimism in the midst of change that we encountered among biopharma executives. "2021 is the year of rebirth for many industries as we turn a page after the pandemic. For biotech it will solidify and bring to new levels how collaboration can transform bringing innovation to patients. The way we look into timelines for drug development will never be the same and a renewed sense of urgency will fuel the industry."

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Networking

The physical distancing necessities provoked by COVID-19 had a massive impact on the industry's modus operandi in 2020 which looks set to persist well into 2021. Medical and partnering conferences went virtual, and so did a vast swathe of other interactions, ranging from facility inspections to deal negotiation and internal company meetings.

"We anticipate that innovation in the biopharma business model will continue to evolve in 2021. Companies had to react and adapt to our new normal in 2020, leading to a decrease of informal networking and in-person business development that would typically take place, especially around major medical conferences," noted Lindsay Rosenwald, chairman, president and CEO of *Fortress Biotech Inc.* As evidenced by the industry's continued activity through 2020, companies including Fortress successfully negotiated such restrictions. "We are fortunate that the Fortress business model is designed to be both opportunistic and diverse, which enables our business development team to be efficient when identifying promising drug candidates, no matter the circumstances."

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Nevertheless, people hanker after in-person interaction. "Face-face interactions are very critical for our industry, and we hope to return to normal by the end of 2021," said Shankar Musunuri, chairman and CEO of *Ocugen Inc.*, which develops gene therapies for blindness.

Mike Clayman, CEO of musculoskeletal therapy developer *Flexion Therapeutics, Inc.*, agreed. "Sometime in 2021, we expect to emerge from the COVID operating environment, and with that, we hope to see an increase in in-person interaction. For a company like Flexion, that connectivity is so important for nurturing our culture and for the spontaneous ideas which further fuel our innovation efforts. This is critical to advancing science and our industry as a whole."

Jim Woody, CEO of 180 Life Sciences, is looking forward to a time when people can "decrease our addiction to Zoom and meet with colleagues." He said: "Many of us realize that the Zoom format diminishes the creative interactions you get with face-to-face brainstorming with your colleagues."

While the general feeling is that a relaxation of lockdown and social distancing rules should happen before year-end, Jonathan Drachman, president and CEO of *Neoleukin Therapeutics, Inc.*, offered a more precise prediction about meetings: "The first in-person, large conventions will occur shortly after Labor Day [6 September]."

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Government, Pricing And Regulation

The change of administration in the US prompted several commentators to offer views on the thorny issue of drug pricing. "With a new Democratic government in place, we might see some headwinds especially focused on drug pricing," thought Enoch Kariuki, VelosBio's CFO.

Robert Fallon, president and CEO of Phosplatin Therapeutics, was of a similar opinion. "The new US administration will argue for lower prescription and generic drug pricing, which could be a component of a government option introduced as component of legislative improvements to the Affordable Care Act," he suggested.

Some expected drug pricing to remain on the backburner while the pandemic continued to dominate.

"The most important issue next year will be what happens with drug pricing – I think it will dominate the discussion. And it's going to be an interesting year. I think it's likely that the government will spend the first part of the year on COVID, but eventually they will come around to pricing. If you think about what Trump did by executive order, there's no reason why Biden couldn't do something similar, but the question is would he? Even if he doesn't, the Street is going to worry about it," said Les Funtleyder, health care portfolio manager at E Squared Capital Management.

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—

Les Funtleyder,
E Squared Capital Management

Neoleukin's Jonathan Drachman agreed: "Pressure to decrease drug costs will re-emerge as the COVID-19 pandemic is contained."

"Pricing is a rare bipartisan issue," declared ZS Associates principal Pratap Khedkar. "With the naming of the new US HHS secretary-designate [Xavier Becerra, Democratic attorney general of California] with his background of legislation, law, and support of more disruptive approaches, there is likely to be continued pressure on drug pricing, once COVID issues subside somewhat.

Will cross-aisle agreement happen on this issue? Will pharma be able to build on its amazing vaccine innovation performance and improved public reputation to associate that innovation with the need to keep funding it? Specific issues like MFN [most favored nation] pricing executive orders may get dealt with, but it is the broader picture here that I am concerned about."

However, Geoffrey Porges and Charles Song, SVBLeerink analysts, thought that there was "a low probability of major adverse political outcomes for biopharma". Writing in their 2021 large biopharma outlook report in December 2020, they said: "Even a Democratic Senate will lack the filibuster-proof majority to enact major drug pricing legislation, and the Biden administration seems inclined to pursue incremental, rather than radical, reforms. Stocks most at risk with potential policy changes to Medicare Parts B and D are AbbVie Inc., *Regeneron Pharmaceuticals, Inc.*, and *Amgen, Inc.*, based on their respective drug portfolios. We believe depressed biopharma multiples could recover in 2H 2021 as investor concerns about major disruption to the economics of the biopharma industry, largely propagated by a minority of Democratic policymakers, are diminished."

US pricing policy aside, a supportive environment from government agencies was generally anticipated.

"Finally, biotech will increasingly be seen as a strategic industry, with more countries developing domestic capabilities, to reduce their dependence on the "biotech superpowers" and prepare to respond more rapidly to future pandemics," said Andrei Floroiu, CEO of *Vaxart, Inc.*

"We anticipate seeing a clear change in the way in which research projects will be funded," said Matthew Durdy, CEO of the UK's Cell and Gene Therapy Catapult. "We are still seeing strong support from government in wanting to facilitate growth and providing the necessary funding to fuel innovation and progress of R&D projects especially on the development side." However, he expected Brexit to exact its toll: "There will be an impact on applications that involve EU funding."

Several executives saw the need for evolution in regulatory agencies' approach to innovative technologies, ranging from new ways of gathering and analyzing data to advanced products to treat disease.
"FDA guidance on standards for the development, clinical evaluation, and manufacturing of gene and cell therapies will remain paramount in 2021, as a greater number of these therapies continue to progress," said Sue Washer, president and CEO of *Applied Genetic Technologies Corporation*. "In addition, pandemic-driven innovations in conducting trials, as well as monitoring and supporting patients remotely, will remain critical in executing clinical research."

Novartis Gene Therapies president Dave Lennon noted that while Novartis had obtained

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approvals for gene therapy in the EU, Japan, Brazil, Israel and Canada in 2020, "we saw a number of other first-generation technologies face setbacks with health authorities delaying approvals and new trials. In 2021, I expect to see steps taken to address this rising regulatory bar."

Hadean's Mimi Keshani focused on simulation as an area that needs regulatory attention: "Simulation will increasingly give us a greater reflection of reality. It is inevitable that someday all drugs and medical devices will undergo a series of *in silico* (virtual) trials before animal or human ones can begin, and it's possible it could be the only trial necessary. In 2021 we expect to see regulation beginning to catch up to this idea, with the FDA already signaling a mandate may be coming soon."

FasterCures board member Annalisa Jenkins foresaw progress in yet another developing area of health care. "We will see the FDA and other agencies approving digital therapeutics particularly in the mental health space," she predicted.

A final note of caution, however, was sounded about the attitude of the FDA to regulatory review in general by E Squared Capital Management's Funtleyder. "Over the last couple of months, it seems like the FDA has become a bit more conservative with respect to approvals. So it will be interesting to see if that's a trend or if that's our imagination. But I have a sense. We're not imagining the additional CRLs [complete response letters]. It seemed like the FDA was pretty lenient there for a while, but recently they seem to have resorted back to an above average [rate of CRLs]. It's something we'll be watching," he told *Scrip*.

Additional Reporting by Joseph Haas.

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