Health Care Reform Advisory: Billion-Dollar Tax Credit and Grant Opportunity for Life Sciences Companies

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Among the varied provisions in the voluminous Patient Protection and Affordable Care Act, a/k/a the Health Care Reform Bill, Congress has appropriated up to \$1 billion in tax credits and grants to defray the costs of therapeutic research by small and mid-size life sciences companies. Beneficial even for companies without income tax liability, these incentives will soon be awarded in an application process that is sure to be highly competitive.

Credits and Grants for Costs of Therapeutic Research in 2009 and 2010

The new, temporary program offers a choice between an income tax credit and a cash grant for up to 50% of a company's costs paid or incurred in 2009 and 2010 and directly related to a "qualifying therapeutic discovery project." A "QTDP" is a project designed to achieve any of the following objectives:

- To treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out research protocols, for the purpose of securing approval of a product by the Food & Drug Administration or Public Health Service
- To diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions
- To develop a product, process, or technology to further the delivery or administration of therapeutics

Some costs are not eligible, such as certain executive compensation, interest, and facility maintenance expenses (such as mortgage or rent payments, insurance payments, utility costs, or the cost of maintenance personnel), and costs relating to certain support functions (*e.g.*, human resources, accounting, data processing, etc.). Qualifying expenses are excluded from other tax incentives such as the R&D credit, orphan drug credit, or bonus depreciation. The QTDP credits and grants are not taxable as income, but the tax basis of any resulting property such as patents will be reduced by 50% of the benefit received.

The QTDP credits and grants are subject to recapture if the patents or other resulting property are transferred within five years. Subject to future clarification in upcoming guidance, the recapture rule could reduce a company's flexibility in strategic transactions. For instance, avoiding recapture may necessitate a stock sale rather than an asset sale when investors choose to exit their investment. Further guidance will be necessary to resolve important questions for the biotech industry, including whether exclusive licenses typically employed in drug development collaborations will trigger recapture, and whether continued development costs shared by the licensor after such a license will be eligible for the credit or grant.

Most Small and Mid-Size Life Sciences Companies Should Be Eligible

Subject to some exceptions, the QTDP credit or grant is available to any business with 250 or fewer employees at the time the application is submitted. Certain non-taxpayers are disqualified, such as federal, state, or local governments, tax-exempt organizations, or partnership or other pass-through entities having such a government or organization as an equity owner. Also disqualified are foreign businesses unless more than 50% of their income from the relevant project is subject to U.S. federal income tax.

Many readers will note that venture capital investors in life sciences companies may themselves include tax-exempt or foreign partners. In the former case, as long as the recipient company is a corporation or the tax-exempt partner participates in the investment through a so-called "corporate blocker," the company will still be eligible for a QTDP credit or grant. In the latter case, the same holds true as long as the recipient company is itself organized in the U.S. or more than 50% of its project income would be subject to U.S. tax.

Application Process and Selection Criteria

Congress has capped QTDP credits and grants at \$1 billion. Even if eligible, life sciences companies must still apply to the Treasury Department for an allocation from this incentive pool. For its part, the Treasury, after consultation with the Department of Health and Human Services, must announce final guidance on the application process and selection criteria by May 21, 2010. Once the program is established, the Treasury must approve or deny applications within 30 days of submission.

To guide the Treasury in making its allocations, Congress has provided both "health care" and "economic" requirements as selection criteria. On the "health care" front, successful applicants must show reasonable potential to accomplish one of the following goals:

- to develop new therapies to treat areas of unmet medical need or to prevent, detect, or treat chronic or acute diseases and conditions,
- to reduce long-term health care costs in the U.S., or
- to significantly advance the goal of curing cancer within the next 30 years

On the "economic" front, the Treasury must also take into consideration which projects have the greatest potential to:

- create and sustain (directly or indirectly) "high-quality, high-paying" jobs in the U.S., and
- advance U.S. competitiveness in the fields of life, biological, and medical sciences

Highly Competitive Process Is Likely

Because of the very broad definition of a qualifying project and lenient eligibility standards, many, and perhaps most, life sciences companies in the contemporary market are eligible for the QTDP credits or grants. A very large number of applications are expected to be submitted once the program is finalized.

Similarly, however, the selection criteria provided for in the statute are vague and do little to narrow the field of applicants. In particular, life sciences companies engaged in therapeutic research will easily satisfy the "health care" requirements. Successful applicants will likely differentiate themselves under the "economic" requirements by showing how their research will support high-wage employment and its importance to U.S. scientific competitiveness.

Applicants will choose between the tax credit and cash grant during the application process. Because many companies do not have positive tax liability, and even those that do will probably prefer cash, virtually all applicants will likely opt for the cash grant. With so many potential awardees and a \$1 billion cap, most recipients will likely receive less than their entire request.

Further Guidance Expected Soon

The Treasury will issue detailed guidance on the QTDP credit and grant program by May 21, 2010. Of course, Mintz Levin's Life Sciences, Healthcare, and Tax attorneys are monitoring these issues closely and will update our clients and friends when the Treasury issues its guidance or as other developments arise.

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For up-to-date information regarding health care reform, please visit our <u>Health Care Reform:</u> <u>Analysis & Perspectives</u> page.

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For further information regarding this or any issue related to Health Care Reform, please contact one of the professionals listed below or the Mintz Levin attorney who ordinarily handles your legal affairs.

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