2014 BDO LIFE SCIENCES RISKFACTOR REPORT

AMID BOOMING MARKET, LIFE SCIENCES COMPANIES LOOK TO SECURE COMPETITIVE EDGE

The ***2014 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.

The life sciences industry is poised for tremendous growth and biotech stocks have been experiencing positive performance despite market volatility. According to *Seeking Alpha*, large cap biotechs have held up very well, and small cap biotech stocks are making a comeback. Moreover, *The Deal* reports that the current wave of small IPOs is being driven by the biotech market, with 13 of the 16 offerings carried out by biotech or life sciences companies. Such findings are in line with the recently released ***2014 BDO IPO Halftime Report***, which found that 54 percent of investment bankers surveyed predict biotech offerings will increase during the remainder of the year.

As growth opportunities abound, life sciences companies are simultaneously exposed to unique industry risks that may impact important business operations. Our second annual analysis of risk factors in the industry identifies these key business challenges that could hinder companies' competitive position in the market. Top risks include navigating the complex regulatory environment, product commercialization, supply chain management and intense competition, as well as many others.

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▶NO. 1 RISK FOR LIFE SCIENCES COMPANIES: SUPPLY CHAIN VULNERABILITIES

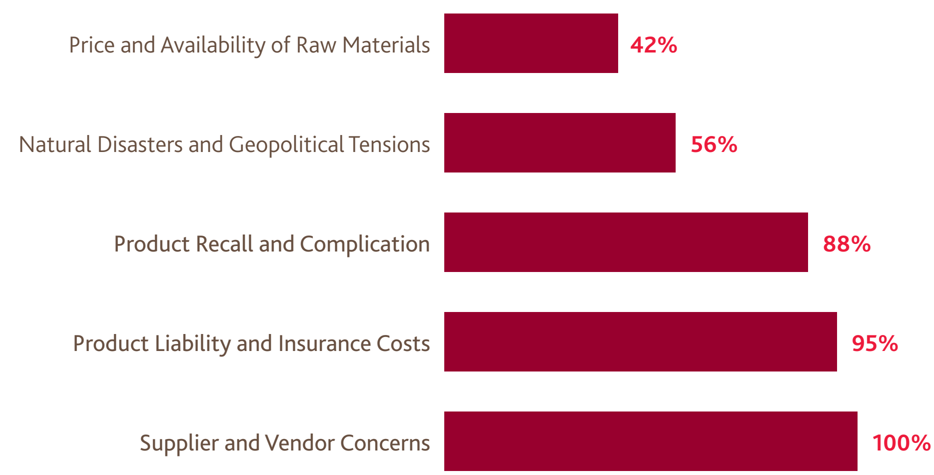
Supply chain vulnerabilities and concerns over suppliers and vendors is the No. 1-cited risk for life sciences companies this year, with all 100 companies analyzed noting this concern. Many life sciences companies rely on third parties to help bring their products to market and to produce critical materials. Companies need to make sure these suppliers comply with certain standards and regulations around product quality. Any compliance setback or supply chain disruption can expose companies to product liability issues and recalls. As a result, 95 percent of companies note significant risks related to product liability and insurance costs, while 88 percent cite product recall and complication concerns.

Supply chain disruptions can result from a number of factors, including the shortage of necessary raw materials, natural disasters and regulatory inspections. As such, 42 percent of life sciences companies cite the price and availability of raw materials as a risk to their business, and 56 percent cite risks related to natural disasters, war, conflicts and terrorist attacks.

▶INTELLECTUAL PROPERTY PROTECTION AND DATA SECURITY CONCERNS ON THE RISE

With uncertainties surrounding patent protection and a recent debate in the Senate concerning patent reform, more and more life sciences companies are pointing to intellectual property (IP) infringement as a concern. Ninety-eight percent of companies cite the protection of their intellectual property as a risk. In today's fiercely competitive landscape, research and development (R&D) is imperative to the long-term growth of life sciences companies, and any claim on their IP can be financially detrimental and give competitors an advantage. Although the pending patent reform bill is aimed to minimize unnecessary lawsuits against infringing firms, many companies are wary about provisions that make it costly for legitimate patent holders to protect their IP. A majority of companies (91 percent) cite concerns related to litigation and legal proceedings, often associating patent challenges with that risk.

