
Legal and Regulatory Update

Recapping Section 48D (qualifying therapeutic discovery project credit) – Will it be extended?

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INTRODUCTION

As part of the Obama Administration's 2010 health-care reform, a one-time program (the 'Program') was put in place that permitted certain biotechnology companies to receive a capital infusion from the US government. The total aggregate benefit paid out under the Program was US\$1 000 000 000, and the Program's participants (which number about 3000) received their respective portions of this benefit either in the form of tax credits or (alternatively and at the participant's discretion) cash grants. The Program was somewhat remarkable because of the participant's ability to elect to receive a cash grant. In fact, an overwhelming number of participants elected the cash grant option.¹ The Program effectively concluded in October 2010, when the full amount of the \$1 000 000 000 in benefits was doled out to the eligible participants. Although the Program was well received by the biotechnology industry, given the current condition of the economic and political environments and rampant criticism of the fisc's deficit spending, there is significant uncertainty regarding the likelihood that the Program will be extended to future years.

THE SPECIFICS

As part of the Patient Protection and Affordable Care Act of 2010 (or 'Act'),² new Section

48D was added to the Internal Revenue Code (or 'IRC'). Section 48D effectively governed the Program's administration, procedures, participant eligibility, selection criteria and the manner in which the tax credits (or grants) were determined and paid out. Under Section 48D, an eligible participant could have received tax credits (or cash grants) equal to 50 per cent of the total 'qualified investments' paid or incurred in the participant's 2009 and/or 2010 tax years with respect to a 'qualifying therapeutic discovery project' (or 'QTDP').³ The total amount awarded to any one participant (or single taxpayer), however, was capped at \$5 000 000 for all projects associated with such participant, with a total cap on the aggregate amount of benefits paid under the Program equal to \$1 000 000 000.

The Program was intended to provide assistance to 'small' biotechnology companies. Accordingly, one of the Program's eligibility requirements was that a participant's total number of employees could not have exceeded more than 250 employees in all of its businesses as of the time it submitted its application to participate in the Program.⁴ In making this determination, both full-time and part-time employees were counted towards this 250 number, and the employees of an affiliated entity were included if the participant

and such affiliate were treated as a single employer under certain IRC provisions.⁵

Ultimately, the total benefits that a participant was eligible to receive depended upon the participant's 'qualified investments' paid or incurred with respect to a QTDP. For purposes of the Program, 'qualified investments' included costs paid or incurred for expenses 'necessary for and directly related to' the conduct of a QTDP.⁶ Although the language defining the term qualified investments could be interpreted to have broad implications, certain expenses were specifically excluded from the definition, such as wages paid to certain highly compensated employees (for example, a chief executive officer), interest expense, facility maintenance expenses (for example, mortgage, rent, utilities, insurance premiums and so on), indirect service costs (for example, administrative costs) and expenditures with respect to which bonus depreciation was allowed.⁷ Under Section 48D, a QTDP included a project designed to:

1. treat or prevent diseases or conditions by conducting or carrying out preclinical activities, clinical trials, clinical studies or research protocols for securing approval of a product under Section 505(b) of the Federal Food, Drug and Cosmetic Act or Section 351(a) of the Public Health Service Act;
2. diagnose diseases or conditions or determine molecular factors of 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.

The Program was administered by the US Department of Treasury in consultation with the US Department of Health and Human Services. Both the Treasury Department (or Internal Revenue Service) (collectively the 'IRS') and the Health and Human Services ('HHS') had very specific roles to play in administering the Program. Under the

Program, each project was examined to determine whether certain scientific and economic criteria were (or were likely to be) met. More specifically, each application was initially reviewed by HHS⁸ to determine if it met the definition of a QTDP and whether the project showed reasonable potential to:

1. result in new therapies that would (a) treat areas of unmet medical need or prevent or (b) detect or treat chronic or acute diseases or conditions;
2. reduce long-term health care costs in the United States; or
3. significantly advance the goal of curing cancer within 30 years.⁹

Each application was reviewed and graded by HHS pursuant to a points system. Applications receiving a failing grade upon initial HHS review were subject to further reviews (up to three in total). Those applications that failed review twice were not recommended for funding. Once approved by the HHS, the IRS reviewed each such approved application to determine which projects had the greatest potential to create and sustain (directly or indirectly) high quality, high-paying jobs in the United States and advance US competitiveness in fields of life, biological and medical sciences.¹⁰ The IRS then certified the qualified investments associated with each approved project.

Although a participant was eligible to receive a maximum award of \$5 000 000 (assuming \$10 000 000 worth of qualified investments were certified with respect to such participant's projects), the maximum amount awarded in respect of any one project did not exceed \$244 479.25.¹¹ The credit or grants were not awarded on a first-come first-served basis, and the maximum amount was a product of the method for determining the total amount of qualified investments allocable to any one project. For purposes of determining the maximum amount, the IRS made a preliminary allocation of benefits among the eligible applications by effectively

certifying an equal amount of qualified investments for each project.¹² If, as a result of this preliminary allocation, the IRS certified an amount of qualified investments for a particular project that exceeded the actual amount of qualified investments with respect to such project, the excess portion was then reallocated equally among those projects that did not receive an amount equal to or in excess of the qualified investments associated with such projects.¹² This allocation process was then repeated until (effectively) \$2 000 000 000 worth of qualified investments were certified by the IRS. As noted above, because participants were eligible to receive a credit or grant equal to 50 per cent of their respective qualified investments, certifying \$2 000 000 000 in qualified investments meant that \$1 000 000 000 was payable in credits and grants under the Program.

