A survey of strategic licensing practices in the pharmaceutical industry

An IBM Institute for Business Value executive brief
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**Introduction**

Pharmaceutical companies are relying increasingly on in-licensed molecules, technologies and services. The ability to develop a competitive advantage in shaping forward-looking licensing strategies, integrating in-licensed products effectively and managing multiple, complex alliance relationships can only become more critical in delivering top-tier performance.

Alliances often appear to be a relatively cost-effective and rapid answer to fill dwindling pharmaceutical company pipelines; however, studies suggest that over half of all alliances fail to achieve their intended outcomes. Many benchmarking studies have been conducted in recent years around the Business Development and Licensing (BD&L) process; these provide excellent insight into the number, type, value and structure of deals. One question which remains unanswered is why some deals go wrong. This survey has, therefore, been carried out to understand the key strategic and operational challenges associated with the in- and out-licensing process and provide some insight into improving the situation.

For the purposes of our survey, we subdivided the licensing process into six stages:

- **Strategy** – How to determine characteristics of licensing deals
- **Find** – How to identify a suitable licensing partner
- **Assess** – How to evaluate the partner, product, target, platform or technology
- **Close** – How to complete due diligence and finalize the deal
- **Transition** – How to plan and operationalize the deal
- **Continue** – How to perform ongoing management and control of the project.

This executive brief is based on the findings from in-depth, structured telephone interviews conducted with 25 senior BD&L executives from different pharmaceutical, biotechnology (biotech), technology and virtual pharmaceutical organizations across Europe, North America and Japan. The companies interviewed were responsible for the following product scope, exhibiting a complete cross-section of the industry today (see Figure 1).
This executive brief begins with a summary of survey results, followed by discussion of the respondents' scope of responsibility, approaches to licensing strategy, means of measuring performance, views on issues encountered in the licensing process and perspectives on key trends, as well as the major challenges and opportunities facing their organizations.

Summary of survey results

### The BD&L function
- Key role in development and execution of licensing strategy
- Varying degrees of empowerment
- Involvement diminishes when deal has been completed
- Considerable recent investment in licensing capability enhancement.

### Strategy determination
- Range of different strategic perspectives, particularly with respect to:
  - What constitutes acceptable return on investment criteria for in-licensing
  - Preferences for stage at which to in-license
  - Varying degrees of flexibility afforded by respondents’ strategies
  - Common approaches to risk measurement and partnering at conceptual level.

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**Figure 1. Scope of product responsibilities of interviewed companies.**

- **New molecular entities (NMEs)**: 23%
- **Biologics**: 18%
- **Information technologies**: 12%
- **Diagnostics**: 6%
- **Devices**: 13%
- **Scientific technologies**: 14%
- **Formulation technologies**: 14%
- **New molecular entities (NMEs)**: 23%

*Source: IBM Business Consulting Services*
## Measuring performance
- Specific key performance indicators or formal metrics were less important to the smaller companies.
- Metrics considered most useful were number and value of deals, expected peak sales potential, risk profile and percentage of margin on in-licensing deals.
- The key reason for many companies not measuring key performance indicators that they consider useful is the perceived complexity of measurement – and, in many cases, there is limited data available.

## Changes in strategy
- Most major pharmaceutical respondents did not expect radical changes.
- Smaller companies are increasing their level of ambition, and hoping to delay out-licensing to optimize the value of their product.
- Responses fell into three categories:
  - Moves to late stage licensing,
  - Focus on efficiency,
  - Improvement and greater selectivity and targeting, and improving partnering.

## Self-assessment
- Almost all major pharmaceutical respondents felt they performed better than rivals generally, except in the “transitioning” stage, perhaps reflecting a lack of external visibility.
- Overall, smaller companies were more self-critical in their responses, though a certain degree of overconfidence was evident with some.

## Pre-deal closure operational issues
- Respondents generally felt that operational issues would not hamper an attractive deal.
- In pre-deal closure stages, quality of data was the most significant barrier for the in-licensees and overcoming it tended to consume significant amounts of resource.
- Smaller companies cited slow or unclear decision-making, which suggests an expectation gap in data quality.

## Post-deal closure operational issues
- Similar challenges were faced by both parties following closure of a deal.
- Key hurdles for in-licensees were technical failure and communication, with market potential, alliance leadership and the definition of roles and responsibilities presenting less difficulty.
- For the out-licensors, primary issues were slow or unclear decision-making and insufficient sponsorship from the licensees.
**Expectations mismatch**

- Twenty to 50 percent of deals did not meet respondents’ expectations
- Key gaps were predominantly manageable operating risks, such as size of the commercial opportunity, management of the partner relationship and the level and capability of resources from both parties
- Risks inherent in the development process were also cited; for example, clinical efficacy and safety.

**Trends**

- Major trends are identified as: increasing size of deals and risk-taking, increasing complexity of deals and greater internal expectations of the results licensing deals will deliver
- Out-licensors also anticipate improved benefits to their companies and a significant shift in the source of new products.

