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Scrip Asks...What Does 2022 Hold For Biopharma? Part 1: Markets, Competition And Business Strategy

Transformative AI Needed To Offset Pressures On Production, Pricing And Supply Chains

by Eleanor Malone

Biopharma industry leaders highlight key concerns and opportunities across production, supply chain and commercial operations. Business transformation is top of mind for many, perhaps unsurprisingly following two years of rapid and mostly successful adaptation to the strictures of the COVID-19 pandemic.

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As we enter the third year of the COVID-19 pandemic, the pharma industry has begun to adapt and grow around its constraints and opportunities. After the all-hands-on-deck scramble in early 2020, businesses are increasingly able to reroute their energies to other priorities once again. Nevertheless, COVID-19 has shed light on systemic weaknesses that need to be addressed, and accelerated shifts towards virtual models of working.

In terms of growth, COVID-19 therapeutics and vaccines will provide a boost in revenues over the coming years, but industry will still need to find new revenue sources as the current generation of blockbusters heads towards loss of market exclusivity. And with pricing pressures from payers and the increasing availability of health and outcomes data and sophisticated means of interpreting them, proving value will become ever more important.

Executives across the industry spoke to *Scrip* about their hopes and expectations around the

business environment for the year to come.

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Where Will Growth Come From?

"The overall global market of biopharmaceuticals is very healthy. It's a $1.2-1.4tn market that is expected to grow at about 4-5% a year until 2025," pointed out Pierre Jacquet, vice chairman of L.E.K. Consulting's healthcare practice. But he cautioned that the past two years have seen "a significant deceleration of growth across different therapeutic areas" because of pandemic disruption, with chronic care products remaining more steady than acute care, hospital-based products which were significantly disrupted by the pandemic. Jacquet expected that "a significant chunk of growth from now to 2026 will come from COVID-19, with $200-300bn in potential vaccine and therapeutic sales over the next 4-5 years." Over this period of time, global biopharmaceuticals' single-digit market growth will be driven by in-line brand growth and new product launches, whereas elsewhere "this is a market that starting in 2022 is exposed to more than $150bn in loss of exclusivity over the following five years" – something that he flagged as a concern about the overall prospects for growth.

Jacquet pointed to the never-ending challenge that big pharma companies face of needing to keep growing their top line, something that is made even more difficult by the impending loss of "$150bn in annual sales due to loss of exclusivity" across industry starting in 2022. "When you are trying to grow $40-50bn in top line revenue at a low single digit, that means every year finding $2-3bn at least of new revenues. These companies have cornered themselves into a scale of revenue growth prospect and loss of exclusivity exposure that will force them to M&A, unless they scale down their business through splits or divestiture…If you keep growing the top line then the pace of innovation and pipeline replacement need to keep increasing every year, and we

all know the R&D productivity of pharma: they are depending more and more on externalization of R&D. That's why we expect M&A to be the level of 2021 or more significant than 2021, with 10-12 transactions exceeding $1bn in size."

As for where non-COVID sources of growth could lie, Jacquet thought oncology was becoming increasingly competitive with a cost of accessing and developing innovation becoming more challenging: "I think we are going to see more and more of the traditional oncology players trying to diversify beyond oncology" even if "the top five or six oncology players [retain] a commitment to oncology" as "one of the pillars of growth". He noted: "It's not what we were seeing in 2015-18, when everyone was buying and consolidating in oncology."

Rather, Jacquet saw anti-infectives as a promising area, including vaccines and COVID-19-related products of different types. He also expected a resurgence of interest in neurology, driven by factors including the increase in mental health problems occasioned by the pandemic, as well as recent innovation in the space. "Immunology is definitely an area that's seeing a lot of activity" and is "a market in the midst of rejuvenation," he also noted, and added orphan diseases as a final area of likely growth, with pharma's interest illustrated by Merck & Co's $11.5bn acquisition of Acceleron last year. (Also see "*Merck's $11.5bn Acceleron Buy Partially Fills Future Keytruda Revenue Gap*" - Scrip, 30 Sep, 2021.)

Craig Martin, CEO of Global Genes, a US-based non-profit organization advocating for rare disease, agreed that "rare diseases will continue to be a major focus area for biopharma in 2022 building off a year in which investment in rare disease partnering and M&A significantly outpaced the rest of the market." However, he warned of a "risk that if markets tighten, biopharma's progress and focus in rare disease will become further skewed toward 'larger' rare diseases, and away from European and other markets where policy, pricing and reimbursement challenges are scaring off biotech."

