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For the Pharmaceutical Licensing Groups

Key Issues for Cross-Border Deals

Outgrowing the Threat of a Takeover

Ensuring the maximum value for your deal

Post-Deal Execution: Ensuring the maximum value for your deal requires careful planning for post-deal management

Since different types of deals (co-development, co-commercialisation, acquisitions and divestments) have different resource requirements post-signing, business development professionals should take this into consideration when negotiating a deal. The best means to accomplish this is to involve an alliance management professional from the start.

By Steve Twait, VP, Alliance and Integration Management (AIM), AstraZeneca

About the Author

Steve Twait has responsibility to continue to shape AstraZeneca's alliance and integration management (AIM) strategy in line with more diverse and varied externalisation deals and to further enhance AZ's AIM capability. Steve joined AZ in January 2015 from Eli Lilly and Company where he was a founding member of Lilly's Office of Alliance Management. Steve is a well published author in Pharmaceutical Executive and Strategic Alliance Magazine and is a board member of the Association of Strategic Alliance Professionals.

AstraZeneca Partnering Philosophy

At AstraZeneca we are committed to creating strong, long-term partnerships that will speed the delivery of innovative, life-changing medicines to the people that need them. Experience tells us that when partnerships are not actively managed, the full potential value to both partners is jeopardised.

Our Alliance and Integration Management (AIM) team participates throughout the deal process, starting at the initial steps of due diligence and contract negotiations. Gaining an early understanding of the strategic, operational and cultural fit between AstraZeneca and our partners enables us to structure the partnership governance and staff the partnership to be most effective right from the start.

Whether engaging in early-stage research collaborations and academic alliances, co-development or co-promotion partnerships, or acquisitions or externalisation of innovative products, we believe that the most successful relationships are built on trust and transparency. We are dedicated to forging strong relationships with our partners at all levels of the enterprise.

Whether or not your company has a dedicated alliance management team, post-signing execution of the transaction needs to be covered by someone. Planning for the work that is required after the deal is signed compels a different approach depending on the type of deal. This article will look at how best to anticipate and plan for the work required after deal signing to get the most value from your transactions.

Externalisation Strategy

AstraZeneca's partnering and externalisation strategy has been keeping our business development colleagues busy for the past several years and will continue to do so going forward. From pre-clinical research collaborations to late-stage development and global commercialisation deals, our partnering strategy focuses on innovative scientific capabilities and value-enhancing business development opportunities across our main therapy areas (Respiratory, Inflammation & Autoimmunity; Cardiovascular and Metabolic Diseases; and Oncology):

- ***Research collaborations*** – increasing academic and early-stage research alliances
- ***Peer collaborations*** – exploring ways of maximising pipeline assets and respective expertise to create value for patients
- ***In-licensing and acquisitions*** – pursuing partnering, in-licensing and acquisitions to strengthen our therapy area portfolios
- ***Externalisation*** – opportunities that create value from the strong science in our portfolio, including out-licensing technologies and potential new medicines

This integrated approach combines our scientific and commercial expertise with our significant business development know-how and experience. It enables us to add maximum value to our partnerships by creating arrangements with a clear strategic fit with our portfolio and commercial capabilities.

Given the diversity of AstraZeneca deals, the business development team works closely with the AIM team to recognise and account for the different resource requirements post-signing depending on the type of transaction. By engaging with the AIM team early in the negotiations, the business development function is able to focus more on the core components of the negotiation process such as business case development, contracting, and negotiation strategy.

Overall, there are three different staffing models required to support the most common business development transactions:

Co-Development / Co-Commercialisation Post-Deal Staffing

Staffing a traditional co-development/ co-commercialisation alliance requires a long-term view. If successful, pharmaceutical product lifecycles can extend over many years or even decades.

Workload peaks and valleys occurring in co-development/co-commercialisation alliances tend to occur over three distinct phases of an alliance lifecycle: Immediately following deal execution, an intense effort is required to start up the alliance properly. Ongoing management during the "steady-state" phase of an alliance often involves long periods of relatively stable activity, interrupted by an abrupt surge in work resolving unforeseen issues that arise.

"Overall, there are three different staffing models required to support the most common business development transactions."

