

Treasury Issues Guidance for 50% Tax Credit/Cash Grant for Life Sciences Companies

May 24, 2010

On May 21, 2010, the U.S. Department of the Treasury (Treasury) issued Notice 2010-45 (the Guidance),¹ which outlines the procedures for obtaining a valuable new 50% tax credit or equivalent cash grant for certain companies in the life sciences industry that made (or will make) a “qualified investment” with respect to a “qualified therapeutic discovery project” in a taxable year beginning in 2009 or 2010.

The credit/grant was part of the recently enacted Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Healthcare Reform Law). These benefits are generally available only to those companies that have no more than 250 employees (with additional limitations on flow-through entities owned in part by governmental or tax-exempt entities), and that incur particular costs associated with the discovery of therapeutic products. For further details about the credit/grant, please see Morgan Lewis’s April 21, 2010 LawFlash, “New 50% Tax Credit/Cash Grant for Life Sciences Companies Requires Timely Determination of Eligibility and Application.”²

The Guidance explains how eligible taxpayers may apply to the Internal Revenue Service (IRS) for a credit or grant, and the criteria that will be used by both the IRS and the Department of Health and Human Services (HHS) in determining whether to award credits or grants.

The key procedural points in the Guidance include:

- Applications may not be filed with the IRS until a new Form 8942 is made available, which will be no later than June 21, 2010.
- The deadline for filing applications for the “first round” is July 21, 2010. A second round will be conducted only if the entire \$1 billion of available funding is not allocated during the first round.
- The IRS and HHS will conduct a preliminary review of the applications until October 1, 2010, when the IRS will begin to approve or deny applications and to notify each applicant of its

¹ Available at http://www.morganlewis.com/pubs/QualifyingTherapeuticDiscoveryProjectCredit_Notice2010-45.pdf.

² Available at http://www.morganlewis.com/pubs/WashGRPP_50PercentTaxCredit_LF_21apr10.pdf.

decision and the amount (if any) certified for a credit or grant. All awards for first-round applicants will be decided by October 29, 2010.

- Applications filed by July 21, 2010 may be made (i) for 2009 only, (ii) for 2010 only, or (iii) for 2009 and 2010. The application may be made on the basis of costs that have not yet been incurred for 2010. A separate application must be filed for each project.
- The IRS will not award more than \$5 million of credits or grants to a single taxpayer for 2009 and 2010 combined, regardless of how many projects a taxpayer sponsors.
- Generally, requests for cash grants filed by July 21, 2010 will be paid to applicants during October 2010 for 2009 investments, and during January 2011 for 2010 investments.

Appendix A of the Guidance describes the information that must be supplied by taxpayers in a Project Information Memorandum (PIM) to be filed with Form 8942. Appendix A also lists some of the information that will be required in Form 8942. HHS will be the main reviewer of the PIM, and the IRS will be the main reviewer of Form 8942.

Form 8942 will require certain information, including:

- An indication of whether the applicant is requesting a credit or a grant in lieu of credit.
- A description of the various costs comprising the qualified investment.
- The full-time employees, part-time employees, and contractors working on the project and their average salaries.
- Whether the project is active, terminated, or suspended.
- Whether the project will produce new (as opposed to existing) technology, and will lead to construction of a production facility.

Appendix A outlines the questions that applicants must answer in the PIM in order for the HHS to determine (i) whether a project meets the definition of a “qualifying therapeutic discovery project” and (ii) whether the applicant has demonstrated that its project shows a “reasonable potential” to meet one or more of the goals specified in the statute.

Appendix A also provides some insights on various positions that will be taken by HHS in its review of the PIM, including:

- Projects designed to treat or prevent diseases or conditions will not include generic drugs, biosimilar products, dietary supplements, and most cosmetics.
- Projects designed to diagnose diseases need not determine molecular factors, and would include point-of-care diagnostics for infectious agents.
- The term “therapeutic” is narrower than the term “therapy” and does not include speech, physical, and cognitive therapies.

- HHS will place more weight on projects that involve a “new therapy”—a therapy that is novel and distinguishable from therapies currently on the market.
- Any claim that a project will reduce healthcare costs must include a reasonable estimate of the savings.

Pending the release of Form 8942, qualifying life sciences companies should begin to prepare the PIM and compile the information to be supplied in Form 8942, in order to be ready to file by July 21, 2010. The PIM is subject to word-count limitations, and will need to be precise and carefully prepared.

Morgan Lewis has the relevant knowledge and skills to assist life sciences companies to prepare an application for a “qualifying therapeutic discovery project” tax credit or grant. If you would like to discuss your potential application or if you have any questions concerning this or any other aspect of the Healthcare Reform Bill, please contact the authors of this LawFlash, **Gary B. Wilcox** (202.739.5509; gwilcox@morganlewis.com) or **Wendy C. Unglaub** (215.963.5281; wunglaub@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

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