And Fabio La Mola, global co-head of L.E.K. Consulting's healthcare practice who oversees the Asia Pacific region, flagged the United Nations Resolution on rare disease announced in December, saying "rare disease policies will start to take shape…Much will still need to be done, but SEA [Southeast Asia] is ready for some renewed focus on the issue."

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Pricing And Reimbursement

Stuart Henderson, global life sciences lead at Accenture, said companies would look at market access in an increasingly holistic way. “The focus for CEOs has shifted from company-level access issues to system-level affordability issues and addressing policy reforms. CEOs cite that their focus is balancing policy change impacts, pricing and profit expectations while improving global affordability and access. Three proposed [US] drug pricing provisions — Medicare negotiation, inflation capping, and Medicare part D redesign — are at the core of the proposed reforms. While each will have meaningful first-order impacts on biopharma revenues, the industry has to be on the front foot navigating and shaping what will likely be more nuanced and lasting ecosystem shifts.”

Analysts at Mizuho acknowledged drug pricing pressures in the world’s biggest pharma market but did not see them as a serious concern for industry this year. “Drug pricing rhetoric will remain an overhang, but we expect the bark to remain stronger than the bite. It is unclear what reforms may ultimately be implemented, but some may help control out-of-pocket spending and boost patient adherence and prescription volumes, helping to offset added pricing pressures,” they wrote in a 5 January biopharma outlook report. “Our commercial companies have been operating in this environment for years and, assuming they continue to deliver meaningful innovation, we believe they will remain relatively immune to incremental changes we might see with US drug pricing policies.”

But Joseph Allen, executive director of the Bayh-Dole Coalition, a group of research and scientific organizations that celebrate and support the 1980 Bayh-Dole Act in the US, argued that innovation could be under threat from government interventions on the pricing front.

"The pandemic underscored the importance of robust intellectual property protections for biopharmaceutical innovation. Without strong IP [intellectual property] protections, US biopharmaceutical firms couldn't have produced three safe and effective COVID-19 vaccines in record-setting time. The Bayh-Dole Act, which permits federally funded universities, small businesses, and non-profit research institutions to license their research made with government support to private companies, has become a driver of our economy. It's the backbone of breakthrough vaccines like Moderna's and game-changing COVID-fighting therapies like Merck's molnupiravir. As we head into the new year, I expect the Bayh-Dole Act to encourage even more breakthrough R&D projects at America's universities, research labs and private-sector innovators to deliver more COVID-fighting technologies we need to end this pandemic once and for all."

Allen went on: "Despite the incredible contributions of biopharma firms working to end the pandemic, many lawmakers are still pursuing counterproductive price control policies that will chill innovation. For example, Senators Elizabeth Warren (D-MA) and Amy Klobuchar (D-MN), along with Representative Lloyd Doggett (D-TX), want the Department of Health and Human Services and the Department of Defense to misuse the march-in provision of the Bayh-Dole Act

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to set the price of federally funded medicines something the provision does not authorize. Doing so would threaten the entire R&D pipeline for new drugs and therapies.

“While anything can happen in an election year, I hope policymakers reject counterproductive plots to undermine Bayh-Dole and appreciate its contribution to our wealth and health. Doing so will help maintain an R&D system that generates hundreds of new therapies, supports thousands of jobs, and keeps the United States at the forefront of technological advancement," said Allen.

James Sapirstein, CEO of *First Wave BioPharma, Inc.*, also warned that price controls could be counterproductive. “Heading into 2022, concerns about price controls are once again looming over the biotechnology and pharmaceutical industry. If history has taught us anything, it is that restricting drug prices inevitably takes a toll on innovation,” he told *Scrip*. “The anti-infective space is a case in point. Years of low prices and low margins chased away industry giants and left the small players struggling to stay afloat. This resulted in a dearth of interest and innovation in the industry. A by-product of this was a decline in new antibiotic development and a rise in bacteria resistant to those antibiotics still in use. Unfortunately, people now lose their lives to this mistake every day. Only recently has there been a renewed interest in anti-infectives due to the COVID-19 epidemic. However, it should not take a once-in-a-generation pandemic to make government and society realize that developing life-saving medicine requires bold innovation combined with substantial investment coupled with the promise of financial reward (to those few companies that succeed). Pharmaceutical price controls seem like a solution to the high cost of healthcare in this country until you’re the one in dire need of a medical miracle.”

