

*Please note the text space limits within the application fields. If you would like to provide images or figures, please submit one additional PDF page (optional Appendix) with your e-mail submission. All forms must be submitted by February 10, 2016. E-mail completed application form(s) to [NCIsbirEvents@mail.nih.gov](mailto:NCIsbirEvents@mail.nih.gov). Review "[Application Guide for NCI Investor Initiatives](#)" for additional instructions.*

**By checking this box, I provide permission to share this application with non-federal investors and reviewers.** (Please note that your application will be reviewed by an external panel of industry personnel and investment professionals. Only provide non-confidential data that can be shared with investors.)

**NCI SBIR Grant or Contract Number for this product/technology:** \_\_\_\_\_ (if you have multiple awards related to this technology/product, list the product you wish to be the focus of this application.)

### **COMPANY INFORMATION**

**Official Company Name:** \_\_\_\_\_

**Company Website:** \_\_\_\_\_

**Company Mailing Address:** \_\_\_\_\_

**Total Number Full-time Employees:** \_\_\_\_\_ **Total Number Part-time Employees:** \_\_\_\_\_

**Company CEO :** \_\_\_\_\_

**Phone:** \_\_\_\_\_

**E-mail:** \_\_\_\_\_

**Contact Person for this Application:** \_\_\_\_\_

**Title/Role:** \_\_\_\_\_

**Phone:** \_\_\_\_\_

**E-mail:** \_\_\_\_\_

**What year was the company founded:** \_\_\_\_\_

**Select One:**

Do you plan to apply for a Bridge Award in the next 12 months?  Yes  No  Bridge Recipient

**EXECUTIVE SUMMARY** (Please provide a short summary of your company & technology – limit 2400 characters)

## 1. TECHNOLOGY/PRODUCT OVERVIEW:

Please describe the technology/product that was funded under the NCI SBIR program, its application, and "how it works." Include the current or potential impact of your product or technology on cancer patients, including the likelihood of clinical adoption and fit with existing practice. Limit your response to 4000 characters.) You may refer to any figures or images to be included in an Appendix PDF.

**Type of Product/Technology:** (Select all that apply)

- |  |  |   |
|--|--|---|
| <input type="checkbox"/> Small molecule              | <input type="checkbox"/> Biologics/Vaccine                       | <input type="checkbox"/> Cell/Gene therapy    |
| <input type="checkbox"/> Surgical or Ablative device | <input type="checkbox"/> Hospital device                         | <input type="checkbox"/> Drug delivery device |
| <input type="checkbox"/> Imaging device              | <input type="checkbox"/> Imaging agent                           |   |
| <input type="checkbox"/> In vitro diagnostic         | <input type="checkbox"/> Bioinformatics/Health IT/Digital health |   |
| <input type="checkbox"/> Research tool               | <input type="checkbox"/> Other (please specify): _____           |   |

**Technology Name:** (Please provide a short, five words or fewer, description of your technology)

**Current R&D Status:**

- |   |  |  |                                    |
|---|--|--|------------------------------------|
| <input type="checkbox"/> Non-clinical technology in prototype development/testing stage |  |  |                                    |
| <input type="checkbox"/> Non-clinical technology in full development/testing stage      |  |  |                                    |
| <input type="checkbox"/> Pre-clinical development                                       |  |  |                                    |
| <input type="checkbox"/> In clinical trials:  | <input type="checkbox"/> Phase I           | <input type="checkbox"/> Phase II          | <input type="checkbox"/> Phase III |
|   | <input type="checkbox"/> Early Feasibility | <input type="checkbox"/> Feasibility/Pilot | <input type="checkbox"/> Pivotal   |
| <input type="checkbox"/> Commercially available   |  |  |                                    |
| <input type="checkbox"/> Other (Please explain below)                                   |  |  |                                    |

## **2. SCIENTIFIC PROGRESS & STAGE OF DEVELOPMENT:**

*Please describe the current stage of development, major technical milestones achieved to date, and how they suggest clinical efficacy. Describe your progress toward the commercialization of the product and comment on how your product/prototype can be scalable and reproducible in a commercial environment. Also, please give a brief overview on the regulatory & reimbursement strategy for the product under development, including an update on current and imminent regulatory applications, approvals, and hurdles. Please limit your response to 3000 characters. You may refer to any figures or images to be included in an Appendix PDF.*

**FDA Application:**  PMA  510(k)  IDE  BLA  IND  NDA  Not applicable (no approval needed)  
**Current Status:**  Not yet submitted  Submitted  Approved  
**Reimbursement Planning:**  Not started reimbursement planning  Identification of CPT codes  Technology Add-ons  
 Insurance Coverage  CMS Processes  Other, (described in write-up below)

## **3. MARKET DESCRIPTION AND PIPELINE PRODUCTS:**

*Please describe the market for the product under development, providing market size and projected market growth, if available. Explain how your product fills a market niche and addresses an unmet need. Describe current and potential future commercial applications, including new products in development, and market segments. Limit 1600 characters.*

**4. COMPETITIVE ADVANTAGE:**

Please list/describe any unique attributes or competitive advantages the product has in the market over both current products and competing technologies under development. Limit 1600 characters.

