Life Sciences Startups – How to Begin

Life Sciences & The Law

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Financial Poise Webinars

FINANCIAL POISE

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Meet the Faculty

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Panelists

Edward Amer - Goodwin

Matthew Ferry - Morrison & Foerster LLP

Bill Walker - Duke Engineering

Ed Pease - Mintz

Moderator

Jay Reilly - Foley Hoag

About This Webinar

Life Sciences Startups – How to Begin

Life Sciences startups are different from other startups. So much depends on the type of technology being developed, the personal strategic goals of the founders, the specific product and its competitive landscape, and even where the technology was created—it can all be overwhelming for even experienced life sciences entrepreneurs. It can be overwhelming to know where to start.

In this episode, we'll lay the foundation for understanding a variety of critical issues, highlighting how building a life sciences company is different from other types of companies. We'll break this mountain of tasks down into manageable bite-sized pieces and help you prioritize what to tackle first.

About This Series

LIFE SCIENCES & THE LAW 2025

This webinar is part of a series titled “Life Sciences & The Law 2025.”

"We Bring Good Things to Life" was an advertising slogan used by General Electric between 1979 and 2003, focused mainly on General Electric's appliances and lighting fixtures. We’d argue that it would be an even better slogan for the Life Sciences industry.

The Life Sciences Industry encompasses companies and organizations that are dedicated to researching, developing, manufacturing, and distributing products and technologies to improve human and animal health. Key sectors within life sciences include biotechnology, pharmaceuticals, medical devices, and diagnostics. The industry’s work ranges from bench research and small-scale manufacturing to performing small and large-scale clinical trials, developing manufacturing processes on a commercial scale, working closely with regulatory agencies, to developing pricing, marketing, and distribution strategies. The life cycle of a drug or medical device often involves many parties controlling the product at various times, involving the bench of university researchers, development by small startup companies, commercialization by larger industry players, diversification by sublicensees, and distribution by resellers.

Life sciences is a highly regulated field due to its direct impact on health and safety, with strict compliance standards overseen by regulatory bodies like the FDA in the United States and EMA in Europe. The industry is characterized by high research and development (R&D) costs, long development timelines, and significant investment in innovation and technology. The life sciences industry is also increasingly interdisciplinary, intersecting with data science, artificial intelligence, and bioinformatics to drive advancements in personalized medicine, gene therapy, and diagnostics.

Episodes In This Series

1. Life Sciences Industry Basics

    Premiere date: 4/29/25

2. Life Sciences Regulatory Overview

    Premiere date: 6/10/25

3. Life Sciences Startups – How to Begin

    Premiere date: 7/29/25

4. Funding a Life Sciences Company

    Premiere date: 10/7/25

5. IP Strategies for Life Sciences Companies

    Premiere date: 11/18/25

Episode #3

Life Sciences Startups – How to Begin

Each Financial Poise Webinar is delivered in Plain English, understandable to investors, business owners, & executives without much background in these areas, yet is of primary value to attorneys, accountants, & other seasoned professionals. Each episode brings you into engaging, sometimes humorous, conversations designed to entertain as it teaches. Each episode in the series is designed to be viewed independently of the other episodes so that participants will enhance their knowledge of this area whether they attend one, some, or all episodes.

Before You start

Know the Company - Validate the business proposition

- Define the Problem Clearly
- Define Your Target Customer
- Define Your Target Investor
- Outline Your Value Proposition
- Test the Solution
- Evaluate the Competitive Landscape
- Assess Willingness to Pay

Know Yourself – What are your own personal goals – Why are you doing this

- Serial entrepreneur
- Taking advantage of an opportunity
- Inventor who will hand this off
- Forming a lifestyle company
- Forming a long-term growth for sale
- Forming a long-term growth company to keep

Know Your Partners – Who are you doing this with

- What skills and resources do they bring to the table
- What do you need from them in the future
- Startups need experts in technology, experts in product, and experts in venture
- creation
- Make sure values and strategic goals are aligned—talk specifics

A Word on Exit Strategy

- Exit strategy influences:
  - ➢ The form of corporation
  - ➢ How you staff the startup
  - ➢ What you pay attention to in growing the startup
  - ➢ How closely you need to observe corporate formalities
  - ➢ Employee compensation and incentives
  - ➢ Succession planning

