

Finance/Funding



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▼ Proactive accounting: a key factor in the success of biotechnology startups

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Neglecting the proper management of accounting functions can jeopardize the trust between a biotech company and its stakeholders.

Entrepreneurs starting up a biotech company have the same priorities as those at traditional technology ventures: to realize their vision and commercialize their technology. Yet the unique challenges of developing and managing a biotech company are often larger in scale as a result of industry-specific technological and regulatory factors. It can cost \$800 million and take 15 years to take a drug from discovery to market in a highly regulated environment, forcing bioentrepreneurs to navigate various strategic alternatives to commercialize their technology. Executives must also contend with a number of other complex regulatory matters, including third-party reimbursement¹. Add to these the endless struggle to raise capital and the long list of stakeholders to which a life sciences company must answer—from shareholders to strategic partners to regulators—and it's no wonder bioentrepreneurs frequently overlook essential infrastructure needs at the early stages of development.

Accounting considerations

Young biotech companies enter into a number of complex arrangements with pharmaceutical companies and other biotech firms and often do not have the infrastructure or resources to reasonably manage their accounting and financial functions from a practical and/or technical perspective. Indeed, many budding bioentrepreneurs would admit that the pressures of commercializing breakthrough technologies and day-to-day business administration make it difficult to assess how well they are currently managing the enterprise.

As the company grows, however, so will the need to be proactive in addressing seemingly 'lower priority' accounting and finance issues. Entrepreneurs who hope to one day take their company public, for example, will be faced with a daunting regulatory environment if they are not aware of relevant accounting practices and internal control matters well in advance of their initial public offering (IPO). Likewise, those who plan to sell their company or technology might find it difficult to attract public suitors if their accounting methods and faulty internal controls raise suspicions related to corporate governance (the 'tone at the top') or the company's ability to appropriately capture and report financial information. In the current financial environment, even private companies will find, as they grow and mature, that appropriate accounting practices can boost the confidence of customers, investors and partners. But accounting problems will threaten to destroy a company's credibility and relationship with these key stakeholders.

“Many executives coming from larger companies are surprised to see how poorly financial records and reports are managed in a startup with limited resources.”

Following are five tips to help biotech startups get on the right path when it comes to managing accounting and financial functions amid the continual struggle to balance the distribution of limited resources among a number of critical priorities.

Tip 1. Get organized early

The first thing bioentrepreneurs should do is get organized. Take a look at your current accounting practices and evaluate what needs to be done to bring standardization to the process. For example, what are the procedures for retaining your documents? Key financial records and documents often include financing agreements, stock option plans and

other equity awards, articles of incorporation and bylaws, leases and other contracts, minutes of the Board of Directors' meetings, licensing and royalty agreements and vendor records. Is there a clear explanation of which documents must be kept and where those files reside? How is financial information captured and stored? You should possess the basic processes and systems of organized financial reporting to facilitate timely information retrieval whenever it is needed throughout the firm's life.

It is also important to designate who is in charge. It's not uncommon for entrepreneurs to wear many hats; for example, a founding scientist can also serve as the company's CEO, chairman and president. His or her responsibilities run the gamut from overseeing the direction of R&D to managing collaborative and shareholder relationships. Will this person also be charged with supervising the accounting function or has that role been assigned elsewhere? Bioentrepreneurs should also consider when to start bringing standardization into the process and how best to allocate the resources needed to do so. There really is no magic here, but time and again early-stage businesses struggle with basic organization, especially in the areas of accounting and finance. The pain of not being organized is generally felt down the road when trying to close a financing, negotiate a strategic agreement, secure a credit facility or complete an acquisition.

Tip 2. Establish reliable internal controls

Another important aspect of accounting for bioentrepreneurs is internal control, especially in the face of new legislation, such as the Sarbanes-Oxley Act (see [Box 1](#)). Basically, 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. This may be true especially for young biotechs, because they often rely on collaborative partnerships with larger companies to help fund their R&D efforts, which requires maintenance and administration of contract provisions alongside traditional financial records.

