



U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health



National Institutes of Health Commercialization Assistance Program
(NIH-CAP)

NIH-CAP 2006-07

**First Interval Tracking
Report**

for the period

July 1 2007 to March 31 2008

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Background & Introduction

Larta tracks the progress of NIH-CAP participating companies for an 18 month period in two 9-month intervals, including a baseline period, which spans the duration of the program. This report provides progress tracking results for the companies that participated in the CAP in 2006-07, for the first interval after the completion of the 2006-07 CAP or July 1 2007 to March 31 2008. This report presents only a summary of the data. Detailed source data can be found in a separate excel file (Processed Tracking 2006-07 Companies First Interval.xls). We discuss first the overall commercialization progress, and then separately evaluate direct CAP impact.

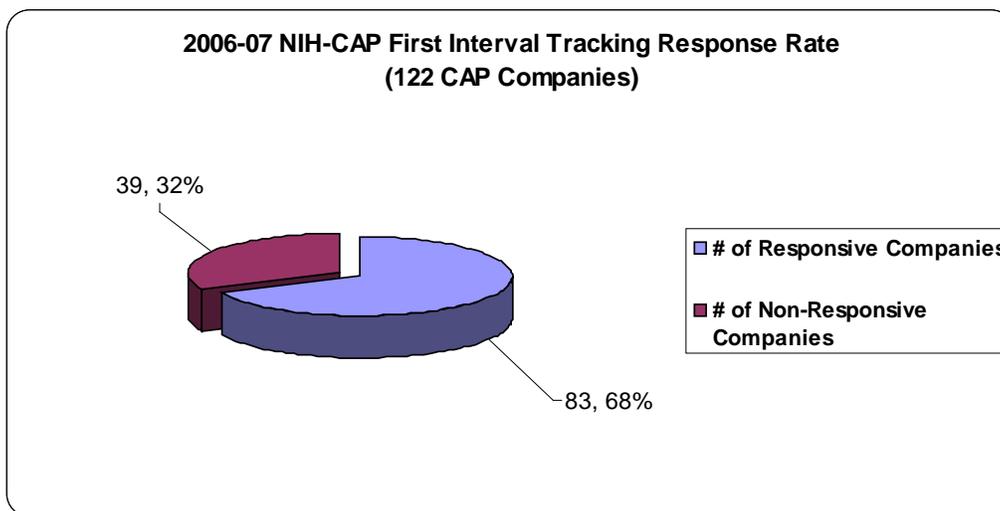
The Tracking Form

The third year of the CAP for NIH SBIR Phase II grantees was launched in July 2006. 125 companies completed the program in June 2007. At the end of the program, all 125 companies were sent baseline tracking forms. For the baseline interval, 2 companies were relieved from tracking (see Appendix A), leaving 123 companies to be tracked. For the first interval, 122 out of these 123 companies were sent tracking forms; one company was relieved from tracking because it 'declined' to provide further tracking information (see Appendix A for [REDACTED]). Some notable features of the tracking form (see Appendix B) are listed below:

- Tracking is focused on quantifiable end results, i.e., deals, revenue growth, increased equity investment, increased employment, M&A outcomes.
- In addition, the form defined a "deal activity pipeline". We hope that this attempt at quantifying complex and often circuitous commercialization efforts will provide some predictive capabilities in the future, somewhat analogous to sales pipeline forecasting.
- Participants were asked to report separately their overall commercialization progress and their evaluation of the CAP impact. While data on companies' commercialization progress are, in principle, objective and could be used in the studies of SBIR program performance in general; their use in evaluating CAP itself is limited due to the lack of a control group of SBIR companies. *In addition, some of the terms used to gauge progress and impact are not clearly defined (indeed are not defined at all), which allows greater subjectivity and interpretation and thus may render some of the outcomes data less useful in making comparisons between different periods or between different years of the CAP.*
- Data on CAP impact are expected to be indicative of CAP significance. Companies rated the CAP impact as 1) Major, 2) Valuable, 3) Minor or 4) None. For purposes of measuring CAP impact, Valuable and Minor impact are determined in this report to be 'Some' impact on the companies.
- Finally, on the question on revenue, we asked companies to identify their largest source of revenue and also to explicitly identify commercial revenue vs. revenue from R&D grants and contracts.

Response Rate

On April 14, 2008, 122 of the 2006-07 NIH-CAP companies were sent the tracking form from Kay Etzler at NIH. 83 of the 122 companies responded to the tracking request (after several email reminders), an encouraging 68% response rate. While the response rate for the baseline period was 74%, a response rate between 65% and 70% for the 1st interval is more than satisfactory given that more time has elapsed since the culmination of the program.



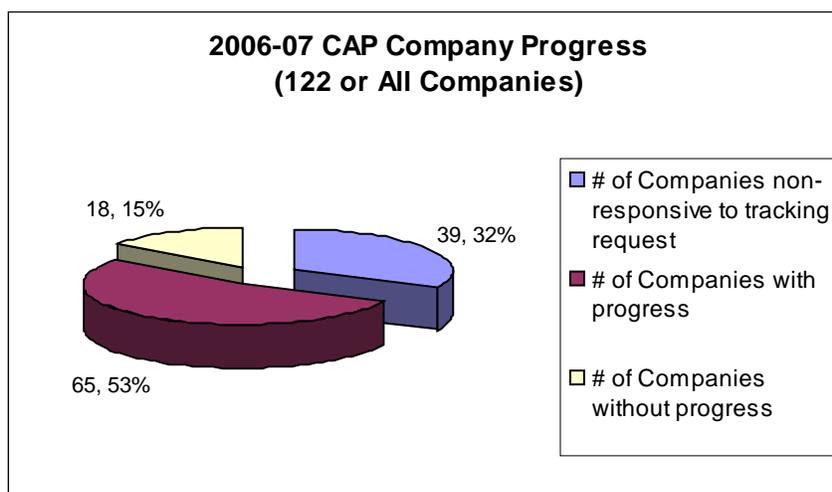
Commercialization Progress

The following charts describe the progress (with the commercialization of SBIR Phase II technologies) that the companies have made during the first interval since the culmination of the CAP. Progress is determined by a positive change in the following categories:

- Activity in Partnerships and Deals
- Revenue
- Growth of Equity Investment
- Growth of Employment
- Acquisitions