Formation

Ownership 101

- You must form an entity:
  - ➢ If you might subject yourself to personal liability.
  - ➢ If you will be generating IP
  - ➢ If you have co-founders
- Corporations
  - ➢ Stock
  - ➢ Common vs. preferred
- LLC's
  - ➢ Percentage ownership
  - ➢ Contractual preferences

Founders Equity Defined

- The term "founders' shares" typically connotes an outright award of stock or units to a founding member of a management team
  - ➢ All founders that are given shares will be taxed at the fair market value of those shares as of the date they are given. Typically, the value of shares and units at the formation stage is nominal.
  - ➢ If the founders pay the fair market value purchase price for their founders' shares, whether with cash or with non-cash contributions to the Company, there would not be a tax impact.
  - ➢ This purchase price can be paid through the contribution of cash, intellectual property and other assets.

Allocating Ownership

- Honestly assess the anticipated contribution of each Founder over the next several years of the Company, and the resources the Founder has contributed to date

- Do not overvalue past contributions
  - ➢ Y Combinator will not invest in a company with a non-active Founder holding more than 10% of the Company
  - ➢ Assign a premium to execution, a great idea is just that, it takes execution to build a successful business
  - ➢ Be realistic about what everybody’s contribution to the value proposition will be
  - ➢ Vesting provisions may be appropriate

- An equal division of equity is rarely the right answer

Tips for Allocating Ownership

- Pick somebody to be in charge
  - Even if you have one person responsible for one area, and another person responsible for another area, somebody needs to be in charge of running the entire business
  - Important for a founder to be self-aware enough if they are not truly broadly qualified they need to defer to the true CEO

- Avoid ownership numbers that could result in tie votes or deadlocks

- Too much emphasis on past contributions can be demoralizing for incentivizing future growth

Preparing for Founder Disputes

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- Consider the dissolution scenario up front
  - ➢ Buy/sell arrangements
  - ➢ Whose business is it
  - ➢ Valuation issues
  - ➢ Tax considerations on buyout

- Common break up scenarios
  - ➢ Health—death, disability, incapacity
  - ➢ Performance—talent, strategic goals, effort, motivation

LLC or corporation? Type of Structure?

- You must have an entity
  - ➢ Do not run your business without the protection of an entity
  - ➢ The two primary alternatives are C Corp or LLC

- Type of asset or assets can drive varying structures

- How to choose
  - ➢ Exit strategy – Single exit or multiple exits
  - ➢ Single asset or platform technology
  - ➢ Tax impacts
  - ➢ Governance differences
  - ➢ Investor strategy

Corporation Overview

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- A legal entity that is established by filing a Certificate of Incorporation with the state
- Managed by a board of directors—oversight
- Run by an executive team—day-to-day operations
- Owned by stockholders that generally do not have liability for the obligations of the corporation
- Different classes of stock, with different rights and preferences, can be established
- **Corporate entities are taxed. Stockholders then get taxed AGAIN on any dividends they receive ("double taxation").**

LLC Overview

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- A legal entity that is established by filing with the state
- May be member-managed or manager-managed
- Members each own a percentage of the company, rather than shares
- An operating agreement may be entered into that allocates different rights and preferences to various different members
- The structure is very flexible
- **This structure also eliminates double taxation**

Startup Life Sciences Funding

Sources of Capital

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- Personal Savings
- Friends and family
- Incubators/Accelerators/Business Plan Contests
- Angels
- Strategic investors
- Government grants
- Venture capitalists
- Startup Life Sciences Funding

Investment Solutions for Early-Stage Life Sciences Companies

- SAFE's and Convertible debt
  - ➢ Simple Agreement for Future Equity
  - ➢ Conversion into equity, valuation cap, discounts
  - ➢ Considerations for each
- Friends and Family Common Stock
  - ➢ Simplest solution, but not as protective for friends and family
  - ➢ Puts friends and family in same position as founders
- Preferred Stock
  - ➢ Economic protections for investors
  - ➢ Governance protections for investors
- Grants
- Bank Debt

Shark Tank Explained – Valuing the Enterprise

- The most important factors in understanding what you own is the value of the enterprise, and what percent of it you own
- Example – $5 million for 20%
- Pre-money vs. post money valuations
- Determining objective valuation
  - (Sum of the parts)
  - (Comparable transactions)
  - (Discounted cash flow)
- **The real value of the enterprise is completely up for negotiation**

Valuing Life Sciences Companies

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- Unlike other startups, valuing life sciences companies can be almost impossible, especially at the early stages

