

WSGR ALERT

APRIL 2009

THE ECONOMIC STIMULUS AND OPPORTUNITIES FOR LIFE SCIENCE COMPANIES - NIH CHALLENGE GRANTS IN HEALTH AND SCIENCE RESEARCH

Let the economic recovery begin. On March 27, the National Institutes of Health (NIH) began accepting applications for its \$200 million NIH Challenge Grants in Health and Science Research program. The application submission period for this first Challenge Grant solicitation will remain open until April 27, 2009.

The American Recovery and Reinvestment Act of 2009 (Recovery Act) is a federal public law passed by the 111th United States Congress and signed into law by President Barack Obama on February 17, 2009. As part of the Recovery Act, NIH is administering the NIH Challenge Grants in Health and Science Research program. Domestic (United States) institutions and organizations proposing novel research in areas that address specific knowledge gaps, scientific opportunities, new technologies, data generation, or research methods in biomedical and behavioral research are eligible to participate in the program. NIH has designated at least \$200 million for use in 2009 and 2010 to fund 200 or more grants. Each grant may not exceed \$500,000 in total costs per year for a maximum of \$1,000,000 total over a two-year project period.

Eligibility

Pursuant to the Challenge Grant solicitation, applicants must be domestic institutions/organizations (i.e., located in the 50 states, territories, and possessions of the United States, Commonwealth of Puerto Rico, Trust Territory of the Pacific Islands, or District of Columbia). The definition for a "domestic organization" contained in the NIH Grant

Policy Statement is as follows: "a public (including a State or other governmental agency) or private nonprofit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant supported activities." As a result, we believe that the Challenge Grants are available for new start-ups and venture-backed or public companies (i.e., typical Wilson Sonsini Goodrich & Rosati clients) who are incorporated in, and whose principal place of business is located in, any of the states of the United States, Commonwealth of Puerto Rico, Trust Territory of the Pacific Islands, or District of Columbia.

In addition, the Challenge Grants recently have been pitched to for-profit organizations by NIH's Small Business Innovation Research (SBIR) coordinator as an available option. As a result, we believe that there is no formal or informal policy on the part of NIH to favor academic institutions during the selection process. Finally, there are no formal domestic stockholder ownership requirements outlined in any of the materials and policies; however, significant foreign ownership may be a factor that NIH takes into consideration when determining award recipients.

Examples of Available "Challenges"

Many of the more than 200 grant opportunities, or "challenges," may be applicable to medical device and biotechnology companies. Illustrative

examples of grants that may be applicable to medical device companies include those related to the following:

- Development of minimally invasive image-guided systems
- Development of improved hearing devices
- Treatment of obstructive sleep apnea
- Development of pediatric medical devices

With respect to biotechnology, some interesting examples of grants are as follows:

- Novel agents for cancer treatment
- Musculoskeletal and skin tissue regeneration
- Cell-based therapies for cardiovascular, lung, and blood diseases

Retained Government Rights

Enacted on December 12, 1980, the Patent & Trademark Act (Public Law 96-517, also known as the Bayh-Dole Act) created a uniform patent policy among federal agencies that fund research, which includes NIH. The Bayh-Dole Act enables businesses and nonprofit organizations to retain the title to materials and products they invent under federal funding. Pursuant to the Bayh-Dole Act, a confirmatory license automatically is granted in favor of the U.S. government. The license is a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the U.S. the subject invention throughout the world. License agreements that include federally funded technology must include a clause addressing

Continued on page 2...

The Economic Stimulus and Opportunities . . .

Continued from page 1...

the government's rights and interests, i.e., "The licensee acknowledges that the U.S. government has certain rights in this invention under 37 CFR 401, including a nonexclusive, nontransferable, paid-up license heretofore granted by the licensor."

Key Information

Applications must be submitted electronically through Grants.gov (<http://www.grants.gov>) using the SF424 Research and Related (R&R) forms and the SF424 R&R Application Guide. Detailed information on this program may be found at http://grants.nih.gov/grants/funding/challenge_award/. The key dates for the solicitation are as follows:

Release/posted date: March 4, 2009

Earliest date an application may be submitted: March 27, 2009

Application due date: April 27, 2009

Peer review date(s): June/July 2009

Council review date(s): August 2009

Earliest anticipated start date: September 30, 2009

Additional Opportunities

NIH has also recently announced an additional opportunity to obtain government funding pursuant to the Grand Opportunity Program. The solicitation for this program states that only applications with budgets greater than \$500,000 in total costs per year for a project period of two years are expected to be considered. In addition, applicants may submit more than one application, provided that each application is scientifically distinct. It is expected that up to an additional \$200 million will be available under this program, for which the application submission period commences on April 27, 2009, and runs through May 27, 2009.

Conclusion

These programs may provide an attractive alternative solution to critical funding requirements of small and medium-sized life science companies at a time when raising capital from venture capitalists, banks, and the public markets has been constrained. We encourage our clients to look into this opportunity and discuss eligibility further with Casey McGlynn, Philip Oettinger, Elton Satusky, or any other member of the life sciences practice at Wilson Sonsini Goodrich & Rosati.



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This WSGR Alert was sent to our clients and interested parties via email on April 6, 2009. To receive future WSGR Alerts and newsletters via email, please contact Marketing at wsgr_resource@wsgr.com and ask to be added to our mailing list.

This communication is provided for your information only and is not intended to constitute professional advice as to any particular situation. We would be pleased to provide you with specific advice about particular situations, if desired. Do not hesitate to contact us.

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