Finance transformation in the pharmaceutical industry

Developing the finance function across the product development life cycle

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The global pharmaceutical manufacturing industry generates more than $950 billion of revenue annually, with the U.S. accounting for 21 percent of the sector’s worldwide revenue. In the U.S., the industry is forecast to grow steadily at an annual compounded rate of 5 percent between 2013 and 2017.1 Although pharmaceutical companies’ recent sales are soaring, only 1,500 companies exist in the U.S., and very few actually begin as pure research and development (R&D) organizations. Unlike other innovation-driven industries, successful pharmaceutical companies that begin as R&D organizations require a long-term planning approach, in order to manage the increasingly difficult pharmaceutical business model.

1 First Research, Industry Overview, NAICS code: 3254
On average, the successful development of a new drug can take between 8–15 years (as shown in Figure 1 above). The total cost of discovering a new product and bringing it to market can range from $500 million–$1 billion. The most expensive stages occur at the start, when companies typically are unable to generate revenue (as shown in Figure 2 above). As a result, the inherently long-term approach of the pharmaceutical industry results in specific business difficulties to the organization during all phases of product development (inception to commercialization). While the length of the development cycle has historically been a challenge for companies in this space, companies are now also facing their toughest competition to date, due to several challenges, including:

- Increased scrutiny of pharmaceutical companies from legislators to reduce “evergreening” (a common patent extension tactic used by pharmaceutical companies), and to develop generic drugs
- Enhanced regulatory pressure on new and old drugs, making the process of obtaining and maintaining regulatory approval more rigorous and stringent than in previous years
- Decreased number of dominant insurance companies authorizing the use of new drugs that are too costly or only slightly more effective than the cheaper alternative

Commercializing new pharmaceutical drugs in the 21st century is harder and more expensive than in previous years, due to these industry challenges and inherent industry traits. In order to succeed in this current environment, companies must proactively design a long-term growth road map beyond research and development. One of the most overlooked aspects throughout the evolution of a new drug (from inception to commercialization) is the key role played by the finance function.

This white paper highlights strategic considerations for your finance function throughout the product development life cycle, starting with the R&D and preclinical phase, through the commercialization phase. Ideally, finance functions will be able to construct their own road map for any and all stages of development after reviewing the following observations.

**R&D and preclinical phase**

On average, it takes a pharmaceutical company 6.5 years to discover, screen and engage in preclinical research and development. During this stage of development, the finance function plays a key role in making sure the organization continues to sustain operations. Cash flow management, strategic sourcing and talent management within new pharmaceutical companies are all crucial components of the finance function’s activities in establishing a solid foundation for future growth.

Budgeting and planning activities are critical components of the cash flow management process, as the organization hires scientists and researchers, and spends money to develop a new drug product. The cash outflow for companies during the initial phase typically accounts for 39 percent of the total amount spent to bring a product through phase IV of the process. Implementing procedures to plan for, and track, spending is critical to support decision-making, and ensure the organization has the necessary cash reserves to sustain operations through the product development life cycle. Companies need the ability to quickly evaluate whether projects are financially and strategically viable. Thorough analysis of costs and potential expenditures must be managed carefully, since most companies are pre revenue to start. Budgeting must be addressed and planned for both the short term and long term. Implementing technology and hiring the right talent must also be considered carefully as pharmaceutical companies grow. While implementing policies, procedures and technology to support these efforts, organizations should not forget that without business unit and departmental accountability, these efforts will not be effective for the organization.
Typically, during the R&D and preclinical phase, companies are not generating revenue, unless they have other drugs being sold commercially or have entered into licensing agreements. Most small R&D companies do not have the resources or need for a full-time treasury department; therefore, these organizations must have talent to help fill this role, as it serves as the main pathway to capital. Consequently, early-stage pharmaceutical companies should seek to attract personnel with broad talent, and expect them to take on various finance function responsibilities. As shown earlier in Figure 2, the initial phase is the most capital-intensive. Therefore, it is imperative to have an efficient treasury function to raise capital, and manage investments and cash flow.

Figure 3

Organizations usually raise funding through venture capital financing, sales of stock (both private and public) or public offerings. However, companies typically begin using private capital prior to entering public markets, which usually occurs in the early clinical phases. Figure 3 demonstrates where the heaviest capital investment is acquired. Along with budgeting, planning and fundraising, purchasing during the R&D and preclinical phase must be given careful consideration.