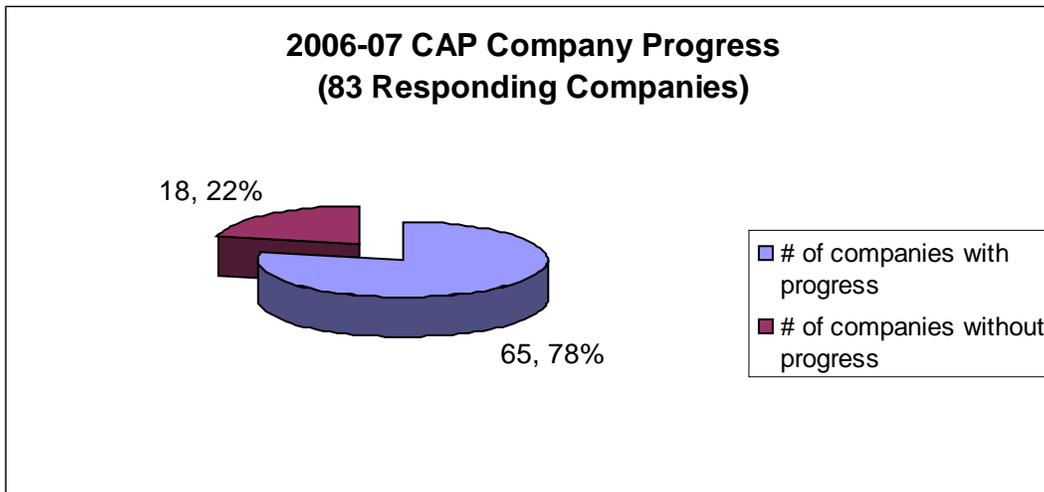
Activity in Partnerships and Deals

65 companies or 53% of all participants showed commercialization progress as shown in the graph below (compared with 70 companies or 57% in the baseline period when 123 companies were tracked).



The chart below outlines commercialization progress with respect to partnership and deal related activities, excluding the 39 companies that were non-responsive to the tracking request. Out of

the 83 companies that responded to the first interval tracking request, an encouraging 65 companies or 78% of the companies indicate commercialization progress in the partnership and deal related activities area. This 78% rate is slightly higher than the 77% rate from the baseline results.



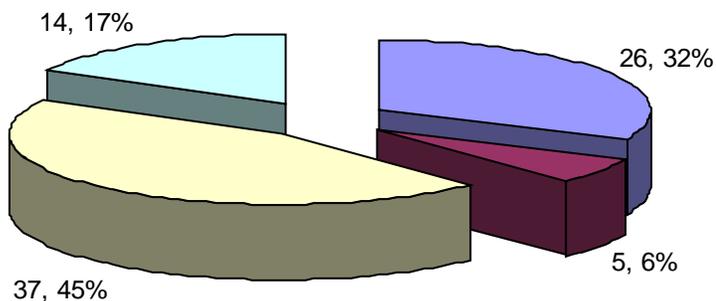
Note that “Progress” is defined as at least one event in at least one of the partnership and deal related activities listed below:

1. Contacts with Investors and Partners
2. Meetings with Investors and Partners
3. CDAs signed
4. Negotiations with Investors and Partners
5. Initial Proposals and Term Sheets
6. Deals

See table and chart below for a breakdown of company *objectives* (i.e. what they are seeking) with respect to partnerships and financing. The data clearly indicate that companies are choosing to pursue partnerships over financing, with a majority of companies leaning toward alliances and collaborations and only five companies pursuing financing exclusively. This is consistent with market and industry trends, which increasingly are leaning toward strategic alliances with early stage companies and previous tracking reports. Several of the CAP companies are not “venture capital ready” and alliances would seem to be more appropriate options with greater potential for success.

Partnership and Financing Activities	Number of Companies
Seeking partnerships	26
Seeking financing	5
Seeking both	37
Seeking neither	14

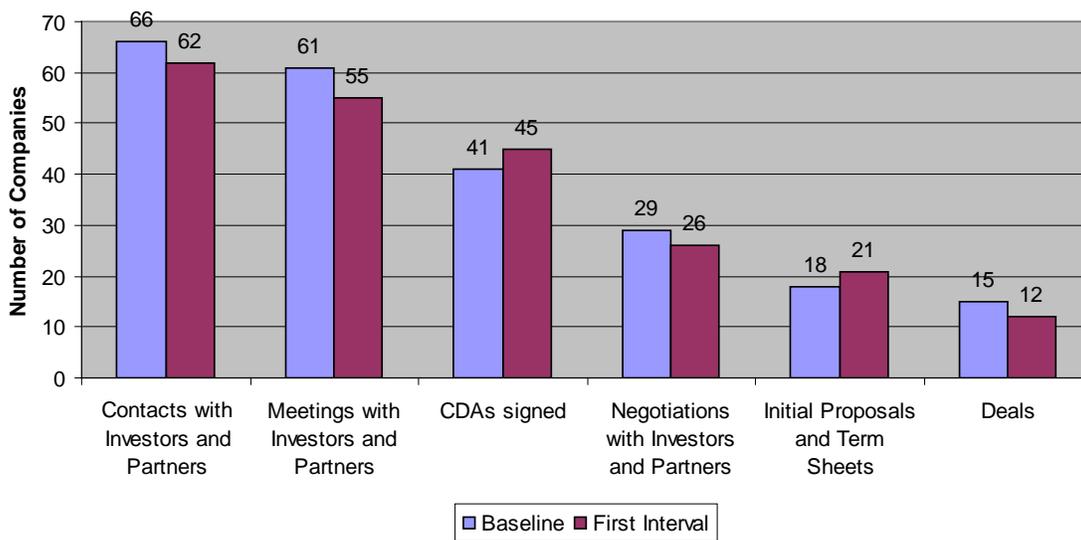
**2006-07 Partnerships and Deal Related Activities Breakdown
(83 Responding Companies)**

