

Rules Issued for Qualifying Therapeutic Discovery Project Credit

On May 21st, the Treasury Department issued rules regarding the Qualifying Therapeutic Discovery Project Credit. The Qualifying Therapeutic Discovery Project Credit program, which is described more fully in our May 11th [article](#), establishes a tax credit of 50% on “qualified investments” in a “qualified therapeutic discovery project.” The rules, which can be found [here](#), help clarify what projects will be eligible, how the projects will be judged and the application timeline and process.

1. What is the timeline to apply for a credit or grant?

The timeline for applications avoids a “first come, first served” rush. The application period will begin on June 21st when the application form for this program (Form 8942) will be issued. Applications must be postmarked by July 21st. A preliminary review of applications will be completed by September 30th to confirm applicants are eligible and their applications are complete. Applicants will receive notice by letter whether they will be receiving a credit and/or grant and payment for any awarded grants by October 29th. Determinations for credits or grants or the amounts of such credits/grants are final and not appealable.

2. What is required for an application?

A complete application for credits and/or grants shall include (1) a completed Form 8942, (2) a Project Information Memorandum, and (3) at the company’s option, a consent to disclose certain limited information regarding the project. In addition, an applicant must have a DUNS number (available free from Dun and Bradstreet at 1-866-705-5711) and be registered with the Central Contractor Registration (www.ccr.gov/startregistration.aspx). Companies must file a separate application for each project.

3. What is required in Form 8942?

Although Form 8942 has not been issued the rules set forth the information required by the form which includes, among other things:

1. The ownership and type of entity of the applicant.
2. The number of the applicant’s full and part-time employees.
3. A description of the applicant’s qualified investments and the dollar amounts thereof.
4. The number of full and part-time employees in the U.S. whose work is directly billed to the project and the average salaries of the employees in each category.
5. The number of contractors in the U.S. paid for work on the project and the average monthly compensation and hours of the contractors.
6. Whether, as of the date the application is submitted, the project is active, terminated or suspended and, if terminated or suspended, why. *A project that has been terminated or suspended because of a pre-clinical or clinical failure, or failure to receive regulatory approval will not be eligible to receive a credit or grant because it will be determined to have insufficient potential to advance U.S. competitiveness.*
7. Whether the project (1) will produce new or significantly improved technology, or a new application or significant improvement to existing technology, as compared to current commercial technologies and (2) is expected to lead to the construction or use of a contract production facility in the U.S. in the next 5 years.
8. Whether the applicant is applying for a grant (instead of a credit) for 2009, 2010 or both years.

4. What is required in the Project Information Memorandum?

The information required in the Project Information Memorandum includes, among other things:

1. A 250 word or less overview of the project for which the credit and/or grant is being sought, including a description of the product, process or technology under development.
2. If the project is likely to (1) lead to the development of new therapies for unmet medical needs or chronic or acute diseases, (2) reduce long-term healthcare costs or (3) significantly advance the goal of curing cancer a 50 word or less statement supporting each of these goals it meets.
3. A 250 word or less statement explaining the scientific rationale of and the research and development plan for the project, as well as the scientific evidence relied upon for the project. The statement may include up to five literature citations.
4. A 250 word or less statement describing the stage of development of the project, including any relevant pre-clinical and clinical trial results.
5. A 250 word or less statement describing the company's resources, management experience and organizational capacity and how such resources, experience and capacity will support successful completion of the project.

5. What information from Form 8942 and the Project Information Memorandum will be used to evaluate which projects best meet the Program's goals?

The program seeks to provide credits or grants to projects that meet both "therapeutic" and "economic development" goals.

To meet the therapeutic goals the application should demonstrate the project has reasonable potential to fulfill one or more of the following goals:

1. Result in new therapies to treat areas of unmet medical need; or
2. Result in new therapies to prevent, detect or treat chronic or acute diseases; or
3. Reduce long-term health care costs in the U.S.; or
4. Significantly advance the goal of curing cancer within 30 years.

To meet the economic development goals the application should demonstrate the project has the greatest potential to fulfill both of the following goals:

- A. Create and sustain high quality, high paying U.S. jobs; and
- B. Advance U.S. competitiveness in the fields of life, biological, and medical sciences.

The Treasury Department will use the information in Form 8942 regarding employees and contractors employed or used on the project (see items 4 and 5 in Question #3 above) to evaluate the job creation goal.

