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Ecosystem of Growth

Why it's important for biopharma to consider alternative ways to expand their business in an ever-changing landscape

By Elaine Quilici

"No man is an island," John Donne wrote in 1624. Though society has changed much over the past four centuries, the quote remains relevant, especially when it comes to drug companies trying to grow their business. In the complicated landscape of pharma and biotechs looking for support in their drug development, the two entities are linked not just to each other but to the market at large. As a result, understanding market dynamics, preparing for the unexpected, figuring out where funding is available, and thinking outside the box have become necessary.

Balancing act

Since emerging in the mid-1980s, biotechs have become a major source of new drug development, bolstered by pharma's weak productivity in R&D more recently. Though some biotechs might tackle regulatory, manufacturing, and sales functions, most still look to forge a relationship with pharma at some point to get their product to market. This might mean securing a partnership or licensing agreement, or getting acquired. Although partnering with a pharma company offers important business and financial benefits, a biotech might alternately look to the stock market (IPOs and secondary offerings) and venture capital firms for funding.

PHARM EXEC'S ANNUAL INDUSTRY OUTLOOK

OUR TRENDS FOR '20

- Financial Runways: Biotech
- Oncology Pipeline Path
- Talent in Pharma
- Smart Voice Technology
- Cell and Gene Cascade
- Data Ownership
- Emerging Markets: MIST

There is a strong relationship between M&As, IPOs, and funding. If the IPO market dries up and venture investments slow down, biotechs depend more on partnerships and exiting via a sale of the company. On the other hand, if the IPO market is robust and venture capitalists are investing generously, biotechs don't have to look to pharma as aggressively.

Overall, the IPO market has been strong for many years. Young & Partners recently reported that during the first three quarters of 2019, 38 IPOs were completed worth $4.3 billion, compared with 50 IPOs worth $4.9 billion in the first three quarters of 2018 (see chart at right).

"We've also had a period where venture capitalists were very interested in biotech," says Peter Young, CEO and president of Young & Partners, and *Pharm Exec* Editorial Advisory Board member. "That allows the biotechs to wait a little longer before they have to either sell or partner."

The number of acquisitions also declined in 2019 for biotechs. After a modest surge in 2018, the volume dropped from $35 billion to $14 billion in the first three quarters of 2019, and there was only $5 billion in deals announced but not closed as of Sept. 30, 2019 (see chart on page 14). The strength of partnering activity and access to venture and public equity funding contributed to this decline.

Acquisitions of pharma companies follow a different drumbeat as companies acquire for strategic, geographic, and revenue-preservation reasons. Young & Partners indicated that the number of M&A deals for pharma through the first three quarters of 2019 were lower than 2018. The volume of pharma deals, however, was much greater—$26 billion in 2018 vs. $80 billion for the same time period. This demonstrated a pickup after years of decline. However, $62 billion of the $80 billion was Takeda's acquisition of Shire. This transaction may portend more mega deals, with Bristol-Myers Squibb's acquisition of Celgene ($99.6 billion) and AbbVie's purchase of Allergan ($86 billion) announced but not closed as of Sept. 30.

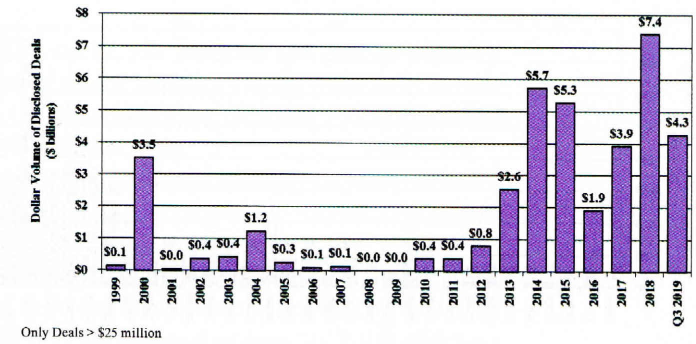
Another change in the biotech-pharma relationship that's worth noting is the shift toward orphan drugs. These drugs require a much smaller salesforce and shorter approval process, and, therefore, much less funding, reducing a biotech's need for pharma companies.

"[These elements are] a positive for the biotechs and a negative for the pharma companies, in relative power," says Young. "But there are signs of some weakening in the IPO markets, which will tip the scales again. That will obviously have a negative impact on venture investing."

Biotech IPO Glance

Worldwide Biotechnology: Dollar Volume of IPOs

- IPO dollar volume in the first three quarters of 2019 was strong, but slowing down versus 2018 on an annualized basis.



Only Deals > $25 million

Source: *Young & Partners*

Ready for anything

As these overlapping elements create an ever-changing environment, it's best for companies to be prepared on many fronts when deciding how to grow.