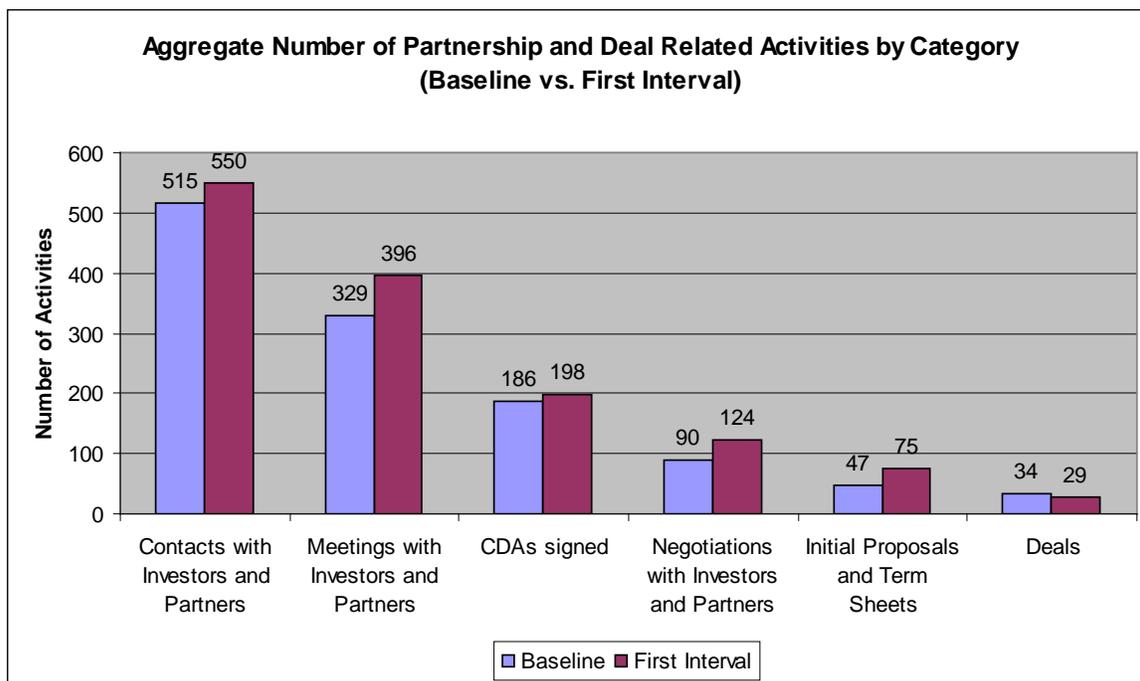


■ # of companies seeking partnerships ■ # of companies seeking financing
■ # of companies seeking both ■ # of companies seeking neither

The charts below indicate the number of companies engaged in multiple partnership and deal related activities and the aggregate number of partnership and deal related activities by category, presented to compare between baseline and first interval.

**Partnership & Deal Related Activity - Number of Companies
(Baseline vs. First Interval)**



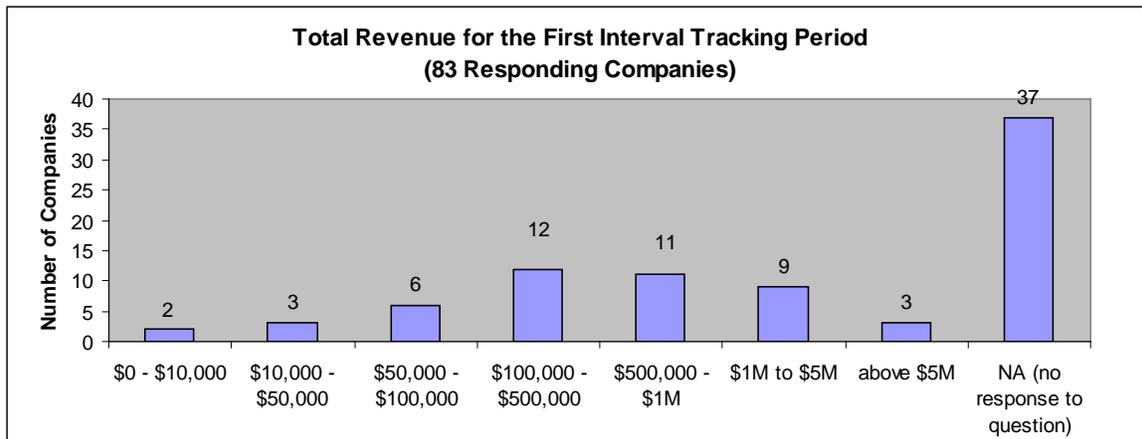
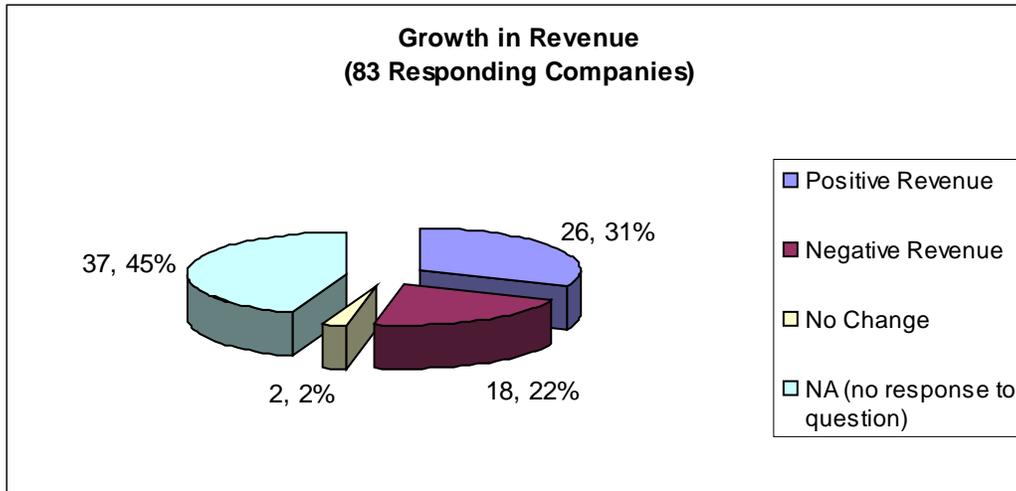


Key observations:

- While slightly fewer companies reporting had partnership or deal related activity from the baseline to the first interval, slightly more companies had initial proposals and term sheets (21 compared with 18 in the baseline). This, despite fewer companies reporting meetings with investors and partners (55 in the first interval, compared with 61 in the baseline).
- The total number of partnership and deal related activities has increased from 1201 to 1372, from baseline to the first interval respectively, indicating the overall pattern of activity is stronger and the intensity has increased considerably as follows:
 - Meetings with investors and partners stood at 396 in the first interval compared to 329 in the baseline period, a 20% increase.
 - Negotiations with investors and partners stood at 124 in the first interval compared to 90 in the baseline period, a 38% increase.
 - Initial proposals and term sheets stood at 75 in the first interval compared to 47 in the baseline period, a 60% increase.

