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IPO Training Camp

Industry Module – Biotech

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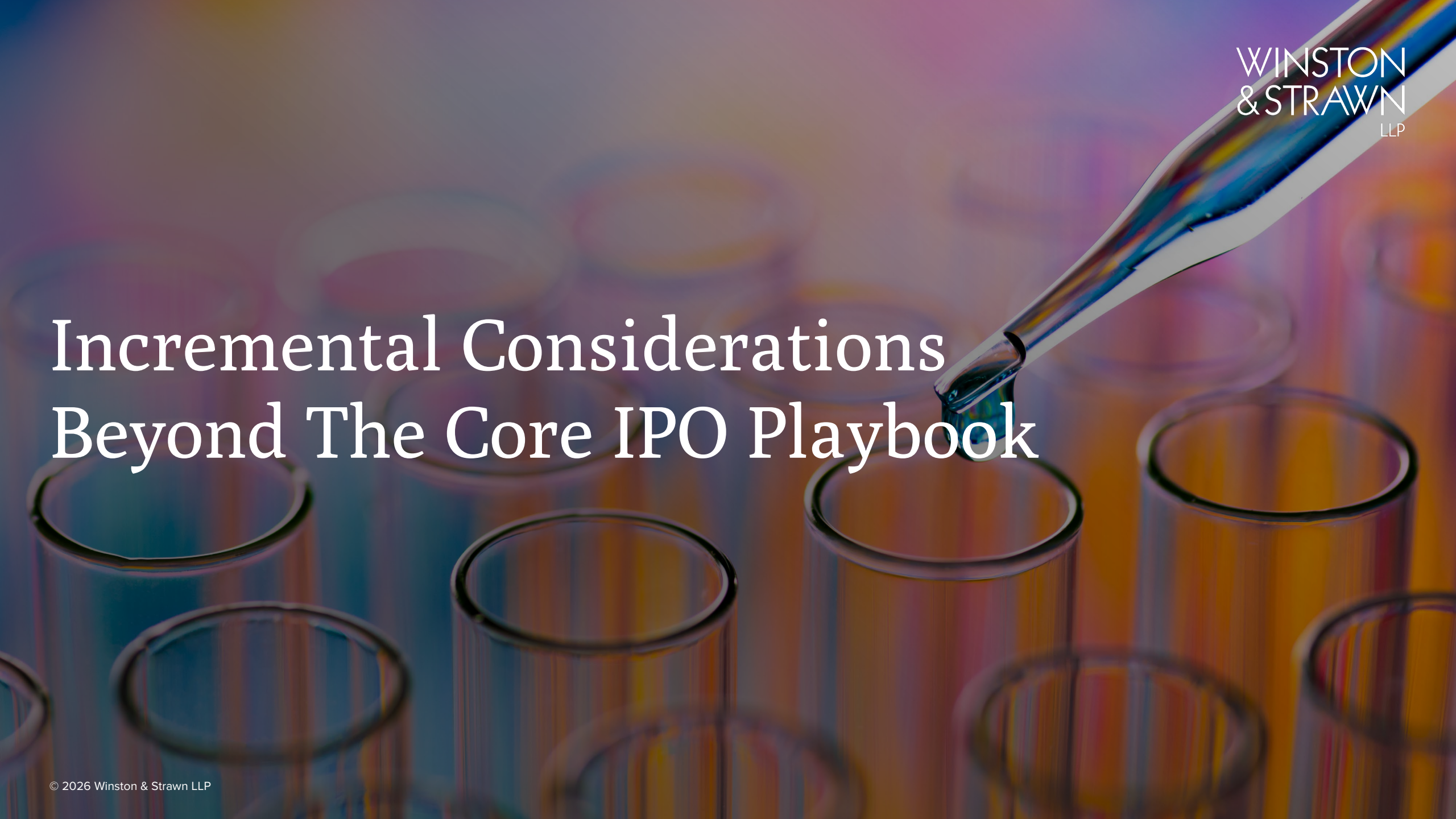

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Incremental Considerations Beyond The Core IPO Playbook

Biotech IPOs – What's Different

MORE THAN A FINANCING EVENT

A biotech IPO is a:

- Clinical Inflection Point
- Regulatory Credibility Test
- Scientific Diligence Exercise
- Litigation Risk Exposure Moment
- Capital Runway Engineering Strategy

STRUCTURALLY DIFFERENT

The IPO market is underwriting the science and probability – not revenue and EBITDA.

Why Biotech IPOs Are Different

- Binary clinical risk
- Pre-revenue or single-asset dependency
- FDA-driven volatility
- Heavy R&D cost structure
- Elevated litigation exposure

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Clinical & Regulatory Strategy

IPO Timing vs. Clinical Milestones

Often the single most important strategic decision.

PRE-DATA IPO

PROS

- Raises capital before dilution from negative data risk
- Secures runway
- May capture favorable sector window

CONS

- Valuation discount due to uncertainty
- Investors demand higher return premium
- Heavy focus on probability modeling

IPO Timing vs. Clinical Milestones (CONT.)

POST-DATA IPO

PROS

- Higher valuation if data is strong
- Better crossover investor participation
- Improved analyst coverage

CONS

- Binary risk if data disappoints
- Narrow execution window
- Sector sentiment can shift quickly

Data Package Readiness

- Locked Database
- Final Statistical Analysis Plan
- Independent Oversight
- Avoid Over-interpretation
- Underwriters will review clinical data rigorously
- SEC scrutiny focuses on language

SEC & FDA Interface

- Avoid promotional tone
- Clarify interim vs. final data
- Proper statistical significance disclosure
- The SEC does not defer to FDA terminology

COMMON ISSUES

- Overstating early-stage safety signals
- Using small sample size conclusions broadly
- Describing non-statistically significant trends as meaningful
- Inconsistent language across investor decks, roadshow slides, Testing the Waters (TTW) materials, and press releases creates exposure

Regulatory Milestone Volatility

EACH OF THE FOLLOWING REGULATORY MILESTONE EVENTS REQUIRE:

- Disclosure Planning
- Insider Trading Blackout Expansion
- Reg FD Discipline
- Media Strategy

DISCLOSURE MUST:

- Accurately describe deficiencies
- Avoid minimizing regulatory concerns
- Avoid implying guaranteed resubmission success

IND – Investigational New Drug Application

WHAT IT IS

- A formal submission to the FDA requesting authorization to begin clinical trials in humans.

WHY IT MATTERS

- IND “clearance” allows Phase 1 trials to begin.
- FDA can impose a “clinical hold” if safety concerns exist.
- Failure to obtain IND clearance delays development and can impact IPO timing.

IPO IMPACT

- Early-stage biotech IPOs may be raising capital specifically to support IND-enabling studies.
- Disclosure must accurately describe preclinical data supporting IND.

End-of-Phase 2 (EOP2) Meeting

WHAT IS IT

A formal meeting with the FDA after Phase 2 trials are completed to discuss:

- Phase 3 trial design
- Endpoints
- Patient population
- Statistical plan

WHY IT MATTERS

- FDA feedback at this stage heavily influences probability of approval.
- If FDA disagrees with trial design, timelines and costs may increase.

IPO IMPACT

- Investors view constructive EOP2 feedback as risk-reducing.
- Companies must carefully describe FDA feedback — avoid implying endorsement or approval.

BTD – Breakthrough Therapy Designation

WHAT IT IS

An FDA designation for drugs that:

- Treat serious conditions, and
- Show preliminary clinical evidence of substantial improvement over existing therapies.

BENEFITS

- More frequent FDA interaction
- Rolling review
- Potential expedited development

WHY IT MATTERS

- Often perceived by investors as a strong validation signal.
- But it is not approval.

IPO RISK NOTE

- Overstating the importance of BTD in S-1 disclosure can create litigation exposure.
- Must clearly state that designation does not guarantee approval.

Accelerated Approval Pathway

(SUBPART H / SUBPART E)

WHAT IS IT

An FDA pathway allowing approval based on a surrogate endpoint reasonably likely to predict clinical benefit.

Common in:

- Oncology
- Rare diseases
- Serious conditions with unmet need

Approval is conditional upon Post-marketing confirmatory trials

WHY IT MATTERS

- Enables earlier commercialization
- Frequently used in late-stage biotech IPO narratives
- Carries material post-approval risk

FDORA REFORM (2023):

FDA now has streamlined authority to withdraw accelerated approvals if confirmatory trials fail or are delayed.

Accelerated Approval Pathway

(SUBPART H / SUBPART E)

(CONT.)

IPO IMPACT

- Valuation models must incorporate confirmatory trial risk.
- Accelerated approval ≠ permanent approval.
- Risk factors must clearly disclose:
  - Confirmatory trial requirements
  - Withdrawal risk
  - Timing uncertainty
- Section 11 exposure if confirmatory trial risk is minimized.
- D&O insurers evaluate accelerated approval status heavily.
- Confirmatory trials may already be underway at IPO — disclosure must clarify timing, enrollment status, and potential delay risk.

BOARD QUESTION

What happens to valuation if confirmatory trial fails?

Other FDA Expedited Programs

FAST TRACK DESIGNATION

- More frequent FDA interaction
- Rolling review eligibility
- Does NOT guarantee approval

PRIORITY REVIEW

- Shortens FDA review clock (~10 months → ~6 months)
- Applies to NDA/BLA stage
- Timeline benefit, not evidentiary benefit

Fast Track and Priority Review affect review timing — not evidentiary standards or approval probability.

Other FDA Expedited Programs (CONT.)

IPO IMPACT

- Often highlighted in S-1 — must avoid overstating significance.
- Investors treat expedited programs as:
  - Timeline accelerators
  - Not probability enhancers
- Must clearly distinguish between:
  - Regulatory interaction benefits
  - Clinical success likelihood

Overstating regulatory designation impact creates litigation exposure.

Advisory Committee (AdComm)

WHAT IS IT

An independent panel of experts convened by the FDA to provide non-binding recommendations on:

- Approval
- Safety concerns
- Labeling

WHY IT MATTERS

- Public meeting.
- Vote results are often highly correlated with approval outcomes.
- Extremely high-volatility event.

IPO IMPACT

- Requires careful communications strategy.
- Blackout periods typically expanded.
- Media narrative must be managed carefully.

PDUFA Date – Prescription Drug User Fee Act Date

WHAT IT IS

- The FDA's target decision deadline for reviewing a New Drug Application (NDA) or Biologics License Application (BLA).

WHY IT MATTERS

- Known "binary" event date.
- Stock volatility often increases as PDUFA approaches.
- Approval, delay, or rejection all materially impact valuation.

IPO IMPLICATIONS

- If IPO occurs close to PDUFA, underwriters will scrutinize risk heavily.
- D&O premiums may increase if binary event is imminent.

CRL – Complete Response Letter

WHAT IT IS

An FDA letter issued when the agency determines it cannot approve the application in its current form.

CRLS MAY REQUIRE

- Additional clinical trials
- Additional manufacturing data
- Labeling changes
- Safety follow-up

WHY IT MATTERS

- Often results in sharp stock declines.
- Frequently triggers securities litigation.
- Creates extended development timelines.

IPO RISK NOTE

- Companies must avoid implying approval probability is high.
- Disclosure should clearly describe potential regulatory hurdles.

