Arnall Golden Gregory LLP

Legal Insight

Improving Disclosure for Public Life Science Companies

Joseph Alley, Jr. and Robert F. Dow

In recent years, the Life Sciences sector has been one of the hottest sectors for initial public offerings. With the growing market for life science companies has come increased scrutiny of their public disclosure. Companies launching new offerings of securities are subject to intense review by the Securities and Exchange Commission (SEC) staff and, in addition, the SEC staff generally reviews the disclosure documents of all SEC-registered companies at least once every three years.

Based on a recent review of recent SEC staff comments, we have compiled the following observations on ways life science companies can improve their disclosure documents and minimize unpleasant surprises from the SEC staff:

- Technical terms which are unfamiliar to non-experts should be defined in the document (e.g., iontophoresis, reticulocytes, or receptor tyrosine kinase).
- The financial statements should include a clear and complete discussion of revenue recognition policies, including the effects of sales returns and revenue and cost sharing arrangements which may affect revenue.
- The Annual Report on Form 10-K and other disclosure documents includes a Management’s Discussion and Analysis of Financial Condition and Results of Operations (MDA) section, which should include, among other things, a thorough discussion of known trends and uncertainties.
- The MDA should describe material uncertainties caused by potential regulatory actions by the FDA and other agencies.
- If the company has received FDA warning letters, it must address its disclosure obligations for contingencies related to those letters.
- Company-specific material risk factors should be described, e.g. risks associated with the Company’s FDA trials, product tests and studies, and product liability (including the amount of product liability insurance coverage, to the extent material).
- The terms of significant strategic partnership, product development, manufacturing, and license agreements should be disclosed.
- If the company receives significant grant revenues, it should consider providing a description of the grant application process and the amount of grants received in each of the past two years.
- The timing and status of any material investigational new drug (IND) applications should be disclosed.
- If the company has significant research and development (R&D) expenses, the company should consider providing a description of its R&D process and a breakdown of total personnel and other expenses by the types of costs included in R&D (i.e. personnel-related costs, consulting, travel, lab supplies, depreciation, stock-based compensation, and miscellaneous expenses).

Especially in the context of a pending offering, having issues such as those mentioned above arise unexpectedly could cause costly delays. Thorough drafting and review can help the company to move through the SEC review process more smoothly.

Authors and Contributors

Joseph Alley, Jr.
Partner, Atlanta Office
404.873.8688
joseph.alley@agg.com

Robert F. Dow
Partner, Atlanta Office
404.873.8706
robert.dow@agg.com

not *if*, but *how*.®

About Arnall Golden Gregory LLP

Arnall Golden Gregory, a law firm with more than 150 attorneys in Atlanta and Washington, DC, employs a "business sensibility" approach, developing a deep understanding of each client's industry and situation in order to find a customized, cost-sensitive solution, and then continuing to help them stay one step ahead. Selected for The National Law Journal's prestigious 2013 Midsize Hot List, the firm offers corporate, litigation and regulatory services for numerous industries, including healthcare, life sciences, global logistics and transportation, real estate, food distribution, financial services, franchising, consumer products and services, information services, energy and manufacturing. AGG subscribes to the belief "not if, but how.®" Visit www.agg.com.

Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
Suite 1000
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: **http://www.agg.com/subscribe/**