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## Commercializing Options for Emerging Pharma – What to Do When Co-promotion Is Not for You?

By PDI Inc

As large pharmaceutical companies continue to struggle with maximizing their ROI due to expiring patents and inefficiencies in their sales force models, emerging pharma companies' attractive pipeline has provided them with many commercialization options well suited to their high-risk, high-reward culture. As a result, co-promotion may not offer the optimal path to success. PDI's Hank Nowak shares some other go-to-market options.

As you prepare for product launch, you are faced with a multitude of tasks that require expertise and resources to reach completion. Key among these are medical education and communication strategies, market research, and sales team development and management. Many companies lacking the internal resources or funds to successfully navigate these waters have entered into co-promotion deals to bring their product to market.

For many, these co-promotion deals are ideally suited to their needs. They obtain the share of voice they need without building the costly infrastructure required to get there on their own. They are also able to leverage their partner's expertise and existing relationships in primary or specialty markets. But for others, these benefits come with problems.

Often there are culture clashes between the co-promotion partners. Emerging pharma tends to take greater risks and act accordingly, while their more established larger pharma partners often take a more conservative approach to risk and operate within a more rigid organizational structure and style. These deals also often lead to a loss of creative control, where the emerging company has little or no say in their new brand's promotional positioning and messaging. Both of these issues pose psychological challenges that can be hard to overcome in daily operations.

From a strategic standpoint, co-promotion arrangements can stifle the development of independent relationships with certain targets, seriously hampering future marketing efforts. Finally, there can be net present value (NPV) erosion compared to the possible NPV had the emerging company taken the brand to market on its own.

## Licensing Options

For some, these drawbacks are reason enough to seek other commercialization options. One alternative is outright licensing of the brand to a pharma partner, which offers emerging companies the ability to profit from their technology without investing in development and commercialization resources. For companies most interested in fueling their research and development efforts, licensing offers a great option. They can gain the rewards of commercialization without losing focus on research opportunities.

There are some great licensing deals now being made as more emerging biotechs are leveraging their pipeline by waiting to license their compounds after they have completed the lower-risk, lower-cost Phase I development. Deals can range from simple to complex as the industry works creatively to fill its pipeline with licensed product. There are deal structures where the licensor can have more say in the future of their product, product-by-product options, payments throughout the life cycle, R&D funding, and equity investment.

Cephalon Inc.'s recent proposed licensing of the lupus drug LUPUZOR from ImmuPharma PLC is an example of a straightforward licensing arrangement. In this case, ImmuPharma would receive a one-time license fee, milestone payments and future sales royalties up to \$500 million upon successful completion of its midstage study, while Cephalon assumes all expenses for Phase II studies and commercialization.

Alfacell Corporation's recent licensing agreement with Strativa Pharmaceuticals for the commercialization of Alfacell's ONCONASE gives Strativa exclusive marketing, sales and distribution rights to ONCONASE for the treatment of cancer in the U.S. and its territories. In addition to double-digit royalties on net sales of ONCONASE, Alfacell receives up to \$225 million in cash milestones plus additional non-dilutive funding, an initial payment of \$5 million and up to \$30 million upon FDA approval of ONCONASE for unresectable malignant mesothelioma (UMM). Alfacell has reserved the option to co-promote ONCONASE in the future with Strativa providing technical expertise for an Alfacell oncology sales force and funding certain associated costs.

As with co-promotion, there are inherent risks to licensing your launch brand. NPV and control of the product are sacrificed. In addition, many emerging or smaller pharmaceutical companies do not have the expertise to manage licensing arrangements. This can create internal turmoil and distract the company from its core research mission. Finally, for companies who may eventually want to enter the commercialization arena, licensing prevents them from developing the marketing expertise needed to launch new brands.

## Going It Alone

What path do emerging companies have to take if neither co-promotion nor licensing is right for them? If they have successfully navigated and funded the FDA approval phases for a new drug, going it alone

may be a realistic option. These companies may have the funding to build their own internal resources to go to market, or they may elect to outsource key sales and marketing needs with PDI.

In either case, pursuing a go-it-alone strategy allows them to maintain their valuation and deliver the highest potential NPV to shareholders, certainly creating investor confidence and generating opportunities to pursue other deals. Such companies are also able to maintain product control and build a successful commercial capability that will serve them in the years to come.

Outsourcing key needs to PDI helps companies mitigate the risks and costs associated with assembling their own go-to-market team and strategies across the four phases of commercialization: Defining, Developing, Delivering, and Deploying. They can tap our extensive industry experience in sales team development and management, market research and medical education to fill the gaps in their own infrastructure and get up and running quickly. And with PDI as their go-to-market partner, they do not experience the competing priorities that might arise with a pharmaceutical partner. Unlike pharmaceutical partners, our goals are 100% aligned with theirs - objectives, systems, management - they are all seamless with the emerging company's mission and directives.

