Partnering

Partnering with the NIH: Now part of the "Value Proposition" for start-ups

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ABSTRACT

Abstract With its "value proposition" statement a start-up company needs to convince potential investors or pharma partners how it will add more value or solve a problem better than others. High value, low cost assets such as those from the NIH ranging from technology to funding to assistance provide such biomedical firms an excellent jump-start in reaching their goals.

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INTRODUCTION

For many years the United States has led the world in government funding of non-military research and development (R&D), notably support for basic and clinical research that directly relates to health and human development. A longtime focal point for such federal investments in biomedical research has been the National Institutes of Health (NIH) along with other government laboratories and university-based research programs. Base funding provided by the NIH alone reached $31.2 billion (excluding economic stimulus funds) in fiscal year 2011; approximately 10% of this funding was spent on internal NIH R&D projects (intramural research) carried out by the approximately 6,000 scientists employed by the NIH. The balance was distributed in the form of grants, contracts and fellowships for the research endeavors of 325,000 non-government scientists (extramural research) at 3,000 colleges, universities and research organizations throughout the world.[1] Each year this biomedical research leads to a large variety of novel basic and clinical research discoveries — all of which generally require commercial partners in order to develop them into products for consumer, scientist, physician or patient use. Thus federal laboratories and universities need and actively seek corporate partners or licensees to commercialize their federally-funded research into products in order to help fulfill their fundamental missions in public health.

1 See NIH Overview at http://www.nih.gov/about/

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OPPORTUNITIES FOR BIOENTREPRENEURS AND START-UPS AT NIH

With well-established mergers and acquisitions across the entire industry, large consolidated pharmaceutical firms such as Pfizer, Novartis or GSK typically now look for later stage, more mature technologies for in-licensing and further development — not the typical pre-clinical invention arising from traditional research programs at the NIH or at universities. This provides a significantly greater opportunity for entrepreneurs and new companies to step in and fill this gap in the product development by taking on these early technologies from research institutions and bringing them to a stage that is acceptable for acquisition, later-stage clinical trials and marketing by large biotech or pharma companies. The reality now is that commercial partners, especially small, innovative ones, are essential to the role of federally-funded research institutions in delivering novel healthcare products to the market. From new or invigorated activities in technical assistance to express technology licensing agreements, to non-dilutive grant funding, there is an attractive array of available options available from NIH that can be utilized to launch or grow start-up companies. Several of these options will be examined in more detail.

IN-LICENSING OF TECHNOLOGY FROM NIH

As is the case with universities, the NIH cannot commercialize its discoveries even with its considerable size and resources — it relies instead upon partners. Commercializing technologies such as vaccines or drugs and then marketing them successfully in a world-wide market is not the responsibility or mission of research institutions or government agency. Companies with access to the needed expertise and money required are needed to undertake continued development of these inventions from NIH or other research institutions into final products. Typically, a royalty-bearing exclusive license agreement with the right to sublicense is given to a company from NIH (if NIH–owned) or the university (if university-owned) to use patents, materials, or other assets to bring a therapeutic or vaccine product concept to market. Exclusivity is almost always the norm for FDA-regulated products due to the risk involved in time, money and regulatory pathway to companies and their investors. Financial terms of the license agreement are negotiable but due reflect the nascent, high risk nature of the discovery. Because the technologies coming from NIH or NIH-funded research are most typically preclinical inventions most licensees are early stage companies or start-ups rather than larger firms who typically want only more proven ideas for new products. In addition to the license agreement there will also often be research collaborations between the licensee and the NIH or university to assist with additional work needed on the product technology. When the licensee is able to sufficiently "de-risked" the technology through its various efforts, these companies then sublicense, partner or get acquired by larger biotech or pharmaceutical firms for the final, most expensive stages of development with the large company expected to be sell the product once it reaches the market.

Since the 1980s federally-funded health research institutions such as the NIH have developed an active but increasingly strategic focus on improving public health through technology transfer activities. As such they are particularly interested in working with start-ups and other early stage companies in the health care area that are looking to develop and deliver innovative products. Rather than just seeking a financial return through revenue generation these institutions are looking to utilize licensing of nascent inventions as a way to increase new company formation, supporting faculty recruitment and retention, enhancing research funding, creating in general a more entrepreneurial culture within the organization, attracting venture investment and development to their specific region (universities) or to the health sector in general (NIH).