**Scope of responsibility**

**In-licensing: Process responsibility**

Responses from major pharmaceutical companies indicate that BD&L either owns or exerts significant influence in the first four stages of the in-licensing process (see Figure 2). However, BD&L appears to have greatest ownership at the close stage, where it has the least reliance on colleagues outside its own function. Nevertheless, in the first three stages of the process, there was a clear divide between respondents – some felt that the BD&L function had ownership of the process although it relied extensively on colleagues’ input from across the organization, whereas others felt that BD&L exercised significant influence while primarily playing a facilitation role.
There were some significant differences in the perceived role of BD&L during the transition phase however, with over half of respondents taking a participatory role and the other half an ownership or significant influence role. Only a small minority felt they owned this part of the process. As product development continued, most BD&L functions had an arm’s length relationship with the project teams.

**Out-licensing: Process responsibility**

As might be expected, out-licensing responsibilities were performed differently. In the smaller companies, BD&L exhibits proportionally more ownership when defining the strategy, finding the buyer and assessing the product (see Figure 3). Interestingly, in one company, it only participated in closing the deal; but in general, ownership for this activity remained within the licensing group. The “participation in close” response came from one of the smallest companies surveyed, where closing the deal was left to the executive team and external lawyers.
During the transition and ongoing development of a product with a licensee, ownership tends to return to the project team, scientists or clinicians. The BD&L function may have some influence during these stages, but in general, its level of responsibility is dwindling.

**In-licensing: Product responsibility**

Of the pharmaceutical organizations surveyed, nearly all BD&L functions had responsibility for in-licensing new molecular entities (NMEs) and biologics, and approximately half had responsibility for each of the other areas (see Figure 4). In many cases, colleagues from discovery played a major role in the areas of scientific and formulation technologies, and colleagues from information technology (IT) played a key role in the IT area. A number of the organizations surveyed did not in-license diagnostics.

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**Figure 3. Process responsibility for out-licensing.**

[Diagram showing process responsibility for out-licensing]

Source: IBM Business Consulting Services.
Out-licensing: Product responsibility

Of the three companies offering biological products, all three also offer NMEs (see figure 5). Of particular interest is the lack of diagnostics within our surveyed group, which corresponds with our findings from the pharmaceutical companies and suggests that out-licensors are responding to the needs of the current marketplace.


Licensing strategies

The strategy development process within large pharmaceutical organizations

Most major pharmaceutical organizations exercise a two-stage strategy development process. Portfolio strategy is initially developed in portfolio review meetings on an annual or semiannual basis to determine gaps in each therapeutic area in the pipeline and to clarify the relative amount of emphasis on in-licensing versus internal development. It is then possible to develop appropriate in-licensing strategies, which are typically presented to an executive committee for approval.

Differences in approaches across the respondents arise in three key areas:

1. Opportunism – Some companies set specific targets that govern their activities, whereas others adopt a fairly opportunistic approach.

2. Use of in-licensing to pursue therapeutic strategy – Some companies view in-licensing as a way of supplementing their existing portfolio, whereas others appear to be more willing to use in-licensing as a more fundamental resource to fulfill strategic direction, as when building a new franchise entirely from in-licensing.

3. Organization of in-licensing activities – In some organizations, the responsibility for portfolio and licensing strategy was devolved considerably, typically to several cross-functional therapeutic area teams; in others, much of the decision-making was retained centrally.

The strategy development process within smaller organizations

As might be expected, within the smaller companies, definition of the strategy involved fewer people, less arduous processes and was more tactical. In general, this occurred at the executive level and was either communicated throughout the organization or to business heads or product teams.

Reasons for in-licensing

While we conducted two separate surveys with different emphases, we learned that almost all of the smaller companies in-licensed probably as much as, or more than they out-licensed. The main difference was that smaller companies would in-licensing technologies, leads or candidates, whereas the larger organizations aimed to bring products in further down the pipeline.
At its most fundamental level, every organization primarily looks towards in-licensing to fill its pipeline gaps, however, interviewees’ responses about why they in-license could essentially be categorized into three strands:

- **Gap filling and portfolio continuity** – To maintain continuous growth by filling pipeline gaps and supplement internal R&D efforts by gaining access to external technology and compounds
- **Opportunistic** – To proactively seek attractive opportunities in their organizations’ focus areas and improve their competitiveness in particular niche markets by strengthening their portfolios in specific areas, or looking to create new franchises
- **Efficiency** – To leverage existing capabilities and resources – such as their sales forces or existing customer bases – as a key driver for in-licensing.

**Is a minimum return required?**
A minority of organizations had a fixed, absolute return hurdle rate that all potential opportunities had to exceed; however, most organizations appeared to apply different hurdle rates for different situations, such as which therapeutic areas were being considered. Some organizations exhibited more flexibility, applying basic hurdle rate guidelines while taking into account the target customer segment, expected time to peak sales from acquisition, whether the product was considered a “break-through,” the likely terms of the deal and so forth. Other companies used different hurdle rates depending on whether an opportunity was considered on opportunistic grounds or as part of their planned portfolio strategy.

