

Biotech Bootsale

Monetising non-strategic assets can be a valuable exercise. Michael O'Sullivan and Richard Brown at Plexus Ventures explain how divesting certain assets can actually achieve greater enterprise value



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Millions have discovered that listing unwanted items on internet auction sites is a profitable alternative to cluttering the attic or putting them out in the trash. Since there is no viable biopharmaceutical equivalent of eBay, companies frequently hold on to non-strategic assets that receive little or no attention within the organisation. Whether due to a lack of internal resources to invest in them, or a belief that the asset has limited future value, the outcome is the same. Inertia takes over and the opportunity languishes. And yet, in many cases these assets can provide a growth opportunity for another enterprise. Thus, the potential exists for the owner to realise financial gain. To maximise these opportunities, biopharmaceutical companies should have a process in place to periodically evaluate plans and projections for non-core assets so as to clearly understand their real value. In turn, biopharmaceutical and pharmaceutical companies should determine whether a given asset's value could be increased by an interested buyer or licensee.

MEANING AND METHODS OF 'MONETISING' ASSETS

'Monetising' is the conversion of assets that generate future cash inflows into present day cash. The biopharmaceutical industry is a rich environment for monetisation opportunities due to the great variety of both real and intangible assets created in the course of conducting research and development activities and the different ways in which companies perceive the value of these assets. Nowhere does the saying, "One man's trash is another man's treasure" apply more than in industries which rely heavily on the creation of intellectual property. Consequently, examples of company transactions involving monetising assets are regularly observed:

- ◆ Out-licensing compounds at all development phases in return for signing fees, subsequent milestone payments and future royalties

- ◆ Selling rights to a future stream of royalty payments
- ◆ Selling full development and commercialisation rights to compounds
- ◆ Selling rights to the use of intellectual property essential to another company's freedom to operate
- ◆ Selling marketed products or entire business units

MOTIVATION TO CONSIDER MONETISING ASSETS

It is extraordinarily expensive and complex to try to compete in all therapeutic areas, so all pharmaceutical companies develop focused strategies that guide their research pursuits and direct their sales and marketing organisations. As a result, assets deemed less promising suffer from constrained resources, either by a deliberate decision to limit resources allocated to them or as a consequence of their never being positioned high enough on the priority list to receive optimal funding.

Astute management recognises two ways to manage under-resourced assets so they deliver maximum value. They either raise the funds necessary to invest in them or they find an external party who can provide the necessary resources to maximise potential.

A variety of benefits is achieved in the process of shedding non-strategic assets:

- ◆ Remove risks associated with a development programme and/or an uncertain revenue stream
- ◆ Focus management attention and financial resources on strategic assets
- ◆ Free up manufacturing and logistical resources
- ◆ Provide an alternative source of capital funds
- ◆ Deliver immediate cash to the asset owner
- ◆ Provide short-term P&L improvement

MONETISE OR MAINTAIN THE STATUS QUO?

In many companies, little attention is paid to developing strategies for non-strategic assets. Development compounds, which do not meet critical success factors in a clinical trial are often placed on the shelf. They rapidly disappear from the list of compounds under development.

For mature products, revenue forecasts are normally flat to declining in direction – the lifecycle curve. Sales support has been diverted to newer, higher potential products, due to an expectation of a higher return on promotional investment. Little is expected of these assets and they rarely surprise by yielding a return above expectations. However, many mature products, particularly those with complex manufacturing processes or diverse geographic sales, can continue to deliver appreciable return for periods well beyond patent expiry. This may be more certain when the product is in the hands of a company that maintains a keen eye on the product's performance.

Herein lies the nub of the issue. In many cases the mature product in the hands of an attentive owner will deliver greater value than being left to wane in the hand of the, often larger, owner whose attention is, understandably, elsewhere. As a result, a potential buyer is in a position to acquire the product at a price that provides a premium to the value that can be returned by retaining the product.

