

# US Funding Opportunities for Early Stage Life Science Companies

*An overview for the Norwegian Life Science industry*

*May 2009*

*Boston, Massachusetts*

[www.innovationnorway.no/boston](http://www.innovationnorway.no/boston)

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Dear Norwegian Life Science Entrepreneur,

Innovation Norway works with the Norwegian life science industry and other stakeholders to promote and facilitate the development of life science companies and their products. Growing a biotech or medtech company is a very capital intensive exercise, we know, and it requires patient and competent risk capital. Nowhere in the world has private equity and risk capital been more freely available than in the US. The US also aggressively funds medical research and innovation through state and federal government grants and provisions. The abundance of risk capital and government grants in the US has helped create a strong and diverse global life science industry. Granted, the current economic climate has made risk capital, IPOs and bank loans more difficult to obtain. However, we believe that this cyclical downturn will shift for the better and that the US with their flair for and reliance on entrepreneurial activity will generate the right economic incentives to fund innovation. Rest assured, the need for more cost effective healthcare, particularly here in the US, will necessitate more innovations. Many of these innovations will come from outside the US. As such, a Norwegian innovation in the life sciences may attract US venture capital or be eligible to receive certain grants.

This report sets out to give an overview of US sources of funding for young and early stage life science companies. Please use this report to explore the opportunities for funding in the US for your Norwegian company. Once you have questions do not hesitate to contact Innovation Norway. Our job is to help you.

Innovation Norway is thankful for the help and contribution from Jørgen Nøvik for putting this report together.

Innovation Norway,

Boston,

May 2009

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## 1 Introduction

The support of life science companies is recognized globally as one of the engines of economic growth but more importantly as the foundation of a healthier society with a wide range of benefits that more than justify the investment needed. Unfortunately, due to the credit crisis and other market woes (IPOs have disappeared and venture capitalists are looking for larger returns) sources of cash globally have begun to be more difficult to obtain. The good news is that there is money available to invest in innovative companies, and because the world is “shrinking” this money can be accessed globally.

The challenge is to be creative and to find new sources of financing, apply for them and ultimately build a business based on their capital. The job of the leadership of a Norwegian life science company is to break down the financial needs of the company and then identify public and private sources of financing. This is the easy part of the job for leadership especially if the funding sources are in Norway. The hard part begins when the entrepreneur has to look for financing outside their country of origin potentially on a different continent. It is even more complicated when the funding source is in a different country with a different culture and corporate leadership has to understand what each financing source is looking for and to address and meet those needs.

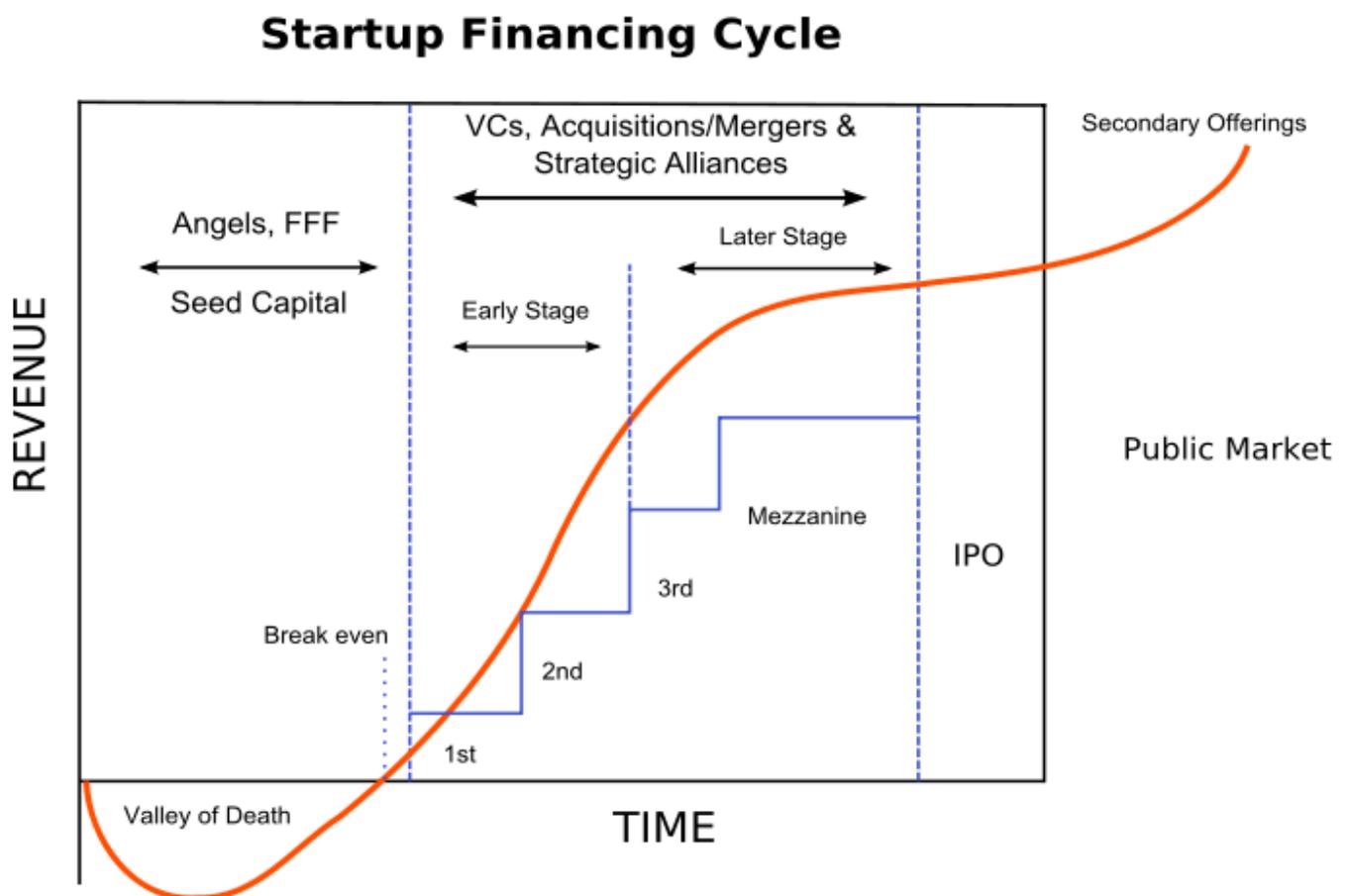
This document was written for the latter group of Norwegian life science companies that are in the early stages of financing and who are thinking outside the traditional paradigm and investigating funding sources, on another continent. It is a review of the major funding vehicles in the USA, what they are looking for and what are the general terms and conditions of an investment.