> ***"Pharmaceutical price controls seem like a solution to the high cost of healthcare in this country until you’re the one in dire need of a medical miracle."***
>
> *James Sapirstein, First Wave BioPharma*

On the generics side, *Teva Pharmaceutical Industries Ltd.*’s vice president and chief regulatory counsel head, global regulatory policy, Brian McCormick, was “concerned about the implications

for the future of generic development given the drug pricing provisions in [US President Biden's] Build Back Better Act. For the first time, there are numerous bills with direct impact to generics simultaneously up for consideration in Congress, and policymakers must recognize their responsibility to patients who rely on generic drugs as they head into the next legislative session."

Beyond the US, "branded generics and generics will see further price pressure in SEA [South East Asia], as countries pay for COVID expenses, and continue to divert budgetary savings to cover more of their population or pay for innovation," warned L.E.K.'s La Mola, who is based in Singapore.

In the digital therapeutics space, Andy Blackwell, chief scientific officer of mental health-focused digital health firm ieso, thinks companies will need to adapt to payers' budgetary squeeze. "Providers will increasingly need to be able to operate within a value-based behavioral care framework as continued financial constraints will drive both public and private payers to demand more value-based contracts," he said. "As such, the companies that use evidence-based measures and protocols to focus on the quality, efficiency and outcomes of care delivered will be the ones in high demand by health systems."

Paul Brennan, president and CEO of *NervGen Pharma Corp.* also saw a path through pricing pressures based on companies effectively designing products that offer clear value in markets around the world. "Emerging life sciences companies will focus more on differentiating their innovations and products for success in global markets. By looking ahead to a 5-to-10-year window, they are realizing that they can effectively plan how to secure market access, partnership and funding. It is important to clearly identify and define the life science company's unique offerings and consider how to differentiate its products to receive reimbursement from health systems," he said, also noting that "the global pandemic has shined a bright spotlight on the critical innovations from the biotech and biopharma community. In 2022, I believe there will be growing recognition and appreciation about the life-enhancing developments that biotech companies are shepherding that go beyond pandemic related disease."

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Regulatory

More regulatory rigor is on the cards, according to Andy Smith, life sciences/healthcare analyst

at Equity Development and author of *Scrip*'s weekly Stock Watch column.

"Hopefully the 2021 Aduhelm approval was the low point for approvals on the basis of what biotech companies call 'on the totality of the data'," he said. "The pushback from payers, FDA Advisory Committee members, EU and Japanese regulators and even some physicians on Aduhelm and the Phase III clinical trial read outs from other anti-amyloid beta antibodies could close the door on this volatile chapter if meeting clinical endpoints continues to elude."

Smith went on: "If you had been either hibernating or in denial in 2021, you would have missed the increasing number of clinical holds for gene therapy companies, some of which have been associated with patient deaths. In combination with the Aduhelm controversy, I would therefore expect regulatory scrutiny, and perhaps the number of approvals, to increase and decrease, respectively, in 2022."

Nicklas Westerholm, CEO and president of Swedish orphan drug developer *Egetis Therapeutics AB*, took a different view on regulatory stringency. "In the past year we continued to see a more pragmatic approach from regulators in the industry when it comes to important or potentially life-saving new drugs. I expect this trend of accelerated approvals to grow in response to urgent unmet medical needs, particularly in areas where medical innovation is coming of age, such as rare diseases," he said. "This year we expect to see the positive impact of the expedited review process in recognition of the importance of diseases historically overlooked, especially in populations that require particular attention, namely with regards to pediatric patients."

Richard Francis, CEO of Purespring Therapeutics, a gene therapy-focused spinout of the University of Bristol (UK), believed that "investors will continue to look outside the US as a fertile ground for the next big innovations in our sector during 2022" and that regulatory flexibility will play a part. For Francis, "The UK has long punched above its weight in scientific leadership, but it now has an increasingly agile and muscular medicines regulator in the MHRA which has taken advantage of the recent decoupling from Europe to make the regulatory framework much more responsive to the needs of UK innovators. Whatever your view on Brexit, I do think MHRA could allow biotechs to take advantage of a speedier and more favorable regulatory environment, especially when it comes to advanced therapies."

