[Scrip Asks…What Does 2023 Hold For Biopharma? Part 3: Global Headwinds]

Tough Times Call For Resilience, Flexibility And Collaboration

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Executive Summary

Headwinds of political instability, violent conflict, inflation and recession accompany us into 2023. *Scrip* surveyed industry leaders on the impacts for biopharma.

For the third installment of our *Scrip Asks…What Does 2023 Hold For Biopharma?* series, we asked industry leaders and experts how the sector would be affected by the global headwinds of political instability, violent conflict, inflation and recession.

Most acknowledged that times are tough and that biopharma cannot remain untouched by the political and macroeconomic situation. In the words of **Marcus Schindler**, executive vice president for research and early development and chief scientific officer at Novo Nordisk A/S, "It will be more difficult and more uncertain than ever before."

Jack Bailey, CEO of oncology company G1 Therapeutics Inc., contrasted the current situation with the biotech boom that peaked in 2021: "It's no longer an environment in which, 'if you build it, they will come'." Biotech companies now need to be ever more mindful of proving their value in terms of addressing unmet medical need, improving real patient outcomes and generating a commercial return: exciting technology on its own may no longer cut it.

But despite concern that some R&D and other activities will be impacted by funding constraints, while escalating costs, supply chain issues and health care staffing could also present diverse negative effects across the sector, a common view was that industry can rise to the challenge.

Biopharma will not be unscathed, but its products are needed and with nimbleness, creativity and adaptation it should ride out the storm, say industry leaders. In fact, disruption could ultimately lead to positive changes.

Handling Uncertainty

"It's been a turbulent time for the global economy and this has had many implications on biopharma," commented **Chris Hollowood**, CEO of **Syncona Investment Management Ltd**.

Some industry commentators talked about companies in the industry needing to batten down the hatches, while others thought they should explore the possibility of adjusting their course in response to the stormy global conditions. For Hollowood, "continued uncertainty [in 2023] will heighten the sector's focus on high-impact medicines where regulatory pathways are clear and reimbursement is securable."

Novo Nordisk's **Schindler** emphasized the need for companies to "have an increased attention to business continuity, supply chains and the resources required."

This could bring about changes. "There will be a movement away from globalization and towards regional/local plays that will impact things like clinical development, regulatory and manufacturing," predicted **Simba Gill**, CEO of Evelo Biosciences, Inc., which develops oral medicines targeting the small intestinal axis to treat inflammatory conditions.

"In times of uncertainty, companies seek to operate more efficiently and keep a close eye on the bottom line," said **Jonas Boli**, chief technology officer of patient prescription access platform technology company **Phil Inc**. "They'll first search for data and insights to help them understand the impacts to their business. Then, they'll phase out solutions that aren't delivering and find new ways to solve the opportunities they find."

"Companies have to be nimble; like speedboats versus tankers," said G1 Therapeutics' **Bailey**. "Whether it's COVID, the war in Ukraine, legislative changes, capital market volatility or any other unknown, you have to be willing to make decisions with 85% of the data. You're never going to have 100% certainty, so you have to take calculated risks, then continually evaluate where you stand and be prepared to change course when necessary. You have to let go of confirmation bias, whether it's related to R&D or operational strategies; to incorporate new evidence and allow it to guide your decisions. Perseverance and tenacity are critical to staying the course, but that doesn't mean staying wed to strategies that are no longer viable."

Biotechs may have one advantage over large pharma companies when it comes to navigating tricky times. "Smaller companies tend to be more agile, because we are accustomed to continually pursuing sources of capital, controlling burn rates and devising creative operational models that reduce bureaucracy and conserve resources," added Bailey. "For example, we are very much a vendor-managed company, and we outsource things like data processing and manufacturing, which allows us to quickly shift gears if one vendor isn't fulfilling our needs, or if global events necessitate rapid change." He concluded with advice that is probably valuable for companies of all sizes: "It's easy to get enamored of all the options and assets, so strategic focus is critical to success."

