PRYOR CASHMAN LLP

LEGAL UPDATE

May 2010 *By: Stephen M. Goodman*

HEALTHCARE REFORM – RESEARCH STIMULUS PROVISIONS

The Patient Protection and Affordable Care Act (PPACA) recently passed by Congress contains two sections that establish new economic subsidies for companies engaged in research for new methods of diagnosis and treatment of human disease, the Qualifying Therapeutic Discovery Project Credit and the Cures Acceleration Network grant program. Because companies in this field tend to have a constant and pressing need for additional funding, competition for these credits and grants is likely to be intense. To prepare clients and friends of the firm who may wish to pursue these opportunities, we are providing this brief summary of the two programs:

QUALIFYING THERAPEUTIC DISCOVERY PROJECT (QTDP) CREDIT

This is a new tax credit directed at companies with not more than 250 employees which have expended money on research projects which have a reasonable potential to:

- result in new therapies to treat areas of unmet medical need or to prevent, detect or treat chronic or acute diseases or conditions,
- reduce long-term health care costs in the United States, or
- advance significantly the goal of curing cancer within the 30-year period beginning on the date Treasury establishes regulations governing the program.

The law establishes a refundable tax credit of up to $1 billion for companies which have incurred expenses for projects which meet these criteria. Companies may seek reimbursement of up to 50% of qualified expenses incurred during 2009 or 2010. Because the tax credit is "refundable", if a company qualifies but does not have revenue, it can still receive the credit in the form of a grant.

By statute, Treasury must issue regulations governing the application process by May 21, 2010 and the regulations must provide for approval or denial of any application within 30 days after submission. Although there is concern that projects could be funded on a "first-come, first-served" basis, some guidance as to the likely form of the application process may be drawn from a review of other volume-capped tax credits, such as the Qualifying Advanced Energy Project (QAEP) Credit (designed to encourage investment in property which "re-equips, expands, or establishes a manufacturing facility" that produces renewable energy) and the New Markets Tax (NMT) Credit (designed to increase the amount of investment capital available for economic development in low-income communities, many of which are affected by brownfields). Each of these programs awards funding based on a variety of qualitative factors unrelated to the speed with which taxpayers submit applications.

For example, under the QAEP Credit process, applicants must submit requests to both the Internal Revenue Service (IRS) and the Department of Energy (DOE), and IRS approval depends in whole or part on a recommendation by the DOE, which ranks projects in descending order based on a variety of criteria. The project receiving the highest ranking is allocated the full amount of credits requested before any credit is allocated to a lower-ranked project and the DOE recommends and ranks projects only until all of the available credits have been allocated.[1]

For the NMT Credit, qualified investment groups apply to the U.S. Department of the Treasury's Community Development Financial Institutions Fund (CDFI) for an allocation of the credit. The application is reviewed and scored to identify those applicants most likely to have the greatest community development impact, using such criteria as the expected impact on jobs and economic growth in low-income communities where investments are to be made, how the application addresses the statutory priorities of investing in unrelated entities and whether the applicant has a track record of serving disadvantaged businesses or communities. Based on the scores, the applications are ranked in descending order of aggregate score. Tax credit allocations are then

[1] Interested readers can review the QAEP Credit regulations at http://www.irs.gov/irb/2009-37_IRB/ar06.html.)

awarded based upon the aggregate ranking, until all of the allocation authority is exhausted. [2]

The new law establishing the QTDP Credit includes similar types of qualitative criteria, such as whether projects are likely to "create and sustain (directly or indirectly) high-quality, high-paying jobs in the United States" and whether they "advance United States competitiveness in the fields of life, biological, and medical sciences". It seems quite possible that, in evaluating applications for the new credit, HHS may serve in a role similar to that which DOE filled for the QAEP Credit.

Since there is very likely going to be a flood of applications as soon as the regulations are published, companies which think they may qualify for the QTDP Credit may want to start assessing the relative strength of their research activities vis-à-vis the statutory selection criteria and documenting the amount of potential qualified expenditures they have made or project to make for taxable years beginning in 2009 and 2010.

CURES ACCELERATION NETWORK

The Cures Acceleration Network (CAN) is established within the Office of the Director of NIH to make funds available "to accelerate the development of high need cures, including through the development of medical products and behavioral therapies." A "high need cure" is a drug or device which, in the judgment of the Director of NIH ''(A) is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and (B) for which the incentives of the commercial market are unlikely to result in its adequate or timely development." CAN is to be overseen by a Board of 24 diverse members from several fields, including research, FDA, venture capital, and patient advocacy. In addition, CAN will work with the FDA to coordinate approval requirements with the goal of expediting the development and approval of products.

