2015 BDO LIFE SCIENCES RISKFACTOR REPORT

PROVING VALUE BECOMES TOP PRIORITY AMONG LIFE SCIENCES COMPANIES

The ***2015 BDO Life Sciences RiskFactor Report*** examines the risk factors listed in the most recent annual shareholder filings of the 100 largest publicly-traded U.S. life sciences companies listed on the NASDAQ Biotechnology Index by revenue. The risk factors were analyzed and ranked in order of frequency cited.

A booming IPO and M&A market, along with stellar biotech performance over the past year, have dispelled concerns around Janet Yellen's July 2014 speech about "substantially stretched" biotech stock valuations that alarmed the life sciences industry and caused investors to be wary of the industry's future. What's more, 2014 was also a record-breaking year for M&A in the pharma, biotech and medical sectors, pulling in $379.5 billion in deals compared to $173.7 billion in 2013.

Despite a positive outlook for the industry, life sciences companies still face unique hurdles when it comes to effectively positioning themselves in a highly competitive marketplace. Our third annual analysis of risk factors in the industry identifies the key business challenges identified by the managements of life sciences companies. The top cited risks include drug reimbursement, a complex regulatory environment, product development and international operations.

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"Life sciences companies, particularly biotechs, are experiencing a profusion of investor attention due to their ability to drive innovation. Although the overall outlook remains positive, the challenge remains to demonstrate sustained value in a highly regulated and competitive environment, making it necessary for companies to continuously expand their product offerings through strategic acquisitions, despite high takeover prices," said **Ryan Starkes, partner and Life Sciences practice leader at BDO USA, LLP**.

LARGEST JUMP AMONG TOP RISKS: DRUG REIMBURSEMENT

For many years, the success of life sciences companies relied primarily on their ability to develop new drugs and overcome regulatory hurdles to increase market share. Today, a key element of profitability of life sciences companies rests in their ability to negotiate pricing with insurance companies and local governments. Recent headlines around Gilead's launch of Solvaldi and Harvoni, specialty drugs to cure the most common type of hepatitis C, shed light on the delicate balance between charging a "fair" price for the value provided by a drug and the ability of healthcare systems to reimburse the costs of "specialty" medications. As new biotechs emerge and global spending for generic medicines rapidly grows, even well-established companies are pressured to prove the "value" that a product brings to third-party payers. This challenge was highlighted in the findings from our report indicating that companies are on high alert when it comes to drug reimbursement, with 96 percent citing concerns related to reimbursement changes and their availability, including payments from Medicare and Medicaid – up from 85 percent in 2014.

DEAL PACE REMAINS STRONG

There have been consistent headlines in the news the past two years about the tremendous growth of the life sciences industry. According to market research firm EvaluatePharma, the value of M&A transactions involving pharmaceutical companies almost doubled to $116 billion in 2014 from $62 billion in 2013.

With deal flow ramping up, companies are facing increasing concerns around the ability to manage and complete an acquisition.

Top 25 Risk Factors for the 100 Largest U.S. Life Sciences Companies

2015 Rank		2015	2014	2013
1.	Competition, consolidation, pressure on pricing	100%	97%	100%
1t.	Federal, state and/or local regulations	100%	98%	100%
1t.	FDA approvals and compliance	100%	94%	94%
4.	Corporate copyright, intellectual property infringement	99%	98%	96%
4t.	Ability to commercialize and market products	99%	97%	96%
4t.	Supply chain, supplier/vendor and manufacturing concerns	99%	100%	93%
7.	Product liability and insurance costs	98%	95%	87%
8.	Reimbursement from third party payers	96%	85%	87%
9.	Product complications, delays, recalls and side effects	93%	88%	88%
10.	Legal proceedings, litigation	92%	91%	84%
10t.	Delays or unfavorable results from clinical trials	92%	87%	80%
12.	Ability to attract and retain key personnel	91%	94%	96%
12t.	General economic and financial market conditions	91%	67%	84%
14.	Collaborations and relationships with other companies	90%	89%	92%
14t.	Volatility of revenue and stock price	90%	97%	92%
16.	Threats to international operations and sales	88%	71%	79%
17.	Maintaining internal controls, financial reporting, accounting standards	87%	76%	68%
18.	Inability to acquire capital	84%	85%	79%
19.	Inability to manage or complete M&A	83%	69%	79%
20.	Changes in healthcare laws and regulations	82%	77%	78%
21.	Hazardous materials – environmental, health and safety laws	81%	73%	66%
22.	Failure to properly execute corporate strategy	79%	66%	69%
22t.	Anti-takeover or change of control provisions	79%	75%	66%
24.	Labor Concerns (post-retirement costs, benefit plans), retention, managing geographically dispersed workforce	78%	40%	24%
25.	Natural disasters, war, conflicts and terrorist attacks	76%	56%	47%

*t – indicates a tie in the risk factor ranking

Specifically, more than four-in-five companies mention these risks in their filings, up from 69 percent in 2014. Alternatively, other companies may be better poised for success and growth through a buyout. As such, 79 percent note issues when it comes to their anti-takeover or change of control provisions that could potentially hinder their position as a viable buyout target.

