Maximising Value Through Out-licensing & Divestments

Leveraging the core Alliance Management skill sets to affect a smooth and efficient asset transfer

By Steven E. Twait, CSAP and Emma Barton PhD

Out-licensing activities are becoming an increasingly important aspect in the business development strategy of many medium to large pharmaceutical companies. However, as with all other deal types, signing the contract is just the first step in the path to maximising the value from the deal. A smooth and efficient transfer of assets is essential to ensure that neither the asset nor the patients it serves, are put at risk. Whilst asset transfer between companies is complex and involves activities not commonly encountered by Alliance Managers when managing traditional co-development alliances; the key skill sets and capabilities that underpin the role make them ideally placed to execute transitions and ensure maximum value is achieved for both parties.

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A Changing Deal Landscape

At AstraZeneca, business development and partnering forms the bedrock that supports our three strategic priorities of achieving scientific leadership, returning to growth and being a great place to work. We are committed to building strong and strategic partnerships that expedite the availability of innovative and life changing medicines to patients. Through this activity our Alliance and Integration Management (AIM) team has a strong tradition of managing long term collaborations which bring innovation into our business. As AstraZeneca, like many of our peers, has narrowed its therapeutic focus to three core areas, we have found ourselves with a wealth of innovation and important marketed brands that we are no longer best placed to bring most effectively to patients. Externalisation activity has therefore become a vital part of the AstraZeneca business development strategy.

Externalising innovation can be done to great effect through long term collaborative partnerships, especially in the case of medicines which are still in development and where fundamental expertise still resides in the company.

> “There may be a significant emotional attachment”

Leveraging the capabilities and expertise of multiple partners to share risk and rewards can be a powerful way to accelerate medicines to market, allowing a business to retain an interest and equity in a therapeutic area outside its direct interest. In some cases, the strategy and portfolio of a business can change to the extent that some established or emerging brands would be better served by another company with specialised sales forces or relationships with particular patient groups. The advantages of divesting a product in this way are multiple. Not only can the divested product be brought to a wider patient group and the brand value maximised, the divestment generates upfront revenues that can be reinvested in the seller’s core business and also releases personnel and internal resources to focus on priority projects. Both out-licensing and divestment deals therefore have a role to play in any externalisation strategy.

Balancing the clear and significant advantages of out-licensing and divestment deals, however, poses a unique set of challenges. The transfer of assets between company portfolios is complex, and it can take several years to fully achieve the handover, which can include Marketing Authorisations, packaging and manufacturing activity.

The availability or accessibility of asset information can be a substantial challenge, especially for a mature asset where many of the original personnel who worked on it have moved on. Information may be embedded in data systems that have been upgraded several times. For larger organisations which operate in many countries across the globe, information may be held by local company entities. Pulling all the pertinent information and data together to share with the partner can be an immense, time-consuming task.

Adapting to Change

Human risk is a challenge that is often overlooked with externalisation deals – handing over control to a partner, whether it be of single assets or entire business units, is of poignancy for personnel working on the asset(s).

There may be significant emotional attachment to an asset or franchise: the asset may represent a career’s worth of research; there may be mixed reaction and response to a deal sparked by a shift in strategic direction, and uncertainty and concern for personal job security with the transfer of assets from a business. In instances where the transfer of personnel or potential redundancies are involved, the sense of insecurity and uncertainty is heightened. Even simple, general uncertainties stemming from first time involvement in transitioning work can potentially spark points of misunderstanding between the out-licensing and in-licensing companies. By its very nature, the process of transitioning a product out of a business successfully will rely on the company’s product or franchise experts – those who are personally affected by the change
at the point where they are experiencing most uncertainty.

Cultural and operational fit between the two organisations involved is also important. Very often - with divestments, the corporate culture of the buyer and seller is very different. Frequently, the attraction of an asset to the other party is a chance to expand a portfolio or geographic presence and so the two companies are likely to be different from each other in terms of size and operational focus, origin of business and geographical location. All of this raises potential challenges when transferring assets between the businesses. There is also a high likelihood of a key priority discrepancy between the organisations with regard to the asset(s) under consideration. For the buyer, frequently the asset in question will be transformational for their business and rightly afforded highest priority; a new asset entering a company generates a lot of excitement and enthusiasm and has high visibility with the senior management. For the seller, particularly if it is one with a large portfolio or the asset is a mature product, the asset represents one of a number that the product or franchise experts usually manage; enthusiasm and focus for working on a brand that no longer belongs to the business, or that a partner will be leading on, can wane over time and needs to be carefully managed throughout the transfer.

