

The Next Era of Biopharma Innovation

Shaping the Ecosystem

By Josh Suskewicz and Ben Wiegand

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Propelled by dramatic advances in biological understanding and life science technology, we have arrived at the dawn of a long-awaited new era in medicine, in which diseases are increasingly predicted and preempted by diagnostics and treatments that are ever-more-precise and personalized. This new era promises enormous benefits to humanity, and presents a major opportunity for the biopharmaceutical industry – but it also poses a disruptive threat to longstanding incumbent business models. Today’s leaders will need to move quickly to embrace new models with a new focus, new skills, and a new role to play in the healthcare ecosystem.

What will the new paradigm look like for biopharma, and in particular biopharma R&D? To answer that question, we must first unpack the old one. Starting about a century ago, large corporations began emulating Thomas Edison’s General Electric, funding departments dedicated to basic and applied research. Life science companies were no exception. They developed ground-breaking drugs and treatments in their own corporate laboratories with their own scientists and academic partners. Biopharma’s role was clear: to discover and develop breakthrough medicines.

As the venture capital ecosystem emerged in the 1980 and 90s, the model evolved. In recent years, biopharmas have increasingly paired their internal R&D efforts with external investments, in-licensing and acquiring promising drugs from startups and academic partners. This entails funding expensive late-stage trials, running new medicines through the regulatory gauntlet, and finally commercializing them globally. Their role is now to industrialize breakthrough therapies.

At the center of this has been the pursuit of the blockbuster drug. As risky, expensive and time-consuming as the drug development process has been, if a drug became widely prescribed, its owner would reap years of massive returns. The ulcer drug Tagamet, for example, developed at a Smith Kline & French laboratory in Great Britain, was the first drug ever to generate \$1 billion in sales, breaking that barrier in 1986. The anti-rheumatic drug Humira, developed in a partnership between Knoll Pharmaceuticals, a subsidiary of BASF Pharma (now a part of AbbVie), and the startup Cambridge Antibody Technology, surpassed \$20 billion a year in sales in 2021, fully 18 years after it was introduced.

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The paradigm has worked so well that it’s understandable that biopharma companies regard the blockbuster drug as a kind of holy grail, and they have built their business models accordingly.

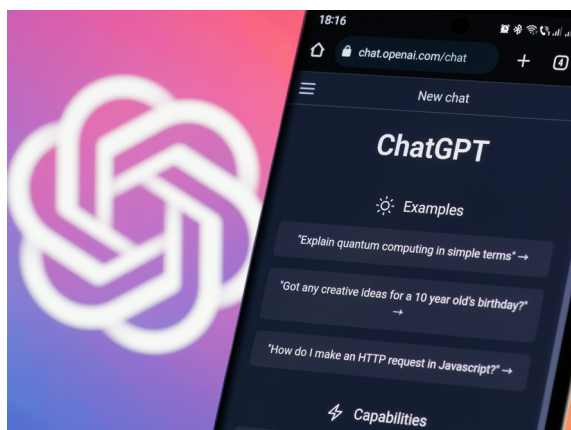
But the transformative life science breakthroughs of the future will require a change in mindset. As one-size-fits-all medications give way to more personalized solutions, the locus of innovation

will shift from products to ecosystems. There will still be powerful new drugs, of course, but they will be integrated with advanced diagnostics, innovative systems to target and deliver them precisely, sophisticated and rapidly evolving means to customize doses and formulations for individual patients, and more.

The ecosystems in which these new approaches are developed, marketed, and utilized are changing as well, as are the business models that ensure their viability. Developing and deploying them will require a broader set of capabilities than any one company is likely to be able to muster, and they are not likely to scale in the same ways that they do now. In this new era, the role of leading biopharma companies will evolve from discovering and industrializing breakthrough therapies to envisioning and catalyzing breakthrough therapies, with all their many interlocking components.