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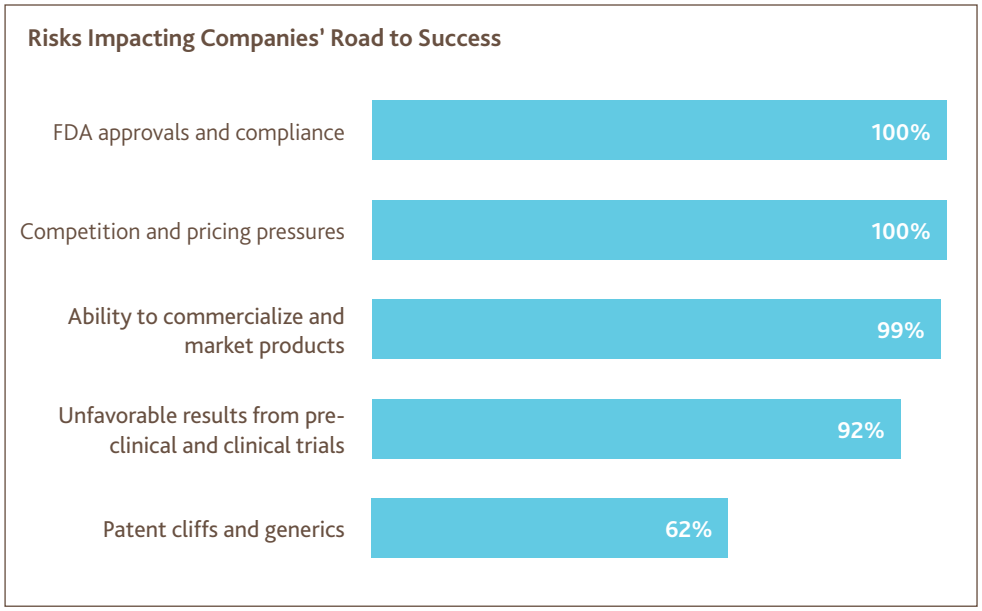
"As risk-based contracting in the provider space continues and healthcare services are increasingly subjected to pay-for-value analysis, companies that sell products and services that cannot demonstrate value will face increasing pricing and margin constraints and downward pressure on valuations," said **Patrick Pilch, CPA, MBA, Managing Director and National Leader, The BDO Center for Healthcare Excellence & Innovation**. "The U.S. is only in the early stages of this trend as accurate measurement and verification of clinical outcomes are becoming a growing area of focus for supporting financial results."

COMPETITION AND REGULATORY ENVIRONMENT HURDLES

According to the IMS Institute for Healthcare Informatics, global prescription medication sales increased from $879.6 billion in 2013 to $936.5 billion in 2014, and this growth can be a factor in the development of new medicines for difficult-to-treat illnesses like cancer. With so many companies wrestling to prove their value and their drug's effectiveness, the ability to commercialize and market products is a growing risk, mentioned by 99 percent of companies, up from 97 percent in 2014. Moreover, as the preference for generic drugs continues to increase among consumers and third-party payers, companies with competing, but pricier, medications may be overlooked – all 100 companies cite competition and pricing pressures as threats.

Not only do life sciences companies operate in an intensely competitive environment, they also face many hurdles when it comes to bringing their product to market. The Tufts Center for the Study of Drug Development, for example, finds that the cost to develop a prescription drug is $2.6 billion, a significant increase from 2003 estimates. Companies also perceive compliance requirements as potential roadblocks. All 100 companies analyzed cite risks associated with FDA approvals and compliance, up from 94 percent in 2014, despite the fact that there has been an upward trend in drug approvals, specifically around orphan drug development. The FDA approved a record 49 orphan drugs in 2014, up from 31 approvals in 2013. Further, 92 percent of companies mention concerns around unfavorable results from pre-clinical and clinical trials.



GROWING CONCERNS AROUND IP INFRINGEMENT AND SECURITY BREACHES

Risks related to intellectual property infringement and corporate copyright are rising concerns among life sciences companies – 99 percent of companies cite these risks, up from 98 percent in 2014 and 96 percent in 2013. As companies rely on their innovative products to cure specific illnesses, they must ensure they are effectively protecting their data and IP, especially with research and development (R&D) spend growing at a rapid pace. According to the same report from EvaluatePharma, the total value of the R&D pipeline increased 18 percent as of June 2015, compared to the same time period last year, and R&D spending is set to grow two percent per year through 2020. Even our 2014 BDO Biotech Briefing found that average R&D expenditures across two groups of biotechs – those with less than $50 million in revenue and those with $50 million to $300 million in revenue – increased 14 percent in 2013.

Further, the persistent threat of cyber attacks have life sciences companies on edge. Last December, The New York Times reported that a group of cybercriminals hacked into more than 100 pharmaceutical and biotech companies to obtain sensitive business information. As such, 70 percent of companies reveal concerns around security and privacy breaches, up from 61 percent in 2014 and 46 percent in 2013.

