Concept note: Innovative Financing Mechanism for Global Health Innovation

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With support from the Global Forum for Health Research, Geneva

Abstract: New drugs, vaccines and diagnostics are needed to address global health. Small innovative companies are an important source of innovation and economic growth not only in the industrialized world but also in some innovative developing countries (IDCs). However, such firms rarely engage in efforts to advance global health. A recent comprehensive study of the US Small Business Innovation Research Award (SBIR) program, conducted by the US National Academies of Science, found that this investment model has a remarkably strong 20-year track record in supporting the creation of academic spin-off companies, encouraging additional private investment, and catalyzing the commercialization and widespread distribution of health innovations to address needs that are specifically identified by public-sector agencies. We are now developing a strategy, based on this gated SBIR model, for donor investment in small companies in IDCs and industrialized countries to stimulate innovation to address local and global health challenges. The full articulation of the model will be completed by May 2009.

New drugs, vaccines, diagnostics and other health technologies are needed to address global health challenges. Small innovative companies are widely recognized as an important source of innovation and economic growth not only in the industrialized world but also in some innovative developing countries (IDCs). Unfortunately, such firms rarely engage in efforts to advance global health, in part because of insufficient market incentives and limited information flows. We are developing a new cost-effective donor investment strategy to increase incentives for small businesses in IDCs and in industrialized countries to address local and global health priorities.

An Effective Model: The author of this concept note recently completed a unique four-year comprehensive study of the US Small Business Innovation Research Award (SBIR) program. This review of inputs, policies, practices and outputs over a 20 year period among the varied SBIR programs of five Federal science agencies found that the SBIR model has a remarkably strong track record in supporting the commercialization and widespread distribution of health care innovations to address needs identified by public agencies such as the US National Institutes of Health (NIH).

SBIR is a highly competitive, gated program providing financial incentives for technological innovation. Funding agencies publish open solicitations that specify public sector goals. Small firms then submit applications to work on these topics. Phase I awards of up to $150,000 support feasibility testing. Phase II awards of up to $1 million and sometimes more support development of prototypes. NIH and some other US Federal science agencies also provide commercialization assistance to SBIR award recipients (e.g., assistance to develop business plans and to identify private investors and potential markets) as they complete work on their award. The large procurement agencies, e.g. Defense, move promising technologies and products towards procurement to meet mission needs including health.

A Successful Record: The SBIR program has been very successful in leveraging additional investments, and in stimulating health product development. About 40 percent of SBIR award recipients attracting early-stage "angel" investors. SBIR award recipients are attractive to

investors because they have already passed through a rigorous Federal peer review process with regard to technical/scientific merit and commercial potential. This creates a positive "crowding in" phenomenon to increase the catalytic impact of the SBIR awards. The program also has a substantial positive impact on the transition of university research to the market through the creation of university spin-off companies. About 60 percent of products from NIH Phase II SBIR awards eventually reach the market.

We are now developing a strategy, based on this gated SBIR model, for donor investment in small companies to stimulate innovation in low- and middle-income countries (LMICs) as a means of more effectively addressing global health challenges. The full "business case" will be completed by May 2009.

New Opportunities: In addition to building on best practices in SBIR models, this strategy will also address new opportunities to partner with developing countries that have a substantial and growing capacity for innovation. The public sector in LMICs collectively invests $2.3 billion USD per year on health research. Lower labour costs and overhead magnify the purchasing power of these investments. A few innovative developing countries already produce most of the drugs and vaccines for procurement by global health funds. All IDCs have success stories from local innovation, and all have potential to do more for global health, particularly with the addition of more effective financing mechanisms.

Possible features of the proposed investment strategy (to pilot in 1 or 2 countries)

- Co-funding between a donor (or consortium of donors) and the host country
- Focus on developing health technologies alone, or both technological & social innovation
- Criteria to select projects that could address local and global health priorities
- Requirement for grantees to develop a Global Access Plan to reach poor populations
- Commercialization assistance to grantees, especially for spin-off and start-up companies
- Technology management capacity building for publicly-funded research institutions
- Assistance to help successful projects access global public and local private markets

A Proven Concept: The concept of an innovation program drawing on the ingenuity of small businesses has a strong track record and seems well positioned to address the challenging needs of global health. Like any new initiative, operational details could make or break the program. The long and varied history in the SBIR model and its flexible goal oriented approach in the United States provides important lessons in how to best structure such a program to better address pressing needs in global health.