## **Defining**

Through our TVG Marketing Research and Consulting company, we start with the proprietary TVG Marketing Model<sup>®</sup> to create a well defined and integrated road map for strategic planning and identifying research needs throughout the product's life cycle. We conduct primary market research, market landscape assessments, competitive simulation workshops, and global strategic workshops to help understand the role all stakeholders play in the success of the brand, including policy makers, prescribers, payers and patients. Drawing upon panels totaling over 400,000 healthcare professionals worldwide, we are able to provide insights into the markets and customers that exist throughout the globe.

## **Developing**

Vital Issues in Medicine (VIM<sup>®</sup>) is an industry leader in the field of medical education for healthcare professionals. Companies can rely on this PDI company to help assess, plan and deliver the educational information necessary to support their field sales efforts throughout the launch and growth phases. Drawing upon literature searches, distinguished key opinion leaders, medical societies and prestigious teaching hospitals and universities, we customize programs of live events, collateral materials and electronic media to meet their needs.

## **Delivering**

One of the most effective ways to deliver brand messages and encourage product trial is through peer-to-peer discussion. Our Pharmakon company is an industry leader in the development and delivery of

unique peer persuasion programs. In the past three years we have conducted nearly 20,000 peer persuasion programs involving more than 200,000 participants. Working with teleconferences, satellite broadcasts, lunch & learn sessions, dinner meetings, weekend events and alternative technologies, we customize a program suitable to the brand's therapeutic class, markets and marketing objectives.

## **Deploying**

Perhaps the most critical element in the successful commercialization of a brand is the field force that is deployed. PDI is known throughout the industry for our ability to deliver quality primary care, specialty and hospital sales teams across a broad range of therapeutic areas. We can customize their team from a variety of models including full- or part-time dedicated teams, using our field management team or theirs.

Our proven ability to launch on time is derived from our award winning, best-in-class recruitment model where we can deliver a qualified, dedicated sales team within 21 days. Before deployment, all PDI reps are fully trained through our award winning talent management programs, including PDI University and other learning platforms to foster top performance in the field. We support our reps with best-in-class tools and systems, including technical support for collaboration tools, mobile connectivity and data security; our sales force automation platform with the necessary hardware, helpdesk, CRM tools and PDI Tracker; field administration of rosters and alignments and related communications; analytics and reporting through our proprietary PDI Informatics, PDI Perform and PDI Analyzer tools; promotional compliance through PDI Comply and PDMA Compliance; and logistical activities involving fulfillment, fleet management and meetings and events.

In many instances, PDI can provide flexible deal structures that enable emerging pharmaceutical companies to meet their strategic and financial objectives. Examples include a partial risk-share arrangement where they fully fund PDI's base sales costs and we earn a profit based on performance, or a full risk-share contract where we fund our sales force and earn a profit based on product performance.

## **Flexibility**

There are many benefits to be derived in going it alone with PDI as an outsourced partner. Not only do companies get to market quickly without the expense and investment of internal resources required to build internal infrastructure, but they optimize their flexibility to react to changes in market conditions. They can move from full- to part-time sales coverage and vice versa, delete certain or all territories, convert our reps to company employees, change marketing research tactics, or cut or add to medical communication efforts without major repercussions within their organization or investor community.

## **Case Study: Navigating and Implementing an Early Stage Commercialization Strategy**

A case in point is that of a recent client who had a molecular diagnostic test they needed to commercialize. The product represented a new approach to disease screening and our client had no

experience in marketing directly to the physician marketplace. Their existing nine-person sales force was limited to selling capital equipment. They had no alignment of territories or a systematic rationale for a physician target list. They also had lacked experienced, professional marketing support to develop physician marketing, detail aids and collateral materials. To complicate the situation, their management team was skeptical about the effectiveness of a field force dedicated to physician details.

Despite this skepticism, PDI was brought on board to provide market analyses, assessments of product potential, and territory mapping for optimal sales force coverage. We also were contracted to hire, train and deploy sales teams.

To accomplish our objectives, we established market analysis assumptions and conducted market research where none had previously existed. We then mapped and realigned 66 territories, with 65 being filled at any one time. We correlated assessment results with territory ZIP codes to identify the busiest practices and hired and deployed the field force to pursue these targets. Although we were initially charged with full responsibility for the development and management of the physician sales team, we successfully transitioned the entire team to our client's employment roster over a two-year period, including the management team at the end of that time. After this initial contract, we continued to hire and train field reps for them until they reached their sales rep goal of 100 reps.

The results were exceptional. According to Verispan and our data on file, our client's revenue doubled to \$66.9 million in the two-year period where we had our reps in the field, and we achieved 40-50% more sales in territories where there was face-to-face selling.

## **Conclusion**

The risks faced in developing a drug are enormous. According to TVG research, development costs of a new Rx drug from initial discovery through FDA approval are typically in excess of \$800 million and only one in 5,000 compounds ever makes it to market. Still, there is a tremendous opportunity for success. Finding the right commercialization option is key. Co-promotion or licensing is not the answer for everyone. For those who have successfully navigated the FDA approval process, going it alone with key functions outsourced to PDI will enable them to quickly reinforce or add to their core competencies so they are able to compete in marketplaces dominated by more experienced players.

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