Regulatory Milestone Volatility

WHY THESE MATTER SO MUCH IN A BIOTECH IPO

THESE MILESTONES ARE

- Highly public
- Highly technical
- Highly volatile
- Legally sensitive

THEY DRIVE

- Reg FD exposure
- Insider trading blackout expansion
- Section 11 litigation risk
- D&O underwriting pricing
- Follow-on financing windows

Unlike most industries, biotech stock price movement is often concentrated around these FDA-driven events.

International Regulatory Strategy

VALUATION MODELS OFTEN ASSUME GLOBAL COMMERCIALIZATION

KEY AGENCIES

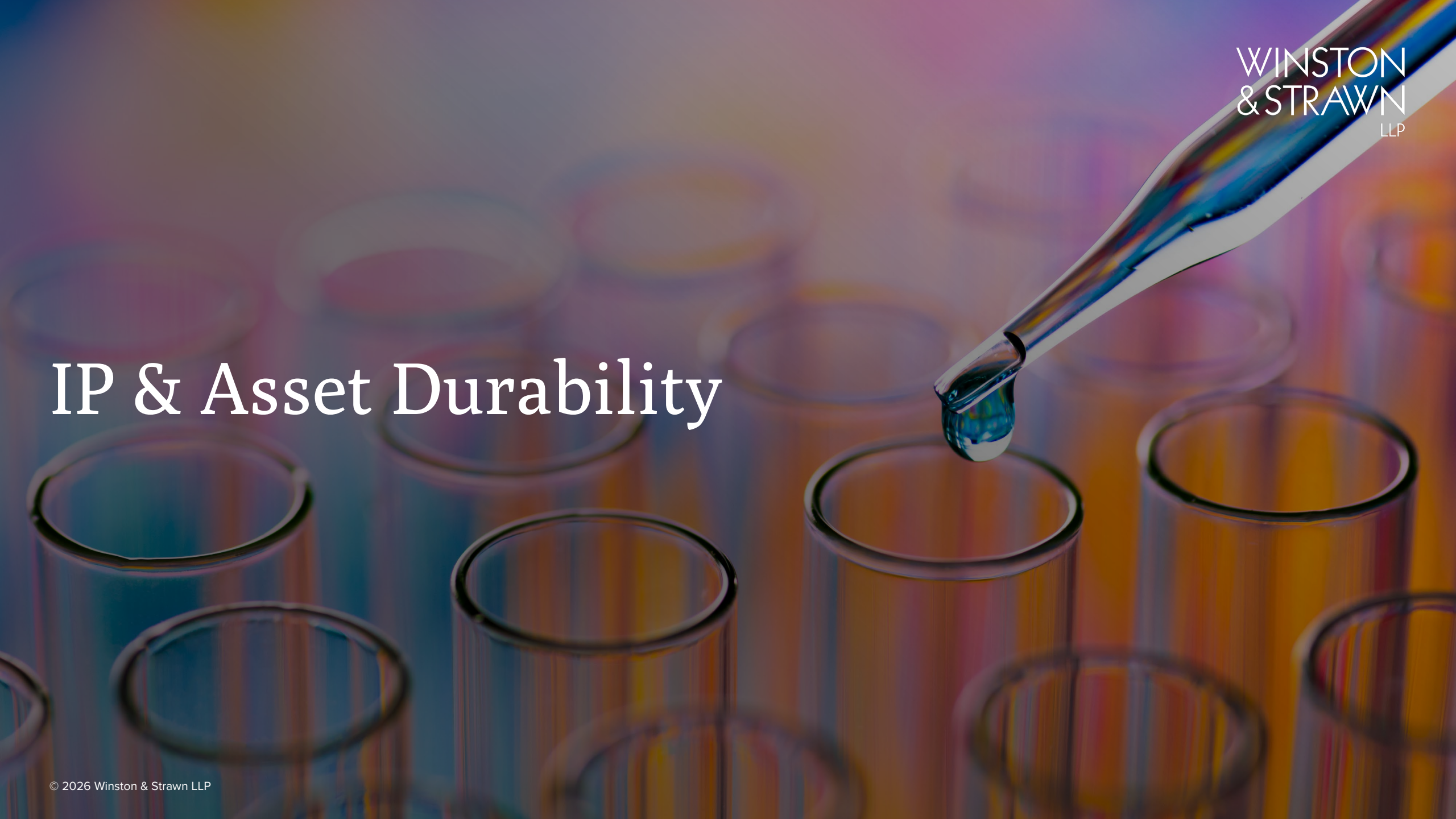
- EMA (European Medicines Agency)
- PMDA (Japan)
- MHRA (UK)
- NMPA (China)

WHY IT MATTERS

- Approval timelines differ.
- Data requirements differ.
- Pricing and reimbursement differ.
- Pediatric investigation plans may be required in EU.

IPO IMPACT

- Must clarify global regulatory strategy.
- EU approval not automatic following FDA approval.
- Global revenue assumptions must reflect jurisdictional risk.
- EMA approval does not guarantee uniform pricing or reimbursement across EU member states — national health authorities determine reimbursement. This can have significant effect on valuation modeling.



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IP & Asset Durability

IPO: The Core Value Driver

Unlike software or consumer companies, where revenue traction may dominate valuation, biotech companies are frequently valued based on:

- Duration of exclusivity
- Strength of patent claims
- Freedom from competitive entry
- Regulatory exclusivity stacking

Investors are underwriting not just science — but monopoly duration.

Composition of Matter Patents

WHAT IT IS

- A patent that protects the actual chemical compound or biologic molecule itself.
- This is the strongest form of pharmaceutical IP protection.
- If someone makes the same molecule — they infringe.

WHY IT MATTERS IN AN IPO

- Considered the “gold standard” of biotech patents.
- Directly drives valuation ceiling.
- Investors often model revenue only through patent expiry.

IPO IMPACT

- The S-1 must clearly disclose expiration dates.
- Investors will ask: “When does core composition expire?”
- If composition patent life is short (e.g., <8 years remaining), valuation discount is significant.
- Weak composition coverage can materially impair IPO pricing.

Method of Use Claims

WHAT IT IS

- Patents that protect how a drug is used — e.g., treatment of a specific indication or patient population.
- Weaker than composition patents because competitors may:
  - Develop alternate uses
  - Design around specific claims

WHY IT MATTERS

- If composition patents expire, method-of-use patents may extend partial protection.
- More vulnerable to generic or biosimilar challenge.

IPO IMPACT

- Must clearly disclose differences between composition and method protection.
- Investors discount valuation if only method-of-use protection exists.
- Risk factors must address potential workarounds.

Patent Term Extension (PTE)

WHAT IT IS

- U.S. law allows limited patent term restoration (up to 5 years) to compensate for FDA regulatory review delay.

WHY IT MATTERS

- Can extend exclusivity significantly.
- Not automatic — must be applied for and granted.

IPO IMPACT

- Companies often assume extension in valuation models.
- Disclosure must clarify that extension is not guaranteed.
- Overstating extension certainty creates Section 11 risk.

Orphan Drug Exclusivity

WHAT IT IS

- 7 years of market exclusivity in the U.S. for drugs treating rare diseases (regardless of patent status).
- Separate from patents

WHY IT MATTERS

- Powerful commercial protection even if patents are challenged.
- Particularly important in oncology and rare disease IPOs.

IPO IMPACT

- Must distinguish between patent protection and regulatory exclusivity.
- Orphan designation does not guarantee approval.
- Investors want clarity on patient population size and competitive landscape.

Data Exclusivity

WHAT IT IS

- Regulatory protection preventing competitors from relying on your clinical trial data.
- Examples:
  - 5 years for small molecules (U.S.)
  - 12 years for biologics
  - EU exclusivity regimes (pending legislative reform)

WHY IT MATTERS

- Operates independently from patents.
- Especially critical for biologics.

IPO IMPACT

- Valuation models include exclusivity stacking.
- Must disclose jurisdictional differences.
- International exclusivity differences affect global revenue assumptions.

IP: Strategic IPO Takeaway

IN A BIOTECH IPO:

Valuation = Probability of Approval × Peak Sales × *Duration of Exclusivity*

- IP directly controls the third variable.
- Weak IP compresses valuation even if clinical data is strong.

Freedom to Operate & Litigation Risk

- Shifting from “What protects you?” to “Can someone block you?”
- Freedom to operate (FTO) is about whether your commercialization infringes third-party patents.
- Even strong patents do not protect you from infringing someone else’s IP.

FTO Analysis (Freedom to Operate)

WHAT IT IS

- A legal analysis assessing whether the company's product infringes any existing third-party patents.
- Usually conducted by specialized patent counsel.

WHY IT MATTERS

- If a competitor holds blocking patents, commercialization could be delayed or require royalties.
- Litigation can begin before or immediately after approval.

IPO IMPACT

- Underwriters may request summaries of FTO analysis.
- If no formal FTO review has been conducted, this is a diligence gap.
- Risk factors must address potential third-party claims.
- Failure to properly disclose known FTO risk can lead to securities litigation.

Patent Disputes/Opposition Proceedings

WHAT IT IS	WHY IT MATTERS	IPO IMPACT
Ongoing legal challenges to patent validity, including: • U.S. inter partes review (IPR) • European opposition proceedings • Declaratory judgment actions	• Pending challenges create valuation uncertainty. • A patent invalidation event can materially impair value.	• Must disclose all material proceedings. • Disclosure must avoid minimizing litigation significance. • Investors will assess probability of patent survival.

Paragraph IV Exposure (Small Molecules)

WHAT IT IS

- Under Hatch-Waxman, generic manufacturers can file a Paragraph IV certification alleging:
  - The patent is invalid; or
  - The generic does not infringe.
- Triggers automatic litigation.

WHY IT MATTERS

- Can accelerate generic entry.
- Can materially shorten exclusivity period.

IPO IMPACT

- Must disclose known Paragraph IV notices.
- Risk factors should explain potential for early generic competition.
- Investors heavily discount valuation if early challenge is likely.

Biosimilar Risk (Biologics)

WHAT IT IS

- Under the Biologics Price Competition and Innovation Act (BPCIA), biosimilar applicants can challenge biologic patents.
- More complex than small-molecule generics.

WHY IT MATTERS

- Biosimilar entry may significantly erode pricing.
- Patent “dance” process can lead to staged litigation.

IPO IMPACT

- Must disclose biologic exclusivity timelines.
- Investors want clarity on patent estate breadth.
- Weak biologic patent coverage materially impacts valuation.

International IP Strategy

WHAT IT IS

- Patent protection across major markets:
  - U.S.
  - EU (including supplementary protection certificates)
  - Japan
  - China

WHY IT MATTERS

- Commercial opportunity often global.
- IP enforcement varies widely by jurisdiction.
- China manufacturing may introduce enforcement risk.

IPO IMPACT

- Disclosure should clarify geographic coverage.
- Global commercialization plans depend on enforceable protection.
- Investors discount revenue projections without strong EU/China coverage.

FTO Impact on IPO Process

UNDERWRITER DILIGENCE

- Will review IP landscape.
- May request outside patent counsel memo summaries.
- May consult independent IP experts.

RISK FACTOR DRAFTING

- Must clearly disclose known threats.
- Cannot imply guaranteed enforceability.
- Must avoid overstating patent strength.