This is not meant to be an exhaustive detailed review, but should contain the information to get Norwegian companies started in the search for financing dollars

in the USA pertaining to their relative place in the startup financing cycle. See Figure 1 below.

The report draws on the expert knowledge of the Innovation Norway Boston office and multiple sources of data and information from private and government representatives and institutions.

Figure 1. Startup Financing Cycle



Source: Kmuehmel and [http://en.wikipedia.org/wiki/File:Startup\\_financing\\_cycle.svg](http://en.wikipedia.org/wiki/File:Startup_financing_cycle.svg)

## 2 Creative approaches to gaining funding in the USA

All of the following funding sources in general have no citizenship requirements except the SBIR/STTR program. Even though there are no citizenship requirements, the chances are obviously increased for a US company. Here are some ways to increase your chances of getting funding from a source in the USA.

1. Create a subsidiary in the USA. Your company will get more exposure to US funding sources and you will be more aware of their availability. It does not have to be expensive, and a US address and a US phone number have implicit value to a reviewer.
2. Creating a subsidiary also makes your company more fundable by angels and venture capitalists. Angels generally only invest in their region so they can watch their investment and possibly help the company grow. Venture capitalists will invest at a distance but would prefer not to get on a plane for every crisis and board meeting.
3. Create a subsidiary in the USA owned 51% by a US citizen. This is an eligibility requirement for SBIR/STTR funding.
4. Create collaborations with US companies. For example – some of the Department of Defense programs explicitly state they would like to see collaboration with a business to move the technology to market.
5. Create collaborations with US researchers. Government grants are peer reviewed in the USA. Therefore your chances are increased if the reviewers know your company or a collaborating company in the USA. In addition, groups that have previously received funding often receive funding again, for example from the non-profits. Align your company in a win-win collaboration with one of these groups.

### 3 Angel funds

#### *Definition*

Many companies are started and funded by “family and friends”. “Angels” are private investors that invest their own money in a business. They are often successful entrepreneurs themselves that have made money and are willing to re-invest. In the USA angels must be high net worth investors which means they have assets over \$1M or have an income of over \$300,000. Angels generally know the entrepreneur or know someone quite well that has connections in to the management team. Angels can provide the entrepreneur with valuable know-how in starting and growing a business. There are also numerous angel networks focused on healthcare. These are groups of angels that meet once or twice a month to review opportunities. They listen to a “pitch” and they then choose if they want to invest and how much they would like to invest. Certain angel networks invest as a group, as a so-called “Band of Angels”.

#### *What are they looking for and how to approach*

With the caveat that “friends and family” invest in anything because they are friends and family, angels who invest in healthcare usually will not invest in therapeutics, but are much more interested in shorter term projects such as devices, diagnostics and informatics. They often will invest in an area they are familiar with and at times will use the investment as a way to become involved with the company. They invest locally in projects for many reasons, one of the main ones being “watching their money”. It is very difficult for an angel to keep track of an investment outside their own state or in a foreign country. Therefore where your company or a branch of your company is located is important. They review the technology but also invest in the individual – they must believe that they are giving money to someone that is passionate and will give them a return on their money better than they can do at the bank. In addition with angel networks, there is often someone in the network that is familiar with the technology and/or the market that can help do some of the due diligence that is required for the investment.

### *General terms and conditions and potential size*

Of the US companies that received angel funding in 2007, the average capital raised was about \$450,000. However, there is no “set amount” per se for angel investors, and the range can go anywhere from a few thousand, to a few million dollars.

Angels expect an average 26% annual return at the time they invest, and they believe that about one-third of their investments are likely to result in a substantial capital loss. They accept an average of 3 deals for every 10 considered. The most common reasons given for rejecting a deal are insufficient growth potential, overpriced equity, lack of sufficient talent of the management, or lack of information about the entrepreneur or key personnel.

Their terms on valuation are generally better than a venture capitalist and they will not necessarily require a board seat. They are also more patient than a venture capitalist about getting a return on their money, and will generally be happy with a return greater than the general stock market. Sometimes if an angel network invests a significant amount of money they will want a board seat, or at least observation rights to attend board meetings.

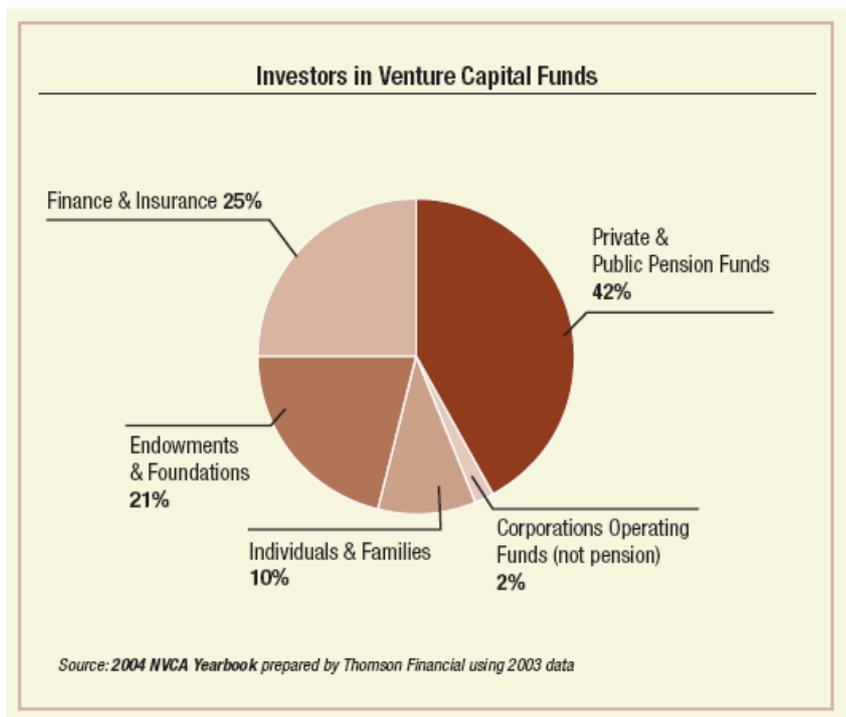
The terrific thing is that angels will invest any amount of money, so if you need under \$1 M this is the group. However, there is no “standard” size on Angel investment deals. See Appendix section 6.1 for a list of deals where angels were active funding partners.

