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Biopharmaceutical Industry and Interrelated Biotechnology Organizations – Accounting and Finance Challenges

Overview

The biopharmaceutical industry and interrelated biotechnology organizations focus on medicines and drugs formulated by biological processes of living organisms. These organizations operate within a heavily regulated environment and face many operational challenges during periods of research and development through commercialization of products. The pharmaceutical development process is highly complex, requiring superior operational focus to address risks and navigate regulatory processes.

In addition to the robust focus on operations, these businesses must also focus on raising capital, collaborating with other organizations and, as the business matures, merger and acquisition related activities and perhaps going public through an initial public offering. The necessary management focus extends well beyond science and operational project matters. Specifically, finance and accounting matters also bring a unique set of challenges. In order to be successful in both the near-term and long-term, businesses must be supported by a strong accounting and finance structure to allow the business to continue to focus on operational aspects without undue distraction.

Discussion

The level of sophistication and requirements of finance and accounting matters increase over time as organizations grow and become more sophisticated. It is important to be proactive and obtain accounting and finance support early and align the group with short and long-term initiatives of the company. Proper focus will allow the company to be well positioned on relevant accounting practices and internal control matters and enhance the ability to appropriately capture and report financial information. This proactive focus on accounting practices and internal controls helps demonstrate effective governance and can enhance the confidence of customers, investors and partners allowing these key relationships to mature.

Finance and accounting organizations, within biopharmaceutical and interrelated biotechnology organizations, face complex issues and must exercise significant judgment in applying authoritative guidance to research and development costs, acquisitions and divestitures, consolidations, contingencies, revenue recognition practices, income taxes, financial instruments, and financial statement presentation and disclosure matters.

Some specific areas of focus follow.

Accounting Matters

General

When forming the accounting and finance support structure, it is very helpful to include members on the team and/or outside support organizations that have accounting and finance expertise in the pharmaceutical and biopharmaceutical industry. Equally important is the need for these individuals to have a business-facing acumen and the ability to organize, control and monitor documents and processes that support the business.

During the early hectic times of the organization, it is highly beneficial to focus on the accounting and finance needs of the company on a short-term and longer-term basis. An honest self-assessment will have ongoing benefits and avoid unnecessary surprises in the future. Early considerations include review of the current state of knowledge within the accounting and finance function, the ability to understand and properly account for ever-increasing complexity of transactions, existing processes related to documentation organization, control and storage, opportunities to standardize processes and the state of basic financial controls.

Once the accounting and finance support structure is secured, whether internally or externally staffed, attention should then be focused on how key documents throughout the organization will be organized, stored and retrieved for future reference. Despite the appearance of simplicity, many newer organizations fail to focus their attention to this space. Establishment of strong practices in this area will establish a structure and foundation on which accounting and finance teams can rely upon throughout the company's lifetime. Policies and practices include such matters as to how records and key documents are approved by management, retained, stored and accessed by only appropriate individuals. Key financial records and documents often include financing agreements, stock option plans and other equity awards, articles of incorporation and bylaws, key contracts, minutes of the Board of Directors' meetings, licensing and royalty agreements and vendor records.

It should be noted that many key accounting areas such as revenue recognition and accounting for leases require full access to underlying agreements to ensure that related activities are accounted for in accordance with Generally Accepted Accounting Principles (GAAP). Implementation efforts are greatly eased when the accounting organization can be confident that the records gathered are complete and accurate.

Early attention should also be given to the company's internal control structure. A strong internal control environment helps management to understand and address risks to the organization. Internal controls and supporting processes help assure that the organization's objectives are met regarding effectiveness and efficiency, reliability of financial reporting, and compliance with laws, regulations and policies.

R&D Funding Arrangements, Licensing Agreements, Collaborations and Milestone Payments

The development of new compounds and products is generally time-consuming and costly. In order to cover the costs of development, it is often necessary for biopharmaceutical and interrelated biotechnology organizations to obtain external funding. The various types of financing transactions often include complex terms and conditions that require careful accounting analysis.

Alliances with more established pharmaceutical organizations are often structured as licensing transactions, co-development agreements, joint ventures, or sales and marketing alliances. These relationships are often vital to growth strategies for both parties. Pharmaceutical companies have the capabilities, operational scale, and available cash to partner with biopharmaceutical and interrelated biotechnology organizations in the development and commercialization of new products. In many of these arrangements, pharmaceutical companies secure rights to percentages of equity or product-licensing rights in the biopharmaceutical company, in exchange for future royalties or product revenues.