Participants were eligible to receive their respective portions of the \$1 000 000 000 of benefits in the form of tax credits or (alternatively) cash grants. The credits were non-refundable tax credits and the grants were generally non-taxable. By electing to receive a grant, participants generally did not have to concern themselves with whether or not they would have enough tax liability to fully utilize any tax credits. However, there were a number of complex tax consequences relating to the receipt and use of credits and grants. Various parameters were put in place to ensure that a taxpayer did not get a double benefit from participating in the Program. For example, participants were required to make adjustments to the adjusted tax basis of certain assets that were purchased with amounts attributable to qualified investments.¹³ Essentially, under such adjustments, a participant was required to appropriately reduce its tax basis in an asset purchased with an expense for which an award was given to ensure that the participant could not receive a depreciation or amortization deduction attributable to a capital investment that was effectively funded through a tax credit or grant issued under the Program. As a further

example, expenses for which a credit was given generally could not be taken into account for purposes of determining credits allowable under IRC Sections 41 (general research credit) or 45C (orphan drug credit).¹⁴ In addition, credits and grants issued under the Program are subject to certain recapture provisions.¹⁵

POSSIBILITY OF EXTENSION

Although various biotechnology organizations have noted the positive impact that the Program has had on the industry¹⁶ and intend to push to have the Program extended into future tax years,¹⁷ as of the date this article was drafted there have been no formal steps taken (or Congressional hearings regarding whether) to expand the Program into future years. In addition, the current political and economic environments call into question whether Congressional leaders will be willing to expand the Program in the foreseeable future, especially since major tax legislation was signed into law at the end of 2010, which (among other things) expanded several other tax breaks and credits. That said, however, the Program created a good footprint on which any future programs or expansions of the existing Program could be based.

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REFERENCES AND NOTES

1. On the basis of data release by the IRS, more than 98 per cent of the participants received grants in lieu of tax credits. See IRS website, Qualifying therapeutic discovery project credits and grants, <http://www.irs.gov/businesses/small/article/0,,id=228690,00.html>.
2. P.L. 111-148 (23 March 2010).
3. Under Section 9023(f) of the Act, the expenses must have been paid or incurred after 31 December

- 2008 and during tax years beginning after such date, and IRC Section 48D(b)(5) further provides that a qualified investment is one that is paid or incurred in a taxable year beginning in 2009 or 2010.
4. I.R.C. § 48D(c)(2).
 5. See Section 4.03 of IRS Notice 2010–45, 2010–23 I.R.B. 734 (21 May 2010) and I.R.C. § 48D(c)(2)(B).
 6. See I.R.C. § 48D(b)(1) and Section 4.01(1) of IRS Notice 2010–45.
 7. I.R.C. § 48D(b)(3). IRC Section 48D(e)(2)(A) provides that a credit (and presumably a grant) will not be allowed for any investment for which bonus depreciation was allowed.
 8. The HHS reviewers were selected or determined by the National Institutes of Health.
 9. I.R.C. § 48D(d)(3)(A).
 10. I.R.C. § 48D(d)(3)(B) (setting forth the IRS's review criteria).
 11. A breakdown of grants and credits is located on the IRS website and can be found under the following link <http://www.irs.gov/businesses/small/article/0,,id=228690,00.html>.
 12. See Section 5.02(5) and (7) of IRS Notice 2010–45.
 13. I.R.C. § 48D(e)(1). See also I.R.C. § 48D(f)(2) (requiring certain adjustments to taxable income and general business credit amounts under Section 38).
 14. I.R.C. § 48D(e)(2)(C). However, in certain instances, such expenditures still included for purposes of determining the 'base period research expenditures' under IRC Section 41.
 15. See, for example, I.R.C. §§ 50, 48D(f)(2).
 16. See, for example, Posting of Admin. All to the good: Biotech companies expect boost from therapeutic discovery grants, tax credits. BIOTechNOW, <http://biotech-now.org/section/business-biotech/2010/10/29/all-good-biotech-companies-expect-boost-from-therapeutic-discovery-tax-credits> (29 October 2010, in this website newsletter, Biotechnology Industry Organization (BIO) discusses a survey it conducted regarding the potential impact that the Program will have on the industry).
 17. See, for example, Greenwood, J. Therapeutic discovery project saves research that can save lives. BIOTechNOW, <http://biotech-now.org/section/jim039s-corner/2010/11/03/therapeutic-discovery-project-saves-research-that-can-save-lives>, (3 November 2011, in this website article, BIO notes that it will advocate before the Congress and the Administration to extend and expand the Program).

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