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CLIENT ALERT

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IRS Issues Form 8942 and Opens Application Period for the Qualifying Therapeutic Discovery Project Program

On June 18, 2010, the Internal Revenue Service ("IRS") released Form 8942, Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program, and officially opened the application period for submitting applications under the qualifying therapeutic discovery project program under Section 48D of the Internal Revenue Code. Read the IRS announcement. View Form 8942 and the instructions for Form 8942. Read our prior client alert relating to this program, IRS Issues Guidance on Qualifying Therapeutic Discovery Project Program.

Form 8942 Highlights

Form 8942 is two pages in length and sets forth a series of questions relating to eligibility for the Section 48D tax credit or the grant in lieu of the tax credit. Some of the questions are in a simple "yes" or "no" format. For example, question 23 on the form asks, "Will the project advance United States competitiveness in the fields of life, biological, and medical sciences?" The applicant must check "yes" or "no."

Question 26 addresses whether the project will produce a new or significantly improved technology, or a new application of or significant improvement to existing technology, as compared to commercial technologies currently in service. Question 27 addresses whether the project is expected to lead to the construction or use of a contract production facility in the United States in the next five years. In contrast to question 23, the instructions indicate that the applicant can attach a statement, not to exceed 250 words, supporting question 26 and a statement, not to exceed 250 words, supporting question 27.

The form also covers the requirements set forth in the statute and in Notice 2010-45 relating to jobs and whether the project has been active, terminated, or suspended. With respect to jobs, the form asks whether the project will create and sustain (directly or indirectly) high-quality, high-paying jobs in the United States. The form then asks for the number of full-time and part-time employees in the United States whose work is directly billed to the project and the average salaries of the employees in each category, to be set forth in a chart. The form also asks for the number of contractors in the United States paid for work on the project, the average monthly hours of those

contractors, and the average monthly compensation of those contractors.

Part III of Form 8942 relates to qualified investment (upon which the credit or grant is based) and provides specific categories for reporting (1) qualified investment derived from employee wages, (2) qualified investment derived from supplies and lab costs, (3) qualified investment derived from depreciable property, (4) qualified investment derived from third-party contractors, and (5) qualified investment derived from other costs, each broken down by tax year.

Instructions to Form 8942 Highlights

The instructions to Form 8942 largely reiterate the requirements in Section 48D and Notice 2010-45. However, the instructions provide important additional guidance. Some of the highlights:

1. The instructions caution that "[e]ach project will be evaluated by itself without reference to other projects. Therefore, dividing a project into multiple projects may result in the projects not meeting the selection criteria under section 48D(d)(3)."

2. The instructions state that applications must be postmarked by July 21, 2010.

3. The instructions indicate that an election for a grant in lieu of a credit for any project will be effective only if an applicant makes the same election on all of the applicant's applications for that tax year (i.e., the "consistency requirement").

4. The instructions emphasize that if the applicant is filing applications for multiple projects, qualified investment included for any project on any one Form 8942 cannot include amounts included in qualified investment for any other project. Rather, qualified investments related to multiple projects must be allocated between the projects, using a reasonable method.

5. The instructions state that qualified investment derived from third-party contractors only includes amounts paid or incurred on behalf of the applicant *pursuant to an agreement that is entered into prior to the performance of the research services relating to the project and the agreement required that the research services be performed on behalf of the applicant*.

HHS Determination Process Qs & As

The IRS has posted ten questions and answers relating to the review and determination process by the Department of Health and Human Services ("HHS"). While many of the questions reiterate the information in Notice 2010-45, a number of the questions provide significant additional guidance.

For example, question 2 provides additional guidance on the meaning of the term "project":

> **Q2. Will dividing a qualifying therapeutic discovery project into multiple projects increase an applicant's chances of receiving the maximum credit or grant in lieu of credit?**
>
> **A.** Each project will be evaluated by itself without reference to other projects. Therefore, dividing a project into multiple projects may result in the projects not meeting the selection criteria under § 48D(d)(3). Moreover, if a research endeavor involves developing a product, such product should not be represented as multiple projects for which multiple applications are submitted. For example, an applicant should not submit derivative or multiple applications that describe:
>
> → the same therapeutic or diagnostic designed to treat or prevent different diseases or conditions;
>
> → the same molecular diagnostic to guide therapeutic decisions related to diseases or conditions; or
>
> → the same product, process, or technology to further the delivery or administration of related or similar therapeutics.

Question 3 addresses whether the credit or grant is available for devices that deliver/administer drugs:

> **Q3. Is a credit or grant in lieu of credit only available for devices that deliver/administer drugs? If so, are there any plans to implement a credit for companies developing medical devices that do not deliver/administer "therapeutics"?**
>
> **A.** A medical device designed to diagnose diseases or conditions could qualify as a qualifying

therapeutic discovery project (see question 2 in the Project Information Memorandum). In addition, a device designed to determine molecular factors related to diseases or conditions (a molecular diagnostic device) to guide therapeutic decisions could qualify (see question 3 in the Project Information Memorandum).