It is best practice to include senior members of the accounting and finance team early and throughout the negotiation and agreement drafting process to ensure key terms and language, within the contracts, accomplish not only the operational, but also the expected intent and accounting outcome. Accounting requirements and considerations that entities must evaluate are complex and subject to varying treatment depending on how the agreements are structured. A thorough understanding of the application of related GAAP to the biopharmaceutical industry and interrelated biotechnology organizations is necessary to properly evaluate the substance and nature of the various types of relationships, risks and related deliverables to determine the appropriate accounting to be applied.

Revenue Recognition

Revenue recognition is one of the most complex and risky areas of accounting. In May 2014, the Financial FASB issued a new revenue recognition standard - *ASC 606,* Revenue from Contracts with Customers. The new standard provides a framework that replaced existing revenue guidance and moves away from previous industry and transaction-specific requirements under GAAP. Under the new guidance, companies must identify contracts that are within the scope of the guidance and apply the appropriate guidance. The standard impacts the accounting for many types of customer relationships within the biopharmaceutical and interrelated biotechnology industries and requires companies to reassess and possibly adjust revenue accounting policies. Determining when and how revenue is recognized in these arrangements can be extremely complicated and subject to significant judgment by management.

Some specific areas that will have potential impact include the way in which companies record up-front fees and milestone payments associated with long-term R&D collaborations; application of revenue recognition rules to multi-year arrangements; and contracts that include a combination of various elements, such as development, licensing and manufacturing components.

The application of revenue recognition criteria requires strong knowledge of the new standard, focused judgment, a thorough understanding of the economic substance and terms of the arrangement, and the ability to objectively track and measure progress against deliverables in the various arrangements.

Organizations will have to evaluate their systems and internal controls to ensure that applicable contracts can be tracked, analyzed and measured against contract deliverable progress. Further, comprehensive and written internal revenue recognition policies must be written and shared throughout the organization to ensure that key employees, and those who are involved in contract negotiations, understand key aspects of the standard.

Gross-to-Net

Revenue generating organizations should also have accounting teams that possess a thorough understanding of Gross-to-Net (GTN) revenue accounting. This theory requires companies to calculate and estimate adjustments that are typically made to the gross price of a product. Many mature organizations use third-parties to commercialize and/or distribute their products. Adjustments include costs of discounts and rebates that distribution companies receive that reduce the gross selling price. Other pricing adjustments, reducing the gross selling price include chargebacks, government rebates and sales returns and drug buy-back programs.

Chargebacks are offered to distribution companies that purchase drugs from a manufacturer at a gross price, known as the Wholesaler Acquisition Cost (WAC), and then sell them to consumers at a different-lower contract price, allowing them to minimize a level of pricing risk in their business. In these arrangements, the wholesaler keeps track of sales to various customers under prices negotiated between the manufacturer and the customer. The wholesaler then “charges back” the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler’s cost of goods (WAC).

Rebates are negotiated pricing adjustments to the gross price and are typically a percentage of the selling price or a per-unit rebate (fixed dollar amount per product sold). These discounts may be applied based upon market share or volumes and may also include incentives for prompt payments. Volume-related rebates are usually calculated upon predetermined sales volume targets agreed by the parties.

Medicaid rebates are discounts and rebates are paid to state governmental entities. Federal rules require that states pay for medicines only at prices derived by very specific calculation applied to the sellers’ sales information. In addition, those companies that want to have their medicines covered by Medicaid must also provide rebates to the state Medicaid programs. For brand medicines, the basic rebate is the larger of a stipulated percentage of the average price paid to manufacturers by wholesalers for medicines distributed to retail pharmacies (known as AMP); or the difference calculated by taking the difference between AMP and the lowest price the manufacturer offers to most other purchasers.

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Returns and drug buy-back programs are generally accepted in the industry and are intended to minimize the financial risks that wholesalers and pharmacies assume when stocking products by allowing them to sell / return unused products with near-term or expired shelf dates back to the manufacturer.

Equity-Based Arrangements

Use of investor equity-based arrangements have become more customary in the biopharmaceutical and interrelated biotechnology industries in recent years. The predominant structure is that an investor makes an initial payment to obtain the rights to specific research and development assets or shares of the investee for a predefined exercise price. These option-based structures provide benefits to the investee including upfront cash when the option is issued, additional sourcing for short-term financing, certain improved balance sheet metrics, and enhance market credibility that may possibly attract other investors for future deals.

In addition to use of options in investor relationships, many biopharmaceutical and interrelated biotechnology companies use equity in lieu of cash to attract employee talent and partnership relationships early on when cash is scarce. Founders, key employees and others in strategic relationships are often awarded equity. Equity awards include different forms, including stock options, restricted stock awards and warrants.