## 4 Venture capital funds

### Definition

Whilst the angel investment community is a more informal network of investors who invest in companies for their own interests venture capital (VC) firms are professional investors who dedicate 100% of their time to investing and building innovative companies on behalf of third party investors or their limited partners. Venture capital funds are a type of private equity capital that is given to early-stage, high-potential and growth companies. Venture capitalists help entrepreneurs build businesses and then sell those businesses, either to the public market in an initial public offering or to more established companies. The investments are generally made as cash in exchange for shares in the company. They can be sector specific such as healthcare or information technology and as well as capital venture capitalists often bring management and technical expertise to their investments. In order to create a fund, venture capitalists (VC) have to raise money for their fund from institutional investors, such as pension funds, insurance companies, endowments, foundations and high net worth individuals. See Figure 2 below.

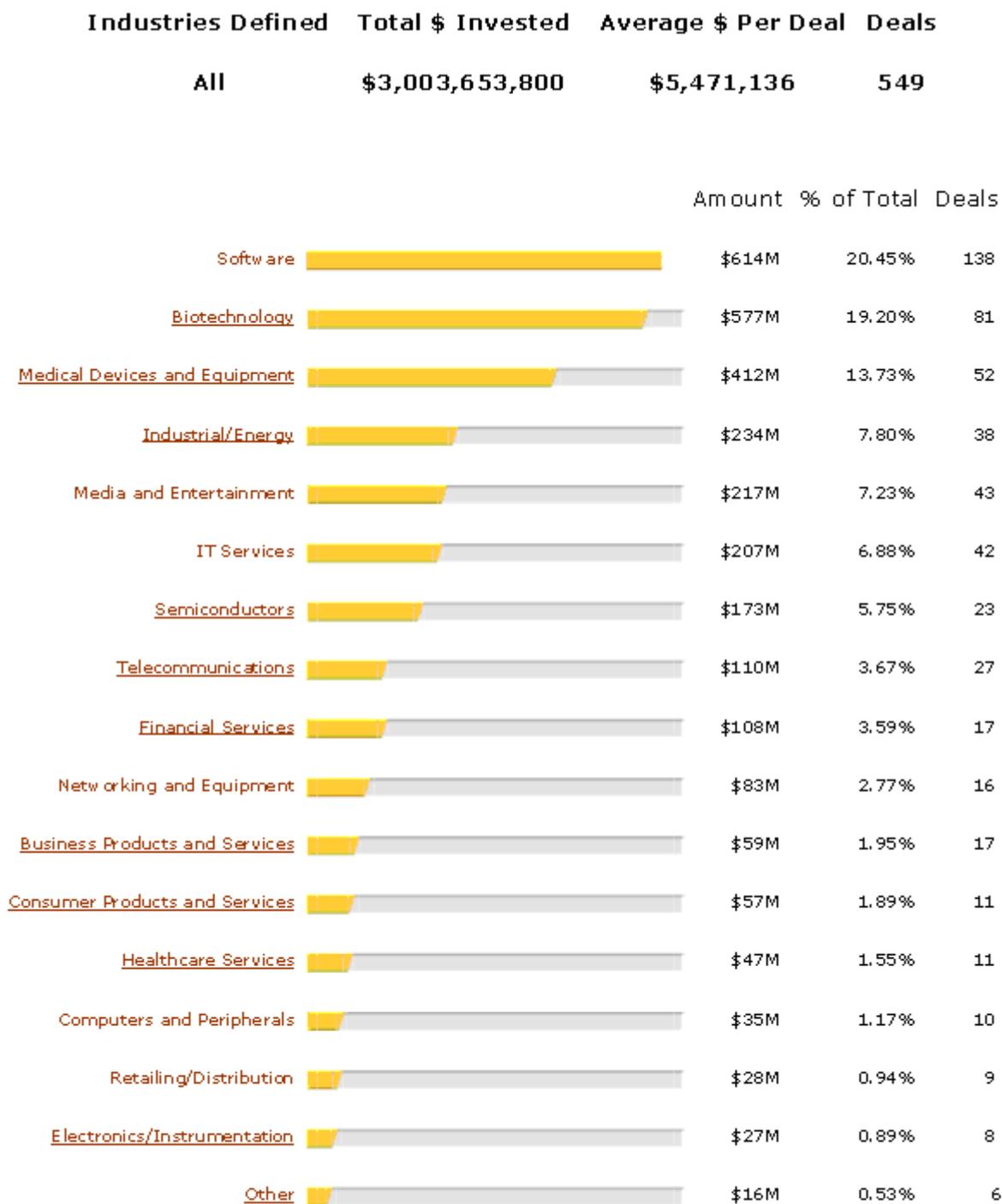
Figure 2. Investors in Venture Capital



The investors who invest in venture capital funds are referred to as "limited partners." Venture capitalists, who manage the fund, are referred to as "general partners." The general partners have a fiduciary responsibility to their limited partners. VCs pool money and invest in companies trying to make a good return for their investors. It is estimated that 40 percent of venture backed companies fail; 40 percent return moderate amounts of capital; and only 20 percent or less produce high returns. It is the small percentage of high return deals that are most responsible for the venture capital industry consistently performing above the public markets. In order to raise a second fund to reinvest in current companies and new ones, VCs have to go back to their investor group and show that they have given them a good return on their money. The compounded Venture Capital Return Rate over many years is approximately 17.8%. Thus - the skill of the VC is picking the winners and helping manage them to a successful exit.

