Evaluating the Success of the Small Business Innovation Research (SBIR) Program: Impact on Biotechnology Companies in Pennsylvania

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Abstract: The Small Business Innovation Research (SBIR) program was created to stimulate technological innovation and business development at early stage companies in the United States. In its 21-year history, the program has channeled over $35 billion of public funds to private businesses in the form of approximately 137,000 grants. However, the question of whether SBIR funding effectively spurs new innovation and promotes commercialization remains controversial. Here, we review efforts to answer this question and perform an independent analysis to evaluate the success of the SBIR program in a representative high technology industry. To do this, we systematically analyzed publicly available data for biotechnology companies based in Pennsylvania that received SBIR funding through the Department of Health and Human Services (HHS) between 1983 and 2014. Our analysis did not find any clear relationships between the amount of SBIR funding received and acquisition of private funding or intellectual property. However, higher SBIR funding rates were associated with current operating status and number of publications, indicating that these additional grants do support commercial operations and the advancement of scientific knowledge. Taken together, our study provides a comprehensive overview of the SBIR program for Pennsylvania biotechnology companies and reveals myriad uses for federal funding to support company development and foster innovation for the public good. These findings underscore the complexity of evaluating the SBIR program and the need for increased standardization and centralization of outcomes data for this large and growing federal program.

Keywords: Biotechnology, Federal funding, Health and human services, Outcomes, Pennsylvania, Small business innovation research, SBIR, Technological innovation.

INTRODUCTION

The federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs were conceived to award financial grants that encourage early stage small businesses to conduct research and development (R&D) with a high commercialization potential [1]. The creation of these programs followed on the heels of the 1980 Bayh-Dole Act (PL96-517), which sought to stimulate the practice of technology transfer and commercialization as a federal response to the economic slowdown of the late 1970s. The SBIR/STTR program was signed into law in 1982 (PL97-219) and was subsequently reauthorized in 1992 (PL102-564), 2000 (PL106-554), and 2012 (PL112-81), extending the program until 2017. The unwavering congressional support for the program reflects the commonly held belief that a source of tax payer-funded non-dilutive equity provides a unique means for entrepreneurs to stimulate economic growth in high-tech industries. However, as the SBIR/STTR program continues to grow in size, the development of reliable metrics to ascertain the return on this investment remains woefully overlooked.

Here, we provide an overview of the objectives of the SBIR program, eligibility and selection criteria, and review attempts to quantify commercialization outcomes. We performed an independent analysis to evaluate the success of the SBIR program in meeting the current objectives of the program. To overcome the limitations of previous studies [2-4] we used an unbiased approach that does not rely on self-reported data and included metrics of innovative capital as indicators of success. We focused our analysis on SBIR grants awarded by HHS, comprising 30% of the national awards, specifically in the Commonwealth of Pennsylvania, the 6th largest recipient. In PA, HHS awarded 290 companies SBIR grants from 1983 to 2014, totaling $360 million (695 Phase I grants and 251 Phase II grants), providing a large and diverse sample size [5]. We gathered data on SBIR award recipients from a variety of sources, and determined if the SBIR funding attracted alternate sources of funding (private and state funding), improved company outcomes (status) and helped spark innovation (increased publications or patents). We analyzed all the available indicators of success, both independently and in aggregate, to determine the impact of SBIR funding. Finally, we highlight seven companies that employed SBIR funds to achieve highly distinct outcomes and discuss the role of the awards in their success.
SBIR Objectives and Overview

The current objectives of the SBIR program are four-fold: to stimulate technological innovation, to meet federal research and development needs, to increase private sector commercialization of innovations developed through federal R&D funding, and to encourage participation in innovation and entrepreneurship by women and socially and economically disadvantaged persons. Rather than appropriating distinct government resources, the SBIR/STTR programs allocate a percentage of the extramural budget of government agencies with annual research budgets of greater than $100 million. The original SBIR appropriation of 0.2% in 1982 has since increased fourteen-fold to 2.9% in 2015, while the STTR program currently accounts for a much smaller, 0.4% appropriation [6], both of which will continue to grow until 2017.