VALUATION MODELING

- Exclusivity duration affects NPV.
- Litigation risk impacts discount rate.
- Royalty stacking reduces margin assumptions.

LITIGATION EXPOSURE

- Post-IPO Failure to disclose credible IP threats = Section 11 risk.
- Many biotech lawsuits cite inadequate patent risk disclosure.

Life Cycle Management Strategy

BEYOND INITIAL APPROVAL, BIOTECH VALUATION DEPENDS ON:

- New indications
- Combination therapies
- Reformulations
- Pediatric expansion
- Line extensions
- Follow-on biologics

WHY IT MATTERS

- Extends commercial life beyond initial exclusivity.
- Enhances valuation multiple.

Life Cycle Management Strategy (CONT.)

IPO IMPACT

- Investors evaluate pipeline depth.
- Must distinguish:
  - Core asset
  - Expansion programs
- Disclosure should avoid implying guaranteed label expansion.

BOARD QUESTION

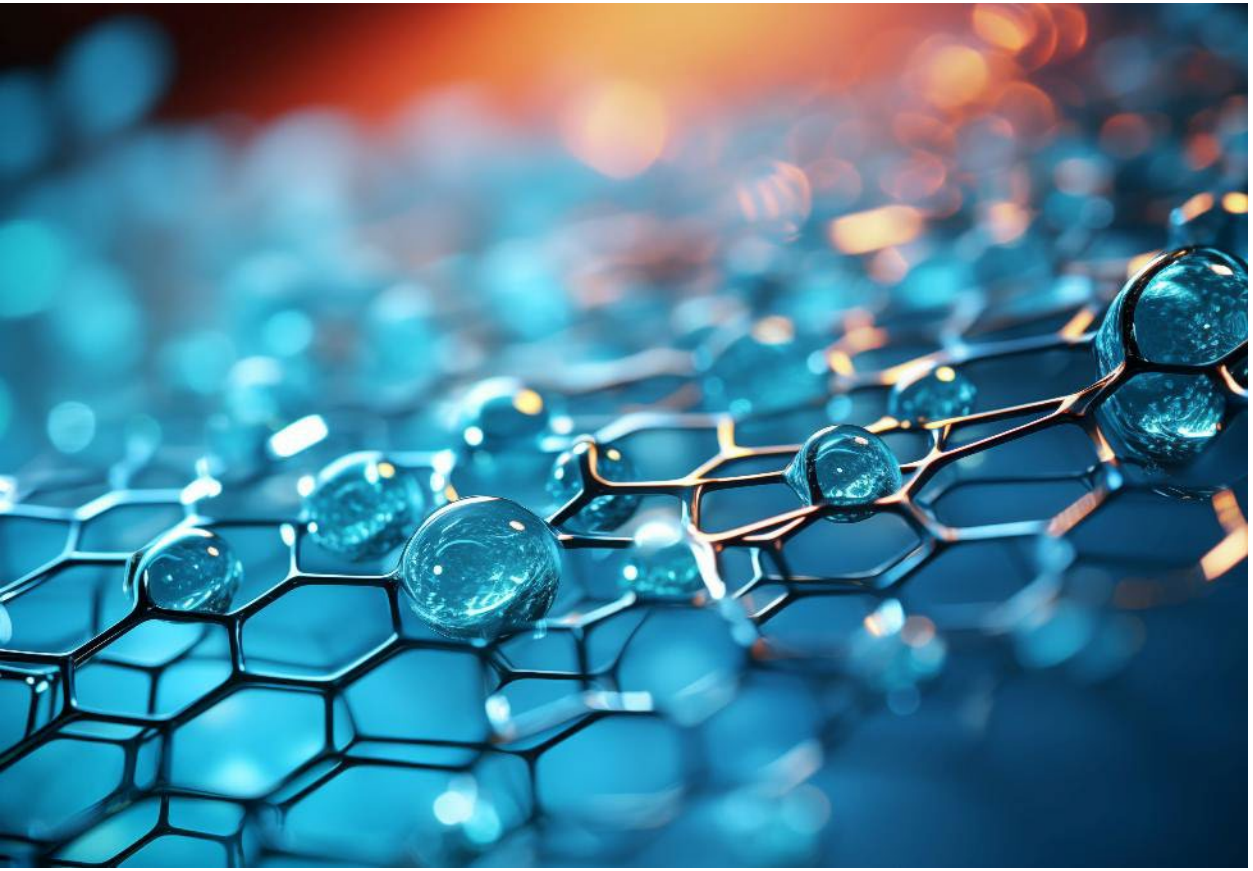
- Is this a single-asset story — or a platform with life cycle durability?
- Keep in mind that label expansion often requires additional Phase 3 trials and carries independent regulatory risk. Life cycle management is not low-risk value accretion.

IP: Big Picture

- Strong IP increases valuation.
- Unresolved IP risk reduces valuation.
- Inadequately disclosed IP risk creates litigation exposure.
- In biotech IPOs, IP disclosure must be:
  - Precise
  - Conservative
  - Clear about expiration dates
  - Clear about challenge risk
  - Clear about geographic limitations

Manufacturing & CMC Risk

CMC & Scale Up



- Clinical data often receives the most attention in biotech IPOs — but CMC (Chemistry, Manufacturing and Controls) failures derail approvals just as often.
- CMC refers to the entire process of:
  - Producing the drug substance (active ingredient)
  - Formulating the drug product (final dosage form)
  - Ensuring consistent quality, purity, and stability
  - Demonstrating regulatory compliance
- In biotech IPOs, investors increasingly scrutinize manufacturing risk — especially in late-stage companies.

CDMO Dependency

WHAT IS A CDMO?

CDMO = **Contract Development and Manufacturing Organization**

MANY BIOTECH COMPANIES:

- Do not own manufacturing facilities
- Rely entirely on third-party manufacturers

CDMOS HANDLE:

- Drug substance manufacturing
- Fill-finish operations
- Stability testing
- Scale-up production

CDMO Dependency (CONT.)

WHY CDMO DEPENDENCY MATTERS

BIOTECH COMPANIES ARE OFTEN

- Single-source dependent
- Contractually constrained
- Operationally exposed to third-party failure

RISKS INCLUDE

- Capacity shortages
- Quality control failures
- Regulatory violations
- Supply chain disruptions
- Termination of agreement

CDMO Dependency (CONT.)

IPO IMPACT

UNDERWRITER DILIGENCE

- Review manufacturing agreements
- Assess termination clauses
- Evaluate exclusivity terms
- Confirm capacity for commercial scale

DISCLOSURE

- Risk factors must address single-source risk
- Must disclose material manufacturing agreements
- Must disclose reliance on limited suppliers

VALUATION

- Investors discount companies with fragile supply chains
- Commercial-stage IPOs require strong manufacturing visibility

LITIGATION RISK

- If a manufacturing issue was known but not disclosed, stock-drop suits are common.

Scale-Up from Clinical to Commercial

This is one of the most underestimated risks in biotech IPOs.

WHAT IS "SCALE-UP"?

CLINICAL MANUFACTURING PRODUCES SMALL BATCHES FOR:

- Phase 1
- Phase 2
- Phase 3 trials

COMMERCIAL MANUFACTURING REQUIRES:

- Larger batch sizes
- Process validation
- Stability validation
- Supply chain robustness

MANUFACTURING AT SCALE IS NOT JUST "MORE OF THE SAME." IT OFTEN INVOLVES PROCESS REDESIGN.

Scale-Up from Clinical to Commercial (CONT.)

WHY SCALE-UP RISK IS REAL

COMMON SCALE-UP CHALLENGES

- Variability in batch purity
- Impurities emerging at larger scale
- Yield loss
- Equipment changes
- Biologic cell line instability

EVEN MINOR PROCESS CHANGES CAN TRIGGER

- Regulatory review
- New validation studies
- Additional CMC filings

Scale-Up from Clinical to Commercial (CONT.)

IPO IMPACT

- **If IPO occurs:**
  - Before commercial validation
  - Before process validation is complete
  - Before pre-approval inspection
- Investors will heavily discount valuation.
- **Late-stage IPOs must disclose:**
  - Status of process validation
  - Commercial manufacturing readiness
  - Planned facility inspections
- Failure to adequately describe scale-up risk has been cited in post-IPO litigation.

Comparability Studies

WHAT ARE COMPARABILITY STUDIES?

When a manufacturing process changes, companies must prove:

- The new product is comparable to the old product.
- Even small changes — such as:
  - Changing facilities
  - Changing equipment
  - Changing raw material suppliers
  - Changing cell lines
- may require demonstrating comparability.

Comparability Studies (CONT.)

WHY IT MATTERS

If comparability cannot be demonstrated:

- Additional clinical trials may be required
- Approval timelines may be delayed
- FDA may issue deficiencies

Comparability failures can materially delay commercialization.

IPO IMPACT

Underwriters will ask:

- Have there been manufacturing changes?
- Are comparability studies complete?
- Is there residual regulatory risk?

Disclosure must:

- Avoid implying equivalence without support
- Clarify if additional validation is ongoing
- Investors may heavily discount IPO pricing if comparability remains unresolved.

Inspection History (Form 483 Risk)

WHAT IS FDA FORM 483?

- If FDA inspects a manufacturing facility and identifies deficiencies, it issues a **Form 483** listing observations.
- These may involve:
  - GMP (Good Manufacturing Practices) violations
  - Quality control deficiencies
  - Documentation failures
  - Data integrity issues
- A Form 483 does not mean approval will be denied — but it is a red flag.

Inspection History (Form 483 Risk)

(CONT.)

WHY IT MATTERS

- If unresolved:
  - Can delay approval
  - Can lead to warning letters
  - Can result in CRLs
- For commercial-stage companies, inspection risk is highly material.

IPO IMPACT

- Disclosure obligations include:
  - Material inspection findings
  - Known warning letters
  - Remediation efforts
- Minimizing inspection deficiencies in S-1 language can create significant litigation exposure.
- Investors increasingly ask:
  - Has the facility passed pre-approval inspection?
  - Is remediation complete?
  - Is a re-inspection required?
- D&O insurers also evaluate inspection risk when pricing coverage.

REMS – Risk Evaluation & Mitigation Strategies

WHAT IS REMS?

An FDA-required program to ensure safe use of certain drugs, which may include:

- Provider certification
- Patient registry
- Restricted distribution
- Monitoring requirements

WHY IT MATTERS

- Increase commercialization cost
- Complicate distribution logistics
- Impact physician adoption
- REMS with Elements To Assure Safe Use (ETASU) can significantly restrict distribution channels

IPO IMPACT

- Must disclose if REMS is expected.
- Impacts SG&A and distribution modeling.
- Investors discount products requiring complex REMS.

Additional CMC Issues

COLD CHAIN LOGISTICS (BIOLOGICS)

- Temperature-sensitive drugs:
  - Require validated transport
  - Introduce supply chain risk

RAW MATERIAL SOURCING

- Single API (Active Pharmaceutical Ingredient) supplier?
- Geographic risk?
- Geopolitical exposure?

QUALITY SYSTEMS MATURITY

- Pre-IPO companies often lack:
  - Robust quality management systems
  - SOP (Standard Operating Procedures) documentation at public company level
- Weak quality infrastructure becomes evident during diligence.

CMC Impact on IPO Process

TIMING

Manufacturing readiness may determine whether IPO can launch.

