Arnall Golden Gregory LLP

Client Alert

Contact Attorney Regarding This Matter:

William H. Kitchens
404.873.8644 - direct
404.873.8645 - fax
william.kitchens@agg.com

Healthcare Reform Bill Presents Significant Opportunity for Life Science Companies Engaged in Innovative Research

Buried in the recently enacted Patient Protection and Affordable Care Act of 2010 is a significant benefit for small- and mid-sized biotech, pharmaceutical and medical device companies. The legislation provides a 50 percent tax credit for investments in qualified therapeutic discoveries for tax years 2009 and 2010, or a grant for the same amount tax free. The latter feature will be of particular benefit to biotech start-up companies as tax credits are worthless to start-ups that are not profitable and do not pay income taxes. The cash grant option will allow more companies to receive an immediate return.

The tax credit/grant program covers research and development costs in tax years beginning in 2009 and 2010 for all qualified "therapeutic discovery projects." To qualify, a company must not have more than 250 employees in all businesses of the taxpayer (e.g., a small biotech project at a large pharmaceutical company will not qualify). These tax credits/grants are available to pass-through entities, such as partnerships or S corporations, as well as traditional C corporations.

A qualifying therapeutic discovery project is a project designed to do one of two things:

1. treat or prevent diseases or conditions by conducting preclinical studies or clinical trials or carrying out research protocols for the purpose of securing approval from the Food and Drug Administration; or
2. diagnose diseases or conditions or to determine molecular factors relating to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions.

The new legislation provides that "qualified investments" include "the aggregate amount of costs paid or incurred in the taxable year for expenses necessary for and directly related to the conduct of a qualifying therapeutic discovery project." Excluded from the definition of "qualified expenses" are the salaries of certain employees identified in Section 162(m)(3) of the Tax Code (e.g., highly compensated chief executive officers). Other expenses that will not qualify include interest costs, facility maintenance (e.g., mortgage or rent, insurance, utilities) and certain indirect costs (e.g., general and administrative expenses).

Arnall Golden Gregory LLP
Attorneys at Law
171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031
404.873.8500
www.agg.com

So what's the catch? True to the adage that "there's no such thing as a free lunch," the new benefit has a substantial limitation unlike most programs establishing tax credits for qualified taxpayers. As presently structured, the tax credit/grant program will not be available in unlimited amounts to all eligible taxpayers. Instead, the new law creates a set pot of money—$ 1 billion for the two tax years. Moreover, companies will have to apply and compete for access to the tax credits/grants, and the money is expected to go quickly.

Consequently, applicants for the program should move rapidly to prepare, as the government is expected to issue regulations implementing the program around May 21st. It will be imperative that applicants demonstrate they have met the key requirements for accuracy, documentation and justification of the expenses for a "qualifying therapeutic project." The law provides that the Department of Treasury will assess applicants' projects in consultation with the Department of Health and Human Services with emphasis on a number of criteria. Although a better picture of what should be included in an application will be forthcoming when the implementing regulations are completed in a few weeks, the new law suggests that successful applicants will demonstrate that their qualifying projects combine both a medical benefit and a jobs and economic advantage.

The medical benefit criteria are grounded on a showing that the project will:

- result in new therapies that will treat unmet medical needs or prevent, detect or treat chronic or acute diseases or conditions;
- reduce long-term healthcare costs in the U.S.; or
- significantly advance the goal of curing cancer within the next 30 years.

The jobs and economic criteria can be met by demonstrating that the therapeutic project will:

- create and sustain high-quality, high-paying jobs in the U.S.; or
- advance U.S. competitiveness in the fields of life sciences, biological sciences and medical science.

There is no bar against research expenses outside the U.S., but the strong sentiment of Congress in including this program as a part of healthcare reform was that the focus of the tax credit/grant should foster domestic jobs.

As noted, Congress directed that the program be in place by May 21st, and applications are to be approved 30 days after they are submitted. This may be ambitious, as the Treasury is still working on drafting the application process; but Congress clearly intends for the Treasury to move expeditiously.

The program has generated significant interest, and undoubtedly the $ 1 billion earmarked to fund the program will not be sufficient to cover all qualifying projects. Left unanswered at this time is whether applications will be reviewed on a "first to file" basis, or whether the implementing ground rules for applications will instead establish a designated time period for all applications to be submitted, which arguably will facilitate more qualitative reviews by the government regarding the projects that should be given priority for the tax credit/grant. Likewise, the law itself establishes no upper limit on the total expenses per project that will

qualify for the tax credit/grant. Given the tremendous costs associated with developing new breakthrough therapies, this leaves open the possibility that the $1 billion cap could be significantly committed by the research expenses of only a relatively small number of qualified projects.

The take-away for the moment is companies should not delay in assessing whether their research and development activities qualify for the tax credit/grant. Likewise, now is the time to determine whether you have the required documentation to tie expenditures to a specific therapeutic project and whether you need to hire experts to assist with the application process. With the race to qualify fast approaching, companies with qualifying projects should take steps to ensure they will be able to file their applications as soon as possible after the final regulations are published.