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# Advice to Biofirms: Be Prepared, Plan Ahead

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Executives with emerging life science companies face some of the most significant transitions in any industry.

As companies progress with their product development, management must maneuver for the first time through a wide range of regulatory requirements, the need for expanded and complex infrastructure, financial statements of increasing complexity, relationships with larger industry partners, and other factors.

Meanwhile, all of these items increase in prevalence against a backdrop of dwindling financial reserves in what continues to be challenging financing environment. At this point, management can't focus solely on growth; it must place a sharp focus on how to lead the company from a prudent financial perspective.

This requires significant advance financial and strategic planning on an annual basis along with the flexibility to adapt as needs and operating environment factors shift.

It is important to start early by initiating your financial and strategic planning for the following year in the third quarter of the preceding year. Start by drafting the company's goals for the next year as well as the initial budget estimates to accomplish those goals.

All CFOs should look at the upcoming year and consider whether significant events or transitions, such as clinical trial success or failure, funding, partnering, a product launch, restructuring, or acquisition, are likely to occur.

Important capital projects facing life science companies, such as a laboratory build-out or the purchase of expensive scientific equipment, are additional planning considerations. All require significant management time and resources and all must be incorporated into the planning and budgeting exercise.

Other activities for the following year, even though they may not be a high-budget or capital item, must be contemplated to reflect the evolving state of the company and the external environment. The reporting of a company's financial statements needs to reflect the changing operations of the company as an important activity.

Finally, nonfinancial considerations for life science companies, such as a change in the regulatory landscape or significant FDA action (PDUFA date), are critical in the planning process.

It is extremely important that these activities and plans be communicated to and discussed with the rest of the executive team. A consensus will be needed, not only on which activities deserve higher priority but also on the amount of capital required to accomplish these activities.

Often, companies will have more projects than human or financial capital resources to complete them. Discussions among the management team and scientific project team are key in determining project priority.


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### Review Everything

A second area of focus is the annual review and testing of internal controls (Sarbanes-Oxley compliance). Life science companies continue to evolve, and it is important that related internal controls are appropriate for the complexity of your company and, if necessary, revised and updated.

Considerations for revising internal controls include: adding new divisions, such as sales and marketing, or manufacturing; installation of new accounting software; significant changes in the number of employees; prominence of a single financial statement line item such as inventory; and entering into a collaborative agreement.

CFOs should challenge internal controls each year to ensure they are keeping up with the company. An early review and testing of updated internal controls with your auditors will help identify and remedy any deficiencies so that they can be retested later in the year.

An exercise that can be valuable to any public company CFO is the review of assumptions of covering analysts. Understanding the assumptions underlying their financial models, including revenue and expense projections, market penetration, or competitive advantages or disadvantages is essential.

One goal of this activity is for the CFO and the company to determine if its current communications approach with the investment community can be improved so that there is a better understanding of strategy and goals. This is particularly important if your company is undergoing a significant transition that results in your company being valued differently by investors than it had been in the past.

A very important item for all life science companies is an understanding of your company's financial status and your expectations of the future funding environment. Planning for future financing activities is critical and demonstrates the proactive thinking of a company's CFO. Raising capital should not be a "do it when we need it" activity. It should be strategic and controlled.

All CFOs should assess their capital needs for the next 18 to 24 months in conjunction with annual budgeting activities and on an ongoing basis.

Preparation for a financing should start about 12 months ahead so that an evaluation of the potential investment bankers and the type of financing that you wish to employ are appropriately evaluated. There are a variety of options such as a traditional common stock offering, PIPE, ATM, registered direct, and convertible debt offering, to name a few.

Each type of financing has pros and cons based on ownership dilution, management time, warrant coverage, and timing of capital-raising.

Understanding the market environment is also critical. Although no CFO has control over it and predicting how it will unfold is difficult at best, it is essential to understand what is happening in the life sciences and overall marketplace. In the life science industry, there continues to be a special situations environment, i.e., companies with good data, especially in cancer, and those hitting major milestones are able to access capital. Companies without these attributes face greater challenges in raising capital.

As in every year, there is a lot to do to prepare for the next year, so start early. Those in the life science industry have particular challenges due to the significant transitions that companies in this sector face.

CFOs should plan budgeting early and generate consensus about company priorities. Internal controls should be reviewed on an annual basis, and times of expected transition deserve particular attention. Review what the analysts are writing and modeling.

Smart CFOs take a proactive view of their company's financial condition and operations. Continually review financial needs over the short and long term and evaluate a number of capital-raising options understanding the pros and cons of each. In short, plan ahead and be prepared. GEN