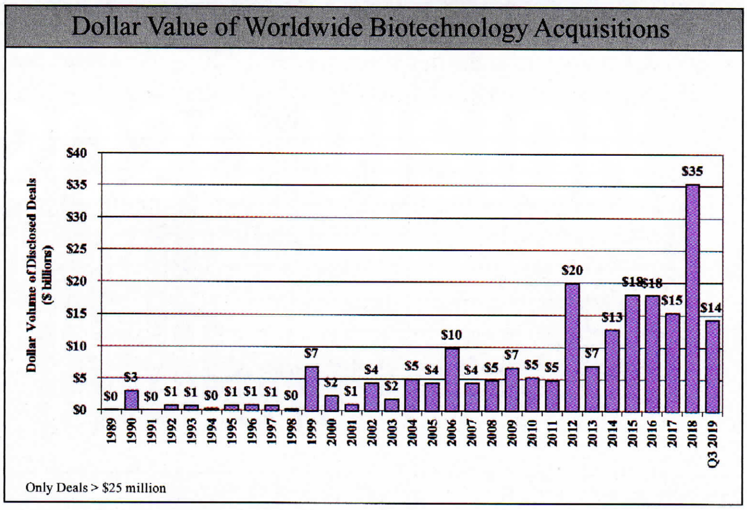
"I think it's impossible to just have one plan and stay with it because there are so many things you cannot control or predetermine what the outcomes will be," says Young. "There's no way to know [how long] the IPO market is going to be strong. You can't have a plan that says, 'Our only plan... is to do an IPO in two years,' because that would be foolish."

Young also says to beware of fads. "Everyone got really excited about CRISPR, and then there were safety issues and some negative press, and all of a sudden it went out—now maybe it's coming back. Those are the things you can't tell."

Jigar Raythatha, CEO of Constellation Pharmaceuticals, learned the importance of having a plan B the hard way. In a *Pharm Exec* podcast (see https://bit.ly/2rnoxXD), Raythatha explained how his biotech was blindsided when its one-and-only plan to partner fell through. After Genentech struck a deal with Constellation, it shifted its strategy and didn't follow through on the acquisition.

"You can probably, in retrospect, call it a mistake," says Raythatha. "[Constellation] had developed the company in a way to kind of hand over the rein. Unfortunately, lesson learned, the company didn't have a plan B." It took Constellation about a year to regroup and develop a new plan.

Biotech M&A Slowdown



Source: *Young & Partners*

"It's important to contingency plan and not necessarily to the same level of planning in each scenario, but thinking through what do you do if your key assumptions don't pan out," says Raythatha. "To have the ability to move into a new direction without having to completely reinvent the wheel, I think is quite important."

> "We've always made sure we have plans B, C, and D in our back pocket in case we need them."

Raythatha believes key stakeholders should be in alignment on major decision points. They should consider market shifts and discuss the company's possible responses to those scenarios. Once that basis is established, the company should be adaptable to quickly flesh out a new plan of action, if needed.

Internal issues, such as toxicity, safety, or manufacturing problems, also can derail a plan. Millendo Therapeutics sustained two clinical setbacks that forced the company to adapt. (For details, listen to *Pharm Exec* podcast episode 46 at https://bit.ly/2SkHMfq.)

"Ever since our first major corporate pivot, our overall goal is to have a pipeline of treatments in endocrine disease, such that if one drug failed, we didn't have to start from scratch," says Millendo co-founder and CEO Julia Owens.

When negative results emerged once again in a separate drug trial, Millendo was already in conversations with Alizé Pharma, and with the right team, money, and skills in place, Millendo was prepared to merge.

"We did two complex mergers and two financings in under 12 months," says Owens. "That's really hard to pull off. But we've always made sure we have plans B, C, and D in our back pocket in case we need them."

Owens' business development background has been helpful in navigating Millendo's deals. For companies that lack such insight, hiring an alliance manager can add value. Lucinda Warren, vice president of business development, neuroscience, Janssen Business Development at Johnson & Johnson Innovation, spoke at the Association of Strategic Alliance Professionals' European Alliance Summit this past November. She described an alliance manager as the "conductor of the orchestra."

The position, whether in-house or outsourced, can provide big-picture oversight and targeted expertise in creating a plan, being proactive, and providing follow-through.

Outside the box

It's important to include a mix of partnering pathways in a company's master plan, not just traditional alliance routes. Sebastian Guth, president of pharmaceuticals in the Americas Region for Bayer, shares his long-term goals in an executive profile on page 32. Though partnering with academic institutions and collaborating with biotechs might sound typical, Guth's overall vision is driven by innovation, evident in Leaps by Bayer, a division that invests in breakthrough ideas.

"We are at an inflection point where breakthrough science is transforming care almost daily," says Guth. "Bayer had to make a clear choice between pushing the boundaries of science, investing in the big bets, or staying in the here and now. And we've made our choice and are convinced that science and innovation are the way to go. In many ways, the decisions that we have made are already being reflected in our portfolio and pipeline today."

With an open-minded outlook such as this and keeping a pulse on the everchanging ecosystem in which biotech and pharma exist, companies can forge ahead with confidence to grow their business. PE

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