



Commercialization Strategies: Launching Your NewCo

Foundations of Cancer Therapeutics Course

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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,

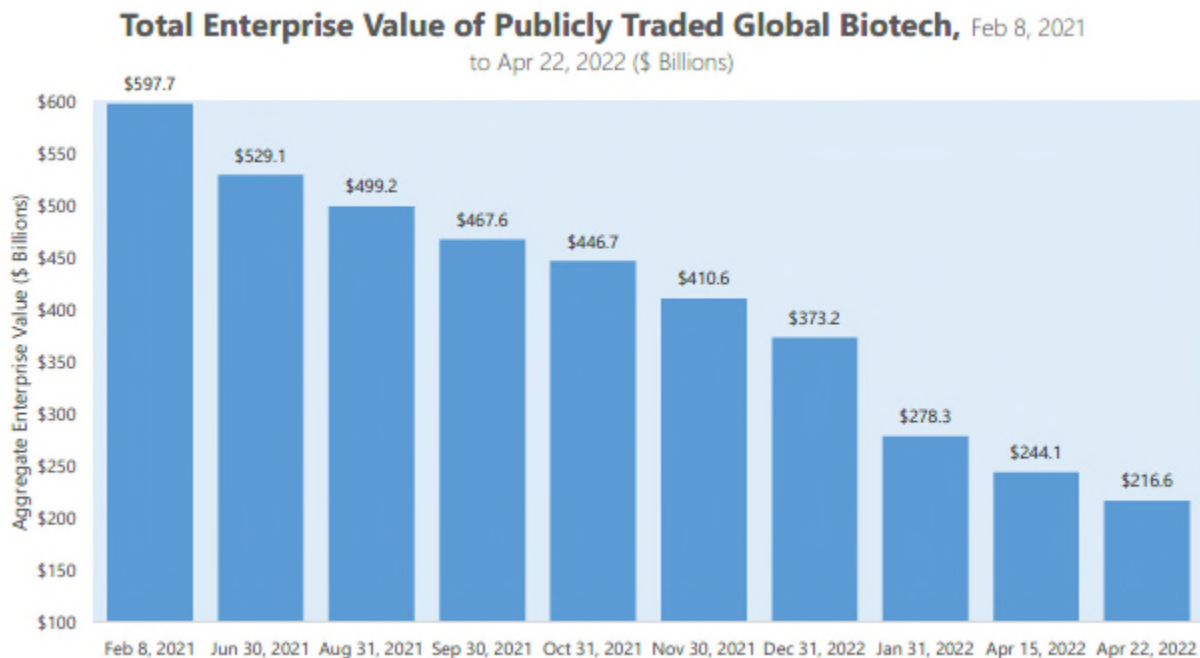
Education

J.D., South Texas College of Law, 1994

B.S., Civil Engineering, Texas A&M University, 1989

Global Biotech Declines Since Peak (Feb. 2021 to Apr 2022)

The aggregate enterprise value of the world's biotech sector is **down 63.8%** since it peaked on Feb 8, 2021. It is now trading well below its aggregate value *before* the pandemic began. Approximately sixty percent of the remaining value is among companies listed on a U.S. exchange.



