Qualifying Therapeutic Discovery Project Tax Credit Program Will Give Economic Boost to Eligible Biotech Firms

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Introduction

The Patient Protection and Affordable Care Act (PPACA) creates a significant economic opportunity for eligible biotechnology ("biotech") companies – in the form of a tax credit or cash grant – if they invest in “qualifying therapeutic discovery projects” ("QTDPs"). This QTDP program, viewed as an extraordinary gift from Congress, provides a 50 percent tax credit for qualified biotech investments for tax years 2009 and 2010, or a tax-free cash grant equal to the same amount.3

According to IRS Commissioner Doug Shulman, the QTDP tax credit program is designed to promote medical research that could improve health and save lives.4 He is encouraging companies participating in groundbreaking biotechnology to apply for the QTDP tax credit or grant.5 There seems to be no down side to applying for the QTDP program, but eligible businesses and their therapeutic projects must pass muster and satisfy specific criteria mandated by the Department of Health and Human Services (HHS) and the Internal Revenue Service (IRS). Eligible biotech firms interested in applying must act quickly because there is a limited window of opportunity to apply. The deadline to submit applications is July 21, 2010.

Overview of the Qualifying Therapeutic Discovery Project (QTDP) Program

Section 9023 of the PPACA outlines the details of the QTDP tax credit and grant program by amending section 48D of the Internal Revenue Code of 1986 (IRC).6 Under the PPACA, a QTDP is defined as a project designed to:

(1) treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out


5 Id.

6 PPACA, supra note 1, at § 48D.
research protocols, for the purpose of securing product approval by the U.S. Food and Drug Administration (FDA);

(2) diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions; or

(3) develop a product, process, or technology to further the delivery or administration of therapeutics.7

The PPACA describes a “qualified investment” as the aggregate amount of costs paid and expenses incurred in a taxable year that are necessary for, and directly related to, the conduct of the QTDP.8 A qualified investment does not include interest expenses, facility maintenance expenses, utility service costs, compensation to the CEO or other highly compensated officers, or other expenses as may be determined by the IRS.9 The QTDP provisions apply to qualified investment expenditures paid or incurred after December 31, 2008, in taxable years 2009 or 2010.10

The total amount of credits and grants that may be allocated nationwide under the QTDP program is limited to $1 billion for the two-year period, beginning with 2009.11 The credit or grant is only available to taxpayers who are engaged in a business with no more than 250 employees, including full and part-time employees.12 Those entities and individuals eligible to apply for either the tax credit or the grant include C corporations, S corporations, limited liability companies, partnerships and individuals who file Schedule C forms.13 However, grants cannot be made to federal, state or local governments, any organization described in IRC section 501(c) that is exempt from tax under IRC section 501(a), any entity referred to in IRC section 54(j), or any partnership or pass-through entity that has any of these types of entities as a partner or holder of an interest.14

The QTDP tax credit covers up to 50 percent of a taxpayer’s qualified investment in a QTDP,15 or in lieu of receiving the credit against tax liability, a taxpayer may receive a cash grant equal to 50 percent of its qualified investment.16 For instance, if a biotech business makes a qualified investment of $1 million, it could potentially receive a $500,000 tax credit, or a $500,000 tax-free cash grant.

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7 Id. at § 48D(c)(1).
8 Id. at § 48D(b)(1).
9 Id. at § 48D(b)(3).
10 Id. at § 48D(b)(5), (f).
11 Id. at § 48D(d)(1)(B).
13 Notice 2010-45, supra note 10, at § 4.03; Qualifying Therapeutic Discovery Projects Basic Information, supra note 10.
14 Notice 2010-45, supra note 10, at § 8.03(7).
15 PPACA, supra note 1, at § 48D(a); Qualifying Therapeutic Discovery Project Program, supra note 2.
16 PPACA, supra note 1, at § 48D(e).
To claim the credit, a taxpayer must first apply to the IRS for certification of its qualified investments.\(^\text{17}\) The IRS will not certify more than $10 million as a qualified investment for any single taxpayer. Thus, the most any taxpayer can be allotted is $5 million in credits or grants for 2009 and 2010, regardless of the number of projects the particular taxpayer sponsors.\(^\text{18}\)