One point that may be inferred from the data is: the numbers of companies involved in actual commercialization activity only provide a partial picture, and that outcomes, even if applying to fewer companies, are more important. However, since we do not delve into any detail regarding the “deals” that are referenced in the tracking form, we cannot determine how robust or long-lived those “deals” may be. One suggestion is that we seek to classify, categorize or otherwise provide guidance or clarification on what constitutes a “deal” to enable us to gain greater clarity on the outcomes pertaining to the companies.

Revenue



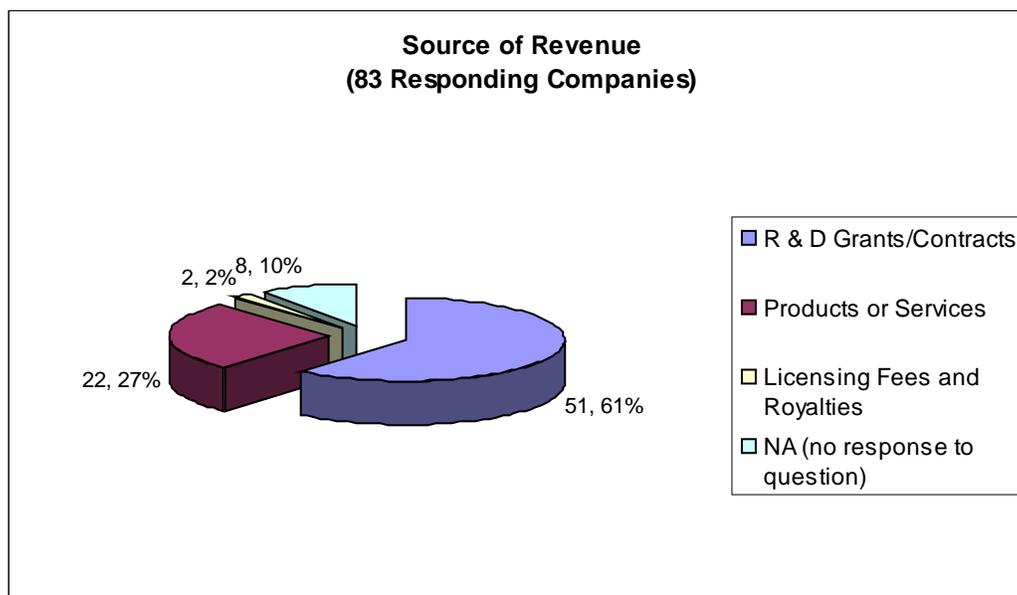
Key observations:

- The level of non-responsiveness among companies to the question on revenue is disappointing. Almost 45 percent of respondents did not provide a response.
- Most of the companies who did answer the question (33) reported revenues between \$100,000 and \$1 million; 9 reported revenues between \$1 and 5 million.
- 3 companies have reported total revenue of over \$5 million and 9 companies between \$1 million and \$5 million.
- The highest revenue reported was \$16 million (██████████).
- See table below for top ten companies with respect to total revenue:

Company Name	Revenue
██████████	\$ 16,000,000
██████████	\$ 10,700,000
██████████	\$ 5,500,000

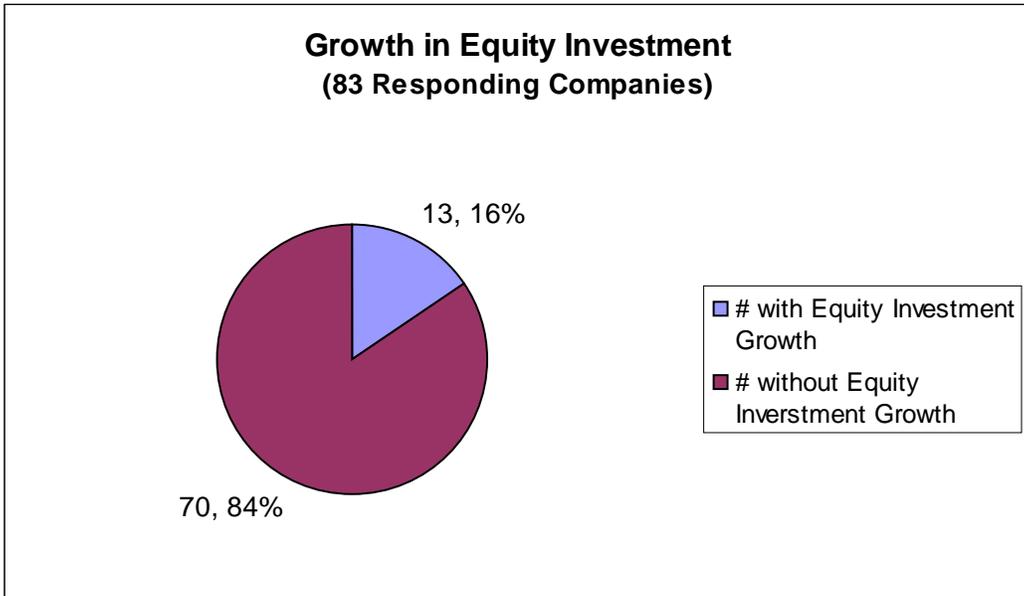
Company Name	Revenue
██████████	\$ 3,000,000
██████████	\$ 2,500,000
██████████	\$ 2,300,000
██████████	\$ 1,700,000
██████████	\$ 1,600,000
██████████	\$ 1,400,000
██████████	\$ 1,380,000

However, R&D Grants/Contracts remain the largest source of total revenue for 61% of companies, as shown below. This trend is the same as with prior tracked CAP companies (2005-06 CAP companies).

