# NCI SBIR Investor Initiatives Application

**OMB No.: 0925-0766**
**Expiration Date: 04/30/2023**

## INSTRUCTIONS

If you would like to provide images or figures, please submit **one** additional PDF page (optional Appendix) with your email submission. If you have a link to a current video pitch of less than 5 minutes, please include the link in the appendix. **All forms must be submitted by EOD February 21, 2023**. Email your completed application to NCIsbirEvents@mail.nih.gov.

Review "Application Guide for Investor Initiatives" for additional instructions. Incomplete applications will be returned.

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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**

☐ By checking this box, I provide permission to share this application with non-federal investors and reviewers.

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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.

NCI SBIR Program Director: Select from dropdown

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## COMPANY INFORMATION

Official Company Name: Year Originally Founded:

Company Website:

Company Mailing Address:

Total Number Full-Time Employees: Total Number Part-Time Employees:

Company CEO:

Email: Phone:

Contact Person for this Application:

Title/Role:

Email: Phone:

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

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## EXECUTIVE SUMMARY

Please provide a short summary of your company & technology. Limit 2400 characters at 9.5 font.

## 1. TECHNOLOGY/PRODUCT OVERVIEW

Type of product/Technology (Select **one** most relevant option):

- ○ Small molecule
- ○ Biologics/Vaccine
- ○ Cell/Gene therapy
- ○ Surgical or Ablative device
- ○ Hospital device
- ○ Drug delivery device
- ○ Imaging device
- ○ Imaging agent
- ○ In vitro diagnostic
- ○ Bioinformatics/Health IT/Digital health
- ○ Research Tool

Technology Description (Please provide a short, 1-3 sentence, description of your technology):

Current R&D Status:

- ☐ Non-clinical technology in prototype development
- ☐ Non-clinical technology in full development/testing stage
- ☐ Pre-clinical development
- ☐ In clinical trials:
  - ☐ Phase I
  - ☐ Early Feasibility
  - ☐ Phase II
  - ☐ Feasibility/Pilot
  - ☐ Phase III
  - ☐ Pivotal
- ☐ Commercially available
- ☐ Other (Please explain):

**Technology/Product Overview Narrative** – 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 3600 characters at 9.5 font. You may refer to any figures or images attached in your one-page appendix.

## 2. SCIENTIFIC PROGRESS & STAGE OF DEVELOPMENT

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 ◯ Identification of CPT codes ◯ Technology Add-ons
◯ Insurance coverage ◯ CMC Processes ◯ Other, (described in write-up below)

**Stage of Development Narrative** – 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 of the regulatory and reimbursement strategy for the product under development, including an update on current and imminent regulatory applications, approvals, and hurdles. Please limit your response to 2700 characters at 9.5pt font. You may refer to any figures or images that you include in your one-page appendix.

## 3. MARKET DESCRIPTION & 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 at 9.5pt font.

## 4. COMPETITIVE ADVANTAGE

Please list/describe any unique attributes or competitive advantages (including IP, invention reports, trademarks, copyrights) the product has in the market over both current products and competing technologies under development. Limit 3200 characters at 9.5pt font.

**INTELLECTUAL PROPERTY**

**List any patent or patent applications.** *(Please enter numeric values where applicable. Feel free to expand on IP in your additional one page.)*

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

## 5. PUBLICATIONS, PRESENTATIONS, & AWARDS

Please list the most significant past and pending publications, presentations, and awards based on the company's technology. Limit 1500 characters at 9.5pt font.

## 6. MANAGEMENT

| Name, Title/Role | Domain expertise | Value Added/Previous Success |
|---|---|---|
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**Management Narrative** – Describe the team or management structure, highlighting years of experience, background, and relevant previous success, experience, and domain expertise. Limit 2700 characters at 9.5pt font.

## 7. BUSINESS DEVELOPMENT & 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 at 9.5pt font.

## 8. FINANCIAL OVERVIEW

**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 |
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**Financial Overview Narrative** – 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 2000 characters at 9.5pt font.

## 9. COMPANY MILESTONES

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

| Milestone | Date |
|---|---|
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## 10. 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

## 11. What would you like to get from your participation in this program?

- ☐ Seeking strategic partner (large business)
- ☐ Seeking investment
- ☐ Seeking scientific collaborators
- ☐ Other: (describe)
- ☐ Customer discovery
- ☐ Increasing company visibility and exposure
- ☐ Gaining insights into competition and/or IP landscape
- ☐ Validating business model

## 12. Select the top 3 meetings/forums that you would like to participate in that are best suited for your technology/product/service

*We will try our best to match you with one of your selected conferences, but it is not guaranteed.*

- ☐ Angel Capital Association Summit
- ☐ BIO CEO & Investor Conference
- ☐ BIO International Convention
- ☐ BIO Investor Forum
- ☐ Biocom's Global Life Science Partnering Conference
- ☐ BioNetwork
- ☐ Biotech Showcase
- ☐ HIMSS Global Conference & Exhibition
- ☐ Life Sciences Summit
- ☐ Medical Alley Innovation Summit
- ☐ MedTech Strategist Innovation Summit
- ☐ Precision Medicine World Conference
- ☐ RESI
- ☐ The MedTech Conference (Powered by Advamed)
- ☐ WSGR Medical Device Conference
- ☐ Other (please specify):

Was your company selected for NCI SBIR Investor Initiatives in 2022? ◯ Yes ◯ No

***If yes*** → *Use your one-page appendix to explain why you are re-applying and include details about progress since being selected last year.*

**ALL APPLICANTS**

We encourage you to include a one-page appendix to expand on any of the above sections or to include graphs, images, and/or charts. If you have a link to an existing video pitch of less than 5 minutes, please provide the link in the appendix.

Please refer to page 3 of the application guidance document for further application instructions.