There are approximately 741 venture capital firms in the United States and they manage approximately \$257 billion. California and Massachusetts are states that have many and large venture capital funds for the life sciences. In 2007, the average venture fund size was \$166 million. In the same year venture capitalists invested approximately \$30 billion into 3,226 companies. See Figure 3 on the next page for sectors that VCs focus on and statistics on deals and amount invested per sector for Q1 2009. Biotech and medtech are strong investment focus areas for VCs.

Figure 3. VC Investments by Industry / Q1 2009



Source: PWC/NVCA/MoneyTreeReport

### *What are they looking for and how to approach*

Venture capitalists are trying to make the best investments possible because they have to make a good return for their limited partners. Therefore they are looking for the best possible projects with the least amount of risk for investment. The most important thing to them is the management team, and especially the leader. They are interested in knowing their track record, if there is a common vision, and if they are comfortable with the person they will be spending a lot of time working with. They look for projects where there is a well defined plan that will reach a clear value creation point before the next round of funding (2-3 years). They receive thousands of business plans every year which means you need to apply a well rehearsed pitch and value proposition to get the appropriate attention. The best way to approach a VC is through an introduction before you send your business plan.

### *General terms and conditions and potential size*

Generally the first money from a VC is the 1<sup>st</sup> or A round. (Friends and family are generally considered seed funding.) It is hoped that by the 3<sup>rd</sup> or C round the company is clear about its exit strategy. VCs will generally take 20-40% equity stake at each round of financing depending on the pre-money company valuation. E.g.:

- Pre-money company valuation: \$5 million
- VC investment: \$1 million
- Post-money company valuation: \$6 million
- Founder equity stake: 80%
- VC equity stake: 20%

Sometimes VCs will commit a certain amount of money but give it out related to agreed-upon milestones (tranching the money). Venture capitalists generally will give a lower valuation than other funding sources, but the trade-off is that they might bring real expertise to the company and they generally will re-invest in their portfolio companies. If they will not reinvest it is a very bad sign for the company and the company may not be able to raise more funds. Venture capital money is not considered "patient" money – they need their portfolio to perform

according to a schedule because they have to show a return to their investors. Venture capital can invest any amount of money. They will put in less than \$1 M sometimes just to allow the company to do one experiment to prove the value of the project. They like to invest for the life of the project until there is an exit – so for example, they will reserve a certain amount of the fund, say \$20 M, to invest over the 5 years until the successful exit. A goal for ROI for a VC can be 10x in 5 years; however, that will be considered a solid hit, and will make up for the more unfortunate investments. See Appendix section 6.3 for guidelines from Novartis Venture Fund Cambridge, who expects 10x – 30x ROI within 2 to 7 years, and expected break even within 1 to 3 years.

In general early stage VC's target 10x return on capital in 3-7 years and late stage VC's target 3-5x in 2-3 years. In terms of % IRR (internal rate of return is the discount rate or cost of capital that makes the net present value of the investment's cash flow stream equal to zero), if the % IRR is greater than the project's cost of capital the project will add value for the VC investment. However, you get very different % IRR's depending your exit strategy (timing) and return required but on average 80% IRR is required for early stage deals and an 84% IRR for late stage deals.

VCs usually syndicate meaning there is one lead VC doing the due diligence and the lead brings in other VCs if they approve the investment opportunity. VCs generally get a significant portion of the company and a board seat. Many more biotech companies have succeeded with no venture money – VCs fund less than 5% of start-up companies! See Appendix section 6.2 for examples of recent VC deals.

For more information, please visit: [www.nvca.org](http://www.nvca.org)

#### 4.1 Corporate venture funds

Most publicly traded life science companies have set up their own internal venture capital funds, which invest in early stage opportunities. They often invest in consortiums with independent venture capitalists and evaluate deals in a similar way. One of the major differences between private venture capital and corporate

funds is that some corporate funds focus on projects that their company may want to in-license someday. A venture capital arm of a big pharma company might invest in a biotech as an 'option' to further expand into a certain disease area or medicines e.g. biologics or biopharmaceuticals.

Examples of corporate venture funds in the life science space are:

Genentech's Genenfund: [www.gene.com/gene/about/alliances/](http://www.gene.com/gene/about/alliances/)

Pfizer's Strategic Investment Group:

[www.pfizer.com/research/licensing/wwbd.jsp](http://www.pfizer.com/research/licensing/wwbd.jsp)

Novartis Venture Fund:

[www.venturefund.novartis.com](http://www.venturefund.novartis.com)

See Appendix section 6.3 for more information on the Novartis Venture Fund

## 5 Investment banks

### *Definitions*

Investment banks are financial institutions that can raise capital for both private and public companies by issuing securities. These organizations raise money for private companies from both private investors and from different size institutions. They also raise capital through public markets and help companies become listed on a stock exchange. Another area these banks manage is mergers and acquisitions. There are many different sizes and types of investment banks, some of which only focus in healthcare such as Leerink Swann and Company

[www.leerink.com](http://www.leerink.com)

Examples of larger banks are Goldman Sachs and J.P. Morgan which have healthcare as a division. These organizations also sponsor industry forums where companies can give presentations. Only selected investors and institutions can attend these events, so they are very good exposure for the companies that are accepted to present.

### *What are they looking for and how to approach*

These banks make money through transactions. They are looking for the best financial opportunities (investment in companies with highest return) to sell to their client base; thus assure financial return and possibly re-investment. As with all investors, these bankers are looking for a great management team with a passionate leader to give presentations to investors. They will perform a significant amount of due diligence before accepting a client by investigating the technology and by speaking to board members, company clients, industry leaders etc. When they are finished they are able to give the “pitch” almost as well as the company. They will work closely with management to create the offering document and the slide presentation. The offering document contains all of the requirements of the regulatory system in the USA wrapped around a business plan which not only describes the biomedical offering but also the associated risks.

