



# Commercialization Strategies: Start Your Own NewCo or Outlicense from Academia

Foundations of Cancer Therapeutics:  
Commercialization

**August 13, 2024**

# Hogan Lovells

---



## Andrew Strong

Partner, Houston

+1 713 899 3930 c

[andrew.strong@hoganlovells.com](mailto:andrew.strong@hoganlovells.com)

Andrew is an experienced and trusted advisor and counsel to public and private life sciences, pharmaceutical, and emerging technology global clients on matters involving corporate formation, public and private financing, M&A, cross-border licensing and joint ventures, employment and executive compensation and intellectual property.

He has experience starting up and selling a successful biotech company that has grown to 600+ employees, has served and presently serves as the general counsel for several private and publicly traded drug development biotech clients and has served as a board member and in leadership positions for NYSE, Nasdaq, and private corporations.

Andrew serves as the Co-Chair of CPRIT's Product Development Advisory Committee (PDAC) and is the Chairman and Co-Founder of K2 Biolabs in Houston, Texas.



## Josh Ling

Associate, Houston

+1 713 632 1479

[josh.ling@hoganlovells.com](mailto:josh.ling@hoganlovells.com)

Josh focuses his practice on mergers and acquisitions, dispositions, joint ventures, securities offerings, corporate governance, and other general corporate matters for public and private companies. He also has experience assisting publicly traded companies with SEC reporting and compliance.

Prior to joining Hogan Lovells, Josh was a tax planning and business transactions attorney at a Houston-based law firm and a senior associate in the M&A tax practice group of a global accounting firm.

***Hogan Lovells is pleased to meet with you to discuss your company or ideas. Please email or call Andrew or Josh.***

# Market Conditions...

---

- The funding “Valley of Death” is real and navigating through it requires planning, persistence and personal connections
  - Planning – when to start up and who is with you; before launching, develop a business plan, test it with SMEs, seek wise advice and start to build your team
  - Persistence – even before launching, you must be committed to seeing this through, it will require more time than you can imagine; follow-up and follow-through
  - Personal Connections – this is critical to the early launch days as the \$ will initially come through your friends, family and professional connections
- There are some sophisticated investors who will come in early but your “\$ ask” needs to be enough to move the needle
- Institutional investors are waiting to see the early clinical data before investing

# Launching Your NewCo





# NewCo Checklist

- Why Launch?
- Is the Science Ready for Primetime?
- Is there Outside Interest in My Technology?
- Will my Institution Play Ball with Me?
- What is Fair to My Institution v. My NewCo
- Who will Lead the NewCo?
- How Much Time am I Willing to Commit to the NewCo
- What about Potential Conflicts of Interest?
- What is the Founder's Dilemma?

# Launching NewCO

---

- Entity Types
  - C-corp
    - Double tax (at entity and upon distribution of profits)
    - Accumulates Net Operating Losses (NOLs)
    - Preferred by most investors (especially institutional)
    - Generally necessary to take public through IPO, de-SPAC
  - LLC (taxed as a partnership)
    - Easier to form and set up
    - One tax (profits and losses allocated annually via K-1)
    - Not preferred by foreign investors (requires blocker corporation)
  - Others: B-corp, S-corp or Limited Partnerships
- Ownership
  - Stock or Shares in C-Corp v. Units in LLC
  - Incentives: Stock Options v. Profits Interests

# Launching NewCo (cont.)

---

- Documentation, Filings and Other Boring Stuff
  - C-corp
    - Articles of Incorporation/ ByLaws
    - Founder Stock Purchase Agreement [83(b) election if vesting]
    - Equity Incentive Plan
  - LLC
    - Certificate of Formation
    - LLC Agreement (DE) or Company Agreement (TX)
  - Additional Documents
    - Federal EIN (S-4)
    - Start Up Package - Board and Stockholder Consents and Resolutions, Employment Letters, Consulting Agreements, Indemnification, NDAs/CDAs (unilateral and two-way)
- Naming / Trademark / Website URL

