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STARTUP & ACCELERATE

Biotechnology, Medical Device, and Other Life Sciences Emerging Companies – Legal Strategies and Venture Capital Financing and Market Trends

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Presentation Outline

1. Background
2. Intellectual Property, Partnerships and Collaborations
3. Overview of Venture Capital Investments

Background

Life Sciences Industry

- Life Sciences industry composed of several different sectors, including biopharmaceuticals, medical devices, diagnostics, research tools, and biomedical materials
- Each sector of the life sciences industry is unique, but in general all sectors of the industry share the following characteristics:
  - High research and development costs
  - Product development risk is high, resulting in many failures
  - Intellectual property protection for products is critical
  - Highly regulated

Regulatory Framework

- Life Sciences is a heavily regulated industry
  - Successfully navigating regulations and associated development steps is critical to the success of a business
- Key Areas of Regulation
  - Safety and efficacy
  - Pricing and Reimbursement
  - Research

Regulatory Framework (cont.)

Key regulatory agencies

- US Department of Health and Human Services
  - US Food & Drug Administration (FDA)
    - safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, and cosmetics
  - Centers for Medicare & Medicaid Services
    - oversight of the Medicare program, the federal portion of the Medicaid program and State Children's Health Insurance Program, the Health Insurance Marketplace
  - National Institutes of Health
    - supports biomedical and behavioral research with the United States and abroad, conducts research in its own laboratories
- State agencies for healthcare and consumer protection

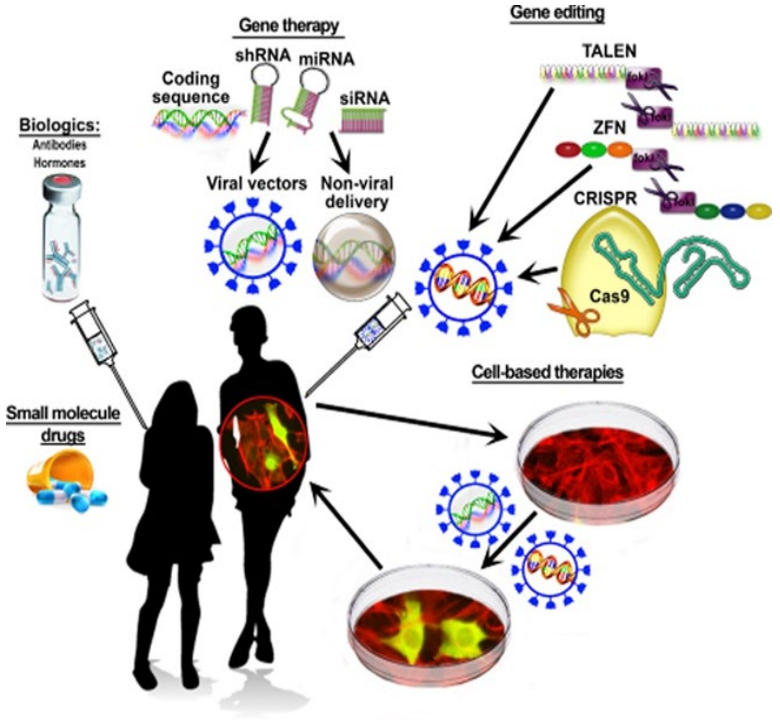
Biotech/pharmaceutical Industry

Biotech/pharmaceutical Industry

- Cost of drug development is VERY high and failure rates are VERY high
- $1.0 billion to $2.0 billion is the estimated cost of bringing a new drug to the market (in 2014, the Tufts report estimated it at $1.4 billion on average)
- 90% of potential drugs fail in clinical development, with higher failure rates for certain indications, such as Alzheimer's disease
  - This does not account for drugs that fail in pre-clinical development (before testing in humans)
- Main reasons for reported drug failure in clinical development are:
  - Lack of clinical efficacy (40%–50%)
  - Unmanageable toxicity/safety (30%)
  - Poor drug-like properties (10%–15%)
  - Lack of commercial needs and poor strategic planning (10%)