Most respondents considered various financial criteria for both early and late stage products and typically used internal benchmarking data to determine fair value in different situations. For the assessment of earlier stage products, respondents generally appeared to rely far more on scientific profiles, with a far greater focus on financial criteria for late stage products – typically, expected net present value (ENPV), although internal rate of return (IRR), return on sales (ROS) and likely peak sales are also often evaluated. Notably, there was considerable variation in respondents’ views on the usefulness of more sophisticated financial techniques.

**Preferences for stage of licensing**
Five respondents from the major pharmaceutical organizations indicated a significant shift toward late stage in-licensing, four had no preference and considered all opportunities equally, dependent on the maturity of each of their therapeutic area pipelines, and four preferred early- to mid-stage opportunities, particularly at proof of concept.
A preference for late stage was driven by numerous factors. A primary reason was need-driven rather than strategy-driven, in that later pipelines were looking thin and therefore these companies favored products that were close to market. A number of respondents also cited the reduced product risk at late stage although they acknowledged that product choice at late stage was much lower.

One respondent stated that many companies had already assembled an extensive toolkit at the discovery end that had enabled them to catch up with biotech on discovery efficiency, therefore enabling them to change the emphasis of their in-licensing program from discovery to later stage product sourcing.

In response to this growing preference, smaller companies are increasingly ambitious with respect to progressing development further before selling their products. Their aim is to optimize the value of the product and reduce the risk for the buyer. Only one of the ten companies surveyed out-licensed exclusively at the preclinical stage, although the other nine were very flexible in their approach.

Finally, some respondents felt that although biotech companies were increasingly demanding profit-sharing agreements, they were also increasingly contributing to the costs of late stage development.

A focus on early stage licensing was typically driven by financial and infrastructure resource constraints. One respondent commented, “Phase III is awesomely expensive,” making it out of reach for smaller companies in some cases. Early stage licensing was sometimes considered advantageous by allowing in-licensees to take advantage of greater product choice and avenues for growth from new mechanisms and exciting science opportunities. One big pharmaceutical respondent stated his company’s preference to focus on mid-stage to ensure that they maintained an appropriate standard of control over the commercialization process, particularly for products that they felt were typically complex for smaller or less experienced players to commercialize.

Most respondents felt that competition for products at all stages appeared to be intensifying. One reported “There are companies that shop for everything they can get their hands on and then decide later on which products to dump.” Another stated “It’s very difficult now to get products with proof of concept that have not already been partnered.” Conversely, while smaller companies have historically done deals primarily so they can report on successes and gain additional investment or internal funding, the general consensus among this group was that they will no longer do a deal just for those reasons.
Partnering preferences

Most major pharmaceutical organizations had a preference for straightforward licensing with exclusive rights while recognizing that it was becoming more challenging to achieve. This difficulty was confirmed by the smaller companies which identified a partnership preference but prefer to limit exclusivity and codevelop the product. This results in a paradox since almost all respondents want to “be in charge of development.” Fortunately, both sides tend to seek alliances rather than joint ventures, which were typically considered complex and fraught with legal complications: “A joint venture is just a compromise — it just makes things very complicated. At the beginning it’s fine but later on, the two organizations’ objectives tend to shift and this makes corporate relationships very difficult.”

One consideration for smaller companies was that most major pharmaceutical firms appeared to consider targeted acquisitions for building specific capabilities in-house or in some instances, for replacing an existing alliance or joint venture that was becoming difficult to manage.

Primarily, the emphasis of respondents’ partnering approaches appeared to vary by product, however, there was some indication that the type of partnering has been gradually shifting to include consideration of the broader “comprehensive alliance model” where several technologies or even entire therapeutic areas are considered within the breadth of a “strategic alliance.”

Deal structures

Deals are generally structured in the classical sense, combining some elements of up-front payment, milestone payments and royalties.

A number of key considerations informed the nature of the deal — these were typically the stage of development at which a product was in-licensed, the out-licensors’ situations and the types of products being in-licensed.

Respondents typically preferred an up-front fee and milestone payment arrangement for early stage, with greater use of royalties for later stage products. However, most respondents spoke of a significant shift in the balance of power between licensor and licensee in recent years. One respondent said, “In an ideal world, we would like exclusive license for milestones and royalties — but we are getting far less able to do this, perhaps only in 20 percent of deals now, compared with about 50 percent just three years ago.”
Out-licensors’ negotiation strength clearly played an important role in the determination of the type of deal, and some respondents stated the importance of being flexible in structuring deals to be attractive to the cash flow needs of both parties. In addition, many respondents appeared to have a preference to “buy-out” technologies rather than offer royalties.

Most respondents did not prefer a specific deal structure, instead using whatever structure made the most sense in a particular situation. Some respondents felt that deal structuring could be used as an effective tool for demonstrating creativity and innovation, meeting both parties’ needs in terms of risks, incentivization and cash flow management.

**Approach to risk-taking by major pharmaceutical organizations**

All respondents evaluated both technical and market risk for potential in-licensed products, typically by initially using some form of in-house risk assessment template to define expected risk at different phases for different therapeutic areas, based on internal and benchmarking experience. This base risk profile is then adjusted, taking into account specific product characteristics.