Meanwhile, in the US, Teva's McCormick noted that "affordable access to generics is in the hands of Congress" with the expected ratification of GDUFA III, which he expects will "include significant improvements that will streamline the FDA review process bringing more affordable options to the patients who need them, including complex generics which account for greater savings for our health care system."

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Supply Chain

"The COVID-19 pandemic continues, and along with it, the catastrophic disruption to the global supply chain," stated Rajiv Khosla, CEO of oral peptide drug delivery-focused contract development and manufacturing organization (CDMO) *Enteris BioPharma Inc.*

"The US drug industry urgently needs to address its overreliance on overseas markets for materials and ingredients needed to produce drugs and the actual manufacturing of medications essential to protecting the health and wellbeing of millions of Americans," he said. "If anything, these problems have worsened over the past year, creating an even greater need to return more of the manufacturing and supply chain to domestic shores. Given this environment, we hope to see US drug makers work with US-based CDMOs to ensure real-time service, the efficient delivery of clinical trial materials to trial sites, and on-time supply of finished product for commercial launch."

"A key theme for the biopharma industry in 2022 will be comprehensively re-evaluating manufacturing supply chain processes."

Helen Sabzevari, Precigen

"A key theme for the biopharma industry in 2022 will be comprehensively re-evaluating manufacturing supply chain processes," predicted Helen Sabzevari, president and CEO of gene and cell therapy developer *Precigen*. "As we enter the third year of the COVID-19 pandemic, companies throughout the industry are continuing to adapt to the seismic shifts within the global economy and public health arenas that have upended prior strategies that relied on just-in-time movement of people and materials."

Sabzevari envisioned this having particular relevance to cell therapy developers, with the associated complexity of the manufacturing process. "I believe that this wholesale re-evaluation will drive important changes in cell therapy manufacturing process," she said. "The manufacture of autologous cell therapies, which potentially offer important safety and efficacy advantages compared with allogeneic therapies, typically involves collecting cells from the patient,

transporting those cells to and from a central processing facility — which may be thousands of miles away — culturing those cells for multiple reagent-intensive rounds of expansion, and then having the patient travel again to a care center for cell infusion.

"Novel strategies that enable point-of-care cell therapy manufacturing have the potential to radically simplify this process by eliminating process steps that may be subject to supply chain issues. Moreover, cell therapy innovators must also accept that patients may not be able to travel repeatedly for cell collection and reinfusion. Addressing these challenges with point-of-care cell therapies could solve several critical supply chain issues while minimizing patients' treatment burden and increasing access to advanced cell therapies with the potential to improve health outcomes."

Jennifer Buell, president and CEO of *MiNK Therapeutics, Inc.*, a developer of allogeneic cell therapies, pointed to wider challenges across the industry. "The impact of the current supply chain limitations has underscored the criticality of in-house capabilities, agility, and high-speed innovation," she noted.

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Production

"Continued investment in streamlining processes within manufacturing and R&D to negate the rise of biosimilar adoption will be fundamental in the role that biopharma plays in the competitive market of treatment advances, improving patient outcomes, and developing curative therapies," said Stephen Page, founder and brand and strategy director at communications agency Page & Page and Partners.

Pandemic achievements could spur progress in this arena. "The speed at which pharmaceuticals companies developed and brought new COVID vaccines to market in 2021 was widely celebrated. Throughout 2022, manufacturers will focus on developing a more efficient production cycle to support speeding up the industry's time to market for all medicines," said Kelly Doering, senior director, industry marketing, pharma, at AspenTech, which provides software and services used by industrial firms to manage their operational processes.

Companies will lean on automation and the latest digital technologies to speed time to market, reduce risks, remove unplanned downtime and prevent bottlenecks, she said. "To support this

vision, pharmaceutical companies are increasingly turning to a digital workflow powered by Industrial AI across planning, scheduling, production and asset management."

Doering foresees an increasing use of "Quality by Design" (QbD) and process analytical technology (PAT), which applies advanced measurement systems throughout product processes to monitor process parameters and their effects on quality. "Such are the benefits that we'd expect to hear much more about both PAT and QbD during 2022."

The growing move from batch to continuous manufacturing "for improved quality, throughput and yield" will also necessitate the use of appropriate technology to monitor process performance continuously and propose adjustments, said Doering. "At the same time, batch control solutions are emerging that can predict batch results and anticipate deviations from target and automate corrective action, enabling more consistent efficient operations." Doering also expects electronic batch record systems, with their ability to improve data integrity, minimize error, reduce paper/manual entries and power industrial artificial intelligence to "drive benefits across pharmaceuticals during 2022."