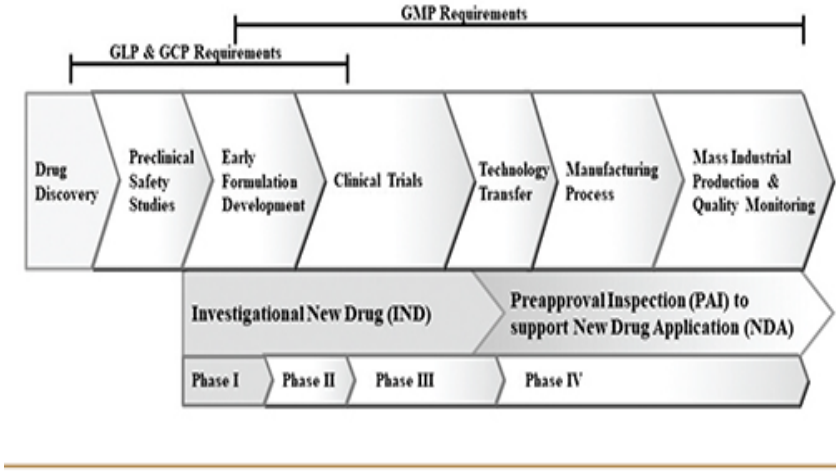
Biotech/pharmaceutical Industry (cont.)

- Unique ecosystem of key players – interrelationships create a complex web of ownership issues, competing interests, and priorities
  - Academics/Hospitals >> Startups >> Biotechs >> Big Pharma
- The Assets: Highly differentiated, technical assets with layers of ownership interests



Typical Development Pathway for Pharmaceuticals

- Long period of time before potential product candidate reaches the end consumer
  - 3-6 years for drug discovery through early formulation
  - IND clearance with FDA immediately prior to clinical trials
  - Clinical Trials Phase I through Phase III (4-8 or more years)
  - NDA/BLA marketing approval needed to move forward to market, but additional steps still required (bulk manufacturing, distribution, monitoring (Phase IV trials))
- As a drug candidate moves through the development process, it gets de-risked and the value proposition changes



Q1 2024 Biotech/pharmaceutical Sector Financing Activity

- PIPEs were open in Q1
  - 48 privately negotiated fundraisings of publicly traded companies totaling $4.4 billion
- Follow-ons are up
  - 48 deals accounting for $10 billion
  - Most in a quarter since 2021
- IPOs are (mostly) positive
  - $3.9 billion in IPO money
- M&A slows after busy Q4
  - 26 deals total $19.4 billion after $60 billion Q4
- VC dollars match 2019
  - 306 total deals investing $12.4 billion into sector

Medical Device Industry

Regulatory Pathways

- FDA classifies devices into **three** classes:

	Premarket Submission?	Submission Type	Time to Authorization	Cost
Class I (Low to Moderate Risk)	Generally, No	N/A – Register/List Device	w/in 30 Days of Entering Commerce	~ $7,500
Class II (Intermediate Risk)	Generally, Yes	510(k)	~6 to 9 Months	~ $21,000
Class III (High Risk)	Yes	PMA	~1 to 2 Years	~ $483,000

- Classification is based on the level of control necessary to provide reasonable assurance of their safety and effectiveness
- The device classification determines, among other things, the type of premarketing submission/application required to market the device

Funding for Medical Devices (2023)

- Medical device companies raised $7.0 billion in venture capital (VC) financings over 474 deals, representing a 19% decrease from 2022
  - Medical device companies raising their first investment rounds brought in $778 million over 108 deals, representing a 18% decrease from 2022. Funding and deals decreased in each successive quarter of the year
  - First round financing deals tended to favor indications with the quicker to market 501(k) pathway as opposed to PMA
- Over 30% of later stage deals (Series B and later) were down rounds, done at a lower valuation than the last financing round
- The top indications for VC financing were:
  - Neuro (focused on neurostim and brain/computer interface) : $1.3 billion over 43 deals
  - Imaging (including both equipment and software): $903 million over 65 deals
  - Surgical: $852 million over 46 deals

M&A for Medical Device Companies (2023)

- Inflation and high interest rates caused M&A activity in the medtech sector to be down for a second straight year in 2023, with a dearth of deals of greater than $1 billion being completed
  - Most medtech deals that were completed were tuck-in acquisitions
- According to EY Firepower, only 46 medtech deals of greater than $100 million were completed as of December 10, 2023, for aggregate proceeds of $33.7 billion
- Some of the more notable M&A deals of 2023 included:
  - Merger of Globus Medical with Nuvasive in a deal valued at $3.1 billion
  - Danaher's acquisition of AbCam in a deal valued at $5.7 billion
  - Thermo Fischer's acquisition of Olink in a deal valued at $3.1 billion

Intellectual Property, Partnerships and Collaborations

Intellectual Property

- Intellectual property critical to investment success
  - Right to use the technology or product to build the business
  - Ability to keep competitors from using your technology or manufacturing competing products
  - Life Science businesses are built around patent portfolios
- Due diligence often revolves around intellectual property due diligence
  - Review of owned/registered patents
  - Freedom to operate (FTO) to evaluate risk of infringement on third party's patents
- Patent portfolios
  - Claim by claim analysis
  - Each claim in the patent determines the scope of rights
  - Both quality & quantity of claims matter
  - U.S. applications vs. foreign applications

Intellectual Property (Especially Patents)

- Owned vs. Licensed IP
- Owned
  - Assignment documents properly prepared, signed and recorded?
  - Any rights of employees, consultants and service providers?

