



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

# *Elements of Successful Product Development Applications*

Monday, November 9

12:30-1:15 pm

PANEL

***Moderator:***

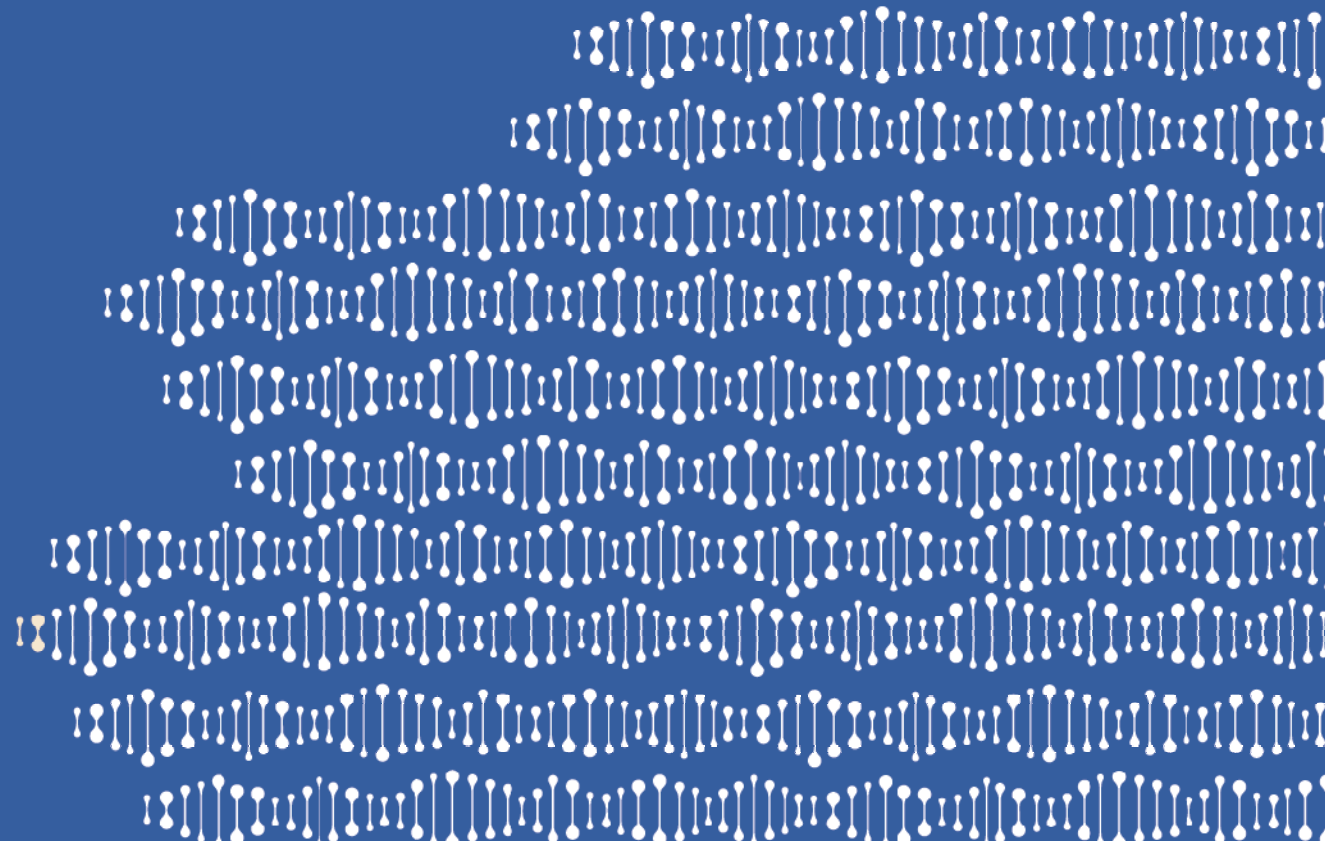
Craig Rosenfeld, MD

***Panelists:***

Kristen Doyle

Rob Sarisky, PhD

Margaret Sampson, PhD



# Product Development Program Overview

*Kristen Doyle*

- *CPRIT's Deputy Executive Officer and General Counsel*
- *Served as Interim Chief Product Development Officer (January 2013 – April 2014, July 2015 – October 2015)*



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- *CPRIT's Unique Role*
- *Product Development Program Priorities*
- *Program to Date*
- *Review Process*

# CPRIT's Unique Role in Fighting Cancer

## Mission

- Create and expedite innovation in cancer research into prevention and cures
- Attract, create, or expand research capabilities
- Create high-quality new jobs in Texas
- Develop and implement the Texas Cancer Plan