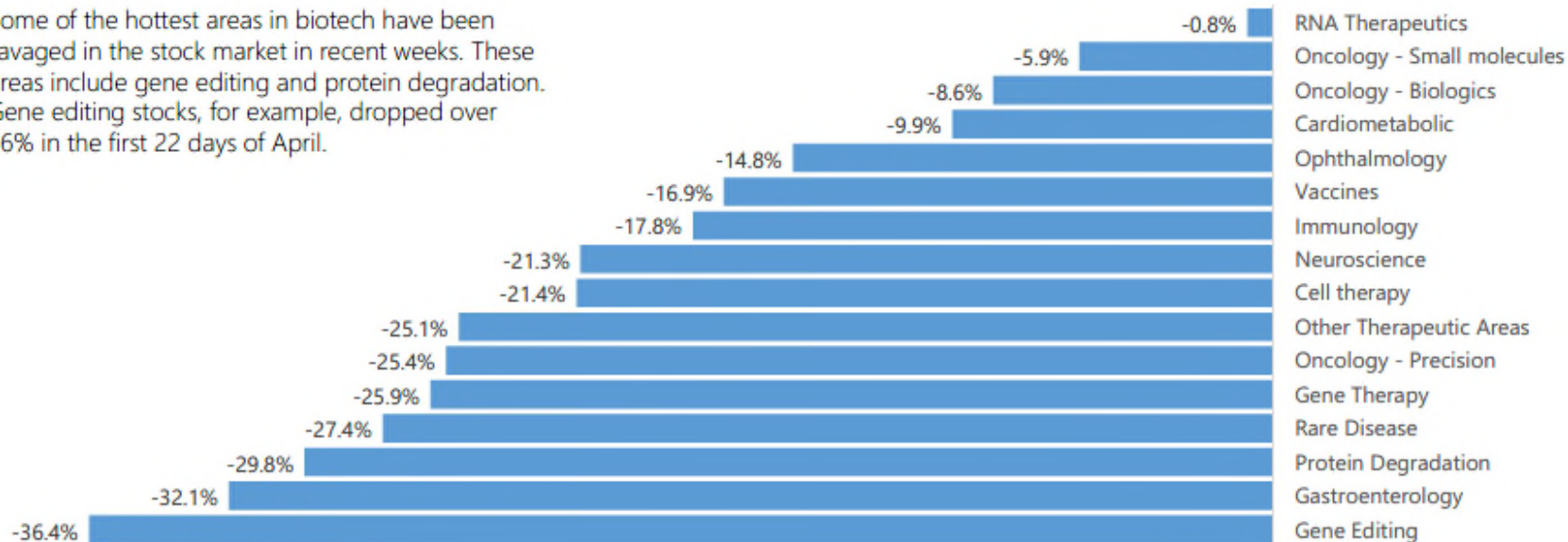
Source: Torrey's Market Update (April 25, 2022) citing Capital IQ

Biotech Market by Modality (April 2022)

Percent Change in Total Enterprise Value of Biotechs Listed on U.S. Exchanges by Focus Area

Mar 31, 2022 to April 22, 2022

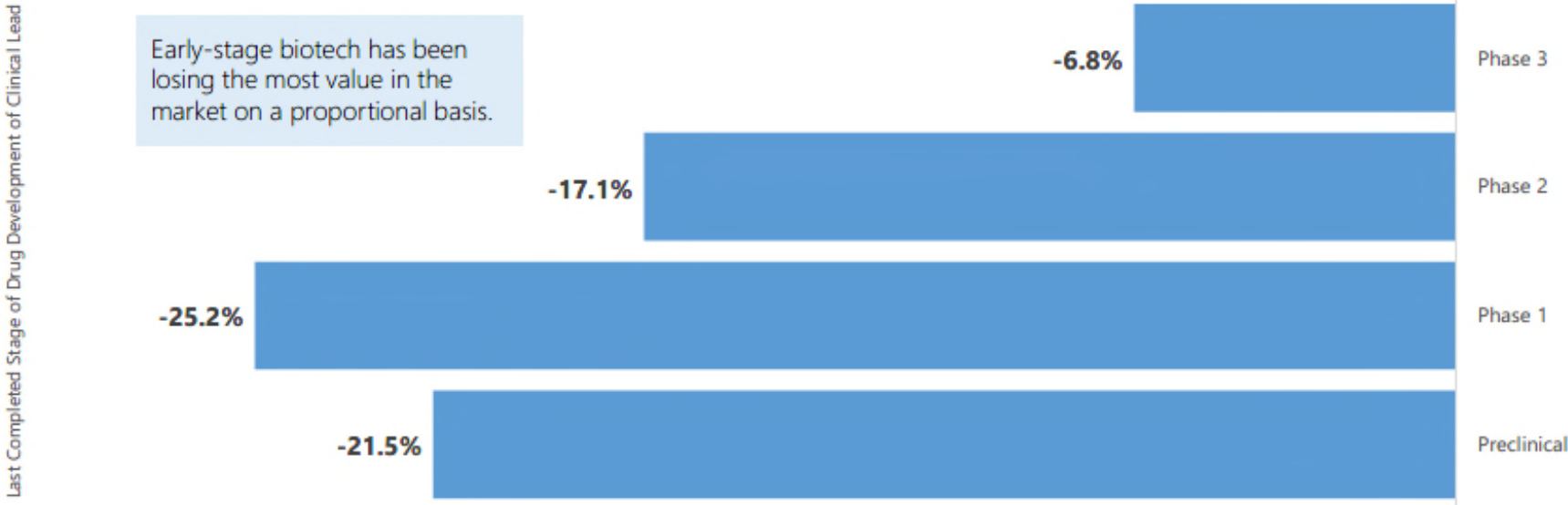
Some of the hottest areas in biotech have been savaged in the stock market in recent weeks. These areas include gene editing and protein degradation. Gene editing stocks, for example, dropped over 36% in the first 22 days of April.