ECONOMIC DEVELOPMENT ASPECTS OF LICENSING & TECHNOLOGY TRANSFER

The economic development potential of biomedical research is being recognized as a fourth mission for such institutions -- going along with education, research and public or community service. Thus it is in this "fourth mission" that bioentrepreneurs can play a key role by establishing companies driven by innovative research discoveries.

The economic importance of licensing and technology transfer has become better recognized by research institutions, including the NIH, during the recent recessionary period. For example, the overall product sales of all types by licensees of NIH intramural research is now reported by the NIH Office of Technology Transfer as approximately $6 billion annually, the equivalent of mid-tier Fortune 500 company. Economic development also was the focus of the October 28, 2011 U.S. Presidential Memorandum — "Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses"[2] . This directive from the White House recognized the economic aspects of innovation and technology transfer for federal research in the way it fuels economic growth as well as creating of new industries, companies, jobs, products and services, and improving the global competitiveness of U.S. industries. The directive requires federal laboratories such as the NIH to support high growth entrepreneurship by increasing the rate of technology transfer and the economic and societal impact from federal R&D investments over a 5-year period. During this period federal laboratories such as the NIH will be (a) establishing goals and measuring progress towards commercialization; (b) streamlining the technology transfer and commercialization processes, especially for licensing, collaborations and grants to small companies; and (c) facilitating commercialization of new technology and formation of new start-up firms through local and regional economic development partnerships.

In addition, many universities and the NIH have set up educational programs that train scientists and engineers to have a greater appreciation as to the importance of commercialization. These include entrepreneurship centers and small business assistance programs at many universities[3], and such things as the "Certificate in Technology Transfer" program given at the Foundation for

2 See http://www.whitehouse.gov/the-press-office/2011/10/28/presidential-memorandum-accelerating-technology-transfer-and-commerciali

3 One such program, for example, is Innovate (http://carey.jhu.edu/our_programs/Innovate/)

Advanced Education in the Sciences (FAES) Graduate School at NIH.[4]

NEW LOW COST START-UP LICENSE AGREEMENTS AT NIH

To better facilitate this "fourth mission" of economic development, the NIH has developed a new short-term Start-Up Exclusive Evaluation License Agreement (Start-up EELA) and a Start-up Exclusive Commercial License Agreement (Start-up ECLA) to facilitate licensing of intramural NIH and Food and Drug Administration (FDA) inventions to early stage companies. These new NIH Start-up Licenses are provided to assist companies that are less than 5 years old, have less than $5M in capital raised, and have fewer than 50 employees obtain an exclusive license from the NIH for a biomedical invention of interest arising from the NIH or FDA. NIH Start-Up Licenses are offered to companies developing drugs, vaccines or therapeutics from NIH or FDA patented or patent pending technologies. The new company must license at least one NIH or FDA-owned U.S. patent and commit to developing a product or service for the U.S. market. The licensee may also obtain in the license related NIH or FDA-owned patents filed in other countries if the company agrees to commercialize products in those countries as well.

Financial terms for the Start-up Licenses are designed with the fiscal realities of small firms in mind and feature either: a one-year exclusive evaluation license with a flat $2,000 execution fee (this license can be later amended to become an exclusive commercialization license) or an immediate exclusive commercialization license. The Start-Up Exclusive Commercial License includes:

- A delayed tiered upfront execution royalty, which would be due to the NIH upon a liquidity event such as an initial public offering (IPO), a merger, a sublicense, an assignment, acquisition by another firm, or a first commercial sale;
- A delayed minimum annual royalty (MAR) or a MAR that is waived if there is a Cooperative Research and Development Agreement with the NIH (or FDA) concerning the development of the licensed technology and providing value comparable to the MAR. Additionally, the MAR will be waived for up to five years during the term of a Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) grant for the development of the licensed technology;
- An initial lower reimbursement rate of patent expenses which increases over time to full reimbursement of expenses tied to the earliest of: a liquidity event, an initial public offering, the grant of a sublicense, a first commercial sale, or upon the third anniversary of the effective date of the agreement;
- Consideration by NIH of all requests from a start-up company to file new or continuing patent applications as long as the company is actively and timely reimbursing patent prosecution expenses;
- A set earned royalty rate of 1.5% on the sale of licensed products;
- A set sublicensing royalty rate of 15% of the other consideration received from the grant of a sublicense;
- Anti-stacking royalty payment license provision can be negotiated by company if it encounters a stacking royalty problem. A stacking royalty problem can occur when a licensee's third party royalty obligations add up to such a high total royalty number such that the project becomes unattractive for investment, sub-licensing or self-development due to low profit margins. Royalty stacking can especially be a problem in the development of biologics due to the breadth of possible third party IP that may be needed compared with traditional small molecule drugs.
- Mutually agreed upon specific benchmarks and performance milestones, which do not require a royalty payment, but rather ensure that the start-up licensee is taking concrete steps toward practical application of the licensed product or process.
- NIH Start-Up Commercial Licenses represent a significant front-end savings in negotiation time and money for new companies since an exclusive license even for an early stage technology might well have expectations prior to negotiations of a immediate execution fee of up to $250,000 or more, a minimum annual royalty due in the first year and beyond of up to $25,000 or more, immediate payment of all past patent expenses and ongoing payments of future patent expenses, benchmark

