

Treasury and IRS release Therapeutic Research Credit Program guidelines and deadlines

On May 21, 2010, the U.S. Treasury and Internal Revenue Service released highly anticipated program guidance on the new Therapeutic Research Credit. IRS Notice 2010-45 provides information about how to qualify for and apply for the credit and optional grant. Most significantly, the guidance notes that applications will be accepted beginning June 21, 2010, pending the IRS release of the required program application Form 8942. Applications must be received by July 21, 2010, giving companies roughly 30 days to complete and submit applications.

Background

The recent health care legislation made available a new credit – the Qualifying Therapeutic Discovery Project Credit – to encourage medical research investments for 2009 and 2010. With only \$1 billion in funds made available, the application process is going to be highly competitive.

The tax credit, or grant, will be fifty percent of the eligible qualifying expenses, as described below. Note that a maximum of \$5 million will be allocated to any taxpayer, in aggregate, for both 2009 and 2010.

Eligibility

Companies in the medical therapeutic research industry with 250 or fewer employees and eligible expenses in 2009 and/or 2010 may apply.

The IRS notice provides additional clarification to the statutory categories of projects eligible for the section 48D program. According to the notice, applicants must have eligible expenses in research in an area designed:

- > To treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out research protocols, for the purpose of securing approval of a product under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act,
- > To diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions, or
- > To develop a product, process, or technology to further the delivery or administration of therapeutics.

Eligible expenses under the program include those costs paid or incurred necessary for and directly related to the conduct of the qualifying therapeutic discovery project. These expenses are likely to include:

- > Direct labor (to include fringe benefits)
- > Supplies used in the conduct of research
- > Contract research expenses
- > Royalties
- > Rental and/or depreciation on equipment used to conduct research

The IRS Notice specifically excludes costs related to:

- > Executive compensation otherwise excluded under section 162(m)
- > Interest expenses
- > Facility maintenance expenses
- > Expenses identified as service costs under Treas. Reg. § 1.263A-1(e)(4)
- > Any other expense as determined by the Treasury Secretary

Note also that an applicant's qualified investment shall be reduced by the amount of any other grant that is excluded from the taxpayer's gross income, unless that grant can only be used for costs *not* included in the definition of qualified investment under the section 48D program. Thus, an applicant must examine other grants it has received related to the therapeutic research for which it seeks to submit a section 48D application.

Finally, the IRS notice provides that government entities or 501(c) organizations are ineligible to receive a grant under the program. Additionally, any partnership that contains one of these entities is ineligible for the grant. Thus, applicants must be certain that no part of its ownership is an ineligible entity.

When are applications due?

The notice states that applications will be due no later than July 21, 2010. Applications must be filed on new IRS Form 8942, which is not yet available, but **will be released by June 21, 2010**. Thus applicants will have at least 30 days to complete and file their applications. Please note that each discrete project must have a separate application. Taxpayers with more than one project should be prepared to complete multiple applications.

Appendix A to the notice sets out the specific items that will be required on Form 8942. There are eleven questions noted, and each has very strict word limits for the applicant's response. Applicants should immediately familiarize themselves with Appendix A and begin building their responses to these questions so that they may accurately complete Form 8942 when it is available. Preparedness is important because time will be of the essence to complete applications, and incomplete applications may not be considered.

What is the decision process?

The IRS will conduct a preliminary application review that will end on September 30, 2010. This review will determine if the application is complete and the taxpayer eligible. After this review, the Department of Health and Human Services (HHS) will conduct a second review to evaluate the applications and make allocations of the credit or grant funding. HHS's review will commence October 1, 2010, and will be completed by October 29, 2010. The notice provides that HHS decisions are final, and no conference or appeal rights exist.

Once the HHS allocates the amounts under the program, for taxpayers claiming the grant for 2009 tax years, Treasury will begin authorizing grant payments by October 29, 2010. The payment date will depend on the date the grant request is made.

Selected projects will have reasonable potential to:

- > Result in new therapies that:
- > Treat areas of unmet medical need,
- > Prevent, detect, or treat chronic or acute diseases and conditions,
- > Reduce long-term health care costs in the US, or
- > Significantly advance the goal of curing cancer within the 30-year period beginning on the date the Secretary established the program.

Assuming a project meets one of the above criteria, IRS and HHS shall also give weight to projects that can:

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

Other information

Grants under this program will not be considered taxable income. However, for portions of the grant applicable to depreciable property, the applicant will be required to reduce their basis in that property by the related amount of the grant.

Applicants choosing a grant will need to provide a Data Universal Numbering System (DUNS) number, as well as register with the federal Central Contractor Registration.

What should you do now?

Because the IRS has not yet released Form 8942, interested applicants should prepare the information detailed in Appendix A to the IRS notice. Applicants also will need to review and document their qualifying expenses. While the notice does not specifically indicate how expenses will be listed, companies should consider breaking these expenses into the relevant categories noted above. Applicants also need to analyze whether they wish to apply for a tax credit or the grant.

How we can help

To date, we have assisted with applications that resulted in more than \$15 million in section 48C (the Qualifying Advanced Energy Project Credit established in August 2009) funding and more than \$840 million for New Markets Tax Credits (NMTC) for our clients. We anticipate the section 48D Qualifying Therapeutic Discovery Project Credit program will be patterned after section 48C program.

By tapping into our deep grant and tax credit application expertise, we will help you navigate:

- > Understanding what qualifies for the \$1 billion in grants or tax credits
- > Program exclusions
- > Preparing for the application process
- > Planning considerations
- > Suggestions for writing a successful application in order to best position your company to receive an award
- > An overview of how programs have worked like this in the past and how to prepare for a quick application process and response

Baker Tilly is a full-service accounting and advisory firm with broad service offerings and deep industry connections, which affords you better access to capital sources and a more extensive knowledge of tax credits and incentives. Our professionals regularly assist clients in successfully applying for tax credits and are ready to assist you. For more information on the wide range of services available to biotech and life sciences companies, connect with us at bakertilly.com/Services or call 800 362 7301.

If you have questions or require further information, please contact your Baker Tilly tax advisor or send an e-mail to tax@bakertilly.com. A webinar presentation that covers the Therapeutic Discovery Project Credit also is available for download at www.bakertilly.com/therapeuticprojectcredit.