An Enterprise-wide Approach

People are key to all successful transactions and transitions, and alliance managers are ideally positioned to optimise the experts within their business to maximum effect; not only to add value to the transition activities post-deal closure, but also as a crucial member of the deal team. Alliance teams have an enterprise-wide network. The nature of managing complex collaborations and driving projects with partner organisations ensures that alliance teams are the central hub for the key functional areas across their business and will have strong relationships with foremost figures within those functions.

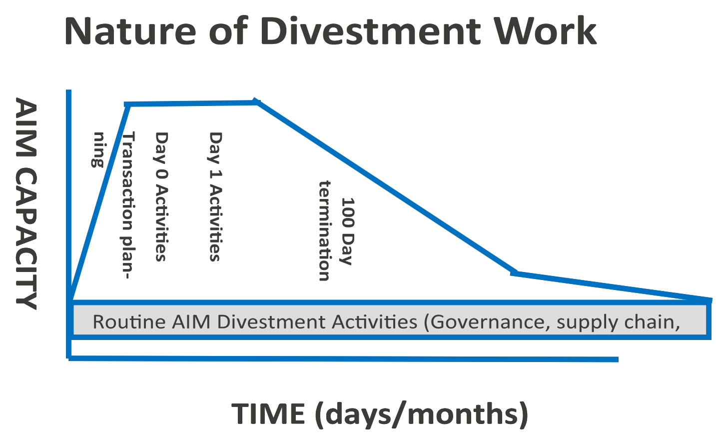
A clear understanding of the asset(s) to be transferred, their strengths and challenges and the likely complexity this will bring to any transition between company portfolios is vital to planning a successful transition and also to influencing early deal documents.

Alliance professionals are strong people managers and typically have a high emotional intellect. This fundamental capability when coupled with an enterprise network makes the alliance manager ideally skilled and well placed to anticipate internal sensitivities across the organisation and to identify and thus mitigate potential human risks for the externalisation.

Alliance professionals have strong internal networks, because they have spent their careers building long-term partnerships with other companies and institutions. This extensive experience of working with different organisations, very often spanning peer pharma, biotech, academic institutions, charitable organisations and governmental interactions means that they are exceptionally experienced to assess the cultural and operational fit between out- and in-licensing organisations, to understand the potential challenges that may occur and plan to mitigate these.

As an alliance manager, one of the key ways to leverage skills and add value to externalisation agreements is to engage early in the deal process. Externalisation activities typically ramp up at a measured pace as transition planning begins, and complete with the maximum level of activity occurring through the first 100 days as the plans are effected and early transitioning begins. As time passes and more activities are handed over to the purchaser, the alliance management workload starts to reduce, tailing off as the last markets transfer and only the manufacturing supply remains.

When an asset is to be transferred from a company portfolio, the timing and pace of activity is within the control of the out-licensing company. Very often a competitive process is initiated which runs to a pre-determined timetable. For the company that owns the asset(s) the target signing and completion date for the deal are therefore generally understood in advance. For the transition manager this is a perfect opportunity to front-load preparation activities and use the time during the deal process to work closely with the deal team. This ensures key planning activities are completed, information transfer activities are started and transition can begin as soon as the deal closes to minimise the time it takes to transfer the business.



Alliance Management from the Outset

The experience, skills and capabilities of the alliance professional have much to offer the deal team, and at AstraZeneca we advocate the **involvement of the transition manager as an active participant in the deal team from the outset**. Thus, they are positioned advantageously to leverage their internal enterprise-wide network to identify the correct functional experts and to coordinate them to understand the product differentiation, competitive advantages and limitations in order to optimise the deal scope and timing of a transaction. The alliance professional as manager for the transition of the asset will need to anticipate the challenges that will arise for the transition team during the planning phase. Early engagement to make this assessment benefits the transition team by front-loading the activities and the business as a whole by removing duplication of efforts by the deal and transition teams.

Simultaneously, the transition manager is able to advise on deal scope and design, and provide insight to the key issues that need to be addressed in the transitional service and supply agreements, such as complex manufacturing processes or specific country regulatory restrictions.