With an average of 39 percent of total spending across all phases occurring in the R&D and preclinical phase, the procurement function plays a significant role in the management of cash spend. Pharmaceutical companies should seek to establish and enforce sound purchasing policies and procedures throughout the organization, and leverage technology to manage and facilitate the overall process. Organizations must develop strong vendor management practices, developing relationships with suppliers, controlling the purchasing process (procure-to-pay) and effectively negotiating contract terms to maximize available funds.

Developing solid capabilities to support the procure-to-pay process is an essential step in tying the organizational operations to the operating budgets, defined as part of the budgeting and planning processes. Establishing a procurement function early on also allows the company to seek opportunities for volume purchasing discounts, further evaluate vendor relationships and drive adoption of processes before the volume of transactions and dollar amounts increase significantly following the commercialization of the prospective drug.

While the establishment of policies, procedures and processes are important factors to the development of an organization in these early stages, companies should not fail to recognize the importance of talent management. Talent management not only includes the hiring and retaining of employees to meet the current needs of the company, but also the strategic planning of talent requirements for the future. Ideally, within the finance function, the organization should seek to retain high-performing individuals with broad knowledge and experience of the different functions within the finance department, but also with relevant industry experience. Ideal candidates will be willing, and have the ability to execute transaction-level activities, in addition to developing the overall vision and capabilities of the finance function.

Companies should not overlook the importance of technology to support these items. Today, many low-cost on-site and software as a service (SaaS) enterprise resource planning (ERP) solutions exist with broad capabilities and scalability perfect for small to midsized organizations. During this stage, companies should evaluate and select a solution that will meet their immediate and long-term needs, with a focus on implementing the features and functionalities that would support their process and cost requirements.

R&D and preclinical finance function focus:
Establishing the finance foundation for future growth
Critical to supporting long-term sustainability and growth. Achieved through cash flow management, strategic sourcing and talent management.

1. **Cash flow management**: Meager cash inflow and an inherently long-term business model makes effective budgeting and planning vital to the organization
2. **Strategic sourcing**: Strategic sourcing reduces and controls costs, as well as promotes organization sustainability
3. **Talent management**: Retain existing and acquire additional talent with relevant experience and broad skills to support the growing needs of the organization
Throughout the clinical trials, companies continue to hire R&D, quality assurance and quality control personnel, as well as higher–level management to support the increased workload associated with executing clinical trials. Future increases in head count to support operations during these phases should be carefully planned as part of the budgeting, planning and forecasting processes. Successfully projecting needs allows the organization to support decision–making regarding the need to hire personnel, use of external resources and ensuring adequate funds are available to support resources as they are acquired.

As the number and size of clinical trials grow, there is an obvious increase in demand for clinical trial product. To meet this demand, companies begin the manufacturing of clinical trial product via several different suppliers, depending on the number of stages in the manufacturing process. As a result, companies must be able to easily track and account for the manufacturing of clinical trial product, in addition to tracking and accounting for clinical trials. Organizations should seek to develop these capabilities through the implementation of technology, policies and procedures to support this need. Since this need impacts multiple departments, including finance, organizations should seek to collaborate with affected departments, in order to understand their unique requirements before implementing a solution. The finance team also must begin building a strong relationship with the manufacturing and supply chain teams, as these departments will work together to value, track and budget for inventory once approval is granted. Lastly, given the certainty of future changes to the manufacturing process, the systems, policies and procedures implemented to support these operations will continue to evolve even after product launch.

The purchasing function’s role during the clinical phases grows significantly. Purchasing is responsible for assisting the supply chain department in engaging clinical material suppliers and manufacturers, ensuring vendor contractual compliance and controlling costs. The purchasing function should be actively negotiating master services agreements (MSAs) with suppliers, in order to minimize risk and manage costs. The purchaser should also be closely monitoring the materials purchased from vendors, and perform continuous analysis by department throughout the organization. If not done so already, the organization should consider further enhancing the procure–to–pay process through the implementation of additional finance technology, such as a requisition system or automated work flow, in order to allow the purchasing function to support the organization as it scales, without a significant increase in purchasing resources. Lastly, by the purchasing function interacting closely with supply chain personnel early on, a vital communication channel is opened and ready to use, in the event of commercialization.