For advanced therapeutics like cell therapies, "manufacturing enablements will be a critical driver to enabling broad access and industrialization of manufacturing. Manufacturing and supply chain independence will be critical. Production space is at a premium and independence here will be coveted," commented MiNK Therapeutics' Buell.

Eric David, CEO of BridgeBio Gene Therapy, agreed that "manufacturing capacity and talent for advanced therapies will continue to be a challenge for 2022."

Cell therapy manufacturing efficiency was also top of mind for Daniel Teper, chairman and CEO of *Cytovia Therapeutics, Inc.* "Cell and gene therapy have demonstrated potential for advancing toward a cure for cancer and other intractable diseases. In 2022 and beyond, market access will become a key consideration," he said. "Off-the-shelf cell therapy with a significant lower cost of goods will facilitate outpatient access to cell therapy for many patients. Large scale production of optimally designed and well-characterized edited cells from a single cell source such as iPSCs (induced pluripotent stem cells) will increasingly be perceived as a competitive advantage for cell therapy companies."

Steve Martin, vice president of global research at lab equipment firm Waters, wanted to see changes to the wider field of bioprocessing. "2021 pressure tested the greater healthcare and life science ecosystems. Now, as we look ahead to next year, the biggest opportunity is specific to bioprocessing, and involves decoupling the product from the process to accelerate the delivery of higher quality medicines to patients. The success of biotherapeutics such as mAbs, cell and gene therapies and vaccines has transformed the life sciences industry, but the processes to manufacture them remain unchanged for decades, even in the face of constant innovation,

because the industry is reluctant to alter well-characterized and well-controlled processes," he explained.

"That's why it's crucial in the coming years that our industry focus and collaborate to break through this barrier to progress in the drug development process so we can deliver novel therapeutics to patients faster. We'll be able to do this by advancing technologies that provide the critical attributes of the biotherapeutic products and enabling flexibility in the process."

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COVID Effects

"Continued business disruption associated with political decisions associated with COVID needs to be planned around regardless of whether future strains continue to be found to be less lethal. A myriad of reactions to the pandemic will likely continue to be observed so businesses need to be nimble and think differently on planning, how and where to gather, where to locate their offices, and how to implement work from home strategies," said Russell Trenary, president and CEO of *Outlook Therapeutics, Inc.*, which is developing an ophthalmic formulation of bevacizumab to treat wet age-related macular degeneration and other eye conditions.

Mike Raab, president and CEO of *Ardelyx Inc.*, sees COVID-19 having a continuing impact on commercial operations, and he thinks larger companies will be at more of a disadvantage. "Commercial companies will need to continue to be creative and efficient in their sales and marketing efforts in anticipation of ongoing pandemic protocols and limitations in accessing prescribers," he told *Scrip*. "Smaller, more nimble companies should be better able to navigate these dynamics given their models of streamlined, focused commercial organizations that are already designed to reach and influence target prescribers."

"Hybrid product launches are here

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Jennifer Herron, chief commercial officer of *ADC Therapeutics SA*, which launched its antibody drug conjugate lymphoma treatment Zynlonta (loncastuximab tesirine-lypl) using a semi-virtual commercial model following US FDA approval in April 2021, also expected adaptations made out of necessity during the pandemic to stick around. “Hybrid product launches are here to stay in 2022 and beyond,” she said. "Given the ever-evolving COVID environment, biopharma companies have had to adjust the ways they educate and engage with healthcare professionals. The sales model now requires a mix of virtual and face-to-face touchpoints and a high degree of flexibility to engage all customers.”

The virtual is here to stay in other areas too, according to Jonathan Rigby, CEO of *Revolo Biotherapeutics*. “With the ongoing COVID-19 pandemic, biopharma will continue to reinvent how it looks from the corporate to clinical perspective, including incorporation of hybrid employment to virtually run clinical trials that can allow for enhanced patient participation. I expect that these reinventions will lead to a more innovative workforce that is better informed by inclusive and robust clinical trial data.”