The alliance manager's in-depth understanding of the interconnectivity between functions, the cross-functional dependency and constraints across those functions, is inherent from managing collaborative alliances. This insight is a rich source of information to a deal team as it is useful for informing the timings and contractual content in order to avoid contractual ambiguity. This is especially true for the **Transitional Service Agreement** where clear and accurate description of the activities that will be carried out by the out-licensing company and the duration of that service is crucial for an efficient post-close execution of the deal.

As with all well-run strategic alliances, governance design is also key to the smooth transition, providing a defined route by which issues can be raised, escalated and resolved between the two organisations. The alliance professional is versed in a variety of governance designs and also experienced in running long term partnerships with organisations of various backgrounds; and therefore is able to ensure a process is adopted which is both robust and practical to execute.

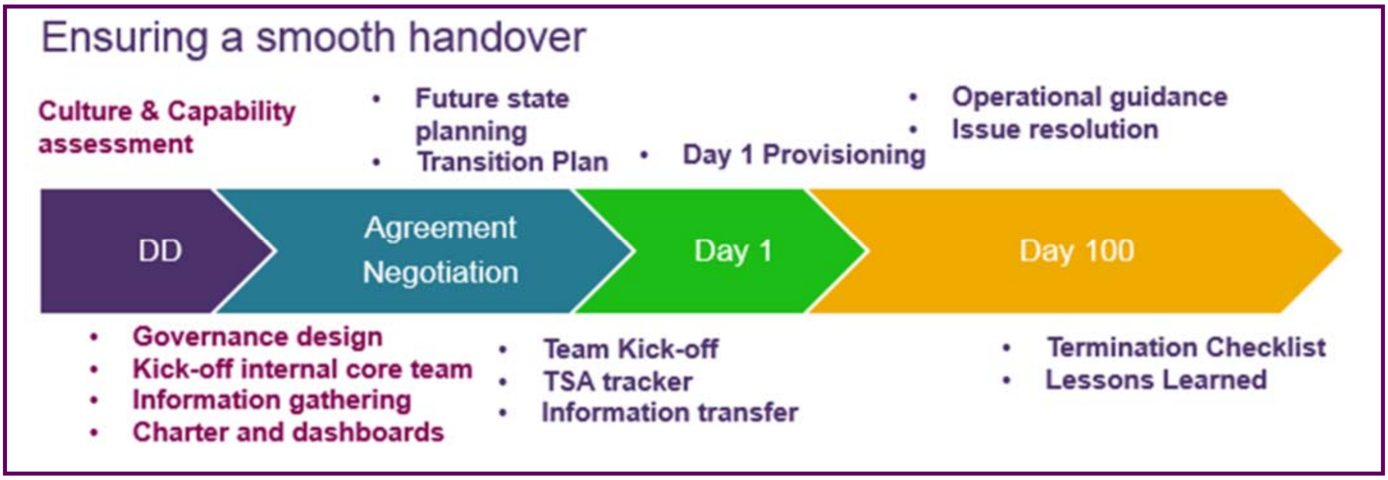
Exposure of the alliance manager to the partner organisation early in the deal process and alongside the deal team is another opportunity to leverage the complimentary expertise of deal and transition experts, contributing to an understanding of the other party's capabilities. This provides insight for the organisation to allow them to anticipate and plan across the functions within their business for the resource and support they will need to provide in order to effect the transfer of the asset. It will also further inform the likely duration and scope of the transitional services that will be required. Where multiple companies are in a competitive process for an asset, understanding the relative capabilities of the potential acquirers - and the full impact of this on the seller organisation against its own priorities - can be an insightful differentiator between bidders.

The presence of the alliance manager during early interactions can also add significant value to the transaction process. It can provide the other party with reassurance of the expertise and capability of the organisation to deliver the asset(s) with minimal impact and disruption. This is especially true when an in-licensing organisation is using the asset to significantly increase its geographical footprint.

The value of externalising products can be realised fully by ensuring a well planned and executed transition of assets between companies. This can only be achieved with strong collaborative and active management of the transition by alliance professionals in both organisations.

Building Lasting Relationships

Transition team on-boarding, a core activity familiar to any alliance manager, is an important first step to reducing the human risk of an externalisation deal. It is key that the company strategy and decision-making leading to the externalisation are well understood. Roles and responsibilities must be clear and there should be a good understanding among all involved of the complexity of the agreement, cross functional dependencies, likely challenges to overcome and duration of involvement so that functional planning can begin across the wider organisation.