A key requirement for biotech startups, therefore, is internal control systems and processes that can help manage such complex arrangements. Internal control priorities range from protecting and managing the company's cash and liquid resources to appropriately accounting for and tracking contractual relationships to corporate governance matters. For example, is there an appropriate segregation of duties among activities involving cash management functions? Who has approval to authorize transactions from routine expenditures to significant contracts? How many labor hours went into meeting a contract provision or milestone, and does the company have appropriate procedures and processes to make reliable estimates? What were the supply and equipment costs used in a collaboration and are those costs allocated appropriately in the financials? How does the company protect its intellectual property (IP)—does it reside on servers that could be penetrated from either internal or external sources? Does the company have an audit committee, and, if so, how often does it meet and are its objectives clearly defined? Systems and processes related to internal control must be considered early on, and must evolve with the business and grow in sophistication as the company grows. The extent and nature of internal control activities is a cost/benefit consideration and should be evaluated in light of the inherent risks that face the business.

Tip 3. Prepare realistic budgets and forecasts

Biomedical R&D is an inherently expensive business, and biotech companies are notorious for burning through years of cash before their efforts pay off. In this cash intensive environment, preparing realistic budgets and forecasts plays an integral role in the organization, but many startups don't get this right. Multi-year lags between discovery and the regulatory approval process make it difficult to gauge how much capital the company will need to realize its vision. For example, how fast will the company grow? What are the expected cash flow and expenses? What about large capital expenditures, such as product manufacturing? What story have I told potential investors with respect to the company's projected financial performance? Do I understand the appropriate revenue recognition model for the business?

Another obstacle to budgeting and forecasting for bioentrepreneurs is the prevalence of collaborative partnerships in the industry. These partnerships often tie cash and/or equity payments to certain development and technical milestones that may or may not be reached over a number of years. A multi-million dollar payment, for example, may hinge on the successful completion of a clinical trial or the identification of a lead compound. Successful budgeting requires companies to carefully define milestones and monitor their progress closely. If milestone completion projections are not reasonable, biotech startups risk running short of cash before the next financing opportunity presents itself. Basic organization and appropriate internal control provide the foundation for credible and realistic budgeting and forecasting.

Tip 4. Issue equity instruments responsibly

Biotech startups, like most venture-backed companies, use equity as a currency to attract talent and partnerships early on when cash is scarce. Founders, key employees and strategic partners are often awarded equity in a number of different forms, including stock options, restricted stock awards and warrants (see [Box 2](#)). One problem is the practice of making oral or informal promises or commitments, without explicit terms or conditions. Employees and advisors are promised certain equity awards upon the formalization or approval of an equity incentive plan or perhaps the successful achievement of a milestone or objective, for example, but

the terms of the award are not properly recorded or maintained. This practice can expose the company to future disputes over key terms, such as pricing and the number of awards granted, as well as additional headaches and distractions. A company that achieves success but does not keep its equity awards and issuance policies in order can expect legal claims to come out of the woodwork. Defending such claims can be extremely expensive and time consuming, yet in most cases disputes may be avoided if equity records are adequately organized and a firm policy is established to ensure that only properly authorized and executed equity arrangements are undertaken.

Another issue arises when entrepreneurs issue equity without fully understanding the accounting ramifications. The use of equity instruments requires complex arrangements that have not only legal and tax components, but also a complicated accounting and financial component. Bioentrepreneurs would be wise to assess the accounting consequences of each type of equity instrument before issuing them. In many cases, this will require some professional advice and counsel. Key questions include: Have you appropriately considered the complex differences between accounting for awards issued to employees versus third parties? Have options been priced reasonably in light of recent financings and developments in the business such as: technological milestones, key management additions and regulatory approvals? Are there revenue recognition implications associated with warrants granted to your strategic partner? How should contingencies or performance conditions of an employee or contractor be factored into the accounting for an equity arrangement?

