Licensing Lifeline:

One Strategy for Catching Up After the Quarantine Pause

- Biotech leaders are starting to confront the long-term consequences of COVID-19 on their businesses
- While those with relevant technologies are sprinting to contribute solutions for testing, treatment, and prevention, others must wrestle with reduced access to providers and delayed clinical trials
- Because biotech companies are often intentionally funded only to the next value catalyst, even relatively modest changes to schedules provoke potentially devastating consequences
- Many leadership teams are turning to licensing as a funding lifeline
- Success in using licensing to bridge funding gaps in the available timelines will require operating with dedicated preparation and unprecedented focus

A Challenging Quarter that Could Undermine Years of Careful Plans

After eight weeks of stay-at-home and quarantine orders, biotech leaders are starting to confront the long-term consequences of COVID-19 on their businesses. For a small share of the industry, there has been a need to shift attention and resources to technologies with the potential to directly influence the prevention, diagnosis, or treatment of the virus. The rest are faced with the need to evaluate the consequences of abrupt changes to the landscape of their operations. Further, they must assess whether a new stability has been established, or if the remaining uncertainty means layers of contingency planning is needed.

Most biotech companies live in a pre-profit state. They create value by moving through milestones that are designed to increase confidence in future commercial success. Rather than gradual changes, key events including early laboratory results, clinical program readouts, regulatory outcomes, and reporting on initial commercial performance drive valuation step changes. Whether private or public, financings are structured to support achievement of the next "catalyst" event, but with little additional runway. Why overfund the company through any one rung on the valuation ladder—better to limit support early and replenish reserves when the cost of that funding has been reduced.

Moving from one catalyst event to the next makes great sense when the environment is generally stable, but it places leadership teams in truly precarious circumstances when navigating through wide-ranging upheaval. No matter how quickly society is able to return to a pre-COVID-19 normal, biotech leaders will need to fill the gaps associated with clinical trial delays, reduced access to health system leaders, and patient reticence to seek health services.

Unfortunately, there is little cushion in biotech's cash reserves to absorb the interruptions. As indicated by the BIO industry organization's tracking in earlier times of financing uncertainty, one third of public biotech companies may be operating with less than a year of cash on hand. Private companies often work even closer to the funding precipice.

Finding Funding—Does Licensing Preserve the Most Value?

Many leadership teams have now completed an initial assessment of the situation, and they are wrestling with the challenge of reaching a delayed catalyst event. They have taken some very painful steps to preserve cash, but they still see a path that is likely to extend beyond their available resources.

Filling the gap with equity sales may not be impossible, but without the benefit of the target catalyst event, the cost of that investment is likely to exceed the company's most recent round (whether public or private). With confidence in the company's programs unchanged, existing investors are calling for management teams to identify alternatives.