Risk assessment at early stage tends to be much more qualitative, compared with later stage products and some respondents were wary about the use of sophisticated risk assessment models. One respondent stated that “some companies are likely to have extremely sophisticated and misleading models to assess risk – if anybody was any good at this game, we would see a material difference in companies’ performance – but we are pretty much all similar in performance”. Another respondent similarly thought that “There are quite fancy models offered by consultants – but it generally falls to the scientific experience of the decision-makers – there is so much luck involved. But it is important how much experience we have in a certain business area – this is the critical issue”. However, respondents were also clear that while it was more difficult to assess risk in early stage products, waiting until later stages required trading off much higher value to attain lower risk.

The due diligence process was seen as an integral part of the risk assessment process. While a number of companies would make in-licensing decisions based on criteria specifying acceptable degrees of risk, some respondents would deal with different levels of risk based on how the deal structure was shaped. One organization’s view of acceptable risk was the amount of money that would need to be invested to know whether a product was working out – in line with the real options valuation concept.
There were opposing views on whether in-licensed products carried inherently more or less risk than those developed in-house. One view is that a company would typically know more about an in-house product than an in-licensed product, and therefore would generally carry greater risk on in-licensed products. However, some thought that because firms typically look more thoroughly at external products, those should actually fail less often than in-house products. There is little substantive evidence to support this, although one survey suggested that licensed opportunities did appear to be more successful than organically grown assets.¹

**Measuring performance**

**How is BD&L performance measured?**

The smaller the company, the less emphasis was placed on adherence to process and performance measures. Of the out-licensors, measurements were predominantly customized and revenue driven. Within the larger organizations, three respondents were measured on a purely qualitative assessment, five on semi-quantitative targets and seven on specific quantitative targets.

For those measured on qualitative assessment, the value, quality and contribution of the deals presented by the function were considered. These respondents argued for a substantial amount of flexibility – without floors or ceilings in financial terms – so that they would not do deals for the sake of it, rather, when a good opportunity presented itself.

Those assessed on semi-quantitative targets were typically measured on the size, complexity and frequency of in-licensing opportunities brought to executive management for a decision, rather than on the number or value of completed deals. Here, typically, multiple measures were considered, perhaps with some element of qualitative judgment. For example, one organization ran a 360 degree review of licensing as part of this performance measurement process.

Finally, those assessed on specific quantitative targets tended to measure numbers or value of in-licensed products that were meeting specific needs, often in comparison with targets for the number and value of deals that could be closed annually.

**Using metrics to monitor business strategy**

Metrics considered to be most useful in monitoring BD&L performance were the number and value of deals, expected peak sales potential, risk profile and percentage of margin on in-licensing deals (see Figure 6). Metrics considered least useful were the percentage spent on in-licensing and the percentage of deals by source institution.
Respondents regularly collect data related to two of the metrics considered most useful: number and value of deals and percentage of margin on in-licensing (which is typically monitored by the finance function). Yet, despite their belief that data on the number or value of deals is useful, a number of respondents do not regularly collect it (see Figure 7).
In addition, although eight respondents felt that estimated peak sales potential was useful, only two were collecting this data. Similarly, seven of those interviewed felt that risk profile was useful, but only one reported collecting this data on a regular basis.

One reason some respondents may not be collecting data on specific metrics is due to a small sample size, making it difficult to draw meaningful conclusions from the aggregated data. In addition, some metrics (for example, risk profile) are viewed as presenting too much complexity to capture in a quantitative fashion.

Some respondents did not differentiate between in-licensed products and those developed in-house for the purposes of one or more metrics. This was most frequently the case with attrition rate. In addition, there were a small number of respondents whose portfolios consisted primarily of in-licensed products, where metrics such as percentage of revenue from in-licensing were essentially irrelevant.

Respondents also used some of the metrics for different purposes. For example, while some primarily used the percentage of revenue from in-licensing to set targets and monitor performance, others used it primarily to communicate the importance of in-licensing activities.

Data that appeared to be collected least related to percentage deals by source institution and percentage deals by source of intelligence, as respondents did not generally feel that these metrics were useful in monitoring performance.

For in-licensing, the two metrics tracked most against targets were the number and value of deals and the percentage of margin on in-licensed products (see Figure 8), which is consistent with their perceived usefulness and the ease of obtaining data. Similarly, the percentage deals by source institution, intelligence and types of collaboration were least frequently tracked against targets.
Proportion of agreements not meeting expectations

While three respondents stated that all of their agreements met their expectations, the majority of respondents felt that 20 to 50 percent of agreements did not. Four broad reasons for this were identified:

- Difficulty in anticipating the evolution of the competitive landscape
- Partnership issues
- Unrealistic expectations
- Difficulty in anticipating regulatory decisions.

A more detailed review of why agreements haven’t met expectations is presented in a later section.

How do organizations expect their licensing strategies to change?

Most big pharmaceutical respondents were not expecting any radical changes in their strategies, but were instead looking at reinforcing their existing strategies. The following themes came from the interviews, but do not represent a unified view:

Figure 8. Metrics tracked against in-licensing targets.

Source: IBM Business Consulting Services.
**Shifting focus from early stage, platform technologies**
- Shift from research alliances to an aggressive focus on late stage – there was one view that if big pharmaceutical companies were able to improve their thin late stage pipelines, there may then be a gradual shift back to early stage opportunities
- Less focus on licensing in platform technologies.