DISCLOSURE

CMC risk factors must be detailed and specific — not generic.

VALUATION

Investors discount:

- Late-stage companies with unvalidated commercial manufacturing
- Companies with unresolved Form 483s

LITIGATION EXPOSURE

If approval is delayed due to CMC issues:

- Plaintiffs often allege inadequate disclosure of manufacturing risk.

CMC: Strategic Takeaways

Clinical success is NOT enough.

APPROVAL REQUIRES:

- Manufacturing validation
- GMP compliance
- Process reproducibility
- Regulatory inspection readiness

BEFORE IPO, BOARDS SHOULD ASK:

- Are we commercially manufacturable?
- Are comparability studies complete?
- Are we inspection ready?
- Do we have single-source risk?
- Is quality infrastructure public-company ready?

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Capital Strategy & Runway Engineering

Runway Expectations

In biotech IPOs, investors are not just buying science — they are buying time.

“Runway” refers to the amount of time a company can operate before it runs out of cash.

Runway = Cash on hand ÷ Monthly burn rate

18-24 Months Runway Expectation

Public biotech investors typically expect IPO proceeds to fund:

- At least 18–24 months of operations
- Through the next major value inflection event (e.g., Phase 2 readout, Phase 3 completion, NDA filing)

WHY?

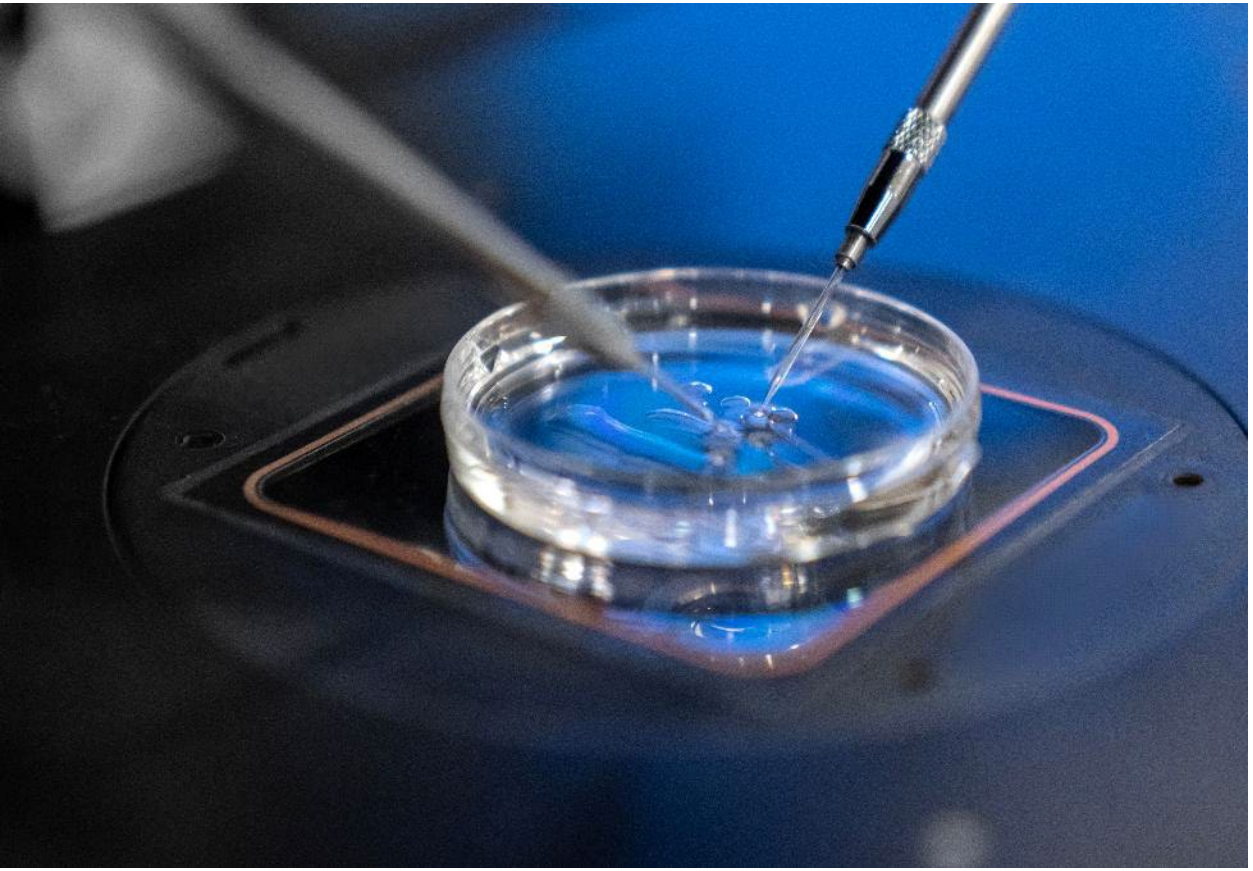
Because biotech investors want:

- A clear catalyst ahead
- Reduced immediate financing overhang
- Reduced near-term dilution risk

If runway is only 9–12 months:

- Investors assume another financing is imminent
- IPO pricing may be discounted
- Demand may weaken

Path to Milestone



Investors want to know: What specific value-creating event will IPO proceeds fund?

EXAMPLES

- Completion of Phase 2 trial
- Initiation of pivotal study
- NDA submission
- Top-line Phase 3 data

An IPO without a clear milestone narrative is much harder to price.

THE MILESTONE ACTS AS A

- Valuation anchor
- Timing anchor
- Risk reduction marker

Burn Rate Clarity

BURN RATE INCLUDES

- R&D spend
- Clinical trial cost
- Manufacturing scale cost
- G&A expansion post-IPO
- Public company compliance cost

COMMON IPO ISSUE

Pre-IPO companies underestimate post-IPO burn due to:

- Increased headcount
- Public company costs
- Investor relations spend
- D&O insurance premiums

Runway: Impact on IPO Process

S-1 DISCLOSURE

- Must clearly disclose:
  - Current cash position
  - Expected runway
  - Assumptions behind burn projections
- Going concern disclosures must align with runway statements (ASC 205-40 and the 12-month look forward requirement)
- Overly optimistic runway projections can trigger litigation if future financing becomes necessary sooner than disclosed.

VALUATION

- Short runway → Discount
  Strong runway → Reduced dilution overhang → Higher valuation
- Investors price dilution risk into IPO demand.

BOARD CONSIDERATION

- Before launching IPO, boards should ask:
  - Does IPO get us through the next meaningful catalyst?
  - Or will we be back in the market in 6–9 months?

Crossover Financing Strategy

CROSSOVER FINANCING REFERS TO

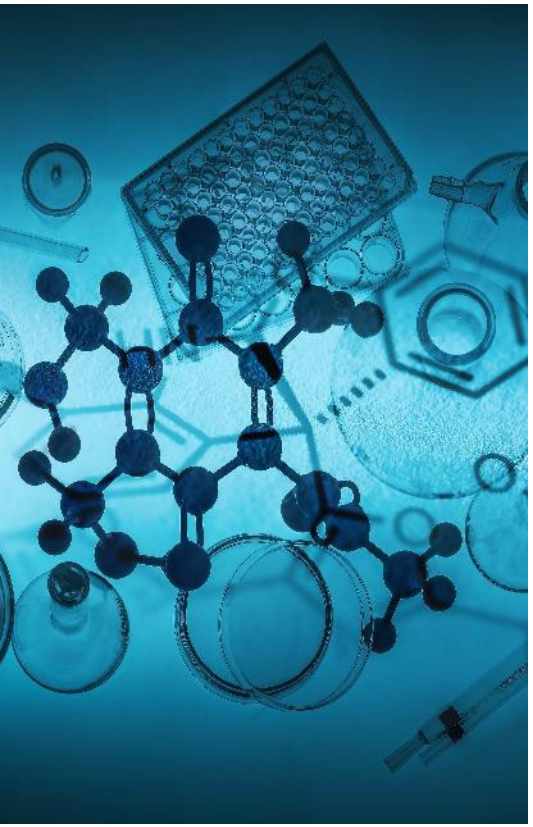
A private financing round conducted shortly before IPO with investors who typically invest in public biotech companies.

- These are often:
  - Healthcare-focused hedge funds
  - Long-only biotech funds
  - Dedicated crossover funds

WHY CROSSOVER ROUNDS MATTER

- Crossover investors provide:
  - Early validation of valuation
  - Anchor orders for IPO book
  - Improved IPO execution certainty
- They effectively “pre-market” the IPO.
- If strong biotech funds invest privately, it signals confidence to IPO buyers.

Crossover Financing Strategy (CONT.)



PRICING SIGNAL

- The valuation of the crossover round becomes:
  - A psychological reference point for IPO pricing
  - A signaling mechanism to the market
- If IPO price is below crossover price:
  - May signal weakness
  - May damage momentum
- If IPO price is significantly above crossover:
  - Risk of post-IPO trading pressure
- Pricing alignment is delicate.

Crossover Financing Strategy (CONT.)

LOCK-UP ALIGNMENT

Crossover investors typically:

- Agree to IPO lock-up periods
- May negotiate shorter lock-ups in some cases

Lock-up alignment matters because if early investors can sell too soon:

- Creates supply overhang
- Signals lack of conviction

IPO investors scrutinize:

- Who invested in crossover
- Their lock-up terms
- Their historical behavior post-IPO

Crossover Financing Strategy (CONT.)

IPO PROCESS IMPACT

TIMELINE

- **Crossover financing often occurs**:
  - 3–9 months pre-IPO
  - During confidential submission phase
- **Must coordinate**:
  - Private placement disclosure
  - S-1 updates
  - Cap table complexity

DILUTION

- Private rounds close to IPO increase share count.
- **Board must balance**:
  - Pre-IPO valuation
  - Dilution impact
  - IPO pricing strategy

LITIGATION RISK

- **Disclosure must**:
  - Describe material terms
  - Avoid preferential treatment issues
  - Avoid misleading about investor support
- Failure to disclose side letters or unusual rights creates risk

Post-IPO Capital Tools

- Biotech IPOs are typically the beginning of capital formation — not the end.
- Because development timelines are long, companies often return to capital markets multiple times.

THE TOOLS:

- ATM
- Follow-on
- PIPE
- Royalty deals
- Strategic partnerships

ATM – At-the-Market Program

An ATM allows a company to sell small amounts of stock into the open market over time at prevailing market prices.

Advantages:

- Flexible and Opportunistic
- Lower transaction friction
- Can raise capital after positive data

Disadvantages:

- Dilutive
- Requires effective shelf registration
- May create subtle trading pressure

IPO IMPACT

Many biotech companies establish an ATM:

- Within 6–12 months post-IPO
- After first follow-on

Investors expect ATM use in biotech. Disclosure in IPO should not imply IPO is final capital raise.

Follow-On Offering

- A marketed public offering conducted after IPO.
- **Often occurs**:
  - After positive Phase 2 or Phase 3 data
  - After regulatory milestone
  - This is common in biotech.

IPO IMPACT

- **IPO should**:
  - Establish clean shelf eligibility timeline
  - Prepare investor base for future raises
- Investors often buy IPO expecting future raises — but timing matters.
- If follow-on occurs too quickly:
  - Signals runway miscalculation
  - Can damage credibility

PIPE – Private Investment in Public Equity

A private placement of shares to institutional investors.

