By Med Ad News staff

Why go CSO, and why now?

Practical options for emerging specialty pharma

By Gerry Melillo

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.

Facts & Figures

While development of personalized medicines has grown since the human genome was first sequenced in 2001, biopharmaceutical sponsors face a number of hurdles that are impeding more rapid market uptake, according to a recently completed study by the Tufts Center for the Study of Drug Development.

Fourteen years after the human genome was initially sequenced, paving the way for development of personalized medicine, **13 percent of drugs marketed in the United States today post pharmacogenomic information on the label**, but developers continue to encounter challenges relating to basic science, regulatory and reimbursement policies, and, equally critical, clinical adoption, according to Tufts CSDD.

"The biopharmaceutical industry is increasingly committed to translating genomic discoveries into personalized medicines, but it needs to overcome scientific, regulatory, and economic challenges," says Joshua Cohen, associate professor at Tufts CSDD. "In particular, the continued development of personalized medicine depends on identifying biomarkers and developing clinically useful diagnostic tests."

He noted, however, that higher R&D success rates alone may not translate into commercial success without physicians increasing the rate at which they prescribe personalized medicines, supported by payer willingness to reimburse users.

Biopharmaceutical companies said they expect investment in personalized medicine to increase **33 percent**, and medicines in development to increase **69 percent**, over the next five years.

Biomarker identification and **diagnostic test development** rank highest in terms of scientific challenges, followed by **regulatory and reimbursement issues**. **Oncology** products continue to rank highest in terms of average share of personalized medicines in development across all phases, followed by **neurology** and **cardiovascular** drugs.

To date, the Food and Drug Administration has approved **137 drugs** with pharmacogenomics information in their labeling, with **20 percent** of all FDA approvals in 2014 for personalized medicines, according to Tufts CSDD.