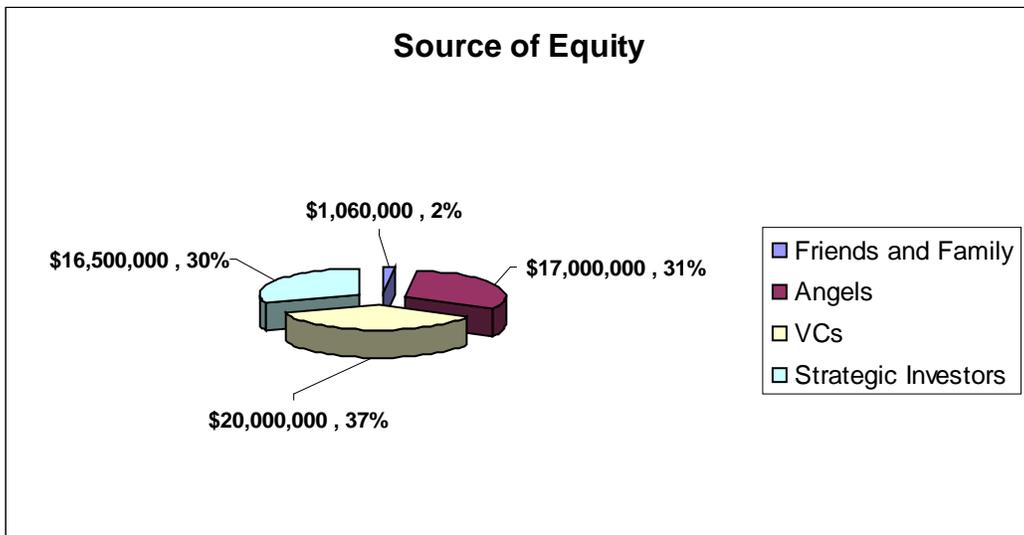


Growth in Equity Funding

The data refers to the *growth* in equity funding for the company as a whole. 13 companies or 16% indicated an increase in equity funding from one or more sources; this is a decrease from the baseline as 19 companies or 21% reported increase in equity funding during that period. One should not read into this any particular conclusive evidence one way or the other, as equity funding has a longer-term horizon, and these numbers will likely be volatile in any particular period. Also, these data only apply to the *growth* of equity funding.



The total amount of new funding by source of funding is shown below.



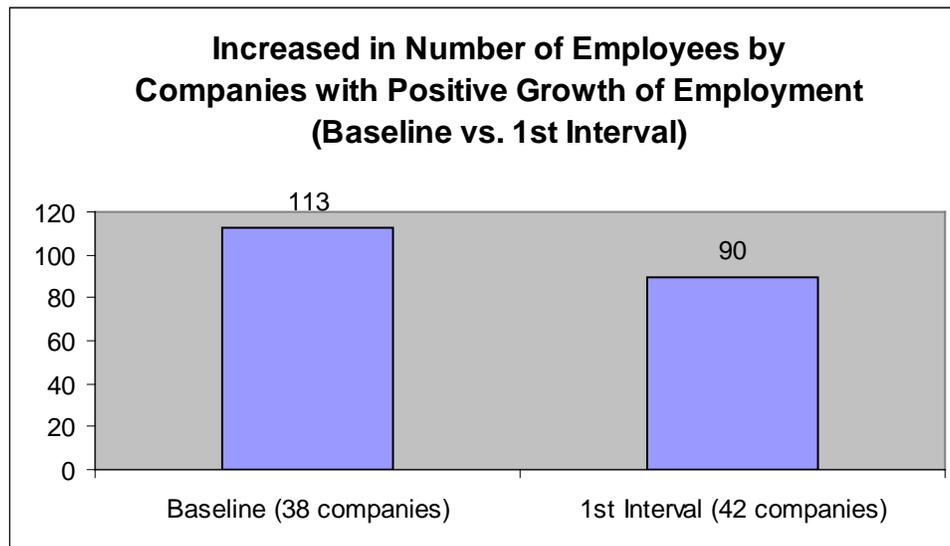
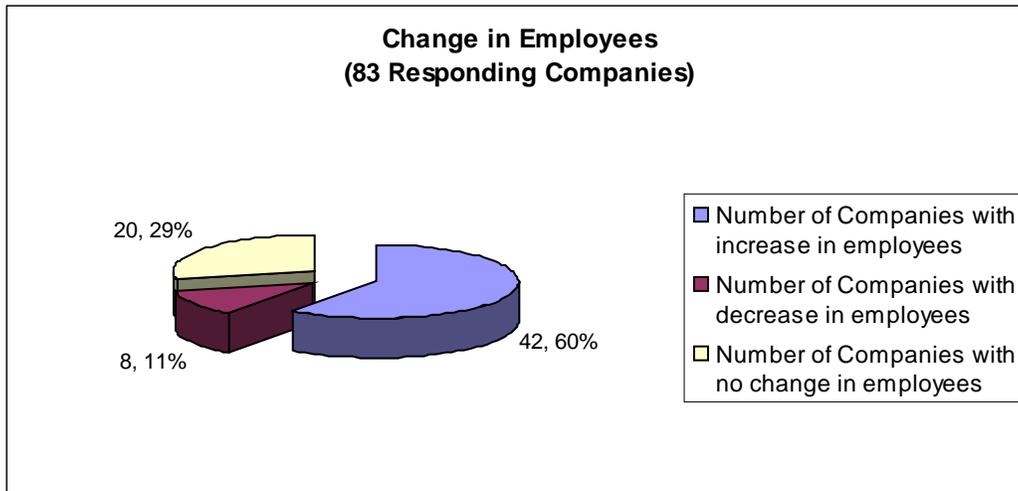
Key observations:

- VC funding (37%) accounted for the largest source of equity funding followed by Angel funding (31%) and Strategic Investors (30%). Note that [REDACTED] accounted for \$10 million of the total VC funding (50% of the total VC fund), [REDACTED] accounted for 13 million of the total angel funding (over 76% of the total angel funding), and [REDACTED] accounted for \$10 million of the total strategic investment (over 60% of total strategic investment). VC and Angel funding played a greater role in the 1st interval than the baseline, when strategic investment funding was dominant.
- In total, about \$54.5 million was raised by the 25 CAP companies that were successful with equity investment compared with \$55 million by 19 companies in the baseline period.
- The bulk of funding went to [REDACTED] (\$13 million in angel funding), [REDACTED] (\$10 million in VC fund), and [REDACTED] (\$10 million in strategic investment).

Other Success Indicators

Employees

42 companies or 60% of the respondents indicated an increase in employees in the first interval period compared with 38 companies or 50% during the baseline period.



Mergers & Acquisitions

Two mergers and acquisitions were reported in the first interval since the culmination of the 2006-07 CAP. Both were significant events, both in terms of size and in terms of applicability of the technology to the acquiring company.

- [REDACTED] is now a division of [REDACTED].
- [REDACTED] was acquired by [REDACTED].