Companies that have neither recently reviewed the list of internal assets whose development has been halted nor critically examined their marketed product catalogue may not realise the potential value that might be gained by monetising assets that could address another company's strategic aims.

ALTERNATIVES TO MONETISING ASSETS

Do Nothing

The most common alternative to monetising assets is the 'do nothing' strategy, which is elected by default if the list of non-strategic assets is not placed in front of senior management. Non-action has the support of those who proclaim, "Don't keep throwing good money after bad," the typical management response when a product manager proposes an investment in a mature product to the company's management committee. While the default alternative might be a plausible option for already-marketed products, there appears to be little to recommend its endorsement for assets under development or for under-leveraged intellectual property.

Up the Investment

The other alternative is to make the investments required to reinvigorate the asset. For a marketed product, this could mean reinstating promotion and/or launching line extensions or new indications. The objective is to improve the return and/or lengthen the practical life cycle of the product. Investment in a compound is intended to navigate it through the perils of the development process.

DETERMINING THE COSTS OF EACH ALTERNATIVE

One might assume that doing nothing implies resource savings. In fact, the opposite is more likely the case.

The Costs of Milking a Marketed Asset

In some cases, investment in promotion for an older product can yield increased revenue, although many inside the company may view the product as 'tired' and as having no further growth potential. This assumption has been challenged in a number of situations. Typically, this occurs when a company launches a new chemical entity in the same position as an older agent, albeit with some promotable advantages. The company seeks to grow the new product by cannibalising the market share of the older product so that the older product's share dutifully drops. On the other hand, some companies have elected to partition the marketing and sales of the older and newer products with different sales organisations and promotional messages, with the result that both products grow. Such an approach guards against the situation where the company tires of the product sooner than the customer does.

Manufacturing a product declining in volume has a negative impact on costs and variances, due to:

- ◆ Less utilisation of dedicated capacity and/or more frequent production line changeovers
- ◆ Continuing need to meet inventory and customer service standards
- ◆ Increase in inventory as a percentage of sales as production runs become less frequent
- ◆ Increase in the percentage of product returns received from wholesale and retail accounts as product movement through the distribution channels slows. For seldom used products, the cost of returns can approach or even exceed sales revenues

Finally, there are regulatory obligations incumbent on the NDA holder, which mandate the regulatory, medical affairs and patent/trademark departments to prepare and file various required documents, collect and report adverse drug events, answer physician, pharmacist and consumer questions, and maintain patents and trademark registrations.

Clearly, the 'do nothing' approach is not a costless strategy. The decision to milk these assets should include an explicit assessment of the costs of not investing and not divesting.

The Costs of Investing in a Compound under Development

The cost of clinical development of a new chemical entity and its risk of failure can be estimated using experience and expert opinion. Prior to, or at the time of, regulatory submission, most companies will have begun certain pre-launch marketing activities, consisting of market research to establish, for example, the optimal product positioning, price, and promotional message elements. Investments in disease

education directed towards thought leaders become significant at this point as well.

Approximately six to 12 months prior to expected regulatory approval, companies feel the need to have a trained sales and marketing organisation in place to handle the launch and subsequent marketing of the product. The degree to which these are incremental costs depends upon whether the newly developed product is targeted to the same or different customers than the company's currently promoted line of products.

Marketing a product outside the company's focused therapeutic areas will be more costly and begs the question as to how best to achieve value from that asset.

The Costs of Divesting an Asset

While it may not be an overriding factor, the process of divesting an asset has certain costs. Primarily, these are personnel related and may involve the finance, legal, manufacturing, marketing, patent and trademark, regulatory, R&D and technical operations as well as country operations for larger organisations.

