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Therapeutic Discovery Tax Program: IRS Guidance and Application Process

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Welcome to the webinar.

We will begin at 11:00am PDT / 2:00pm EDT.

A Discussion of the Therapeutic Discovery Tax Program

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Agenda

- TDPC Overview
- Treasury/HHS Guidance
- Award and Certification Process
- Application Overview
- Tax Technical Issues
- Q & A

Overview – Therapeutic Project Discovery Credit

- TDPC was included in the enacted healthcare reform law (March 23, 2010)
- TDPC provides meaningful capital infusion
  - $1 billion
  - 50% of investments in new therapeutic discovery projects
- Modeled after the Qualifying Advanced Energy Project Credit Program but with cash grant option
  - Allocated investment tax credit
  - "Grant in lieu of credit" mechanism
- Treasury and HHS had 60 days to establish program (May 21, 2010)

Overview – TDPC: Key Features

- Companies may elect to forego credits for grants
- Credits exchanged for equivalent amount in a grant
- 50% investments in qualifying projects in calendar 2009 and 2010 (or fiscal 2010 and 2011)
- Limited to companies with 250 employees or fewer
- Total $1 billion program
- Grant excluded from gross income for federal income tax purposes
- No double dipping – if claim TDPC for investments, must forgo other tax benefits
  - R&D credit, Orphan drug credit, bonus depreciation

Overview – New Guidance

IRS Notice 2010-45 (May 21, 2010)

- Establishes TDPC program
- Includes definitions, IRS/HHS responsibilities, program specs, allocation procedures, info req’d to apply for certification, disclosures, special tax rules
- $5mm cap per taxpayer regardless of # of projects
- Equal distribution with reapportionment process
- Each project must file separate application

Application/Key Guidelines

- June 21 – Application published (Form 8942; irs.gov)
- **July 21** – Deadline to file applications (postmark)
  - **Not first come, first serve basis**
- September 30, 2010 - IRS preliminary review completed
- October 29, 2010 – Certification letters that approve or deny applications and authorize payment of certain grants

Qualified Investments

- Aggregate costs paid or incurred in 2009 and 2010 tax years for expenses <u>necessary for and directly related to the conduct of</u> a qualifying therapeutic discovery project.
- Excluded costs:
  - Remuneration for an employee described in §162(m)(3)
  - Interest expenses
  - Facility maintenance expenses
  - Service costs identified under Regulation §1.263A-1(e)(4)
  - Any other expense determined by Treasury/IRS as appropriate
  - IRS Notice – Reduce qualified investment for the amount of any grant excluded from gross income if grant can be used to pay or incur otherwise eligible costs

Qualified Therapeutic Discovery Projects

Projects Designed to:

1. Treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials & clinical studies or carrying out research protocols for the purpose of securing FDA approval of a regulated pharmaceutical or biologic, <u>or</u>

Qualified Therapeutic Discovery Projects

2. Diagnose diseases or conditions or determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions, <u>or</u>

    - **IRS Notice – Any product that diagnoses a disease or condition meets this criteria (does not have to determine molecular factors or be a molecular diagnostic)**

3. Develop a product, process, or technology to further the delivery or administration of therapeutics.

    - **IRS Notice – Must further delivery or administration of therapeutics (i.e., drugs or medical devices)**

Selection Criteria

Consider only those projects that show <u>reasonable potential</u> to:

1. Result in new therapies to treat areas of unmet medical need, <u>or</u>

2. Result in new therapies to prevent, detect or treat chronic or acute diseases, <u>or</u>

3. Reduce long-term health care costs in the U.S., <u>or</u>

4. Significant advance the goal of curing cancer within 30 years

<u>AND</u>

Consider which projects that have the <u>greatest potential</u> to:

5. Create and sustain high quality, high paying U.S. jobs, and

6. Advance U.S. competitiveness in the fields of life, biological, and medical sciences

6-Step Award and Certification Process

1. **IRS conducts preliminary review**
   - Determines applicant eligibility & if application is complete
2. **HHS reviews application**
   - Determines if project is qualifying
   - Determines if project shows reasonable potential to meet therapeutic objectives (per statute)
3. **IRS reviews application**
   - Determines if the project is among the projects that have the greatest potential to create/sustain U.S. jobs & advance U.S. competitiveness

