IRS NOW ACCEPTING APPLICATIONS FOR $1 BILLION THERAPEUTIC DISCOVERY CREDIT PROGRAM

Life Sciences Alert
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The IRS is now accepting applications for the $1 billion pool of funds earmarked by the health care reform bill (the Patient Protection and Affordable Care Act of 2010) for small and mid-size biotechnology companies to provide needed funding to support critical research and development programs under the qualifying therapeutic discovery tax credit program. The application period began June 21 and ends July 21.

The IRS and Department of Health and Human Services (HHS) will review applications by September 30 and approve or deny them by October 29.

The qualifying therapeutic discovery tax credit is designed to further the goals of reducing health care costs, increasing employment, and enhancing the worldwide competitiveness of U.S. biomedical companies.

The credit will be awarded to successful applicants pro rata from a $1 billion pool. Only firms with fewer than 250 employees are eligible, and only expenses from 2009 and 2010 will qualify for reimbursement. The maximum benefit available to any firm is 50 percent of its qualified investment related to a "qualifying therapeutic discovery project" (QTDP), up to $5 million. Thus, for example, if a company has $1 million of qualified investments in 2009 related to a QTDP, it may be eligible to receive a $500,000 tax credit or nontaxable grant. The same firm may submit more than one application, but the $5 million limit is per firm rather than per project or per tax year. If desired, companies may elect to receive a grant in lieu of a credit, which should benefit start-up companies that have not yet become profitable.

Qualifying Projects

A QTDP is a project that is designed to develop a product, process, or therapy to diagnose, treat, or prevent diseases and afflictions by (a) conducting pre-clinical activities, clinical trials, clinical studies, and research protocols or (b) by developing technology or products designed to diagnose diseases and conditions, including molecular and companion drugs and diagnostics, or to further the delivery or administration of therapeutics.

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Business Tax

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Tax Credits

IRS Notice 2010-45 establishes the QTDP program and provides the procedures under which an eligible applicant may apply for certification. Certification will be granted only if all of the following requirements are met:

- HHS determines that the applicant's project is a QTDP;
- HHS determines that the applicant's project shows reasonable potential to (a) result in new therapies to treat areas of unmet medical needs 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 30 years; and
- IRS determines that the applicant's project is among those projects with the greatest potential to (a) create and sustain (directly or indirectly) high-quality, high-paying U.S. jobs and (b) advance U.S. competitiveness in the fields of life, biological, or medical sciences.

More detailed specifications are set forth in Notice 2010-45.

Application for Certification

IRS Form 8942 (Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program) has been created to be used by companies to apply for certification. Separate applications are required for each QTDP. A project information memorandum is also required, as well as a consent to disclose certain information to permit publication of information concerning program awards. The project information memorandum must describe scientific details of the project. It will be reviewed by HHS to determine whether the project meets the definition of a QTDP and shows a easonable potential to meet one or more of the required goals of the statute.

New York City Tax Credit

In addition to the federal tax credit, businesses working in biotechnology field in New York City may also be eligible for a tax credit that can be applied against the New York City General Corporation Tax and Unincorporated Business Tax. To be eligible, a company must:

- Be engaged in biotechnologies,
- Be an emerging technology company or a company whose ratio of research and development funds to net sales equals or exceeds the average ratio for all companies surveyed by the National Science Foundation,
- Have no more than 100 full time employees, 75 percent of whom are employed in New York City,
- Have a ratio of research and development funds to net sales that equals or exceeds six percent during the calendar year ending in the tax year for which the credit is claimed,
- Have annual product sales of $10 million or less, and
- Have gross revenues, including the gross revenues of its affiliates and related members, not exceeding $20 million or the calendar year immediately preceding the tax year or which the credit is claimed.

Applications must be submitted no later than January 15 ollowing the calendar year for which the credit is claimed. For example, if a credit is claimed for the year 2010, the application will be due on or before January 15, 2011.

For More Information

Two of the most critical aspects of the QTDP application and certification process are determining (a) whether a articular project may qualify as a QTDP and (b) what expenses may be considered qualified investments, hich will form the basis for calculating the amount of he requested credit or grant.

If you have questions regarding either of these areas or ny other procedural or substantive aspect of the QTDP program, please contact:

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About Hodgson Russ's Life Sciences Practice Group

The attorneys in our multidisciplinary Life Sciences Practice Group combine legal excellence with industry experience to assist established, growing, and start-up companies with the critical issues facing life science companies. Among other areas, we assist with regulatory compliance; corporate financing, including venture capital; cross-border and immigration issues; intellectual property; reimbursement for medical products, drugs, and health care services; mergers, acquisitions, and joint ventures; enforcement actions, including recalls, seizures, and FDA warning letters; and product liability defense.