Best practices in the area include formalization of the various plans, maintenance of the documentation and ongoing monitoring of the impact on the overall capitalization structure. These seemingly simple organizational-type efforts can greatly reduce future exposure to disputes over key terms, such as pricing and the number of awards granted. Formalization of the transactions must be subjected to proper authorization by appropriate level of management to ensure alignment with overall management intent.

It is extremely important that management obtain input from supporting legal, tax and accounting teams during the creation of these arrangements to ensure entrepreneurs in this space fully understand ramifications. Prior to issuance of any type of equity instrument, the accounting and finance team will advise on the accounting consequences of the equity instrument, such as the determination of whether the financial statement treatment is appropriately “equity” or whether accounting guidance demonstrates the instrument should be classified as a liability. The accounting team will understand differences between accounting for awards issued to employees versus third parties, assess the reasonableness of pricing of the options in light of recent financings and developments in the business such as technological milestones, and consider other areas such as key management additions to the business and regulatory approvals. Often the accounting team will secure the services of outside valuation experts during the exercise.

The accounting team will also advise on such things as revenue recognition implications associated with warrants granted to strategic partners, and the accounting impact of contingencies or performance conditions of an employee or contractor equity arrangement.

Again, it is highly desirable to include senior members of the accounting and finance team early and throughout the process to ensure key terms and language within the contracts accomplish the expected intent and accounting outcome.

Leasing

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-02, Leases (Topic 842), which replaced Accounting Standards Codification (ASC) 840. The two most impactful parts of this new standard are the classification criteria for operating and financing leases for lessees, and the treatment of operating leases on the balance sheet. Public entities were required to report leases under ASC 842 in fiscal years beginning after December 15, 2018; all other entities have until fiscal years beginning after December 15, 2021 to conform to this new standard.

Although time-consuming, arguably the most important step in implementing the new standard is gathering and storing data related to a company's lease population to be used in a lease administration system. Companies should determine a proper administration system to aid with the data collection, and the necessary calculations and disclosures in their financial statements.

The main choice for selecting a lease administration system will be whether to use an off-the-shelf software solution or manually track leases using a spreadsheet. Before making this determination, companies should conduct a survey within the organization to ensure they have a good understanding of their entire lease population. There are numerous factors to consider, including total number of lease contracts; types of leased property; lease payment terms, including escalating rent clauses; security deposits and other initial direct fees; ability to enter into contract modifications; and residual value at the end of the lease.

Systems

In the early days of many organizations, accounting and finance systems that are basic in nature may be suitable. Most organizations that are maturing at a good pace quickly realize that these basic platforms will be insufficient for mid and long-term purposes. Use of very basic accounting packages, supplemented by spreadsheets and highly-manual processes lack integration of information throughout the organization.

In the past, robust accounting packages were sometimes costly, and required use of internal servers and localized software implementations. Over recent years, the cost and method of delivery of these packages has greatly improved. There are several cloud-based and affordable solutions that can quickly supply organizations with accounting and reporting packages that address the need to satisfy investors, maintain compliance, and make data-driven decisions.

Movement towards more sophisticated solutions can create challenges for the organization, but an upfront needs-based review of system requirements can avoid ongoing smaller, incremental required changes that can be disruptive, expensive and painful.

It is important to select a solution that will sustain momentum by delivering what the organization needs immediately, but with a view towards ongoing automation, scalability, ability to track project costs, reporting requirements, and greater insight into the business for management. As more systems are added for the growing organization, it is also important to consider data integration to focus on how the different systems will share data to be able to address evolving internal and external reporting and procedural needs.

Beyond general ledger, fixed assets, accounts payable, accounts receivable and other basic functionality, biopharmaceutical and interrelated biotechnology organizations will eventually require systems that can support Project Accounting, Inventory Costing and Cost of Goods Sold calculations, multiple entities and consolidations, and internal and external reporting requirements.

A discussion of these system needs is included below.

Project Accounting, Inventory Costing and Cost of Goods Sold

In order to track progress of individual projects, properly represent Cost of Goods Sold and Inventory costing, while also meeting reporting requirements of investors and government compliance agencies, it will be necessary to implement systems or enhanced manual processes to meet the needs.

Systems-based solutions generally will result in more efficient use of the accounting team's resources, reduce the risk of error, and provide a clearer understanding of the costs associated with each project. The accounting team, CFO and Controller will surely appreciate the positive impact of a properly-sized system solution. Others in the organization, such as project managers, will also benefit. With proper implementation, information can be shared via dashboards and reporting tailored to supply easy access to data that's meaningful and actionable. Transparency of project costs will allow active cost management and allow data-backed decisions to be made. Dashboards tailored specifically to the management team, the board, and investors may also enhance satisfaction levels and address areas of concern up-front.