4 For more details see www.faes.org.

royalties in the range of up to $1,000,000 or more, significant sublicensing consideration and earned royalties in the range up to 5% or more depending on the technology.

Because many, if not most of the technologies developed at the NIH and FDA, are early stage biomedical technologies, the time and development risks to develop a commercial product are high. Depending on the technology and the stage of formation, of the potential licensee company, the company may prefer to enter into the Start-up EELA to evaluate their interest before committing to a longer term Start-up ECLA. Bioentrepreneurs can identify technologies of interest by searching licensing opportunities on the NIH Office of Technology Transfer (OTT) website[5] and by following through with getting in touch with the listed licensing contact. Model template agreements for the Start-Up Licenses and other details on the licensing process can be found on the OTT "Start-up Webpage"[6].

RESEARCH COLLABORATION PROGRAMS AT NIH FOR START-UPS

For some entrepreneurs there is a misperception that NIH scientists (unlike their university counterparts), are not allowed to interact with private sector firms due to the implementation of strict government ethics and conflict of interest rules. While it is true that NIH investigators, in general, cannot engage in outside consulting with biotechnology and pharmaceutical companies in their personal capacity, the fact is that technology transfer-related activities are actually among the "official duties," in which NIH scientists are encouraged to participate. These activities may include the reporting of new inventions from the laboratory and assisting technology transfer staff with patenting, marketing and licensing interactions with companies. NIH scientists can also officially collaborate with industry scientists through the use of various mechanisms including more complex Cooperative Research and Development Agreements (CRADAs) and Clinical Trial Agreements (CTAs) as well as simpler Confidential Disclosure Agreements (CDAs) and Material Transfer Agreements (MTAs).

In a CRADA research project, which could run for several years, NIH and company scientists can engage in mutually beneficial joint research, where each party provides unique resources, skills and funding, and where either partner may not otherwise be able to solely provide all the resources needed for successful completion of the project. In such an arrangement, the details of the research activity to be carried out and the scope of the license options granted to discoveries emanating from the joint research are clearly spelled out in advance. A CTA would typically involve the clinical testing of a private sector company's small molecule compound or biologic drug. The company gains access to the clinical trial infrastructure and clinical expertise available at NIH; however unlike as occurs with a CRADA the company partner does not have any licensing rights to intellectual property that is generated during the clinical research project. NIH usually enters into these agreements only in cases where such trials would be difficult or impossible to run in other places. NIH is particularly interested in clinical trials involving rare or orphan diseases that affect 200,000 or fewer patients per year in the U.S. A Material Transfer Agreement is a popular mechanism for exchanging proprietary research reagents and is used by scientists worldwide. NIH investigators actively use this mechanism to share reagents with scientists in other non-profit organizations. Proprietary and/or unpublished information can be exchanged between NIH researchers and company personnel in advance of making a decision to enter into a CRADA or CTA via the use of a CDA.

Of the collaborative mechanisms described above, a CRADA is perhaps the most comprehensive and far-reaching. Such agreements can provide additional funds for an NIH lab, while providing the collaborating company with preferential access to the NIH scientist's future discoveries and access to scientific and medical expertise during the research or clinical collaboration. A CRADA is not, however, intended to be a means for NIH to provide funding for a new company; in fact, the NIH cannot supply any funding to its CRADA partners. The easiest way for an entrepreneur to access this expertise is to simply approach the agency officially either by contacting a scientist directly or by contacting the institute technology transfer office and/or technology development coordinator[7].