OFTEN USED	PIPES CAN	IPO IMPACT
• When markets are volatile • After stock price drop • When speed is critical	• Include discounts • Include warrants • Create dilution optics	Heavy reliance on PIPEs post-IPO may: • Signal weak capital markets access • Suggest valuation support challenges

IPO DISCLOSURE SHOULD CLEARLY EXPLAIN CAPITAL NEEDS TO AVOID SURPRISE PIPE NECESSITY.

Royalty Financing

- Company sells future royalty streams in exchange for upfront cash.
- Common in biotech.

ADVANTAGES	DISADVANTAGES	IPO IMPACT
• Non-dilutive (equity preserved) • Access to capital without share issuance	• Reduces long-term revenue • Can impair strategic flexibility	Investors evaluate: • Whether royalty stacking erodes margin • Long-term commercial economic

IPO DISCLOSURE SHOULD CLEARLY EXPLAIN CAPITAL NEEDS TO AVOID SURPRISE PIPE NECESSITY.

Strategic Partnerships

LARGE PHARMA PARTNERSHIPS MAY INVOLVE:

- Upfront payments
- Milestone payments
- Co-development
- Co-commercialization

THESE CAN:

- Reduce capital need
- De-risk development
- Provide validation

BUT MAY:

- Cap upside
- Reduce control

Post-IPO Capital Tools: IPO Process Impact

IPO VALUATION

- Strong runway + crossover support → Higher confidence
- Short runway + unclear capital plan → Discount

DISCLOSURE

Must avoid implying IPO solves all capital needs – Biotech investors assume future raises.

DILUTION MODELING

Board must understand:

- Pre-IPO dilution
- Post-IPO overhang
- ATM impact
- Future shelf use

LITIGATION RISK

Overstating runway sufficiency or minimizing need for future capital can create exposure.

Strategic Board-Level Takeaways

A BIOTECH IPO IS:

- Not a liquidity event.
- Not a final capital raise.
- Not a single transaction.
- It is one stage in a multi-year capital formation strategy.

BEFORE IPO, BOARDS SHOULD CLEARLY UNDERSTAND:

- What milestone are we funding?
- How much dilution is tolerable?
- When will we likely raise again?
- Are crossover investors aligned?
- Is our capital plan credible to public biotech funds?

WINSTON & STRAWN LLP

Governance & Board Composition

Scientific Credibility at the Board Level

In biotech IPOs, the board is not just a governance body — it is part of the investment thesis.

Public biotech investors scrutinize the board for:

- Scientific depth
- Regulatory experience
- Commercialization capability
- Capital markets credibility

In many cases, the board composition signals probability of approval and commercialization success.

Key Players:

- KOL (Key Opinion Leader) representation
- Former FDA officials
- Pharma executives
- R&D oversight expertise

KOL Representation – Key Opinion Leaders

A **Key Opinion Leader** is a recognized expert in a specific therapeutic area — often:

- Academic physician-scientists
- Leading clinical investigators
- Authors of pivotal research

They may:

- Advise on trial design
- Participate in advisory boards
- Speak at scientific conferences

WHY IT MATTERS

KOL involvement signals:

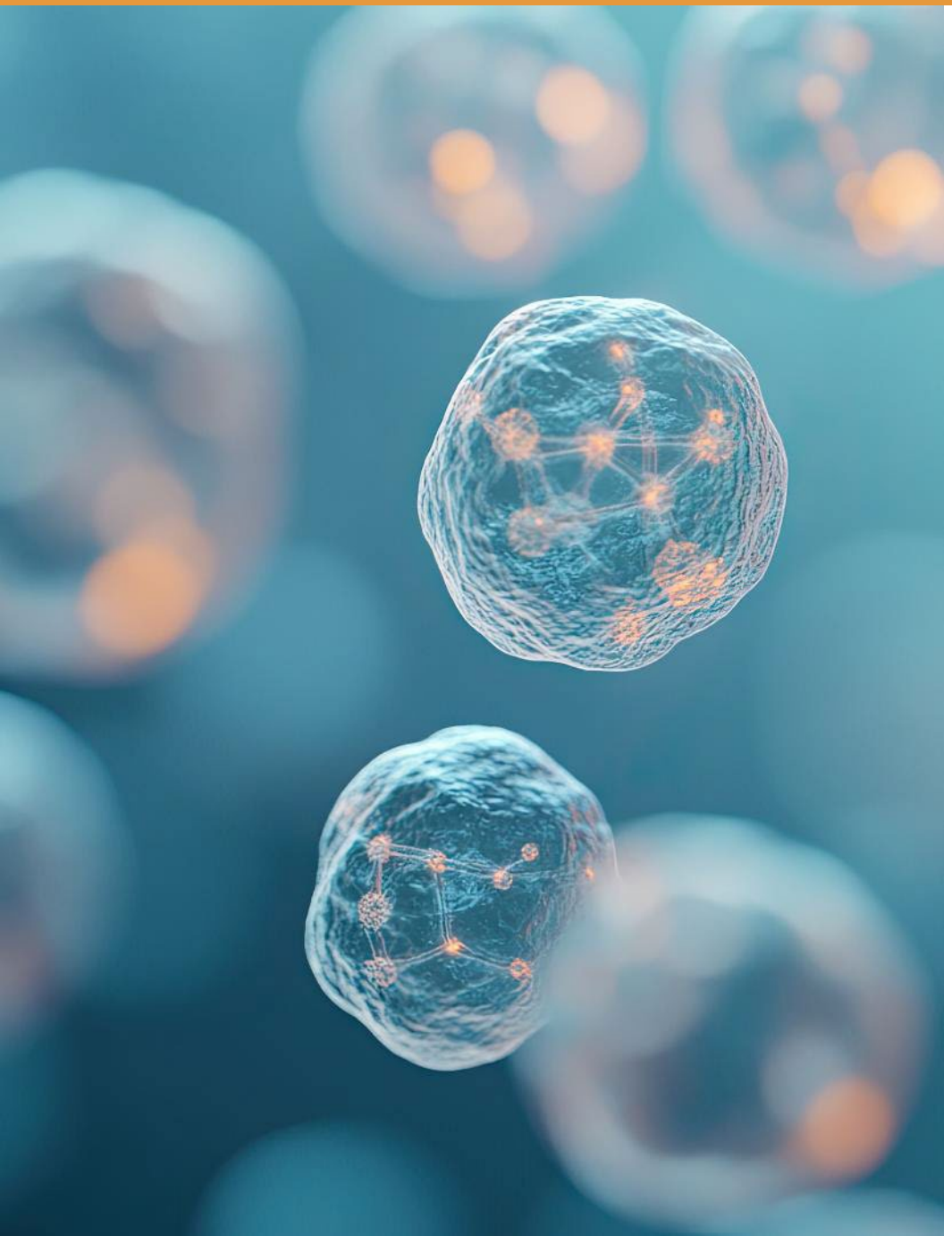
- Scientific credibility
- Market acceptance potential
- Clinical relevance of the therapy

However, formal board membership must be evaluated carefully.

KOL Representation – Key Opinion Leaders (CONT.)

POSITIVE	GOVERNANCE RISKS	DISCLOSURE MUST
• Enhances investor confidence in scientific strategy • Strengthens roadshow narrative • Signals strong clinical alignment	• Potential conflicts of interest • Independence classification issues under exchange rules • Related-party transaction disclosure	• Clarify roles • Disclose compensation • Avoid overstating scientific endorsement

INVESTORS MAY QUESTION WHETHER A KOL BOARD MEMBER:	
	• Has financial incentives • Is independent from management



Former FDA Officials

- Board members or advisors with prior FDA experience:
  - Former division directors
  - Regulatory policy experts
  - Former reviewers

WHY IT MATTERS

- FDA experience suggests:
  - Regulatory pathway insight
  - Strategic trial design knowledge
  - Familiarity with agency expectations
- However, this must not be framed as:
  - “Inside access”
  - Regulatory favoritism

Former FDA Officials (CONT.)

IPO IMPACT

- Underwriters and SEC will be sensitive to:
  - Any implication of influence over FDA decisions
  - Promotional statements about regulatory certainty
- Disclosure must:
  - Avoid implying guaranteed approval
  - Avoid suggesting preferential treatment
- Improper framing can create regulatory and litigation risk.

Pharma Executives

WHAT DOES THIS INCLUDE?

Former executives from:

- Large pharmaceutical companies
- Commercial-stage biotech companies
- Business development leadership

WHY IT MATTERS

They bring:

- Commercial launch expertise
- Market access experience
- Reimbursement insight
- Scaling capability
- In late-stage IPOs, commercialization credibility becomes critical.

IPO IMPACT

Investors want assurance that:

- The company can transition from R&D to commercialization
- There is strategic partnership capability
- Market launch risk is manageable
- For Phase 3 or NDA-stage IPOs, commercial leadership credibility heavily influences valuation

R&D Oversight Expertise

BOARDS MUST HAVE:

- Clinical trial design literacy
- Statistical literacy
- Safety monitoring awareness
- Oversight of independent data monitoring committees

THIS IS ESPECIALLY IMPORTANT IN:

- Platform companies
- Multi-asset pipelines
- Adaptive trial designs

IPO IMPACT

- Audit and risk oversight must include:
  - Clinical risk oversight
  - Manufacturing risk oversight
  - Safety signal governance
- Public investors expect boards to understand binary risk dynamics.
- Weak board scientific oversight may:
  - Reduce institutional investor demand
  - Raise governance red flags

Broader Governance Implications for IPO

Before IPO, biotech companies often transition from:

Founder/scientist-heavy boards TO **More independent, public-company-ready boards**

MUST EVALUATE

- Exchange independence requirements
- Committee composition (Audit, Comp, Nominating)
- Financial literacy requirements
- Clinical oversight framework

Anti-Takeover & Defensive Provisions

- Pre-IPO governance decisions include:
  - Classified board structure
  - Supermajority voting provisions
  - Exclusive forum clauses
  - Poison pill (post-IPO adoption)

WHY IT MATTERS

- Early-stage biotech companies are:
  - Frequent acquisition targets.
  - Vulnerable during volatility.

Anti-Takeover & Defensive Provisions (CONT.)

IPO IMPACT

- Governance structure affects institutional support.
- ISS may oppose certain provisions.
- Must balance:
  - Founder protection
  - Market governance expectations
- Delaware law permits classified boards and poison pills, but ISS and institutional investors increasingly oppose multi-classified structures without sunset provisions.
- Board must decide pre-IPO: Do we optimize for independence or acquisition defense?

Dual-Class Stock Structures

SOME BIOTECH IPOS ADOPT	PURPOSE	IPO IMPACT
• Dual-class voting structures • High-vote founder shares	• Preserve scientific leadership control. • Protect long-term R&D vision.	• Mixed institutional support. • Index inclusion limitations (S&P exclusion), potentially reducing passive fund ownership. • Governance advisory scrutiny.

BOARD MUST WEIGH	Control retention vs. investor demand breadth.

Compensation & ISS Sensitivity

- Biotech compensation structures differ significantly from other industries.
- Because many biotech companies:
  - Are pre-revenue
  - Are cash-constrained
  - Need to attract highly specialized scientific talent
- They rely heavily on equity compensation.
- However, equity structure directly impacts IPO reception.

