



External innovation

How biopharma companies are bolstering R&D pipelines through deal-making

A report from the Deloitte Center for Health Solutions

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Introduction

MANY biopharma companies, in pursuit of a balanced portfolio and a robust development pipeline, are increasingly sourcing research and development (R&D) assets externally. In fact, the proportion of biopharma revenue generated by drugs sourced from other companies rose from 41 percent in 2005 to 50 percent in 2014.¹ As biopharma companies seek such external deals to source assets for innovation, in general, they have three structuring options: licensing, mergers and acquisitions (M&A), and joint ventures (JVs) (figure 1).

The differences between these types of deals are not always clear cut; some deals may include elements of other types. But what factors should companies examine when deciding what type of deal to pursue, and do deal types differ in the ways they accelerate development and deliver long-term value? In this article, based on an analysis of almost 3,000 biopharma deals over the past decade, we evaluate the pros and cons of each deal type, present research on their relative success rates, and offer some reasons for success or failure. (See the appendix for more information on our research methodology.)

Figure 1. Three main types of external innovation



Licensing

The licensor firm grants rights to another firm to produce and/or sell a product. The licensee pays compensation to the licensing firm in return for access to intellectual property or technical expertise.²



Merger & acquisition (M&A)

M&A refers to the acquisition or merger of companies or assets. In an acquisition, the acquiring firm can control more than 50 percent of a target firm's equity.



Joint venture (JV)

In a joint venture, an association of two or more individuals or companies engage in a separate business enterprise for profit.³

Source: Deloitte analysis.

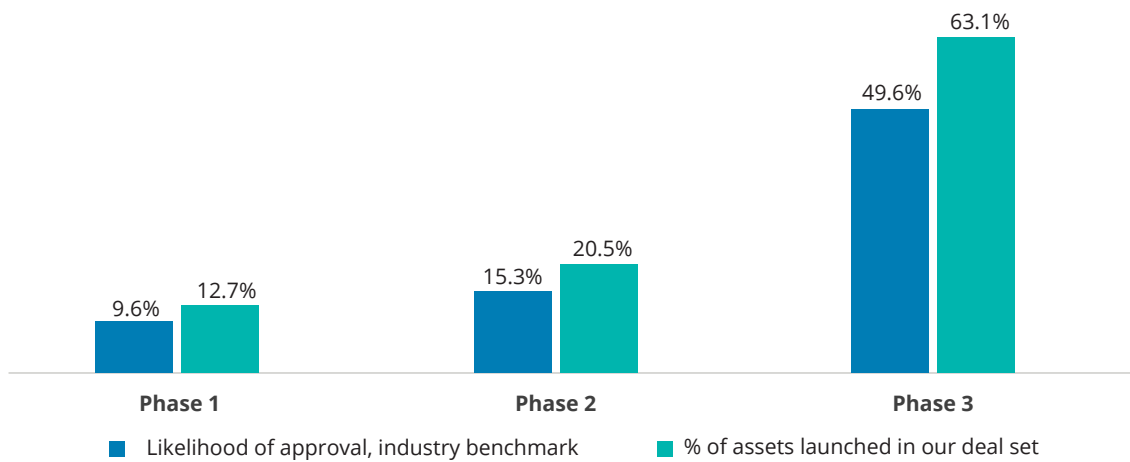
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Why pursue external innovation?

THE rise in external innovation among biopharma companies could help companies turn around decreasing returns on R&D efforts overall. According to Deloitte research, returns on biopharmaceutical innovation have declined from 10.1 percent in 2010 to 3.7 percent in 2016.⁴ Further, biopharma assets sourced via open innovation approaches are three times more likely to be success-

ful than those sourced via traditional approaches.⁵ An analysis of our current data set confirms that launch rates among externally sourced drugs are consistently higher than the industry benchmark noted by Biomedtracker, which analyzes the likelihood of approval (LOA) for internally developed and externally sourced drugs across therapeutic areas (figure 2).

Figure 2. Externally sourced assets' launch rates are higher than industry benchmarks (2007–2016)



Source: Deloitte analysis of Cortellis Deals Intelligence, March 2017; “Clinical development success rates 2006–2015,” Biomedtracker, Biotechnology Innovation Organization (BIO), May 2016.