SBIR/STTR grants are structured into three phases, which denote increasing likelihood of commercialization. Phase I aims to assist businesses in assessing and proving the feasibility and commercial potential of the project. Funding for this phase is typically $150,000 and may encompass a period of six months or 1 year. Phase II funds are more substantial, typically $1 million over two years, and are intended to support continuing efforts to achieve both research (i.e. product feasibility, testing, etc.) and business or regulatory milestones (i.e. partnerships, securing investors, approval of regulatory bodies, etc.). Phase III is intended for near-commercialization and market entry of the product developed through Phase I and II [6]. Phase III is not supported by funding from federal government. Rather, it is expected that the Phase II recipients will actively solicit and obtain alternate sources of capital such as venture funding, contracts or private partnerships to conduct the Phase III portion of the program.

Eligibility and Selection

To be eligible to receive an SBIR grant, applicants must be a for-profit, US-based company with 500 employees or less. The Principal Investigator’s primary employment must be with the small business, and ownership of the company must be more than half by US individuals [7]. STTR applicants must be engaged in a formal collaboration with a US research institution, and have arrangements in place for intellectual property exchange and a strategy for commercialization. Generally, the grant process lasts four to nine months, starting with solicitation on broad or focused topics. Proposals relating to the solicitation are submitted and peer reviewers individually assign each grant a preliminary score for each of five review criteria; including significance, investigator(s), innovation, approach, and environment for research grants and cooperative agreements [8]. SBIR applications are then reviewed a second time by an advisory council (scientists, public officials) who evaluate it based on scientific and technical merit, availability of funds, and relevance to the programs priorities. The program director ultimately has the final say in which applications are funded.

Is the SBIR Program an Effective Use of Taxpayer Money?

Following continued congressional approval, the SBIR/STTR program has become the single largest source of non-dilutive federal funding for small companies. This highly competitive program not only offers stable and predictable funding, but helps to differentiate fledgling companies and attract private investment. However, whether the SBIR program efficiently advances its mandates has been questioned [9]. It remains controversial whether this form of private enterprise stimulation is a productive use of federal funding that might be better spent supporting university-based research. Additionally, there is growing concern that changes to the law allowing for majority venture-backed companies to compete for SBIR awards could crowd out companies that lack other sources of funding [10].

As part of the SBIR Reauthorization Act of 2000, U.S. Congress requested that the National Research Council (NRC) conduct a comprehensive study of the SBIR program. In response, the NRC published a series of reports evaluating the five agencies that provide more than 90% of SBIR funding [11-15]. The methodology included a broad range of approaches, including Phase I and Phase II surveys, case studies, data analysis, and interviews [16]. The NRC found that the SBIR program has made significant progress in meeting the goals put forth by legislation, and concluded that the program increased private sector commercialization and stimulated technological innovation [4]. Furthermore, SBIR-funded projects successfully attract additional funding, including funding from venture capital and acquisition by investors and expand the scientific knowledge base [4].

The NRC study found that while the program clearly met its assigned objectives, there was room for improvement. The major initiatives proposed by this study were a) to increase total funding and funding per grant, b) change eligibility to include venture capital-backed companies, c) to establish a centralized database system for reporting progress of a project, d) to create a Commercialization Readiness Program allowing agencies to use up to 10% of their funding to support Phase III efforts. Impressively, all of these initiatives were incorporated into the 2012 reauthorization of the act, highlighting the utility of outcome-based metrics in informing policy and the efficacious use of federal funds.

Link and colleagues independently analyzed the datasets collected by the NRC [2, 3]. In their reports, they argued that the SBIR program decreases the barriers to innovation that force small firms to underinvest in R&D. Furthermore, they found that university involvement increases the probability of successful commercialization outcomes. The entrepreneurial risk of the SBIR program as a whole was estimated to be on average just greater than 50%, but with a large range of outcomes [3]. They also analyzed outcomes of companies funded by DoD Phase II awards [2] For this group, the probability of commercialization success was ~0.47. Based on their analysis, the authors posited that a carefully calibrated predictive model could improve the overall performance of the program.