Andy Smith, life sciences and health care analyst at **Equity Development** and *Scrip*'s Stock Watch columnist, warned that the wave of COVID-19 affecting China following the end of the zero-COVID policy, potentially exacerbated by travel associated with the lunar New Year, could have repercussions for "companies like AstraZeneca PLC [which] will start to see bigger sales declines there than they have already."

Smith also warned about "knock-on effects of Russia's actions" which would "undoubtedly impact global contract research organizations that conduct clinical trials there" as well as more widely "across Europe including Ukraine and the Baltic states" – even if Russia itself is not a major market for pharma companies.

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Manufacturing And Supply Chain

When COVID-19 emerged in China (a major source of active ingredients and manufacturing for the sector), concerns over the global supply chain were ignited, and a push for "on-shoring" manufacturing rapidly gained momentum. Within a year or so, the need to quickly establish production and distribution for billions of doses of the new COVID-19 vaccines further challenged the industry's infrastructure. With infections running high in China as we start 2023, and trade and political tensions heightened globally, the subject remains a live one for pharma.

"Globally, we could see increased trade tensions with China and possibly India. I think every organization that is manufacturing or sourcing from these countries, and others, needs to be very aware of their supply chain and how they can mitigate disruptions should they occur," warned **Michael Cruse**, chief operating officer of Reneo Pharmaceuticals, Inc., a California-based company developing therapies for rare genetic disorders. "It is customary practice for companies to develop secondary suppliers for critical elements in their supply chain. Going beyond this, companies need to establish a global strategic supply of essential inputs to ensure that supply disruptions do not occur. Our industry must be very aware of global headwinds and geopolitics so that patients do not suffer the negative consequences of these situations," he added.

"Political instability and conflicts may limit access to drugs, excipients, processes and it may be overcome by operating multiple manufacturing facilities, having a robust distribution infrastructure, and putting greater emphasis on developing stable medicinal products that are easily transportable," said **Susan Conroy**, CEO of specialty medicine company **TheraKind**.

"Speaking from the point of the specialized logistics systems that support distribution, the future will be very much about putting resilience into action. The pandemic and its continued effects, as well as a range of interconnected macroeconomic and geopolitical challenges, have led to an industry-wide rethink of how we construct and maintain supply chains," said **Cathy O'Brien**, vice president for international sales at logistics group **UPS Healthcare**.

"For the decade prior to the pandemic, we saw a period of relative stability. The pharmaceutical industry was focused on lowering costs and moving most of its API production bases to Asia. At the same time, more biologics came into the market, requiring specialized storage and transport conditions – all with virtually no margin for error. The result was longer, more complex supply chains," she continued.

"With the need to distribute billions of doses of Covid-19 vaccines we saw new and expanded supply chains built and tested in record time – making clear the crucial need for resilient, multi-modal, end-to-end temperature-controlled cold chain delivery, as well as and the ability for our industry to quickly pivot and build flexible, resilient supply chains to deliver when it's needed most.

"From a distribution point of view, this means that we are not only looking at a shortened supply chain but potentially a greater number of production sites. And the effort to re-shore may be more complicated than governments think."

Stephen Gunstream, CEO of California-based reagents manufacturer **Teknova**, flagged up the additional challenge of adapting capacity built during the pandemic to the broader future needs of the biopharma industry. "I think we will find a mismatch of capacity built during COVID-19 vaccine development and the need for novel therapies. The discovery, development and manufacturing needs for emerging modalities like cell and gene therapy require smaller, more customized and complex solutions, and are not well supported by the facilities and equipment generated for global COVID-19 vaccine development," he said. "I believe in 2023 industry stakeholders will have to evaluate whether to delay or modify current infrastructure to meet the needs of the next generation of therapeutics."

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Pricing Pressures

Global economic constraints are adding to the ongoing downward pressure on drug pricing, and pharma will need to be mindful if it is to expect reimbursement for therapeutic innovation.