**Improving efficiency of the in-licensing process**
- Better targeting and selectivity in products being sourced
- Doing more deals, faster and at the same quality
- Building up search capacity in specific areas in which they want to be more active.

**Approaches to partnering**
- More effective use of partnering to balance risk through risk sharing
- Entertaining more complex partnership arrangements as a way of attracting a better choice of products
- For Japanese companies, increased effort with Japanese academia and other Japanese companies that don't have marketing capabilities.

Nine out of ten smaller companies expected changes to their licensing strategies. Interestingly, they were also unified in the changes they foresaw, which included: holding on to more rights later in a product's development, retaining commercial rights, if possible, targeting development to products likely to obtain rapid regulatory review and approval (such as products for unmet medical needs or with orphan drug status) and increasing the number of deals that include in-licensing of more early stage candidates.

**The licensing process**
Each respondent was asked to subjectively rate its own functions relative to its rivals – nearly all respondents considered themselves better than their rivals in the first three stages of the process (see Figure 9). Respondents were not, however, given an opportunity to rate themselves as “industry average”. Nevertheless, the results probably reflect the substantial effort that many organizations have recently made in improving their internal BD&L capabilities. Indeed, some of the respondents rating themselves as industry leaders appeared to be able to back this up with regular survey findings from collaborators. “Many of our partners have told us that many other companies don’t respect them in the way that we do – there is a real meeting of minds between us and other partners.”
Confidence in their own performance is less evident with the out-licensors, though for the first three stages of the process more than half of the respondents replied that they were either industry leaders or better than their rivals (see Figure 10). One technology provider felt it was the industry leader during the transition and ongoing development of its product. Of note is the drop in the number of responses for transition and continue. In both cases, this is because the companies have either not done a deal recently or because it was a standard transaction requiring no involvement from the out-licensor beyond deal close.
The results highlight the significant room for improvement across the process, especially by the out-licensors. During the transition and ongoing development of the product, a number of respondents mentioned the necessity of understanding the other parties' needs and responding with sensitivity. One respondent said, "Many people inside our company believe that the people that we've licensed to will simply crawl into their hole after the deal is done, and that from time to time we'll throw them a royalty check".

Figure 11 highlights those issues that respondents experienced frequently, with either minor or major implications. The results suggest that with the exception of lack of availability of quality data, most of these operational issues were not perceived as significant contributors to deal failure during the pre-deal closure stages. However, the lack of quality data appeared to consume significant resource during the due diligence stage in order for the organizations to reach appropriate decisions.

**Figure 11. Causes of failure during pre-deal closure for in-licensing.**

- Inadequate resource
- Too many external parties involved
- Insufficient coordination between internal interfaces
- Slow or unclear decision making
- Insufficient sponsorship
- Financials not viable once reviewed by senior management
- Ineffective communication with licensor
- Lack of budget available to enter into deal
- Lack of quality data available for decision making
- Differences in ways of working causing conflict
- Changes in senior management
- Deal partners choose a different party to enter the deal with
- Unequal benefit sharing between partners
- Objectives of partners not compatible
- Drastic changes in business environment (e.g. M&A)

Source: IBM Business Consulting Services.
Among those issues that were highlighted by a minority of respondents were: lack of budget available to enter deals, inadequate manpower during the early stages due to the magnitude of BD&L activity, objectives of partners not compatible, deal partners choosing other parties, insufficient sponsorship and slow decision-making.

A similar picture was seen from the out-licensors’ perspectives (see Figure 12). Of most significance, however, were the frequent occurrence of slow or unclear decision-making (reported by 80 percent of respondents) and unequal benefit sharing between partners (reported by 50 percent). Unclear decision-making coupled with inadequate resource is likely to jeopardize any deal closure, however, respondents from both sides felt they would usually be able to overcome many of these issues if they were particularly interested in pursuing a deal – despite possible difficulty, such challenges would not typically lead to deal failure.

In contrast to the pre-deal closure stages, respondents highlighted a number of issues that appeared to cause difficulty after completion of the deal (see Figure 13). However, two of the main causes of failure were predictably considered uncontrollable to a great extent by many: failure in the underlying technology or clinical trials and expected results being slow to materialize. Nevertheless, six respondents pointed to ineffective communication as a frequent issue and four of these respondents identified this as a major cause of post-deal closure failure.
Other cited issues were market potential overestimated, differences in ways of working, poor alliance leadership and poorly defined roles and responsibilities. However, it is worth stressing that a minority of respondents highlighted these issues.

Of respondents that did not think these controllable operational issues led to the failure of recent deals, many said that the situation was very different one to two years ago, and had only recently changed as a result of focused efforts to improve their abilities to partner more effectively. Some of the actions that helped enable these improvements were changes in BD&L reporting structure to improve speed of decision-making, appointments of alliance managers and redesigned product transitioning processes.