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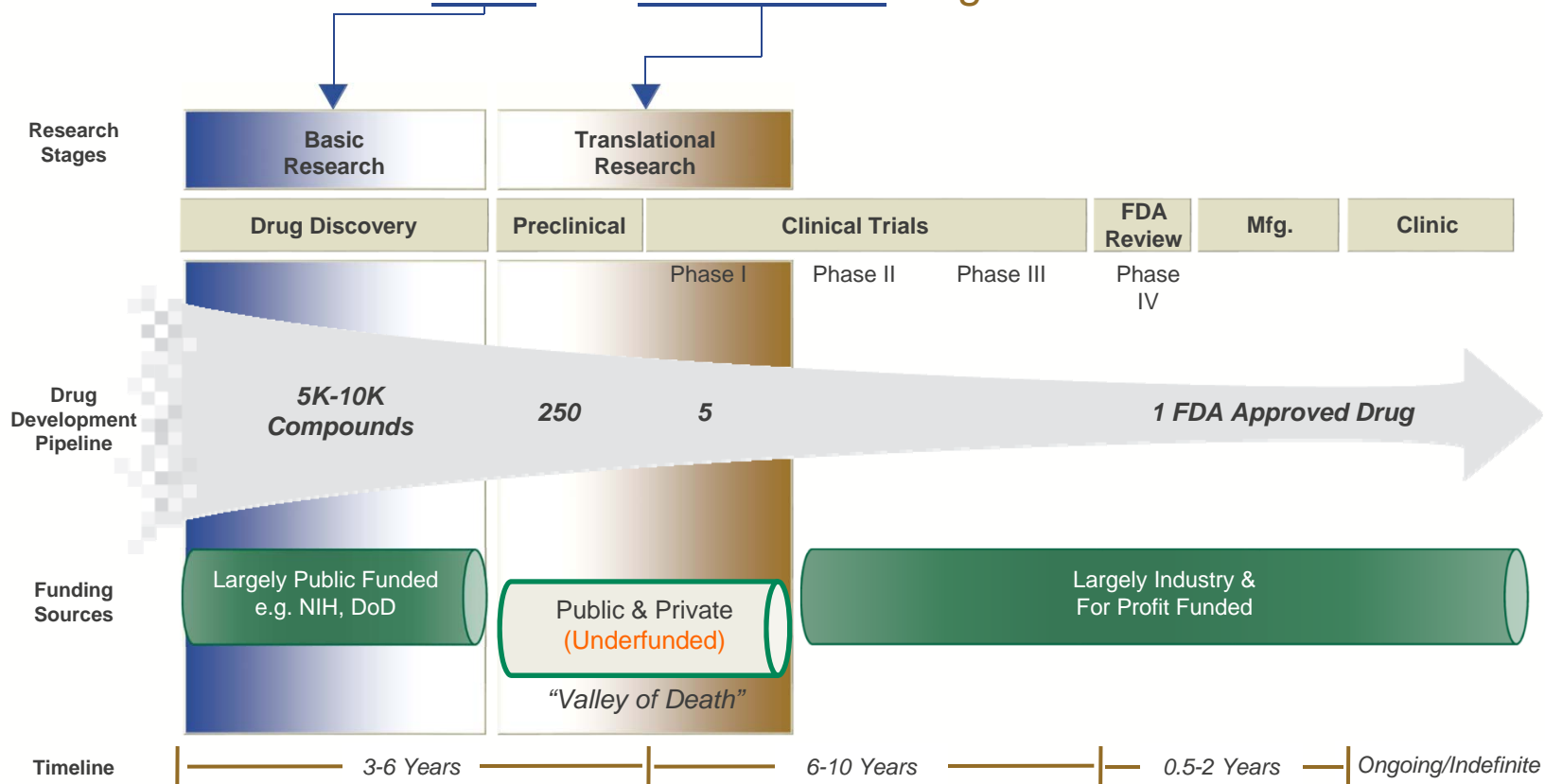
## Action

**Award merit-based, peer reviewed grants to Texas-based entities and institutions for cancer-related research, product development and the delivery of cancer prevention programs and services.**



# CPRIT's Unique Role in Fighting Cancer

CPRIT focuses on the basic and translational stages of cancer research.



