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WHY GO CSO, AND WHY NOW?

The life sciences industry has undeniably entered a new environment for product launches.

Not only are the products changing, but those inventing and commercializing the products are transitioning as well. According to a recent research study published by McKinsey, product commercialization trends through 2018 point to:

• 75 percent of the brands being launched to be "specialty" drugs, up from 58 percent in 2008

- 53 percent of the new drugs being classified as "moderate or no differentiation"
- Over half of these new drugs coming from companies launching their first brand
- Only one out of 10 members of the typical launch team having ever launched a product

Certainly, moving past the patent cliff and entering the world of genomic medicines and specialty biologics has created more pressure on the industry to produce under an even higher level of scrutiny. Small and emerging biopharmaceutical companies are particularly challenged to succeed within this environment. These companies are working with limited resources, and looking to optimize investor cash in every way possible. And although staff from these organizations may have very competently shepherded the company through research and development, many do not have the requisite skill set to fully commercialize the brand.

Faced with this reality, and with so many invested resources at stake, what does an emerging specialty pharmaceutical company do when its product is ready for

commercialization? How does the company ensure the best chances for brand acceptance... whether it is introducing a highly differentiated specialty medicine or fighting for market share with a "me too" brand?

For many years, emerging specialty pharma companies have sought partnerships with large pharmaceutical companies to bring their brand to market. Large pharmaceutical companies, looking for drugs to quickly and cost effectively enter their pipelines, are happy to partner. Deals abound, from licensing product to selling commercialization rights outright. For some, these partnerships are the answer but for others, despite assurances to the contrary, their larger partner's sales team does not meet performance expectations.

As a result, more and more specialty companies are searching for alternative options to bring their brand to market. One would be to "go it alone," using any remaining investor cash to maintain control of commercialization efforts and minimize risk. Going it alone, however, could mean investing as much as \$10-15 million to field a 50-person team (or \$200-250K, fully loaded, per rep/year) yet still involve significant risk. With the complexities of today's market entry, another more prudent option is to outsource and leverage a contract sales organization's (CSO) already vetted and proven infrastructure plus tap its built-in economies of scale from multiple client engagements. Another advantage? Partnering with a CSO allows companies to enter the marketplace with minimal risk.

Working with a CSO also allows emerging pharmaceutical companies to build flexibility into their sales model from the outset, an attribute its larger pharmaceutical counterpart is finding critical to delivering a positive return on investment (ROI). With an experienced CSO partner, emerging companies can easily build an agile, scalable, responsive team to meet customer needs, making sure to address critical market segments with the right type of sales representatives and scaling up and down as the market dictates with no impact on its own operation.

Reduced commercial overhead spend

Many commercialization experts within emerging pharma companies have been lulled into thinking that an internally built effort will achieve their objectives. They believe that simply overlapping departments and eliminating some key support structures will support reaching performance targets with limited resources. Too soon they learn this is not the case. There are many hidden costs in building a successful sales team. Functions such as talent selection, training and human resources support; compliance; operations and analytics; fleet management; IT and sales force automation – are all critical to success, demanding expertise, time and money to develop and function efficiently. Yet, all of these functions are already well-established capabilities within a CSO, and can be put to use to support a product with very little lead time. In this way, a CSO can help the brand get to market faster, more quickly recouping investments. By working with a CSO, the biopharma company can actually enjoy the best of two worlds. It can maintain its desired control over commercialization but can also tap into the strategic and tactical experience a CSO partner can bring to the table.

Zero to launch services

Since CSOs began in the 1980s, today's CSO has evolved to meet changing market dynamics. Now, in addition to sales teams of varying types and sizes, CSOs offer a complete commercialization package. Just as there are many ways to partner with big pharma, there are many ways to engage the services of a CSO to create the control desired over commercializing the brand.

CSOs now help emerging pharma companies define their outreach strategies as well as execute them with an assortment of field and virtual representative profiles. CSOs have established expertise in such areas as market analysis, targeting, and state and national payer access and reimbursement. They also offer call centers and digital platforms to access health care providers, with built-in reporting to keep programs on track. And, because CSOs have the advantage of working with companies across many specialties, their insights draw from a wide experience that can further enrich the overall engagement.