Where products are out-licensed, the picture is a little different (see Figure 14). Probably of most concern is the 50 percent of respondents who reported that there was insufficient sponsorship within the licensee. One insightful comment associated with this finding was, “The best deals are done with Japan, where once the company has decided to buy the product, they take it very seriously and give it the priority it deserves.”
The other main issues were similar to those experienced by the in-licensees. It is worth noting that similar issues are seen pre- and post-deal and many of these could be eliminated as they should be categorized as simple operational improvements.

When asked about key reasons why respondents’ expectations were not met in previous deals, two key themes emerged (see Figure 15). Firstly, as one might expect, clinical efficacy and safety are likely to be major causes of failure in deals – however, there was some sense that perhaps because products were in-licensed there was somehow a higher expectation of success, even with respect to these factors. Secondly, however, a number of respondents mentioned that the resources provided by the licensors and the capability levels of the licensors did not meet their expectations. One respondent stated, “We work a lot with biotech companies – they tell you that they will have the next phase available by a certain time, but they are normally late and cannot live within the budget – and come back and ask for more. Our management is therefore very uneasy about partnering.”
Figure 15. Expectations sometimes or rarely met with in-licensing.

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<td>Licensor capability levels</td>
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Number of responses

Source: IBM Business Consulting Services.

To a lesser extent, the regulatory acceptability and manufacturing complexity of in-licensed products were nevertheless key causes of unmet expectations. Particularly in the Japanese environment, one respondent stated, “The Japanese healthcare authority is extremely conservative compared with the FDA and EMEA. Even if a product has been approved in North America and Europe, you can't count on it being approved in Japan’.

Interestingly, an almost identical response was provided by the out-licensors, though this group reported animal data, regulatory acceptability and completeness of data available more frequently (see Figure 16). Of particular concern is the mismatch in resources reported by both sides, where 50 percent of respondents from each group felt that either the resource levels or the resource capabilities did not meet expectations.
Managing partner relationships at an operational and strategic level

Most respondents’ organizations had defined responsibilities for managing relationships at both an operational and strategic level.

At the operational level, there has been a drive for many major pharmaceutical organizations to set up “alliance management” roles with a responsibility for managing operational relationships, as a distinct role from that of project management. The scope of responsibility was typically dependent on the importance of a particular product – generally not the case for the smaller companies, who left their scientists to manage projects through transition and ongoing development. Some companies also had specific conflict resolution bodies that met on a regular basis.

At a strategic level, most companies had semiannual or annual steering committee meetings on a product-by-product basis for all important deals. Composition of the steering committee would typically reflect the type and phase of product.

Few organizations appeared to have an oversight group to monitor the status of all in-licensing relationships collectively, and some respondents felt that this would be inappropriate due to substantial differences in the types of relationships that were managed. However, most organizations had oversight committees to review the progress of all projects, whether in-licensed or developed in-house.
### Key trends

#### Figure 17. Views on key trends for in-licensing.

- **Increase in product choice**
- **Increased product novelty**
- **Improved licensee benefits**
- **Increased deal size**
- **Pharma take more risk**
- **More parties involved**
- **Shift in source sellers**
- **More third parties involved**
- **More visibility of opportunities**
- **Greater deal complexity**
- **Greater internal expectations**

Source: IBM Business Consulting Services.

#### Figure 18. Views on key trends for out-licensing.

- **Improved licensee benefits**
- **Increased deal size**
- **Pharma take more risk**
- **More parties involved**
- **Shift in source sellers**
- **More third parties involved**
- **More visibility of opportunities**
- **Greater deal complexity**
- **Greater internal expectations**

Source: IBM Business Consulting Services.

### Product choice – In-licensing

Respondents were divided on whether their organizations would benefit from increased product choice from in-licensing. On the one hand, most did believe that there was a constant bubbling of technologies and continuing emergence of opportunities from biotech companies and academia. However, many felt that the demand for these opportunities was also intensifying, with some companies looking at expanding the therapeutic areas from which they in-license, biotech firms increasingly choosing to go into product development and some big companies “taking everything at any price” and fueling the market, with the net effect probably being “less out there.”
**Novelty – In-licensing**
Generally, respondents were cautiously optimistic that greater novelty would originate from pharmacogenomics. However, some felt that while there were a lot of things on the way from genetic engineering, they were unlikely to offer blockbuster potential in the medium-term, and that smaller companies were more likely to benefit from these.

**Benefits**
Few major pharmaceutical respondents felt that benefits to the licensee were likely to improve due to increasing demand driving up deal values. The smaller companies, which reported that the benefits to them were likely to increase, confirmed this.

**Size of deals**
Almost all respondents were expecting deal size to continue increasing, however, there were some thoughts that there may be a backlash at some stage, as the growth in deal values becomes unsustainable. Many referred to the lessons learned from the ImClone/BMS deal and suggested that caution must be exercised to verify only appropriate value is captured.

**Risks**
Most respondents felt that “as Pharma companies become more desperate,” they are taking on more risk. However, a minority felt that big pharmaceutical companies were too conservative to take on more risk than they already have.

**Number of parties involved**
Respondents expressed mixed views in this area. Some respondents were seeing some more complicated deals coming about, with more parties becoming involved as the size of deals increased. However, others felt that highly complex deals involving multiple parties were falling out of favor.