> *to stay in 2022 and beyond."*
>
> *Jennifer Herron, ADC Therapeutics*

Duncan Emerton, executive director, EMEAI custom intelligence at Pharma Intelligence, was optimistic that the industry is in a strong position to weather any remaining COVID shocks. “Prior to the emergence of the Omicron variant there was much discussion on how humanity was planning its shift from pandemic to endemic management of the virus. SARS-CoV-2 will be with us for many years to come, but the hope was that it could be managed in a similar fashion to influenza. With the emergence of Omicron, many countries around the world have plunged back into national lockdowns in an attempt slow the spread of the virus,” he said. “The big difference between what’s happening now and the winter of 2020/2021 is that the industry is far more resilient as it continues to adapt to life with COVID. Gone are the widespread disruptions to clinical trials. Digital technologies continue to have a positive impact, from discovery all the way through to disease management. And COVID vaccines and treatments continue to be developed and approved at pace. Progress into 2022 will undoubtedly be impaired by the rise of Omicron, and this is likely to persist through H1 2022, but the impact is unlikely to be as significant as last

year."

> *"With some CMOs reporting a two-year backlog, drug makers are facing long queues to get CTM manufactured, a situation that could significantly delay preclinical and clinical trials this year."*
>
> *Hing Wong, HCW Biologics*

HCW Biologics, Inc CEO Hing Wong, though, warned that COVID-19 had created pressure on resources that could cause widespread problems across drug development. "Biotech research is a victim to the supply chain issues that developed due to COVID. The shutdown for one, but there is a longer lasting impact from the race to develop and approve vaccines and antiviral treatments has overshadowed a critical issue that could have a major impact on clinical trials for all biopharma companies in 2022 and 2023," he said.

"COVID-related research and drug studies have and continue to consume considerable resources. This and the near-record amounts of capital created by the biotechnology industry over the past two years have combined to create a research log jam with contract research organizations and contract manufacturing organizations unable to keep up with demand for their services. With some CMOs reporting a two-year backlog, drug makers are facing long queues to get CTM [clinical trial material] manufactured, a situation that could significantly delay preclinical and clinical trials this year," Wong cautioned.

However, the life science sector's critical contributions during the pandemic should yield dividends, according to Clive Dix, CEO of *C4X Discovery Holdings plc* and former chair of the UK's Vaccine Task Force, which led efforts to discover and roll out COVID-19 vaccines. "It will be important to capitalize on the optimism that the vaccine Task Force has generated for the life sciences industry as a whole," he said. "By keeping the momentum there, it will encourage more private investment to come to the UK which in turn will allow us to see positive actions and real deliverables from the UK life sciences industrial strategy. This will not only highlight the incredible science done here in the UK but harnesses the potential for all rich nations to work together to help deliver vaccines to our friends in poorer countries."

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Data

AspenTech's Kelly Doering expected real-world data to "have a greater impact on decision-making in pharma," with industry making increasing use of "powerful digital and analytics tools" to aggregate and analyse real-world data from different sources.

Jim Gabriele, CEO of cancer informatics company M2GEN, agreed. "In 2022, we will continue to see biopharma companies embrace the potential of bioinformatics and AI [artificial intelligence] to solve the world's greatest health-related challenges. The ability to collect, organize, analyze, and visualize clinical and genomic data is continually improving, prompting biopharma and technology companies to collaborate for the betterment of patients in need. At M2GEN, we began a collaboration with Microsoft in 2021 to enhance and scale our data-driven solutions for the discovery, research, and development of new oncology therapies. We expect more partnerships like these to emerge and drive innovation throughout the industry in the years ahead."

"In 2022, we will continue to see biopharma companies embrace the potential of bioinformatics and AI [artificial intelligence] to solve the world's greatest health-related challenges."

Jim Gabriele, M2GEN

When it comes to AI, expect there to be more "demand for artificial Intelligence and machine learning tools that can be easily plugged into data scientists' existing workflows without requiring an organization to implement an enterprise solution," said Jane Reed, director, life sciences at Linguamatics, an *IQVIA* company, a provider of a natural language processing-based AI platform.

"As we saw during the pandemic with the rapid vaccine development response, companies don't have months and months to implement end-to-end solutions, or they risk missing market opportunities. Instead, data scientists require agile tools that can be inserted into existing processes to find the answers they need, whether for one specific task or to solve multiple issues across the organization," added Reed. "With a cloud-first

strategy, pharma companies will take advantage of new cloud-based approaches for tools like natural language processing (NLP) to help them address market needs more quickly."