The Treasury Department will use the information in Form 8942 regarding (1) whether the project is active, suspended or terminated, (2) what technology or application the project will produce, and (3) whether the project is expected to lead to the construction or use of a contract production facility (see items 6 and 7 in Question #3 above) to evaluate the U.S. competitiveness goal.

The Treasury Department will use the information provided in the Project Information Memorandum regarding (1) the scientific rationale and R&D plan for the project, (2) the scientific evidence relied on in

the project, (3) the stage of development of the project, and (4) the applicant's resources, management experience and organization capacity (see items 3 – 5 in Question #4 above) to evaluate both the therapeutic and economic development goals.

The Treasury Department will use the information provided in the Project Information Memorandum regarding (1) whether new therapies will be developed, (2) healthcare costs will be reduced, or (3) advancements will be made to cure cancer (see item 2 in Question #4 above) to evaluate the therapeutic goals.

6. What clarifications do the rules make to the Program?

- The maximum credit/grant any one company can obtain is \$5 million (i.e., 50% of \$10 million of qualified investments) for 2009 and 2010 combined.
- Projects for generic drugs, biosimilars, dietary supplements and cosmetics do not qualify as Qualifying Therapeutic Discovery Projects.
- For projects involving a product, process or technology to further the delivery or administration of therapeutics, "therapeutics" includes drugs, medical devices and most biologics, but does not include other therapies such as speech, physical or cognitive therapies.
- If a company intends to show that the project has reasonable potential to result in new therapies to treat areas of unmet need or prevent, detect or treat chronic or acute disease, the "new therapy" must be novel and meaningfully distinguishable from currently marketed therapies. A therapy will not be considered a "new therapy" if it's in the same class as existing therapies unless such therapy is expected to offer a significant enhancement in safety or effectiveness.
- If a company intends to show that the project has reasonable potential to reduce health care costs, the application should describe actual cost reductions, not simply a substitution of one cost for another, provide reasonable estimate of savings and demonstrate a reasonable potential to achieve such savings.
- Qualified investments may include, among other expenses, wages (other than for certain executive officers), supplies and lab costs, depreciable property and contractor costs.
- If the IRS issues a credit based on qualified investments expected to be made in 2010 and the credit exceeds a company's actual qualified investments, then the credit shall be reduced by 50% of the difference between the credit and the company's actual qualified investments.

7. Will the identity of the applicants, projects and credits/grants be disclosed publically?

Upon making a determination that an applicant will receive a credit and/or grant, the IRS will publicly disclose the identity of the applicant and the amount of the credit and/or grant. Due to a quirk in the legislation authorizing the program, applicants receiving a grant for qualifying investments will have the type and location of their project disclosed. The IRS is not statutorily authorized to disclose the type and location of a project for which an applicant is receiving a credit. The IRS is requesting that applicants for

a credit in 2009 and/or 2010 or a grant in 2010 provide an authorization to disclose the type and location of the project to which the application relates. However, applicants are not required to provide such authorization to receive a credit or grant.

8. How is confidential information treated?

The IRS expects that other than the information it will disclose as discussed in the Question #7, the information in an application would be exempt from disclosure under the Freedom of Information Act (FOIA). Nonetheless, the rules provide a straight forward method to identify, mark and protect trade secrets and confidential, privileged or otherwise exempt information.

9. Helpful hints

- Your opportunity to distinguish your project from hundreds of others is primarily through a few 250 word answers. As T.S. Eliot said, "If I had more time, I'd have written a shorter letter." Start early so that your answers will use the limited space provided in an efficient and persuasive way.
- If your application contains your or a third party's trade secrets or confidential or proprietary information, use the procedures provided to protect such secrets or information from disclosure under FOIA.
- Do not rely on any presumed background knowledge of the reviewers of your company's application. It is unlikely the reviewer of your application will be familiar with your project's technology or have a scientific or medical background. This is not a scientific grant proposal.
- No supplemental materials or materials incorporated by reference, such as brochures, DVDs or other presentations or scientific papers (other than the references allowed in the Project Information Memorandum) are permitted and therefore will not be considered.

Together with your accounting/tax team and auditors, Fabbri Law is available to assist you with the application process.

William Fabbri
617-875-7190
wfabbri@comcast.net

©2010 Fabbri Law, LLC

Because of the generality of this update, the information provided herein may not be applicable in all situations and should not be acted upon without specific legal advice based on particular situations.