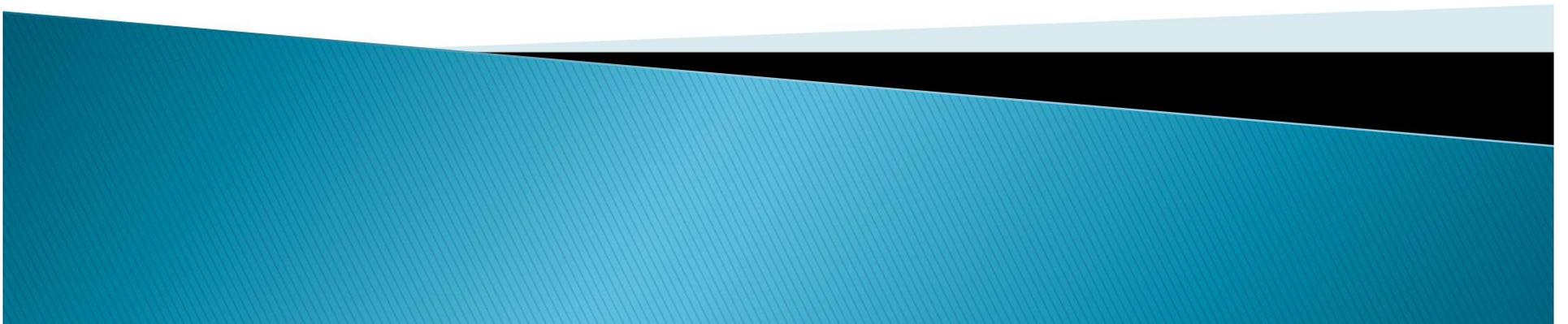


Leveraging Partnerships as a Startup in Life Sciences

ENET Meeting June 7, 2022



My background: Naomi Vishnupad Ph.D.

- ▶ Entrepreneur business executive with 20+ years experience in life sciences
- ▶ Has developed and introduced novel pharmaceutical and consumer products into the market
- ▶ Chief Scientific Officer at Romeg Therapeutics, LLC
- ▶ President and COO at Imaginative Research Associates, Inc.
- ▶ Inventor on several patents resulting in marketed products in dermatology, inflammation, and pain
- ▶ Has a doctorate in immunology, is a recreational runner and lives and works in the Boston area



Company Background

- ▶ Romeg Therapeutics LLC founded in 2015 develops drug therapies for unmet needs, usually a novel dosage form of an already approved drug to provide benefit to patients over the existing therapies
- ▶ Romeg's first drug approval was the first and only liquid colchicine product for the prophylaxis of gout
- ▶ Imaginative Research Associates Inc. is a private company providing patented innovative product technologies for the dermatology industry, including Rx, OTC, and cosmetic products.



Important Considerations When Seeking Partners

- ▶ Are you product or service company?
- ▶ Do you need to in license any patents, IP, or technology for your product or service? For example are you working with or partnering with an academic institution that has IP you need?
- ▶ Do you have an invention or need to file a patent application to obtain patents for potential licensing partnerships?
- ▶ Does your product or service require FDA approval or regulatory filings?
- ▶ What development work do you need to do? Product development, analytical, clinical?
- ▶ What type of companies do you need to move your product/service towards commercial viability?
- ▶ Do you have a NCE or novel product/technology
- ▶ What is the potential market?
- ▶ What is the estimated time to market?
- ▶ What is your exit strategy/goal for the product/technology



Types of Partnerships

Strategic Investment

- ❖ Investor company to fund startups such as VC's, angel investors, or larger companies
- ❖ Hands off transaction, investor is not involved in day to day activities

Co-development

- ❖ Joint contributions of labor, IP, capital, and assets
- ❖ Teams from both companies work together to develop product
- ❖ Usually involves upfront investment and milestones as development progresses.
- ❖ Early stage partnerships can be with CMO's/R&D companies and late stage with marketers and commercial partners

Joint venture

- ❖ A large life science company and a startup with aligned technologies form a new joint entity
 - ❖ A very integrated partnership with significant collaboration
 - ❖ Can be well negotiated for both parties for the new entity
 - ❖ Limits the individual company's liabilities
 - ❖ Challenging exit strategies
- 