Average cost for approved drug: **\$1 Billion**

General timeframe to approved drug: **10-15 years**



# Product Development Research Program

## Goals

- To improve patient care through expedited innovation and product development
- To foster economic development in Texas' emerging life sciences industry and the creation of high-quality new jobs in this state
- To provide a direct return, through intellectual property and revenue sharing, on the investments made by Texans



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## Grants

### Product Development Research Grants

*27 grants announced totaling \$251 million*

- More than \$60 million total grant funds expended
- Over \$380 million invested in R&D with matching funds
- 293 jobs added

Product Development Portfolio

as of August 2015

# CPRIT-Supported Companies Throughout Texas

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|                        |          |
|------------------------|----------|
| <b>Austin area</b>     | <b>8</b> |
| <b>College Station</b> | <b>3</b> |
| <b>Dallas</b>          | <b>4</b> |
| <b>Houston</b>         | <b>9</b> |
| <b>Lubbock</b>         | <b>1</b> |
| <b>San Antonio</b>     | <b>1</b> |

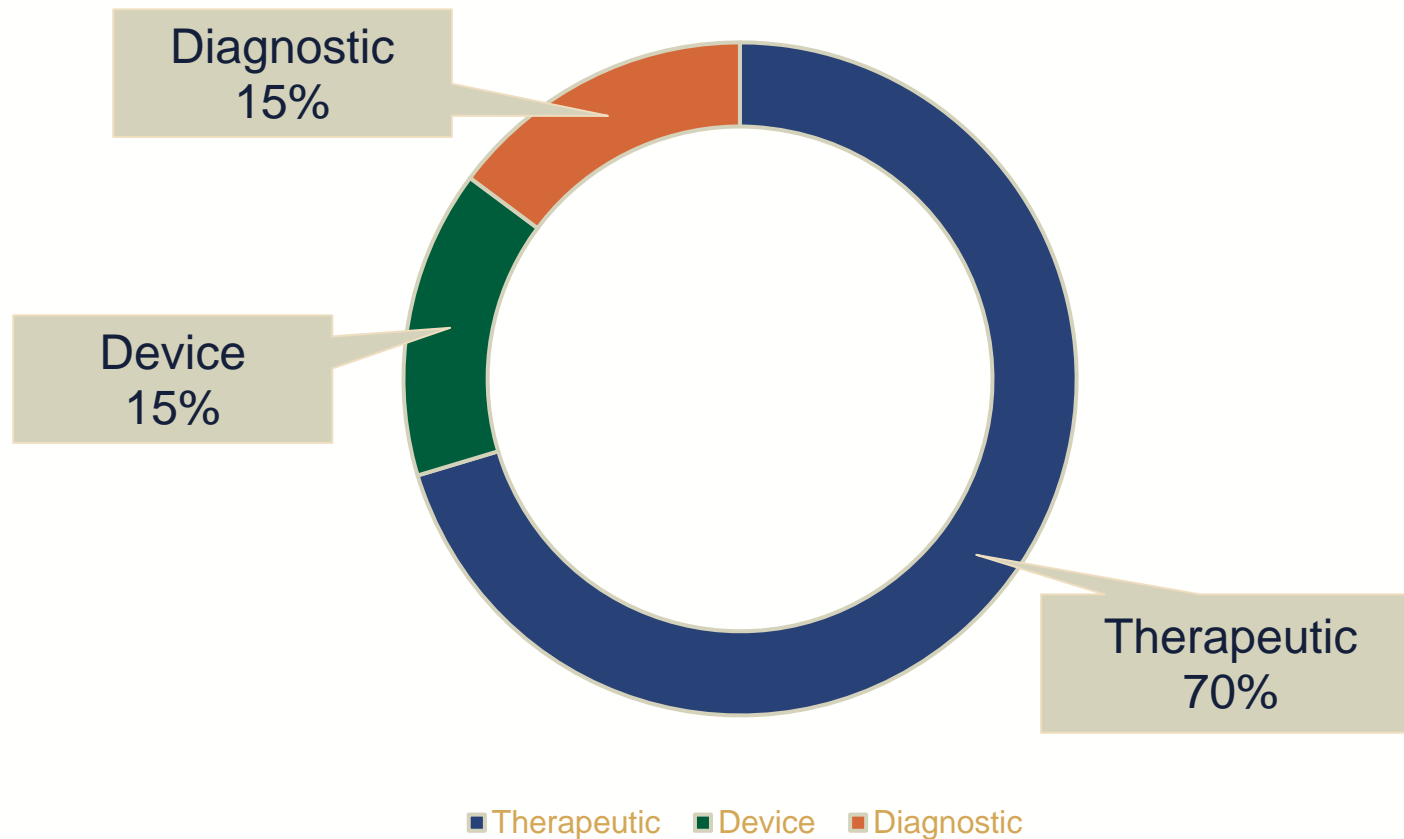
(as of August 2015)