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China

Helen Chen, Greater China managing partner and head of China life sciences for L.E.K. Consulting, foresaw some key developments in China this year. Firstly, a shift in big pharma's attitude towards the Chinese market for cell and gene therapy products. "Multinational pharmas ranging from *Novartis AG* and *Bristol Myers Squibb Company* to *Bayer AG* and *Astellas Pharma, Inc.* have moved into regenerative medicine in a big way, whether through the company's own initiatives or by acquisitions and investments. But despite the frenzy of global activity, the big pharmas have done little to bring their cell and gene therapies to China, other than their CAR-Ts a few years back," she observed.

However, China has an active cell therapy pipeline comparable to that of the US and China's regulatory agency, the National Medical Products Administration (NMPA), "has been systematically establishing technical regulations for cell therapy since 2017," Chen noted, adding that industry insiders expected there to be a similar regulatory framework for gene therapy.

> *"I expect 2022 will see some big pharmas exploring options to bring their hard-won cell and gene therapy assets to China."*
>
> *Helen Chen, L.E.K. Consulting*

"It's now time. I expect 2022 will see some big pharmas exploring options to bring their hard-won cell and gene therapy assets to China. There have been some explorations already. For example, Novartis applied for clinical trial authorization (CTA) in October 2021 for Zolgensma [onasemnogene abeparvovec], its US-approved gene therapy for spinal muscular atrophy (SMA), and is rumored to be negotiating with NMPA to waive clinical trials for Luxturna [voretigene neparvovec], an adeno-associated

virus vector (AAV) based gene therapy for retinal dystrophy, also approved in the US. Novartis was also the first pharmaceutical company to take full advantage of the Marketing Authorization Holder (MAH) policy, a national scheme introduced in December 2019 after several years of pilots, to collaborate with a CMO [contract manufacturing organization] for Kymriah, CAR-T for B-cell lymphoma."

Chen suggested that "international companies may have deprioritized China because of perceived foreign investment restrictions, or perennial concerns around government pricing targets." However, she warned that "continuing to take this approach will mean missing out on potentially substantial commercial opportunities in the market with the world's largest patient pool. Yes, the government is encouraging local innovation, but the local innovators will also need to figure out an approach to commercialization in China. Different technologies, different diseases and different asset stages will require a range of approaches. In many situations, Chinese companies will need the expertise of big pharma to be successful. The most progressive and innovative international companies will be thinking hard about how they can navigate the challenges of China to help the country's pharmas and benefit from the commercial gains to be made."

Chen also sees shifts becoming necessary in the way Chinese companies put their assets to work to realize their full potential – and generate a return on investment.

"The current wave of innovation and biopharma company formation taking place in China has been supported by a tremendous amount of private and public capital, driven in part by Hong Kong Exchange's Chapter 18A for pre-revenue companies and Shanghai Stock Exchange's emerging technology board. To quickly ramp up and show progress, many of these companies licensed China-rights from western biopharmas. As the China market changed, the initial excitement around international regulatory standardization – such as the ability to submit international data for NDA in China and significantly earlier reimbursement, has now morphed, as companies need to deliver on their investor promises," she explained.

"For those companies whose lead assets are licensed for China only, investors increasingly recognize that many have been valued on global commercial potential, similar to a typical US biopharma. There is only a limited time window for these companies to realign their portfolio, overall strategy and stories to the wider world.

"Even when these biopharmas have global commercial rights for their products, many of their CEOs, often founder-scientists, have not thought much beyond getting product approval, or only have vague ideas for commercialization or partnering for international development.

“For Chinese biopharmas to maintain their pipeline, business and capital market trajectory, they will need to step up their planning and future partnering and/or commercialization game. Global ambitions require assets with global rights, global development and global commercialization. There are multiple and complex strategic challenges for Chinese companies in deciding how and when to pivot and expand on the global stage. And there will be roles to play for many of the big pharmas in assisting them,” predicted Chen.

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Helen Chen, L.E.K. Consulting

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Rethinking The Organization

"The last two years have highlighted two major features that are core to our industry. First, the biopharma industry can adapt under pressure even when every aspect of our business is under stress. Second, our industry has an outsized role to play to safeguard global human health and society. We have shown how breaking down silos between organizations and collaboration across the industry helped mitigate the effects of a debilitating global pandemic that had the potential to do far worse,” said Amrit Chaudhuri, co-founder and CEO of SmartLabs, a Boston-based firm that designs and operates research environments.