6-Step Award and Certification Process

4. **IRS determines certification amount**
   - Applies ratable allocation method that incorporates a project-by-project investment limitation (50%) and overall per taxpayer cap
   - See example
5. **IRS issues certification letters**
6. **Treasury pays cash grants in lieu of credits where applicant has elected on Form 8942 to receive grant**
   - Must have DUNS number
   - Must register with Central Contractor Registration

HHS to Analyze Two Key Questions

1. **Is the project a Qualifying Therapeutic Discovery Project?**
2. **Does the project show reasonable potential to achieve one or more therapeutic objectives?**

Review Project Information Memorandum

- Applicants to provide responses to 11 questions
  - Questions 1-8 (50 word narrative support positive assertions)
    - Responses regarding Eligibility & Selection Criteria
  - Questions 9-11 (250 words each)
    - Scientific rationale & provide 5 literature citations
    - Stage of development for project
    - Resources (financial, managerial) to support project
- HHS makes binary determination per project –“eligible” or “ineligible”

IRS to Analyze Selection Criteria

- **Is the project <u>among those projects that have the greatest potential</u>:**
  - a) to create or sustain (directly or indirectly) high quality, high-paying jobs in the U.S., and
  - b) to advance U.S. competitiveness in the fields of life, biological, and medical sciences
- Review Form 8942
- Applicants to provide responses to 11 questions/data fields
  - Questions 1-6 (applicant info, employees, ownership structure, grant election)
  - Questions 7-11 (number of direct & indirect employees, avg. salaries, avg. contractor monthly compensation/hrs, status of project, expected use or construction of contract production facility, new or improved IP)

Allocation Methodology

- Certification of qualified investment initially allocated equally among all eligible projects (making it through HHS/IRS selection process)
  - 1,000 projects = certification of $2mm qualified investment per project ($1mm in credit or grant per project)
- Certification remaining from initial allocation returned to pot to the extent initial allocation is greater than qualified investment; “excess” is then reapportioned equally to all other projects that remain eligible for more allocation
  - Project A - $2mm initial allocation minus $1mm of qualified investment = $1mm “excess” allocation returned to pot and reapportioned equally among projects that remain eligible for more allocation
- If any Applicant receives more than $10mm in allocation (i.e., $5mm in credit or grant), the “excess“ is reapportioned equally to all other projects that remain eligible for more allocation
- Iterative process

Example - Allocation Methodology

	A	B	C	D (B + C)	E	F (D + E)	F x 50%
	Qualified Investment	Initial Allocation	Reapportioned Allocation based on Qualified Investment	Certified Qualified Investment After Reapportionment	Reapportioned Allocation based on Taxpayer Cap	Certified Qualified Investment After Reapportionment	Tax Credits or Grants (50% of qualified investment certified by IRS)
Company A	$1mm	$2mm	($1mm)	$1,000,000		$1,000,000	$500,000
Company B (app #1)	$5mm	$2mm	$166,667	$2,166,667	($166,667)	$2,000,000	$1,000,000
Company B (app #2)	$6mm	$2mm	$166,667	$2,166,667	($166,667)	$2,000,000	$1,000,000
Company B (app #3)	$3mm	$2mm	$166,667	$2,166,667	($166,667)	$2,000,000	$1,000,000
Company B (app #4)	$5mm	$2mm	$166,667	$2,166,667	($166,667)	$2,000,000	$1,000,000
Company B (app #5)	$6mm	$2mm	$166,666	$2,166,666	($166,666)	$2,000,000	$1,000,000
Company C	$10mm	$2mm	$166,666	$2,166,666	$833,334	$3,000,000	$1,500,000

Common Grant Eligibility Questions

- Is the applicant eligible where project already received NIH funding or a SBIR grant in 2009?
- Is the applicant eligible where a minority interest is owned by tax-exempt entity (e.g., university or non-profit)?
- Does the answer change if the applicant is a pass-thru entity (e.g., partnership or S-corporation)?

Technical Tax Issues

- How does one determine if applicant is eligible under 250 employee rule?
- Does the cost of IP qualify?
- How does the significant change in plans rule work?
- Will taxpayers electing to receive cash grant in lieu of credits be subject to federal law applicable to other grant programs?

TDPC: Other Key Features

- Disclosure of Information
  - IRS will disclose the identity of all awarded applicants and amount of certified credit or grant
  - IRS will publish the type and location of the project only if applicant has elected to receive a grant for the 2009 tax year, or provided consent for additional public disclosure
  - FOIA

Q&A

THANK YOU

for joining us today.

Questions?

Please contact:

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