    See Employment Agreements, Invention Assignment Agreements, employment policies
- Licensed
  - Exclusive vs. non-exclusive
  - Field of use
  - Territorial coverage
  - Right to enforce (generally for exclusive licensee)
  - Right to direct and control patent prosecution

Partnerships and Collaborations

- Partnerships and collaborations are a unique attributes of life science industry
  - Partnerships and collaborations among life science companies' are integral part of success
  - Used to address unique obstacles in the life science industry
    - Share development costs
    - Leverage resources of large pharmaceutical companies for research and development, clinical studies, distribution channels and marketing
    - Avoid or reduce need to build marketing and distribution capabilities
    - Allow companies to diversify product portfolios and hedge risks
  - Create different economic models
- Types of partnerships
  - Joint development
  - Manufacturing and branding
  - Distribution, sales and marketing

Overview of Venture Capital Investments

Other Sources of Capital

- Non-dilutive sources of capital
  - Significant reliance on early-stage funding from governments and other non-investor sources (foundations, etc.)
  - If used, must understand associated limitations (e.g., government march in rights for intellectual property)
- Sponsorships by academic institutions and government grants come with strings attached
  - Reporting obligations
  - March-in rights (see above)
  - Joint ownership of IP
  - Other government regulations, e.g., Federal Acquisition Regulations (FAR), which regulates how federal executive agencies purchase and acquire supplies and services with appropriated funds

Day to Day Oversight of Portfolio Company

- Venture investors maintain close contact with private companies in portfolio
  - Combination of board attendance
  - Visits to physical location of companies
  - Frequent communication with executive management

Target Companies for Venture Capital Investments

Challenges

- Development stage businesses
- Frequently cash flow negative
- Often no revenue
- Limited sources of capital - traditional debt capital from banks not available
- Private companies - liquidity of investment limited

Target Companies for Venture Capital Investments - continued

Opportunities

- High growth potential
- Innovations in business and technology
- New markets
- Intellectual property critical to value proposition and business plans
- Investors increasingly global

Structure of Venture Capital Investments – Common Characteristics

- Target company is a Delaware corporations, taxed as a C corporation under US tax code
- Investors hold less than 50% of the capital stock and voting rights (minority, non-controlling investments)
- Investment instrument is convertible preferred stock
  - Converts into common stock
  - Different series (Series A, Series B, Series C, etc.)
  - Preferred stock has negotiated rights, preferences and privileges

Structure of Investments – Common Characteristics

- Rights, Preferences and Privileges of Preferred Stock fall into three broad categories:

Structure of Investments – Common Characteristics - continued

1. Economic Rights

- Liquidation preferences (priority returns in event of sale of business, liquidation or dissolution)
- Dividend
- Redemption
- Anti-dilution rights
- Preemptive rights for new issuances by the Company
- Rights of first refusal and co-sale rights on other stockholders transfer of stock
- Registration rights for the stock, if and when the company goes public

Structure of Investments – Common Characteristics - continued

2. Governance Rights

- Investor representative on board of directors/Observation rights with respect to board of directors
- Special stockholder voting rights on extraordinary corporate events (e.g., sale of business, new financings, changes of investors rights)
  - Allows investors to block such events
  - Called "Protective Provisions"
- Special voting rights of the member of the Board of Directors appointed by investor holding preferred stock

Structure of Investments – Common Characteristics - continued

3. Information Rights

- Financial information
  - Audited financial statements – annual
  - Unaudited financial statements – monthly and quarterly
  - Operating budgets, revenue projections, monthly costs/expenses
- Business information
  - Business plan, annual operating plan, R&D plan, product roadmap
  - FDA approvals and timeline
- Meetings with management and key personnel

Structure of Investments – Common Characteristics - continued

Process:

- Business and financial due diligence
  - Precedes negotiation and signing of term sheet
- Term sheet
  - Investors' legal counsel involved
- Legal due diligence
  - Starts after term sheet is signed
  - Concurrent with negotiation of definitive financing agreements
- Definitive financing agreements
  - Typical period of time from signing term sheet to closing financing is 4–6 weeks
  - Simultaneous signing and closing

Biography

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Scott D. Karchmer counsels entrepreneurs and emerging and established companies in business transactions. Representing global clients in the biotechnology, medical device, software, data analytics, financial services, fintech, and networking and storage industries, he advises companies at critical junctures in their lifecycles. Scott handles formation, raising funds from venture capitalists, initial public offerings, mergers and acquisitions (M&A), investments, divestitures, and other issues organizations confront. He also advises venture capital firms and other investors in connection with investments in private companies.

