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### IRS ESTABLISHES PROCEDURES FOR APPLYING FOR THE THERAPEUTIC DISCOVERY TAX CREDIT

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**The Internal Revenue Service has announced procedures under which certain biotech companies can apply for tax credits or cash grants for qualifying therapeutic discovery projects. These procedures are described in more detail below. The IRS has indicated that the application form required for submitting applications will be available no later than June 21, 2010, and the application deadline will be July 21, 2010. The IRS will approve or deny applications no later than October 29, 2010.**

#### Background

The Patient Protection and Affordable Care Act created a new federal program to subsidize certain costs paid or incurred in 2009 and 2010 by certain biotech companies in qualifying therapeutic discovery projects. The subsidy is available to offset 50% of the costs of eligible projects in the form of a nonrefundable tax credit or a cash grant. The total amount of credits that can be certified under the

program is capped at \$1 billion for the 2-year period beginning with 2009. Only small biotech companies that employ not more than 250 employees are eligible for credits under the new program.

The new program, contained in Section 48D of the Internal Revenue Code, requires biotech companies to obtain certification from the Treasury for qualifying investments. On May 21, 2010, the Internal Revenue Service (IRS) released [Notice 2010-45](#). The Notice sets forth the procedures under which an eligible taxpayer may apply for certification from the IRS of a qualified investment with respect to a qualifying therapeutic discovery project as eligible for a credit or a grant under the program.

#### Definitions

##### ***Qualifying Therapeutic Discovery Projects***

A qualifying therapeutic discovery project includes a project which is 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.

#### ***Qualified Investments***

A company's qualified investment for any taxable year includes costs paid or incurred in such taxable year for expenses necessary for and directly related to the conduct of a qualifying therapeutic discovery project. This includes research costs as well as capital expenditures for equipment used in the qualifying

project. Qualified investment is limited to the amount certified by Treasury as eligible for a credit.

Qualified investment does not include remuneration paid to certain officers, interest expense, facility maintenance expenses (including mortgage or rent expense, insurance, utility and maintenance expenses), and certain indirect service and general and administrative costs.

### **Eligible Taxpayer**

An eligible taxpayer is a taxpayer who employs not more than 250 employees in all businesses of the taxpayer at the time of the submission of its application. The term "employee" includes both full-time and part-time employees but does not include leased employees.

### **Applying for Certification from the IRS Under Notice 2010-45**

The Notice provides that the IRS will certify an eligible taxpayer's qualified investment associated with a qualifying therapeutic discovery project under the qualifying therapeutic discovery project program, for which an application has been submitted pursuant to the Notice, only if:

- (1) The Department of Health and Human Services (HHS) determines that the taxpayer's project is a qualifying therapeutic discovery project;
- (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 and 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 on May 21, 2010; and

- (3) The 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.

Applications for certification will be made on new Form 8942, "Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program." According to the Notice, Form 8942 will be released no later than June 21, 2010. An application for certification may be filed from the date the application form is released by the IRS until July 21, 2010, after which time applications will not be accepted (absent a second round of allocations). Preliminary review of timely filed applications will end on September 30, 2010.

Under Section 48D of the Code, the Secretary of the Treasury is required to take action to approve or deny any application within 30 days of the submission of the application. For this purpose, all applications will

be treated as submitted on October 1, 2010, the day after which preliminary review ends. This will avoid a rush to the door to file an application. An application for certification may include a request for certification of a project's costs for taxable years beginning in 2009, 2010, or both.

The IRS will determine whether to certify all or a portion of a taxpayer's qualified investment eligible for the therapeutic discovery project credit or grant after HHS has completed its review of all applications submitted by eligible taxpayers.

The IRS will certify all or a portion of an eligible taxpayer's qualified investment for each qualifying therapeutic discovery project for which an application has been submitted that meets the certification requirements set forth in the Notice. The aggregate amount of qualified investments that will be certified by the IRS will not exceed \$2 billion, such that the total amount of credits and grants allocated under the program will not exceed the \$1 billion limitation of Section 48D. The Notice provides that the IRS will certify an equal amount of qualified investment for each project that meets the certification requirements. However, in no case will the IRS certify more than the amount of the qualified investment attributable to a project. If a project would otherwise receive certification for an amount of qualified investment that exceeds the qualified investment described in the application as attributable to

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the project, the unused certification amount will be apportioned equally among all other projects receiving a certification for only a portion of their qualified investments. Such reapportionment will continue until no project receives certification for an amount that exceeds the qualified investment described in the application as attributable to the project.

Additionally, the IRS will not certify more than \$10 million as a qualified investment for any single taxpayer, such that no taxpayer shall be allocated more than \$5 million in credits or grants in the aggregate for 2009 and 2010, regardless of the number of the taxpayer's projects.

According to the Notice, the IRS will approve or deny a taxpayer's application for Section 48D certification no later than October 29, 2010, which is within 30 days after the date timely-filed applications will be considered to be submitted, and will notify the

taxpayer of its decision by letter. The IRS will, upon making a certification for credit or grant, publicly disclose the identity of the applicant and the amount of the credit or grant with respect to the applicant. In addition, upon making a certification with respect to taxpayers that have either elected to receive a grant for the 2009 tax year or provided consent with respect to their application for credit, the IRS will also publish the type and location of the project that is the subject of the application for Section 48D qualifying therapeutic discovery project certification in the event the project receives an allocation.

If a taxpayer prefers to receive a grant rather than a credit, the taxpayer must make an affirmative election on its Form 8942. If a taxpayer is submitting an application for certification of a qualified investment made in both 2009 and 2010, then the taxpayer may apply for a grant for 2009 only, 2010 only, or both 2009 and 2010.

Appendix A to the Notice sets forth in detail the information that must be provided by an applicant for certification, including various questions that must be answered in a Project Information Memorandum to be filed with the applicant's Form 8942.

**Eligible taxpayers intending to submit an application should carefully review Appendix A to the Notice as soon as possible and begin to assemble the required information and draft the required narratives so that they will be able to timely file Form 8942 and the Project Information Memorandum with the IRS.**

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