### *General terms and conditions and potential size*

Investment banks come in all sizes and this will dictate the amount of money they will raise for a company. The minimum is around \$1-2 M and the maximum is in the billions. If you are a small company, find a smaller boutique investment bank who you can work with closely that, if possible, focuses in healthcare. These banks will have a clientele that is interested in investing in healthcare deals, and their terms are generally more favorable than a venture capitalist. They require both stock and cash as a percentage of the deal. Recent numbers have been around 6% in stock and 6% in cash as percentage of the deal, and they also may request a board seat to “manage” the investment they are making.

See Appendix section 6.4 for an example of a recent investment bank deal.

## 6 Corporate partners

### *Definition*

Deal making in the biomedical industries includes a variety of agreements between companies from complex discovery, target research and development deals to simple late-stage product acquisitions. Corporate deals for early stage drugs and devices are on the increase because of increased competition and thinning pipelines at biomedical companies. These companies have discovered that a lot of true innovation is occurring at the smaller biomedical companies and that over-head can be much less. In addition - deals are attractive growth vehicles for large companies because they offer access to intellectual property and talent. Talent can be very important since many of the most talented people prefer smaller organizations. Deals occur when two companies discover that they have complementary technologies, intellectual property rights and/or expertise which they would like to exploit, but cannot do alone. Generally research and development continues at the smaller biomedical company. The larger companies manage clinical and regulatory and commercialization because they have more experience in these areas.

For the smaller companies deal making provides income, speeds product development and marketing and helps companies grow. A pharmaceutical company cannot take away the risk associated with human clinical trials, but a deal is a clear validation of the market opportunity. Early stage deals today are more partnerships allowing the licensor to retain more rights and control over product development. These relationships have led to the development of a new executive position called Alliance Manager, who is in charge of the sometimes difficult communications between two very distinct cultures. Most biomedical companies want to become involved in joint research projects with larger companies, not only to obtain funding but also to enhance their reputation and validate their technology. Biomedical companies get an infusion of cash for continuing research and development work, a chance to pull in big dollars down the road, and validation for their platform or drug discovery engine

### *What are they looking for and how to approach*

Every company has its own wish list of technologies and products it is seeking. The more advanced the technology or product, the more appealing it is for the company. It is critical that you do the homework necessary to know who are the potential partners for your products and why they should be interested. This can be a very time consuming endeavor but should be part of the development process. Through-out the development of the product you should begin to create the relationships with potential partners at disease specific meetings, tradeshow and meetings at the larger company. The better they know you, the more likely it is going to lead to a partnership. If they do not know you, try to find someone that has an inside track into the company. They, like venture capitalists, are deluged with new opportunities – you want yours to get the attention it deserves.

### *General terms and conditions and potential size*

For a company this is the best possible way to raise money. It not only gives you cash to support research, but it validates the technology and also the commercialization avenue. The potential size varies. It can be under \$1 M and just support a first right of refusal opportunity to get to proof of concept or be a complete deal in the hundreds of millions range. Deals consist usually of an upfront payment of cash in exchange for an equity position in the company, or milestone payments at specific value inflection points such as regulatory events, patients enrolled, and approvals in various countries. There is another type of deal which is currently emerging called an option. Instead of buying companies or licenses to their experimental drugs, companies have started to acquire options, to be exercised depending on the results of clinical trials. It mitigates risk for the buyer without diluting the potential rewards. In a recent deal \$100 M was paid for an option and if the data is good another \$250 M. If the clinical trial fails, the \$250 M will not be paid.

See Appendix section 6.5 for example of a corporate partnering deal between the Norwegian biotech company Affitech and Roche, where Affitech receives payments based on research milestones.

## 7 Disease foundations and non-profits

### *Definition*

Disease advocacy groups and foundations are privately funded not-for-profit philanthropic organizations which are committed to improving awareness of diseases and raising funds to develop products for prevention and cure of the disease. A substantial part of their money can come from drug and device makers who donate millions of dollars to these disease-related not-for-profits annually. The disease foundations make meaningful contributions to the development of tests and therapeutics across the development pipeline, from cohort development to actual drug discovery. Unlike venture capitalists, which invest in biomedical companies for equity stakes, disease foundations tend to back biomedical companies for specific programs with direct benefits to its constituents, the patients. The foundations provide capital that boosts the value of the company without adding a new supply of shares that can dilute the value. Plus, the relationships with the patient groups bring companies access to experts in the field and patients for clinical trials. In return for investments, disease foundations hope to get new treatments for patients and perhaps some financial return such as royalties on drug sales.

### *What are they looking for and how to approach*

These groups invest in disease specific research and development. Some of them are specific to one disease such as the Diabetes Foundation and some invest in different diseases such as the Gates Foundation. They are looking for prevention and cure of particular diseases. In addition, they will evaluate the scientific validity similar to any investor. They support many recognized leaders in the specific disease area. These individuals can potentially make introductions into the foundations. They all have web sites with descriptions of their grants and submission dates. In addition, many of them are at trade shows for specific diseases. The foundation will perform due diligence just as any investor to evaluate the science, technology and management team. Their money and survival is based on the trust individuals and companies have that their money will be used to develop cures for disease. It is critical that they follow their mandate.

### *General terms and conditions and potential size*

Foundations do not take equity stakes in the companies in which they invest. The funding amount varies depending on the disease and the project. They are often able to give seed funding for example \$50,000 with clearly defined achievable goals or milestones related to R&D. They will want to be certain that the project is both scientifically sound as well as has enough resources to achieve its goals. They often invest in multi-center studies. They can invest globally but some may have international restrictions which can be found on their web sites.