"The environment is challenging, and given the headwinds, it means a continued push to significantly lower the total cost of care – a tectonic shift is in progress to reimburse clinicians and systems for patient outcomes, not procedures," commented **David Morgan**, CEO of Zephyr AI Inc., a precision medicine analytics specialist. "Because of that, we must build tools and products that will lead to the development of new therapies and novel indications of existing drugs which can drastically improve patient outcomes and significantly lower the total cost of care."

"Pharma must increasingly appreciate the world that it is operating in and be prepared to justify prices with evidence of real-world patient impact. As such, pricing and clinical development strategies must adjust accordingly," agreed **Chris Tapper**, senior associate at **Cambridge Innovation Capital**.

Despite the challenging environment for drug pricing, **James Sapirstein**, CEO of gastro-intestinal therapeutic developer First Wave BioPharma, Inc., thought that the impact of the Inflation Reduction Act in the US could be mitigated before it comes into effect. "A divided Congress can place a check on new legislation to target pharmaceutical prices that would crimp new drug development," he said.

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Investment Challenges

Karen Zaderej, CEO of nerve repair specialist AxoGen, Inc., expressed concern "that we will observe that a recession had started late in 2022, and hopefully will resolve before the end of 2023, which will impact priorities and biopharma spending decisions."

"The investment climate could continue to be difficult, especially if interest rates rise," said First Wave's **Sapirstein**.

These conditions could have a dampening effect on innovation.

"Despite the scientific advancements made in R&D and bioprocessing capacity over the past two years, the current market environments provide a strong headwind for biotech and pharma in 2023. Unfortunately, I believe this will limit investment in novel early-stage therapies, due to the desire to conserve capital in the first half of 2023," warned Teknova's **Gunstream**, although he thought "we may see an increase in spend in the back half of the year."

Sarah Howell, CEO of reformulation company Arecor Therapeutics plc, agreed that the "main impact [of the headwinds] is slow deployment of capital, which in turns slows the innovation engine, particularly within biotech, which requires capital to support it."

And **Suzanne Saffie-Siebert**, CEO of UK RNA therapeutics company SiSaf Ltd., commented that "political and economic headwinds affect the funding environment for biopharma and may force smaller companies to delay projects and investment." Nevertheless, she did not expect catastrophic effects, adding that "the need for treating and curing disease does not end in times of crisis and most pharmaceutical R&D will continue as planned regardless of short-run trends or political instability."

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Costs And Staffing Issues

"Some life sciences companies are experiencing challenges with escalating costs from clinical trials, driven by inflation, difficulty staffing and challenges in recruiting patients. This can have a material impact on how drug and medical device makers advance their programs," said **Jody Staggs**, president and interim CEO of specialized finance company **SWK Holdings**. "The increasing costs leave less margin of safety for patient recruitment and may reduce cash available to advance a treatment to its next clinical milestone. Higher clinical trial costs add to a company or program's cash burn while skewing the revenue needed to justify funding certain programs."

"Biopharma and other industries will continue to navigate in an environment that, although improved compared to last year, will not be completely resolved in many cases from most of the challenges we faced during the pandemic. A key headwind, particularly in the US, is the nursing and hospital support staffing challenges that have constrained hospitals, from both a capacity and financial standpoint," commented Axogen's **Zaderej**.

On staffing in the pharma industry itself, Amarin Corporation plc CEO **Karim Mikhail** saw a silver lining: "[One] impact we see from these types of destabilizing events is that they do cause the global pharmaceutical talent pool to grow due to the anticipated layoffs and down-sizing across the industry. While unfortunate for many companies and individuals and their families, this allows companies like Amarin to be more selective in filling roles with the right talent to help meet objectives and advance our strategy."