KEY CONCEPTS

- Milestone-based equity
- Burn rate
- Overhang
- Equity plan size

Milestone-Based Equity

Many biotech companies structure equity grants around:

- Clinical trial milestones
- Regulatory milestones
- Data readouts
- Commercial launch events

These are often:

- Performance-based RSUs
- Option grants tied to development triggers

WHY IT MATTERS

- Aligns incentives with value-creating events.
- However, binary milestones create:
  - Incentive concentration risk
  - Short-term decision bias risk

IPO IMPACT

Proxy advisory firms (Institutional Shareholder Services (ISS) and Glass Lewis) scrutinize:

- Performance metric clarity
- Objectivity of milestones
- Board discretion

Poorly structured milestone metrics may:

- Lead to negative say-on-pay recommendations
- Impact post-IPO governance perception

Burn Rate

- Burn rate (in compensation context) refers to the percentage of outstanding shares granted annually as equity compensation.
- Biotech burn rates are often higher than industrial companies and technology companies due to:
  - Heavy equity use
  - Retention competition
  - Scientific talent scarcity

IPO IMPACT

- ISS compares burn rate to industry peers.
- **Excessive burn rate may**:
  - Trigger negative ISS recommendation
  - Raise dilution concerns
  - Depress stock price post-IPO
- **Boards must model**:
  - Historical burn
  - Expected future burn
  - Impact on fully diluted share count

Overhang

- Overhang = Total outstanding equity awards + shares reserved for issuance divided by total outstanding shares.
- **High overhang signals**:
  - Potential dilution
  - Future supply pressure
- Biotech IPOs often launch with higher overhang than other sectors.

IPO IMPACT

- **Investors assess**:
  - Fully diluted share count
  - Impact of option exercise
  - Future equity plan replenishment
- Excessive overhang may reduce IPO demand or compress pricing range.

Equity Plan Size

IPO companies typically adopt:

- New omnibus equity incentive plan
- Evergreen provisions (automatic annual increases – controversial)

IPO IMPACT

ISS frequently opposes:

- Large evergreen provisions
- Broad discretionary increases

Some companies now limit:

- Evergreen percentage
- Duration of automatic increases

Overly aggressive equity plan size can:

- Attract governance criticism
- Increase litigation exposure in extreme cases
- Reduce institutional investor support

Compensation Disclosure Risk in IPO

BIOTECH IPO S-1 MUST

- Clearly describe compensation philosophy
- Avoid overstating performance rigor
- Avoid implying guaranteed milestone achievement

If clinical milestones are missed and compensation was awarded aggressively, plaintiffs may cite disclosure inconsistency.

Strategic Takeaways

IN BIOTECH IPOS: GOVERNANCE IS PART OF VALUATION

INVESTORS ASSESS

- Does this board understand science?
- Does this board understand regulation?
- Is compensation aligned with long-term value?
- Is dilution controlled?
- Is equity overhang manageable?

BEFORE IPO, BOARDS SHOULD EVALUATE

- Independence balance
- Scientific credibility
- Compensation burn modeling
- Equity plan sizing relative to peers

Board-Level Questions to Ask Pre-IPO

- Does our board composition enhance or weaken our investment thesis?
- Are our milestone metrics objective and defensible?
- Is our equity plan size appropriate for public company scrutiny?
- What is our fully diluted share count post-IPO?
- Will ISS likely support our plan structure?

Litigation & D&O Exposure

Elevated Securities Litigation Risk

Biotech IPOs statistically experience a higher rate of post-IPO securities litigation than many other sectors.

WHY?

- Valuation is binary-event driven
- Clinical and regulatory outcomes are uncertain
- Stock price volatility is extreme
- Disclosure often involves complex scientific judgment

KEY CONSIDERATIONS

- Section 11 exposure
- Stock-drop suits
- Forward-looking statement scrutiny
- Safe harbor limitations

Section 11 Exposure

WHAT IS SECTION 11?

Section 11 of the Securities Act of 1933 creates liability for:

- Material misstatements or omissions in a registration statement (including an S-1).

KEY FEATURES:

- Strict liability for the issuer (no intent required).
- Negligence standard for directors and underwriters.
- Plaintiffs do not need to prove reliance.

This is a powerful litigation tool.

Section 11 Exposure (CONT.)

WHY SECTION 11 RISK IS ELEVATED IN BIOTECH

Biotech S-1s contain:

- Clinical trial data descriptions
- Safety characterization
- Statistical interpretations
- Regulatory pathway assumptions
- Manufacturing readiness statements

If later events contradict earlier disclosure, plaintiffs may allege:

- Overstatement of efficacy
- Understatement of safety concerns
- Inadequate disclosure of regulatory risk
- Failure to disclose known trial limitations

Even if management acted in good faith, outcome divergence can trigger suit.

Section 11 Exposure (CONT.)

IPO PROCESS IMPACT

SECTION 11 RISK AFFECTS:

- Underwriter diligence intensity
- Risk factor drafting depth
- Scientific disclosure language discipline
- Comfort letters and expert involvement
- D&O insurance pricing

BOARDS MUST UNDERSTAND

Every sentence in the S-1 about clinical or regulatory matters is potentially litigated later.

Stock Drop Suits

WHAT ARE STOCK-DROP SUITS?

- **After a significant decline in stock price, plaintiffs' firms frequently file class actions alleging**:
  - Misleading prior statements
  - Omitted material risks
  - Inflated expectations
- **In biotech, stock drops often follow**:
  - Failed trial readouts
  - Unexpected adverse events
  - FDA Complete Response Letters (CRLs)
  - Advisory committee negative votes

Stock Drop Suits (CONT.)

WHY BIOTECH IS PARTICULARLY VULNERABLE

Biotech stocks can fall 40–70% in a single day following:

- Missed primary endpoints
- Safety signals
- Regulatory rejection

This creates:

- Large damages models
- Plaintiff firm interest
- Media attention

IPO IMPACT

- Boards must plan for litigation before IPO.
- **Disclosure should**:
  - Clearly explain trial design limitations
  - Acknowledge binary outcome risk
  - Avoid implied probability statements
- **Litigation exposure also impacts**:
  - D&O insurance limits
  - Underwriter indemnification negotiations
  - Post-IPO communications strategy

Forward-Looking Statement Scrutiny

WHAT IS A FORWARD-LOOKING STATEMENT?

Statements about:

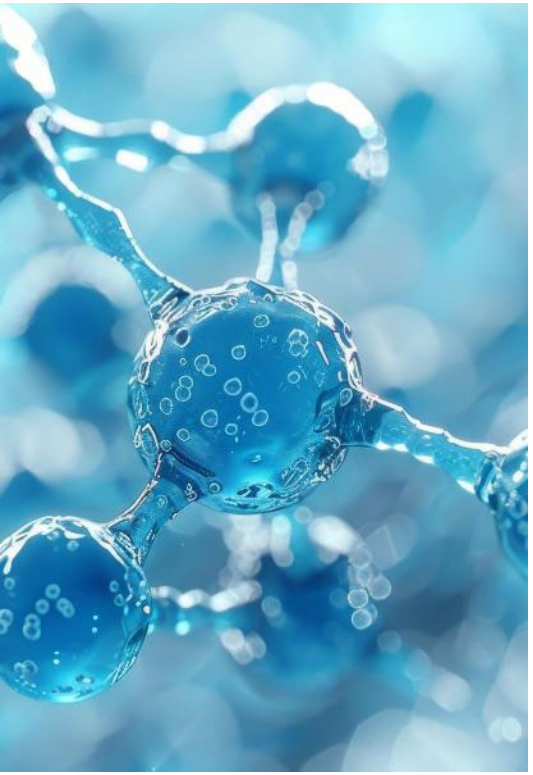
- Expected regulatory approval
- Anticipated trial results
- Commercial launch timing
- Market penetration

are considered forward-looking.

KEY

These can receive “safe harbor” protection in certain circumstances — BUT NOT in IPO registration statements under Section 11.

Forward-Looking Statement Scrutiny (CONT.)



WHY THIS MATTERS IN BIOTECH IPOS

- **Many biotech statements blend**:
  - Historical data
  - Interpretation
  - Projection
- **EXAMPLE**: "Our Phase 2 results support advancement to Phase 3 and we believe our therapy may represent a significant improvement over standard of care."
- **Plaintiffs may argue**:
  - The statement implied probability of approval.
  - The company failed to disclose known risks undermining that conclusion.

Forward-Looking Statement Scrutiny (CONT.)

IPO PROCESS IMPACT

- **In IPO registration statements**:
  - Safe harbor does not protect against Section 11 claims.
  - Cautionary language is helpful but not dispositive.
  - Balanced presentation is critical.
- **Companies must avoid**:
  - Implied approval certainty
  - Overly optimistic tone
  - Selective data presentation

Safe Harbor Limitations

WHAT IS THE SAFE HARBOR?

- The Private Securities Litigation Reform Act (PSLRA) provides protection for forward-looking statements if:
  - They are identified as forward-looking; and
  - Accompanied by meaningful cautionary language.

HOWEVER

The PSLRA safe harbor does NOT apply to IPO registration statements.

Safe Harbor Limitations (CONT.)

WHY THIS IS CRUCIAL

- Biotech IPO S-1s cannot rely on safe harbor protections for forward-looking statements.
- Therefore:
  - Risk factor specificity becomes critical.
  - Disclosure must be balanced.
  - Data interpretation must be precise.
- After IPO, earnings calls and press releases can rely on safe harbor — but the S-1 cannot.

Strategic Takeaways

BIOTECH IPOS ARE LITIGATION MAGNETS BECAUSE

- Outcomes are uncertain.
- Stock reactions are severe.
- Disclosure is complex and subjective.

THE BEST DEFENSE IS

- Conservative drafting
- Clear risk acknowledgment
- Thorough underwriter diligence
- Robust board oversight

D&O Insurance Considerations

- **D&O insurance (Directors & Officers insurance) protects**:
  - Directors
  - Officers
  - In some cases, the company
- from liability arising from securities litigation and other claims.

- In biotech IPOs, D&O considerations are significantly more complex and costly than in many industries.
- **Key considerations**:
  - Higher premiums
  - Expanded Side A coverage
  - Underwriting focus on pipeline stage
  - Binary event exposure

Higher Premiums

BIOTECH IPO D&O PREMIUMS ARE OFTEN MATERIALLY HIGHER THAN	WHY? BECAUSE INSURERS UNDERSTAND	PREMIUMS INCREASE IF
• Industrial companies • Consumer companies • Software companies	• Section 11 exposure • Stock-drop frequency • Binary clinical risk • Regulatory unpredictability	• Major readout is imminent • Regulatory decision is near • Pipeline is concentrated in one asset

Side A Coverage

D&O insurance typically has three components:

- **Side A**: Protects individual directors/officers when company cannot indemnify them
- **Side B**: Reimburses company when it indemnifies individuals
- **Side C**: Covers entity securities claims

Side A Difference-in-Conditions (DIC) coverage provides additional protection if primary policy fails.

WHY SIDE A MATTERS IN BIOTECH IPOS

Because:

- Section 11 claims can name directors personally
- Settlements can be large
- Bankruptcy risk (in extreme biotech failure) may impair indemnification
- Boards often increase Side A limits pre-IPO.

