



# Overview of Cancer Therapeutics Commercialization

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# What does it mean to commercialize a cancer therapeutic?

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# Routes to Technology Development in Biotech



## Pros

- Least demand on time
- Potential for personal impact
- Ability to troubleshoot challenges
- Default path

## Cons

- Difficult to partner early projects
- Possibility that the project is dropped
- Large demands on time
- Lack of expertise and/or connectivity
- No patient impact

**Flexibility is key!**





**You Are The**  
**Best Advocate**  
**For Your Technology**

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# Communicate with your Office of Technology Commercialization early and often

- Each office has a different approach to licensing
- Start of an ongoing conversation – these are your partners
- May help find a partner or pharma licensor
- Helps you to understand what your office considers as success



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# Starting a Startup

The first question is...  
**Should you?**

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# The 3 pillars of biotech commercialization

## Technology

- The heart of your company – this is the only thing that you can't fix!
- How is your solution better than everything else?
- What else can be done with this technology?

## Vision

- How does this fit into the current treatment landscape?
- What is unique about your strategy?
- Are you focused around a core technology, a core problem, or both?

## Team

- Who is leading this team, and have they done it before?
- Who else is "in"?
- Does anybody but you believe in this vision?

**Focus on these pillars before worrying about funding!**



# Tell Your Story, Iterate On Feedback

- What is the problem?
- Why has it not been solved?
- What are you doing to solve it?
- How many people can this help?
- Who else has tried and/or failed to solve this?
- What resources and people have you gathered?
- **What do you need and what will you do with it?**





# Gather Data: My Five Rules

- **Talk to everybody:** Don't be afraid to ask dumb questions!
- **Be bold:** Approach the unapproachable in service of your mission
- **Be respectful:** Have an agenda for your conversations, don't expect others to do your thinking
- **Look for the holes:** Every conversation should be framed around finding out why this isn't a good idea
- **“Failure” is always an option!**



# Define Goals – common goals

- **Seed (\$0.5M - \$5M)**
  - Licensing
  - Team building – executive and SAB
  - Outside validation of data / other key experiments
  - Optimization work (if needed)
- **Series A (\$5M - 30M+)**
  - Team building
  - Preclinical > IND or Phase I
  - Begin work on secondary assets
- **Series B (\$25M - \$80M+)**
  - Team building
  - Phase I studies lead
  - Secondary Assets



# Milestone Definition

- Milestones should be the decision points for continued funding – and your continued efforts!
- Funding is often disbursed in *tranches* – Chunks of funding tied to specific milestones
- Use key inflection points from your Goals that add significant value (versus things that merely have to get done)
- **Questions to ask yourself:**
  - What are the 2-3 challenges that, if solved, would enable the next round of funding?
  - What are the 2-3 milestones that would enable a sale/partnership/etc.?

# Develop Plan

01

Align goals to rough timeline

02

Include as much detail as possible, trim later

03

Buffer in "figuring it out" time







# How do I find a ~~CEO~~ team?

Co-Founder  
Advisors  
Specialists  
Clinicians

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# Funding Buckets



NIH RO1s  
NCI NExT Program  
CPRIT  
Foundations



SBIR / STTR  
NCI NExT Program  
CPRIT  
Foundations



Friends & Family  
Angel Investors  
Venture Capitalists



**SBIR · STTR**  
America's Seed Fund



**NATIONAL CANCER INSTITUTE**  
SBIR Development Center

**Fast-track  
(phase I & II)**

**NCI SBIR phase IIB  
Bridge Award**



- Proof-of-concept
- Up to \$400K over 6 to 12 months

- Research & development
- Commercialization plan required
- Up to \$2M over 2 years

- Technology validation & clinical translation
- Follow-on funding for SBIR phase II awardees from any federal agencies
- Expectation that applicants will secure substantial 3rd party investor funds
- **\$4 M over 3 years**

- Commercialization stage
- Use of non-SBIR/STTR funds

	Standard award	Hard cap	Waiver cap (IC specific)
<b>Phase I</b>	\$150,000	\$252,131	NCI: \$400,000
<b>Phase II</b>	\$1.0M	~\$1.68M	NCI: \$2.0M



## Key Applications

- Continued optimization and de-risking
- Secondary product development
- Secondary application development
- Supplementary funding

## Disadvantages

- Long application cycles
- Competitive: 10-20% payline
- Cannot support full development in therapeutics (or even many devices)
- US Citizen ownership requirement (>50%)
- Work must be completed in US
- SBIR – PI must be >50% employed by company





# Product Development

- **Seed Awards**

- \$3 million & 3 years
- Early-stage concept that may not have a final lead product
- May have a minimal team, many consultants
- Clear business case, clear product development process understanding and plan

- **Texas Therapeutics Company RFA**

- No official cap, historically \$20 million max & 3 years
- Mature concept <1 year from IND
- Veteran, experienced product development team
- Clear business case, clear product development process understanding and plan
- Detailed plan for clinical trials, regulatory pathway, and commercialization process

