

The biopharmaceutical market is approaching a significant slowdown due to biological products' patent expirations that threatens growth, while the industry has been slow to develop new treatments to replenish the pipeline. To bridge this innovation gap, pharma CEOs will need to expand their use of alliances to form stronger ecosystems that can foster innovation. These ecosystems can be used in tandem with mergers and acquisitions (M&A) as a pipeline development strategy.

Ecosystems can provide significant advantages over pharma's traditional approaches to driving growth - internal research and development and M&A - including increased efficiency, greater creativity and innovation, and accelerated speed with which products reach the market. Compared with M&A, ecosystem participation provides a less-risky and faster route to filling a company's innovation pipeline.

In fact, ecosystems are already contributing undeniable value to life sciences businesses overall – according to the recent EY Ecosystem Study – with life sciences respondents attributing 14.6% of total annual revenue, 14.1% in incremental revenue growth, 14.4% in incremental earnings and 13.7% in cost reductions to these models.

The study also shows that the payoff for organizations that get ecosystems right is significant. Those life sciences organizations with high-performing ecosystems (based on a maturity scale involving adoption of best practices and contribution to revenue) attribute even more value to those ecosystems, driving 1.6 times the cost reduction, adding 1.7 times more to annual revenue and achieve 2 times the incremental revenue growth of low-performing ecosystems.

## Why the innovation gap is growing

Many life sciences companies need to increase their pace of successful treatment development. Patent expirations put US\$356b in global prescription sales at risk through 2028, according to a report from Evaluate Pharma. At the same time, development times and the cost of bringing new drugs to market have increased, while big pharma approval rates have trended down.

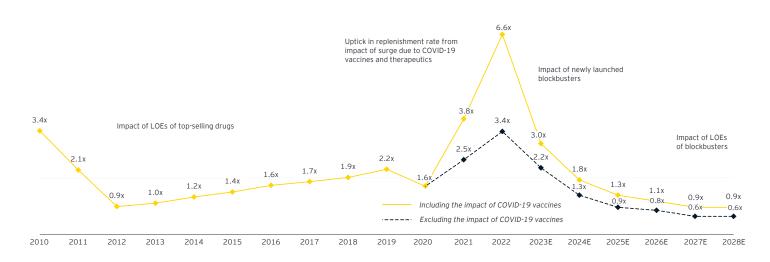
The rate of pipeline replenishment is one way to understand a company's sales growth. The replenishment rate shows the ratio of incremental sales from products launched in the last five years to losses in sales from patent expirations over the same time period. That rate is forecast to fall from 2022 through 2026 as industry sales at risk from upcoming patent expirations outweigh sales from new products to be launched.

EY analysis of the replenishment rates of the top 25 biopharma companies by revenue suggests the ratio will drop more than 80%, from 2.5 times in 2021 to 0.6 times in 2028 (see Figure A). Companies with a ratio of less than 1 are losing more sales due to patent expirations than they are recouping from pipeline products. The forecast innovation deficit comes as these major biopharmas are launching fewer products themselves - and pushback from legislators and payers curbs the ability to achieve sales growth through price increases.

This reduction in growth is evident from the fact that big pharma's new molecular entity (NME) approval rate fell to 46% in 2021 from 77% in 2011, while smaller biotech companies have seen their approval rate rise to 54% from 20% over the same period (Figure B).

Figure A: Pipeline replenishment trend

### Diminishing top-line replenishment rate over the years1



Source: EY analysis, Evaluate Pharma

**Note:** Analysis includes major pharma players contributing ~70% of industry revenues <sup>1</sup> The pipeline replenishment rate has been defined as ratio of incremental sales from products launched in last 5 years to loss in sales from product LOEs in last 5 years E.g.: For 2010, increase in sales from new product launches and decline in sales from LOE of products between 2006-2010.