CAP Impact

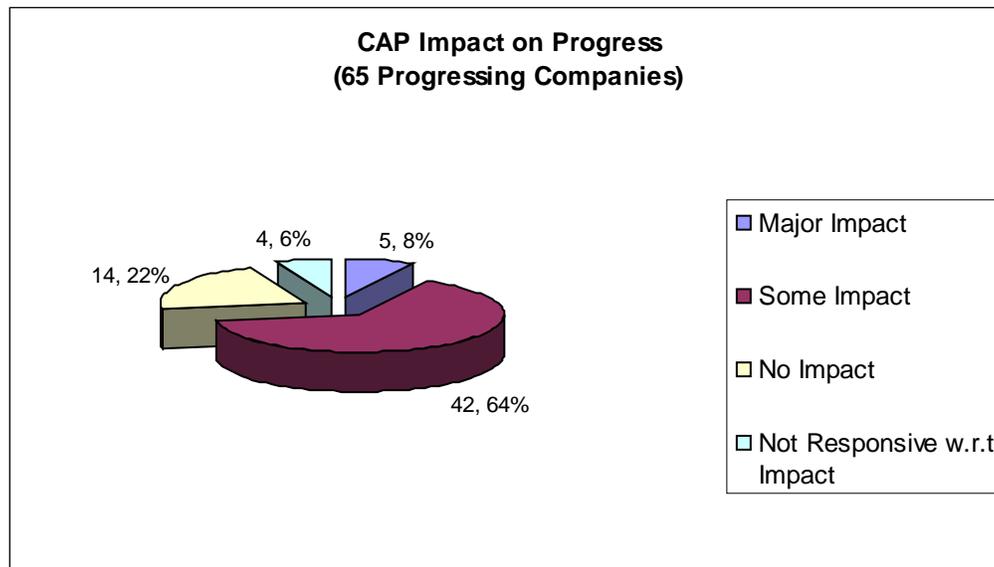
CAP Impact was rated by the companies as either 1) Major, 2) Valuable, 3) Minor or 4) No Impact. CAP impact was determined for the following activities that have been addressed earlier in the report (Note that Valuable and Minor impact are aggregated in this report and are reported here to denote 'Some' impact on the companies).

- Activity in Partnerships and Deals
- Revenue
- Growth in Equity Investment

Note that the data here represent companies' subjective assessments on the impact of CAP with respect to specific commercialization outcomes. Companies have separately outlined their feedback on the CAP, the results of which have been submitted to NIH.

Activity in Partnerships and Deals

Progress is defined as at least one activity in at least one of the partnership and deal related activity categories.



Key observations:

- 5 of the 65 “progressing” companies (i.e. having at least one activity in at least one of the partnership and deal related activity categories) have attributed the CAP with major impact and 42 companies have attributed the CAP with some impact.
- 72% of the progressing companies have attributed major or some impact to the CAP on partnership and deal related activities, compared with 86% for the baseline period.

Comments from CAP participants regarding CAP impact on partnerships and financing deals are shown below. Note that these are comments from companies that attributed the CAP with major or some impact.

“The Legal counsel that we found through the NIH CAP and that was partially covered through the program assisted us in negotiating the terms and company position in the negotiated partnership deal.”

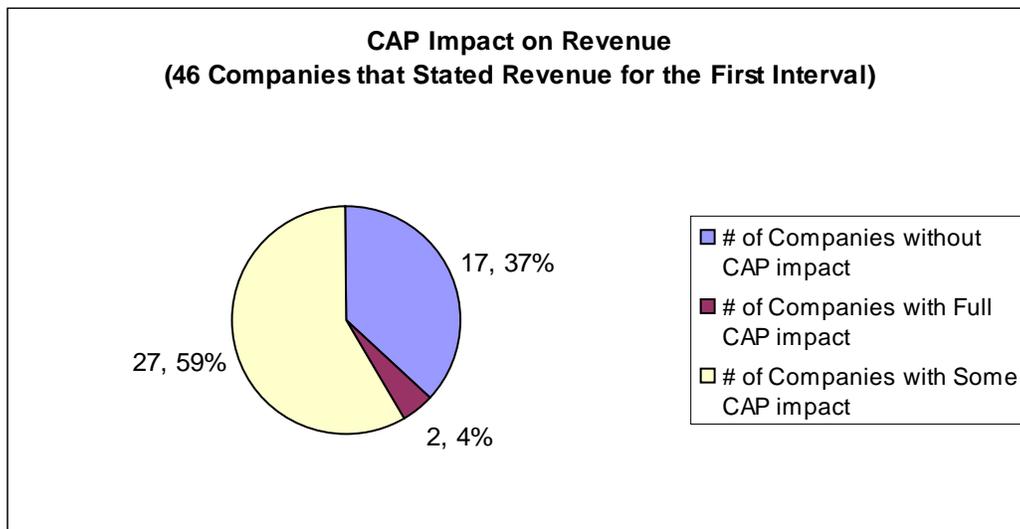
“We could not possibly have done this without the CAP program and the contacts that it generated for us. We learned what needs to be done to commercialize a product, and how to go about it.”

“Learning about contract and intellectual property issues during the CAP has given me confidence that I can achieve positive business outcomes while negotiating legal and commercial contracts on behalf of [REDACTED].”

“Although participation in the CAP has not had a major impact on [REDACTED] in a tangible way – nonetheless, it was very well-organized and focused on key areas for early stage biotechnology companies. Thus, it is expected to have a major impact in the long term.”

“The CAP process helped us build a firm foundation on which we have developed our current business plan, strategy and financial model.”

Revenue



The above chart shows the impact that CAP had on the companies' revenue for those companies that stated revenue for the first interval tracking period.

Key observations:

- 29 companies of the 46 companies (63%) that indicated change in revenue attributed the CAP with some or full impact.

