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Life Sciences Companies Face Special Disclosure Challenges

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Life sciences companies operate in a financially sensitive environment-their market values rise or fall rapidly on perceptions about their products. As more life sciences companies enter the public marketplace, they must be prepared to face special disclosure challenges. Fortunately, these issues can largely be addressed through solid disclosure policies and controls.

While they represent only 2% of U.S. public companies, the volatility of life sciences companies' stock prices and the laser attention on their disclosures has resulted in their being defendants in a disproportionate share of shareholder lawsuits-17% in 2003 and 10% in 2004, according to PricewaterhouseCoopers' 2004 Securities Litigation Study. Of cases filed against biotechnology companies, 81% allege misrepresentations relating to the company's products, and 45% contain allegations relating to clinical trial results according to 'Woodruff-Sawyer: A Study of Shareholder Class Action Litigation (2002).'

In addition to litigation risk, life sciences companies have two major regulatory agencies monitoring their activities. The FDA and SEC recently have enhanced their inter-agency cooperation, announcing a centralized procedure for FDA staff members to make referrals to the SEC. Liaison officers now streamline the FDA's technical assistance to the SEC in its review of the public filings of life sciences companies.

A recent investigation in September 2005, in which the SEC filed a civil fraud suit against Biopure Corp., is an example of the regulatory agencies' cooperation. The SEC began its investigation of Biopure in late 2003, after Biopure allegedly failed to disclose communications with the FDA concerning a product, Hemopure, and its clinical trial progress. When the company disclosed the SEC's investigation, its share price dropped 14%. The SEC's District Administrator publicly acknowledged that the SEC's investigation was prompted by a communication received from the FDA.

There are several steps life sciences companies can take to reduce the risk of an SEC investigation or litigation:

Disclosure Controls

Every life sciences company should ensure that appropriate company personnel learn-in a timely manner-about information that might involve a mandatory disclosure or impact the company's stock. Each company must analyze all the elements of its disclosure system, including financial reporting, investor communications and legal compliance. Managers in key operational areas, such as clinical development and manufacturing, should be aware of how issues within their areas of responsibility can play a role in increasing the risk of securities litigation.

Disclosure controls should extend to all public communications, including financial statements, earnings releases, press releases, prospectuses, annual reports and Forms 8-K. For life sciences companies, disclosure controls should also cover presentations at scientific conferences, publications and information presented to analysts and credit rating agencies. Any material information posted on the company's Web site should first be disseminated in a regulatory filing or press release and later reviewed on a regular basis. Any hyperlinks to third-party sites should be accompanied by a clear and prominent disclaimer.

Disclosure controls and procedures are effective only if information that is material to the company is being identified, gathered and communicated to the appropriate senior managers, including the CEO and CFO, on a timely basis.

Communications Policies

An important component of good disclosure controls is the company's communications policy. Companies should ask three main questions concerning the policy:

1. Does the policy designate authorized spokespersons and the topics on which they can speak-for financial information, clinical results and any other areas investors frequently ask about?
2. Does the policy address the disclosure of information and data for products in development?
3. Is the policy broadly disseminated such that all employees understand how news flow about the company should be treated?

As a general rule, companies should not sponsor, link or participate in chat rooms or message boards. As important, the communications policy should make clear that the company will not respond to rumors. By being explicit concerning rumors, the company can avoid serious securities law issues, including the risk of selective disclosure or the perception that the company intends to, and will, monitor and correct third-party statements.

Disclosure Committees

Disclosure committees also play a critical role in monitoring a company's disclosure controls and procedures. For life sciences companies, the committee should include the CFO or controller, the chief medical officer and representatives from marketing, medical affairs and investor relations. The company's legal counsel generally serves as the chair of the committee and provides guidance on issues such as what information is material, and when and how it should be disseminated to the public.

From a corporate governance perspective, the committee serves a critical role in managing disclosure controls by identifying, gathering and reporting on disclosure issues to the CEO, the CFO and, when appropriate, to the company's audit committee. The CEO and CFO are required to certify the company's disclosure controls quarterly, while the audit committee is required to review quarterly earnings releases.

Clinical Results

Clinical trials deserve special attention. It is important to note that the FDA does not require a company to disclose the status of clinical trials, or even the existence of an Investigational New Drug application. The FDA, by statute, will not publicly disclose the existence of an application unless it previously has been disclosed.

Nevertheless, investors demand that a company provide progress updates on its products in development. The problem-and the risk-often lies in the tendency to present data in the most favorable light. Disclosure policies should explicitly require that counsel (and regulatory personnel) be notified when clinical results are imminent. Counsel's review is essential so that appropriate and balanced disclosure of the data can be prepared, and so that any releases or public statements contain appropriate forward-looking statements or list risk factors that are specific and meaningful.

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