Growing Pains: What Biotechnology Companies Transitioning to Commercialization Need to Know

Introduction

The pharmaceutical market has grown during the past five years, owing to a burgeoning elderly population and an increased demand for prescriptions boosted by a rising middle class. In the five years to 2019, industry revenue is anticipated to grow at an annualized rate of 3.7 percent to $1.4 trillion. In 2014, this growth rate was 7.5 percent.¹ According to the World Health Organization, one-third of this market is currently controlled by the 10 largest drug companies in the United States and Europe.²

To remain competitive, companies are under increasing pressure to innovate, introduce new products quickly, clearly demonstrate the efficacy and safety of those products and market them effectively. And they must accomplish all of this in an intense regulatory environment and in a global economic climate that remains unpredictable.

These challenges are real for large, multinational pharmaceutical companies with established portfolios of products and vast distribution networks; they are even more real for biotechnology startups. Below, we list some of the key risks and challenges that biotechnology companies of all sizes must address successfully to achieve their objectives and propel growth.

Key Risks and Implications

Access to Capital

The journey from molecular compound to commercial pharmaceutical product is long and complex. Moving a drug through various phases of research, preclinical development, clinical trials, and finally, regulatory approval often requires significant capital and sustained liquidity. Biotechnology companies can expect to spend $350 million to get a single drug to market.

An emerging biotechnology company often has limited financial resources, and this is driving many startups to consider going public. A generally strong initial public offering (IPO) market and the recent strong performance of many new biotech companies that have taken this route are encouraging this trend.³ Some young biotech companies have attracted investors even though they are only in the clinical trial phase.

³ According to the Thomson Reuters data shared by the National Venture Capital Association (NVCA), there were 114 venture-backed IPOs in 2014, 56 percent of which were in the biotech sector. http://nvca.org/pressreleases/venture-backed-ipo-exit-activity-extends-streak-20-offerings-fifth-consecutive-quarter/
An IPO introduces its own set of challenges, as companies going public on the NYSE or NASDAQ are required to meet regulatory and compliance requirements, most notably the internal control over financial reporting provisions of the Sarbanes-Oxley Act (SOX). Effectively managing the company’s capital through the drug development life cycle and developing an effective strategy for addressing increased regulatory compliance requirements as a public company are thus critical to the long-term viability of a biotechnology company as it moves toward commercialization.

**Resources**

As a biotech company moves towards successful commercialization, it may find that the skill sets and resources that helped support its research and development (R&D) efforts are insufficient to meet the resource demands of a global pharmaceutical organization. Intensified hiring of sales, marketing, distribution and compliance staff must happen in a relatively short period to prepare for commercial launch. To this end, companies need to have robust processes, people and systems supporting their human resource activities in order to identify qualified candidates and onboard new employees quickly and efficiently. Inability to attract qualified candidates and build the required functional teams in a timely manner may have a negative impact on the company’s preparedness for commercialization, and ultimately, product sales.

**IT Infrastructure, Systems and Processes**

Biotechnology companies tend to focus investment on R&D activities and funding clinical trials, not on building IT systems – and that’s to be expected. However, commercialization requires a biotechnology startup to refocus some of its resources on IT systems and infrastructure to ensure the systems can support the startup’s transition to a pharmaceutical company. This may require significant investment in new systems (e.g., enterprise resource planning, or ERP), as well as adequate planning to allow sufficient time for testing and implementation of these systems prior to commercialization or requests for regulatory approval. Startups that don’t yet have commercial-level operations may need to seek the advice of a third party to design and implement such systems and the processes supported by them. Companies will also need to consider how their systems support compliance requirements, such as the Physician Payments Sunshine Act. Finally, a strong IT governance structure is needed to promote standardization and consistency across the organization.

**Regulatory Approvals**

Regulatory approvals are a crucial part of bringing a drug to market, and as such represent a significant area of potential risk for pharmaceutical companies of all sizes. The process of obtaining U.S. Food and Drug Administration (FDA) and corresponding non-U.S. regulatory approvals can be enormously costly and time-consuming. No matter how much work is involved – or how well-established the biotechnology or pharmaceutical company – there is no guarantee approvals will be granted. Factors such as slow enrollment in clinical studies can delay or completely derail regulatory approvals. If these approvals cannot be secured in a timely manner, the company may face significant restrictions on the use of the product. Unexpected changes to regulations also can lead to delays in product development. Regulatory demands will continue to increase in the future, as biotechnology and pharmaceutical companies are now expected to prove the linkage among the benefits, risks and cost of products.

**Operations on a Global Stage**

Once a drug product has been cleared for release, companies may need to establish regional operations in new markets if their existing footprint is inadequate. To accomplish this, some companies may opt for a shared-services model and/or rely on third-party service providers to
support certain activities, such as finance and accounting. Establishing an organizational structure that can support the company initially and through scalable growth is critical to long-term success; it is also a challenge, as the rate of business change is often unpredictable. Navigating the political and cultural landscape of new markets and understanding how to effectively do business under local conditions are common hurdles with market expansion, and establishing standardized processes, policies and procedures is often easier said than done.