- ◆ Identification of non-strategic assets, either by interviewing the leaders of decision-making committees within R&D, marketing and manufacturing, or by combing the minutes of past committee meetings for assets that have lost their resourcing
- ◆ Creation of valuations for each asset, with all costs and benefits quantified. Separate valuations should be prepared from the perspectives of the potential buyers and the seller of the asset, so that both a target price and a minimum acceptable price can be established. This analysis from the buyer's perspective will usually illuminate the characteristics of the most likely buyers of the asset
- ◆ Identification and profiling of potential buyers
- ◆ Preparation of non-confidential and confidential descriptions of the asset
- ◆ Deciding upon deal terms and negotiating the most favourable price and terms for the asset
- ◆ Managing the due diligence process and follow-up

After the deal has been signed, manufacturing and technical staff will need to engage in the transfer of necessary technology and regulatory control to the partner, ensure legal compliance, and manage a smooth transfer of marketing responsibility where appropriate.

Some of these activities may be outsourced to external firms but the overall cost should not be overlooked.

PREPARING VALUATIONS TO SUPPORT DECISION-MAKING

To select the best action plan for a given asset, all scenarios undergo valuation. Therefore the enterprise should develop valuations in each of the following scenarios:

- ◆ According to 'status quo' assumptions
- ◆ If certain investments are made to support the asset
- ◆ In the event of divestiture, including savings resulting from discontinuing both direct and indirect support for the asset

Some contend that divesting a product will not lead to a reduction in overhead expenditure. This is faulty thinking, as all expenditures are variable in the longer term.

Other factors to be considered are reductions in working capital (such as receivables and inventory). In particular, the divestment of a low-volume product will free up manufacturing infrastructure, which in turn may reduce the need for future capital expenditure.

As a result of creating the valuations, the seller can ensure the proceeds received on divestment are appropriate compensation for the asset being sold. Conversely, the seller can ensure its price is not too high by recognising the savings incurred by divesting the asset.

Some may consider it unnecessary to obtain a premium over the asset's valuation, but many believe it is appropriate to cover the costs associated with executing the deal and the transition of the asset to the buyer. An alternative to a percentage premium is to set a specific value below which the costs of doing a deal outweigh the benefits. The targeted gross proceeds set a clear goal for executives to achieve.

THE BUYER'S PERSPECTIVE

It is advantageous to estimate the value of the assets being divested from the point of view of the buyer. What are the

Year	t	1	2	~	9	10	11
Sales		10,000	9,500		6,302	5,987	
Gross profit		6,500	6,175		4,097	3,892	
%		65%	65%		65%	65%	
Regulatory costs	2.5%	250	238		158	150	
Administrative costs	3.0%	300	285		189	180	
Total expenses		550	523		347	329	
Residual value					0	0	5,987
Pretax profit		5,950	5,653		3,750	3,562	
Tax	35%	2,083	1,978		1,312	1,247	
Net profit		3,868	3,674		2,437	2,316	
Changes in NWC		50	75		50	47	898
Free cash flow		3,818	3,599		2,388	2,268	6,885
Discounted cash flow (DCF)		3,470	2,974		1,013	875	2,413
Cumulative DCF		3,470	6,445		19,545	20,420	22,833
Discount rate	10.0%						
		NPV=	22,833				

A 'failed' asset gains new life with a new company

Cubicin® (daptomycin), from Cubist Pharmaceuticals is a novel antibiotic indicated for the treatment of drug-resistant gram-positive bacterial infections. Daptomycin was discovered by Eli Lilly in the early 1980s. Concerns about skeletal muscle toxicity at dosages as low as 6mg/kg per day in divided doses led to voluntary suspension of clinical trials in 1991. In 1997, prompted by the increasing need for new agents against gram-positive pathogens, Cubist Pharmaceuticals licensed the worldwide rights for daptomycin from Lilly and initiated clinical trials in 1999 employing a daily dose of 4-6mg/kg, on the basis of data from pharmacodynamic studies. In 2003, the US FDA approved daptomycin at the 4mg/kg dose for the treatment of complicated skin and skin-structure infections, due to methicillin-sensitive and methicillin-resistant *Staphylococcus aureus* and other organisms, and in 2006, at the 6mg/kg dose for the additional indication of bacteremia, including right-sided endocarditis, caused by methicillin-susceptible and methicillin-resistant *S aureus* (1).