# Product Development Portfolio

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## PROJECTS FUNDED



# CPRIT Product Development Grants





# Product Development Research Grants

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## FOLLOW-ON FUNDING

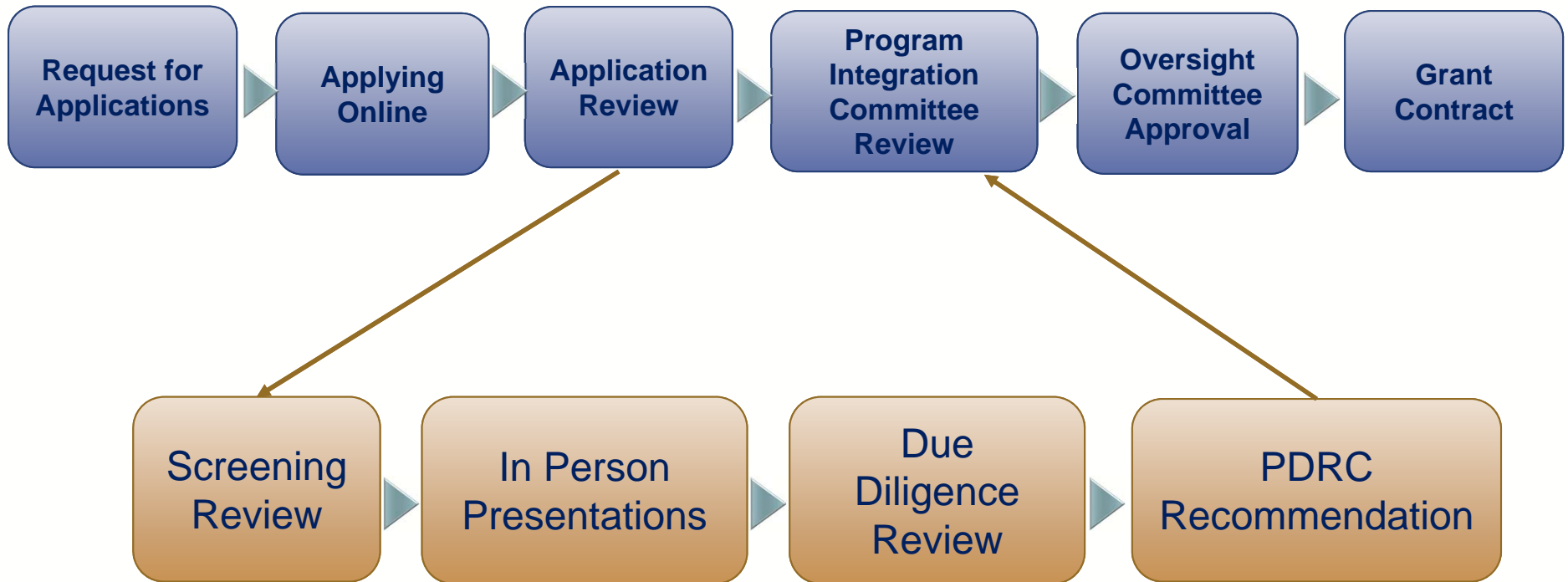


CPRIT funding has prompted **\$927.5 million** in follow-on investment funding for CPRIT-supported companies



# Product Development Review Process

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# Product Development Review Council



Jack Geltosky, PDRC Chair



David Shoemaker, PDRC Vice-Chair



Kapil Dhingra, M.D.



Roy Cosan, B.B.A.



# Product Development Application Success Rate

| Cycle  | Submitted | Invited to Present | Approved by Oversight Committee | Contracts Awarded | Success Rate Percentage |
|--------|-----------|--------------------|---------------------------------|-------------------|-------------------------|
| FY10.2 | 25        | 9                  | 4                               | 4                 | 16                      |
| FY11.2 | 14        | 7                  | 1                               | 1                 | 7                       |
| FY12.1 | 32        | 8                  | 2                               | 2                 | 6                       |
| FY12.2 | 24        | 11                 | 4                               | 4                 | 16                      |
| FY12.3 | 31        | 11                 | 0                               | 0*                | --                      |
| FY13.1 | 26        | 11                 | 4                               | 3**               | 15                      |
| FY13.2 | 14        | 4                  | 2                               | 1**               | 14                      |
| FY13.3 | 10        | 0                  | 0                               | 0*                | --                      |
| FY14.1 | 43        | 19                 | 4                               | 4                 | 9                       |
| FY15.1 | 30        | 17                 | 6                               | 6                 | 20                      |
| FY15.2 | 46        | N/A                | 20                              | 20***             | --                      |
| FY15.4 | 16        | 10                 | TBD                             | TBD               |                         |
| FY16.1 | 25        | 12                 | TBD                             | TBD               |                         |

\* - The application review process was stopped due to the funding moratorium.

