UNLOCK EUROPE TO CREATE VALUE

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The European Union (EU) is the second largest pharma market in the world[1] and represents a major opportunity for U.S. biotechnology companies. Due to the perceived complexity of launching in Europe, many biotech companies licence their products to partner companies. Often as a result, the full value of the product is not realised by the parent company. With a greater understanding of the region, companies can make more informed choices, secure better deal terms with partners and explore alternative commercialization options.

The Opportunity in Europe is Not Always Reflected in Company Value

U.S. biotech companies typically focus commercialization efforts on the U.S. pharmaceutical market, as it is both the biggest market and the one with which executives are most familiar. Investors routinely seek assurance that executives are planning for successful U.S. commercialization, with attention on Europe.

The opportunity that the European region provides is typically not fully understood or articulated by executives. This prompts investors to price in the value that Europe offers based on high-level assumptions and the default position that the product will be commercialized by a well-established, Europe-based partner. This means that the true value of Europe is lost, and the company's total value is not recognized.

Deeper Knowledge of Europe Creates Value

Though the European market can appear complex and confusing, executives should secure a foundational knowledge of the region, particularly the size of the opportunity and its accessibility. When this knowledge is well articulated, investor confidence increases, boosting total company value. It also enables companies to make better-informed decisions, secure better deal terms and explore alternative commercialization options.

Companies with products in Phase 2 clinical trials are extremely well placed to assess the European opportunity. Outputs of Phase 2 trials need to be combined with a deep understanding of what endpoints in Phase 3 are required to secure regulatory approval, access, a favourable price and reimbursement in Europe. Unfortunately, many U.S. biotech companies leave exploration of Europe until Phase 3 trials are underway.

Such delay is understandable because when resources are limited, teams will tend to simply focus on the U.S. However, once Phase 3 trials are underway, it is too late to incorporate additional insight on reimbursement and access in Europe into their design. This subsequently depresses the total value of the company.

Though companies have limited funds, EVERSANA's experience is that any investment in gaining understanding in Europe drives an increase in company value of 10 times the investment. By allocating a minimum of $200,000 to better understand Europe, company executives can expect to see an increase in value of approximately $2 million.

European Commercialization Key Business Questions

KEY QUESTION	What is required to secure marketing authorisation?	What is the size of the opportunity in Europe (patients/$)?	Which countries should we launch in and in what order?	What evidence is required to launch successfully?	What price can we realistically hope to achieve?
OUTPUT	Regulatory plan	Market size and estimated product forecast	Market prioritisation and launch sequence	Gap analysis and evidence generation	Price corridor

Partnership Carries Risk

Partnering is often the default option for U.S. biotech companies when launching a product in Europe, as a partner company with a well-established European presence provides reassurance that subsequent commercial success will be achieved. Unfortunately, partnership is not without risk. European companies vary considerably in terms of their commercial execution capability, creating the risk that choosing a weak partner will lead to weak returns. Additionally, U.S. biotech companies frequently lack substantive understanding of the size and accessibility of the opportunity in Europe, which leads to asymmetrical negotiation and poor deal terms.

The process of finding a partner can also be costly, with the need to vet numerous potential partners before finding the right one. Once a partner is found, many companies do not take into consideration how demanding the process of supporting a partner in Europe can be. In most situations, when dealing with a regional commercialization partner in Europe, the U.S. company will be responsible for manufacturing, regulatory and reimbursement issues, and coordination of the partnership. Meanwhile, the product may not see significant uptake in Europe for several years, during which time the U.S. manufacturer will have to financially support the rollout of the commercialization partnership and meet the demanding, even if reasonable, needs of the European partner.

Managing the partnership will likely require the hiring of an alliance manager and putting in place other supportive infrastructure. However, the cost to support the launch could exceed the royalty earned. The product revenue will go to the commercialization partner. Suppose the U.S. manufacturer has a 10% royalty on a product that sells $10 million. It could conceivably cost more than the $1 million earned on the royalty to support the partnership.

Finally, investors want to feel confident that any partnership deal that is struck does not hinder the long-term prospects for an exit. A partnership could create complications for downstream exit strategies, as a potential buyer will likely want to unwind any existing deals that had been created with the commercialization partner. This prospect could be enough of a barrier to turn off any potentially interested parties.

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Alternative Commercialization Options Can Create Value at Low Risk

Armed with a greater understanding of the European market and the potential pitfalls of partnership, U.S. biotech executives are well placed to explore other commercialization options. Selling the asset can generate immediate, though limited, revenue and is often reserved for assets that are unlikely to be commercially successful. Licencing to a partner is often the route taken, but as we have outlined above, it is not without risk. This leads some companies to consider launching the product themselves. This can be attractive for organisations that seek to become a fully integrated, global pharmaceutical company, but it is high risk. Decisions about European commercialization need to be made while a product is in Phase 3 trials, the output of which can potentially destroy the commercial opportunity and with it the high level of investment required to launch.

It is only very recently that a fourth option has become available: contract commercialization. EVERSANA is a leader in this field and can identify the right commercialization partners in every country, not just for the short-term gain but also for the long-term commercialization strategy. EVERSANA has boots on the ground in Europe and possesses the capabilities to fully manage the entire commercialization process. And when making a deal with EVERSANA, the non-exclusive coordination of subcontracts makes it easy to pull back in the event of an acquisition. EVERSANA will get a product into the right markets and has the expertise to know which markets to avoid so that reference prices do not collapse the product in the U.S.

An ideal partner is one large enough and sophisticated enough to execute a pan-European strategy while not being so big that it demands significant economic terms. As a regional player with a footprint in both the U.S. and Europe and perfectly aligned incentives, EVERSANA is the best solution for maximizing the value of a product in Europe.

Four Commercialization Options

1 SELL

Minimum Risk / Minimum Reward

- Secure immediate, although limited revenue
- Relinquish ownership including any oversight regarding:
  - Market positioning
  - Product line extensions
  - Prioritisation relative to owner's other brands/products
- Forego any future revenue based on product performance and competitive environment

2 LICENSE

Moderate Risk / Moderate Reward

- Secure partial revenue upfront and additional, although limited revenue throughout product lifecycle
- Relinquish ownership and rights to prioritise over licensing partner's other products
- Share, although limited, in any future revenues, based on product performance and competitive environment

3 LAUNCH INTERNALLY

High Risk / Maximum Reward

- CapEx and risk of building internal teams > $m's
- Potential FDA delay risk and cost of having to make staff redundant
- Team member expertise can be deep but may lack broader market knowledge
- Entire financial burden

4 EVERSANA PARTNERSHIP

Minimum Risk / Maximum reward

- Retain sales revenues less small percentage and commercialisation costs
- Minimise financial exposure – pay for costs only after launch and when revenues are being generated
- Maintain full product ownership and drive prioritisation and life cycle management decisions

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