Much of the previous literature on the efficacy of the SBIR program has relied on data self-reported by the principal investigator. An inherent limitation of such surveys is the potential for bias, including the possibility that companies with greater commercialization success may be more likely to respond to the surveys, or that respondents may be more likely to provide favorable answers. Given the lack of objective commercialization data from small
companies, such as sales statistics and R&D expenditures, care must taken when drawing conclusions from these analyses.

**METHODOLOGY**

**SBIR Awards Data**

In order to compile publicly available data on the year, phase, and amount of SBIR awards, we performed a search of the SBIR.gov database [17] and filtered the results by program (SBIR), agency (HHS), phase (Phase I and Phase II), year (1983 - 2014), and state (Pennsylvania). A total of 325 companies met these criteria. Special company-ownership conditions were excluded from analysis (women-owned, minority-owned, and companies in Historically Underutilized Business Zones, n = 35) because of the different criteria that apply to these companies, resulting in a final total of 290 companies analyzed.

**Alternative Sources of Funding**

Data on private funding received by the companies of interest in the form of venture capital and private equity investments was compiled from Thomson ONE’s private equity screening and analysis tool [18]. To determine the amount and type of funding granted by the state of Pennsylvania, we searched the database of the Pennsylvania Department of Community and Economic Development (DCED) using the state grant investment tracker [19], containing information starting from January 1, 2000.

**Company Status**

All of the companies receiving SBIR funding were binned by current operating status as private, public, acquired, defunct, or unknown. Unlike companies designated “public”, those designated “private” do not offer publicly traded equity and are held exclusively by co-founders and a select group of investors. “Acquired” companies had a majority ownership stake and operational control assumed by another company. “Defunct” companies are either dissolved or no longer incorporated in the Commonwealth of Pennsylvania. Information on current operating status of companies was compiled from numerous public sources, including the company websites, Biospace [20], Bloomberg [21], and Business Insider [22]. The results were then cross referenced with the United States Securities and Exchange Commission’s database of Electronic Data Gathering, Analysis, and Retrieval (EDGAR) [23], as well as the Pennsylvania Department of State’s Business Search Database [24]. Entities that were unable to be verified with either database were labeled “Unknown”.

**Publications and Patents**

To determine publications associated with companies awarded SBIR funding, we used the journal publication search engine of the National Center for Biotechnology Information [25]. Searches were restricted to publications authored by the principal investigator of a given SBIR grant in the 15 years following approval of the first award. The company name was verified in the author affiliation section of each publication.

The production of intellectual property was assessed as the number of United States patents issued with the company in question as the primary assignee and Pennsylvania as the assignee state. Only patents issued after the date of issue of the first SBIR award were considered. All data were obtained from public records of the United States Patent and Trademark Office [26].

**Aggregate Analysis**

We compiled a comprehensive analysis of commercialization outcomes in the form of a weighted average of the various metrics: private funding; state funding; patents; publications; and operating status. Companies were scored on a relative scale from 0 to 9 for each metric using the following equation to account for non-normal distributions: 

\[ S = 1 + \log_{10}(V) \]

where \( S \) is the parameter score and \( V \) is the numerical value of the parameter. Parameters equaling 0 or unavailable were scored as 0. The remaining parameter scores were placed into one of nine bins. Company status was scored accordingly: defunct (0), active (3), acquired (6), public (9). The aggregate outcome score of our model was calculated as the average of each parameter score for a given company, assigning equal weight to each parameter in accordance with the stated goals of the SBIR program. Outcome scores were compared to total SBIR funding to determine the relative effectiveness of this investment.

**RESULTS**

**The Funding Landscape of SBIR Grants Awarded by HHS**

To understand the funding landscape of the SBIR program through HHS, we examined the amount of SBIR funding awarded on a per-state basis (Fig. 1A). California and Massachusetts companies received by far the highest amount of SBIR funding, with $1.8 billion and $1.3 billion respectively, accounting for 34% of the total amount of HHS funding awarded. These statistics are not surprising, given that California and Massachusetts are home to several of the country’s top research institutions and serve as hubs of biotechnology innovation [27]. Maryland, New York, and North Carolina are the next most highly funded states, together accounting for $1.5 billion (16%). Pennsylvania companies ranked 6th overall, receiving $360 million (3.8%) of SBIR funding from HHS.