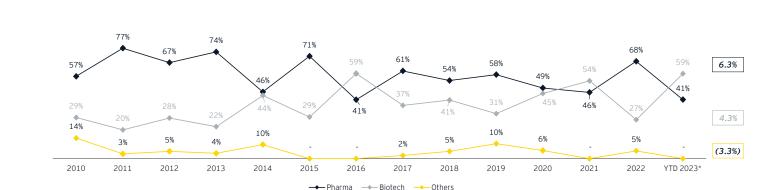
Figure B: NME approval rate increases for biotech

# NME

approvals



CAGR '10-'22



Source: FDA.gov, secondary research, EY analysis

Note: \*YTD 2023 includes FDA approvals

The listed NMEs include both small-molecule drugs approved under a New Drug Application (NDA) and new biological products approved under a Biologics License Application (BLA).

The decline in the replenishment rate comes even as the industry continues to spend more on R&D every year. R&D as a percent of sales has increased consistently from 14.6% in 2011 to 16.9% in 2023, according to an EY analysis of CapitallQ data for the top 25 biopharma companies.

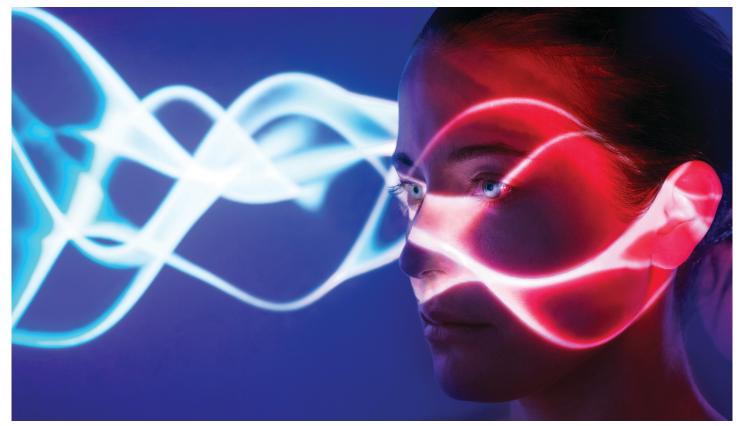


Figure C: Average R&D spend of the industry has increased from 14.4% to 16.9% in the last 12 years



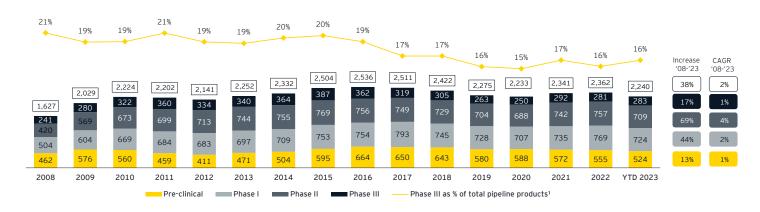


The increasing complexity of advanced medicines and investment in treatments that do not end in success make R&D more expensive.

Longer development times and a tripling of costs for developing new prescription medicines that gain market approval are also weighing on productivity. Over the last decade, even though the number of candidates entering preclinical and phases I and II at the top 25 biopharma companies has grown by 1%-4% CAGRs, phase III candidates have declined by 1% and the share of phase III candidates in the pipeline has fallen from 19% in 2012 to 16% in 2022, according to Evaluate Pharma (Figure D).

Figure D: The clinical trial pipeline

## Number of products in clinical trials - Historical years\*



Source: EY Analysis, Evaluate Pharma

Note: ¹Represents pipeline data for key 25 pharma companies analysed in the deck, as sourced from Evaluate Pharma; ²Represents Ph III as % of Ph I + Ph II + Ph III assets.

