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Applying for the Therapeutic Discovery Project Credit: Immediate Action Needed

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The U.S. Treasury recently released guidelines addressing the Section 48D certification and application process. These guidelines are important for any small pharmaceutical, biotech, life science or medical device company interested in applying for the tax credit or cash grants provided by the qualified therapeutic discovery project (QTDP).

As previously announced, the QTDP credit or cash grants equals up to 50% of the qualified investments that an eligible taxpayer makes during a tax year beginning in 2009 or 2010 on qualifying projects. A total of \$1 billion has been allocated to this program, and there is a cap on the amount an eligible taxpayer may receive. No single taxpayer may receive more than \$5 million in cash grants or as a tax credit even if qualified expenses exceed \$10 million, regardless if the taxpayer submits multiple qualifying projects. This per taxpayer cap is further limited by the \$1 billion program limitation since any credit or cash granted may be reduced pro rata among all qualifying projects. Also of note, cash grants (but not tax credits) to partnerships or S corporations are further limited if the entity has any foreign or tax-exempt shareholders or partners.

Taxpayers must submit a separate application for each qualifying project they wish to be considered for the tax credit or cash grants. Applications are to be submitted on Form 8942, which is to be released no later than June 21, 2010. A successful filing is one that is completed and postmarked 30 days from the release of the application, July 21, 2010. From July 22 through September 30, the IRS and Department of Health and Human Services (HHS) will review all submitted applications to determine taxpayer eligibility (i.e. 250 or less employees) and project qualification. All timely filed applications will be deemed to be submitted as of October 1, giving the IRS until October 29, 2010, to approve or deny applications. Since the review is not on a "first come, first served" basis, there is no benefit to filing early. Since all projects will receive equal evaluation, it is better advised to take the full allotted time to make a complete application that thoroughly addresses all the points in the application. It is particularly important to "get it right" the first time, since there is no appeals process.

The application will essentially consist of two parts. Part one is primarily focused on a detailed accounting of the 2009 and 2010 qualified expenses. Again, the qualified investment amount is the aggregate amount of costs paid or incurred in the tax year for expenses necessary and directly related to the conduct of a qualified therapeutic discovery project. Qualified expenses include such items as wages, supplies and equipment, and payments to contractors. Excluded expenses are salaries to executives, facility maintenance expense (e.g. rent, insurance), service costs (i.e. general and administrative expenses), and interest expense.

Part two is a Project Information Memorandum that must include detailed responses to questions about the project. These questions are specifically designed to help the IRS and HHS assess how the project will achieve certain goals, the company's research and development plan, the stage of the project development, and any trial results. In addition, general information about the company and the project must be supplied. Again, the QTDP is designed to advance healthcare.

Accordingly, the questions will be designed to ascertain the viability of a project:

- to treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out research protocols;
- to diagnose diseases or conditions or to determine molecular factors related to diseases or conditions; or
- to develop a product, process, or technology to further the delivery or administration of therapeutics.

Additionally, the IRS must consider:

- those projects that show reasonable potential to result in (1) new therapies; (2) reduce long-term health care costs; or (3) significantly advance the goal of curing cancer in the next 30 years; and
- those projects that have the greatest potential to (1) create and sustain high quality, high-paying US jobs; and (2) advance US competitiveness in the fields of life, biological, and medical sciences.

There are word count limitations for each question, from 50 words per question to 250 words per question. Thus, although an application will need to be thorough in describing the project, it will also need to be concise.

Each applicant should begin their preparation for the application as soon as possible. Applicants should start now to determine their qualified investments for 2009 and 2010, as well as their estimated qualified investments for the remainder of 2010. Supporting documents for the qualified investments are highly recommended. They should also begin drafting the accompanying Project Information Memorandum, and craft it to address the above considerations in a succinct manner.

Rowbotham & Company can help with the preparation of these applications. Please contact [Mark Kelly](#) or [Eric Symkowick](#) for further assistance with this process.

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