We also examined the total number of SBIR grants awarded by HHS since its inception in 1983 (Fig. 1B). We observed a steady increase in the number of grants awarded by HHS, except for a strong deviation when the number of Phase I awards increased markedly from 769 total awards in 1997 to 1399 awards in 2003. The total award numbers returned to 1997 levels around 2005 and have remained constant since. When examining the total amount of SBIR dollars awarded by year, we found a steady increase in funding except for a strong dip in grant dollars in 2000, when Phase II funding dropped precipitously to 1993 levels (Fig. 1C). Interestingly this drop was not a result of a
reduction in Phase II grants awarded, but rather a decrease in the amount per Phase II award (Fig. 1D). Overall, these results show that while the total number of awards has fluctuated, the amount of funding has steadily increased. Given the latest reauthorization act, funding is expected to continue to increase until at least 2017.

We used the following metrics to assess the impact of receiving an SBIR grant: acquisition of additional private or state funding; company status (i.e., public, private, acquired, or defunct); number of publications by the company; and patents held by the company. Much of this information was readily available through public search engines, and information was obtained for all or nearly all companies (Table 1).

### Acquisition of Private Funding

To examine the relationship between SBIR funding and company outcomes, we started by focusing on the acquisition of additional funding through private or public sources. Of the 290 companies in our database, only 77 were listed in the Thomson ONE database (Table 1). Of those

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**Table 1. Summary of data collected for PA HHS SBIR funded companies.**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Outcome</th>
<th>Companies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Fraction*</td>
</tr>
<tr>
<td>Status</td>
<td>Determined</td>
<td>263</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>27</td>
</tr>
<tr>
<td>State Funds</td>
<td>Awarded</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>Not awarded</td>
<td>258</td>
</tr>
<tr>
<td>VC/PE</td>
<td>Backed</td>
<td>71</td>
</tr>
<tr>
<td></td>
<td>Never backed</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>213</td>
</tr>
<tr>
<td>Publications</td>
<td>Publications</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td>No publications</td>
<td>202</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>33</td>
</tr>
<tr>
<td>Patents</td>
<td>Patents</td>
<td>101</td>
</tr>
<tr>
<td></td>
<td>No patents</td>
<td>189</td>
</tr>
</tbody>
</table>

*Fraction of the 290 companies analyzed.
companies, 71 received funding ranging from $50,000 up to $138 million. The Pennsylvania DCED database was used to access information on state funding [19]. We found that 32 companies received funding ranging from $3,000 to $5.7 million.

We examined the correlation of total SBIR funding and the amount of private funding received (Fig. 2), but did not observe any strong correlation between these two variables. Interestingly, the companies with the highest amount of SBIR funding received little to no private funding. These included Integral Molecular and LifeSensors, two companies that received over $10 million in SBIR grants but $0 to $100,000 in private funding. In contrast companies that received the highest amount of private funding tended to receive less than $3.5 million in SBIR funding. These included Immunicon Corporation and Adolor Corporation, which both received over $137 million in private funding but only about $1 million in SBIR funding. We also identified a number of companies that represent moderate SBIR funding and moderate amounts of private funding. These contrasting funding outcomes likely represent distinct company models for the use of SBIR funding.

**Company Profile: Integral Molecular**

Integral Molecular, founded in 2001, is a private biotechnology company that develops monoclonal antibodies against unconventional membrane-associated targets for drug discovery and research applications [33]. Integral Molecular is best known for its commercially available lipoparticles containing membrane-associated proteins of interest, with a focus on targets relating to infectious and inflammatory diseases [34]. Much of the foundational research for the company was conducted in the late 1990s at the nearby University of Pennsylvania [35], from whom Integral licensed the core intellectual property. Integral is noteworthy for receiving more SBIR funding than any other PA company and giving back to the research community in the form of numerous scholarly publications.