Licensing and JV outperform M&A when it comes to progressing assets through development phases

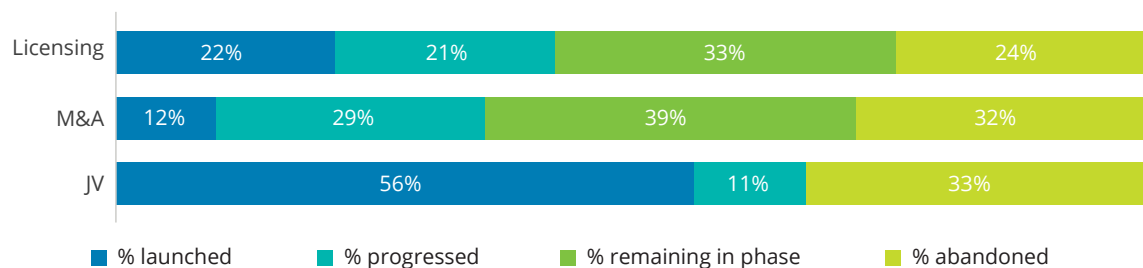
DO biopharma companies tend to prefer one deal type over others in R&D? Our research indicates a resounding “yes.” Among the transactions we analyzed, licensing was by far the most prevalent approach, comprising about 93 percent of the deals in our data set. M&A came in second at 6 percent, while JVs made up just 1 percent of the deals.

When we looked at success rates among the three types of deals—that is, the likelihood that an asset would launch or progress—licensing and JV deals appeared to enjoy higher success rates than M&A. We evaluated the first five years of our data set to allow sufficient time for assets to progress in

R&D. For deals executed between 2007 and 2012, a greater percentage of assets sourced through licensing (22 percent) and JVs (56 percent) made it to market than assets sourced through M&A (12 percent) (figure 3).

We also evaluated the frequency with which assets progressed out of the phase at which they were sourced. Here, too, licensing agreements were more likely to progress than M&A ones (figure 4). Phase transitions and progression are crucial measures to assess if assets are advancing toward launch, remaining in phase, or are discontinued or suspended following the deal.

Figure 3. Assets sourced via licensing and JV were more likely to launch and progress in R&D as compared to M&A over 2007–2012



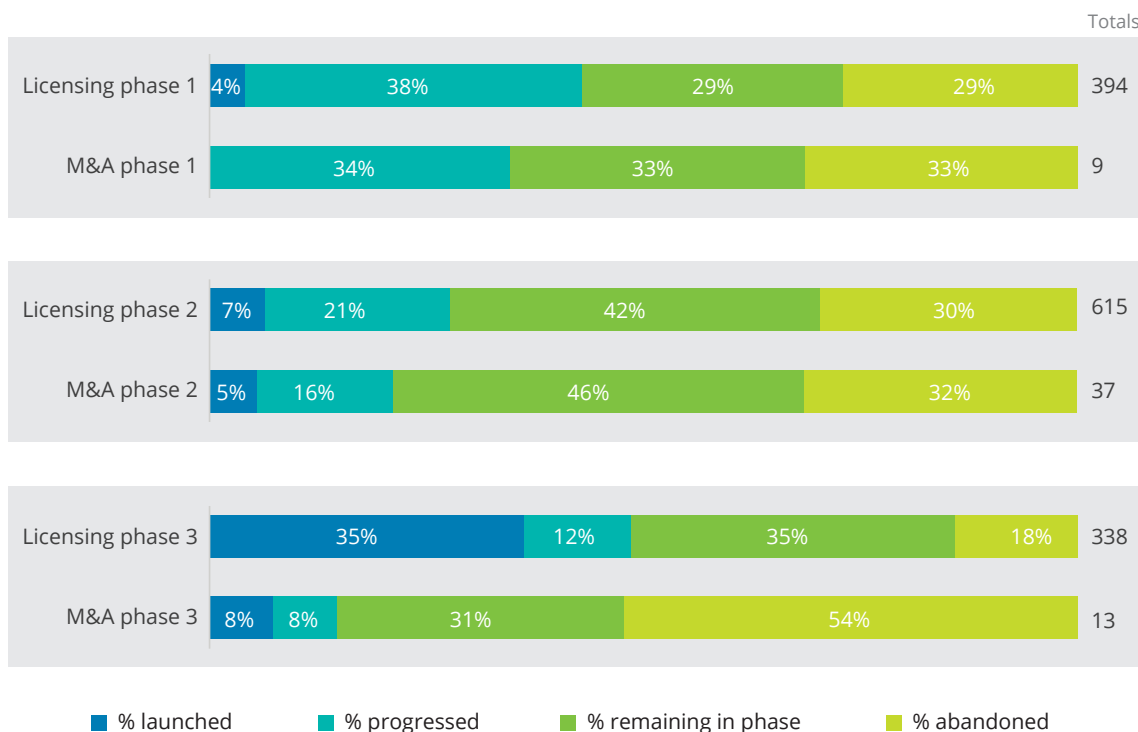
Note:

