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SEC Gives Biotech Companies Relief--Adopts Rules Exempting Certain Research And Development Companies from the Definition of an Investment Company Under The Investment Company Act of 1940

The Securities and Exchange Commission (the "SEC") has adopted rule 3a-8 (the "Rule") under the Investment Company Act of 1940, as amended (the "1940 Act"), which provides a non-exclusive safe harbor from the definition of investment company for certain bona fide research and development companies ("R&D companies").[1] The Rule is designed to provide R&D companies, like companies involved in the research and development of biotechnology products, with increased flexibility in raising and investing capital for research, development and other operations.

Briefly, under the Rule, an R&D company may rely on the non-exclusive safe harbor if: (a) its research and development expenses, for the last four fiscal quarters combined, are a substantial percentage of its total expenses for the same period; (b) its net income derived from investments in securities, for the last four fiscal quarters combined, does not exceed twice the amount of its research and development expenses for the same period; (c) its expenses for investment advisory and management activities, investment research and custody, for the last four fiscal quarters combined, do not exceed 5 percent of its total expenses for the same period; (d) its investments in securities are generally "capital preservation investments", with certain exceptions for "other investments" including "collaborative research and development arrangements" with strategic partners; (e) it does not hold itself out as being an investment company and is not a special situation investment company; (f) it is primarily engaged, directly or through majority-owned subsidiaries or companies that it controls primarily, in a non-investment company business, as evidenced by the activities of its officers, directors and employees, its public representations of policies, its historical development and an appropriate resolution of its board of directors; and (g) its board of directors has adopted a written investment policy regarding the company's capital preservation investments.

The Rule becomes effective on August 19, 2003. The background for the Rule and the elements of the Rule are discussed below.

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[1] See Certain Research and Development Companies, Investment Company Act Release No. 26077 (June 16, 2003), [hereinafter "Adopting Release"].

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I. Background

A. Definition of Investment Company

The 1940 Act contains two definitions of investment company that are relevant to an operating company. Section 3(a)(1)(A) defines an investment company as any issuer that is, or holds itself out as being engaged primarily, or proposes to be engaged primarily in the business of investing, reinvesting, or trading in securities.[2] Section 3(a)(1)(C) defines an investment company as any issuer that is engaged or proposes to engage in the business of investing, reinvesting, owning, holding, or trading in securities, and that owns or proposes to acquire investment securities having a value exceeding 40 percent of the value of the company's total assets (exclusive of government securities and cash items) on an unconsolidated basis.[3] Notwithstanding that an issuer may meet the definition of an investment company in section 3(a)(1)(C), such issuer may be deemed not to be an investment company under section 3(b)(1) or section 3(b)(2) of the 1940 Act.

Section 3(b)(1) provides a self-executing exclusion from the definition of investment company for a company primarily engaged, directly or through wholly-owned subsidiaries, in a non-investment company business.[4] Section 3(b)(2) of the 1940 Act allows a company that falls within the definition of investment company in section 3(a)(1)(C) to apply to the Commission for an order. Pursuant to section 3(b)(2), the Commission, upon application by the company, may find and by order declare the company to be primarily engaged (directly, or through majority-owned subsidiaries or through controlled companies conducting similar types of businesses) in a business other than that of investing, reinvesting, owning, holding or trading in securities.[5]

In The Matter of Tonopah Mining Co. of Nevada ("Tonopah"), the SEC adopted a five factor analysis (the "Tonopah Test") to determine a company's primary business under section 3(b)(2).[6] Under the Tonopah Test, the SEC looks at the company's historical development, its public representations of policy, the activities of its officers and directors and, most importantly, the composition of the company's present assets and the sources of its present income. The Tonopah Test has also been used to determine whether a company satisfies the primary business test under section 3(b)(1) of the 1940 Act.[7]

B. Research and Development Companies

When applied to an R&D company, the asset and income factors of the Tonopah Test may not accurately reflect the non-investment company business of the R&D company. Often R&D companies require significant amounts of capital to fund long periods of research and development.

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[2] §15 U.S.C. 80a-3(a)(1)(A).

[3] §15 U.S.C. 80a-3(a)(1)(C).

[4] §15 U.S.C. 80a-3(b)(1).

[5] §15 U.S.C. 80a-3(b)(2).

[6] 26 S.E.C. 426, 427 (1947).

[7] See Moses v. Black, Fed. sec. L. Rep. (CCH) P 97,886 (S.D.N.Y. 1981).

These activities may not result in income for several years. R&D companies also may set up joint ventures to perform joint research and development with strategic partners. These joint ventures may include non-controlling interests in the joint venture. These non-controlling interests and many of the investments in which R&D companies invest their capital are investment securities under the 40 percent test of section 3(a)(1)(C). Furthermore, research and development expenses and any resulting "intellectual property," are not typically recognized as assets on a balance sheet prepared in accordance with generally accepted accounting principles ("GAAP"). Accordingly, an R&D company may find that most of its assets are investment securities and little of its income is operating income and, as a result, the R&D company may fall within the definition of an investment company and not be able to use the Tonopah Test for relief.