## Benefits of an ecosystem approach

Life sciences executives understand that an ecosystem model can provide significant advantages over traditional business approaches, according to the Ecosystem Study, which included more than 100 life sciences C-suite executives. These advantages include:

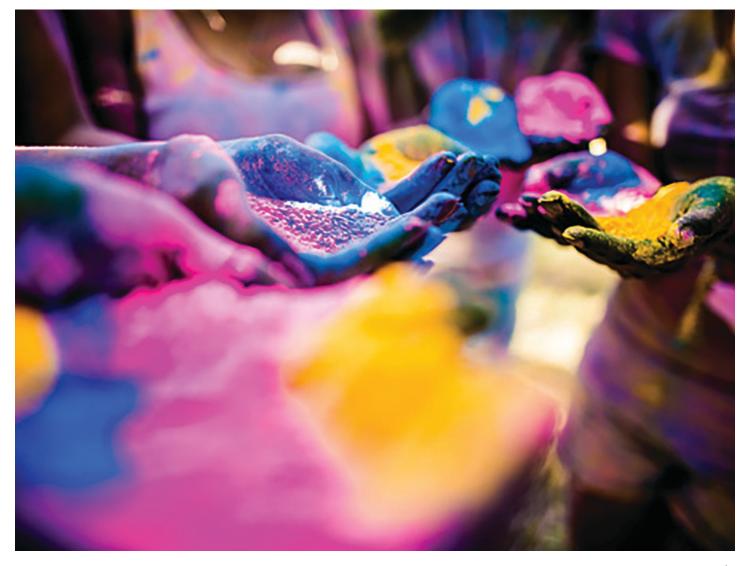
- Increasing efficiency and reducing costs (59% of life science executives surveyed)
- Creating new, joint products (54%)
- ► Fostering creativity and innovation (55%)

Specific to R&D, executives believe the advantages of an ecosystem approach are:

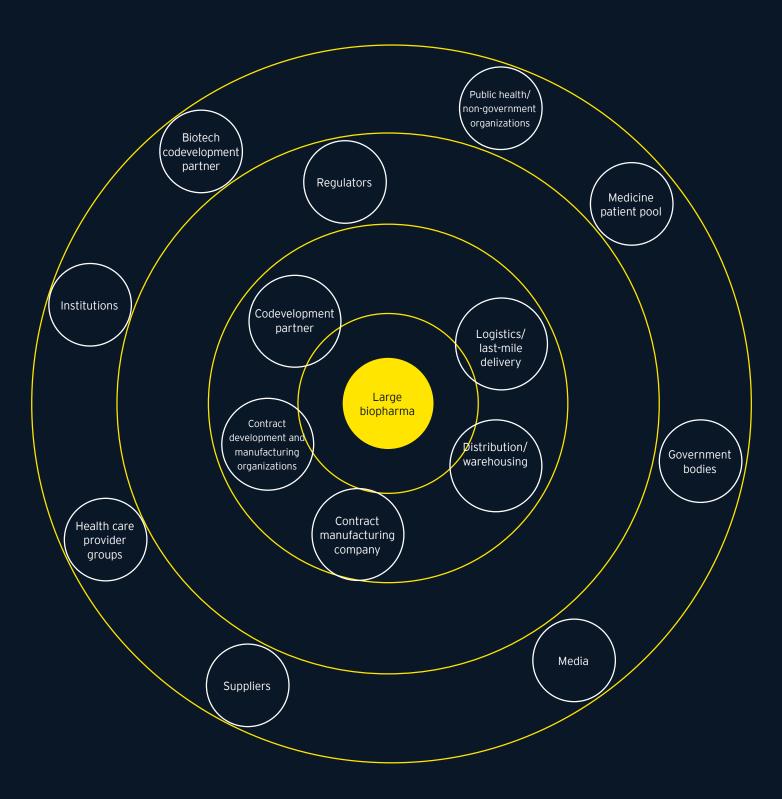
- Greater access to talent (60%)
- ► Improved likelihood that R&D will be successful (58%)
- ► Sharing of R&D assets such as labs and testing facilities (55%)

## What is a biopharma ecosystem?

Ecosystems are business arrangement between two or more entities designed to create and share a higher level of value collectively for a common set of customers than the members can create individually considering time, capital, brand permission, market access and other real-world constraints. An example of participants in an ecosystem could be big pharmaceutical companies that bring access to knowledge, resources and technical expertise, as well as the ability to drive commercialization; smaller biotechs that may have novel R&D; contract research organizations to conduct trials; contract development and manufacturing organizations (CDMOs) to help produce the drugs; and tech companies and data providers for sharing the right information at the right time with patients, caregivers and providers.