As mentioned, there are several cloud-based and affordable solutions that can quickly supply organizations with needed functionality. The project accounting portion of the solution should enable tracking of all costs related to specific projects, including time, materials and testing costs. The solution should also provide the ability to accurately allocate shared costs to provide insight into fully-loaded costs and resulting potential profitability.

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Consolidations and Reporting

Legal Entity Structure & Consolidations

As the organization continues to expand 3rd party relationships, investments and legal entities, with varying degrees of ownership, biopharmaceutical and interrelated biotechnology organizations will need systems that can support accounting for multiple entities and consolidations to allow reporting and review of the organization at different levels.

Beyond the system need, accounting expertise is also required to determine whether an entity should be consolidated. Since entity ownership may depend on differing levels of risks and rewards of the parties, it is necessary for the accounting team to carefully analyze arrangements with those parties to ensure proper accounting and reporting.

Reporting

Reporting requirements in many biopharmaceutical and interrelated biotechnology companies will initially be fairly basic and focused on the needs of investors. As organizations grow, the availability of management and externally-oriented reporting will be required. In order to satisfy these increasing needs, many companies will move towards full GAAP financial statements and ultimately will move to SEC-style financial statements. Systems and accounting knowledge must be sufficient to support this effort. The enhanced level of reporting provides a strong back-bone for a possible future initial public offering, carve-out and sale of portions of the business or merger activities.

Financial Planning and Analysis

Successful management of the multiple aspects of biopharmaceutical and interrelated biotechnology organizations will put continual pressure on accounting and finance organizations to deliver deeper knowledge of the business by utilizing enhanced reporting packages, statistics, benchmarking, and analytics.

Information gathered at the lowest-reliable level possible will allow the organization to prepare more realistic budgets and forecasts at a summarized and/or project-level. Successful budgeting and forecasting requires companies to carefully define milestones and monitor their progress closely. If projections are not reasonable and based upon sound historical information and careful input from project managers, surprise variances to budgets and forecasts may arise, and potentially lead management to rely upon inaccurate cash requirements and other resource needs.

Organizations also should not underestimate the effort and value of projecting capital expenditures and funding to ensure alignment with the strategic plans of the organization. Further, additional effort is necessary to coordinate the estimation process with any external organizations that are under collaborative arrangements.

Controls

Internal control refers to the processes and systems that are established to ensure financial transactions are properly authorized, recorded and reported, and that assets are safeguarded against improper use. Internal control focus ranges from protecting and managing the organization cash to appropriately accounting for and tracking contractual relationships to overall corporate governance matters.

The extent and nature of the internal control environment is a cost/benefit consideration and should be tailored to specific business needs and inherent risks that face the business. The internal control framework may be fairly basic in the initial phases of the organization and will generally move towards a more complex internal control structure. In order to comply with standards required as an SEC registrant (public company) it will be necessary to comply with Sarbanes Oxley guidance. An interim step for many companies is to adopt more vigorous control structures over time, which are not fully compliant with Sarbanes Oxley, but are vastly improved over basic controls. These control structures are sometimes referred to as *SOX-lite*.

Audit Readiness

Many biopharmaceutical and interrelated biotechnology organizations that are in early days, do not expect the level of preparation, coordination and time commitment that is required for the typical audit process. Companies should meet early in the process with the external audit firm team to understand documentation required, the overall audit process, key deadlines, etc. Strong communication paths between management, individuals that will be involved in the audit and the external audit firm is essential. Often, the internal accounting team does not have sufficient time or knowledge to ensure a successful audit. If external consulting resources are required, coordination and communication with this group is equally important.

Final Thoughts

Biopharmaceutical and interrelated biotechnology organizations operate in a highly complex operating environment, requiring superior operational focus to address risks and navigate regulatory processes. In addition to the robust focus on operations, these businesses must also focus on raising capital, collaborating with other organizations and, as the business matures, merger and acquisition related activities, and perhaps going public through an initial public offering.

Finance and accounting matters bring a unique set of challenges. In order to be successful in both the near-term and long-term, businesses must be supported by a strong accounting and finance structure to allow the business to continue to focus on operational aspects without undue distraction. It is important to be proactive and obtain accounting and finance support, both internally and via external consulting firms, early and align the group with the short and long-term initiatives of the company.

Fidato Partners understands the unique challenges in your industry and has a proven hands-on track record of providing accounting and finance support and guidance to biopharmaceutical and interrelated biotechnology organizations at every stage of the organization's lifecycle.

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