If an early stage company needs access to NIH materials for commercial purposes outside a formal collaboration, this usually would be done utilizing an Internal Commercial Use License Agreement rather than a MTA. These are non-exclusive license agreements to allow a licensee to use (but not sell) technology in its internal programs. Here, materials (either patented or unpatented) are provided, and drug screening uses are permitted. The financial structure of this agreement can be either a single payment, paid-up term license or annual royalty payments, though the second structure is more popular with

5 See http://www.ott.nih.gov/Technologies/AbsSearchBox.aspx

6 See http://www.ott.nih.gov/docs/PHS-Startup-License-Term-Sheet-05172011.docx

7 See http://www.ott.nih.gov/nih_staff/tdc.aspx

start-up companies. Each functions, however, without "reach through" royalty obligations to other products being used or discovered by the licensee. "Reach through" royalty provisions in a license agreement are particularly detrimental to start-up firms as they create downstream royalties or grant-back rights to the licensor on the future sales of downstream products that are discovered or developed through the use of licensed technology, even though the final end product may not contain or otherwise infringe the licensed technology. Popular internal research technologies licensed in this manner include such materials as animal models and receptors.

BASIC & CLINICAL RESEARCH ASSISTANCE

Basic & clinical research assistance from NIH institutes may also be available to companies through specialized services such as drug candidate compound screening and pre-clinical and clinical drug development and testing services, which are offered by several programs. These initiatives are particularly targeted towards developing and enhancing new clinical candidates in the disease or health area of particular focus at various NIH institutes. The largest and perhaps best known programs of these types at NIH are those currently run in the National Cancer Institute (NCI)[8]. The NCI has played an active role in the development of drugs for cancer treatment for over 50 years. This is reflected in the fact that approximately one half of the chemotherapeutic drugs currently used by oncologists for cancer treatment were discovered and/or developed at NCI. The Developmental Therapeutics Program (DTP) promotes all aspects of drug discovery and development before testing in humans (preclinical development), and is a part of the Division of Cancer Treatment and Diagnosis (DCTD). NCI also funds an extensive clinical (human) trials network to ensure that promising agents are tested in humans. NCI's Cancer Therapy Evaluation Program (CTEP), also a part of DCTD, administers clinical drug development. Compounds can enter at any stage of the development process—with either very little or extensive prior testing. Drugs developed through these programs include well-known products such as cisplatin, paclitaxel and fludarabine.

Beginning in 2012 the NIH has been able to established a new center, called the National Center for Advancing Translational Sciences (NCATS), that is designed to assist companies with the many costly, time-consuming bottlenecks exist in translational product development[9]. Working in partnership with both the public and private organizations, NCATS will seek to develop innovative ways to reduce, remove, or bypass such bottlenecks to speed the delivery of new drugs, diagnostics, and medical devices to patients. The Center will not itself be a drug development company, but will focus more on using science to create powerful new tools and technologies that can be adopted widely by translational researchers in all sectors.

NCATS was formed primarily by uniting and realigning a variety existing NIH programs that play key roles in translational science. Programs that will be integrated into NCATS include:

- *Bridging Interventional Development Gaps* - which makes available critical resources needed for the development of new therapeutic agents.
- *Clinical and Translational Science Awards* - which fund a national consortium of 60 medical research institutions working together to improve the way clinical and translational research is conducted nationwide. These institutions will serve as a primary test bed for NCATS activities.
- *Cures Acceleration Network* - which enables NCATS to fund research in new and innovative ways.
- *FDA-NIH Regulatory Science* - which is an interagency partnership that aims to accelerate the development and use of better tools, standards and approaches for developing and evaluating diagnostic and therapeutic products.
- *Molecular Libraries* - which is an initiative that provides researchers with access to the large-scale screening capacity necessary to identify compounds that can be used as chemical probes to validate new therapeutic targets.
- *Office of Rare Diseases Research* - which coordinates and supports rare diseases research.
- *Therapeutics for Rare and Neglected Diseases* - which is a program to encourage and speed the development of new drugs for rare and neglected diseases.