- Total deals: 1,699 (licensing 1,621; M&A 69; and JV 9).
- “Launched” refers to products that made it to market.
- “Progressed” refers to assets that advanced to the next phase of research and beyond.
- “Remaining in phase” refers to assets that are reported to be in the same phase as when sourced.
- “Abandoned” includes drugs for which no development was reported, or where information on current development status was not available.

Source: Deloitte analysis of Cortellis Deals Intelligence, March 2017.

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Figure 4. Licensed drugs were more likely to progress to the next phase compared to those acquired through M&A over 2007–2012



Note: Due to the small number of total JV deals (9) over this time frame, they are not included in this comparative analysis.

Source: Deloitte analysis of Cortellis Deals Intelligence, March 2017.

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WHY PURSUE SINGLE-ASSET TRANSACTIONS, AND WHAT ABOUT MEGAMERGERS?

Our analysis compares licensing with single-asset M&A only. We evaluated deals in our data set working under the assumption that the buyer’s rationale for pursuing the deal is to advance innovation. However, some single-asset transactions could be pursued for different reasons. For example, a company may seek to acquire an asset to thwart a competitive threat, or a buyer’s interest may lie in the acquisition of key talent and capabilities rather than a specific asset. In these situations, success may be defined differently than asset progression through R&D to market.

It is also important to note that our data set excludes deals where multiple assets are involved. Assets acquired as part of a portfolio might outperform the single-asset deals we evaluated, but these were not considered as part of our analysis.



The differences in success rates raise some interesting ideas about how deal strategy impacts R&D execution.

COLLABORATION COULD BE THE KEY TO SUCCESS

Our data suggests that greater collaboration and commitment to a drug's success lead to progression in development and a greater likelihood of launch. Licensing involves working with a licensor that is committed to the continued success of the asset. This helps create accountability for both the licensee and licensor to hit key milestones. In M&A, if the strategic focus of the acquiring company changes, assets could linger in development pipelines without being progressed or terminated, especially in phase 1 or 2.

Our data suggests that greater collaboration and commitment to a drug's success lead to progression in development and a greater likelihood of launch.

M&A MAY BE MORE DISRUPTIVE THAN LICENSING

Key talent or capabilities could be lost in M&A transactions, potentially disrupting R&D. The acquiring company might underestimate the integration demands of an acquisition compared to a transformative megamerger. Thoughtful post-merger integration planning—including dedicating sufficient resources to execute the plan—could increase the success of acquired assets.

ACQUIRERS MIGHT BE MORE DECISIVE THAN LICENSORS IN TERMINATING DEVELOPMENT PROGRAMS

Abandonment does not always equal failure: Terminating programs with a low likelihood of commercial success saves companies from making additional investment that will not generate a return. According to our research, a higher percentage of development programs sourced via M&A were abandoned across phases than those via licensing. This could suggest that acquirers are more willing to terminate development programs that are not likely to be successful. Licensors may struggle to gain consensus with licensees to make the same hard choice.

DEAL STRUCTURE COULD REFLECT ASSET VALUE

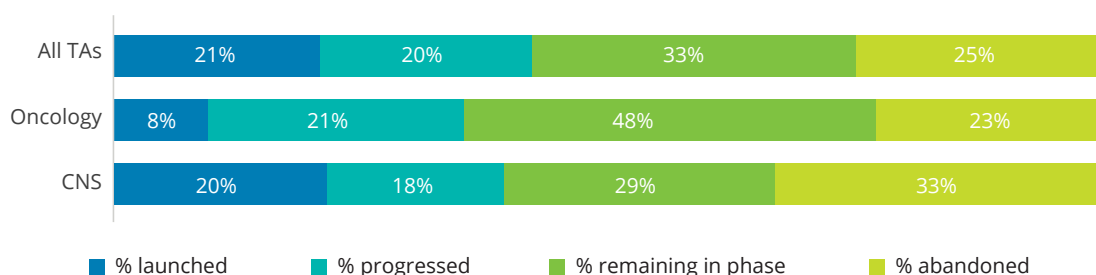
If one party is willing to give up control of an asset through a merger or acquisition, does that suggest that the asset is of lower quality? Or does it mean that the asset was highly valued and drew an attractive acquisition bid? It is possible that the deal type reflects the seller's commitment or perceived value of the program. Often, novel and highly sought-after assets are tied up in licensing agreements early on in development, leaving a smaller pool of assets to shop from in later phases. Further, an attractive acquisition bid that prompts a sale might overvalue the asset.