**Company Profile: LifeSensors, Inc.**

LifeSensors, Inc. is a private biotechnology company founded in 1996. The company develops and manufactures an array of tools to support ubiquitin-based research and therapeutics, including the detection and purification of ubiquitylated proteins [36]. In addition to commercial sales, the company generates revenue by licensing its broad patent portfolio. This business model was facilitated early on by no fewer than 21 SBIR awards.

**Acquisition of State Funding**

Very few companies that received SBIR grant money also received state funding (Table 1). At $14.5 Million total, state funding provided acute stimulus to those that received it. State grants awarded fell into two categories: young (less than eight years old) companies that received state dollars as tax credit (the Keystone Innovation Zone Tax Credit program) and companies that received commonwealth funding in the form of job creation stimulus (Job Creation Tax Credits and Opportunity Grant Program). Eighteen companies that received the KIZ Tax Credit were awarded between $13,500 to $260,000, while grants for job creation secured by nine companies ranged from $3,000 up to $5.7 million. Interestingly, companies with a large amount of federal grants, including Progenera Inc, Neurodox Development LLC, and Infrascan Inc., were awarded less than $100,000 of state money through the KIZ Tax Credit Program. The small number of companies that received both state and federal funding make it difficult to discern any pattern or relationship between SBIR and state funding.

**Current Company Status**

Using the public record we were able to assign a status to over 90% of SBIR awardees: public, acquired, private, and defunct (see methods). On average, public companies received the most funding ($1.69M) followed by acquired and private companies ($1.27 and $1.18M respectively), whereas defunct companies received significantly less ($0.6M). When company status was compared to total SBIR funding (Fig. 3), the discrepancy in funding versus status became apparent: 62.5% of publicly traded companies received more than $1M, whereas 52.6% of currently defunct companies received less than $100,000. Some of the most highly SBIR funded public companies include Discovery Laboratories Inc. ($1,309,955), Viropharma Inc. ($2,441,359), and Integra Inc. ($2,748,889). However, an interesting outlier is the Genaera Corp., which received $1,801,796 in SBIR funding, but was dissolved after several of its drugs failed to win FDA approval. Overall, these results support the notion that the SBIR program is generally meeting the stated goals of increasing private sector commercialization.
Company Profile: ViroPharma, Inc.

ViroPharma Incorporated, is a biopharmaceutical company that develops and commercializes products that target treatment for serious diseases with a focus on products for clinical settings. The company was founded in 1994, and was publicly traded on the NASDAQ exchange prior to its acquisition in January 2014 by Shire Incorporated [37]. As a subsidiary of Shire Incorporated, ViroPharma continues to produce and distribute products. At the time of its acquisition, ViroPharma was best known for its expertise in targeted treatments for orphan diseases, a result of strategic acquisitions of other biotechnology corporations, including field leading Lev Pharmaceuticals in 2008 [38] and DuoCort Pharma in 2011[39].

Company Profile: Genaera Corp.

Genaera Corp. was founded in 1987 and dissolved in 2009. Originally focused on the treatment of metabolic diseases, specifically type 2 diabetes and obesity, the company was never able to translate promising preliminary data into a commercially viable drug. Following the failure of several lead compounds; including Locilex, Squalamine, and Trodusquemine, Genaera Corp. downsized and ultimately dissolved in mid-2009 [30].

Publications and Patents

Publication records were found for 55 (18.9%) of the companies analyzed, totaling 204 SBIR-backed publications (Table I). There was a slight positive trend between SBIR dollars awarded and number of publications by company (Fig. 4A). In contrast there was no correlation between amount of private or state funding and the number of publications (data not shown). Although the relationship between SBIR funding and publications is weak, it appears that federal funding is more strongly associated with publications than private or state funding. These data suggest that the SBIR program is meeting its goal of supporting the development of innovative capital.

Approximately 1 in 3 companies went on to secure at least one patent after receipt of the first SBIR award (Table I). On average, 3.16 patents were secured per SBIR-funded company. Of those companies that secured intellectual property (IP): 27.7% secured a single patent; 16.8% secured two patents; 18.8% secured three to four patents; 30.7% secured five-sixteen patents; and 6% secured greater than sixteen patents. Patent activity showed little correlation with SBIR funding (Fig. 4B). However, patent number was clearly low in companies that received greater than $5 million or five separate awards over the time period studied. This suggests that beyond these thresholds, additional funding yields diminishing returns with regard to the creation of intellectual property.