See Appendix section 6.6 for an example of a funding case from the Juvenile Diabetes Research Foundation (JRDF) [www.jdrf.org](http://www.jdrf.org)

## 8 Incubators

### *Definition*

A biomedical incubator is a business that provides affordable space, incentives and services for start-up to early stage companies. They develop due to the recognition of the need for affordable laboratory space for the commercialization of innovations from life sciences and related technology industries. They are focused on supporting new innovative biomedical start-ups and early stage businesses by offering them a variety of services including experts in the areas of business planning, human resources, regulatory issues as well as accounting, tax and legal services. They offer laboratory and office space as well as shared facilities such as kitchens and reception areas. These incubators are helpful to entrepreneurs offering them access to other small biomedical organizations in the building and to vendors, suppliers and outside financing sources. They are often associated with universities and medical centers which place their biomedical start-ups in a building and help with initial financing. They then give the companies access to university capabilities such as scientists, scientific libraries, animal and research core facilities. Incubators can be private or quasi-governmental or city or regionally supported. Many incubators are also targeted toward specific industries (biopharma, high-tech, cleantech etc.), and will not only have the facilities needed, but also a funding network within the same sector.

### *What are they looking for and how to approach*

The incubator's mission is to support the growth and development of small businesses for the region. They are looking for creative entrepreneurs with sound business plans. It is hoped that the technology will become a bricks and mortar business adding jobs and economic growth to the regions. When evaluating which companies to accept into the incubator, they use many of the same criteria as an investor because they are making both a financial and time investment in the start-up. The incubator will need to see the company's business plan and financial plan similar to an investor. They will want to meet with you and understand your business model and how you will fit in the incubator. Incubators in universities will still consider businesses from outside the school for an incubation space.

### *General terms and conditions and potential size*

Biomedical incubators help emerging companies succeed by providing cost-effective, high quality laboratory space and support services. A start-up business usually will be in an incubator for around 3 years although they will not be generating revenue when they leave the space. The start-up generally has enough laboratory space for 1-5 people and also a small office space. Most incubators offer some start-up funding which varies with the incubator. This can be between \$100 and \$250,000 and can be a grant or a loan. In exchange some incubators take an equity position in their tenant companies.

## 9 State Government funding sources

### *Definition*

The majority of the States in America have programs supporting the Life Science industry. States with strong life science clusters in biotech and medtech are California, Massachusetts, New York, Maryland, North Carolina and Minnesota to name a few. Typically these states harbor some of the leading medical teaching hospitals in the nation and they get a considerable share of the NIH funding. Massachusetts received \$2.3 billion from the National Institutes of Health in fiscal 2007. California received \$3.5 billion for the same year. To further support and secure economic development in the life science sector some states have voted through legislations that will allocate more tax money to the benefit of the life science industry. The Massachusetts Life Sciences Center (MLSC) is an example of an organization embodying this intent. The MLSC was established to promote the life sciences within the Commonwealth of Massachusetts. It is tasked with investing in life sciences research and economic development. This work includes making financial investments in public and private institutions growing life sciences research, development and commercialization as well as building ties between sectors of the Massachusetts life sciences community.

### 9.1 The Example of the State of Massachusetts and MLSI

On May 8, 2007, during a speech at the BIO 2007 conference, Governor Deval Patrick announced a new Massachusetts Life Sciences Initiative (MLSI). The Initiative includes a \$1 billion investment package (over ten years) to enhance and strengthen the state's internationally recognized leadership in the life sciences. The Patrick Administration's strategy brings together industry, academic research hospitals and public and private colleges and universities to coordinate this effort, spur new research, strengthen investments, create new jobs and produce new therapies for a better quality of life. The Governor's initiative is administered by the Massachusetts Life Science Center (MLSC) and is focused on five points of the development cycle to ensure a comprehensive statewide strategy: funding, planning, research, development and commercialization.

Funding from MLSC includes the following programs:

- Life Sciences Tax Incentive Program (for more information <http://www.masslifesciences.com/taxincentive.html>)
- Life Sciences Accelerator Program (for more information <http://www.masslifesciences.com/taxincentive.html>)
- Cooperative Research (for more information [http://www.masslifesciences.com/grants/coop\\_awards.html](http://www.masslifesciences.com/grants/coop_awards.html))

For an example on MLSC funding from the State of Massachusetts, see Appendix chapter 7.

## 10 Federal Government funding sources

### 10.1 US Government grants from NIH for medical research collaboration with academia

#### *Definition*

Government grants for biomedical research in the USA come from the National Institutes of Health (NIH). The National Institutes of Health is made up of 27 different Institutes and Centers (see Appendix chapters 4 and 5 for complete list). Each has its own specific research agenda, so for example there is the National Cancer Center (NCI) and the National Institute of Allergy and Infectious Disease (NIAID). The NIH provides funding for academic research performed in universities and academic centers. Grant review is performed by the peer review system which means that individuals working in the area will be reviewing the grant proposal. The NIH also has the Small Business Innovation Research which will be discussed in this chapter under section 10.2.

#### *What are they looking for and how to approach*

Each type of NIH grant program has its own set of eligibility requirements. Applicant's eligibility information is contained in each funding announcement. While the principal investigator conceives and writes the application, NIH recognizes the applicant institution as the grantee for most grant types. NIH supports scientists at various stages in their careers, from pre-doctoral students on research training grants to investigators with extensive experience who run large research centers. NIH is committed to supporting new and early stage investigators. Reviewers give new and early stage investigators special consideration, and NIH has programs targeted specifically for these populations. With Barrack Obama as the new president there are many changes going on at the interface of government and healthcare. It will be important to watch his policies because these will establish how government money is allocated.

The recent U.S. American Recovery and Reinvestment Act (ARRA) has a recovery bill containing \$10.4 billion dedicated to NIH. \$7.4 billion is split among institutes,

centers, and the Common Fund for scientific research projects. See section 10.3 of this chapter and Appendix chapter 8 for more information on the ARRA and the impact on the Life Science industry.