SPOTLIGHT: ONCOLOGY AND CNS UNDERPERFORM AS COMPARED TO ALL THERAPEUTIC AREAS

Our research showed that central nervous system (CNS) treatment and oncology were the top two therapeutic areas (TAs) for deal-making activity, followed by infectious disease (these three areas accounted for 46 percent of deals in our data set). The vast majority of deals for both therapeutic areas were via licensing (97 percent for oncology, and 98 percent for CNS).

Given the challenging scientific nature of these therapeutic areas, it was no surprise that many companies try to hedge against clinical failure by employing a licensing strategy. Our data also shows that when it comes to rates of launch and progression, oncology and CNS deals underperformed other therapeutic areas (figure 5).

Figure 5. Oncology deals were more likely to remain in phase as compared to all TAs; central nervous system (CNS) deals were more likely to be abandoned than all TAs over 2007–2012



Note: Includes all deal types across all phases for all TAs (n=1,699), oncology (n=331), and CNS (n=206).

Source: Deloitte analysis of Cortellis Deals Intelligence (March 2017).

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In oncology, deals were more likely to remain in phase than to progress or be abandoned. This may reflect the rapid pace of change in the scientific understanding of disease and molecular targets. Some older programs may have been shelved to make room for new ones. It is possible that more recent oncology deals may be more successful than the older deals evaluated in our data set. More recent deals tend to include assets that pursue specific biomarkers or a targeted approach, and clinical activity can be seen as early as phase 1. Product approval can be accelerated using studies in smaller populations, sometimes before phase 3. A targeted approach could also decrease the likelihood that compounds in development will be discontinued due to scientific failure in later stages.

In CNS, the high rates of launch (20 percent) and progression (18 percent) are encouraging, but higher-than-average abandonment rates (33 percent) might indicate high clinical failures in this therapeutic area. Clinical failures, even in later stages, might explain the increased percentage of abandoned CNS development programs in our analysis.

Deal costs may sway companies' strategy

COMPARISONS in success rates address only one part of the question, “what deal type generates more value?” Significant differences in the cost of licensing deals versus M&A deals might lead a business development executive to make a trade-off on success rates. For example, even if an M&A deal might have a lower likelihood of success, it may be worth considering if the deal price is much lower than licensing.

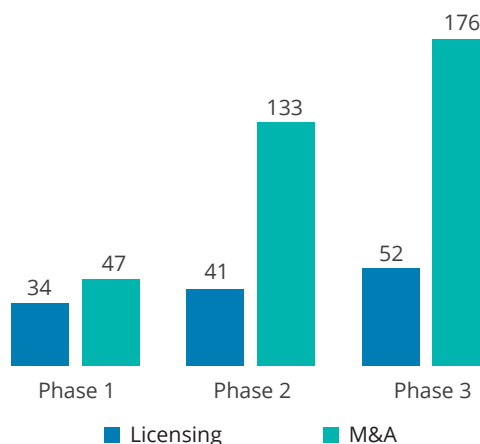
To explore this relationship, we compared average cash at risk, or average up-front payments, of both licensing and M&A deals (inclusive of both contingent M&A and outright acquisition deals) from 2007 through 2016 (where data was available). For both licensing and M&A, the average amount paid up front increases as products progress through R&D, from phase 1 to 2 and 3. However, average up-front payments are consistently higher for M&A than licensing (figure 6).

The lower up-front payments associated with licensing, combined with licensing’s higher success rates over M&A, would appear to suggest that licensing is a more logical choice across all phases. However, licensing deals could include significant costs related to milestone payments and royalty streams, costs not captured here. And while 50 percent of M&A deals analyzed use a contingent structure, meaning some payments are deferred until certain milestones are met, the other 50 percent reflects a one-time payment for outright acquisition of a company or asset. This could mean that total deal costs for licensing might exceed M&A in some instances.