- Variables influencing valuation of life sciences companies:
  - ➢ Indication being pursued
  - ➢ Size of addressable market for the indication
  - ➢ Benefits of solution vs. standard of care
  - ➢ Size and duration of clinical trials
  - ➢ Cost of goods of the solution
  - ➢ Supply chain issues
  - ➢ Competition and uptake challenges

- Most of these, even the specific indication, are not known for earlier funding stages of life sciences companies

"Send Me Your Deck"

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- The deck should start with Problem-Solution-Magic
- The whole deck revolves around describing ROI for the Investor
- Define the unmet medical or scientific need
- Explain the science, but don't overwhelm
- Share any preclinical, clinical, or proof-of-concept results

- Describe the commercial opportunity
  - ➢ Describe market, addressable market, competition
  - ➢ Describe revenue opportunity
  - ➢ Describe timelines, revenue growth, and product end of life

- Discuss the raise, and how the investment will be used to achieve inflection points that would permit further investment or an exit

Intellectual Property

Intellectual Property for Biotechs

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Overview

- Patents patents patents
- Know-how
- Data
- Trade secrets
- Trademarks
- Domain names

Working with Third Party Contractors and Consultants

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- Ownership and Confidentiality are Paramount
- It is imperative that you own arising IP
  - ➢ The default is generally that the company creating the IP owns the IP unless the IP is <u>specifically assigned</u> to the other party
  - ➢ The company paying for the services in many (most) cases should be the owner of the intellectual property created
- For you to own IP that has been created for you by someone else, the contract must say (i) that <u>you own it,</u> <u>**AND** (ii) "We, the contractor, hereby assign</u> all rights in the intellectual property underlying the deliverable to you." The <u>present</u> assignment is key.
- Confidentiality Agreements act as a license to use confidential information
  - ➢ The definition of purpose is critical—it must be specific and it must be narrow
  - ➢ Confidentiality provisions must prohibit the other party from using your confidential information for anything other than that narrow purpose
  - ➢ The Confidentiality Agreement must also restrict the other party's representatives

Advisors and Employees

Finding and Hiring Employees

- Ease into these relationships—be slow to trust
  - ➢ Set clear expectations
  - ➢ Arrangements should be reflected in a clear agreement
  - ➢ Rights of termination should be clear
  - ➢ How to vest equity

Hiring Employees – The Bare Minimum

- Get Assignment of Inventions Agreements and Confidentiality Agreements from all employees the day they start
- Don't hire somebody as an "independent" consultant if they're really an employee
  - ➢ There is no such thing as a "1099 employee"
  - ➢ IRS issues
  - ➢ The "consultant" can bring claims against the company for not treating them like an employee
- Adopt <u>and train</u> on basic policies and procedures
- If there are issues, address them clearly in a non confrontational manner early, and <u>document</u> the conversations

Incentivizing Employees – Equity and Equity-like Incentives

- Cash Incentives
  - ➢ Cash Bonus Program
  - ➢ Phantom Equity

- Equity Incentives
  - ➢ Restricted Equity
  - ➢ Options
  - ➢ Profits Interests

Incentivizing Employees – Cash Bonus Program

Overview

- Employee has a right to a cash bonus in the event the company is sold
- The Company typically sets aside a bonus pool, and each employee is given a percentage of the bonus pool
- Rights to share in the bonus pool can vest over time
- When the employee leaves, they forfeit their rights to a bonus

Incentivizing Employees – Cash Bonus Program *(cont'd)*

Pros

- Employee is not a stockholder
- Taxes are deferred until the bonus is awarded
- Provides employees with achievable incentives

Cons

- Employees may not feel like stockholders

Incentivizing Employees – Restricted Stock

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- Restricted stock or restricted units are grants of stock or units that are typically given to employees early in the company's life when valuations are still low

  - ➢ The employee is an owner of all of the shares or units immediately.
  - ➢ The employee is taxed on the difference between the fair market value of the stock on the date of each vesting event and any price that may have been paid
  - ➢ Employees typically elect to accelerate payment of stock to date of grant by filing an 83(b) election

Incentivizing Employees – Restricted Stock

- Forfeiture or repurchase of stock
  - ➢ If the employee leaves, the company has the right to repurchase any unvested stock at the original issue price
  - ➢ Typically, the company has the right to repurchase any vested stock at fair market value

- Cons
  - ➢ Employees of LLC's are treated as members for tax purposes
  - ➢ Taxes payable by the employee could be significant.