Risks Related to Supply Chain Management



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

2014 Rank		2014	2013
1.	Supply Chain and Supplier/Vendor Concerns	100%	93%
2.	Federal, State and/or Local Regulations	98%	100%
2t.	Intellectual Property Infringement	98%	96%
4.	Competition and Consolidation	97%	100%
4t.	Ability to Commercialize & Market Products	97%	96%
4t.	Volatility of Revenue/Stock Price	97%	92%
7.	Product Liability and Insurance Costs	95%	87%
8.	Ability to Attract and Retain Key Personnel	94%	96%
8t.	FDA Approvals and Compliance	94%	94%
10.	Legal Proceedings	91%	84%
11.	Collaborations and Relationships with Other Companies	89%	92%
12.	Product Complications, Recalls and Side Effects	88%	88%
13.	Delays or Unfavorable Results from Clinical Trials	87%	80%
14.	Reimbursement from Third Party Payers	85%	87%
14t.	Inability to Acquire Capital	85%	79%
16.	Changes to Healthcare Laws & Regulations	77%	78%
17.	Changes to Accounting Standards and Regulations	76%	68%
18.	Anti-Takeover and Change-in-Control Provisions	75%	66%
19.	Environmental, Health and Safety Laws	73%	66%
20.	Threats to International Operations	71%	79%
21.	Inability to Manage or Complete M&A	69%	79%
22.	General Economic Conditions	67%	84%
22t.	History of Operating Losses	67%	68%
24.	Failure to Properly Execute Strategy	66%	69%
25.	Breaches of Technology Security, Privacy and Theft	61%	46%

*t – indicates a tie in the risk factor ranking

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"Despite recent market volatility, the biotech industry is seeing positive growth and robust M&A activity," said **Ryan Starkes, partner and Life Sciences practice leader at BDO USA, LLP**. "As life sciences companies work to deliver positive shareholder return, our analysis shows they are intensely focused on protecting their IP, product integrity and their competitive position by carefully evaluating vendor, collaboration and acquisition opportunities."

Data security issues have been top of mind for life sciences companies as well, especially with recent headlines around data breaches at large companies. According to *The Wall Street Journal*, the healthcare sector is plagued by a high number of cybersecurity issues as the industry continues to upgrade its data to electronic medical records and share data over health exchanges. As these changes occur, companies are faced with strict requirements to report, maintain and protect various types of customer and patient data, such as the U.S. Physician Payments Sunshine Act and the Health Information Technology for Economic and Clinical Health Act. In fact, for the first time this year, data security and privacy breaches reached the top 25 risk factors overall, with 61 percent of companies citing it as a risk. Any privacy breach of customer and patient data could lead to arduous compliance issues and reputational risks.

▶AS LIFE SCIENCES COMPANIES CONTINUE TO GROW, M&A OPPORTUNITIES ABOUND

According to *Mergermarket*, the pharmaceutical, medical and biotech industry is the leading sector for merger and acquisition (M&A) activity this year, with deal activity being valued at $252.5 billion. As biotechs continue to grow and report positive earnings, they are becoming more attractive to large healthcare companies. In fact, *Bloomberg* recently reported that more large pharmaceutical companies are looking to biotechs for acquisitions in 2014.

With many life sciences companies depending on strategic investments from pharmaceutical companies to grow their business and with M&A opportunities plentiful, business risks are high. Sixty-nine percent of companies cite risks related to successfully managing or completing M&A. In addition, 75 percent of companies note concerns over anti-takeover or change of control provisions that could hinder buyout opportunities, up nine percentage points from last year.

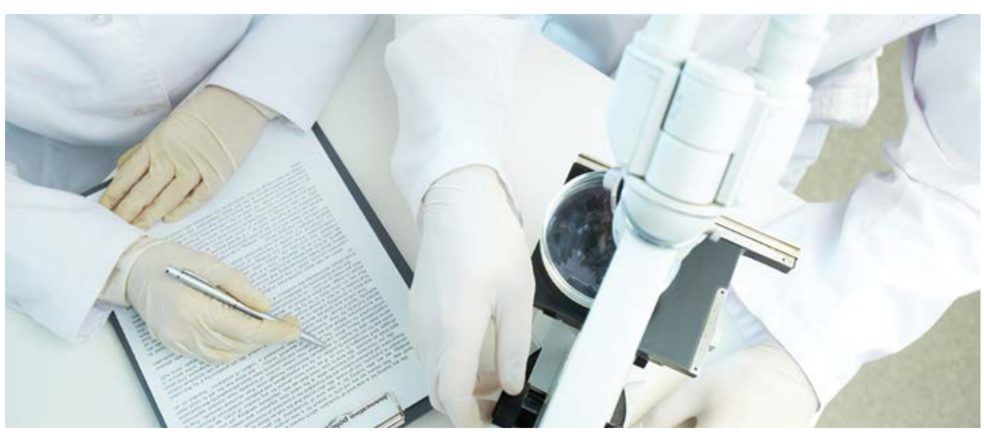
▶REGULATORY ENVIRONMENT CONTINUES TO CREATE OBSTACLES FOR COMPANIES

The regulatory environment is always top of mind for life sciences companies, especially because regulations and compliance standards are constantly being updated and developed. As such, nearly all companies (98 percent) cite federal, state and local regulations as a concern, and the Affordable Care Act (ACA) was cited by more than three-in-four companies (77 percent). Healthcare reform has greatly impacted the life sciences industry overall by not only bringing on additional compliance concerns and penalties, but also uncertainty regarding revenues due to potential impact on reimbursements and coverage driven by increased competition.