Underwriting Focus on Pipeline Stage

Insurers heavily evaluate:

- Phase of development
- Upcoming readouts
- Concentration risk
- Manufacturing readiness
- Prior regulatory interactions

Late-stage Phase 3 IPOs with near-term PDUFA may face:

- Higher premiums
- More restrictive policy terms

Binary Event Exposure

Binary events include:

- Phase 2 readout
- Phase 3 readout
- Advisory committee vote
- FDA approval or CRL

If IPO occurs near such events:

- Insurers price in higher risk
- Coverage negotiations become more complex

IPO Process Impact of D&O Issues

D&O AFFECTS:	
1. TIMING	Insurance must be bound before effectiveness.
2. COST MODELING	D&O premiums materially increase post-IPO G&A expense.
3. BOARD COMFORT	Independent directors often require robust coverage before joining board.
4. UNDERWRITER INDEMNIFICATION	Underwriters evaluate insurance sufficiency relative to indemnity obligations.

Strategic Takeaways

Before IPO, boards should ask:

- Are we drafting disclosure assuming litigation will occur?
- Are risk factors specific and tailored?
- Do we understand that safe harbor does not protect the S-1?
- Are D&O limits sufficient given binary event exposure?
- Does Side A coverage protect individual directors adequately?

Biotech IPOs should be approached with the assumption that:

- If there is a significant negative event, litigation is likely.
- Preparation reduces exposure.

Financial & Valuation Nuances

Financial Profile Differences

BIOTECH IPO FINANCIAL STATEMENTS OFTEN LOOK DRAMATICALLY DIFFERENT FROM TRADITIONAL IPO CANDIDATES.

Investors evaluating biotech companies do not focus on:

- EBITDA
- Profit margins
- Traditional growth metrics

Instead, they focus on:

- Cash runway
- Development burn
- Capital efficiency
- Probability-adjusted value of pipeline

R&D Concentration

- **In many biotech IPO candidates**:
  - 70–90% of operating expenses are R&D
  - SG&A is minimal pre-commercialization
  - No product revenue exists
- **R&D includes**: clinical trial costs, CRO (Contract Research Organization) fees, investigator payments, manufacturing for clinical supply, preclinical research, and regulatory consulting

WHY THIS MATTERS

- Biotech is essentially investing in: Future optionality.
- Accounting treatment:
  - R&D is expensed as incurred (no capitalization under GAAP).
  - This produces persistent net losses.

R&D Concentration (CONT.)

IPO IMPACT

VALUATION CONTEXT

Losses are expected and not necessarily penalized — but burn discipline is scrutinized

DISCLOSURE

S-1 must clearly explain:

- Drivers of R&D expense
- Pipeline allocation of spend
- Expected increase in spending

TREND DISCLOSURE

SEC expects discussion of known trends — such as:

- Planned Phase 3 trial cost increase
- Expansion of clinical footprint
- Increased manufacturing investment
- Boards should ensure R&D narrative aligns with capital needs.

Minimal or No Revenue

- Many biotech IPO candidates are pre-revenue or reliant on collaboration revenue.
- **This creates**:
  - No traditional revenue growth narrative
  - No recurring revenue base
  - No margin metrics

IPO IMPACT

- **Because there is no revenue base**:
  - Investors model future peak sales instead.
  - Analyst coverage focuses on pipeline probability.
- **Disclosure must avoid implying**:
  - Predictable commercialization timeline
  - Guaranteed revenue conversion
  - Revenue projections are not included in S-1s, but narrative around market opportunity must be carefully framed.

Collaboration Accounting (ASC 606)

- **Biotech companies often enter into**:
  - Licensing agreements
  - Co-development agreements
  - Strategic partnerships
- **These frequently include**:
  - Upfront payments
  - Development milestones, Regulatory milestones, Commercial milestones
  - Royalty streams

ACCOUNTING COMPLEXITY INVOLVES SIGNIFICANT MANAGEMENT JUDGMENT

- **Under ASC 606 (Revenue Recognition), companies must determine**:
  - Whether performance obligations are satisfied over time or at a point in time
  - Whether milestones are probable and not constrained
  - Whether revenue must be deferred

Collaboration Accounting (CONT.)

IPO IMPACT

UNDERWRITERS & AUDITORS WILL SCRUTINIZE

- Revenue recognition policies
- Judgment around milestone probability
- Disclosure of variable consideration

SEC COMMENT LETTERS OFTEN FOCUS ON

- Whether milestone payments were appropriately constrained
- Adequacy of disclosure of performance obligations

IMPROPER REVENUE RECOGNITION CAN TRIGGER

- Restatement risk
- Litigation exposure
- Credibility damage

Milestone Revenue Volatility

MILESTONE PAYMENTS CREATE

- Lumpy revenue recognition.
- **Example**:
  - $50 million milestone triggered upon Phase 2 success
  - Followed by quarters of minimal revenue
- This can distort financial comparability.

IPO IMPACT

- **Disclosure must explain**:
  - Revenue variability
  - Lack of recurring revenue
  - Dependence on milestone triggers
- Investors do not value biotech on milestone revenue alone — but volatility can distort perception if poorly explained.

Strategic Takeaways

BIOTECH FINANCIALS REQUIRE

- Clear explanation of R&D spend
- Transparent runway modeling
- Careful revenue recognition
- Conservative milestone accounting

The financial story must support — not contradict — the clinical narrative.

Section 382 & NOL Utilization Risk

Biotech companies accumulate:

- Significant Net Operating Losses (NOLs)
- R&D tax credits

Under Internal Revenue Code §382: An "ownership change" may limit annual NOL utilization.

An IPO can trigger:

- Ownership change
- Annual NOL limitation formula

WHY IT MATTERS

- Reduced ability to offset future taxable income.
- Impacts long-term cash flow modeling.

Section 382 & NOL Utilization Risk (CONT.)

IPO IMPACT

- Standard S-1 risk factor for biotech.
- CFO must model post-IPO NOL utilization limits.
- **Boards should understand**:
  - Whether protective NOL rights plan is needed.
    - Adoption of an NOL rights plan (tax benefit preservation plan) pre-IPO may be considered but must be balanced against governance optics.
  - Whether pre-IPO ownership shifts already triggered §382.
- Failure to address NOL limitation impacts financial modeling credibility.

Section 174 – R&D Capitalization (Post-TCJA)

- Under amended §174: R&D must be capitalized and amortized (5 years domestic / 15 years foreign).
- No longer immediately deductible.

WHY IT MATTERS

For biotech companies:

- Increases near-term taxable income.
- Impacts cash flow.
- Changes financial statement presentation.

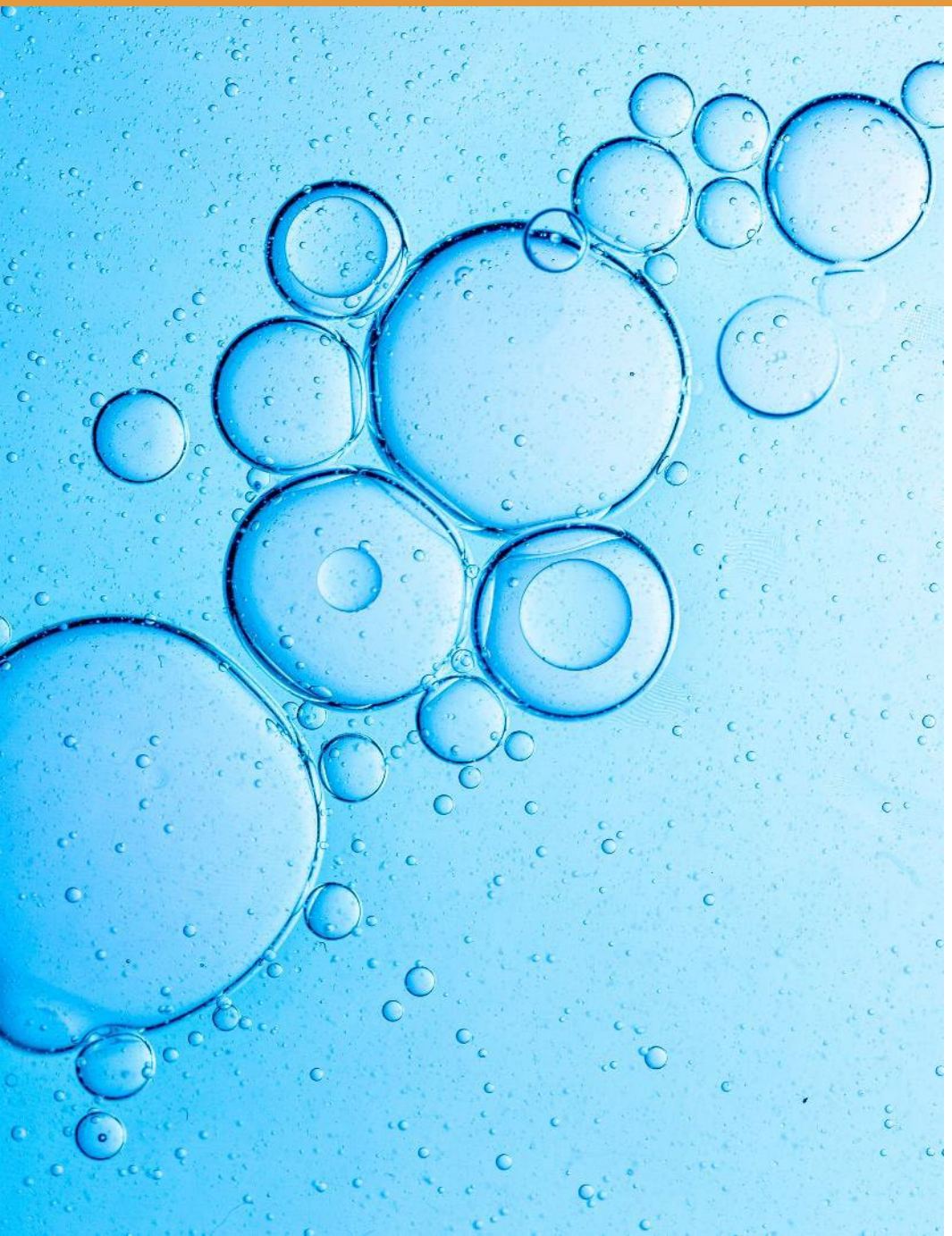
IPO IMPACT

- Burn rate modeling must reflect capitalization.
- Cash runway projections affected.
- Investors increasingly aware of §174 cash impact.

BOARD SHOULD CONFIRM

Financial models reflect current tax law — not historical expensing assumptions.

Legislative reform proposals exist, but current law requires capitalization — IPO financial models must reflect current law unless change is enacted.



Biotech Valuation Framework

- Biotech valuation differs fundamentally from traditional IPO valuation.
- **Instead of**: Revenue × Multiple
- **Investors use**: Risk-adjusted discounted cash flow models.