Incentivizing Employees – Options

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- Stock options or unit options provide employees with the right to purchase a fixed number of shares or units in the future
  - ➢ The purchase price is equal to the fair market value of the equity on the date of grant
  - ➢ Typically, the employee cannot purchase the shares until the option is vested

- Pros
  - ➢ Employee is not a stockholder until exercise
  - ➢ Taxes are deferred until exercise
  - ➢ Exercise can be deferred significantly

- Cons
  - ➢ If options are exercised, Company has a fiduciary duty to the stockholder

Finding, Hiring and Firing Advisors

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- Your advisors (lawyers, accountants and consultants) should have the patience to explain things to you in as much detail as you want, as many times as you want
- There are NO stupid questions—your business depends on you having a thorough understanding
- Shop around for advisors, and ask friends and colleagues for recommendations
- Your advisors should be crystal clear about what their fees are and how they work--don’t be embarrassed to try and negotiate those fees
- You can fire an advisor whenever you want—they shouldn’t hold it against you, it happens all the time

Questions or Comments?

If you have any questions about this webinar that you did not get to ask during the live premiere, or if you are watching this webinar On Demand, please do not hesitate to email us at info@financialpoise.com with any questions or comments you may have. Please include the name of the webinar in your email & we will do our best to provide a timely response.

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Meet The Faculty

Ed Amer - eamer@goodwinlaw.com

Ed Amer represents private equity and venture capital firms, operating companies and investors in a broad range of transactions, including leveraged buyouts, carve-outs, exits, growth equity financings and general corporate representation, with a particular focus on the healthcare and life science industries. Prior to pursuing a career in law, Ed worked as a lighting technician in the motion picture industry.

Matt Ferry - MFerry@mofo.com

I'm a partner in MoFo's Technology Transactions Group, advising innovative and mission-driven life sciences and technology companies. I have more than a decade of experience in structuring, drafting, negotiating, and executing strategic transactions where intellectual property (IP), technology, data, and information assets drive the deal, and I leverage my previous experience in patent prosecution and IP litigation to provide a holistic perspective and overall business strategy to my client's transactions.

I focus my practice on areas that better humanity and the world. I believe we do our best we believe in the mission of our industry and contribute to the ecosystem.

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Ed Pease - ecpease@mintz.com

Ed brings more than two decades of experience to the representation of high-growth businesses and the venture capital, private equity, and other investors who support those companies.

With extensive experience representing entrepreneurs and companies operating in a broad range of industry verticals, including technology, financial services, life sciences, digital & social media, and energy & sustainability, he is a trusted advisor throughout the life cycle of his clients, from formation to exit. Founders have come to rely on Ed's creative and strategic legal solutions and sound business advice in connection with equity structuring, intellectual property protection, complex commercial transactions, and strategic licensing and partnership transactions.

In his work for private equity funds, venture capital funds and family offices, Ed routinely lends his expertise to clients pursuing early and later-stage growth equity investments, acquisitions, dispositions and recapitalizations. This work routinely involves guiding investment firms through their own formation, structuring and fundraising projects.

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Jay Reilly - jreilly@foleyhoag.com

Jay represents biotech, medical device, diagnostic and software companies, as well as universities and nonprofits, in strategic transactions in the life sciences industry, particularly complex collaborative arrangements and technology acquisitions and dispositions. Jay has extensive experience negotiating and closing joint ventures, licensing arrangements, mergers and acquisitions, and venture capital financings. He also handles day-to-day agreements such as manufacturing, clinical trial, consulting and sponsored research agreements. He is currently a partner at Foley Hoag.

Bill Walker - bwalker000@gmail.com

Bill Walker, director of Engineering Entrepreneurship at Duke University, has been appointed to the North Carolina Board of Science, Technology and Innovation (NCBSTI) by Governor Roy Cooper.

NCBSTI encourages, promotes and supports research in scientific, industrial and engineering research, and its potential impact on industry and commercial enterprises throughout the state. It primarily focuses on accelerating North Carolina's next generation of technologies and their associated companies by investigating emerging areas that could impact the state and studying the competitiveness of the state's industry and research institutions in these fields.

"I've been engaged in North Carolina's culture of innovation since 1986, and I've been excited to see how technological innovation improves lives and create meaningful, high-paying jobs," said Walker. "I'm grateful for this opportunity to serve the people of the state and to engage Duke in the ongoing effort to make North Carolina even more competitive."

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