- **Requirements**

- All funds must be matched 2:1 CPRIT:Outside funds
- Texas residency obligation

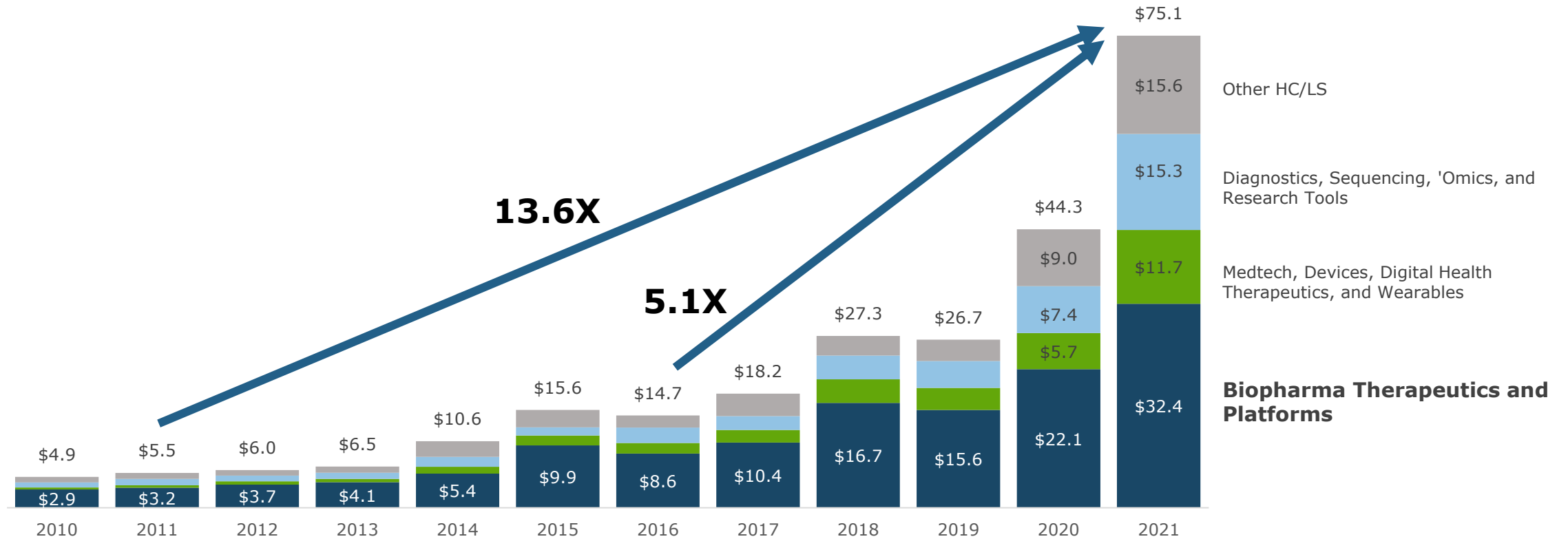


# Investment

- **Trade ownership (equity) for capital**
  - Who is in control?
  - What is your role?
  - How much ownership is fair?
- **Alignment of expectations is often necessary**
  - Investing in a company, or a technology they will build a company around?
  - How quickly to move? What is an acceptable outcome?
- **Must be able to make a clear business case with known risks and rewards**
  - Teachable skill, just like good grantsmanship

# Life Sciences Investing

Venture Totals - Healthcare and Life Sciences by Subsector (\$B)



Source: DealForma Database

DEALFORMA



# Types of investors

- **Grants and Public Funding**
- **Friends and Family**
- **Angel Investors**
- **Institutional (Venture Capital) Investors**
  - Classic VC
  - Venture Creation Models
- **Venture Studios**
  - Typically centered around an operations team
  - Often have limited capital, and rely on outside fundraising syndicates
- **Corporate Venture**
- **Service Partners**



# Deals that “check all the boxes”



Team



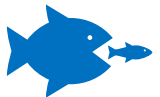
Technology



Intellectual Property



Market / Target Indication



Competition



# Common Pitfalls

- Not focusing enough on getting the right team
- Having an unbalanced capitalization table
- Underappreciating emerging technologies
- Not clearly demonstrating your differentiation
- Show me the data!
- Limited or indefensible IP filings
- Setting a budget based on what you “should” raise, versus setting a raise based on a budget
- Incorrect corporate structures
- Lack of agreements with key personnel
- Poor terms set by previous investors
- **Trying to fundraise before you are ready**

# TMCi Accelerator for Cancer Therapeutics



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

Gulf Coast Consortia  
QUANTITATIVE BIOMEDICAL SCIENCES

**utmb** Health

TMC*i*





# TMCi Accelerator for Cancer Therapeutics

- Prepares companies for success in every stage of growth by creating a **solid foundation**
- Supports a **critical stage** of company formation and launch
- **Brings together** founders, talent, knowledge, and investors



# Accelerator Structure and Benefits

## 2022 Accelerator Schedule

<b>January</b>	Bootcamp
<b>February – July</b>	Bimonthly in-person curriculum
<b>September</b>	Grant submission TMCi Accelerator for cancer therapeutics SUMMIT

## Benefits

- Expert consultant access
- Executive mentor advisory sessions
- Grant writing support for SBIR and CPRIT applications
- Investor introductions
- GCC CPRIT core access

**All benefits to participants are 100% Free**

# 2022 cohort focus areas

## Cell Therapy



Robert Jenq



Bruna Coradetti



Xiaotong Song

## Targeted Therapy

### Breast Cancer



EtiraRX



Riverwalk Therapeutics



Ratna Vadlamudi

### Metabolomics



Phillip Scherer

## Immunotherapy



StellaNova



Stephen Safe



Hans Hammers  
Xiankai Sun



Atomic Therapeutics

### Oral Cancer



CAD Rx



Cara Gonzalez



Subhash Chauhan



Shuxing Zhang

## Delivery Platform



Musiq Bio



OmniNano

## Diagnostic



SceneXo

## RNA Modifying



Wenbo Li



George Calin





# Questions?

ACT  
Applications  
**OPEN**  
until Oct 7

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