CAN grants are intended to be distinct from NIH grants targeting basic scientific research, focusing instead on commercialization of scientific discoveries. Senator Arlen Specter, who introduced this piece of the legislation, says he intended it to serve as "a bridge across the valley of death," referring to the funding gap that many development-stage companies experience between their initial funding rounds and their ability to attract institutional venture capital. To this end, the statute authorizes grants of up to $15 million per project per fiscal year, with authorization for a total of $500 million for fiscal 2010 "and such sums as may be necessary for subsequent fiscal years".

Unfortunately, the appropriation for funding CAN has yet to be made. Citing factors such as the health benefits for Americans, the potential for reducing overall healthcare costs, the international competitive advantages and the direct economic stimulus of supporting commercialization, more than 50 organizations, such as the Biotechnology Industry Organization, the Alliance for Aging Research and multiple non-profits dedicated to fighting particular diseases, have called on the congressional Labor-HHS appropriations' subcommittees to begin funding CAN at the $500 million level for fiscal 2011.

FOR MORE INFORMATION:

Pryor Cashman will continue to monitor developments relating to both of these programs. Please feel free to contact the following members of our life sciences practice group if you have questions or wish to discuss the tax credit or CAN grants:

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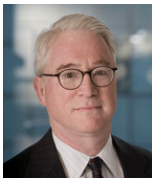
The foregoing is intended to summarize certain SEC interpretive guidance, and does not constitute legal advice. Please contact the Pryor Cashman attorney with whom you work with any questions you may have. If you would like to learn more about this topic or how Pryor Cashman LLP can serve your legal needs, please contact Stephen M. Goodman at (212) 326-0146.

[2] Information regarding the NMTC process can be found at http://www.cdfifund.gov/.

About the Author



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Stephen M. Goodman is co-head of the Mergers and Acquisitions Practice at Pryor Cashman LLP. He has extensive experience representing technology-based companies in public offerings; private placements; limited liability company, partnership and joint venture agreements; and complex arrangements for the acquisition, sale, development and commercialization of patents, copyrights and trademarks, in particular for drug compounds and formulations, software and other technology. He has written on topics ranging from export controls relating to biotechnology research to raising seed capital for entrepreneurial companies and has lectured on various aspects of pharmaceutical/biotech collaboration agreements.

Mr. Goodman has been responsible for negotiating and documenting the following representative transactions:

- On behalf of a multi-national professional publishing company, acquisitions of the stock or assets of more than thirty targets, in transactions ranging in value up to $1 billion, including acquisitions involving counsel in multiple jurisdictions, auction transactions and several involving friendly tender offers for the stock of publicly-traded companies
- On behalf of a development stage biotechnology company, a private financing of $8.4 million to advance a client's two lead drug programs and a "double-dummy" reverse merger a second biotechnology company, creating a single company with multiple drug programs which has been purchased by a public pharmaceutical company for more than $100 million
- On behalf of an early pioneer in internet music delivery, two private preferred equity financings, the second led by a major hedge fund
- On behalf of a company developing compounds believed to have wound-healing and other regenerative properties, acquisition of a portfolio of patents for certain compounds together with clinical trial data filed with regulatory agencies related to these compounds
- On behalf of a public company in the field of monoclonal antibody research, an initial and a secondary public offering
- On behalf of a company in the field of RNAi therapeutics, acquisition of an entire division of a company engaged in RNAi research for influenza
- On behalf of a warehousing logistics software company, a set of master documents for licensing and maintaining the company's software
- On behalf of a company offering menu-driven iPod applications for foreign language translation, a license to utilize voice recognition software to enhance the utility of its programs
- Multiple licenses for the use of university or research institute technology, including a license for exclusive worldwide rights to patents and patent applications covering a naturally occurring peptide and its derivatives in the fields of obesity, appetite suppression, reducing food intake, inducing weight loss and inducing satiety and another for a compound with potential for treating various conditions of the central nervous system, including addiction
- A Feasibility Study, Option and License Agreement for the development of a client's lead drug candidate for moderate-to-severe pain
  Agreements with major textbook publishers for conversion of print or electronic textbooks into interactive formats utilizing client's proprietary software and coding

Mr. Goodman is a 1977 graduate of New York University School of Law, where he was Order of the Coif and Articles Editor of the Annual Survey of American Law.