Question 4 in the Project Information Memorandum focuses on the requirement of § 48D(c)(1)(C). To qualify under question 4, a product, process, or technology must further the delivery or administration of therapeutics. For the purposes of § 48D(c)(1)(C), the term "therapeutics" means drugs or medical devices, as those terms are defined in Section 201(g) and (h) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 321(g) and (h). Biologics that are licensed under the Public Health Service Act (PHSA) will generally be either drugs or medical devices. Thus, a drug-eluting stent or infusion pump would be an example of a product that furthers the delivery or administration of a drug and would meet the requirements of this provision. However, a medical device, or other product, process, or technology that does not further the delivery or administration of a drug or medical device would not meet the requirements of this provision because such products do not deliver or administer a therapeutic within the meaning of § 48D(c)(1)(C). The term "therapeutic" is narrower than the term "therapy," which appears elsewhere in § 48D. Therefore, products, processes, or technologies that deliver other therapies which are not therapeutics, such as speech, physical, and cognitive therapies, would for the same reasons be excluded.

A non-diagnostic medical device may be a "qualifying therapeutic discovery project" if such project is designed to "further the delivery or administration of therapeutics." An applicant seeking certification for a non-diagnostic medical device will need to explain how the product furthers the delivery or administration of a drug or device.

Any credit or grant for products not currently included in § 48D would require that Congress pass new legislation.

Question 5 addresses therapeutics that are not drugs, such as stereoscopic and radioscopic therapies, and whether such therapeutics qualify for the credit or grant:

Q5. In the Appendix A examples provided in the discussion of Project Information Memorandum, both medical devices administer drugs. However, there are other therapeutics that are not drugs, such as stereoscopic and radioscopic therapies. Are devices that administer radioscopic and/or stereoscopic therapies qualifying medical devices?

A. A non-diagnostic medical device may be a "qualifying therapeutic discovery project" if such project is designed to "further the delivery or administration of therapeutics." For the purposes of § 48D(c)(1)(C), the term "therapeutics" means drugs or medical devices, as those terms are defined in Section 201(g) and (h) of the FFDCA, 21 U.S.C. 321(g) and (h). Biologics that are licensed under the PHSA will generally be either drugs or medical devices. However, a medical device, or other product, process, or technology that does not further the delivery or administration of a drug or medical device would not meet the requirements of this provision because such products do not deliver or administer a therapeutic within the meaning of § 48D(c)(1)(C). The term "therapeutic" is narrower than the term "therapy," which appears elsewhere in section 48D. Therefore, products, processes, or technologies that deliver other therapies which are not therapeutics, such as speech, physical, and cognitive therapies, would for the same reasons be excluded.

Consistent with this guidance, non-diagnostic devices that are used to deliver "therapy," but not "therapeutics," would not meet the statutory definition of a qualifying therapeutic discovery project. An applicant seeking certification for a non-diagnostic medical device will need to explain how the product furthers the delivery or administration of a drug or device.

Question 7 addresses whether a project that has multiple purposes, one of which satisfies the threshold criteria for the credit or grant, qualifies for the credit or grant. The answer to this question states that "[w]hile the statutory purpose (i.e., the purpose identified in the response to questions 1-4 [of the Project Information Memorandum]) need not be the sole potential use of the project, it must be the primary purpose, i.e., the purpose for which the project was designed."

Additional questions and answers address certain of the requirements applicable to the Project Information Memorandum and the application review process. The questions and answers confirm that review by HHS will be accomplished by reviewers coordinated by the National Institutes of Health ("NIH"). In addition, the questions and answers confirm that there is no competitive advantage for applicants to file their applications earlier than the July 21 deadline.

IRS Qs & As

The IRS issued separate questions and answers (13 in total), addressing certain questions raised with respect to qualified investment and the IRS review of the applications. Highlights include the following:

1. The IRS states that legal and/or accounting fees and expenses related to the protection of intellectual property rights generally are not eligible for the credit or grant.

2. The IRS states that licensing fees paid to NIH and other agencies or universities generally are eligible for the credit or grant, provided such fees are directly related to the qualifying therapeutic discovery project.

3. The IRS restates the guidance relating to employee remuneration covered by section 162(m) of the Code and adds that an applicant may not include any portion of the remuneration of the principal executive officer, or an individual acting in such capacity, or of its three most highly compensated officers as qualified investment even where those individuals are engaged in work directly related to the conduct of a qualifying therapeutic discovery project.

4. Question 11 addresses a project that benefits a section 501(c)(3) organization:

   Q11. Can a for-profit biotechnology company apply for a grant for a project that could have benefits for a §501(c)(3) organization?

   A. An applicant that is legally organized as a partnership or other type of pass-thru entity may not apply for a grant if a § 501(c) organization exempt from tax under § 501(a) is a direct or indirect partner or other holder of an equity or profit interest. The fact that a § 501(c) organization may benefit from a project conducted by an applicant does not preclude the applicant from applying for a grant, as long as either (a) the applicant is not legally organized as a partnership or other pass-thru entity, or (b) the organization is not a partner or other holder of an equity or profit interest in the entity.

Our tax lawyers at Hunton & Williams specialize in programs similar to the new program for qualifying therapeutic discovery projects. Our tax lawyers routinely advise clients in all areas involving tax credits, including investment tax credits similar to this new credit, and have advised and successfully represented a number of clients in their applications for grants in lieu of tax credits under the 2009 stimulus act. We also have advised and represented clients in tax credit allocation programs preceding this new credit. Our tax lawyers will coordinate and work with lawyers in our Food and Drug practice group and Intellectual Property group, as appropriate, to help clients evaluate the tax credit/grant program, determine eligibility, and prepare applications.