

## Qualifying Therapeutic Discovery Project Credit or Grant

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The Patient Protection and Affordable Care Act of 2010 established a new tax credit and cash grant program for certain small and mid-sized companies that engage in a “qualifying therapeutic discovery project.” This tax incentive provides a significant financial opportunity for smaller biotechnology companies. The credit equals 50 percent of the aggregate costs paid or incurred in a tax year for expenses necessary for, and directly related to, the conduct of a qualifying therapeutic discovery. In lieu of the credit, a taxpayer can request a grant of 50 percent of the qualified investment. This alternative may be useful for companies that may not have taxable income that can be offset by a credit. The credits and grants are available only with respect to expenditures made in a taxable year beginning in 2009 or 2010 and can only be requested by a company with 250 or fewer employees at the time of application. The total amount of credits and grants allocated to this program is capped at \$1 billion. The specific provisions of this tax credit are codified in new Internal Revenue Code § 48D.

### ELIGIBLE PROJECTS

A qualifying therapeutic discovery project is designed to accomplish any of the following:

- Treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials or clinical studies for the purpose of securing approval of a product by Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act;
- Carry out research protocols for the purpose of securing approval of a product Federal Food, Drug, and Cosmetic Act or 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, molecular drugs and companion drugs and diagnostics to guide therapeutic decisions; or

- Develop a product, process or technology to further delivery or administration of therapeutics

### EXCLUDED EXPENDITURES

The credit or grant is not available to the following costs:

- Compensation of executive employees, including the Chief Executive Officer and the company’s four highest compensated officers for the taxable year;
- Interest expenses;
- Facility maintenance expenses;
- Service costs; and
- Any other expense as determined by the Secretary as appropriate to carry out the purposes of this new credit.

### ALLOCATION CRITERIA AND APPLICATION PROCESS

The Secretary of the Treasury, in conjunction with the Department of Health and Human Services, is required to establish a program to consider and certify qualified investments within 60 days of enactment (i.e. no later than May 21, 2010). Taxpayers must obtain certification for qualifying investments by applying with the Secretary. Once the program is established, the Secretary of the Treasury has 30 days from the date an application for a credit is submitted to approve or deny the application. The identity of all entities that receive a qualifying therapeutic discovery project credit will be publicly disclosed.

In determining qualifying projects, the Secretary will consider only those projects that show reasonable potential to:

- Result in new therapies to treat areas of unmet medical need or to prevent, detect or treat chronic or acute disease or conditions,
- Reduce long-term health care costs in the United States, or
- Significantly advance the goal of curing cancer within a 30-year period. (§48D(d)(3)(A))

In addition to these qualifications, the Secretary will also take into consideration projects that have the greatest potential to:

- Create and sustain (directly or indirectly) high quality, high paying jobs in the United States, and
- Advance the United States’ competitiveness in the fields of life, biological, and medical sciences.

There are several rules that prevent double tax benefits, including bonus depreciation, basis adjustment, research and development credits, and clinical testing expenses for certain drugs for rare diseases or conditions.

Due to the limited availability of funds, it is important for smaller companies in the biotech industry to begin evaluating their current and planned projects to determine which, if any of their projects could qualify for the credit, and how to document and quantify their expenditures to request certification if they are interested in taking advantage of this new tax incentive.

For questions regarding this Client Update, please contact either of the following Burns & Levinson attorneys:

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