Generally, principal investigators and other personnel supported by NIH research grants are not required to be U.S. citizens; however, some NIH programs/mechanisms have a citizenship requirement. Any citizenship requirement will be stated in the program announcement or request for applications. In general, domestic or foreign, public or private, non-profit or for-profit organizations are eligible to receive NIH grants. For purposes of this policy, a "foreign component" is defined as *performance of any significant element or segment of the project outside the United States (U.S.) either by the grantee or by a researcher employed by a foreign institution. Proposed research should provide special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the U.S. or that augment existing U.S. resources.*<sup>1</sup>

These grants are composed of a short abstract, background, specific aims, and a detailed description of the methodologies to be used to meet the grants specific aims. It is critical to remember that these grants are reviewed by peers and these individuals are measuring how your basic work might ultimately result in a new drug or device or methodology. The reviewers will first focus on the importance of the work, then whether it is scientifically feasible and last whether you have the capabilities, experience and expertise to do the work. Many of these grants fund multiple laboratories who share the funding because no single lab has all of the technology and expertise.

### *General terms and conditions and potential size*

There are a wide variety of grants available for research. There are four submission dates per year for regular programs and there are requests for proposals thru-out the year. Grants are usually for 1-5 years with an average of 3 years. They pay both direct and indirect costs in the USA. The indirect costs are

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<sup>1</sup> <http://www.nih.gov/>

over-head charged by the university and negotiated between the university and NIH. The amount varies depending on the area of focus and the research requirements. Early investigator grants can be \$100,000 (direct costs) and large program projects can be in the multi-millions. There are yearly progress reports which are used to judge if you will get another grant. See Appendix section 8.1 for examples of NIH grants awarded to two biotechs. For more information on NIH go to [www.nih.gov](http://www.nih.gov)

## 10.2 US Government SBIR and STTR grants for medical research in industry

### *Definition*

The Small Business Innovation Research (SBIR) program is a program to support domestic small businesses to engage in Research and Development that has the potential for commercialization and public benefit. Currently, eleven US Federal agencies participate in the SBIR program and five Federal agencies participate in the Small Business Technology Transfer (STTR) program (see Appendix chapters 1, 2 and 3). One of the other large budgets for health related grants in addition to NIH is the Department of Defense which supports a large amount of work related to the health of the soldier in the field and at the base.

### *What they are looking for and how to approach*

The STTR and SBIR programs are similar in that both programs seek to increase the participation of small businesses in Federal research and development and to increase private sector commercialization of technology developed through Federal research and development. On an SBIR application, the primary investigator must have his/her primary employment (more than 50%) with the small business at the time of award and for the duration of the project. On an STTR application, the principal investigator may be employed by the small business or the participating non-profit research institution as long as he/she has a formal appointment with, or commitment to, the small business.

The SBIR and STTR programs differ in two major ways. First, under the 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, 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 percent of the STTR research project is to be conducted by the small business concern and at least 30 percent of the work is to be conducted by the single, "partnering" research institution.

### *General terms and conditions and potential size*

Only United States small businesses are eligible to submit SBIR applications. A qualified small business is one that, on the date of award for both Phase I and Phase II funding agreements, meets ALL of the criteria as described in the current SBIR or STTR parent funding opportunity announcements available from the previously mentioned NIH Small Business Funding Opportunities website. The current requirement on ownership is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, except in the case of a joint venture, where each entity to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States.

The SBIR/STTR grant is different than the grants awarded to universities and academic institutions. The SBIR/STTR grants have 2-3 phases. The first phase is short – often 6 months and the grant is \$100,000. The second phase is generally 1-2 years and \$750,000. These numbers can vary. Generally Phase I pays for a small proof of concept and phase II a something much closer to the market, such as testing clinical samples. For more information go to Appendix chapter 1 or <http://www.sbir.gov> and to Appendix section 8.2 for an industry example of SBIR funding.

## 11 The American Recovery and Reinvestment Act (ARRA)

### *Definition*

The American Recovery and Reinvestment Act (or the Obama Stimulus Package) is an unprecedented effort to jumpstart the US economy, create or save millions of jobs during the economic recession that started in 2008. For the Life Sciences the Act provides:

- Medicaid Coverage and COBRA \$112 billion in additional funding. This will provide temporary increases in Federal Medicaid contributions for states, including additional DSH allocations. Also provides a subsidy for COBRA benefits for recently unemployed individuals.
- National Institute of Health (NIH) and Department of Health and Human Services \$10.4 billion in additional funding. This funding is for construction projects, acquiring scientific equipment, encouraging education and workforce growth, and conducting medical research. Of this, \$8.2 billion is for support of scientific research priorities. See Appendix chapter 8 for more information on ARRA funding allocations to NIH.
- Health Information Technology \$19 billion of incentive payments. This funding is intended to support the Health Information Technology for Economic and Clinical Health Act for the development of health information technology and to provide monetary incentives to spur the adoption of electronic health records. It also revises existing health information privacy protections.
- National Science Foundation \$3 billion in additional funding. These are earmarked to support research and construction projects.
- Agency for Healthcare Research and Quality \$700 million in additional funding. These funds are to be used for comparative effectiveness research.
- Defense Health Program \$400 million in additional funding. These funds are to be used to improve and repair military medical centers.

For more information on:

### *Contracts*

Please look up [www.FedBizOpps.gov](http://www.FedBizOpps.gov) for all federal government contracting opportunities. All federal agencies must announce proposed contracts expected to exceed \$25,000 on [www.FedBizOpps.gov](http://www.FedBizOpps.gov)

The site lists all major solicitations, contract awards, subcontracting opportunities, surplus property sales and foreign business opportunities. For actions related to funds made available by the American Recovery and Reinvestment Act, use the Search Recovery Actions option on [www.FedBizOpps.gov](http://www.FedBizOpps.gov).

### *Grants*

Federal agencies offer more than 1,000 grant programs and access to approximately \$400 billion in annual awards. Note that federal grants are not federal assistance or loans to individuals. Rather, organizations can search and apply for grants from 26 different federal agencies through the [www.Grants.gov](http://www.Grants.gov) site. For grant opportunities related to the American Recovery and Reinvestment Act, use the Find Recovery Act Opportunities option on [www.Grants.gov](http://www.Grants.gov).

### *Loans*

[www.GovLoans.gov](http://www.GovLoans.gov) is a Web site designed to help you learn more about federal loans. The site will help you determine which loans may be right for you and where to find more information about them. You can also visit [www.GovBenefits.gov](http://www.GovBenefits.gov) where a screening tool will help you find government benefits you may be eligible to receive. The site also provides information about how to apply for those programs.