Naturally, companies are seeking ways to generate cash inflow during the clinical trial phases. Many early–stage organizations will enter into milestone agreements with bigger pharmaceutical companies. Generally, other established pharmaceutical companies will obtain a financial position in the potential product, and compensate the development company for meeting development milestones. Successfully reaching a milestone creates revenue, and therefore, a need for an accounts receivable function. Depending on the significance of revenue, the number of products being developed and how far along the clinical trials have progressed, companies should evaluate the need to develop processes, and enhance systems to support these operations.
During the clinical trial stages, companies should begin to evaluate and develop a tax strategy to support short-term and long-term operations. Given the complexity of domestic and global tax laws, companies should seek to hire outside legal and tax assistance to start analyzing and developing an appropriate tax structure for the future organization. For those seeking to establish global operations, additional consideration should be given to topics such as intellectual property (IP) transfers and licensing transactions.

As the finance function develops throughout the different phases of the product development life cycle, it is important that it establishes itself as a credible partner to the other functions in the organization. This partnership, critical to the establishment of efficient and effective processes, is achieved through a shared understanding (and agreement) of the roles and responsibilities of each function, the upstream and downstream impact of key operating decisions and the information needs of each function.

Registration and FDA NDA approval

On average, a U.S. pharmaceutical company spends 1.2 years bringing a new medicine to market, and longer in other global markets. In the U.S., the final stage begins with registration for a New Drug Application (NDA) with the Food and Drug Administration (FDA). While the FDA processes the NDA and conducts their review of the prospective drug, the finance function’s primary focus should be preparing for product launch.

During this period, the finance team’s roles and responsibilities grow and become more central to the organization. This growth includes the addition or enhancement of capabilities to support the accounting for product revenue, tracking of product manufacturing costs and physical inventory, and financial and management reporting. Developing these capabilities includes additional policies and procedures, which are required to support operations, often driven by contractual agreements between manufacturers, distributors and vendors. In addition to enhancing these capabilities, the finance function must fully establish itself as a collaborative partner with the rest of the organization. Therefore, communication between the finance, supply chain, legal, commercial and information technology (IT) departments is imperative.

Pharmaceutical companies often enter into agreements with contract manufacturing organizations (CMOs), drug distributors, specialty pharmacies, specialty distributors, hospitals and other businesses that will help them reach patients. At this time, collaboration within the organization should have been established during the later clinical trial phases, and should become second nature to all departments when working with external parties.

Finance function focus:

Product launch preparation

1. Revenue recognition
   a. Method – Selecting sell-through or sell-in
   b. Technology – Recording transactions, receiving data from customers and using technology to perform trend analysis

2. Process and policy
   a. Development – Defining inventory, revenue, consolidation, procure-to-pay processes and policies
   b. Implement – Employing processes and training personnel to ensure streamlined work flow

3. Collaboration – Communication with all stakeholders across the organization

The amount of capital spent by companies in the registration phase accounts for 5 percent of the total spent to bring new drugs to commercialization. Initially, companies will often receive positive or negative feedback from the FDA. In the event that the feedback is positive, organizations will typically begin preparations for product launch by hiring several sales associates, supply chain managers and finance management, which results in an increase of total company compensation. The budget forecast becomes a higher priority when management begins to compare revenue to cost of goods sold moving forward. A budgeting system should be deployed, or be in the process of being implemented, in order to hit the ground running and forecast effectively once the drug is approved.

Cash flow

Sustaining cash flow in a prerevenue company is vital during the final stages before commercialization. Companies need to continue normal operations effectively and efficiently, while ramping up most functions across the organization in preparation for product launch. Precommercialized pharmaceutical companies with positive feedback from the FDA can raise capital relatively easy. However, investors will begin to question why current rounds of financing have not sufficed; this may uncover poor operations or management.

If the organization wishes to outsource manufacturing of its products, contractual agreements with CMOs regarding the purchasing of future product material that will ultimately end up in the finished product need to be carefully crafted during the registration phase. Companies must understand that, for the first time, the medicine’s ingredients will be capitalized, and have an impact on the balance sheet upon FDA approval. The purchasing department must seek the best prices, and negotiate appropriate contractual terms that limit the liability risk of owning inventory. The accounts payable
Selecting the proper revenue recognition method is a critical task that the (AP) department should be educated on. Understanding the payment terms, with the legal and commercial department during the planning phase, is essential. Advisors will lean towards (or are strongly persuaded to use) methods that are public, that are launching their first drug and have no history. This area is the method by which companies recognize revenue. Typically, life sciences companies will select and disclose whether they plan to recognize revenue based on the sell-in or sell-through accounting method. The sell-in method refers to recognizing revenue at the point in time the product is purchased by the entity that sells the product directly to the patient. Alternatively, the sell-through method recognizes revenue when the product has reached the patient. The primary difference to the organization is that the latter of ten results in increased deferred revenue balances, and a greater level of effort to validate and recognize revenue.