Hastening a New Model of Innovation

The emerging model for innovation in biopharma is likely to look much more like the high-tech ecosystems that giant companies like Google, Microsoft, and Meta preside over. These companies are not just makers and marketers of products, but enablers and integrators of complex systems. Consider Microsoft's multibillion-dollar investments in OpenAI, whose discoveries and advanced capabilities like ChatGPT are reinvigorating its legacy systems like Bing.



Microsoft doesn't own OpenAI or its inventions, but as a major funder they can direct its efforts towards the solutions they need. Similarly, defense contractors like Lockheed have long worked in a "lead systems integrator" model, in which a "prime contractor" is charged with bringing an array of technologies and their suppliers together, orchestrating complex programs that invent fundamentally new systems over the course of years and decades. These industries are set up to innovate at the ecosystem level – and this is what the biopharma leaders of the future will do as well.

An early example of this is Provention Bio's TZIELD, recently approved as the first-ever disease interception drug for type-1 diabetes. While this approval was a monumental achievement in and of itself, Provention's success was enabled by years of work to create an ecosystem in which interception of T1D is possible.

Autoimmune diseases like T1D begin long before symptoms become apparent, so finding people that are on this journey – often young children – before they feel sick is a major challenge. In addition to developing TZIELD, Provention worked with researchers, advocacy groups, and industry partners to develop and deploy new screening models to enable earlier diagnosis,

and it partnered with Sanofi on a commercialization model to bring the therapy to patients around the world. This integrated network of partners promises to transform the standard of care in T1D.

Most biopharma incumbents are still doing well enough in the old paradigm that it will take bold leadership action to change their practices and business models to prepare for the new paradigm. There may be a natural reluctance to the notion of becoming more like a systems developer and integrator, as opposed to a sole owner of a therapy.

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But by building strategic partnerships with a multitude of startups and smaller companies, they will wield their capabilities, financial power, and scale to shape the innovation ecosystem to better meet both the public's and their own needs. And this in turn will ensure that the most critical problems are being worked on

and solved, and that the once-unimaginable medical breakthroughs of the future—like curing cancer, intercepting Alzheimer's disease, and preventing childhood obesity—become realities.

Some high-profile venture capitalists in the life science field have already embraced this role, most notably Flagship Pioneering, the fund behind Moderna and many other successful biotechs. In an interview with CNBC's SquawkBox, Flagship's chairman Noubar Afeyan noted that its aim is not to cure illnesses so much as to develop solutions that work "upstream" of disease. "How can we make new tools, technologies, and interventions that allow us to act much earlier than when a disease is in its full bloom and therefore very difficult to handle?" he asked. "Not only do we need capital to do that...we need innovation, and that innovation in turn needs capital and a long-term point of view."

What can incumbent companies do to transform themselves into systems integrators? They will need to shift their strategic focus in five ways:

1. **Lead with vision.** The new mindset begins when leaders set out an actionable vision for the future and then galvanize an ecosystem of partners to bring it to life.
2. **Develop greater clarity on the problems they need to solve.** Medicine is shifting from a diagnose-and-fix model, in which doctors marshal drugs and treatments to cure or manage diseases, to one that uses a wide range of technologies, drugs, and services to prevent, predict, and pre-empt diseases.
3. **Ensure they have the technical capability to solve the problem.** While biopharmas may have some of the necessary capabilities under their own roofs, most will need to mobilize an array of new ones via partnerships, investments, and acquisitions.

- 4. Ensure they have the right business model to incentivize, deploy, and monetize the solution.** Given the complexities, the costs, and the varieties of development and commercialization models that go into these solutions, new funding models and distribution systems will likely be called for.
- 5. Ensure that regulatory and governmental frameworks allow their new solutions to thrive.** Getting a drug or treatment approved by regulators is hard enough, but convincing doctors to prescribe it, insurance companies to pay for it, and consumers to take advantage of it may require system wide change.



The new era in life science innovation has already begun. To take advantage of this inflection, biopharma will have to re-think and revise its role, from owners and buyers to visionaries and shapers.

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