There is additional assistance available to firms in other in other disease areas including infectious diseases, drug abuse and many others. A general web portal for listing such public resources has been put together

8 For more information about DTP, see http://dtp.nci.nih.gov/ and for more information about CTEP, see http://ctep.cancer.gov/

9 For the latest developments here, please see http://ncats.nih.gov/

at NIH by the *CTSA (Clinical & Translational Science Awards) Resources for Researchers Webpage*[10]. All in all, such efforts can provide a wide variety of technical assistance (often at little or no cost) for pre-clinical and even clinical development of novel therapies or other biomedical products by start-up firms.

SELLING PRODUCTS TO THE NIH

One of the most commonly overlooked NIH opportunities by biomedical-focused companies is the ability to sell products and services at NIH. Indeed for start-up companies looking to develop new products used in conducting basic or clinical research, the NIH may be their first customer. With an intramural staff of about 18,000 employees, laboratories in several regions of the country (with the Bethesda campus in Maryland home to the majority), and an annual intramural budget of about $3.1 billion, NIH is perhaps the largest individual institutional consumer of bioscience research reagents and instruments in the world. A variety of mechanisms for selling products and services to the NIH are possible, including stocking in government storerooms. Selling to NIH can be a seen as a daunting task for new companies because of the U.S. government's complex acquisition process. However, there are a few simple steps that companies can take, such as establishing a Blanket Purchase Agreement (BPA) with NIH and getting their goods and services into the NIH stockroom. Once these hurdles are cleared, it is much easier for NIH scientists to buy from such companies, and if the quality of goods and services provided by a particular biotech company is superior, an NIH scientist can justify buying solely from that very source.

Companies that provide products and services to NIH laboratories can not only generate cash flow and revenues to fuel R&D, but also begin to demonstrate their commercial acumen to would-be partners and investors. Being a large research organization, the NIH has numerous R&D contracting opportunities. For further information on such opportunities, visit the NIH Office of Acquisition Management and Policy website[11].

The annual NIH Research Festival is also an excellent starting point for companies hoping to sell products to the NIH[12]. This event is held every fall at the Bethesda, MD campus and every spring on the Frederick, MD campus. Part scientific, part social, part informational and part inspirational, this three-day event draws a variety of small to medium-sized bioscience companies. These events attract almost 6,000 NIH scientists, many of whom come to these gatherings to learn about and potentially purchase the latest research tools and services.

NIH FUNDING OPPORTUNITIES FOR START-UPS — SBIR PROGRAM

In addition to contracting opportunities, the NIH can provide private sector entities with non-dilutive funding through the SBIR and STTR programs[13]. The NIH SBIR program is perhaps the most lucrative and stable funding source for new companies and unlike a small business loan, SBIR grant funds do not need to be repaid.

Other noteworthy advantages of SBIR programs for small companies include: retention by the company of any intellectual property rights from the research funding; receipt of early stage funding that doesn't impact stock or shares in any way (e.g., no dilution of capital); national recognition for the firm; verification and visibility for the underlying technology; and finally, generation of a leveraging tool that can attract other funding from venture capital or angel investors.

The SBIR program itself was established in 1982 by the Small Business Innovation Development Act to increase the participation of small, high technology firms in federal research and development activities. Under this program, departments and agencies with R&D budgets of $100 million or more are required to set aside 2.5% of their R&D budgets to sponsor research at small companies. The STTR program was established by the Small Business Technology Transfer Act of 1992 and requires federal agencies with extramural R&D budgets over $1 billion required to administer STTR programs using an annual set-aside of 0.3%. In FY 2010 NIH's combined SBIR and STTR grants totaled over $690 million.

The STTR and SBIR programs are similar in that both seek to increase small business participation and private-sector commercialization of technology developed through federal research and development. The SBIR Program funds early-stage research and development at small businesses. The unique feature of the STTR Program is the requirement for the small business applicant to formally collaborate with a research institution in Phase I and Phase II.

Thus the SBIR and STTR programs differ in two major ways. First, under SBIR program, the principal investigator must have his/her primary employment with the small business concern at the time of award and for the duration of the project period, however, under the STTR program, primary employment is not stipulated. Second,

10 This can be found at: https://www.ctsacentral.org/content/resources-researchers

11 For specific programs see at http://oamp.od.nih.gov

12 See http://web.ncifcrf.gov/events/springfest/2011/ and http://researchfestival.nih.gov/

13 See http://grants.nih.gov/grants/funding/sbirsttr_programs.htm

the STTR program requires research partners at universities and other non-profit research institutions to have a formal collaborative relationship with the small business concern. At least 40% of the STTR research project is to be conducted by the small business concern and at least 30% of the effort is to be conducted by the single, "partnering" research institution.