\*\* - An applicant that was approved for an award declined to execute the award contract.

\*\*\* - Applications in this round were submitted by researchers at academic institutions for Early Translational Research Awards.



# Review Criteria

## Criteria

- Significance and Impact
- Product
- Market Plan
- Development Plan
- Competitive Landscape
- Scientific Plan
- Management and Staffing



## Questions Reviewers Ask

Will the work result in the development of innovative products?  
Will the outcome substantially impact cancer?

Is there a proof of relevance?

Is there a realistic picture of market size and penetration? An adequate assessment of potential competitors?

Is the plan or pathway well characterized and appropriate? Are there milestones? Does the budget support the plan?

Is the applicant aware of the competitive landscape and intellectual property issues?

Is the project based on a feasible research framework? Are the methods appropriate?

Does the applicant have the appropriate level of management experience to execute the strategy? Does the team have the needed experience?

# Key Themes for a Successful Application

*Rob Sarisky, PhD*

*CPRIT Product  
Development Review  
Panel Member*

*Chief Business Officer,  
Forma Therapeutics*



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- Excellence in Science
- Nuts and Bolts
- Project Plan and Contingencies

# Excellence in Science

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- Propose novel, original science - a great idea is only the start
- Embrace the competitive funding process
  - Go well *beyond a direct extension* of your ongoing research
  - Exit your comfort zone to *diverge from common approaches* being used simultaneously in many labs worldwide
  - *Think beyond a standard team compilation* that solely brings together conventional combinations of scientists all from related disciplines
- Iterate, seek counsel, and iterate again prior to submission
  - Bounce ideas off colleagues and incorporate into successive drafts
  - Tailor application to CPRIT, rather than repurposing from other applications
  - Painstakingly comb through the literature for current and competitive insights
  - Seek to stand out from the crowd
- Describe the possibility of enduring influence from proposed work
  - Highlight the impact factor and return on investment



# Nuts and Bolts

## Rules of the Game

- **Follow the Directions**
- **Structure for Success**

- **Focus and Emphasis are your best friends**



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## Watercooler Tips

Sounds simple on paper, albeit harder in practice

Write with extreme clarity so proposal is easy to read

Preliminary Studies - should prove that the specific aims are achievable and that the methods are appropriate to get the desired information

*An outstanding application addresses a difficult problem in a way that seems so simple in retrospect, leaving reviewers to wonder why they didn't think of the idea first*

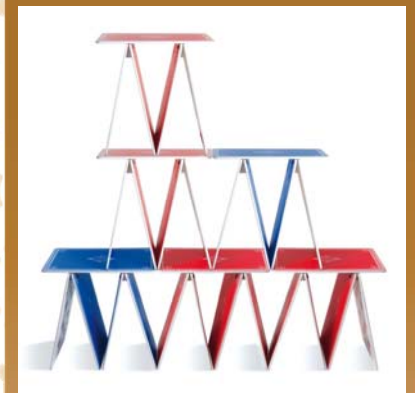
Inclusion of all the requisite information doesn't necessarily equate to a well-organized, easily understandable proposal

Overwhelming reviewers with copious detail and peripheral supplementary material will (a) make it more difficult for reviewers to make connections between the various aims, (b) may result in proposal being deemed unrealistic and insufficiently focused



# Project Plan and Contingencies

- Project Plan - promise or peril?
  - Timetable, funding requested, deliverables and the critical path **are all interrelated**
- Timetable –
  - A well-thought-out timetable is imperative, especially for complex proposals
  - It informs reviewers the PI has really thought the project through
- Funding –
  - Request an appropriate amount of funding or reviewers may question the applicant's competence in proposed area
- Critical Path –
  - **Define workhorse assay, the funnel of studies to be done, and what constitutes a Go-NoGo**
  - Neglecting to discuss alternative experimental outcomes or propose alternative approaches isn't ideal
  - If proposal lacks a fallback plan of alternative strategies, then entire house of cards for project plan can collapse



# Intellectual Property Due Diligence Overview

*Margaret Sampson,  
PhD*

*Partner, Baker Botts,  
LLP*



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Does the Applicant have protectable intellectual property, for example, patentable inventions?

Has the Applicant filed to protect its intellectual property?

What is the scope of the existing and potential intellectual property protection?

Has the Company obtained all rights to its intellectual property?

Is any of the Company intellectual property licensed from other parties?

What is the scope and what are the conditions of such intellectual property licenses?

Has the Company secured ownership rights to intellectual property being generated on its behalf?

# Questions from the Audience

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