Types of Partnerships

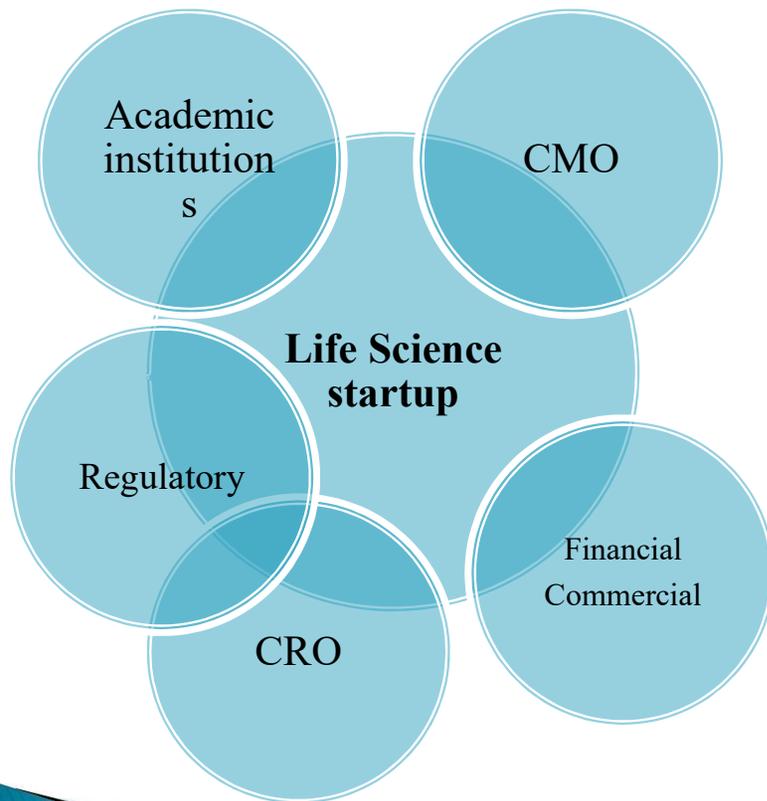
Licensing agreement

- ❖ Occurs at any stage of product development
- ❖ Upfront payments, milestones, and royalties to inventor/developer for rights to further develop and commercialize
- ❖ Sometimes potential for multiple licensing partnerships with the same IP: For example different therapeutic areas or U.S. and outside U.S. rights
- ❖ Less collaboration between the parties
- ❖ Licensor can lose profit potential and control of the product in the market
- ❖ Can be challenging for Licensor to keep informed on the Licensee's efforts/activities

Co-marketing Agreement

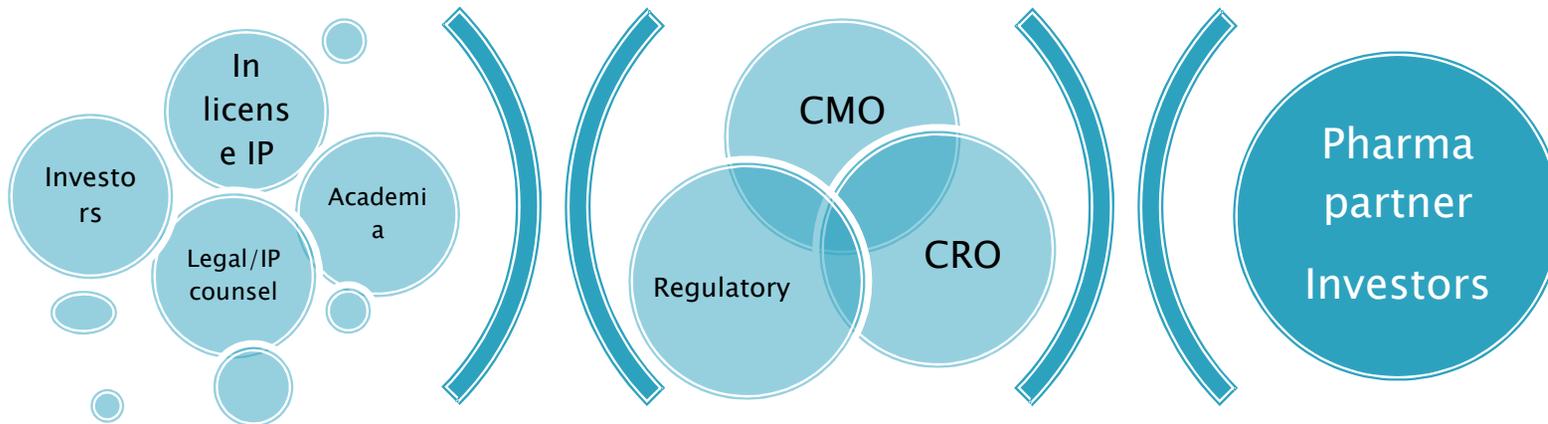
- ❖ Usually later stage product
 - ❖ Involves royalty payments for rights to product and/or sell
 - ❖ Often both companies sell the product
 - ❖ Can divide different markets between partners: For example digital marketing versus sales force
 - ❖ Beneficial when financing or marketing efforts are limited
- 