Tip 5. Be cognizant of revenue recognition issues

Revenue recognition is one of the most complex and risky areas of accounting. At issue are items such as the way in which biotech firms record up-front fees and milestone payments associated with their long-term R&D collaborations. The accounting rules and interpretations can be troublesome for cash-hungry biotechs, which frequently have a tendency to think of nonrefundable payments as revenue received, when that is not necessarily the case. And the focus has only intensified in recent years as the US Securities and Exchange Commission continues to hone in on revenue recognition practices and accounting guidance covering the topic continues to proliferate. This is particularly true for life sciences firms, which frequently have among the most complex revenue-earning arrangements.

The application of revenue recognition rules to complex, multi-year arrangements is a detailed exercise that involves keen 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 arrangement. Receipt of cash is just one factor in understanding and finalizing the appropriate revenue recognition policies and practices. In addition, systems and strong internal controls are often necessary in order to appropriately track and measure progress. Even more complexity lies in arrangements that include some combination of various elements, such as development, licensing and manufacturing components. Determining when and how revenue is recognized in such arrangements can be extremely complicated as a result of the technical interpretations and subjective judgments that must be made.

Those starting biotech companies should be wary of revenue recognition issues—both when forming collaborations and contracts and when recording revenue from such arrangements. Establish a comprehensive and written internal revenue recognition policy and ensure that key employees, particularly those who are involved in contract negotiation, understand the ground rules.

In summary

Every entrepreneur wants to realize his or her vision as quickly and efficiently as possible. The danger is that when an executive is focused on key priorities, such as product development and corporate financing, he or she may neglect 'trivial' accounting and financial issues during early-stage development. If a stumbling block emerges in the accounting field, then professional consultants should be contacted, because mistakes in this area can lead to loss of credibility with stakeholders and even jeopardize future plans of reaching the public markets. Approaching accounting and financial management proactively, however, can build trust with customers, investors and partners, and increase the likelihood of a smooth liquidity event.

Box 1: Internal controls: more than getting the numbers right

Although private companies are, for the most part, immune to the provisions of the Sarbanes-Oxley Act (SOA), bioentrepreneurs with liquidity aspirations in the form of an IPO or acquisition should be mindful of the act's "internal controls" provision.

SOA was enacted in 2002 in response to highly publicized corporate scandals such as Enron and WorldCom. Among its many requirements is a provision for public companies to include in annual reports an assessment of their "internal control structure." On the surface, SOA seems to refer only to financial matters when it talks about the need for corporate management to report on and assess internal company controls. However, the provisions spread far beyond finance and accounting into areas such as operations and regulatory matters. That means biotech startups that neglect corporate governance and internal control-related matters may find themselves compromised when a liquidity event, such as a strategic acquisition or a public offering, presents itself. The ramifications of not being reasonably prepared range from delays and inconvenience to reduced valuations or not getting a deal done at all.

Box 2: Glossary

Equity instruments. Collective name for common stock, preferred stock, stock options, warrants, etc.

Common stock. The ownership interests in a company that typically give holders the right to vote and the right to receive ordinary dividends (when declared).

Preferred stock. Stock that typically grants its holders those rights and preferences over those rights of common stock holders. Such rights and preferences may include conversion features, liquidation preferences, stated dividends, participating dividends and redemption features. Certain types of preferred stock may entitle the holder to special voting rights. Because of these characteristics of preferred stock, this type of instrument generally has a higher value per share than common stock and typically results in greater offering proceeds per share to the company as compared to a common stock offering.

Stock option. A contract that gives the holder the right, but not the obligation, either to purchase or to sell a certain number of shares of stock at a predetermined price for a specified period of time.

Warrant. Gives the right to purchase an equity instrument, usually common stock or preferred stock, that companies typically issue to nonemployees (similar to an option, except that options are typically issued to employees).

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