Meanwhile, UPS's **O'Brien** flagged that "a further challenge is the need to balance the availability of energy and inflationary costs in what will be an unpredictable environment." She said: "Public-private partnerships will continue to be crucial, much like we saw for COVID-19 vaccine development and distribution, to create the scalable, sustainable and cost-friendly solutions that can work across the industry."

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Serving Those In Need

"Unfortunately, whether we are talking about political instability, conflicts, economic downturns or global pandemics, all of these issues impact patient health," pointed out Amarin's **Mikhail**. The same sentiment was expressed by Reneo's Cruse, who also commented: "As an industry, we need to look towards war-torn areas to see what we can do to ensure our therapies continue to reach patients in need without regard for return. Doing what is right by helping those suffering in very challenging circumstances is the morally right choice and the correct business choice."

Thinking more broadly, **Cruse** went on: "With high inflation and a likely recession on the horizon, the need for patient assistance programs will remain high. Companies and non-profits need to re-examine their thresholds for their assistance programs. It is time to take the poverty level plus 200% or 300% threshold and move it higher so patients can continue on critical therapy. I also believe there's an opportunity to start looking more holistically at each individual's unique life situation and allow more exceptions to a pure income means test. The assistance should be available to families so they don't have to make trade-offs between a needed prescription or food, utilities or having an environment where their children can pursue their educational goals. We can develop programs for these people too."

Novo Nordisk's **Schindler** also warned that the precarious situation "might also affect our ability to collaborate globally. In line with that, it is important to stay clear on our values, continue to focus on our purpose to serve the people suffering from and living with the diseases for which we are seeking to find treatments."

"This is not the first time the health innovation sector has needed to navigate a turbulent world. The COVID era is still with us and the confusion around what and who to believe has become more endemic and turbulent," observed **Gil Bashe**, managing partner, chair global health at **Finn Partners** and a member of the incubators, accelerators and equity committee of the **Prix Galien Award**. "As long-time Galien Foundation friend and former Merck & Co., Inc. chair and CEO Ken Frazier reminds us, there is a line between politics and policy. The Galien Foundation champions health innovation to improve and save people's lives. We are moving our efforts into Africa and Asia. Around the world, we will champion efforts around collaboration and innovation. When people stop talking and working together, then we all lose."

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Surviving And Thriving

There will always be winners and losers in a crisis. The challenge is how to be one of the former.

"These global headwinds create uncertainty for investors, regulators and management teams and will continue to favor companies that have cash, talented teams and value-creating catalysts to ride out the storm," said **Troy Wilson**, CEO of Kura Oncology, Inc.

Focusing on offering solutions that are really needed should insulate companies, suggested Cambridge Innovation Capital's **Tapper**: "Regardless of global instability, the need to develop and provide clinically meaningful therapies that can address real patient unmet need will continue to be a powerful tailwind, even in the most troubled of waters."

"Instead of settling for treading water, now is when life science companies can set out to transform processes and offerings for patients to improve health outcomes."

And for First Wave's **Sapirstein**, "People are always going to need their medicines and innovation in the sector will continue. On a top-line basis, there might be little change in how business gets done."

But others thought more radical change could – or should – emerge from the turmoil.

"Technology has revolutionized almost every other industry, making it more convenient and affordable for consumers to access products and services. Health care should be no different," said **Deepak Thomas,** Phil Inc.'s CEO. "Pharma needs to take a leap of faith to emerge from the COVID-19 public health crisis and navigate continued economic and political uncertainty. Instead of settling for treading water, now is when life science companies can set out to transform processes and offerings for patients to improve health outcomes."

For Evelo Biosciences' **Gill**, "innovation will continue to grow outside the US in regions like China, India and the Middle East, leading to products that are tapping into a different model and a different system. China is already doing this now."

The current challenges could be viewed as an opportunity for creative destruction. As Gill commented: "Times of instability create disruption and innovation. Sometimes systems, products and ideas need to be destroyed to create something better."

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Additional reporting by Joseph Haas.

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