# Vaccine ecosystem example



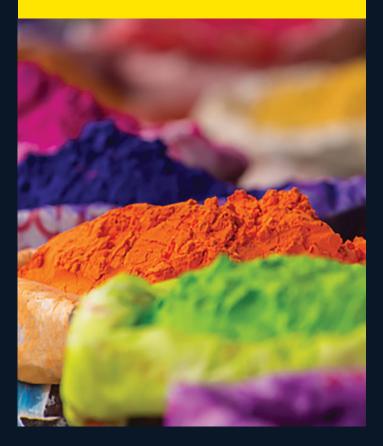
According to the EY <u>Ecosystem Survey</u>, high-performing ecosystem relationships contribute significant value to the company and drive enterprise performance. They do this by:

- Building better growth opportunities
- Improving R&D leverage through access to assets, skills and ideas
- Increasing capital leverage by creating higher-value opportunities

## How to make an ecosystem work

There are several industry-leading practices identified in the Ecosystem Study that life sciences executives can adopt.

- Regular C-suite or board-level review of ecosystems
- Having a corporate function dedicated to track progress
- Having a business development function that identifies potential partnerships
- Having a dedicated ecosystem budget
- Operating ecosystems as a distinct line of business
- Designating one person to have clear ownership of cultivating and managing ecosystems



#### Actions life sciences execs can take now

Life sciences executives can consider the following steps as they build an ecosystem mindset.

- 1. Build robust and agile ecosystems to support alliances and M&A. While M&A is still a key tool for acquiring innovation, ecosystems can offer higher-growth opportunities (53%), faster execution (50%) and better outcomes (50%), according to life sciences executives. Companies can start to build strong ecosystems by establishing an ecosystem development function with a dedicated budget. C-suite or board-level review is also essential, and companies may also bring in a third party to manage the ecosystem.
- 2. Go early with alliances with an option for Phase II assets. As mentioned, ecosystems offer significant advantages over traditional R&D by providing greater access to talent and expertise as well as mitigating risks by reducing cost and accelerating time to market. As such, they increase the return on R&D investment. Entering into alliances for promising assets early with an option to acquire at the Phase II stage could provide a good balance between risk and return, maximizing the value of assets versus developing them in-house. For the treatment developer, linking with a larger company can provide the scale and commercial capabilities to bring a drug to market.
- 3. **Don't neglect traditional M&A.** While an alliance approach can help shrink the innovation deficit, pressure to do M&A will accelerate as patents expire in 2025-2027. The pace of deal-making has seen a decline since 2020, and the year 2022 saw the lowest M&A in terms of value in the last several years; while firepower, a company's capacity to fund transactions based on the strength of its balance sheet, in biopharma has remained near record levels, exceeding US\$1.47trillion. In 2020 and 2021, biopharma companies had the luxury of employing a watchful, waiting approach. However, with pipeline replenishment diminishing beyond 2022 and the innovation deficit widening by 2025, companies need to increase their deal-making to maintain and sustain long-term growth.

### Conclusion

This study suggests major biopharma companies will be challenged to meet their growth objectives if they rely too heavily on their internal R&D alone. Taking an ecosystem approach that fosters alliances and M&A with companies producing early-stage products, digital investing and technology can help close the innovation gap that big biopharmas face in coming years.

## Methodology

The EY Ecosystem Survey 2021 draws on insights from over 800 professionals in top management or C-level roles, including 100 respondents from the life sciences industry, to understand their current ecosystem relationships and the inherent advantages and challenges faced in maintaining them over the years.

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