

New Federal Tax Credit and Grant Opportunities for Therapeutic Discovery Projects

Small companies engaged in or invested in therapeutic research and discovery projects designed to prevent, diagnose and treat acute and chronic diseases may be eligible for a tax credit (OR a cash-in-lieu of grant) of up to 50 percent of a qualified investment. Because the total amount available is capped for credits and grants at \$1B, qualified companies should pursue this opportunity as soon as possible.

Background

The Patient Protection and Affordable Care Act was signed into law by President Obama on March 23, 2010. A companion bill, The Health Care and Education Reconciliation Act of 2010, was signed into law on March 30. Together, the bills will significantly change the nation's health care system.

The bills added new Internal Revenue Code section 48D to enact a provision entitled "The Qualifying Therapeutic Discovery Project Credit," which allows a tax credit for new therapies to prevent, diagnose and treat acute and chronic diseases. The credit is equal to 50 percent of the qualified investment made by an eligible taxpayer in certain therapeutic discovery projects during tax years beginning in 2009 or 2010. An eligible taxpayer is a small business with fewer than 250 employees at the time of application submission. The credit will be subject to an overall cap of \$1B over the two-year period.

What Expenditures Qualify?

A qualified investment is the aggregate amount of the costs paid or incurred for expenses necessary for, and directly related to, the conduct of the qualified project. Certain costs are excluded, such as interest expenses, facility maintenance expenses (mortgage or rent, insurance, utility, and maintenance personnel), certain service costs, and payments to the CEO of the company or any employee the SEC has required to report his salary to shareholders based on the fact that he is among the four highest compensated officers.

A qualified therapeutic discovery project is one that is designed to treat or prevent diseases or conditions by conducting preclinical activities, clinical trials, and clinical studies, or carrying out research protocols. These activities must be conducted for the purpose of securing approval of a project under section 505(b) of the Federal Food, Drug, and Cosmetic Act of section 351(a) of the Public Health Service Act. Projects aimed to diagnose diseases or conditions or determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions also qualify, as do projects designed to develop a product, process or technology to further the delivery or administration of therapeutics.

Grant or Credit?

The applicant may elect to apply for a grant (in the form of a refundable tax credit) rather than a credit. The grant election is important because it allows companies that do not anticipate having a significant tax burden to receive benefits. The expectation is that many life science startup companies are in this position and will likely pursue the grant option. If a grant is received, a credit may not also be received in the current or subsequent taxable year.

If the applicant elects to apply for a credit, The Therapeutic Discovery Project Credit is structured to prevent taxpayers from taking a double benefit. If a benefit is allowed for an expenditure related to depreciable property, the basis of that property must be adjusted for the amount of credit received. Further, a benefit will not be allowed for any investment for which bonus depreciation is allowed. Additionally, the expenses included in the calculation of the benefit will not be allowed as a tax deduction to the extent of the amount of the benefit claimed. Finally, any expenses taken into account for this benefit may not be used to calculate the Orphan Drug Credit or the research tax credit.

Award Process

The Treasury Secretary will review each application and will award the credit based on several criteria. First, the Secretary will only consider projects that show a reasonable potential of:

- Creating new therapies that treat areas of unmet medical need or prevent, detect, or treat chronic or acute diseases or conditions;
- Reducing long-term health care costs in the U.S.; or
- Significantly advancing the goal of curing cancer within the next 30 years.

Additionally, the Secretary will consider which projects have the highest potential to create and sustain jobs in the U.S. or to advance U.S. competitiveness in the fields of life, biological and medical sciences

Current Timing and Considerations

The Secretary of Treasury along with the Secretary of Health and Human Services are required to establish a program to review and consider each project for certification and allocation of credits within 60 days after the enactment of the Patient Protection and Affordable Care Act (i.e., May 23). Once this application process is released, applications can be submitted. Further, once an application is received a review of the application must be completed within 30 days of the submission. Once the grant has been certified, the grant will be paid during the 30-day period beginning on the latter of the date of the grant application or the date the qualified investment is made.

At the current time it is not clear how the application process will apply the funding cap when differentiating between Qualifying Therapeutic Discovery Project applications for cost incurred in 2009 and proposed in 2010.

Next Steps and Comments

As substantial as the new benefit is, taxpayers must act quickly to apply as there is only a fixed amount of money available (\$1B for the next two tax years). It will be important for taxpayers to submit applications that: take the award criteria into account, properly document proposed costs and do not include unallowable expenses. Qualified costs should be accounted for and documented separately for each project so that each project can be evaluated separately on its merits and improve the taxpayer's chances of having the grant or credit awarded for one or more projects.

For more information, contact Joyce Waterbury at 919.301.6715.

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