Risk mitigation

Having access to the broad experience in product commercialization efforts a CSO offers is certainly one way to mitigate risk. However, working with a CSO can significantly lessen launch risks for two other important reasons. First, the emerging pharmaceutical company outsourcing commercialization to a CSO doesn't need to make any long-term investment in

commercial infrastructure so if sales targets are not met, there are no losses to absorb. Second, when any downsizing or department restructuring needs to occur, it is done on the CSO side. Indeed, most CSO contracts have a timely termination clause to handle any downsizing responsibilities. Fleet, severance and technology equipment are all handled by the CSO.

Surpassing target goals: a case study

CSO engagements can be structured in many ways to meet the sales targets and ROI goals of the emerging biopharma company. Some outsource the entire commercialization process to the CSO, with a CSO account manager reporting into the biopharma's senior management. Others choose to maintain partial internal control over the sales force; while others intend to eventually directly employ members of the CSO team, and therefore, utilize an embedded model with internally supplied field management.

The following case demonstrates such an embedded model engagement. In this situation, the biopharma company had an existing front line management team built during a failed launch with an established pharmaceutical company partner. It wanted to leverage its existing regional management team in the new engagement with the CSO, using it to coach and train the CSO field reps with useful selling techniques. Its end game was to bring the CSO field team in house should the initial launch efforts prove effective.

The biopharma company used its internal sales leadership team of a senior vice president of sales and four regional frontline sales managers. These individuals had corresponding management on the CSO team in account executives and field liaisons. (See Figure 1) The structure of the relationship with the CSO met the letter of the law for co-employment while giving the biopharma sales managers full autonomy to coach, train and monitor the sales force. The sales force performed like employees of the biopharma when in actuality, their paycheck, vehicle and IT field support came from the CSO. To make sure the team members would be eventually suitable to the biopharma's internal environment, the CSO worked closely with the biopharma company throughout the recruiting and onboarding process to identify ideal candidates for long-term employment with the company.

Improving the call quality in this engagement was particularly important to both the biopharma company and the CSO. Both parties felt the prior product representation fell short because call quality was not where it needed to be. To address this, the CSO sought recruits who had three to five years of prior successful experience selling in the pharmaceutical industry so they could best address this specialty segment. In addition the performance of the group was strengthened by the experienced biopharma's sales management team's active role. These seasoned sales managers were able to create their own standards of excellence for benchmarking selling skills based on actual prior experience, and also controlled the content and execution of the product's positioning and messaging. In an IMS study of call measures comparing the earlier pharma team to the CSO team, 52 percent of the CSO sales calls were considered of excellent quality, while only 23 percent of the original pharma team sales calls achieved the same level.

As a result, the group hit the ground running. After less than six months of engagement, the CSO field team had eclipsed the contract's overall objectives. Total and new prescriptions had surpassed the prior pharma team performance in even its highest month, and this was with half the total number of monthly sales calls. Total and new scripts were also on a steady growth curve, allowing the biopharma company to forecast a break-even and a pro-forma ROI revenue line for future planning.

The CSO drew upon its analytic capabilities to assess territory coverage and recommended that an additional 26 territories be covered. The resulting sales trend and financial footing was so positive, the company was able to bring the original CSO sales team of 40 aboard as direct employees ahead of schedule, while continuing to leverage the CSO's other 26 field reps and operational and back-office functions. This strategy allowed the biopharma company to continue to conserve investor cash while maximizing revenue streams and bottom line profits.

The future impact of "Going CSO"

Certainly the parameters of every CSO engagement are individualized to that engagement and can lead to different outcomes. However, the upside in any such partnership can be significant when executed properly. Outsourcing definitely allows companies to utilize state-of-the-art systems and automation platforms normally outside their ability to procure. They benefit from experienced talent, with no internal recruitment and onboarding processes. The list goes on.

However, achieving brand success with a CSO does more than help secure the financial viability of the emerging pharma company. By establishing the validity of the company's research and development platform with the marketplace, this success paves the way for future market acceptance of products in the company's pipeline. And with the cost of product development skyrocketing amidst increasing regulations, the opportunity to create an environment of acceptance for future products can certainly be a strong motivational factor for engaging a CSO.