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## Therapeutic Project Tax Credit/Grant Program Enacted

On March 23, the president signed the H.R. 3590, the Patient Protection and Affordable Care Act (the "Act"). The Act establishes a tax credit equal to 50 percent of "qualified investment" in a "qualifying therapeutic discovery project." At its election, a taxpayer may receive a grant in lieu of the tax credit equal to 50 percent of the qualified investment. The Act allocates \$1 billion for the program for investments made in 2009 and 2010. This new tax credit and grant program provides a significant financial opportunity for companies in the biotechnology industry.

**Qualifying projects.** In general, a "qualified investment" includes costs paid or incurred for expenses necessary for and directly related to a "qualifying therapeutic project." A "qualifying therapeutic project" is a project designed (A) 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 under section 505(b) of the Food, Drug and Cosmetic Act or section 351(a) of the Public Health Services Act, (B) to diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions or (C) to develop a product,

process or technology to further the delivery or administration of therapeutics.

**Credit or grant available only to small employers.** The credit is available to taxpayers with no more than 250 employees in all of its businesses. It is available only for expenditures made in 2009 and 2010. The total amount of credits/grants available is limited to \$1 billion.

**Competitive process.** Taxpayers will be required to apply for an allocation of the available amount and the applications will be reviewed by Treasury in consultation with the Department of Health and Human Services ("HHS"). Selection will be based on (A) projects that show reasonable potential (i) to result in new therapies (I) to treat areas of unmet need or (II) to prevent, detect or treat chronic or acute diseases and conditions, (ii) to reduce long-term health care costs in the United States or (iii) to significantly advance the goal of curing cancer within a 30-year period, and (B) projects that have the greatest potential (i) to create or sustain high-quality, high-paying jobs in the United States and (ii) to advance US competitiveness in the fields of life, biological and medical sciences. Qualifying therapeutic discovery projects do not qualify for the research credit, orphan drug credit or bonus depreciation.

The credit also reduces depreciable basis by an amount equal to the credit.

**Grant in lieu of tax credit.** If a taxpayer elects to take a grant in lieu of the tax credit, the grant is not included in taxable income. Grants are to be made within 30 days after the later of the date of application and the date the investment is made. Grants shall not be made to any federal, state or local government (or any political subdivision, agency or instrumentality thereof), any 501(c) organization that is tax exempt, certain electric cooperative companies and non-profit electric utilities, a possession of the United States, the District of Columbia, an Indian tribal government and any partnership that has a partner who is described in any of the above categories. In making the grants, the

Secretary of the Treasury is to apply rules similar to those in Section 50 of the Code. In applying those rules, if the investment ceases to be a qualifying investment, the Secretary of the Treasury shall provide for recapture of the appropriate percentage of the grant in such manner as the Secretary of the Treasury deems appropriate.

**Application process.** We expect the Treasury Department, in consultation with HHS, to issue guidance on how applications for an allocation of credits should be filed, timing of the application process and other procedural information. We do not anticipate that applications will be accepted prior to issuance of such guidance.

Our lawyers are available to assist clients in evaluating the tax credit/grant

program, determining eligibility and preparing applications. Our tax lawyers at Hunton & Williams have significant experience in programs similar to the new program for qualifying therapeutic projects. We routinely advise clients in all areas involving tax credits, including investment tax credits similar to this new credit, and have advised and successfully represented a number of clients in their applications for grants in lieu of tax credits under the 2009 Recovery Act. We also have advised and represented clients in tax credit allocation programs preceding this new credit. Our tax lawyers will coordinate and work with lawyers in our Food and Drug practice group and Intellectual Property group, as appropriate, to assist clients in understanding the credit and applying for an allocation of the tax credits.

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