**Source sellers**
Just over half the respondents felt that there would be a shift in source sellers – this reflected the increasing proportion of the industry pipeline being supplied by biotech. However, one respondent stated that the quality of data available had suffered as the major source of in-licensed products has migrated from small pharmaceutical companies to biotech.
Also reported was some emergence of products from developing countries such as India and China, as well as an increasingly commercial orientation in academia.

**Third parties**
Most respondents did not expect any significant increase in the use of third parties in the licensing process. The minority of respondents that did expect an increase referred to the use of more advisors as deal complexity increased.

**Visibility**
Most respondents felt that the visibility of opportunities was generally improving as out-licensors were becoming more sophisticated “in getting their stories out” and as better use of communication technologies and the Internet created a more visible forum for out-licensors to optimize the value from their products. In addition, others spoke of an increasing trend for public auctions. All in all, respondents felt that there was generally a greater awareness about what's in the industry pipeline.

**Complexity**
“It used to be that you met with a small company and you would be trying to explain to them what the deal would look like. Today I'm seeing that even small companies are showing up with a fair degree of expertise in doing the deal.” The majority of respondents felt that deal complexity was rising, with deals covering increasing numbers of scenarios to address more and more potential loopholes – “big, standard deals are becoming increasingly detailed”. One respondent felt that this was the case because “there is more and more mistrust that your partner will not be able to handle the situation in an amicable way.”

However, some respondents also felt that some of the complexity was being driven by increasingly complex financial structures, in order to meet rising expectations for profit sharing and risk management needs.

**Internal expectations**
All respondents felt that internal expectations in their organizations were increasing as major pharmaceutical organizations looked to in-licensing, partnering and acquisition as key strategies in their search for continuous growth and smaller companies fight for survival in an ever-competitive and suboptimally funded environment.
Key challenges highlighted by major pharmaceutical respondents

- Differentiation is becoming more difficult as all big Pharma have virtually identical goals
- As the “giants” continue to grow in size, the capability gap between medium Pharma and “giant” Pharma continues to grow, and has implications for partner attractiveness
- For those operating in many therapeutic areas, keeping up with the opportunities and technologies that are continually emerging, before or in line with the competition
- Continually bringing in attractive and innovative new opportunities within the expected financial terms, as competition for these opportunities intensifies
- Attracting, developing and keeping the best people.

Key opportunities highlighted by major pharmaceutical respondents

- Taking advantage of in-licensing opportunities from changing product portfolios due to merger and acquisition (M&A) activity
- The ability for medium-sized Pharma to differentiate themselves from the “giants” as the internal complexities of scale kick in by:
  - Improving internal integration with BD&L playing a key role – “We should be less of a transaction shop”
  - Improving relationships with partners – “If you have a track record to be a successful partner, you will be; if not, you will probably find the environment very tough indeed.”

Key challenges highlighted by smaller company respondents

- Surviving a buyers market – There are too many poor products available for licensing. Rather than sort between them, buyers tend to devalue all products
- Consolidation of the industry is leading to fewer people to sell to and more pressure on the buyer, possibly leading to a decrease in the level of risk taken
- Appropriate value capture – Doing the right deals with the right partners and optimizing the configuration of the deals for both parties
- Producing quality products to fill the pipelines
- Achieving optimal development timelines for a product in light of tightening regulatory attitudes.
**Key opportunities highlighted by smaller company respondents**

- Lots of hungry people to whom firms can out-license and lots of underfunded companies to offer in-licensing
- Mining through the rapidly increasing activity in early stage chemistry and biology to expand the pipeline
- For novel compounds with meaningful clinical data, there will be tremendous value to the out-licensor due to the dwindling pipeline of the larger companies.

**Optimizing the value of an alliance**

It has long been accepted that strategic alliances are an essential component of the pharmaceutical and biotechnology industries. The greatest challenge for both today and in the future is to optimize the value of the alliance, reduce the expectations gap and deliver high-quality products in the shortest possible time. A number of major pharmaceutical companies have recently set up alliance management groups in an attempt to bridge the gap. In addition, they are streamlining their processes: for example, focusing on making the process of building a relationship work as well as the process for doing the deals.

While organizations are unable to influence a number of the factors that present major challenges, they do have the ability to exercise a significant level of control over others to improve their competitive performance (see Figure 19).

*Figure 19. Ability to respond to key challenges.*

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Pre-deal operational</th>
<th>Post-deal operational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market risk / return curve</td>
<td>Quality of data (earlier stage)</td>
<td>Safety and efficacy outcomes for early stage opportunities</td>
</tr>
<tr>
<td>Complexity of deals</td>
<td>Increasing competitiveness for out-licensing opportunities</td>
<td>Actual changes in market potential for in-licensed opportunities</td>
</tr>
<tr>
<td>Visibility of competitor performance</td>
<td>Improved due diligence and coaching of teams to improve data quality</td>
<td>Product transitioning processes</td>
</tr>
<tr>
<td>Clarity of strategy &amp; required supporting capabilities</td>
<td>Clarity of position being taken on risk / return curve</td>
<td>Late identification of safety / efficacy issues</td>
</tr>
<tr>
<td>Clarity of position being taken on risk / return curve</td>
<td>Approach to measuring licensing performance</td>
<td>Greater realism in market potential expectations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ineffective two-way communication</td>
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<tr>
<td></td>
<td></td>
<td>Resource levels and capabilities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Alliance leadership</td>
</tr>
</tbody>
</table>

*Source: IBM Business Consulting Services.*
This would suggest that there are five keys to the success of an alliance:

- People and infrastructure
- Culture
- Science and technology
- Processes
- Project teams

Taking each of these individually, we will explore what changes are required today and what the future may hold.