However, he thought a major transformation was still needed. “In our participation in solving the challenges, I can't help but feel that we got lucky in how our industry found solutions to meet the resourcing and mobilization challenges to blunt the pandemic. Before the pandemic, we had already identified severe challenges to how biopharma creates the necessary resources and infrastructure to support the next generation of research in the pipeline. Our pandemic response exemplified that our infrastructure and resourcing models are stretched too thin and were not built to provide the industry with the flexibility to address new targets and new modalities.

“We are on the precipice of a transformation in how our industry resources science for the

future. I believe the next major industry-wide shift will be creating the first on-demand universal infrastructure and resource set to address research, development, and commercialization," declared Chaudhuri.

Pointing out that CEOs at top life sciences companies now see innovation as their top priority in 2022 (according to research by Accenture which has seen it edge above talent and access this year), Accenture's Henderson noted that traditionally big pharma had relied on external sources for innovation. However, he specified that this year the focus would be on the need to transform at pace, even as high biopharma talent turnover (15.6% according to Atlas Venture's 2021 Year In Review) acts as a headwind.

"A better path to innovation at speed requires performing multiple simultaneous transformations across their organizations — something we call compressed transformation. This includes transforming multiple parts of the enterprise in parallel rather than taking a sequential approach," he said. "It's the only way to deliver on a company's purpose and a vision for the future that includes more collaboration, better R&D productivity and fewer failures. As well as more value-based health care and reasonable access for those in need."

For Pete Mariani, executive vice president and chief financial officer of *AxoGen, Inc.*, which specializes in regenerative medicine surgical products for nerve repair, hybrid working models are here to stay.

"The medtech/biopharma industry is somewhat unique in that much of the core work must be done onsite in an R&D lab or manufacturing environment. I believe that, in large part, true innovation is born from the collaboration and free exchange of ideas that transpires during face-to-face in-person meetings and working sessions. Organic interaction often serves as the foundation for inspiration and creativity," he acknowledged. "While technology advances have allowed many of us to successfully work from home, impromptu conversations and the resulting camaraderie is difficult, if not impossible, to replicate in a fully virtual environment. Connections with co-workers are often forged and strengthened outside of formal meetings during unscheduled interactions."

Nevertheless, that is not the full picture. "The past two years have taught us that the flexibility and focused work time that often accompanies working from home is equally valuable and contributes to productivity and employee satisfaction," said Mariani. "I believe the best next normal is a combination of in-office and work-from-home that allows us to leverage the benefits of both."

Paula Ragan, CEO and president, *X4 Pharmaceuticals*, foresaw other implications. "I expect a continuous trend towards virtual work which might make talent recruitment even more competitive for biotech companies given the lack of location ties when employees choose the

right job," she said. "We will see companies innovating to renew employee policies, benefits, and company culture, to become more attractive to job seekers."

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>
> *Paula Ragan, X4 Pharmaceuticals*

Meanwhile, Julien Pham, founder and managing partner, 3CC|Third Culture Capital, thought the virtual culture would create new opportunities to tap into a wider global ecosystem. "In 2022, we'll see more cross-border collaborations and global scaling at earlier corporate and R&D stages than ever before," he said. "Remote teams, whether in healthtech or biotech, will take more risks and be more pragmatic in adopting tech solutions and leveraging cross-border resources and R&D incentives to get from point A to point B. If 2020 and 2021 showed us that decisions could be made without in-person meetings, 2022 will prove to us that strategy can be efficiently executed when early-stage entrepreneurs think about resources creatively, outside of their go-to network. Being able to invest in early stage within this global framework will be a clear and unique advantage."

"2022 is going to be a year of opportunity for change, an opportunity to look to a new future with new ways of doing things and with new priorities," said Tom Oakley, CEO of medical imaging technology company Feedback plc. He thinks disruptive enterprises with new approaches to health challenges will have an advantage. "Challenger companies will start to outstrip established entities because they move faster, are more innovative and are closer to customers. Many established companies have had to eat into their reserves during COVID meaning they are increasingly cash dependent and having to compete more equitably with smaller companies, something that they are ill equipped to do, they can't just adopt the 'wait them out' strategy anymore and will have to compete on the basis of their products not their bank balance. 2022 will be the year of the challenger as the champion of change. System challengers like us are not just embracing the change but are driving it and large

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