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WINNING THE GOLD: REGULATORY & INTELLECTUAL PROPERTY STRATEGIES FOR ATTRACTING EARLY-STAGE INVESTORS

Dr. Lisa Jenkins VanLuvanee
Chief Operating Officer
Vice President, R&D
Facet Life Sciences

Jeremy Cubert, J.D.
Partner
Potomac Law Group

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What do investors want to see?

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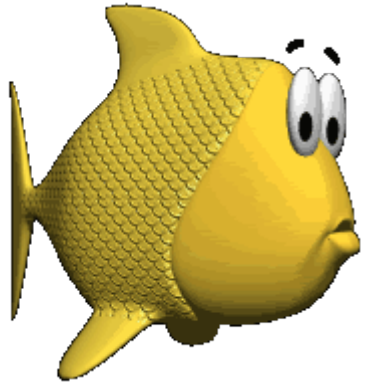
An example for discussion: FishyCo

- Entrepreneur
- Approaching an academic organization studying fish oil for the treatment of anxiety
- Some initial interest from angel investors
- What's next?



FishyCo's product strategy

- What is our corporate goal and objective?
  - What are we hoping our product will bring to the market?
  - Do we plan take our asset "all the way"?
  - Is FishyCo building a company or developing a product (or both!)?
  - Are we developing in more than one country? When?
  - Does FishyCo's financials support our product strategy?
- Work with the end in mind

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Intellectual product strategy

- What is intellectual property and why is it important?
  - Know-How, Patents, Copyrights, Trademarks
  - Contracts
  - Collaborations
  - People

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Intellectual product strategy (cont.)

- Protect IP Assets
  - Preserving IP
    - Identifying IP Assets
    - Publications, Presentations
  - Building a patent portfolio
    - R&D, Collaborations
      - Secure Rights
    - Provisional Patent Applications
    - Domestic and Foreign Protection

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Intellectual product strategy (cont.)

Mitigate Risk

- Due Diligence
- Freedom To Operate
  - Identifying IP Assets
  - Publications, Presentations
- Patentability – Products of Nature; Diagnostics
- Building a patent portfolio
  - Provisional Patent Applications
  - Domestic and Foreign Protection

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IP protection for early stage products

- Manufacturing
  - Contracts
  - Methods
  - Formulations
- Preclinical
  - Mechanism of Action
  - Toxicity
  - Pharmacokinetics

FishyCo's regulatory strategy

- How do we progress our product in the United States (US FDA)?
  - Is my product regulated and how?
  - Do I need to prepare an application for FDA review?
  - Should I talk with FDA?

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What is an IND?

- IND = Investigational New Drug Application
- A collection of information related to a drug product that is being studied for use in the **diagnosis, cure, mitigation, treatment, or prevention of disease**.

What does an IND include?

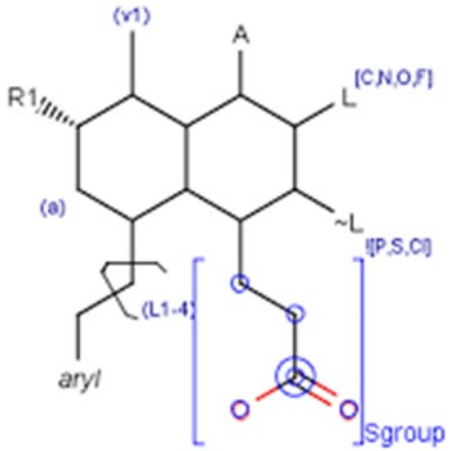
Preclinical Information

- Pharmacology – MOA and ADME (absorption, distribution, metabolism, elimination)
- Toxicology –
  - Acute and chronic toxicity
  - Reproductive and embryofetal toxicity
  - Mechanistic toxicity
  - Carcinogenicity/mutagenicity
- Compliance with GLP is expected for pivotal *in vitro* and *in vivo* studies

What does an IND include (cont.)?

Manufacturing Information

- Drug Substance, Drug Product (and Placebo!)
  - Description of physical, chemical, or biological characteristics and evidence supporting identity
  - Description of method of preparation
  - Limits to ensure the identity, strength, quality, and purity
  - Stability data
  - Note: GMP product is NOT required
- Environmental Assessment



What does an IND include (cont.)?

Clinical Information

- Detailed protocol for proposed study
- Previous human experience (if any)
- Investigator information
- Labeling
  - Investigator's Brochure
  - Carton / container labeling
- Commitments to follow US law:
  - Informed consent
  - Investigational Review Board oversight

How do I know if I'm ready to go to IND?

Talk to FDA!

- Pre-IND "Type B" meeting
  - Meeting request
  - FDA will respond within 21 days
  - Meeting scheduled in ~60 days
  - Background package - due 30 calendar days before meeting
  - Written Comments Only
- You are permitted to have as many pre-IND meetings as you need (new with PDUFA VI).
- There is no fee

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IP protection at clinical stage of development

Clinical Considerations

- Indication
- Companion Diagnostics
- Dosing
- Labeling

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Key to success – Align IP and regulatory strategy

IP and Regulatory must work together

- Maximize value at all stages of development
- Minimize missteps and lost opportunities
- Keep costs in check

Questions and contact information

Dr. Lisa Jenkins VanLuvanee
Lisa.Vanluvanee@facetls.com
1-267-309-9454

Jeremy Cubert, J.D.
JCubert@PotomacLaw.com
1-301-337-7523