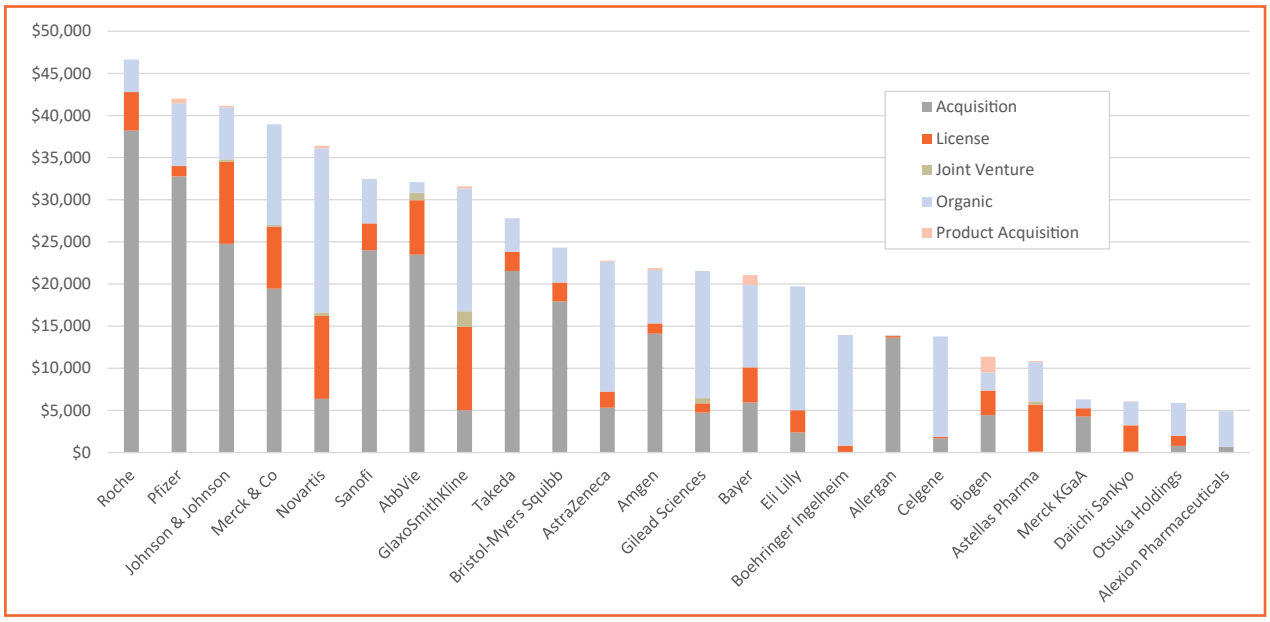
Assessing a landscape with few good options, teams have tried to identify approaches that access the required funding while preserving as much of the company's value as possible. Many have turned to licensing as the "least bad" option. Licensing has the potential to hive off a selected portion of value (isolated to one product, one geography, or one application), but leadership teams should be realistic about the time, effort, and potential returns an accelerated licensing program may offer.

Licensing in Normal Times

Licensing is a well-established component of biotech's strategic arsenal. In earlier times, emerging companies often funded the development of innovative technologies through a series of regional deals or applications of platforms to selected opportunities. Large pharma partner organizations provided valued technical and regulatory capabilities as well as access to otherwise inaccessible markets. As shown in Figure 1, the largest pharmaceutical companies received an average of 15% of their 2019 revenue from licensed assets.

There is a caution, however. Although licensing is an important part of the biotech landscape, deals with large up-front payments, the near-term fees that are needed as a bridge to the next catalyst, are the exception rather than the rule. Figure 2 shows the distribution of disclosed up-front payments for deals that occurred between 2015 and Q1 2020. Only 13 of 38 deals for