**5. INTELLECTUAL PROPERTY:**

Please describe the strength of your company's IP portfolio including issued patents, composition claims, and intellectual property licensed to the company (pertaining to this product) from academic or other institutions. List the patent title and numbers in the table below. Highlight your company's strategy to protect its IP.

Status (Filed, Provisional, Approved)	Number	Title	Date of Filing

List any invention reports, trademarks, or copyrights. (Please enter numeric values where applicable.)

	# Filed	# Approved	Subject matter or name of mark
Invention Reports			
Trademarks			
Copyrights			

**6. PUBLICATIONS, PRESENTATIONS, AND AWARDS:**

Please list the most significant past and pending publications, presentations, and awards based on the company's technology. Limit 1500 characters.

**7. MANAGEMENT:**

*Describe the team or management structure, highlighting years of experience, background, and relevant previous success, experience, and domain expertise. You may provide additional information, as necessary. Limit 1000 characters.*

Name, Title/Role	Domain expertise	Value Added/Previous Success

**8. BUSINESS DEVELOPMENT AND PARTNERSHIPS:**

*Please list and specify any current or pending partnerships (e.g., strategic partner, licensing partner, manufacturing, distribution, technical collaboration, etc.) the company currently has related to the full commercialization of this product. Please also indicate what kind of partnerships you are seeking and the timing for seeking those partnerships. Please list company spin-offs, if any. Limit 1500 characters.*

**9. FINANCIAL OVERVIEW:**

*Describe funding received to develop your technology. List the revenue per year for the last 3 years. Also list projected revenue for the SBIR funded product/service (such as product revenues, consulting or licensing fees) and expected timeframes. How much funding are you currently seeking and what is your timeline for seeking funds? What do you plan to accomplish with these funds? Limit 1500 characters.*

**Capital Raised to Date:** Please fill out the table below with information about capital that the company has raised since inception (include pre-incorporation awards, grants, private equity, venture capital, strategic partners, IPO, etc.):

Date	Type (grant, angel, venture, etc)	Source(s)	Amount	Additional Comments
8/2013	Series A	Generic Biotech Venture	\$3.5M	Example

**10. COMPANY MILESTONES:**

Please list major technical and commercial milestones expected over the next 24 months.

Milestone	Date

**11. What is your vision for the company’s future? (Check only one)**

- Stand-alone company mostly based on government R&D grants and contracts
- Stand -alone company mostly based on licensing revenue and/or commercial (R&D) contracts
- Stand-alone company mostly based on commercial sales of products or services
- Merge with, or be acquired by, another company
- Initial Public Offering – IPO
- Unsure

**12. What would you like to get from your participation in this program? Limit 600 characters.**

**13. List in order of preference up to 3 meetings/forums that you would like to participate in that are best suited for your technology/product/service. Limit 600 characters.**

## **Additional Information**

(The following page is ***NOT*** provided to reviewers and does not count toward the application page limit)

May we share this page with a Federal contractor for the purpose of program evaluation?

### **Company Demographics** (Select all that apply):

8(a) Qualified by SBA

(If interested in learning more about 8(a) requirements and certification, see <https://www.sba.gov/content/8a-requirements-overview>)

Inclusion of Women:  Majority Owned       Co-Owned       Leadership Role (describe): \_\_\_\_\_  
 No Role/Other Role(s)       Prefer not to answer

### Inclusion of Socially Disadvantaged Persons\*:

Majority Owned       Co-Owned       Leadership Role (describe): \_\_\_\_\_  
 No Role/ Other role(s)       Prefer not to answer

*\* A socially disadvantaged person is defined by federal law as an individual who has been subjected to racial or ethnic prejudice or cultural bias within American society because of their identification as a member of a group without regard for their individual qualities. The Small Business Administration (SBA) presumes that the following individuals are socially disadvantaged: Black Americans, Hispanic Americans, Native Americans, Asian Pacific Americans, and Subcontinent Asian Americans*

### **What do you think are the (external) barriers to your technology being adopted** (Check all that apply and use the space below to specify so that SBIR staff can suggest tools that may help)

- Implementing a regulatory/reimbursement strategy is the principle barrier to getting this product into use and adoption (the product needs regulatory approval or pathway)
  - Product differentiation is not explicit (your product/service does not stand-out among other similar offerings)
  - Reimbursement codes are not in place (e.g. if the technology/product is new or untested)
  - The current product(s) is well-entrenched (they have a strong position in the market)
  - The field is crowded with competitors pushing other products that are similar to ours (the number of competitors is large)
  - We have no competitors
  - We're a start-up and it is difficult to get the attention of large players in the market (larger players overlook or discount the existence of a start-up)
- (Please specify below):
- None of the above (Please specify below, limit 600 characters):

**What is the number of jobs (permanent or contractor) created by this NIH-funded SBIR technology to date?** \_\_\_\_\_