Remarkably, private investment also showed little correlation with patent activity (data not shown), suggesting that this source of funding tends to value the quality and profitability of specific ideas, rather than the size of the patent portfolio of a given firm. Of those companies who secured at least one patent and received state funding, there was a strong positive correlation between the two variables (data not shown). Thus, there appears to be a bias in the state government programs towards funding companies with the strongest records of securing intellectual property.
Aggregate Analysis

In order to summarize the diversity of data sources and potential outcomes represented in this study, we performed an aggregate analysis (see methods). The distribution of scores in this analysis ranged from 0 to 9, representing increased probability of success (Fig. 5). Of the > 290 companies analyzed, the average score of 1.4 and average SBIR funding of approximately $1.1 million was used to separate performance quadrants. We concluded that successful companies were those that received an above average aggregate score (35% of total companies). Our analysis revealed that an above average aggregate score could be achieved regardless of amount of SBIR grant funding acquired (18% below average SBIR funding, 17% above average). Interestingly, the companies with the highest aggregate score tended to cluster in the $3 million range of SBIR funding, a level that is hypothetically attainable with only three Phase II awards. To gain more insights into the results produced by this analysis, we profiled companies of interest that achieved above average aggregate score.

Company Profile: Centocor

Centocor was founded in 1979 to develop monoclonal antibody-based diagnostics for the rabies virus [28]. Centocor’s success can be attributed to its pursuit of partnerships and collaborations with academic labs, including the Wistar Institute and the Dana-Farber Cancer Institute. After an initial public offering in 1982, Centocor attempted to develop the drug Centoxin to treat gram negative bacterial infections; however, it did not win FDA approval. Following this failure, the company approached bankruptcy, but was acquired by Johnson & Johnson in 1999. Centocor now operates as a subsidiary of Johnson & Johnson, under the name Janssen Biotech, and has successfully launched commercially significant products, including Remicade®.

Company Profile: Cephalon

Founded in 1987 as a small research house dedicated to combating neurodegenerative disorders, Cephalon quickly completed an initial public offering and grew to more than 200 employees over the next six years. Despite early struggles securing FDA approval for an ALS therapeutic, Cephalon received preliminary approval to sell the anti-narcolepsy drug Provigil® and the painkiller Actiq® by 1998 [29]. These successes extended Cephalon’s reach into global markets and provided a launch pad for a number of productive collaborations and licensing deals, eventually leading to its acquisition by Teva Pharmaceutical Industries in 2011. The continued pace of innovation has allowed the company to secure over 200 patents to date- more than any SBIR-backed Pennsylvania company in history.

Company Profile: Immunicon Corp.

Immunicon is a publicly traded biomedical company founded 1983. It is best known for development of cell- and molecular-based human diagnostic and life science research products [31]. Its greatest success was the FDA approved cancer diagnostic tool, CellSearch™ System, for the detection of circulating cancer cells. However, due to legal disputes and costs associated with its partner company, Veridex LLC., Immunicon filed for bankruptcy in 2008 [32] and was acquired by Veridex LLC (now Jensen Diagnostics).

Centocor, Cephalon, Inc., and Immunicon Corp are exemplary companies that achieved above average aggregate scores despite receiving below average SBIR funding (Table 2). Centocor and Cephalon Inc. achieved their high aggregate scores through obtaining large amounts of addition private (>$20 million) and state (> $3 million) funding, high numbers of patents (>180), and were acquired by larger

![Fig. (4). The relationship between measures of company innovation and SBIR, state, and private funding (A) Scatter plot comparing publications and SBIR funding among those companies that published at least one paper. (B) Scatter plot comparing acquisition of patents and the sum of SBIR funding among those companies that received at least one patent. (publications and patents plotted on log scale).](image-url)
firms. In contrast, Immunicon Corp. received few patents but obtained nearly $137 million in private equity and went public. Despite their success, these companies received very little (<$1 million) in SBIR funding through HHS. The highly positive outcomes of these companies, both in terms of commercialization success and generation of innovative capital, suggests that high SBIR funding is not necessarily associated with increased success.

