



THERAPEUTIC DISCOVERY PROJECT CREDIT PROGRAM GENERAL GUIDE

The Therapeutic Discovery Project Credit was included as part of the landmark healthcare reform legislation recently enacted into law. Lawmakers rightfully realized that the therapies developed by emerging life science companies are crucial to the underlying goal of providing access to quality healthcare for all Americans. As the Treasury Department, in consultation with the Department of Health and Human Services (HHS), begins work on implementing this new program, the following serves as a general guide for companies.

What is the Therapeutic Discovery Project Credit Program?

Modeled after existing tax credits for investments in Qualifying Advanced Energy Projects, this newly enacted program creates a credit to encourage investments in new therapies to prevent, diagnose, and treat acute and chronic diseases. The credit amount would be equal to **50% of investments** in “**qualifying therapeutic discovery projects**” for **2009 and 2010**. For example, eligible investments include conducting pre-clinical activities, employing scientists and researchers, purchasing equipment, and conducting clinical trials.

How will this impact my emerging company which has no tax liability?

Unlike the current general business tax credits, such as the R&D credit or the orphan drug credit, this new Therapeutic Discovery Project Credit will allow companies to “cash in” their credits for a grant in an equal amount. This means an immediate cash infusion for companies looking to continue their innovative research and development.

How does the “grants in lieu of therapeutic credits” feature work?

As part of this new “grants in lieu of therapeutic credit” program, companies can apply to the Treasury and HHS for an allocation of Therapeutic Discovery Project Credits. Companies can **exchange their allocated tax credits for an equivalent grant** for their 2009 and 2010 qualified investments. The grant, like the credit, is equal to 50% of investments in “qualified therapeutic discovery projects” for 2009 and 2010.

Am I eligible for the therapeutic discovery project credit? If so, what types of projects would qualify for credit?

Companies with **less than 250 employees are eligible** for this new credit. Companies must demonstrate work performed on a “**qualified therapeutic discovery project**” is designed to:

- 1) treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, or clinical studies, or carrying out research protocols, for the purpose of securing approval of a drug or biologic,
- 2) diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions, or
- 3) develop a product, process, or technology to further the delivery or administration of therapeutics.

When allocating credits, what will Treasury and HHS base its selection criteria on?

Treasury and HHS, in determining qualifying projects, would:

(A) take into consideration only those projects that show reasonable potential—

(1) to result in new therapies to treat areas of unmet medical need, (2) to prevent, detect, or treat chronic or acute disease and conditions, (3) to reduce long-term health care costs in the United States, or (4) to significantly advance the goal of curing cancer within a 30-year period AND

(B) take into consideration which projects would have the greatest potential—

(1) to create and sustain (directly or indirectly) high quality, high-paying jobs in the United States, and (2) to advance United State competitiveness in the fields of life, biological, and medical sciences.

When will the Treasury and HHS implement the program?

The legislation gives the Treasury, in consultation with HHS, **60 days** to **establish a therapeutic discovery project program**. That means guidance establishing the rules of the road for applying for these incentives must be published on or before May 21, 2010. We expect this guidance to give applicants an additional 30 to 60 days to prepare applications in response to program guidance. This conclusion is based on how the similarly allocated “qualifying advanced energy project” tax credits were awarded.

Once the program is established, how long will it take Treasury to process my application?

Treasury is required to take action to approve or deny an application within **30 days of submission** of the application.

Is it possible for my company to file applications for credit allocations for 2009 & 2010 expenditures at the same time?

Though more details will be provided when regulatory guidance is released, it appears that multi-year applications can be submitted simultaneously for both 2009 and 2010.

Could my credits or grant be recaptured?

Yes. If the allocation of credits awarded to your company for 2010 exceeds the actual amount of qualified investment incurred for the qualified therapeutic discovery project, then the

credits can be recaptured. Likewise, if the amount of the grant awarded exceeds the amount allowable after the actual amount of qualified investment is subsequently determined, then the grant can be recaptured as well. But rather than requiring grant repayment, such amount would be recaptured as an increase in tax by reason of an investment ceasing to be a qualified investment.

If I claim the therapeutic credit, are there other tax benefits that I must forgo?

Qualified therapeutic discovery project expenditures would not qualify for the R&D credit, orphan drug credit, or bonus depreciation.