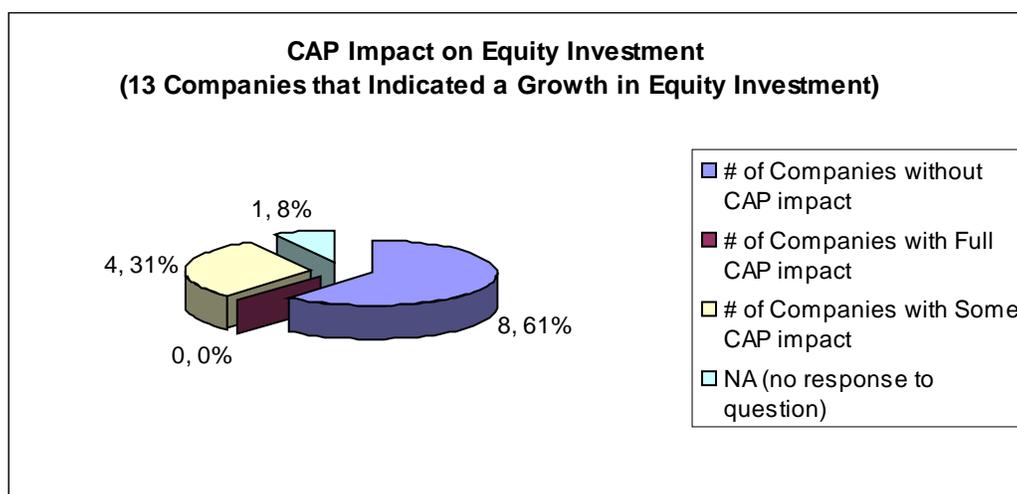
Comments from CAP companies that attributed the program with full or some impact on revenue are provided below:

“The CAP program gave me the confidence and the impetus to take the plunge and run the company in 2007 off a line of credit. I ramped up the sales and marketing effort which led to the major contract with the drug store chain. We are using that as an investment to capitalize on the staff training program for direct care workers of long term care facilities. Many thanks to CAP for all the help and support given to me.”

“The CAP program experience has focused us on appropriate markets for our products and potential means for market access. Pharma seems to be a particularly viable area and we have been focusing particular attention here. We are pursuing the Pharma market very aggressively. A team of MBA students is pursuing the Pharma market for us, plus we are attending and

exhibiting at key venues. Some time later this year we should have a better idea of the potential of the Pharma market.”

Growth in Equity Funding



The above chart shows the impact of CAP on equity investment for those companies that showed a growth in equity investment.

Key observations:

- 31% of the 13 companies that indicated a growth in equity investment attributed the CAP with some impact compared with 32% of the 19 companies that indicated a growth in equity investment in the baseline period.

Comments from these companies that attributed the CAP with some impact include:

“Helped to prepare for and present to potential financial partners, such as investment banks and VC’s.”

“We are in the beginning stages of speaking with venture firms re: investment in [REDACTED]. The CAP program gave us access to [REDACTED] who have been active advocates on behalf of [REDACTED] in our fundraising activities. Through their networks they have been able to gain access to the top investment firms in the country funding opportunities in this area of technology development.”

Summary

The 2006-07 tracking effort yielded a reasonable response rate of 68%.

Partnership and financing:

Commercialization progress in terms of partnership and financing activity stands at a healthy 65 companies or 78% of the 83 responding companies. The total number of partnership and deal related activities has increased from 1201 to 1372 compared to the baseline. A key point here is that this increase occurred despite a drop in the number of companies reporting initial meetings with investors and partners. The drop was made up for by an increase in the number of term sheets. Interesting to note is the fact that despite a lower number of meetings with investors and partners, a larger number of CDA’s were signed compared with the baseline.

Revenue growth:

26 companies or 31% of the responding companies have stated revenue for the first interval period and 18 companies or 22% of the responding companies have reported no revenue growth (reported as “negative”). On the face of it, the latter may seem to be of concern. However, one should be careful not to read too much into these data. Given the fact that most CAP companies are R&D grant-dependent (R&D Grants/Contracts remain the largest source of total revenue for 61% of companies). The point here is that this number, for grant-dependent companies, is not a particularly reliable indicator of commercialization success. In cases where companies report outside revenue (i.e. non-grant) as part of their response to the question on revenue, here too we should not read much into data that suggest a drop in revenue; companies often need to re-invest discretionary revenue in activities that may not yield immediate results in any particular period. It is only over the long-term that a more reliable picture on revenue growth can be truly ascertained.

Of note here is that companies reporting “negative” revenue growth attribute CAP with impact across the spectrum, from “minor” to “major”.

Equity funding growth and source:

13 companies or 16% indicated an increase in equity funding, a decrease from the baseline when 19 companies or 21% reported an increase in equity funding. VC funding accounted for the largest source of equity funding followed by Angel funding. In total, about \$54.5 million was raised by 25 CAP companies that were successful with equity investment compared with \$55 million by 19 companies in the baseline period.

Conclusions:

The CAP continues to have a significant influence and impact on partnering and financing activities. Revenue growth among respondents was strong, in aggregate, increasing from \$6.5M to \$12.1M, baseline to first interval. As we show below, increases in almost all categories tracked was in evidence.

Of concern is the subjective nature of the terminology used. We suggest that a clearer definition be provided for some of the terms being referenced in the tracking form, including “deals”, “major”, “valuable”, “minor” impact, CAP impact on “revenue” and overall impact. Also, we believe that many respondents currently are guided only by CAP directly linking them with investors and partners, which could easily mask the true impact of the program in *preparing* them for such commercialization outcomes. In addition, we need to provide a spectrum of outcomes when asking for data on “deals” as a guide to respondents, and allow for participants’ comments in responding to such questions; this may uncover the nature and potential longevity of such outcomes.

Nevertheless, even with what we believe to be less consistent data, the program continues to yield positive feedback from companies.

Key results are summarized below as well as a comparison to the baseline:

2006-07 NIH-CAP Company Growth by Categories *Baseline vs. First Interval*

	BASELINE	FIRST INTERVAL
Revenue Growth Number of Companies	26	26

	BASELINE	FIRST INTERVAL
Revenue Growth Amount	\$6.5M	\$12.1M
Equity Investment Number of Companies	19	13
Equity Investment Amount	\$55M	\$54.6M
Employment Growth Number of Companies	38	42
Employment Growth Amount of Growth	113	90
Contacts with Investors and Partners Number of Companies	66	62
Contacts with Investors and Partners Number of Contacts	515	550
Meetings with Investors and Partners Number of Companies	61	55
Meetings with Investors and Partners Number of Meetings	329	396
CDAs Signed Number of Companies	41	45
CDAs Signed Number of CDAs	186	198
Negotiations with Investors and Partners Number of Companies	29	26
Negotiations with Investors and Partners Number of Negotiations	90	124
Initial Proposals and Term Sheets Number of Companies	18	21
Initial Proposals and Term Sheets Number of Proposals	47	75
Deals Number of Companies	15	12

	BASELINE	FIRST INTERVAL
Deals Number of Deals	34	29

APPENDIX A

2006-07 CAP companies relieved from tracking:

Company Name	Notes
██████████	██████████ is not presently trying to commercialize the technology that was studied under the CAP since additional research effort is needed to produce a commercializable product (this was discovered during completion of the Phase II project technical effort). No further progress with respect to this technology will be reportable.
██████████	██████████ will not provide any additional tracking information. As a result, NIH relieved the company from further tracking.
██████████	Partially completed CAP and shifted focus to a different technology.