Figure 1. Source of 2019 Large Pharma Revenue



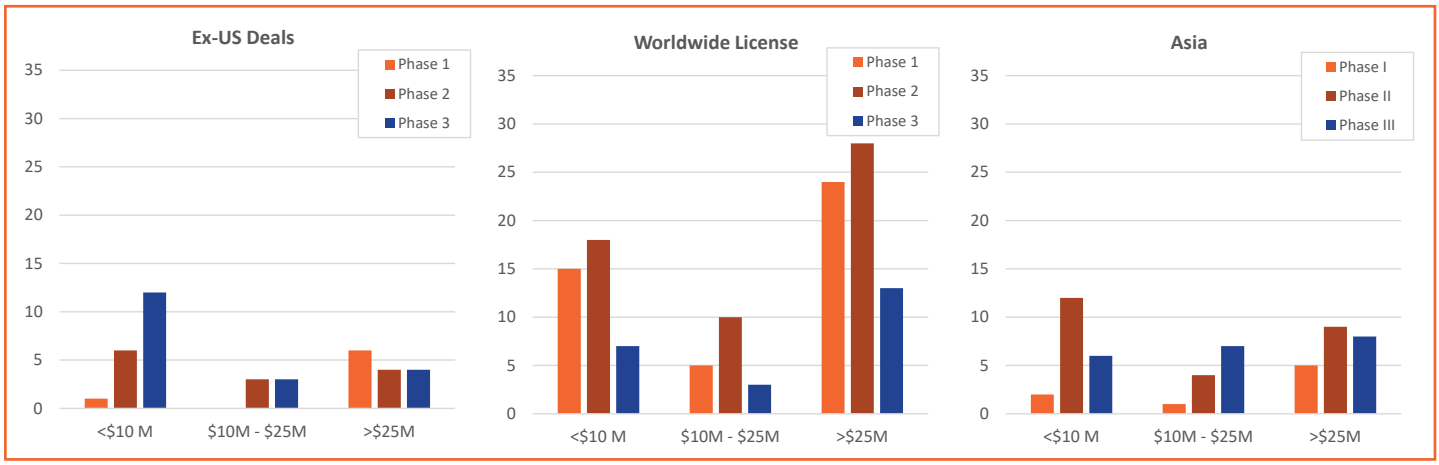
Source: Evaluate Pharma

ex-US rights achieved an upfront payment of more than $25M. Slightly more than half of the global licenses had an upfront above that threshold.

Those companies with large financial gaps to fill are likely to decide that licensing is not the most efficient source of liquidity. However, others may find that a transaction designed around selected geographies or covering only a nonessential program can provide the right balance of preserving participation in a program's upside while accessing the needed funds to retain the organization's core.

Even in the best of times, licensing programs require careful planning and focused execution. The current changes to communications and systems for governance decision making will pose additional challenges. Biotech leaders and their targeted partners will need to demonstrate flexibility and resilience to complete these deals. With this in mind, the following action steps are offered as guidance for companies pursuing a licensing strategy amid an industry that has been forced to adopt new ways of approaching these transactions.

Figure 2. Upfront Payments for Deals Completed Between 2015 and Q1 2020



Source: Evaluate Pharma

Leadership Team Action Steps:

1 BE SPECIFIC AND PURSUE THE RIGHT DEAL

In normal circumstances, deal makers are encouraged to be creative when outlining a proposed transaction. Allowing a higher degree of freedom presents more opportunities for negotiation and, presumably, a greater chance of finding the right deal mix. The downside of this approach is the increased time that is required to review and negotiate alternative deal terms. With a goal of covering a near term financing gap, out-licensors should be as specific as possible in describing the opportunity that is being made available.

2 DESIGNATE A STEERING COMMITTEE

Even when conducted under a sense of urgency, licensing deals are complex. Multiple layers of decision-making authority can slow down the process as each party probes specific concerns. To meet the currently required timelines, leadership teams will need to designate a multi-functional task force to get the deal in place—and the board should rely on a steering committee with authority to keep the process moving forward. Of course, the final transaction will need to follow established governance processes, but the deal journey will be accelerated if interim decisions can be made by a trusted team that is not subject to questioning or censure from other voices.

3 RECOGNIZE THAT THERE IS A COST OF HOLDING ON

A key benefit of licensing for the out-licensor is the continued participation in the upside potential of the program. That means the near-term value can be limited. Depending on the nature of the asset, in-licensors may design a deal that captures for them 40 percent to 60 percent of the program's anticipated value. For an early stage asset, the out-licensor may be ceding 60 percent of the asset's value to the partner—and the up-front payments may only be 20-30 percent of that of that. So, a company relying on out-licensing to fill the need for a $25M gap may need to identify an opportunity with risk-adjusted expected value of $200M.

4 PREPARE WELL

There is a familiar process to out-licensing programs. They begin by drawing up a list of potential partners who are likely to find the subject asset relevant. Then, an outreach is conducted where non-confidential information is provided. Often, those initial contacts are made as content for a confidential electronic data room is being gathered. In the current circumstances, the momentum must be maintained from the time a partner expresses a level of interest, confidentiality documents are drawn up and meaningful diligence can begin. The confidential electronic data room should be in place and fully populated in advance. Thus, the licensing program benefits from the initial enthusiasm that exists as the partner begins consideration of the opportunity.

