

Attention Small Biotechs and Pharmas: Significant New Tax Incentives for Small Therapeutic Development Companies Enacted by Health Care Reform Legislation

April 23, 2010

The Patient Protection and Affordable Care Act (the “Act”) signed by President Obama on March 23, 2010 contains a significant new tax incentive for qualifying therapeutic development companies (“biotechs”) in the form of the Qualifying Therapeutic Discovery Project Credit (the “Therapeutic Tax Credit”). The Therapeutic Tax Credit allows qualifying biotechs to claim a nonrefundable credit for 50 percent of their qualified investment costs in covered projects for their 2009 and 2010 tax years.

Biotechs that did not report enough taxable income for their 2009 tax year to use the Therapeutic Tax Credit may elect to receive nontaxable cash grants in lieu of claiming tax credits. For biotechs that elect to receive nontaxable cash grants, the Therapeutic Tax Credit is essentially found money through which these biotechs effectively recoup investment costs already made in a previous tax year. The Therapeutic Tax Credit is important for the small to mid-sized biotechs covered by the Act because such companies typically do not have enough taxable income to claim research and development (“R&D”) tax credits or are otherwise prevented from claiming R&D tax credits by the alternative minimum tax rules.

The Therapeutic Tax Credit is limited by the \$1 billion in credit and grant funds allocated by the Act. In as much as the credit is available on a first come, first served basis, biotechs will have to move quickly to file applications for funds once the Treasury Department releases its application.

Qualifying Biotechs

Only companies with 250 or fewer employees may qualify for the Therapeutic Tax Credit. For purposes of determining the number of a company’s employees, the Treasury Department will count employees within a controlled or affiliated group. The rule is designed to prevent larger companies from claiming the credit or grant funds intended only for small to mid-sized biotechs.

Qualifying Costs

The Therapeutic Tax Credit applies to the aggregate amount of costs paid or incurred after December 31, 2008 in a qualifying biotech’s tax years

beginning in 2009 and 2010 for expenses necessary for, and directly related to, the conduct of a qualifying therapeutic discovery project. Qualifying therapeutic discovery projects are ones that develop a product, process, or therapy to diagnose, treat, or prevent diseases and afflictions:

- (1) by conducting pre-clinical activities, clinical trials, clinical studies, or carrying out research protocols, for the purpose of securing approval of a product from the Food and Drug Administration;
- (2) by developing technology or products designed to diagnose diseases or conditions, including molecular and companion drugs and diagnostics; or
- (3) that otherwise further the delivery or administration of therapeutics.

The limited scope of qualifying projects reflects the objective of the Therapeutic Tax Credit to support biotechs engaged in certain types of research. Excluded from eligibility for any credit or grant funds are compensation for high-ranking executives, interest expenses, and certain overhead and indirect costs associated with operating a business.

Application for Funds

The \$1 billion available under the Therapeutic Tax Credit will be distributed based on applications received by the Treasury Department working in consultation with the Department of Health and Human Services. The Act directs the Treasury Department to release its application within 60 days of the date of enactment of March 23, 2010 and to approve or reject applications within 30 days of receipt. Although not yet released, language in the Act indicates that it is likely the application, in addition to focusing on whether the claimed costs can be substantiated, will focus on the following two criteria:

- (1) whether the costs are associated with medical benefits meaning that they
 - (A) result in new therapies that will treat areas of unmet medical need or prevent, detect, or treat chronic or acute diseases and conditions,
 - (B) reduce long-term health care costs in the United States, or
 - (C) significantly advance the goal of curing cancer within the next 30 years; or

This memorandum is intended only as a general discussion of these issues. It is not considered to be legal advice. We would be pleased to provide additional details or advice about specific situations. For additional information on this important topic, please feel free to call upon your Dewey & LeBoeuf relationship partner.

No part of this publication may be reproduced, in whole or in part, in any form, without our prior written consent.

Pursuant to U.S. Treasury Department Circular 230, any tax advice contained in this communication (including any attachments) was not intended or written to be used, and cannot be used, for the purpose of (i) avoiding tax-related penalties or (ii) promoting, marketing or recommending to another party any matter(s) addressed therein.

© 2010 Dewey & LeBoeuf LLP
All rights reserved.

For further information on Dewey & LeBoeuf, please visit www.dl.com

- (2) whether the costs are associated with creating or sustaining high paying, high quality jobs in the United States and advance US competitiveness in the areas of life, biological and medical sciences.

The Act indicates that meeting either of these criteria will advance a biotech's chances of receiving a Therapeutic Tax Credit. These criteria further underscore the Act's goals to use the Therapeutic Tax Credit to promote certain types of research. Given the strict cap on the amount of credit and grant funds available under the Therapeutic Tax Credit, qualifying biotechs likely should begin preparing their submissions to the Treasury Department in advance of the release of the application for funds.

For more information, please contact Stanton J. Lovenworth at +1 212 259 6420 or slovenworth@dl.com, Abraham N.M. Shashy, Jr. at + 1 202 346 7900 or ashashy@dl.com, or your Dewey & LeBoeuf relationship lawyer.