GLOBAL EXPANSION INCREASES COMPANIES' RISK EXPOSURE

As companies expand their business operations abroad to respond to ongoing competition, they expand their exposure to risks associated with global expansion. Our report reveals that companies are concerned about commercial operations, supply chain, regulatory compliance and managing global talent. Specifically, 88 percent of companies mention threats to international operations and sales, up from 71 percent in 2014, while

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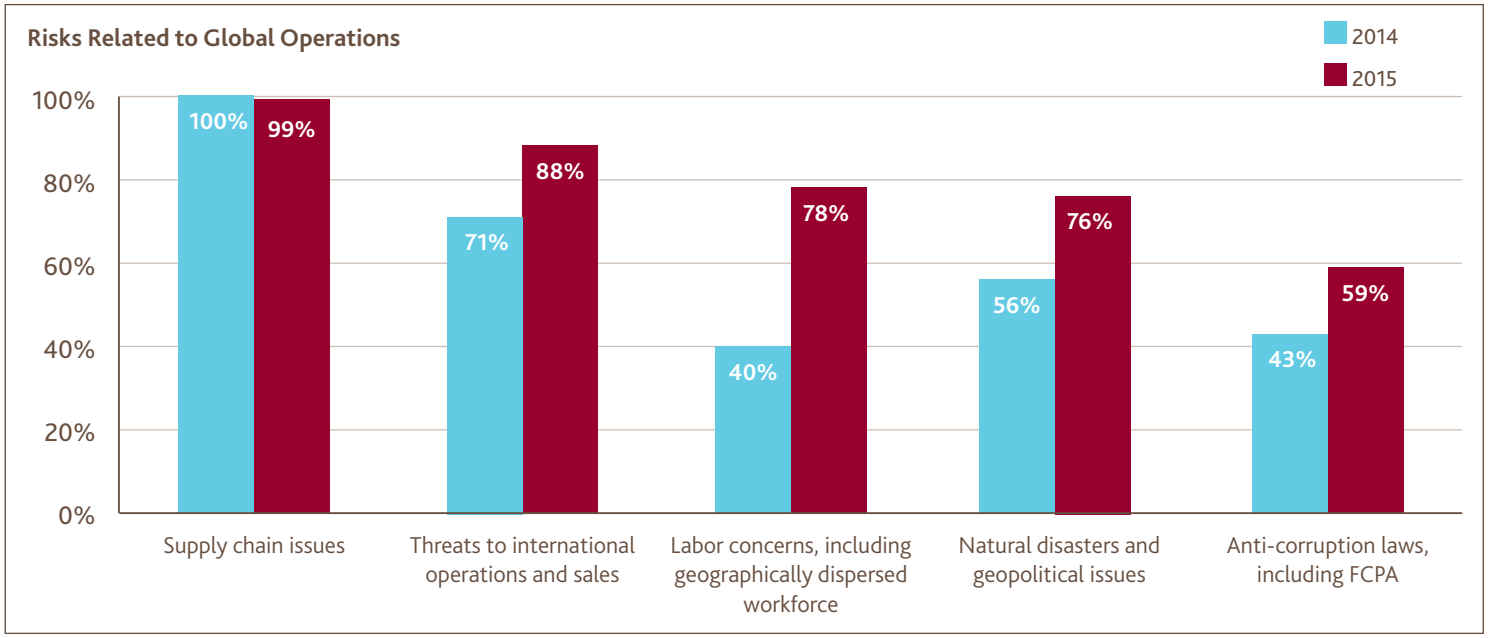
"While the issue of cybersecurity touches every company in every industry, life science companies face a notable amount of cybersecurity vulnerability related to their intellectual property. As a best practice, identifying the most valuable information assets and understanding their lifecycle from creation to disposal will allow life science organizations to design and implement a robust risk management strategy," said **Shahryar Shaghaghi, managing director at BDO Consulting and leader of the firm's Technology Advisory Services Practice**. "Additionally, when creating internal controls to manage cybersecurity risk, it's important to remember that data attacks are often perpetrated by both internal and external sources."

59 percent report risks related to anti-corruption and anti-bribery laws, including the Foreign Corrupt Practices Act (FCPA). Seventy-eight percent also cite labor concerns, including supervision of a geographically dispersed workforce, up from 40 percent in 2014.

At the same time, supply chain challenges, particularly when dealing with international partners, remain a top concern. This year, 99 percent of companies cite risks related to supply chain, including supplier/vendor and manufacturing concerns, on trend with last year (100 percent) and 2013 (93 percent). Moreover, factors outside of a company's immediate control, such as natural disasters and geopolitical issues, can impact supply chain and international operations – 76 percent of companies note these risks in their filings.

Life sciences companies have a lot to manage – from evaluating and completing M&A transactions and developing ideas into viable products, to ensuring they remain compliant with both domestic and international regulatory bodies. Therefore, when it comes to business challenges, companies need to understand the implications and complexities of these potential risks so they can conduct the necessary due diligence and implement the proper internal controls to prevent violations and setbacks.



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