Life Science Partners



- **Academia**: Early R&D/ideas/IP partners
- **CMOs**: product development, analytical, CMC, manufacturing, etc.
- **Regulatory consultants**
- **CROs**: Clinical studies
- **Financial/Commercial**: investors, advisors, later stage development, marketing partners, larger pharma/biotech companies

Identify Partner Needs at Each Stage



Idea/Concept:

Do you need to license IP or any academic studies or conduct early R&D for proof of concept?

Can contract with universities for early R&D, IP, or referencing studies

What work needs to be done to secure patents?

Do you need capital investment?

Development: What formulation, analytical, toxicology, packaging studies, etc. need to be done?

The CMO is an important partnership.

What clinical studies are required for approval? A regulatory consultant and a good CRO are strategic partners

Late Stage: Do you need investors to fund clinical trials or an established pharma/biotech company to license or acquire the IP/technology/IND/NDA?

Co-development and Marketing partners

Strategic Alliances

Small business working with small business

- ▶ When you find a good partner/company to work with, nurture the relationship
- ▶ Academia looks for partners to license out IP or research studies
- ▶ CMOs: Development and Manufacturing partners may be willing to do the work for an equity stake or a share of future profits
- ▶ CRO's may work with startups to reduce clinical study costs if the relationship is long term
- ▶ Work with advisors, legal counsel, regulatory consultants who understand startups and small business
- ▶ Look for smaller service companies to partner with, because they are nimble and move quickly and will be more responsive to you.



Examples

- ▶ Partnered with various CMO's to further develop novel dermatology and skin care products and then structured manufacturing and supply agreements with the CMO and a licensing agreement with the commercial partner
- ▶ Conducted early R&D on acne products, contracted with a CMO to further develop the product, and licensed out the products and IP to large pharmaceutical companies for upfront payments, milestones, and royalties
- ▶ At Romeg Therapeutics, raised capital from investors, worked with consultants, CMOs, and CRO's to develop product and obtain FDA approval and licensed the IP and NDA out to a pharmaceutical company for commercialization
- ▶ I have worked with one of the CMO's for over 20 years as both a licensee in my dermatology business and a development and manufacturing partner for the start up.



Necessary Considerations

- ▶ Protect novel technology, ideas, products: Confidentiality agreements are necessary
- ▶ Alliances and contracts require legal counsel and attention to detail
- ▶ Potential partners will conduct extensive diligence on the startup, and the startup should also conduct diligence on the larger company. Ask for information and ask lots of questions.
- ▶ Negotiations can often be contentious, try and leave emotions out
- ▶ Require regular communication, reports of activity and multiple contacts in contracts and agreements
- ▶ Partners, particularly manufacturing, clinical, and commercial are critical to the success of life science startup's products and services, so choose wisely.
- ▶ Startups should make sure that there are internal partners or trusted external advisors to assist with troubleshooting and avoid your own echo chamber



Thank you!

My contact information:

naomi@imaginativeresearch.com



Questions

- ▶ How do you find commercial marketing/licensing partners?
- ▶ Have you had a failed partnership or alliance?
- ▶ What do you think about accepting company stock or shares instead of cash for upfront or milestone payments?
- ▶ What problems have you encountered with partners?

