

# Client Alert

Latham & Watkins  
Tax Department

## The Qualifying Therapeutic Discovery Project Tax Credit

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The newly established Qualifying Therapeutic Discovery Project tax credit (the Therapeutic Discovery Credit) may provide significant financial benefits to small and medium-sized biotechnology and life sciences firms and their investors. The Therapeutic Discovery Credit, established by the Patient Protection and Affordable Care Act enacted on March 23, 2010, provides \$1 billion in tax credits and grants for expenditures necessary for and related to "qualifying therapeutic discovery projects."

The legislation provides that the Secretary of the Treasury (Treasury), in consultation with the Department of Health and Human Services (HHS), has until May 21, 2010, to issue guidance on applying for the credit. In advance of the release of guidance from Treasury, there are several steps taxpayers can take that may increase their chances for a successful application.

### Therapeutic Discovery Credit Basics

Under newly enacted Internal Revenue Code (Code) section 48D, a taxpayer may receive, as either a tax credit or a grant, 50 percent of the amount of certain "qualified investments" made in a taxable year beginning in 2009

or 2010. Because the Therapeutic Discovery Credit is payable as either a tax credit or a nontaxable grant, at the election of the applicant, taxpayers that have operating losses and are thus unable to utilize tax credits currently may nevertheless recognize a current cash flow benefit from this program.

Certain entities that do not pay federal income tax, however, are not eligible for a grant, including federal, state or local governments (or subdivisions, agencies or instrumentalities thereof), certain tax-exempt organizations and "qualified issuers" as defined in Code section 54(j)(4). Partnerships and other pass-through entities with ineligible partners or members are also not generally eligible to receive grants.

For purposes of the Therapeutic Discovery Credit, a "qualified investment" is the aggregate amount of costs paid or incurred for expenses necessary for and directly related to the conduct of a "qualifying therapeutic discovery project," which amount must be certified by Treasury. A qualifying therapeutic discovery project is a project designed to:

- treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials and clinical studies

or carrying out research protocols aimed at securing Food and Drug Administration approval of a product,

- diagnose diseases or conditions,
- 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.

A "qualified investment" does not include certain types of costs, such as compensation paid to certain highly compensated employees, interest expenses, facility maintenance expenses (which include mortgage or rent payments, insurance payments, utility and maintenance costs and the costs of employing maintenance personnel), certain indirect costs including personnel, data processing and accounting costs, and any other expenses determined to be appropriate for exclusion by Treasury.

In order to be eligible for the Therapeutic Discovery Credit, a taxpayer (in all of its businesses) must employ not more than 250 people at the time it submits its application, taking into account certain aggregation rules that apply to groups of affiliated taxpayers. In addition, the Therapeutic Discovery Credit legislation provides for certain limitations intended to prevent "double dipping." These limitations include:

- No deduction is permitted for expenses for which a Therapeutic Discovery Credit is received.
- If credit is given for qualified expenditures relating to depreciable property, the tax basis of that property must be reduced by the amount of the credit.
- Expenditures for which a Therapeutic Discovery Credit is received will generally be excluded from the determination of the amount of certain otherwise potentially available

tax credits (such as those relating to certain research and clinical testing expenditures under Code sections 41 and 45C).

### **Selection Criteria**

Because a maximum of \$1 billion has been appropriated for the Therapeutic Discovery Credit, it will almost certainly be necessary for Treasury to apportion this amount among competing applicants. Code section 48D directs Treasury to take into account several factors in making these determinations. In particular, taxpayers will need to show that a project has a reasonable potential to:

- result in new therapies to treat areas of unmet medical need or to prevent, detect or treat chronic or acute diseases or conditions,
- reduce long-term health care costs in the United States, or
- advance significantly the goal of curing cancer within the 30-year period beginning on the date Treasury establishes the program described in the following section.

Treasury is also directed to take into consideration which projects have "the greatest potential (i) to create and sustain (directly or indirectly) high-quality, high-paying jobs in the United States, and (ii) to advance United States competitiveness in the fields of life, biological, and medical sciences." In addition, Treasury will publish the identities of and amounts awarded to successful applicants.

### **Application and Selection Program**

Code section 48D requires Treasury, in consultation with HHS, to establish a Therapeutic Discovery Credit application and selection program by May 21, 2010. Until applicable guidance is issued, however, it is not possible to predict with certainty what the application or selection process will entail.

Inasmuch as the statute requires Treasury to approve or deny applications within 30 days of submission, there is a possibility that projects may be funded on a "first-come, first-served" basis. However, the application process for a similar tax credit — the Qualifying Advanced Energy Project Credit (the Advanced Energy Credit) established by the American Recovery and Reinvestment Act enacted in February 2009 — awarded funding based on factors unrelated to the speed with which taxpayers submitted applications.

Given the substantial similarities between the Advanced Energy Credit and the Therapeutic Discovery Credit and the relatively short time period during which Treasury is required to establish the application and selection program for the Therapeutic Discovery Credit, there is at least a possibility that the application guidelines for the Therapeutic Discovery Credit will be similar to those for the Advanced Energy Credit.<sup>1</sup>

### **Recommendations**

Interested taxpayers may wish to begin gathering documentation that could be useful in establishing eligibility for the Therapeutic Discovery Credit and substantiating the amount of potential qualified investments made or projected to be made in taxable years beginning in 2009 and 2010. In addition, taxpayers should consider beginning the process of identifying discrete creditable projects based on, among other things, an assessment of the relative

strength of such projects vis-à-vis the statutory selection criteria and ability to substantiate the amount of qualified investment allocable thereto.

Taxpayers may also wish to consider reviewing or consulting counsel with respect to the DOE and IRS application guidelines for the Advanced Energy Credit.<sup>2</sup> The Advanced Energy Credit guidelines, although not directly applicable, may provide a preview of the mechanics and substance of the application process for the Therapeutic Discovery Credit. Finally, interested taxpayers should consult counsel and monitor the IRS and HHS websites for information and guidance related to the Therapeutic Discovery Credit.

### **Endnotes**

<sup>1</sup> The application process for the Advanced Energy Credit required applicants to submit requests to both the Internal Revenue Service (IRS) and the Department of Energy (DOE), and IRS approval depended in whole or part on a recommendation by the DOE. Moreover, the Advanced Energy Credit application window remained open for a period of months, with several intermediate deadlines.

<sup>2</sup> DOE information and application materials can be found at: <http://www.energy.gov/recovery/48C.htm>.

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