Genaera Corp. and ViroPharma, Inc. received high aggregate scores and average SBIR funding (Table 2). Both of these companies scored highly in our analysis because they received large amounts of private funding (>18 million) in addition to numerous publications or patents. In contrast to the companies profiled in the previous section, these companies received moderate amounts of SBIR funds (~2 Million). Interestingly, despite the similarities these companies had divergent overall outcomes as ViroPharma, Inc. was acquired and Genaera Corp. is now defunct due to failed clinical trials. These companies highlight the fact that although moderate levels of SBIR funding can be associated metrics of success, the ultimate outcomes of companies in this space is highly variable given the high risk and cost of bringing a drug to market in the US.

LifeSensors, Inc. and Integral Molecular are private biotechnology companies that received above average aggregate scores (Table 2) based on receiving moderate numbers of patents and publications. In contrast to the previous companies profiled, neither LifeSensors, Inc. nor Integral Molecular received significant private or state funding (<$0.1 million) and remain private today. Both companies have received over $10 million in SBIR funding through numerous awards. These companies represent an alternative use of SBIR funds, whereby companies obtain high numbers of SBIR grants in lieu of obtaining larger quantities of dilutive equity. This may represent a strategy for founders to maintain high percentage of ownership stake and to control direction of the company.

**LIMITATIONS**

While we attempted to be as unbiased as possible, this study has several limitations that must be acknowledged. First, the data set is incomplete, as not all information (especially from private companies) is publicly available. Second, the element of longevity or viability over time, while a critical metric of the success of a company, historically has not been reported to HHS. For this reason, care must be taken when evaluating the

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**Table 2. Summary of companies profiled.**

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Founded</th>
<th>Total SBIR Funding</th>
<th>Aggregate Analysis Score</th>
<th>Status</th>
<th>Private Funding</th>
<th>State Funding</th>
<th>Pubs</th>
<th>Patents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centocor</td>
<td>1979</td>
<td>$0.29 Mil.</td>
<td>7.2</td>
<td>Acquired</td>
<td>$20.18 Mil.</td>
<td>$3.00 Mil.</td>
<td>3</td>
<td>182</td>
</tr>
<tr>
<td>Cephalon Inc.</td>
<td>1987</td>
<td>$0.47 Mil.</td>
<td>6.4</td>
<td>Acquired</td>
<td>$40.04 Mil.</td>
<td>$5.75 Mil.</td>
<td>0</td>
<td>209</td>
</tr>
<tr>
<td>Immunicon Corp.</td>
<td>1987</td>
<td>$1.80 Mil.</td>
<td>3.0</td>
<td>Defunct</td>
<td>$18.11 Mil.</td>
<td>$0</td>
<td>1</td>
<td>21</td>
</tr>
<tr>
<td>Genaera Corp.</td>
<td>1987</td>
<td>$0.94 Mil.</td>
<td>5.0</td>
<td>Acquired</td>
<td>$137.9 Mil.</td>
<td>$0</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Integral Molecular</td>
<td>2001</td>
<td>$11.17 Mil.</td>
<td>2.8</td>
<td>Private</td>
<td>Unknown</td>
<td>$0</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>LifeSensors, Inc.</td>
<td>1996</td>
<td>$10.02 Mil.</td>
<td>3.4</td>
<td>Private</td>
<td>$0.10 Mil.</td>
<td>$0</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>ViroPharma, Inc.</td>
<td>1994</td>
<td>$2.44 Mil.</td>
<td>1.8</td>
<td>Acquired</td>
<td>$28.25 Mil.</td>
<td>$0</td>
<td>7</td>
<td>0</td>
</tr>
</tbody>
</table>