Engagement with the buyer transition team is essential to the planning process and as deal negotiations progress, transition managers from both organisations can use the time to align on principles for transfer, agree rules of engagement between their teams and confirm governance design.

At AstraZeneca we consider a face-to-face kick-off meeting between transition teams an essential starting point and the single most effective way the alliance professional can mitigate the human risk of the deal. A meeting held over two days not only removes time pressures, allowing ample opportunity for joint briefing and alignment of transition teams, functional breakout sessions and wider cross-functional discussion between teams, but also allows for some social interaction. The time is formally used for high-level cross-company planning to pave the way for more detailed plans through subsequent regular functional meetings between

> “Communication is at the heart”

companies, but the single most important objective is to **allow the functional team members to start to build a close relationship with their counterparts**. It is essential to a smooth transition of assets that when issues and challenges arise, our functional colleagues feel comfortable engaging in open and frank dialogue to find resolutions collaboratively. Again, early engagement is critical to maximising the impact of the activity and something we seek to do ahead of deal closure to ensure that when day 1 arrives, the transition teams have completed as much of the planning as possible and can start to act on those plans immediately.

As time progresses beyond day 1, the role of the transition manager moves from operational guidance to ensuring that the teams remain aligned and focused on their deliverables and timings, tracking the progress of the transfer against the TSA timings. Not all organisations have the benefit of an alliance management capability and one of the necessary value-adds that an alliance management professional can bring is flexibility and a collaborative approach to driving results. A good alliance manager will spot the gap in alignment within their partner organisation. They will then use their own expertise and a fair and balanced approach to galvanise both company transition teams into a collaborative approach to transition, driving key cross-functional and cross company alignment to ensure that transition occurs smoothly and at the optimal times.

Communication is at the heart of alliance management and is no less important in the externalisation arena; the transition manager can play an important role in issue resolution, representing the first stage in the escalation process. Their internal and external networks can serve well to leverage the learnings of others and help inform of potential solutions or propose alternative options. In this position they can play a useful role in briefing senior management and stakeholders, ensuring that they are updated on progress and achievements of the transitioning team. This communication leverages the senior management to help remove any internal barriers or to hold high-level cross company discussion to promote resolution if required.

Winding Down with Purpose

It can be difficult to determine where a transition ends; different functions across the business will hand over their activities supporting the transferring asset at different times. For some, the involvement is an intensive few months, for others, dependent on market authorisation transfer or manufacturing set up, involvement can be several years. So when the transition is finally complete, for how long should specific functional contacts remain in place to answer any arising queries?

Practises common to long-term partnerships and alliances sign-off translate well to the transition wrap up scenario, differing predominantly in timing of the wrap up. In the alliance setting, wrap up typically happens for differing functions in parallel; with an externalisation agreement, the timing of handover varies so widely that a formal sign-off on a function by function basis giving an appropriate time for final wrap up questions is most effective. This guarantees that both parties are certain of the deadline to ensure everything has transferred and follow up on any queries; the externalisation functional lead can formally hand over and redeploy their time to othe r projects; and both parties are clear on the circumstances under which further information requests are appropriate and how to do so if required.

One of the many benefits to specifying a wrap up and formal sign off on a function by function basis is that it allows for a timely review of the transition for that function, a chance to capture lessons learned and to memorialise them in a central corporate ‘memory’ within the alliance management and integration team. It is also an important chance to promote

that success and personal achievement is rewarded. One of the challenges for the alliance professional managing an outbound transition is the level of enthusiasm in their organisation for working on an asset that is no longer managed by their organisation.

At AstraZeneca we have worked hard to ensure that the value externalisation work brings to the business is clearly understood throughout the organisation, and that individuals who contribute positively and are instrumental to the smooth transitioning of assets are recognised at senior management level. We try to affirm that the experience of working on a transition is valued as an opportunity for personal development and is also a very positive experience. Through this approach we have cultivated an enthusiasm for externalisation work with many people willing to work on subsequent externalisation projects. This has allowed us to embed transitioning capability across our organisation and to generate a community of functional transitioning experts which will allow us to execute future externalisation agreements, learning and improving with every deal.