The SEC recognized the uniqueness of R&D companies in issuing an order to the ICOS Corporation in 1993 (the "ICOS Order").[8] In the ICOS Order, the SEC modified the Tonopah Test in determining the primary business of an R&D company for purposes of sections 3(b)(1) and 3(b)(2) of the 1940 Act. The modified test is based upon how the company uses its income and assets, instead of its sources and composition. Under the ICOS Order, an R&D company's status determination focuses initially on three factors: (1) whether the company uses its securities and cash to finance its research and development; (2) whether the company has substantial research and development expenses and de minimis investment expenses; and (3) whether the company invests in securities in a manner that is consistent with the preservation of its assets until needed to finance operations. If a company meets these initial three requirements, the SEC will then examine the remaining factors of the Tonopah Test (i.e., the company's historical development, its public representations of policy, and the activities of its officers and directors).

The Rule is intended to update and codify the analysis set forth in the ICOS Order. It should be noted, however, that the SEC stated that any company that wishes to determine its status under the 1940 Act in accordance with the ICOS Order may continue to do so.[9]

II. Elements of the Rules

The following are the principal elements of the Rule.

A. Substantial Research and Development Expenses

To qualify for the non-exclusive safe harbor from investment company status, the R&D company's research and development expenses, for the last four fiscal quarters combined, must constitute a substantial percentage of its total expenses for the same period.[10] The Rule does not define the term "substantial." The SEC stated that it intentionally left the term "substantial" undefined in order to allow R&D companies to take into account fluctuations in the composition of their expenses

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[8] See ICOS Corp. Inv. Co. Act Release Nos. 19274 (Feb. 18, 1993) (Notice) and 19334 (March 16, 1993) (Order).

[9] See Adopting Release, supra at n.17.

[10] 17 C.F.R. §270.3a-8(a)(1) (2003) [hereinafter "Rule 3a-8"].

over time.[11] While the SEC would consider research and development expenses that constitute a majority of a company's total expenses to be substantial, they note that there are circumstances when research and development expenses that constitute less than a majority of a company's total expenses, notwithstanding non-recurring items or unusual fluctuations in recurring items, also may be considered substantial.[12]

For purposes of the Rule, research and development expenses are those expenses defined as such in FASB Statement of Financial Accounting Standards No. 2 , Accounting for Research and Development Costs, as currently in effect or as it may be subsequently revised.[13]

B. Net Income from Investments

The R&D company's net income derived from investments in securities, for the last four fiscal quarters combined, may not exceed twice the amount of its research and development expenses for the same period.[14] The SEC notes that this requirement permits R&D companies to meet their capital needs by raising and holding more capital than currently permitted under the ICOS Order, while ensuring that an R&D company's primary focus remains funding its research and development activities, rather than generating revenue from its investments.[15]

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[11] See Adopting Release, supra, at II.A.

[12] Id. at n.19.

[13] Rule 3a-8(b)(9). Pursuant to Statement of Financial Accounting Standards No. 2 (Fin. Accounting Standards Bd. 1974) ("SFAS No. 2"), "research" means planned search or critical investigation aimed at discovery of new knowledge with hope that such knowledge will be useful in developing a new product or service or a new process or technique or in bringing about a significant improvement to an existing product or process. "Development" means the translation of research findings or other knowledge into a plan or design for a new product or process or for a significant improvement to an existing product or process whether intended for sale or use. Pursuant to SFAS No 2, research and development expenses would include costs incurred for materials, equipment, facilities, personnel salary and wages and other personnel related costs associated with research and development, intangibles, contracted services and a reasonable allocation of indirect costs. General and administrative costs that are clearly not related to research and development activities are not included as research and development expenses.

[14] Rule 3a-8(a)(2).

[15] See Adopting Release, supra, at II. B.

C. Insignificant Investment-Related Expenses

The R&D company's expenses for investment advisory and management activities, investment research and custody, for its last four fiscal quarters combined, may not exceed 5 percent of the total expenses of the company for the same period.[16]

D. Investments in Securities

1. Capital Preservation Investments

(a) Definition

The R&D company's investments in securities are required to be capital preservation investments, subject to two exceptions for "other investments," discussed below.[17] The Rule defines "capital preservation investments" as investments made to conserve capital and liquidity until the funds are used in the company's primary business or businesses.[18] The SEC noted that, in general, capital preservation investments are liquid so that they can be readily sold to support the R&D company's research and development activities as necessary and present limited credit risk.[19]

(b) Board-Approved Policy

The board of directors of the R&D company must adopt investment guidelines designed to assure that the company's funds are invested in a manner consistent with the goals of capital preservation and liquidity.[20]

2. "Other Investments"

R&D companies increasingly are collaborating with other companies to conduct joint research and development, and it is not uncommon for an R&D company to seek to acquire a non-controlling interest in securities of another company pursuant to such a collaborative arrangement. The Rule seeks both to clarify the extent to which an R&D company relying on the non-exclusive safe harbor may make investments other than capital preservation investments, and specifically to reflect the increased use of collaborative relationships to conduct research and development.