Developing these policies and procedures can be complicated, as guidelines are heavily scrutinized that can impact the reporting of external financial results to the street for public companies in the life sciences industry. One such area is the method by which companies recognize revenue. Typically, life sciences companies will select and disclose whether they plan to recognize revenue based on the sell-in or sell-through method. The sell-in method refers to recognizing revenue at the point in time the product is purchased by the entity that sells the product directly to the patient. Alternatively, the sell-through method recognizes revenue when the product has reached the patient. The primary difference to the organization is that the latter of these results in increased deferred revenue balances, and a greater level of effort to validate and recognize revenue.

Due to increased regulation and scrutiny on the top-line revenue numbers, significant challenges exist in reliably estimating gross-to-net deductions, including: product discounts, copay assist programs, government reimbursements and returns. Therefore, companies that are public, that are launching their first drug and have no sales history, will lean towards (or are strongly persuaded by auditors) the sell-through method. Each revenue methodology requires data transfer from the distributors dealing directly with the customers. Companies should implement systems that can receive electronic data interchange (EDI) to maximize efficiency of accounts receivables from all customers. Furthermore, collaboration with the legal and commercial department during the design phase of the contracts with pharmacies, insurance companies and government medical organizations must be designed carefully, because it will ultimately impact revenue. Selecting the proper revenue recognition method is a complex decision, which affects the bottom line. High-profile pharmaceutical companies should enlist subject matter advisors to ensure the correct method is selected and implemented properly.

In addition to preparing revenue processes and policies, the company must also plan for inventory tracking and capitalization during the registration stage. Consider designing and implementing an inventory tracking and costing software or an intricate Microsoft Excel system. Prior to the commercialization go-live date. A well-positioned company will understand how inventory will be tracked throughout the supply chain — raw materials (RM), work in progress (WIP) and finished goods (FG) — and document memos supporting expiration dates, clinical inventory and accounting treatment of overhead, shipping, waste and quality assurance testing. Policies defining the accounting treatment of the inventory should near final stages at this time. Collaboration with the supply chain and manufacturing departments is vital during the registration phase. The supply chain and manufacturing departments need to understand the business decisions now affect the financial statements at both the income statement level — cost of goods sold (COGS) and balance sheet level (inventory) — versus just affecting R&D costs. In addition to understanding how inventory will be tracked, the organization needs to define its cost methodology (standard, actual, batch, etc.), and implement systems to capture costs. Companies also tend to have irregular inventory for a period after FDA approval, because material that will be used in commercial product had been previously expensed. Therefore, COGS will also be relatively low following FDA approval.

As reiterated through each of the phases outlined in previous sections of this document, it is important to insist all departments collaborate with finance during contractual agreement negotiations. Policies for contracts, such as distribution agreements, pharmacy sales, purchasing from CMOs, insurance companies and government pricing, should be implemented and followed. As finance is involved with the contract execution process, the department is able to plan future processes to follow when the go-live date occurs. The processes that are built for revenue recognition and inventory capitalization need to be Sarbanes-Oxley (SOX)-compliant, in most cases, which can result in hiring a third party to design and implement controls.

At this time, companies should implement their tax structure plan, crafted in the later clinical stages, especially if the organization is expanding overseas. If an IP sale was selected, it is critical that the IP transfer is timed correctly. During this phase, companies typically sell the IP to the new entity, transferring the rights to sell the product.

Preparation for the product launch is not only limited to the development and implementation of policies, procedures and systems. In order to support the added responsibilities of the finance function following the product launch, finance should begin hiring necessary resources to support the additional business processes and those with the necessary experience to drive company growth domestically and internationally. Each company’s gaps will be different, so it is important to identify and address deficiencies prior to commercialization, in order to smoothly transition to a fully commercialized pharmaceutical company.

