Internal Revenue Service Establishes Qualifying Therapeutic Discovery Project Program

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The Health Care and Education Reconciliation Act of 2010 enacted on March 23 (the Act) added a new nonrefundable investment tax credit for qualified investments in qualifying therapeutic discovery projects (QTDPs). The Act also creates a mechanism to allow an eligible taxpayer to receive a cash grant in lieu of the credit. The credit/grant may be of significant benefit to small and mid-sized biotech companies (no more than 250 employees) and their investors.

In accordance with requirements of the Act, the IRS issued Notice 2010-45 on May 21 to establish the qualifying therapeutic discovery project program (the QTDP Program). The Notice sets out the details of how an eligible taxpayer may obtain certification that will allow it to claim the credit/grant for its qualified investments in a QTDP. The program is managed by IRS in consultation with the Secretary of Health and Human Services (HHS).

A project is considered to be a **qualifying therapeutic discovery project** if it is designed:

1. To treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies for the purpose of securing approval of a product by the Food and Drug Administration;
2. To diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing diagnostics to guide therapeutic discussions; or
3. To develop a product, process or technology to further the delivery or administration of therapeutics.

A **qualified investment** is defined as the aggregate amount of costs paid or incurred for expenses necessary for and directly related to the conduct of a QTDP. It does not include:

1. Compensation of the CEO, and if their compensation must to be reported to shareholders under Securities Exchange Act of 1934, the four most highly compensated officers (other than the CEO);
2. Interest expenses;
3. Facility maintenance expenses, including insurance, mortgage or rent, utility and maintenance costs, and costs of employment of maintenance personnel;

4. Service costs under Reg. 1.263A-1(e)(4) (general and administrative costs); or
5. Any other expenses that are determined by the IRS to be appropriate to carry out the purposes of the program.

The Notice indicates that, applying this last factor, IRS has determined that a qualified investment should be reduced by the amount of any grant excluded from gross income unless the grant can only be used for costs not included in the definition of qualified investment.

The amount of the credit generally equals 50 percent of qualified investment in QTDP. The total amount of credits that the IRS may allocate under the program cannot exceed $1 billion ($2 billion aggregate qualified investments) for the two-year period beginning with 2009. The IRS has indicated it plans to make essentially equal allocations among all certified projects (but not exceeding qualified investment). The Notice sets out the procedures for obtaining certification of each eligible taxpayer's qualified investment in QTDP based on application to IRS with review of HHS. The maximum amount certified for any single taxpayer is limited to $10 million ($5 million for 2009 and 2010) regardless of the number of projects the taxpayer sponsors.

The Notice provides that IRS will certify an eligible taxpayer's qualified investment under the QTDP Program only if:

1. HHS determines that the taxpayer's project is a QTDP;
2. HHS determines that the taxpayer's project shows reasonable potential (a) to result in new therapies, (i) to treat areas of unmet medical need or (ii) to prevent, detect or treat chronic or acute diseases or conditions; (b) to reduce long-term health care costs in the United States or (c) to significantly advance the goal of curing cancer within the 30 year period beginning May 21, 2010; and
3. IRS determines that the taxpayer's project is among those projects that have the greatest potential (a) to create and sustain (directly or indirectly) high quality, high-paying jobs in the United States and (b) to advance United States competitiveness in the fields of life, biological and medical sciences.

To obtain certification in the primary allocation round[1] , a taxpayer must file new IRS Form 8942 "Application for Certification of Qualified Investment Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Program" for each QTDP on or before July 21, 2010[2]. Each application will receive preliminary review to determine if the taxpayer is an eligible taxpayer and whether the application is otherwise complete. The preliminary review will end on September 30, 2010. The Act requires the IRS to take action within 30 days of submission of the application. For that purpose, October 1, 2010, the day after the preliminary review ends, is considered the date of submission. The IRS will approve or deny applications no later than October 29, 2010, and will notify the applicant by letter. No conference of right or right of appeal of any decisions are available.

Pursuant to the Act, upon making certification for credit or grant, IRS will publicly disclose the identity of an applicant and the amount of the credit or grant. IRS will also publish information of the type and location of the QTDP (subject to certain limitations and restriction set out in the Notice). The IRS has indicated it expects 1,200 applications for certification under the QTDP Program.

For additional information about the QTDP Program or assistance with applying to IRS for certification, please contact Allan Weiner.

[1] If the full $1 billion available allocation is not made in the primary round, additional rounds may be conducted.

[2] Form 8942 will be released on or before June 21, 2010. Consequently eligible taxpayers should begin gathering information for submission as soon as possible.