The PPACA requires the U.S. Department of the Treasury to consult with the HHS to establish specific procedures for awarding certification to qualifying QTDP project sponsors.\(^\text{19}\) As consistent with this mandate, the Department of the Treasury, through the IRS, issued Notice 2010-45, which outlines the procedures an eligible taxpayer must follow to obtain the necessary certification that will allow it to claim the credit or grant for its qualified investments in a QTDP.\(^\text{20}\)

**Procedures for Applying for the QTDP Economic Boost**

Taxpayers must follow specific procedures to apply for certification.\(^\text{21}\) The IRS will certify an eligible taxpayer’s qualified investment under the QTDP program only if certain criteria are satisfied.\(^\text{22}\) First, HHS must evaluate each project and determine if:

1. the taxpayer’s project is a qualifying therapeutic discovery project; and
2. the taxpayer’s project shows reasonable potential
   a. to result in new therapies
      i. to treat areas of unmet medical need, or
      ii. to prevent, detect, or treat chronic or acute diseases and conditions,
   b. to reduce long-term health care costs in the U.S., or
   c. to significantly advance the goal of curing cancer within the 30-year period beginning on May 21, 2010.\(^\text{23}\)

Once HHS approves the project under the above criteria, the IRS will certify a taxpayer’s qualified investment only after determining the taxpayer’s project has great potential to:

1. create and sustain (directly or indirectly) high quality, high-paying jobs in the U.S, and

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\(^{17}\) *Id.* at § 48D(a)(2); *Qualifying Therapeutic Discovery Project Program, supra* note 2.

\(^{18}\) *Notice 2010-45, supra* note 10, at § 5.02(7).

\(^{19}\) *PPACA, supra* note 1, at § 48D(d)(1)(A); *see Notice 2010-45, supra* note 10.

\(^{20}\) *Notice 2010-45, supra* note 10.

\(^{21}\) *See generally id.* and at § 6.01-.02

\(^{22}\) *Id.* at § 5.01.

\(^{23}\) *Id.*
Taxpayers must file separate applications for each QTDP project for which they are seeking certification. The application packet includes two documents: (1) the new IRS Form 8942, titled “Application for Certification of Qualified Investment Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Program,” and (2) the Project Information Memorandum, as described in Appendix A to Notice 2010-45.

The IRS opened the application process for just a limited time frame of approximately 30 days – from June 18, 2010 through July 21, 2010. Completed applications must be postmarked no later than July 21, 2010.

Once applications are received, HHS and the IRS will commence their separate review processes. The IRS will issue certifications of qualified investments by October 29, 2010, and at that time, will publicly disclose the identity of the applicant, the type and location of the project, and the allocation amount of the credit or grant. One or more allocation rounds may be conducted if any portion of the available $1 billion remains unallocated after the primary allocation round.

Conclusion

Biotech companies should heed IRS Commissioner Doug Shulman’s invitation and take advantage of this economic opportunity. A QTDP grant could be a significant financial boost for early-stage, pre-revenue companies engaged in therapeutic discovery and development projects, but are not yet generating revenues or sufficient profits to incur tax payments. Moreover, a QTDP tax credit could be a significant tax benefit for those companies with tax liability. The bottom line is that, with this new QTDP program, biotech businesses could potentially reap economic benefits.

Biotechnology companies that are interested in the QTDP program should act quickly to seize this limited window of economic opportunity. Time is of the essence for those companies that want to apply. Those still interested, but who miss the deadline, should nevertheless continue to monitor the IRS and HHS websites to verify whether any portion of the available $1 billion remains unallocated after this primary allocation round. Companies that missed the deadline may get a second chance if the IRS and HHS conduct one or more additional allocation rounds.
Health Law Perspectives (July 2010)
Health Law & Policy Institute
University of Houston Law Center
http://www.law.uh.edu/healthlaw/perspectives/homepage.asp

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