NCI SBIR Investor Initiatives Application

OMB No.: 0925-0766

Expiration Date: 04/30/2023

Public reporting burden for this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0766). Do not return the completed form to this address.

INSTRUCTIONS

If you would like to provide images or figures, please submit <u>one</u> additional PDF page (optional Appendix) with your emails ubmission. 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 NClsbirEvents@mail.nih.gov.

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

	red by an external panel of industry personnel and investment FIDENTIAL DATA THAT CAN BE SHARED WITH INVESTORS						
\square By checking this box, I provide permission to s	\square By checking this box, I provide permission to share this application with non-federal investors and reviewers.						
NCI SBIR Grant or Contract Number for this product/technolog If you have multiple awards related to this technology/product, list the product NCI SBIR Program Director:							
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 mg	onths? Yes No						

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 Imaging agent
Hospital device In vitro diagnostic
Drug delivery device Bioinformatics/Health IT/Digital health

Imaging device 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 Phase II Phase III Phase III

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
(Filed, Provisional, Approved)			

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			

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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

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.

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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
iming 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

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.

COMPANY MILESTONES

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

Milestone	Date

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

Seeking strategic partner (large business) Customer discovery

Seeking investment Increasing company visibility and exposure

Seeking scientific collaborators Gaining insights into competition and/or IP landscape

Other: (describe) 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

Life Sciences Summit

Medical Alley Innovation Summit

MedTech Strategist Innovation Summit

BIO Investor Forum Precision Medicine World Conference

Biocom's Global Life Science Partnering Conference

BioNetwork The MedTech Conference (Powered by Advamed)

Biotech Showcase WSGR Medical Device Conference

HIMSS Global Conference & Exhibition Other (please specify):

Was your companyselected for NCI SBIR Investor Initiatives in 2022? Yes No

If yes \rightarrow Use your <u>one-page</u> 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.