# Early Days of Your NewCo

---

- Intellectual Property Underpins Everything
  - Typically licensed out of academic research institution or licensed/acquired from other parties
  - IP protection in major markets (US / EU / Asia)
  - Naming / Trademark / Website URL
- Technology / Clinical Advancement
  - Pre-clinical studies -> Clinical Supply -> Clinical Studies -> Registration
  - Sponsored Research for New IP/Improvements
  - Clinical Research Organizations (CROs) and Contract Development and Manufacturing Organizations (CDMOs)
  - Submission of IND / 510K Premarket Notification
  - Activation of clinical sites / patient enrollment

**“Your early development decisions can make or break your timeline and cash burn. All agreements binding others to perform key services for your company are critical to your success!”**



# Early Days of NewCo (cont.)

---

- Management Team / Board of Directors / Scientific Advisory Board
  - An experienced team of drug developers creates confidence in investors/partners
- Leadership Team and Key Departments
  - Pre-clinical / Clinical Teams
  - CMC / Regulatory
  - Finance / Administration
- Public / Investor Relations
  - Take advantage of major developments and achievements; seek out publications in peer-reviewed journals and conferences
  - Create a communications machine to churn out positive news
- Know the Market Opportunity and Key Competition

# Start-Up Funding

## Dilutive v. Non-Dilutive

**Dilutive** means you are selling or giving away equity in the Company in exchange for cash or other value and your ownership % is reduced

**Non-Dilutive** is funding into the Company for technology advancement and does not result in a reduction of your ownership % (e.g., US government funding, CPRIT award, bank loan, etc.)

# Start up Funding Fuels Drug Development

---

- Company Start Up
  - Biotechs consume LOTS of money VERY FAST
  - Early outside money is often in the form of Convertible Debt or SAFE Notes
    - Promissory Note that converts at a discount upon a qualified financing event
    - Usually family offices and angel investors (individually or through syndicates)
    - Key Terms: Maturity Date, Interest Rate, Discount, Qualified Financing, Cap
  - SEC Compliance (33/34/40 Act and Investment Advisors Act)
- Development Timeline & Budget
  - Absolutely critical to think in 3 year horizons (best case, likely case)
  - Build your NewCo operating budget to inform how much you need to raise
  - Informs (1) funds that you need to raise and (2) value inflexion points (or de-risking events in the drug development)

# Off the Ground and Growing, Gaining Speed

---

- Early Financing (Dilutive)
  - Series Seed and A Preferred Financing Rounds
    - Convertible Notes (plus Interest) at Discount to Preferred Pricing
    - Liquidation Prefs (participating and non-participating)
    - Board representation
    - Blocking Rights / Pro-rata Rights
  - Investment Brokers (cash, success fees – Watch Out!)
- Company Valuation
  - Pre-money / Post-money on Preferred Stock
    - Look at comps in same space / development timeline
    - How much \$\$ has been invested into the technology/Company
  - A 409A valuation is for your common stock (not preferred stock)
  - Management team credentials can drive higher value (CEO, CMO, CSO, CFO)

# Attaining Maximum Velocity, Post Take Off

---

- Subsequent Financings
  - Series B, C, etc. Preferred Financing Rounds
  - Public Capital Markets
    - IPO, de-Special Purpose Acquisition Corporations (de-SPAC), M&A
  - Partnering / Joint Development
- Company Valuation (Part Deux)
  - Timing of financing – Up Round, Flat Round, Down Round
    - Down round could trigger anti-dilution provisions of prior preferred (who does that hurt the most?)
  - Prior use of proceeds and meeting timelines establishes credibility

# Capitalization Table

Who owns what % of the Company now and into the future (next financing)