A business development executive may want to think about how success rates impact potential future value. For example, even if the total costs of a

licensing deal could exceed those of M&A in phase 3, leaders may wish to consider whether licensing’s threefold advantage in success rate in phase 3—47 percent of phase 3 assets progress or launch after licensing deals, versus 16 percent for M&A (figure 4)—might offset licensing’s greater cost.

Figure 6. Cash at risk—calculated as average up-front payments (\$M)—are higher for M&A deals across all phases (2007–2016)



Note:

- We evaluated average up-front payment values of the deals where data was available (583 deals)
- 531 licensing deals (phase 1: 108, phase 2: 249, and phase 3: 174)
- 52 M&A deals (phase 1: 8, phase 2: 28; and phase 3: 16), of which 26 appear to have contingent structures (phase 1: 6, phase 2: 13, and phase 3: 8).
- Due to the small number of total JV deals over this time frame (19), they are not included for this comparative analysis.

Source: Deloitte analysis of Cortellis Deals Intelligence, March 2017.

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What factors should you consider when selecting a deal type?

As we noted earlier, licensing deals are not necessarily always the preferred option. Each deal type has advantages and disadvantages, and there are scenarios in which an M&A or JV might be the optimal solution. Table 1 gives an overview of strategic reasons that buyers and sellers might consider each kind of deal.

Here are some important factors companies should consider when evaluating what type of deal they should pursue.

- **Cash at risk.** R&D organizations can seek to reduce their financial exposure by using deal structures that make payment contingent upon hitting specific milestones. This type of structure is typical in R&D licensing agreements, but can also be incorporated into M&A agreements—for instance, subsequent payments to the acquired company are contingent on achieving key milestones or metrics. Contingent M&A deal structures, however, can be harder to execute. Companies with constrained R&D budgets might seek to use licensing or contingent M&A structures to limit their cash at risk, especially when M&A valuations are high.
- **Asset value.** Another question that companies in pursuit of innovation should consider is whether or not the seller or licensor’s preferred deal strategy reflects the value of the assets being pursued. Buyers or licensors might want to consider if the seller’s preferred M&A strategy suggests a lower-value asset or an overpriced acquisition bid.
- **Expanding into new therapeutic areas.** Companies may pursue different strategies depending on how reliant they are on the partner

to advance the drug asset in question. When a buyer or licensor is entering into new disease areas, and the target company’s know-how would be critical to the success of drug development, companies might choose to license assets; but when they have expertise in the targeted disease area and are able to progress assets through development independently, M&A may be a better choice.

- **Strategic commitment to the asset in question.** Where a company has a clear commitment to advancing a particular asset, licensing may be a better choice, as it involves a licensee working with a licensor that is committed to the continued success of the asset. This accountability for both the licensee and licensor to hit key milestones could drive greater success in R&D phases. However, in cases where the strategy of an acquiring company is still in flux and there is a high likelihood of the strategic focus

TAX AND ACCOUNTING CONSIDERATIONS

Each type of deal structure has different tax and accounting implications. M&A, for example, can come with some tax benefits if the target company has net operating losses or R&D incentives that can be utilized by the acquiring company to reduce cash taxes. However, M&A also requires consolidation of assets, liabilities, and other financial items of two or more entities into one, which could negatively impact financial statements.

changing, M&A can ease prioritization of the development program. Assets can be put on hold, or their progress can be calibrated as per the acquirer’s needs.

- **Ownership structure.** Companies might choose to pursue different strategies depending on their ownership structure and investor preferences. For example, small privately owned

companies might prefer to be acquired as a way for venture investors to realize a return on their investment. Public companies, however, might want to retain value and license assets instead. Private companies that are seeking out external innovation may avoid acquiring public companies because of the complications that it could create.

Table 1. Deal types and potential strategic rationale, advantages, and disadvantages