Source: Torrey's Market Update citing Capital IQ

Biotech Market by Stage of Development (April 2022)

Percent Change in Total Enterprise Value of Biotechs Listed on U.S. Exchanges by Stage of Development, March 31, 2022 to April 22, 2022



Source: Capital IQ and Torreya Analysis

Despite the Challenging Biotech Market...

- Biotech employment continues to rise and certain areas of expertise are in high demand
- Private Capital markets are tight but holding and pre-money valuations are under intense pressure
- Venture / private debt placements still brisk
- M&A activity and technology licensing / asset sales are exploding

Launching Your NewCo

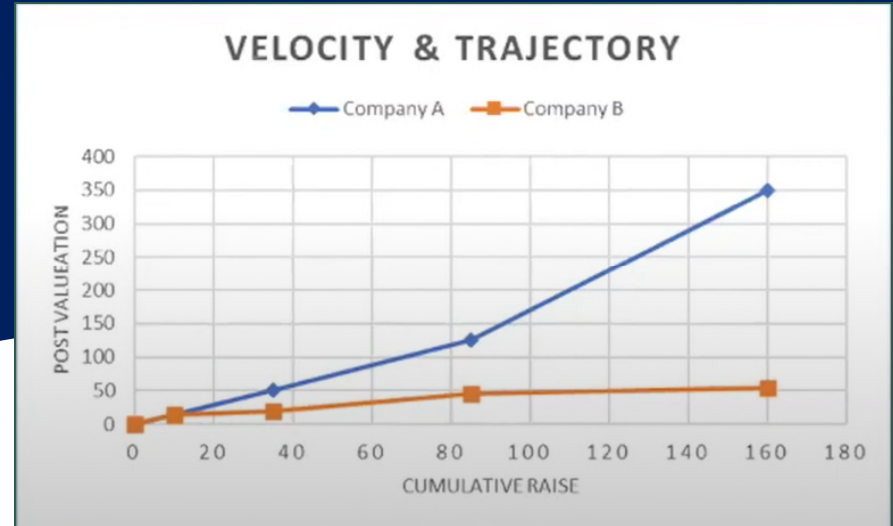


Wherever your starting point is as a technology developer...

Your future success is all about velocity *and* trajectory

Velocity is the race to develop and advance your drug with limited funds

Trajectory is hitting the value increasing inflexion points along the way with key data so that you can raise more funds





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 Advancement
 - Pre-clinical studies -> Clinical Supply -> Clinical Studies -> Registration
 - Submission of IND / 510K Premarket Notification
 - Sponsored Research for New IP/Improvements
 - Clinical Research Organizations (CROs) and Contract Development and Manufacturing Organizations (CDMOs)

“Your early drug development decisions can make or break your timeline and cash burn. Take all agreements binding other to perform 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
 - Early outside money is often in the form of Convertible Debt
 - 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
 - Absolutely critical to think in 3 year horizons (best case, likely case)
 - Informs (1) funds that you need to raise and (2) value inflexion points (or derisking 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%
Total	5,000,000	100%	5,500,000	100%	6,250,000	100%

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 transaction

The value that underpins the value of a NewCo is the Patents and Technology Often Licensed from a Founder's Institution

- Technology transfer and data sharing
- Scope of licensed IP
- Flow-down of upstream commitments
- Diligence obligations
- Economics
- Assignment and sublicensing
- Other issues



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

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





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