

E-ALERT | Health Care

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HEALTH CARE REFORM: THERAPEUTIC DISCOVERY PROJECT TAX CREDITS AND GRANTS FOR SMALL EMPLOYERS

On March 23, 2010, President Obama signed into law Pub. L. No. 111-148, the Patient Protection and Affordable Care Act (PPACA). Shortly afterwards, on March 30, 2010, President Obama signed into law Pub. L. No. 111-152, the Health Care and Education Affordability Reconciliation Act of 2010 (the Reconciliation Amendments), amending PPACA. PPACA, as now amended by the Reconciliation Amendments (collectively, the Act), will have far-reaching effects for the entire health care sector.

This alert, part of a series explaining the impact of the Act on life sciences companies, will summarize the provision of the Act relating to therapeutic discovery project tax credits and grants, found in section 9023 of PPACA.

Executive Summary

- The Act establishes a nonrefundable tax credit equal to 50% of a “qualified investment” in a “qualifying therapeutic discovery project” for companies with no more than 250 employees for expenditures made in 2009 and 2010.
- Eligible companies that wish to avail themselves of the credit must participate in a formal application and certification process.
- A company may elect to receive a grant in lieu of the tax credit in the amount of 50% of the “qualified investment.” This allows companies that are not yet tax-paying to take advantage of the program.
- The total amount of credits and grants allocated to the program may not exceed \$1 billion.

Employee Headcount

- The number of employees for purposes of the credit is calculated at the time of the submission of the tax credit/grant application and includes employees in all businesses of the taxpayer.

Qualifying Therapeutic Discovery Projects and Qualified Investments

- A “qualifying therapeutic discovery project” is a project that is designed to:
 - Treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials and clinical studies, or by carrying out research protocols, for the purpose of securing approval of drugs (under sections 505(b) of the Federal Food, Drug, and Cosmetic Act) or biologics (under section 351(a) of the Public Health Service Act);

- Diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions; or
- Develop a product, process, or technology to further the delivery or administration of therapeutics.
- In general, a “qualified investment” includes costs paid or incurred for expenses necessary for and directly related to a “qualifying therapeutic discovery project.” However, costs related to the following are excluded:
 - Compensation for the CEO and four highest-paid officers;
 - Interest expenses;
 - Facility maintenance expenses (mortgage or rent payments, insurance payments, utility and maintenance costs, and costs of employment of maintenance personnel);
 - Indirect costs (such as general and administrative costs) related to administrative, service, or support departments (such as personnel, accounting, data processing, security, legal, etc.); and
 - Any other expenses as determined by the Secretary of the Department of the Treasury (Treasury) to be excluded.

Grant in Lieu of the Tax Credit

- A company may elect to receive a grant in lieu of the tax credit in the amount of 50% of the qualified investment. The grant option is intended for start-up or other firms not able to utilize a tax credit due to the absence of tax liability.
- The Act provides that any grant awarded is to be paid within 30 days of the date of the application for such certification or the date the qualified investment is made, whichever is later.
- The following organizations are ineligible to receive the grant: federal, state, or local governments (or any political subdivision, agency, or instrumentality thereof), tax exempt 501(c) organizations, qualified issuers of a clean renewable energy bond as defined by section 54(j)(4) of the Internal Revenue Code (IRC), and certain partnerships or other pass-through entities.
- The grant is not includible in the recipient’s income for federal income tax purposes.
- If the investment ceases to be a qualifying investment, Treasury must provide for recapture of the appropriate percentage of the grant.

Competitive Certification Process

- Eligible companies must apply for certification for an allocation of the credit or grant, and the applications will be reviewed by a “qualifying therapeutic discovery project program” to consider whether investments qualify for certification.
- The Act requires that this program be established by May 22, 2010 by Treasury, in consultation with the Secretary of the Department of Health and Human Services.
- In order to be selected for certification, a project must demonstrate that it:
 - Has reasonable potential to result in new therapies to (1) treat areas of unmet medical need or (2) prevent, detect, or treat chronic or acute diseases and conditions;
 - Will reduce long-term health care costs in the United States; or
 - Will significantly advance the goal of curing cancer within the next 30 years.

- In addition, Treasury will take into account which projects have the greatest potential to (1) create and sustain (directly or indirectly) high quality, high paying jobs in the United States and (2) advance the United States' competitiveness in the fields of life, biological, and medical sciences.
- Treasury must approve or deny an application within 30 days of submission.
- Upon making a certification, Treasury will publicly disclose the identity of the applicant and the amount of credit awarded to the applicant.

Interplay with other Tax Rules

- Taxpayers will not receive research credits (under section 41 of the IRC), orphan drug credits (under section 45C of the IRC), or bonus depreciation for expenditures that qualify for the qualifying therapeutic discovery project credit or grant.
- With certain exceptions, expenditures included in the amount of the credit are nondeductible.
- The basis of qualified expenditures that are subject to depreciation must be reduced by the amount of the investment tax credit for that expenditure.

Effective Date

- The credits and grants are available only for expenditures made in 2009 and 2010, and all applications must be received before January 1, 2013. Additional guidance is expected to be issued by May 22, 2010.

Outstanding Issues and Implementation Challenges

- Key to the availability of the credit will be Treasury's definition of terms such as "reasonable potential" to result in new therapies, "unmet medical need," and what "significantly advances" the goal of curing cancer.
- Treasury has the authority to exclude "any other expenses" it deems appropriate from the definition of a "qualified investment."

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There are many detailed changes in the Act. We would be pleased to discuss these changes and their potential impact on your industry, company, or customers.

If you have any questions concerning the material discussed in this client alert, please contact the attorneys listed below:

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