Companies that successfully take advantage of the short registration period will ultimately see better results when the drug is granted commercialization.
Commercialization

Drug products that have been recently approved for marketing in the U.S. or Europe are known as “recent approvals.” FDA approval is the date when pharmaceutical companies will go live. As discussed in the previous section, commercialization of a medicine requires an increasing level of attention to the AR, revenue recognition, inventory, contract management and tax functions within the finance department. However, if the systems and processes were successfully implemented during the registration phase, this transition should be relatively smooth.

Once a product receives commercial approval, finance employees and other stakeholders will have been trained on all systems, software, processes and policies that will be used for the first time. A learning curve will still exist, no matter how much preparation a company has; however, preparation reduces information overload and makes reconciliations less painful. It is vital for all stakeholders to meet routinely, and discuss what is working and what needs to be altered, in order to work more effectively. As FTEs become comfortable with new responsibilities, these meetings will quickly turn into process, data and software improvement meetings. At this time, any new projects must be documented, planned and thoroughly vetted, since companies can easily become overwhelmed with all of the change.

Commercialization is the beginning of a company’s data history. Data such as sales, payer mix, cost, credit and cash history must all be captured and analyzed on an ongoing basis. Organizations must not overlook documenting the young history of the commercialized company, because this data will be used later to support excess and obsolete (E&O) reserves and payer mix estimates and changing revenue recognition accounting policies to sell-in. Companies should consider developing robust Excel models, or investing in business intelligence software, to produce business analytics prior to commercialization. This information will prove especially valuable to public companies that need to defend all material estimates to auditors.

Pharmaceutical companies finally receive their price to sell the new drug from the FDA upon approval. Although the revenue department can now plan for payer mix reserve and return estimates with more precision than before, the function will still be faced with complex reporting and reconciliation issues. Issues such as Veterans Affairs (VA) and Department of Defense (DOD) chargebacks, Medicare gap coverage, Medicaid best price, copay assistance and many other price adjustments will be complicated, and must be meticulously documented during the first few quarters of sales. Cost of sales recognition depends on the recognition of revenue, further complicating these transactions from the start. It is imperative that the finance department continues to work with the commercial team to monitor and confirm payer mix estimates, as communication will remain important throughout the existence of the business.

Systems for budgeting, inventory costing and tracking, forecasting and general ledger (GL) accounting should be implemented or nearly complete. Once the product gains traction in the market, the people responsible for forecasting, budgeting, costing and tracking inventory quickly become overwhelmed with information, and can benefit from the appropriate technology. A good budgeting process and system will also help the heads of the finance department talk to boards and investors with more precision and reliability. An effective inventory system should be able to adapt, especially as new suppliers are either added or eliminated, and as the company expands globally. At this point, companies should have a good idea of how reserves and other GAAP accounting-related issues will be treated.

Best practicing companies will take a look at the processes, policies and controls implemented and used in the first quarter after approval. Many of these practices will need to be refined as the company settles into normal operations. However, this is a good opportunity to reflect and customize processes, policies and controls to the company’s new and projected needs.

All of the other finance functions remain incredibly important, and continue to perform similar roles as in prior stages.

Conclusion

R&D companies evolving to become fully commercialized pharmaceutical companies must be proactive during the growth of the organization, while balancing the amount spent on growth. A proactive approach for designing and implementing infrastructure to support the transition through phases will gradually mold the culture of the company to a commercialized organization, and eliminate simple miscommunication and resistance to change. Along with the evolution of infrastructure, pharmaceutical companies going through drastic changes cannot underestimate the power of active hiring, before any potential problems occur. Solid processes, policies and controls should be carefully constructed and implemented as much as possible prior to commercialization. This approach
will create communication throughout the organization, and become an incubator for an organization working together across all lines of business.

It is imperative that the organization welcomes the finance function to act as a partner with all departments. Change management also cannot be overlooked throughout the development of the organization. Although a delicate approach is recommended, at times, forced communication will be encouraged. Finance departments always need to focus on both long-term and short-term strategies regarding personnel and IT infrastructure.

The delicate nature of an R&D company’s evolution into a fully commercialized company requires a plan, strict budget adherence and good guidance. Aspiring commercialized pharmaceutical organizations should carefully consider seeking outside guidance to time system, process, policy and personnel implementation. External advisors have experience in assisting companies through all stages of the R&D life cycle, and can serve as a great partner to guide companies from the preclinical phase through commercialization.