Alliance managers should work to anticipate and plan for issues that could evolve in an alliance. An important, and often overlooked, activity requiring alliance management support involves terminating or "unwinding" an alliance when it reaches its natural conclusion or abruptly ends for some other reason.

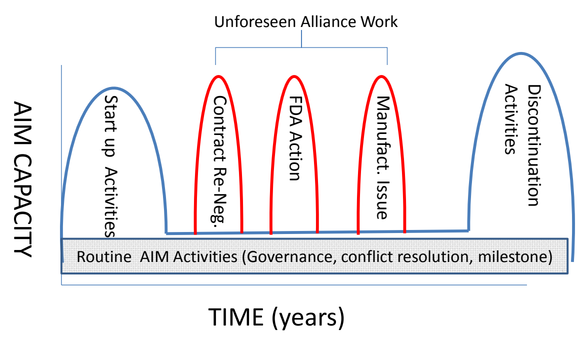
Ideally, an alliance manager or post-deal manager works collaboratively with the business development team early in the deal process to assess the strategic, operational and cultural fit with the partner. Alliance managers can also assist the business development team by taking the lead in negotiating the governance provisions in the contract since they will be implementing the governance for the life of the alliance. As long as an alliance manager is not asked to start up or wind-down multiple alliances at the same time, they should have the capacity to oversee a portfolio of co-development/co-commercialisation alliances.

Asset Divestment Post-Deal Staffing

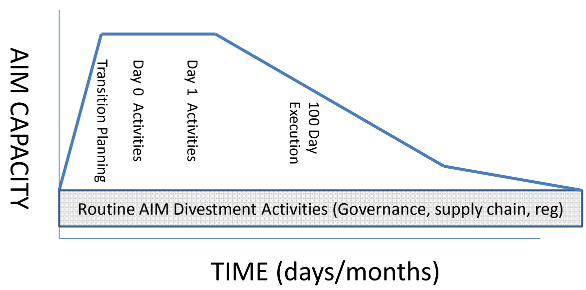
Generally, when the business development team initiates the process for the divestment of an asset, activity unfolds at a measured pace. Not every company involves alliance management at the early stage, but should do so in order to give the opportunity to add value on several fronts.

In the asset divestment process, alliance management workload ramps up in the beginning, along with others on the deal team, then maxes out during negotiations, signing and closing, and then should taper off after closing as the transfer to the buyer occurs.

Nature of Alliance Work



Nature of Divestment Work



Planning for post-deal management of a divestment project should theoretically be easier than other types of deals, because the company divesting the asset is in control of the sale process. Thus, this position gives the business development deal team the time and ability to seek assistance from an alliance manager.

> “Alliance management support on divestments should be complementary”

Alliance managers can add value to the business development process by acting as the linkage between the deal team and the corporate functions supporting the asset being divested. They should already have a well-established network across the company such as with clinical development, manufacturing, regulatory, operations, legal, and other supporting groups.

Alliance managers should leverage their network to assess the complexity of the asset transfer process. This assessment requires a general understanding of the asset, including its supply chain, marketed countries, as well as the end customer. Familiarising the deal team with all aspects of the asset, from manufacturing through commercial, the alliance manager can thereby facilitate a smoother and quicker investigation identifying issues relevant to the divestment negotiations.

The business development deal team should rely on the alliance manager to investigate and detect issues that can and should be dealt with in the transitional services agreement (TSA). Again leveraging their established network, an alliance manager can ascertain special circumstances or complications, such as complex manufacturing processes or specific country regulatory restrictions that will need to be considered in the TSA.

When an alliance manager discovers potential issues and points them out to the business development team, they are better informed as they proceed down the sell-side process. During negotiations, transition-planning involving the alliance manager allows the business development team to identify the number of resources working on the project and understand the resource burden on the company that will be necessary to transfer the asset successfully to the other party.

As with other deal types, the business development team should involve an alliance manager in sell presentations with prospective buyers. Exposure to the prospective buyer allows the alliance manager to learn about its capabilities and capacity to take on the asset. The alliance manager should be able to estimate how long company resources will be needed to support the transfer to the buyer.