As a major mechanism at NIH for achieving goals of enhancing public health through the commercialization of new technology, the SBIR and STTR grants present an excellent funding source for start-up and other small biotechnology companies. The NIH SBIR and STTR Programs themselves are structured in three primary phases.

Phase I: The objective of Phase I is to establish the technical merit and feasibility of the proposed research and development efforts and to determine the quality of performance of the small business prior to providing further federal funding in Phase II. Phase I awards are normally $150,000, provided over a period of six months for SBIR and $100,000 over a period of one year for STTR. However, with proper justification, applicants may propose longer periods of time and greater amounts of funds necessary to establish the technical merit and feasibility of the proposed project.

Phase II: The objective of Phase II is to continue the research and development efforts initiated in Phase I. Only Phase I awardees are eligible for a Phase II award. Phase II awards are normally $1 million over two years for SBIR and $750,000 over two years for STTR. However, with proper justification, applicants may propose longer periods of time and greater amounts of funds necessary for completion of the project.

SBIR-TT Phase I & Phase II: Under this new program (SBIR-Technology Transfer or SBIR-TT) undertaken at the National Cancer Institute (NCI) at NIH and in the process of being expanded to other NIH institutes, SBIR Phase I and Phase II awards are given in conjunction with exclusive licenses to underlying background discoveries made by an intramural research laboratory at the institute.

SBIR Phase II Bridge: The NCI SBIR Program has created the Phase II Bridge Award for previously funded NCI SBIR Phase II awardees to continue the next stage of research and development for projects in the areas of cancer therapeutics, imaging technologies, interventional devices, diagnostics and prognostics. The objective of the NCI Phase II Bridge Award is to help address the funding gap that a company may encounter between the end of the Phase II award and the commercialization stage. Budgets up to $1 million in total costs per year and project periods up to three years (a total of $3 million over three years) may be requested from the NCI. To incentivize partnerships between awardees and third-party investors and/or strategic partners, competitive preference and funding priority will be given to applicants that demonstrate the ability to secure substantial independent third-party investor funds (i.e., third-party funds that equal or exceed the requested NCI funds). This funding opportunity is open to current and recently expired NCI SBIR Phase II projects.

Phase III: The objective of Phase III, where appropriate, is for the small business concern to pursue with non-SBIR/STTR funds the commercialization objectives resulting from the Phase I/II research and development activities.

Those who hope to receive an SBIR or STTR grant from the NIH must convince the NIH institute that the proposed research is unique, creates value for the general public at large through advancements in knowledge and treatment of disease and is relevant to the overall goals of NIH. It is important to contact the program officials ahead of time within the particular component of NIH from where funding is sought in order to determine whether the proposed research plan fits these criteria. For start-ups, generally SBIR applications are most successful when they include: an entrepreneur-founder with experience in the field; a highly innovative technical solution to significant clinical need; an end product with significant commercial potential; a technology in need of more feasibility data that the proposed research project would generate; and finally a project that, if successful, would have reduced risk and become more attractive for downstream investment. At NIH, applications are reviewed three times a year. Companies should also be aware that changes for these programs at NIH will be in the works as a result of the recent re-authorization of the programs by Congress.[14]

CONCLUSION — NIH NOW PART OF THE "VALUE PROPOSITION" FOR START-UPS

With its leading edge research and funding programs and focus on the healthcare market, the NIH has a strong record in providing opportunities for private sector entrepreneurs to create both high growth companies and develop profitable medical products. Indeed, a study published in the *New England Journal of Medicine*[15] in 2011 showed the intramural research laboratories at the NIH as by far the largest single non-profit source of new drugs and vaccines approved by the FDA. Clearly this cannot be done without productive partnerships with private industry — past, present and (of course) future. Savvy bio-entrepreneurs and start-up firms can now come to NIH

14 *Ibid.*

15 *N Engl J Med. 2011 Feb 10;364:535-541.*

not only for funding in the form of SBIR grants, but also for product development leads through various licensing and partnership mechanisms. In addition, the intramural NIH laboratories can be seen as an early adopter customer that embraces new biomedical research products as well as a source of expertise, resources and assistance that may not be available elsewhere. Thus entrepreneurs and start-up firms need to fully comprehend, appreciate and utilize the full value that NIH brings to their own work, product development and, of course, to public health.