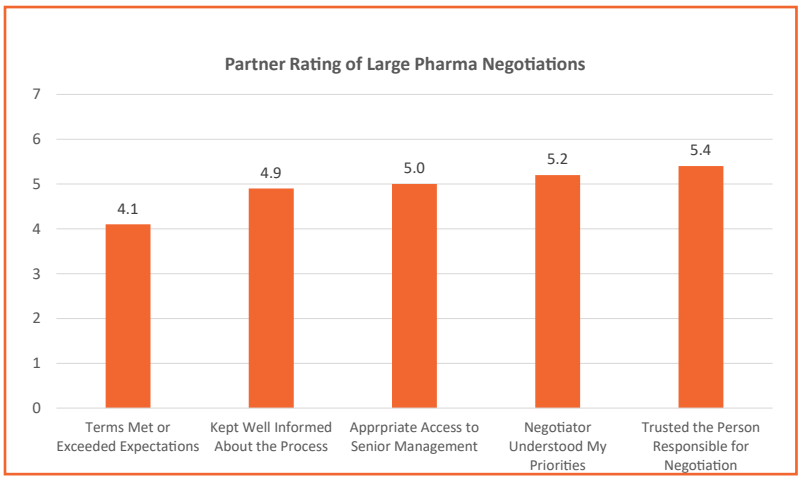
5 PROACTIVELY ADDRESS ANTICIPATED CHALLENGES

Whether it is an early safety signal, a potential competitive challenge, or still-forming IP protection, most biotech programs have known areas of risk. Licensing teams tasked with completing a deal within an aggressive timeline cannot count on potential partners to form their own views on those issues. The team should form potential strategies for resolving each of the anticipated challenges and prepare packages that offer a roadmap to the partner on actions that will drive resolution of the issue. Further, negotiators should be prepared to outline specifics on the responsibility each organization will hold for the action plan once the deal is completed.

6 EMBRACE DIGITAL INTERACTIONS

Stay-at-home requirements and subsequent travel restrictions have upset the very core of business relationship building. There is no question that personal interactions and shared experiences drive the trust that is at the heart of successful partnering negotiations. The biotech industry has formed an extensive and successful infrastructure for building those relationships. In fact, in Triangle Insight's 2018 partnering survey, we found that out-licensors expressed an extremely high level of trust in the individuals with whom they had completed a recent transaction (see Figure 3).

Figure 3. Negotiating Performance of Large Pharma Organizations



Source: Triangle Insights Group 2018 Partnering Performance and Reputation Survey

Unfortunately, much of the dealmaking infrastructure centers on an annual calendar of scientific and business meetings. In 2020, those sessions have been forced to adopt a digital format. Teams that are counting on a near-term completed transaction are going to need to make the digital format work. This is going to mean acting as much like a sales team as a licensing team. They will need to go out of their way to identify shared points of interest and personal contacts. Where possible, some discussion rosters should be expanded to include attendees who have previous personal experience with individuals from the partner organization. As much as possible, an expectation should be set to include video in these interactions. Finally, many of the desired transactions are going to target individual geographies. Balancing the time zone inconveniences builds rapport, and including representatives with native language skills wherever possible can help avoid delays associated with miscommunications.

7 PURSUE MULTIPLE OPTIONS IN PARALLEL

Changes to the biotech business landscape and healthcare delivery environment will continue to occur in the coming months. At best, management teams can identify and prioritize options within what is known at any given time. This means the timing for cash needs may continue to change and the timing for pursuing financing alternatives will remain uncertain. Moreover, deal negotiators cannot allow themselves to be in a position where a potential partner can readily recognize that the company is becoming increasingly desperate. A licensing solution may be a priority, but it cannot be the only approach pursued. Leadership teams need to adopt a multipronged approach that includes traditional financing, debt programs, and asset sales along with licensing.