A large portion of the American Recovery and Reinvestment Act funding will go to states, territories and tribes, which will in turn distribute funds through grants, contracts, subsidies, loan programs, etc. For more information about the ARRA opportunities in general look to [www.recovery.gov](http://www.recovery.gov).

## 12 Department of Defence funding sources

The United States Department of Defense (DoD) has 7 agencies that fund external research. Of these two are focused on medical technology and therapeutics. These are the Defense Advance Research Projects Agency (DARPA) and the US Army Medical Research and Material Command which oversees the Congressionally Directed Medical Research Programs (CDMRP). These DoD agencies are therefore looking for research that has a close connection to defense. Program Officers in the various DoD agencies are given a large amount of discretion in making funding decisions, and having a relationship with the Program Officer is extremely important to potential applicants. Establishing a relationship with a Program Officer is not difficult; they are often receptive to phone calls and e-mails and are usually happy to discuss a potential applicants' research and whether it fits the agency's needs; they also attend professional conferences on research topics of interest to their organizations. All funding opportunities for DoD are listed at [www.Grants.gov](http://www.Grants.gov)

From the menu on the web site select "Department of Defense" under "Agency" to see all recent funding opportunities issued by DoD agencies.

### 12.1 Defense Advanced Research Projects Agency (DARPA)

#### *Definition*

DARPA's mission is maintenance of the technological superiority of the U.S. military and prevention of technological surprise from harming national security by sponsoring revolutionary, high-payoff research bridging the gap between fundamental discoveries and their military use.

#### *What are they looking for and how to approach*

DARPA has been the place for people with ideas too crazy and too risky for most research organizations. DARPA is an organization willing to take a risk on an idea long before it is proven. All of DARPA's research is performed by outside researchers at large and small businesses, universities, non-profit institutions, government laboratories and other outside research organizations. Since DARPA's interests lie in transitioning new technology into military use as quickly as

possible, faculty researchers are advised to team with defense industry or defense lab researchers when proposing new research. Typically, a researcher who would like to propose a research project addressing research priorities outlined in the Long Range Broad Agency Announcements (BAA) contacts the Program Officer to discuss his/her project idea. If the Program Officer is interested, he or she will request a white paper (also called a preliminary proposal). White papers are short summaries of the project idea, and rules for white paper length and format can be found in the agency long range BAA or will be designated by the Program Officer. If the Program Officer likes the white paper, he or she will request a full proposal.

In addition, the defense agencies (with the exception of the CDMRP) announce funding opportunities in a variety of ways, including Broad Agency Announcements (BAAs) – each agency typically issues a “Long Range BAA,” which outlines technical research interests and priorities of the agency over a several-year range covered by the BAA, as well as targeted BAAs, which address more specific competitions and other targeted solicitations. DARPA funds these researchers based on a competitive review of proposals that are submitted in response to a solicitation calling for research ideas.

For information on opportunities available only to small businesses, visit the Department of Defense Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) website [www.dodsbir.net](http://www.dodsbir.net) or DARPA's Small Business Support Center (SBSC) [www.darpa.mil](http://www.darpa.mil) The term and conditions for grants are the same as for the general SBIR and STTR programs.

### *General terms and conditions and potential size*

DARPA does not have citizenship restrictions for receipt of funding. The project money is at all levels and for one to multiple years. The terms and conditions are clearly out-lined in the Broad Agency Announcements. These can be discussed directly with the program managers. Congressionally Directed Medical Research Programs (CDMRP)

### *Definition*

The CDMRP's mission is to support medical research “to eradicate diseases and support the warfighter.” CDMRP differs significantly in mission, culture and

procedures from the other DoD agencies. The culture and operating procedures of the CDMRP are closer to those of the basic research agencies such as NSF and NIH than those of DoD, with the exception that the mission and the vision of the office are very closely tied to Congressional direction and can therefore change significantly from year to year. Money for the CDMRP is not considered part of the DoD's mission, and is therefore not included in the DoD's requested budget. Dollars to fund CDMRP are added every year during the budget approval cycle by the members of the House or Senate, in response to requests by consumer advocates and disease survivors.

### *What are they looking for and how to approach*

Currently, the CDMRP has eight research programs - seven focus on research to cure a set of diseases selected by the U.S Congress, and the eighth program focuses on addressing minority and underserved populations:

- Breast Cancer
- Prostate Cancer
- Ovarian Cancer
- Neurofibromatosis
- Tuberous Sclerosis Complex
- Chronic Myelogenous Leukemia
- Prion Diseases
- Minority and Underserved Populations

Funding opportunities are made public by Program Announcements, which can be found at the websites for each of the research programs or at the

[www.grants.gov](http://www.grants.gov)

website. The CDMRP uses a wide range of funding mechanisms, all of which are listed in the "Award Mechanisms" pull down menu on the award search site at

<http://cdmrp.army.mil/scripts/search.asp>

### *General terms and conditions and potential size*

CDMRP does not have citizenship restrictions for receipt of funding. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution. The project money

is at all levels and for one to multiple years. For more general information on CDMRP funding go to <http://cdmrp.army.mil/fundingprocess.htm>

## 12.2 Biomedical Advanced Research and Development Authority (BARDA)

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development and purchase of the vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies.

The NIH is also in the department of Health and Human Services. BARDA manages Project BioShield, which includes the procurement and development of medical countermeasures for chemical, biological, radiological, and nuclear agents, as well as the advanced development and procurement of medical countermeasures for pandemic influenza and other emerging infectious diseases that fall outside the auspices of Project BioShield. In addition, BARDA manages the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).

BARDA grants funding in co-operation with National Institute Allergy and Infectious Disease (NIAID), one of the divisions of NIH which manages the application processes. For an example of a business case funded by BARDA go to Appendix chapter 9. For more information on BARDA go to [www.hhs.gov/aspr/barda](http://www.hhs.gov/aspr/barda)

## 13 Appendix