*Issued and Outstanding, Partially-Diluted Basis and Fully-Diluted Basis*

Name	Issued and Outstanding Shares	Percentage Issued and Outstanding	Partially Diluted Shares	Percentage Partially Diluted	Fully Diluted Shares	Percentage Fully Diluted
Founder A	3,000,000	60%	3,000,000	55%	3,000,000	48%
Founder B	2,000,000	40%	2,000,000	36%	2,000,000	32%
Employee 1	0	0%	500,000	9%	500,000	8%
Option Pool	0	0%	0	0%	750,000	12%
<b>Total</b>	<b>5,000,000</b>	<b>100%</b>	<b>5,500,000</b>	<b>100%</b>	<b>6,250,000</b>	<b>100%</b>

# Summary of Key Start Up Documents (C-Corp)

---

- Company Bylaws
- Foreign Qualifications
- Founders Stock Purchase Agreements
- 83(b) elections
- Action of Incorporator
- Federal Employer Identification Number (SS-4)
- Initial Board Consent
- Initial Stockholder Consent
- NDA / CDA / PIAs
- Consulting Agreements
- Executive Employment Agreements / Employee Offer Letters
- Incentive Plan Docs
  - Equity Incentive Plan
  - Stock Option Agreement
  - Incentive Plan Procedures



# Licensing Transactions

*The first “value” in a NewCo is its intellectual property which is often licensed from a third party*

- Who is the licensor (institution, you, NewCo)?
- Scope of Licensed IP
- Flow-down of upstream commitments
- Diligence obligations
- Economics (upfront, equity, milestones and royalties)
- Assignment and sublicensing
- Technology transfer and data sharing
- Other considerations



# Licensing transaction *(continued)*

## Key considerations

### Complexity



#### Licensor

- Territory exclusivity and licensed field dictate body of agreement
- Economics often cash upfront, equity (usually PubCo), milestones and royalties
- Must consider global regulatory and clinical trial strategy and data generation
- Diligence milestones
- Data privacy / sharing
- Manufacturing



#### Licensee

- Broad field and territory desired but usually will have higher diligence requirements
- Push economics to later milestones and royalties and include stacking provisions
- Control patent prosecution and IP infringement
- Royalty term and step downs
- Tech / data transfer and manufacturing
- Sublicensing / assignment

# Licensing Considerations (cont.)

---

- Address who owns follow-on IP / Improvements in license agreement
- Have advisory/consulting agreements in place with key inventors
- Perform due diligence on any technology and IP to be in-licensed
  - Make sure you are licensing from the actual owner of the IP
- Don't charge your sublicensee the same amount of royalties in a specific country after your patent expires (patent misuse)
- Keep track of license agreement requirements (reports, payments, milestones)
  - The license agreement could be terminated if you do not fulfill your obligations and do not cure within the timeframe to do so

# Selecting a transaction

- Must be a strategic fit or need
- A “Champion” on both sides of the table is critical
- Business / legal considerations
  - Term sheets play an important role
  - Leverage of Parties
  - Shareholder Approvals
  - Tax Structuring
  - Target Structure
  - Valuations





Hogan  
Lovells

[www.hoganlovells.com](http://www.hoganlovells.com)

"Hogan Lovells" or the "firm" is an international legal practice that includes Hogan Lovells International LLP, Hogan Lovells US LLP and their affiliated businesses.

The word "partner" is used to describe a partner or member of Hogan Lovells International LLP, Hogan Lovells US LLP or any of their affiliated entities or any employee or consultant with equivalent standing. Certain individuals, who are designated as partners, but who are not members of Hogan Lovells International LLP, do not hold qualifications equivalent to members.

For more information about Hogan Lovells, the partners and their qualifications, see [www.hoganlovells.com](http://www.hoganlovells.com).

Where case studies are included, results achieved do not guarantee similar outcomes for other clients. Attorney advertising. Images of people may feature current or former lawyers and employees at Hogan Lovells or models not connected with the firm.

© Hogan Lovells 2021. All rights reserved. P092766