**People and infrastructure**

The quantity and capability of resources assigned to the development team is a major problem for both in- and out-licensors. As more deals occur late in the pipeline, there is pressure on small- and medium-sized companies to build or acquire capability in both product development and alliance management. These skills will be critical in managing the product transition and maintaining progress in an increasingly complex environment.

Major pharmaceutical companies are establishing a partnership infrastructure that tends to include these roles:

- **Alliance executive** – Responsible for championing the partnership at the most senior level of the organization
- **Alliance leader** – Responsible for providing direction to the team(s), ensuring consistency with the portfolio and being accountable for the alliance
- **Alliance manager** – The “on-the-ground” business and process resource responsible for the relationship. Key skills for the alliance manager role include listening, facilitation, influencing and conflict resolution.

These alliance roles are in addition to a normal project team structure, whereby the project leader and project manager would be responsible for delivery of the actual project.

Clearly, smaller companies are not in a position to formally mirror these roles; however, by employing the right people to management and technical positions, they are likely to have a ready-made capability which can evolve throughout the product lifecycle. With ongoing M&A, there is an influx of highly-skilled and knowledgeable resources entering the job market on a regular basis. These people have the potential to play a key role in bridging the gap between large and small companies.
Culture
During our interviews, a number of comments emerged around the different cultures and pressures facing the different parties within an alliance. In addition, addressing cultural differences within countries and companies appears to be important to the success of a relationship.

One observation from the smaller companies was the lack of sponsorship from the licensee. Although this concern is likely to be eliminated – or at least mitigated – by the institution of alliance specialists, team members still need to break away from the “not invented here” syndrome and treat each project as if it were their own. Out-licensors must also resist the temptation to “throw the product over the wall and move on,” as there will inevitably be residual contractual obligations.

In short, the operating models of major pharmaceutical and smaller organizations are fundamentally different. Small companies offer greater flexibility and responsiveness than their larger competitors can. These cultural and operating differences need to be considered when defining the joint operating model within a licensing relationship – failure to do so leads to frustration and mistrust on both sides.

Science and technology
Drug development is fraught with possible negative outcomes within its science and technology. In this survey, clinical data and product over-valuation were reported as major causes of deal failure. Despite this, there is some evidence to suggest that in-licensed products may have a greater chance of success than home-grown products, especially if they are in-licensed later in development, due to more critical and objective evaluation during the due diligence process.

Improving the chance of success for internally and externally developed products is possible, by deploying modeling and simulation technologies during the due diligence process. New in silico technologies which apply computer modeling to biology and physiology promise to deliver great benefits. More than half of the top 40 pharmaceutical companies use modeling and simulation technologies during drug research and development – the question is, how many of them apply these techniques to evaluate in-licensed projects?
Processes
Operational challenges can be proactively managed when moving into an alliance situation. Formal processes for transitioning a product in-house, though available, appear to vary in their effectiveness. The major challenge facing companies is the transfer of data and documents from one party to the other – either in totality or in part – due to ongoing development by the partner or other third parties. Our client experience mirrors this fact and it remains a constant source of frustration to project teams struggling to obtain critical regulatory information.

Standardization and streamlining of key business processes continues to be a challenge for research and development based pharmaceutical companies, despite countless re-engineering projects. This impacts the ability to manage development in a partnership or alliance arrangement. Key processes should be clearly defined, jointly, at the outset of the deal.

Similarly, out-licensors need to take a longer-term view of the implications of their operational activities, given the probability that a third party will develop their products. Low price, tactical buying of contract research organization (CRO) services, for example, often turns out to be very expensive later in development due to the costs associated with migration and integration of data from multiple sources.

Project teams
Working within project teams, across a complex pharmaceutical organization matrix is complicated at the best of times, but adding third parties can be extremely challenging. Managing this situation will rely on early involvement of the project leader and manager, as well as the technical team. Proactive management of potential issues, honesty and openness by both partners will facilitate smooth operation of the alliance. This may sound like common sense; however, there was a general recognition during the survey, that transitioning and continuing development of the product requires improvement.
**Conclusion**

There is a general recognition within the industry that alliances will become the mainstay of drug development in the near future. In order for them to be successful – and for the industry to return to the prosperity it once enjoyed – these relationships need to be taken very seriously and managed accordingly. In addition, as science and technology become more available and facilitative, pharmaceutical organizations can take advantage of innovations to optimize their success. To discuss the implications of this survey for your company, contact us at iibv@us.ibm.com. To browse other resources for business executives, visit our Web site:

ibm.com/bcs

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**Reference**