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**Fig. (5). Aggregate analysis of HHS SBIR funded companies in Pennsylvania.** Scatter plot of aggregate score as a function of total SBIR funding by company. Red lines indicate average SBIR funding of approximately $1.1 Million and average aggregate score received of 1.4. Percentages indicate the proportion of companies found in each quadrant.
metric of company status. Third, since the SBIR update system does not require publications to be reported by companies, it is difficult to associate publications with company, grant number, or primary investigator. Instead we were limited to primary literature databases, which require labor-intensive searches based upon single search features. If SBIR funded companies were required to report publications produced from the funding, a stronger record of achievement in this area could be reported and analyzed. Fourth, we do not report when the grants or private funding were received, and were unable to correlate if they directly impacted intellectual property development or publication. Finally, many aspects of commercialization data are not publicly available, so we were unable to assess the current profitability of a given company. Therefore, we caution the reader to be aware of the above limitations and caveats when reviewing the results of this study.

**DISCUSSION AND CONCLUSION**

Despite a wide degree of variation, it is clear from our analysis that SBIR awardees often win additional funding from private and state sources and can use the SBIR funding to promote innovation and product development. Being awarded such grants through the competitive bid process provides peer-reviewed validation of the core technology under investigation. However, when directly comparing the amount of SBIR funding to factors such as ongoing company status, private financing, publications or patents, it is difficult to determine if SBIR funding directly leads to increased measures of success for these criteria. We did not uncover any significant correlation between amount of SBIR funding and the amount of private funding raised subsequently, nor the number of publications or patents. In contrast, it is clear that companies that underwent a significant liquidity event (going public or acquisition) had received higher levels of SBIR funding. Therefore, such SBIR funding can be described as being important but not sufficient to result in a liquidity event later. In order to gain better insight as to the success of the SBIR program, we adopted a top-level approach to simultaneously consider all of these factors. Using this aggregate analysis, we determined that additional SBIR funding over $2.5M did not lead to a higher aggregate score, which would predict greater success.

Additionally, we have identified that companies tend to either use SBIR funding as a springboard for additional private funding or subsist on additional rounds of SBIR funding presumably to not dilute their ownership, or to redirect their research into more fruitful areas of study as time goes on. Regardless of which strategy was used, it is clear that the SBIR program does meet, at least in part, the goals of stimulating innovative research, supporting the commercialization of technologies by startup companies, and creating jobs.

Here, we developed and implemented an alternative approach for evaluating the SBIR program through objective non-self reported data. However, our study highlights the difficulty associated with obtaining concrete metrics of commercial output. It is obvious that models used to predict the commercial potential of new technologies are most accurate when derived from massive sets of objective data. However, the nature of accountability among managers of small businesses limits the transparency of certain key metrics, such as sales figures, from anyone other than potential investors.

In order to combat this limitation, federal agencies should independently audit awardees to obtain accurate and objective commercialization data. In this way future analyses can provide an accurate and complete view of the programs effects, and ultimately lead to selection of awardees with highest commercialization potential. Our study also demonstrates the utility of pooling data from disparate public resources into aggregates that serve as useful proxies for determining if SBIR awardees are meeting the goals of the program. At minimal expense, data from the NCBI and USPTO regarding SBIR-funded companies could be compiled into a single open resource, such as SBIR.gov. Companies applying for additional awards could then be more thoroughly evaluated on past performance pertaining to both commercialization and creation of innovative capital. Together, adoption of these recommendations will help to ensure optimal use of federal funds to stimulate the private sector and sustain high-tech innovation.

**LIST OF ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>DCED</td>
<td>Commonwealth of Pennsylvania Department of Community and Economic Development</td>
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<tr>
<td>DoD</td>
<td>Department of Defense</td>
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<td>HHS</td>
<td>Health and Human Services</td>
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<td>NRC</td>
<td>National Research Council</td>
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<td>R&amp;D</td>
<td>Research and Development</td>
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<td>SBIR</td>
<td>Small Business Innovation Research</td>
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<td>STTR</td>
<td>Small Business Technology Transfer</td>
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**CONFLICT OF INTEREST**

PBG Healthcare Consulting is a volunteer-based student-run organization at the University of Pennsylvania. PBG has current or historical relationships with three of the companies profiled herein, and has received standardized donations for purposes of academic enrichment at the conclusion of consulting engagements.

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**REFERENCES**