**Regulatory Compliance**

In a global environment, regulatory compliance remains a top concern, and multinational pharmaceutical companies must be acutely attuned to the requirements of each jurisdiction or country in which they operate. Compliance with the Foreign Corrupt Practices Act (FCPA) and the Sunshine Act are just two examples. Small biotechnology companies that face a first-time approval of a drug by the FDA or an international regulatory body may be less aware of such compliance requirements. Establishing mechanisms to educate employees on compliance requirements and monitor their activities is imperative to minimize the risk of noncompliance and avoid significant fines or penalties from regulatory bodies.

**Reimbursement Policies of Third-Party Payers**

Another area of risk for pharmaceutical companies is the effect that third-party payers (e.g., Medicare, Medicaid, private health insurance companies) may have on the pricing or appeal of a drug product. These third parties regulate the level of reimbursement provided to physicians or clinics utilizing the product. If reimbursement under these programs is too low, if it takes too long to secure reimbursement or if third parties are unwilling to provide reimbursement, a pharmaceutical company may be adversely and materially affected in its ability to market its product.

**Contracting With Third-Party Manufacturers and Distributors**

Partnering with a larger, established pharmaceutical company – either handing over the whole commercialization and accepting royalties, or retaining some rights to commercialization – has been an attractive and popular route for biotechnology companies historically. However, this option is not right for everyone, as a shift in control can potentially have an adverse impact on the product or company. Some companies choose to “go it alone” and contract with a third party to manufacture and distribute their products. In either instance, the company must ensure adequate controls are in place to safeguard and handle the active pharmaceutical ingredients (APIs) and other aspects of the product to ensure compliance with manufacturing standards. Additional complexities emerge when a product begins to be sold globally and companies engage third parties abroad to store and distribute their products. Identifying a third-party vendor capable of maintaining and growing the company’s distribution network long term is critical. Moreover, companies must ensure third parties have the appropriate safeguards and internal controls in place around inventory to ensure product safety and to enable reliable reporting of financial and accounting information to management.

**Conclusion**

The issues outlined here represent only a snapshot of the complex risk landscape that biotechnology companies must navigate to succeed in commercialization. Companies that partner with, merge with, or acquire biotechnology firms as a way to jump-start innovation and maintain a pipeline of new products also must consider the fact that they will be sharing the risk burden of these startups as they bring their drugs to market. Partnering with outside experts who understand the complex dynamics and risks involved in growing the enterprise can help both biotechnology and pharmaceutical companies meet the high expectations of investors, regulatory bodies and the public.
About Protiviti

Protiviti (www.protiviti.com) is a global consulting firm that helps companies solve problems in finance, technology, operations, governance, risk and internal audit, and has served more than 60 percent of Fortune 1000® and 35 percent of Fortune Global 500® companies. Protiviti and our independently owned Member Firms serve clients through a network of more than 70 locations in over 20 countries. We also work with smaller, growing companies, including those looking to go public, as well as with government agencies.

Named one of the 2015 Fortune 100 Best Companies to Work For®, Protiviti is a wholly owned subsidiary of Robert Half (NYSE: RHI). Founded in 1948, Robert Half is a member of the S&P 500 index.

About Our Life Sciences and Pharmaceuticals Practice

Companies within the life sciences industry are among the most regulated in the world (FDA, the FCPA, the Sunshine Act, the Prescription Drug Marketing Act of 1987 and OBRA 1990, among others). Additionally, these companies are subject to privacy and data protection laws, corporate governance and consumer protection laws, cyber threats, fraud detection and prevention laws, and increasingly demanding customers.

At Protiviti, our life sciences industry experts understand the challenges faced by pharmaceutical, biotechnology and medical device companies. We can assist your organization with services such as internal audit outsourcing and co-sourcing, pre- and post-acquisition guidance, compliance reviews and revenue risk management.

Some of our key solutions designed to help you turn challenges into competitive advantages include:

- Mergers and Acquisitions (M&A) Due Diligence – Planning and Assessment
- Acquisition Integration – Planning and Execution
- IPO Readiness – Public Company Transformation
- Internal Audit Co-Sourcing
- Internal Audit Outsourcing
- Revenue Risk Management
- Supply Chain Optimization
- Enterprise Risk Assessment

Contacts:

Susan Haseley  
+1.469.374.2435  
susan.haseley@protiviti.com

Gordon Tucker  
+1.415.402.3670  
gordon.tucker@protiviti.com

Kyle Furtis  
+1.212.399.8636  
kyle.furtis@protiviti.com

© 2015 Protiviti Inc. An Equal Opportunity Employer M/F/Disability/Vet. Protiviti is not licensed or registered as a public accounting firm and does not issue opinions on financial statements or offer attestation services.