APPENDIX B

NIH-CAP 2006/2007

COMMERCIALIZATION PROGRESS TRACKING FORM- FIRST INTERVAL

July 1 2007-March 31 2008

PLEASE RETURN BY APRIL 28, 2008 TO KETZLER@LARTA.ORG

Company Name:
CAP SBIR Grant #:
Name of Individual Completing Form:
Position:
E-Mail:
Telephone:

Please fill in the **COMPANY COMMERCIALIZATION PROGRESS TRACKING** form below.

NIH is very interested in your commercialization progress and in your feedback as to whether the CAP program was helpful. Now we are looking for your inputs about your commercialization progress from July 1, 2007 until March 31, 2008, which is the first nine-month period after the completion of the program. At the end of the next nine-month interval (January 2009), you will receive a similar form in order to assess the long-term impact of the CAP. We also believe that such tracking can be beneficial to you as a management tool to periodically assess your company's progress and growth.

The tracking form is divided into four parts: (1) partnerships and financing activities, (2) revenue (3) equity investment, (4) and other success indicators (employees, acquisitions). It may be difficult to "measure" the impact the CAP may have had on your progress; however, the questions allow for your **opinion** to be expressed. **As indicated in the questions below, please provide information and indicate CAP impact only for those activities that you are pursuing and are applicable to your commercialization process.**

1. PARTNERSHIPS AND FINANCING ACTIVITIES

- a) Are you seeking partnerships? Yes ____ No ____
- b) Are you seeking financing? Yes ____ No ____
- c) Are you seeking both partnerships and financing deals? Yes ____ No ____
- d) **Please respond to this question only if you are seeking partnerships and/or financing.** With regards to your CAP-related technology, please indicate your company's progress in terms of partnership and financing activities. State the number of partnership and financing related activities in which your company has engaged between July 1, 2007 and March 31, 2008. If you are pursuing both partnerships and financing, add the numbers together. Please only state numbers and not qualitative data.

	Number of Partnership and Financing Related Activities Your Company Has Engaged in Between July 1, 2007 and March 31, 2008	Describe Significant Outcomes
<p>Contacts with Investors and Partners</p> <p>Count only contacts you had a meaningful conversation with about your mutual interests</p>		
<p>Meetings with Investors and Partners</p> <p>Meetings can be face-to-face or by phone/web but should involve exploration of potential deals in some detail.</p>		
<p>Confidential Disclosure Agreements signed</p> <p>CDA (NDA) agreements are generally a pre-requisite for any serious discussion with potential partners. Investors generally do not sign CDAs.</p>		
<p>Negotiations with Investors and Partners</p> <p>At this stage, all parties are interested in the deal and you are exploring various give and take.</p>		
<p>Initial Proposals and Term Sheets</p> <p>These are proposals of key terms of the deal and serve as the basis for the final agreement.</p>		
<p>Deals</p> <p>Signed legal documents and money in the bank. Please indicate the dollar amount of each deal.</p>		

e) **Please respond to this question only if you are seeking partnerships and/or financing.** Please indicate the impact of the CAP on your partnership and financing related activities for the period July 1, 2007 to March 31, 2008.

___ Major Impact ___ Valuable Impact ___ Minor Impact ___ No Impact

Comments:

2. REVENUE

Please report the results for the whole company and not just your CAP-related technology. Do not include SBIR grants or other government contracts (except when asked about R&D Grants/Contracts in d) below).

- a) Please state the total company revenue in Q4 2006, Q1 2007 and Q2 2007.

_____ (\$millions)

- b) Please state the total company revenue in Q3 2007, Q4 2007 and Q1 2008.

_____ (\$millions)

- c) Please state the total revenue as of March 31, 2008

_____ (\$millions)

- d) Please indicate the largest source of revenue (**Choose one only**)

R&D Grant/Contracts _____ Products or Services _____ Licensing Fees and Royalties _____

- e) Please indicate the impact of the CAP on the change in company revenue for the period

July 1, 2007 to March 31, 2008.

____ Major Impact ____ Valuable Impact ____ Minor Impact ____ No Impact

Comments:

3. EQUITY INVESTMENT

- a) Are you seeking equity investment? Yes _____ No _____

- b) **Please respond to this question only if you are seeking equity investment.** Please state the total amount of equity investment received by the whole company INCLUDING your CAP-related technology in the time period July 1, 2007 to March 31, 2008. Please only state quantitative and not qualitative data.

	Amount of Equity Investment
Friends and Family	
Angels High net worth individuals; always invest as individuals although may belong to angel organizations.	

	Amount of Equity Investment
VCs Institutional investors	
Strategic Investors Investors that are looking to achieve other goals in addition to financial returns. Typically corporations seeking to fill or expand their product lines.	

- c) **Please respond to this question only if you are seeking equity investment.** Please indicate the impact of the CAP on equity investment received for the period July 1, 2007 to March 31, 2008.

___ Major Impact ___ Valuable Impact ___ Minor Impact ___ No Impact

Comments:

4. OTHER SUCCESS INDICATORS (EMPLOYEES, ACQUISITIONS)

- a) Have the number of employees in your company increased since July 1, 2007? If yes, please specify the number of employees on July 1, 2007, versus the current number of employees, and the titles/positions of the new employees in the table below.

	Employee Information
Number of Employees in July 1, 2007	
Current Number of Employees	

- b) Has your company been acquired? Yes ___ No ___

If yes, NIH would like to continue tracking the progress of the SBIR-developed technology. Please provide the following information.

	Acquisition Information
Name of the Acquiring Company	
Change in Company Name as a Result of the Acquisition	

	Acquisition Information
Change in Company Contact Information as a Result of the Acquisition	
Additional Details	

THANK YOU ONCE AGAIN FOR YOUR PARTICIPATION IN THE 2006/2007 CAP AND FOR YOUR FEEDBACK. IT WAS A DELIGHT TO WORK WITH YOU AND WE WISH YOU THE BEST OF SUCCESS.