Closing

Most experienced licensing executives will report that deals regularly take a year or more from the initial contact to a completed transaction. Closing a deal in six months is a true exception. However, as leadership teams now evaluate the altered realities of their path to a catalyst event, many are seeing licensing as the most attractive option for extending a cash runway without capitulating to down round valuations. Success will only be possible with a highly professional process and decision-making procedures that recognize an appropriate sense of urgency. As with so many personal and professional matters affected by COVID-19, biotech executives must express a we'll-get-through-this confidence. Getting to that point will require finding the best option in many circumstances when none of the choices are truly desirable. Licensing may be the option that some of these leaders find most palatable.

About Triangle Insights Group

Headquartered in Research Triangle Park, Triangle Insights Group, LLC is a strategy consulting firm providing guidance on the most critical business issues to leaders in life sciences organizations. The firm's approach combines deep knowledge of the industry across therapeutic areas and functional groups, with a dedication to creativity and disciplined critical thinking. Recommendations from Triangle Insights Group are original, relevant to the industry environment, and supported by rigorous analytics. Clients of Triangle Insights Group include large pharmaceutical companies, emerging biotechnology firms, diagnostics manufacturers, medical device companies, and private equity investors.

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Has thirteen years of pharmaceutical and consulting experience. Gautam focuses on providing strategic guidance to clients within life sciences organizations. His recent engagements have involved commercial assessment, indication prioritization, white-space strategy, commercial model design and in-licensing/out-licensing support.

Gautam has provided strategic advice to a wide range of clients, spanning Top-5 pharmaceutical manufacturers, emerging biotechnology manufacturers, bio-pharmaceutical investors, and service providers to bio-pharmaceutical companies. He has spoken at several industry conferences (LES, CED, EBD, BIO-Windhover, CHLA, Banff Venture Forum) and has published a peer-reviewed article on deal timing.

His previous employers have included GlaxoSmithKline, Boston Consulting Group and Campbell Alliance, where he was a Senior Practice Executive and led business/corporate development efforts for the central region. Gautam received his M.B.A. from the Fuqua School of Business at Duke. He holds an M.S. and a B.S. in Bio-Statistics from UNC-Chapel Hill.

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Chris has worked as a Senior Practice Executive with Campbell Alliance where he led the company's Business/Corporate Development efforts for the NY and NJ region. His recent management consulting experience has centered on corporate strategy and market opportunity assessments for life science companies and investors.

While at GlaxoSmithKline, Chris's scientific accomplishments led to multiple patent authorships and peer-reviewed publications, as well as discoveries resulting in over $30 million in company cost savings. In business development roles, Chris was responsible for corporate strategy and reviewing in-licensing and out-licensing opportunities. Chris earned an M.B.A. from the University of North Carolina Kenan-Flagler Business School as a member of Beta Gamma Sigma academic honor society. He has an M.S. from the University of Buffalo and a B.S. in Biochemistry from the University of Rochester.

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Recent by-lined articles have appeared in Pharmaceutical Executive, InVivo, Nature Biotech, RPM Report, and Scrip. In addition, Ben's case studies on the pharmaceutical industry have been used in graduate business programs.

Ben is the chairman of the Life Sciences Sector of the Licensing Executive Society. He has also been a member of the program committee for the BIO International Convention. Prior to the founding of Triangle Insights Group, Ben was the leader of the Business Development Practice at Campbell Alliance and a partner in the Strategy practice at Oliver Wyman (formerly Mercer Management Consulting/Strategic Planning Associates). Ben earned an M.B.A. from the Stanford Graduate School of Business and a B.S. from Duke University.

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Barrett's previous management consulting positions in the life sciences industry were with Campbell Alliance and Boston Healthcare Associates. He also founded an independent life sciences consulting firm prior to the founding of Triangle Insights.

His background also includes client-side experience within the pharmaceutical industry. For plasma manufacturer Grifols Therapeutics (previously Talecris), Barrett led market intelligence for the pulmonary franchise including Prolastin-C, an orphan drug indicated for alpha-1 antitrypsin deficiency. Barrett received his M.B.A. from the Tuck School of Business at Dartmouth College. He holds a B.A. from the University of Virginia. He has been a lecturer at several life science industry conferences.