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[16] Rule 3a-8(a)(3).

[17] Rule 3a-8(a)(4).

[18] Rule 3a-8(b)(4).

[19] See Adopting Release, supra, at II.D.1.

[20] Rule 3a-8(a)(7).

The Rule permits an R&D company to make investments other than capital preservation investments ("other investments") to a limited extent. In setting the limits, the Rule distinguished between investments made pursuant to a collaborative research and development arrangement and other investments that are not made to preserve capital and liquidity. The Rule permits an R&D company to acquire investments that are not capital preservation investments if, immediately after the acquisition, no more than 10 percent of the company's total assets consist of other investments or no more than 25 percent of the company's total assets consist of other investments so long as at least 75 percent of those investments are made pursuant to collaborative research and development arrangements.[21] The Rule's limits on other investments must be calculated and complied with at all times during which an R&D company seeks to rely on the Rule, not just at the time other investments are acquired.

E. Collaborative Research and Development Arrangements

The Rule defines a collaborative research and development arrangement as a business relationship which (i) is designed to achieve narrowly focused goals that are directly related to, and an integral part of, the R&D company's research and development activities; (ii) calls for the R&D company to conduct joint research and development activities with the investee or a company controlled primarily by, or which controls primarily, the investee; and (iii) is not entered into for the purpose of avoiding regulation under the 1940 Act.[22] In other words, an investment in securities made pursuant to a collaborative research and development arrangement must be an investment in securities of a company (or of a company controlled primarily by, or which controls primarily, the company) with which the R&D company is engaged in the collaborative research and development arrangement.[23] Of course, a collaborative research and development arrangement may involve other parties as well.[24]

1. "Joint Research and Development"

The SEC recognized that the term "joint" could be interpreted to require the companies to be equally involved in the research and development throughout the entire research and development process. The SEC realizes that research and development activities within collaborative arrangements often are guided by a joint steering committee with members from both companies, with one company or the other primarily responsible for conducting research and development at different stages. The SEC stated that it would consider an arrangement involving research and development

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[21] Rule 3a-8(a)(4)(i) and (ii).

[22] Rule 3a-8(b)(6).

[23] See Adopting Release, supra, at II. E.

[24] Id. at n. 45.

activities done sequentially or through a joint steering committee to be "joint" within the meaning of the definition.[25]

2. Other Relationships

The SEC considered whether other relationships, such as a licensor-licensee relationship with respect to a patent or other intellectual property rights, should be included in the definition of a collaborative research and development arrangement. The SEC does not believe that a licensing or similar agreement, by itself, demonstrates a sufficient nexus to the licensor's primary business to justify treating an investment in the licensee differently from any other speculative investment.[26] Similarly, the SEC does not believe that manufacturing and joint marketing activities should be included in the definition of a collaborative research and development arrangement.

F. Other Requirements

1. Valuation

The Rule requires a company to value its assets in accordance with section 2(a)(41)(A) of the 1940 Act. Section 2(a)(41)(A) provides, in relevant part, that for purposes of section 3 of the 1940 Act, the term "value" means: (i) with respect to securities for which market quotations are readily available, the market value of those securities; and (ii) with respect to other securities and assets, fair value as determined in good faith by the board of directors.

2. Consolidation

The Rule requires that the percentages relating to assets, expenses and net income set forth in the Rule are to be determined on an unconsolidated basis, except that an R&D company should consolidate its financial statements with the financial statements of any wholly-owned subsidiaries.

3. No Holding Out

The company may not hold itself out as being engaged in the business of investing, reinvesting or trading in securities and cannot be a special situation investment company.[27]

4. Must Engage in a Non-investment Company Business

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[25] Id. at II.E.1.

[26] Id. at II.E.2.

[27] Rule 3a-8(a)(5). Generally, a special situation investment company is a company in the business of acquiring majority interests in other companies, operating them to increase their value, selling them within a short period of time and realizing capital gains.

The company must be primarily engaged, directly, through majority-owned subsidiaries or through companies which it controls primarily, in a business or businesses other than that of investing, reinvesting, owning, holding, or trading in securities, as evidenced by:

(a) the activities of its officers, directors and employees;

(b) its public representations of policies;

(c) its historical development; and

(d) an appropriate resolution of its board of directors, which resolution or action has been recorded contemporaneously in its minute books or comparable documents.[28]

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This memorandum is not intended to provide legal advice with respect to any particular situation and no legal or business decision should be based solely on its content. Questions concerning issues addressed in this memorandum should be directed to Steven R. Howard (212) 373-3508 or Thomas M. Majewski (212) 373-3539.

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[28] Rule 3a-8(a)(6).