

Client Alert

Latham & Watkins
Tax Department

IRS Publishes Application Guidelines for Qualifying Therapeutic Discovery Project Tax Credit

The newly established Qualifying Therapeutic Discovery Project tax credit (the Therapeutic Discovery Credit) may provide financial benefits to small and medium-sized biotechnology and life sciences firms and their investors. The Therapeutic Discovery Credit, established by the Patient Protection and Affordable Care Act of 2010 enacted on March 23, 2010, offers \$1 billion in federal income tax credits and grants for expenditures necessary for and directly related to "qualifying therapeutic discovery projects" in taxable years beginning in 2009 and 2010 (combined).

The amount of eligible expenditures qualifying for the Therapeutic Discovery Credit must be certified by the Internal Revenue Service (the Service). On May 21, 2010, the Service published Notice 2010-45 (the Notice), which contains guidance on the application requirements and process to obtain such certification. This *Client Alert* provides an overview of the certification program established by the Notice. For additional background relating to the Therapeutic Discovery Credit generally, please see our prior *Client Alert* titled "The Qualifying Therapeutic Discovery Project Tax Credit," published April 19, 2010.¹

Application and Certification

Process. Applications for certification must be filed on or before July 21, 2010. All applications received on or before July 21, 2010 will receive equal consideration in the process (*i.e.*, the program does not provide priority consideration for applications received before the deadline). During the preliminary review phase, which ends on September 30, 2010, the Service will review applications to determine whether applicants meet the eligibility criteria and that the application is complete. Certification notifications will be mailed to applicants on or before October 29, 2010.

The \$1 billion available under the Therapeutic Discovery Credit program will be allocated among qualifying projects, and in no event will a single taxpayer receive more than \$5 million in credits or grants (across all of the taxpayer's projects). On a conference call held May 21, 2010 announcing the release of the Notice, officials from the Service noted they anticipate receiving thousands of applications. Accordingly, the amount of credits or grants that any single taxpayer may ultimately receive under this program will depend upon the number of taxpayers who are successful in having their projects certified in this process, and may be substantially less than \$5 million.

"All applications received on or before July 21, 2010 will receive equal consideration."

Certification Criteria. Applications for certification will be approved based on the following criteria:

1. The Department of Health and Human Services (HHS) must determine that the taxpayer's project meets the statutory definition of a "qualifying therapeutic discovery project" (generally, a project designed to treat or prevent diseases or conditions by conducting pre-clinical or clinical activities or carrying out research protocols with the goal of securing FDA approval, 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);
2. HHS must determine that the project has 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 advance significantly the goal of curing cancer within the 30-year period beginning on May 21, 2010; and
3. The Service must determine that the project is among the projects that have the greatest potential to create and sustain high quality, high-paying jobs in the United States and to advance United States competitiveness in the fields of life, biological and medical sciences.

Application Overview. An application will consist of two parts, each of which is discussed in greater detail below:

1. **The Form.** Form 8942 (the Form) will include information regarding eligibility for the Therapeutic Discovery Credit and the amount and nature of qualifying expenditures. Form 8942 is not yet available but will be released no later than June 21, 2010, and will be available on the Service's website, www.irs.gov.

2. **The Memorandum.** The "Project Information Memorandum" (the Memorandum) will be reviewed by HHS to determine whether the applicant's project meets criteria 1 and 2 described under "Certification Criteria" above.

Taxpayers must submit a separate application for each qualifying therapeutic discovery project for which they are seeking certification.

The Form. Appendix A of the Notice lists the information to be submitted on Form 8942. Although the Form has not yet been published, taxpayers can begin gathering the information listed in Appendix A and the requisite back-up documentation to support the amount and nature of creditable expenditures and the number of full and part-time employees and contractors (and their salaries) whose work is directly related to the project.

The Form will also be the means by which applicants may elect to receive a grant in lieu of a tax credit. To make that election, applicants will need a Data Universal Numbering System (DUNS) number from Dun and Bradstreet² and must register with the federal government's Central Contractor Registration.³ If an applicant is requesting certification for expenditures made in both 2009 and 2010, the applicant may apply for a grant in either year or both. Applicants may amend a previously filed Form 8942 to receive a grant in lieu of a credit, but in no case may an applicant file such amendment later than the due date (including extensions) for the filing of its tax return for the taxable year in which the qualified investments were made.

The Memorandum. Appendix A of the Notice also contains a detailed overview of the substance and format of the Memorandum. HHS will review the Memorandum to determine whether the project satisfies the definition of a qualifying therapeutic discovery project.

Among other things, the Memorandum must describe:

1. The scientific basis for concluding that the project is likely to result in new therapies, reduce long-term health care costs in the United States or advance the goal of curing cancer within the next 30 years;
2. The stage of development of the project, including the results of any pre-clinical or clinical trials; and
3. The applicant's resources, managerial experience and organizational capacity.

The Service has imposed word limits on answers to each of the questions taxpayers must answer in the Memorandum (in many cases, 250 words or less).

Recommendations. Applicants should review Appendix A to the Notice (including the detailed requirements regarding the format of and questions to be addressed in the Memorandum), identify the project or projects for which applications will be filed and begin gathering the materials required to file a successful application. Most importantly, applicants should begin to prepare responses to the questions in the Memorandum. Developing persuasive and responsive answers that fit within the word limits will likely require substantial time, and applicants should begin this process as soon as possible.

Endnotes

¹ Available at http://www.lw.com/upload/pubContent/pdf/pub3484_1.pdf.

² A DUNS number may be requested, at no cost, by calling 1-866-705-5711.

³ <http://www.ccr.gov/startregistration.aspx> .

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