Counseling public companies on securities law, governance, and general corporate matters, Scott represents clients in capital markets transactions. He advises on private investments in public equity (PIPEs), registered direct offerings, convertible debt offerings, 144A offerings, and underwritten offerings. Scott is the pro bono chair of Morgan Lewis's San Francisco office. He serves on the board of directors for Legal Services for Children, a San Francisco-based nonprofit organization that provides legal counsel to individuals under 18.

Biography

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Ben Rho counsels life science, healthcare, and technology companies on transactional matters, including advising clients on negotiating and structuring acquisitions, divestitures, joint ventures, corporate partnering, licensing, and other complex collaborations. Drawing on his background and experience in patent law, Ben brings an awareness and appreciation for intellectual property and science related issues that can arise in intellectual property focused transactions.

Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Abu Dhabi
Almaty
Astana
Beijing
Boston
Brussels
Century City
Chicago
Dallas
Dubai
Frankfurt
Hartford
Hong Kong
Houston
London
Los Angeles
Miami
Munich
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Orange County
Paris
Philadelphia
Pittsburgh
Princeton
San Francisco
Seattle
Shanghai
Silicon Valley
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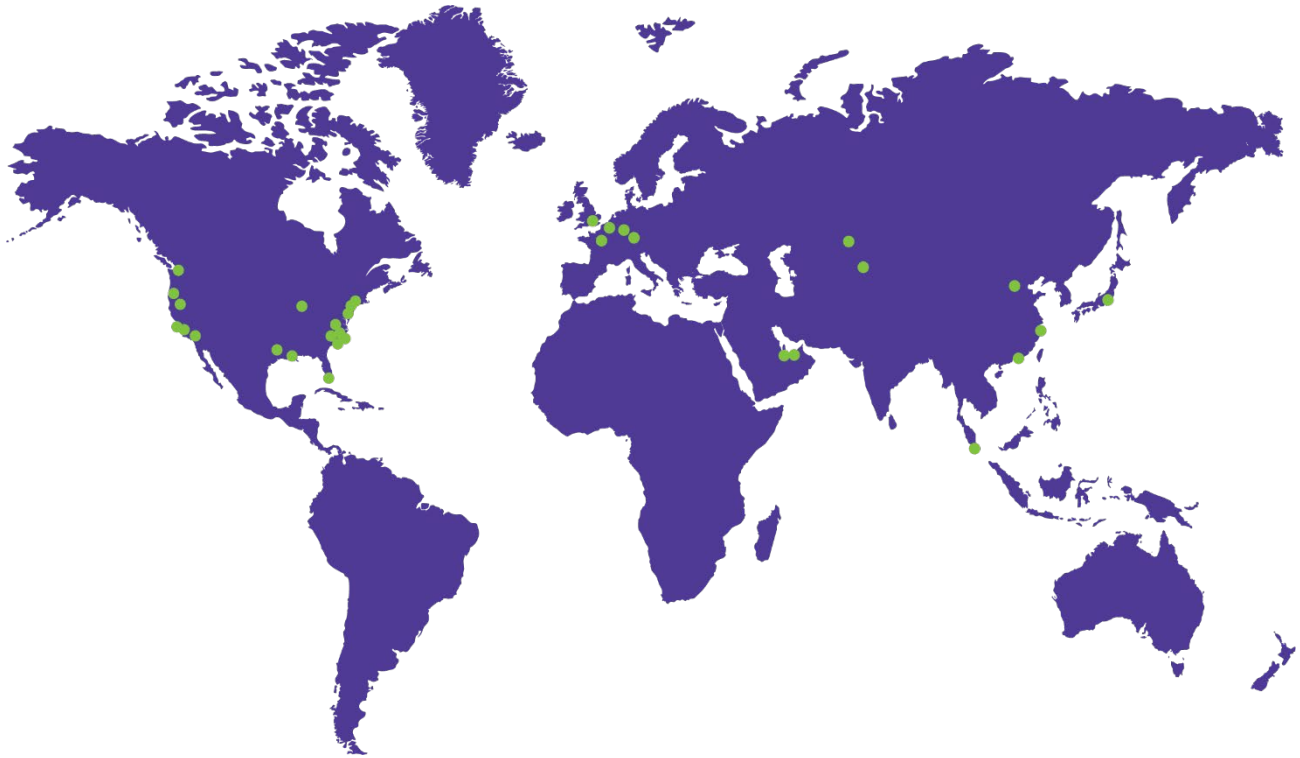

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