Companies mentioned challenges specific to compliance with the ACA, including the amended False Claims Act, which makes companies liable for defrauding governmental programs, and the Sunshine Act, which requires manufacturers of drugs, medical devices and biologicals that participate in U.S. federal healthcare programs to report certain types of payments given to physicians and hospitals. In addition, life sciences companies contend with competitors who create biosimilars—products that aren't exact substitutions, but cheaper and generic versions of the original drug. According to *Forbes*, in the U.S., traditional generics get automatically substituted by the pharmacists unless a physician suggests otherwise. With generic drugs being the favorable option, many companies in the study (85 percent) note the availability of product reimbursements by government authorities and healthcare providers as a risk to their business.

This year, 76 percent of companies noted risks associated with changes to accounting standards and regulations, up from 68 percent in 2013. Concerns over the new revenue recognition rules, which were released by the Financial Accounting Standards Board and International Accounting Standards Board in May, likely contributed to the increase, as implementation will be a key area of focus for life sciences companies in the years ahead. Although the rule will not take effect until 2017, companies need to start focusing on how the new requirements could impact business practices (e.g., collaboration agreements, IP licenses) and the related impact on revenue recognition.

In addition to new accounting standard challenges, 73 percent of companies cite concerns related to environmental, health and safety laws, up from 66 percent in 2013. As life sciences companies partner with suppliers and manufacturers to develop their products, both parties must comply with the proper use and disposal of hazardous materials, which can be costly, timely and may interrupt normal business operations.



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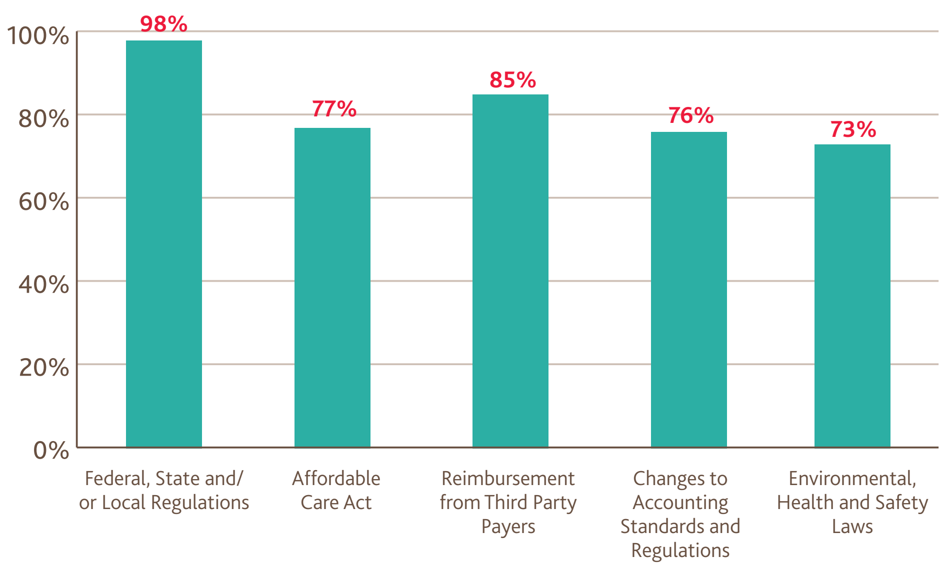
"Reporting issues are top of mind for life sciences companies, particularly for those who have added complexity due to government contracts," said **Eric Sobota, managing director of BDO's Government Contractor Advisory Services**. "As companies navigate compliance and contract requirements, particularly in light of the new revenue recognition standards, they must take a proactive approach to implement effective controls to manage risks and competitively position themselves for future contracts."

▶BARRIERS TO PRODUCT COMMERCIALIZATION

The life sciences industry is replete with regulations, especially when it comes to bringing its products to market. Nearly all companies (94 percent) specifically point to risks associated with the rigorous FDA approval process and compliance requirements, which is in line with last year's findings. The FDA recently announced a $37.5 million grant to support the Clinical Trials and Transformation Initiative (CTTI) that plans to improve both the quality and efficiency of clinical trials, a critical component of the approval process. This is great news for the 87 percent of companies who cite delays from clinical trials as a risk; however, risks also exist post-approvals.

Regulatory Challenges Facing Companies



Ninety-seven percent of companies cite their ability to effectively commercialize and market approved products as a top concern, and another 89 percent note risks related to collaborations, which often provide critical resources for life sciences companies to commercialize products.

▶TALENT RETENTION REMAINS A PRIORITY AMONG LIFE SCIENCES COMPANIES

According to *FierceBiotech*, large biotech companies have more than tripled their staff headcount over the past decade. This employment trend is in line with ***BDO's 2013 Biotech Briefing***, which found that the number of employees at biotechs increased 13 percent from 2011 to 2012. As life sciences companies continue to grow and the labor market improves, life sciences companies are contending with increased competition for top talent from peers, as well as other technology sectors. As a result, companies are more focused on their ability to attract and retain leadership and other key employees, a concern cited by 94 percent of companies.

ABOUT THE TECHNOLOGY & LIFE SCIENCES PRACTICE AT BDO USA, LLP

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