Deal type	Rationale—buyer/ licensee	Rationale—seller/ licensor	Advantages	Disadvantages
Licensing	<ul style="list-style-type: none"> • Access to talent and expertise • Traditional contingent payment structure allows risk sharing • Economically viable option for constrained budgets, especially when M&A valuations are high 	<ul style="list-style-type: none"> • Access to capital and capabilities to help get to the next value inflection point • Upside associated with the asset is retained • Company investors may be seeking an IPO 	<ul style="list-style-type: none"> • Access to new capabilities or technology • Access to new geographic regions 	<ul style="list-style-type: none"> • Shared decision-making can complicate or delay operational progress • Each party is dependent on the other to achieve key milestones or goals
Merger & acquisition (single-asset companies or deals)	<ul style="list-style-type: none"> • Ownership of new product(s) • Redundant capabilities are reduced, thus lowering costs 	<ul style="list-style-type: none"> • High valuations could be lucrative for current investors and employees • An exit option for private investors 	<ul style="list-style-type: none"> • Streamlined decision-making after transition of ownership • Contingent M&A deals could allow for additional payments tied to value creation • Potential tax benefits for the buyer 	<ul style="list-style-type: none"> • Alignment on valuation for public companies may be difficult • Tend to be more disruptive in nature; may result in loss of key personnel and tacit knowledge • Consolidation of assets could have a negative accounting impact
Joint venture	<ul style="list-style-type: none"> • Able to align on goals with little definition of specific products or technology • Complementary capabilities are maximized 		<ul style="list-style-type: none"> • Ideal for areas where scientific mechanisms are not well-known • Entry into new or unknown markets 	<ul style="list-style-type: none"> • Complex financial structure

Source: Deloitte analysis.

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How can you be successful executing different deal structures?

ONCE a company decides on which deal structure to use, it should take specific steps to help ensure the success of the deal depending on the deal type:

- **Licensing or contingent M&A:** While considering this option, companies should identify key programmatic risks, align key milestones and payments to those risks, and invest time in building strong collaborative working relationships. A stepwise approach could include:
 - Determining key risks, and setting up the deal structure to mitigate those risks
 - Understanding the value each brings to the table in addressing key risks that were identified during deal diligence
 - Clearly aligning the incentives in the deal terms
 - Investing time in building a post-deal relationship, and scheduling periodic check-ins to help ensure all parties continue to be aligned and that progress is being made in achieving key goals
- **M&A:** Biopharma companies should consider thorough due diligence and integration planning in advance of the transaction to help increase the success of assets sourced through M&A. In a Deloitte Survey conducted by OnSearch⁶ (a market research firm), executives working closely on M&A pointed to the following success factors:
 - Following a stepwise approach helped bring faster integration
 - Understanding each other's governance process and the target company's internal controls could help streamline decision-making⁷

- Measuring and achieving synergies is key to success
- A communication strategy involving management from both sides helps execute the integration effectively⁸
- **JVs:** To successfully execute a JV, companies should work toward developing a contractual agreement with time-bound objectives, defined ownership structure, and clarity on profit/loss sharing. Specifically, they should consider:
 - Creating a compelling value proposition for all stakeholders involved by establishing clear goals and objectives⁹
 - Developing a governance policy that includes division of responsibilities, ownership rights, lines of accountability, and clearly defined leadership roles¹⁰
 - Establishing a good risk and performance management system, with defined protocols for decision-making¹¹
 - Dedicating and incentivizing skilled resources who understand the product, and have existing relationships with markets they are selling to¹²

As biopharma companies look to reverse the trend of declining return on R&D investment, they are likely to search for therapies that have the potential to drive significant revenue growth.¹³ While biopharma companies tend to opt for licensing as a preferred deal structure in R&D, under some circumstances, M&A or JV could be a better option. But whatever the deal type, planning and due diligence are important for companies to beat the odds and leverage deal-making to successfully build R&D pipelines.

Appendix

Research methodology

WE analyzed Cortellis Deals Intelligence data for select licensing, M&A, and JV deals that took place between 2007 and 2016 to help us understand trends, progression of assets through phases of development, deal terms, and how this varies across deal types and therapeutic areas:

1. We excluded deals related to medical devices and diagnostics, generics, and scientific or technology platforms. The final analysis was carried out on around 3,000 single-asset transactions that occurred in R&D phases (preclinical through registration) over the past 10 years.
2. Under the three deal types—licensing, M&A, and JVs—we focused on deals executed between the preclinical and registration phases:
 - Licensing deal types included patents with exclusive and nonexclusive rights, development/commercialization licenses, and technology/other proprietary licensing terms.
 - M&A deals included those that were either acquisition in whole or in part, or drug-asset divestments sold by the principal company to a partner company. Deals including multiple assets were excluded to allow for more accurate comparisons between M&A and licensing.
 - JV deals included those where a principal and partner come together to form a venture. The distribution of deals sourced in each phase was similar for M&A and licensing.
3. We excluded deals where no information was reported on the clinical status of assets (at deal start or current) or deal terms.
4. Finally, we shared our initial findings with industry experts to get their insights on preferred strategies, explanations for trends, and thoughts on making each type of deal successful.

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