reasons a company might wish to acquire your 'non-strategic' asset? Acquiring companies can have either strategic or tactical reasons. Witness the growth of the speciality pharmaceutical company. Firms such as Forest Laboratories, King Pharmaceuticals, Reliant Pharmaceuticals and, most recently, Meda, have built their early foundations on acquiring older products from multinational companies.

Among strategic reasons to acquire assets would be to facilitate market entry into a new region. In recent years, some Japanese companies have acquired mature products to provide their European or US organisations with experience of a therapeutic class and corresponding physician speciality, in advance of launching their own products. Similarly, companies may seek to attain critical mass in specific countries through in-licensing.

In 2003, Sankyo was planning the launch of Olmetec® (olmesartan), its novel angiotensin receptor-blocker. To strengthen its expertise in this therapeutic area, Sankyo acquired certain European rights to two mature Novartis cardiovascular products – Lopresor® (metoprolol tartrate), a sustained release beta blocker, and Lomir® (isradipine), a calcium-channel-blocker.

Among tactical reasons to buy assets, there is an increase in efficiency when adding products yielding revenue at very little incremental cost. This is the case when adding complementary products to an existing portfolio of promoted products. Acquiring companies may also see the opportunity to increase revenues by increasing promotion to certain customers or by raising price at a faster pace than the asset owner has been willing or able to do in the past. After Eli Lilly sold the US rights for its oral Vancocin® (vancomycin hydrochloride) capsules in 2004, the buyer, Viropharma, raised the published

Table 2: Target gross proceeds

Milking net present value (NPV)		22,833
Capital expenditure saved*		1,000
Working capital gain*		1,550
Net proceeds required		20,283
Premium	10%	22,311
Tax charge	30%	9,562
Target gross proceeds		31,873

* If not included in the NPV

price of this patent-expired but single source product by around 80 per cent, in several steps over two years.

HOW TO MANAGE THE MONETISING PROCESS

In monetising assets, the goal should be to extract the maximum value. In most cases, this can be achieved only by competitive bidding. If the targeted gross proceeds are not realised then the seller should retain rights to the asset.

Methods of achieving your goal:

- ◆ Run a controlled auction
- ◆ Carefully select companies to be targeted
- ◆ Set a timeline for action and keep prospective bidders on this timeline
- ◆ Aim to generate two or more offers of sufficient value to invite those parties into due-diligence
- ◆ Perform due diligence on those bidders. Evaluate their actual capabilities so as to judge the likelihood they can deliver on their bid (for example, bidding a high royalty rate but achieving a lower sales revenue could affect whom you wish to have as your partner)
- ◆ Provide draft agreements to those invited into due diligence and require the bidder to provide 'marked-up' agreements simultaneously with the binding offer

The latter point is of utmost importance. In many instances, an agreed deal has fallen apart when lawyers get into the vagaries of representations and warranties. By receiving a marked-up copy of the definitive agreement drafts as an integral part of the binding offer, the seller can negotiate from strength by refusing to entertain the offer if certain of the contractual amendments are unacceptable or even deal breakers.

The process of running a controlled auction can be facilitated by use of an independent third party. This party will act as a firewall between the firms and reduce the inevitable tensions that arrive in negotiation.

CONCLUSION

Many non-core assets have an underlying value, which may be more effectively realised in the hands of an interested third party. Sophisticated organisations should evaluate the value of non-strategic assets and, if a higher value can be achieved by monetising the asset, take the necessary steps to do so. ◆

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Reference

1. **Clinical Infectious Diseases 2004; 38: pp994-1,000; Cubicin® website**