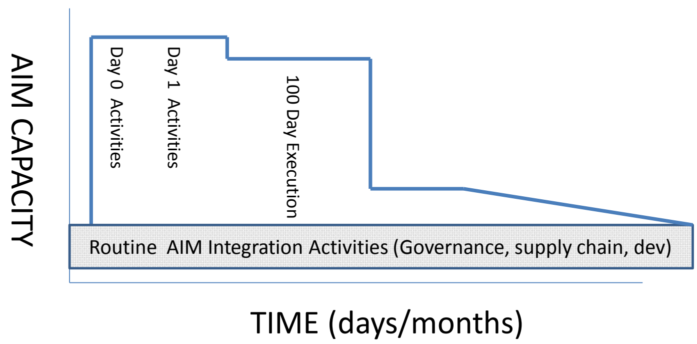
Transferring a marketed product to a small single product company may require a longer transition period while the smaller company gears up in areas such as manufacturing, regulatory, or clinical operations to take on the work. The alliance support and knowledge helps the business development team decide the scope of services that should be provided in the TSA.

Alliance management support on divestments should be complementary to the business development team’s primary objectives and allow the deal team to stay focused on negotiating the financial terms and execution of the divestment contract. Additionally, during negotiations, the alliance manager can begin to prepare employees in affected departments how to be more effective in eventually transferring their work product and processes post-closing.

Asset Acquisition Post-Deal Staffing Model

Corporate acquisitions are one of the most widely researched and publicised types of business deals in the industry. One can readily access comprehensive articles that thoroughly research the business successes and failures of acquisitions. While this article focuses on asset acquisitions, the principles and workload model applies to both asset and corporate acquisitions. It is well documented that one of the reasons acquisitions do not achieve their full value is poor integration.

Nature of Integration Work



Accordingly, the business development team needs to thoughtfully plan for integration during negotiations even under compressed timelines. In the asset acquisition process, the buyer often has significantly less time to plan. Therefore, the integration management workload ramps up rapidly along with others on the deal team, staying at a fever-pitch through signing, closing and at least for the first 100 days.

The post-deal management workload should begin to taper off after the first 100 days of operation, but can have a long steady state period of ongoing work depending on prolonged transfer of activities, such as manufacturing and clinical operations.

Many of the same reasons cited above for early engagement of the post-deal management team in alliances and divestments apply to integration of asset acquisitions. Successful acquisition integration involves an intense, sustained and well-coordinated effort across all departments. Our experience with asset acquisitions at AstraZeneca have guided us to identify and develop integration experts in many of the key enabling functions such as IT, HR, manufacturing, finance, quality, and clinical development. Having a “go-to” person in each of the key functions with integration experience on one or two acquisitions will go a long way in supporting future deals and elevating enterprise-wide integration capabilities.

AstraZeneca places a high priority on ensuring Day-1 is a flawless and memorable experience when the asset acquisition involves transferring employees to AstraZeneca. The integration team creates a separate workstream led by HR dedicated to the “Day-1” experience.

For example, when AstraZeneca acquired the diabetes product portfolio from Bristol Myers Squibb in 2013, a tremendous amount of planning occurred during negotiations to ensure that the 4,000+ employees felt welcome from the start. This meant they had new laptops, could access IT systems, and knew that their benefits and payroll had transitioned seamlessly.

A well-coordinated, cross-functional integration planning process during negotiations allows the business development team to focus on their area of expertise, negotiating the Asset Purchase Agreement.

Summary

Negotiating and crafting a pharmaceutical asset purchase agreement, license agreement, or co-development/commercialisation agreement is a complicated, difficult and fast paced process. Few people envy the life of a business development professional. Days are long, negotiations often require working around the clock, evenings and weekends.

During the negotiation process, business development leaders should not hesitate to accept the help of the alliance management group or post-deal manager. As the work post-deal is different depending on the type of deal, anticipation and planning for those differences is a must. Early involvement of an alliance manager that can carry out such tasks is critical for post-deal success and eases the business development professional's burden.

In the end, our joint objective is to ensure our companies get full value from the negotiated deal. By working collaboratively, before, during, and after the negotiations allows our teams to contribute their respective expertise to achieve the full potential.

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