KEY CONCEPTS TO UNDERSTAND:

- Probability-adjusted NPV
- Peak sales
- Competitive landscape
- Time to commercialization
- Market size sensitivity
- Drug Pricing, Reimbursement & the Inflation Reduction Act (IRA)

Probability-Adjusted NPV (rNPV)

- rNPV = Risk-adjusted Net Present Value
- **This involves**:
  - Estimating peak sales
  - Modeling future cash flows
  - Applying the probability of clinical success
  - Discounting back to present value
  - **Probability of Success**
- **Industry benchmark probabilities vary by phase**:
  - Phase 1 → Approval: low
  - Phase 2 → Approval: moderate
  - Phase 3 → Approval: higher
- Small changes in assumed probability materially impact valuation.

Probability-Adjusted NPV (rNPV) (CONT.)

IPO IMPACT

- IPO timing relative to phase progression can:
  - Significantly alter valuation
  - Affect investor appetite
  - Impact crossover participation
- Disclosure must avoid implying specific probability percentages unless grounded in industry data.

Peak Sales Modeling

- **Investors estimate**:
  - Addressable patient population
  - Penetration rate
  - Pricing assumptions
  - Competitive positioning
- Peak sales is often a primary valuation driver.

IPO IMPACT

- **S-1 must carefully describe**:
  - Market size assumptions
  - Competitive therapies
  - Reimbursement landscape
- Overly optimistic TAM (total addressable market) assumptions are frequently cited in litigation.

Competitive Landscape

INVESTORS MODEL:

- Other drugs in development
- Mechanism-of-action overlap
- Timing of competitor data
- Patent overlap

A competitor's positive Phase 3 data can materially impact valuation.

DISCLOSURE MUST:

- Identify known competitors
- Avoid minimizing competitive risk
- Update for recent competitor developments

Failure to disclose material competitive risk may create exposure.

Time to Commercialization

TIME HORIZON AFFECTS

- Discount rate
- Capital needs
- Dilution modeling

LONGER TIME TO APPROVAL

- Reduces present value
- Increases capital required
- Increases dilution

IPO IMPACT

Late-stage IPOs generally price higher than early-stage IPOs due to shorter commercialization timelines.

BOARDS MUST UNDERSTAND

TIME = DILUTION

Market Size Sensitivity

- **Small changes in**:
  - Patient population size
  - Pricing
  - Market share
- can materially change valuation.
- **EXAMPLE:** 10% change in penetration rate may shift EV (Enterprise Value) by hundreds of millions.

IPO DISCLOSURE SENSITIVITY

- **S-1 must avoid**:
  - Overstating prevalence
  - Using inflated epidemiology data
  - Assuming unrealistic pricing
- Investors will independently validate these assumptions.

Drug Pricing, Reimbursement & the Inflation Reduction Act (IRA)

Biotech valuation is not just clinical — it is pricing-dependent.

KEY VARIABLES

- Medicare reimbursement
- PBM (Pharmacy Benefit Manager) negotiations
- Formulary placement
- Co-pay exposure
- Commercial payer access

Drug Pricing, Reimbursement (CONT.)

THE IRA – MEDICARE DRUG PRICE NEGOTIATION (BEGINNING 2026)

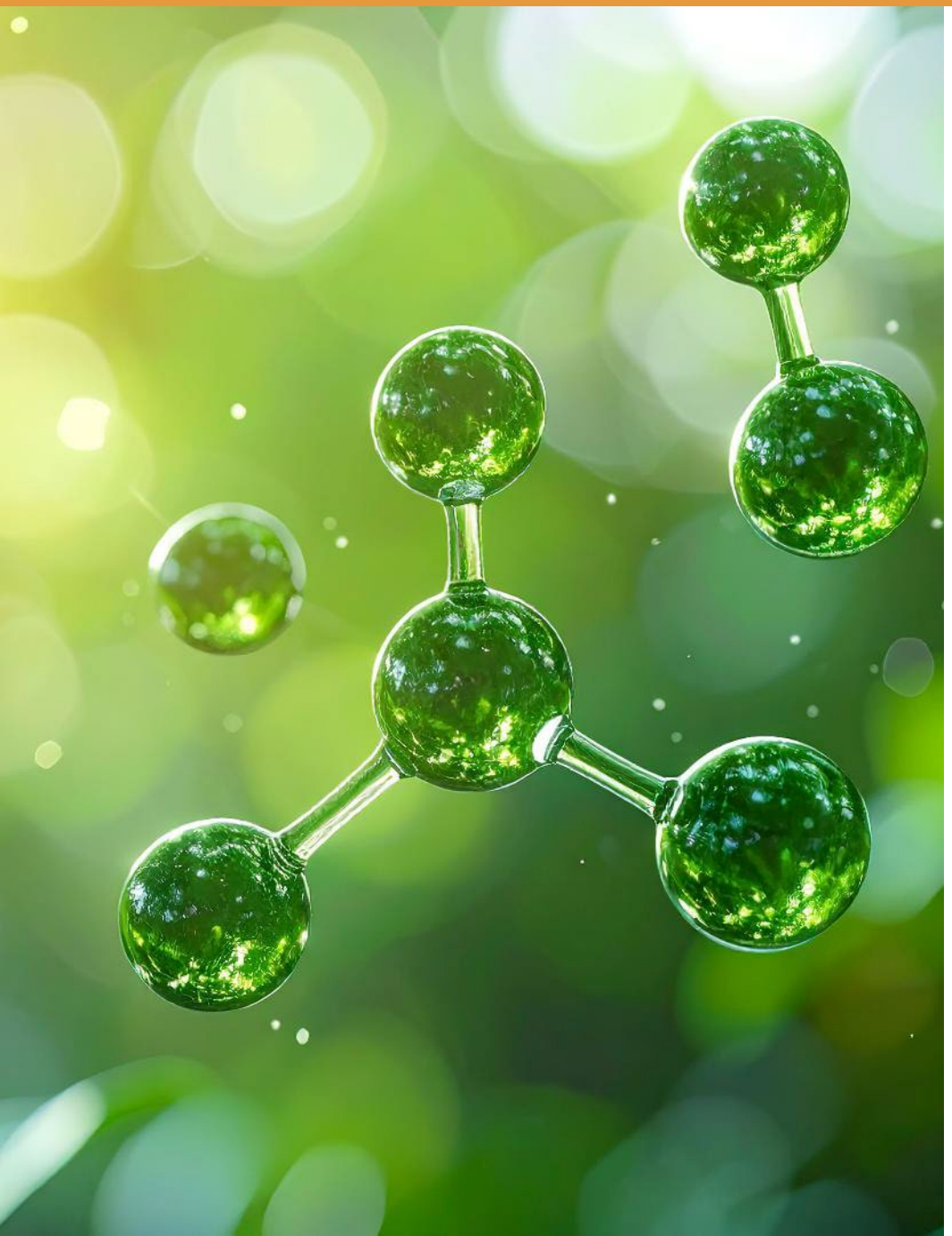
- Certain drugs become eligible for Medicare price negotiation.
- Negotiation applies only to certain high-expenditure Medicare drugs without generic/biosimilar competition.
- **Eligibility timeline** (measured from date of FDA approval):
  - 9 years post-approval (small molecules)
  - 13 years post-approval (biologics)

WHY THIS MATTERS

- **For small-molecule IPO candidates**:
  - Effective exclusivity window may compress.
  - Negotiation risk impacts peak sales modeling.
- **For biologics**:
  - Longer protection window (13 years).
  - Structural valuation advantage vs. small molecules.

IPO IMPACT

- S-1 must disclose IRA eligibility timing.
- **Valuation models must reflect**:
  - Negotiation risk
  - Margin compression
- Late-stage assets close to negotiation eligibility require enhanced disclosure.
- **Investors increasingly ask**: "How many unencumbered years of pricing power remain?"



Strategic Takeaways

BIOTECH VALUATION DEPENDS ON:

- Scientific probability
- Exclusivity duration
- Market size realism
- Capital efficiency
- Competitive timing
- Drug pricing

UNLIKE MOST IPOS:

- Financial statements explain the past. Valuation is driven almost entirely by the future.
- **This increases**:
  - Disclosure sensitivity
  - Litigation exposure
  - Diligence intensity
  - Board oversight responsibility

Board-Level Questions to Ask Pre-IPO

- Are our market size assumptions conservative and defensible?
- Have we stress-tested probability assumptions?
- Is our revenue recognition policy defensible?
- Does our burn rate align with our valuation story?
- Are our competitive disclosures current?

WINSTON & STRAWN LLP

Communications & Volatility Management

Event-Driven Volatility & Communications

- Biotech companies face **event-driven volatility**, and communication discipline before, during, and after IPO can materially affect:
  - Pricing
  - Litigation exposure
  - Regulatory scrutiny
  - Secondary offering windows
  - Long-term investor credibility

KEY CONSIDERATIONS:

- Investor base differences
- The Binary event cycle

Investor Base Differences

- One of the biggest differences in biotech IPOs is the investor base.
- **Unlike many other sectors, biotech IPO allocations are typically concentrated among**:
  - Sector specialists
  - Science-focused funds
  - Event-driven investors
- **Understanding who is buying your IPO affects**:
  - Roadshow strategy
  - Disclosure tone
  - Capital raise timing
  - Volatility management
- Let’s break down the categories.

Specialist Biotech Funds

- These are institutional investors focused almost exclusively on life sciences.
- **They often have**:
  - In-house MDs or PhDs
  - Clinical trial modeling expertise
  - Deep regulatory experience
  - High portfolio concentration in biotech
- **Examples** (general category, not referencing specific firms):
  - Dedicated healthcare hedge funds
  - Biotech long-only funds

Specialist Biotech Funds (CONT.)

WHY THEY MATTER

THEY

- Drive IPO book quality
- Anchor crossover rounds
- Influence IPO pricing range
- Provide analyst coverage access

THEY SCRUTINIZE

- Mechanism of action
- Trial design
- Statistical robustness
- Competitive differentiation
- IP durability

Specialist Biotech Funds (CONT.)

IPO PROCESS IMPACT

- **Roadshow messaging must**:
  - Be scientifically rigorous
  - Anticipate technical questions
  - Avoid marketing tone
  - Include detailed pipeline narrative
- Specialist investors can detect overstatement quickly.
- **If they lose confidence**:
  - Book quality weakens
  - IPO pricing suffers
  - Post-IPO support diminishes

Long-Only Healthcare Investors

These are institutional funds that:

- Invest across healthcare sectors
- May hold positions longer-term
- Focus on risk-adjusted return

They may not be as technically deep as specialists, but they:

- Provide price stability
- Support secondary offerings
- Reduce post-IPO volatility

Long-Only Healthcare Investors (CONT.)

IPO IMPACT

- Strong long-only participation:
  - Improves aftermarket stability
  - Signals credibility
  - Reduces flip risk
- Boards should understand allocation mix:
- Too much hedge fund allocation can increase volatility.

Hedge Funds / Event-Driven Investors

THESE INVESTORS OFTEN FOCUS ON

- Binary clinical events
- Regulatory catalysts
- Short-term volatility

THEY MAY

- Enter pre-data
- Exit immediately post-data

Hedge Funds / Event-Driven Investors (CONT.)

IPO IMPACT

- High hedge fund participation can:
  - Increase trading volatility
  - Amplify stock swings around data releases
  - Increase likelihood of sharp stock drops
- Underwriters attempt to balance allocation across:
  - Specialists
  - Long-only funds
  - Event-driven investors
- Investor mix influences long-term stock performance.

Retail Participation Post-Data

RETAIL INVESTORS OFTEN ENTER AFTER:

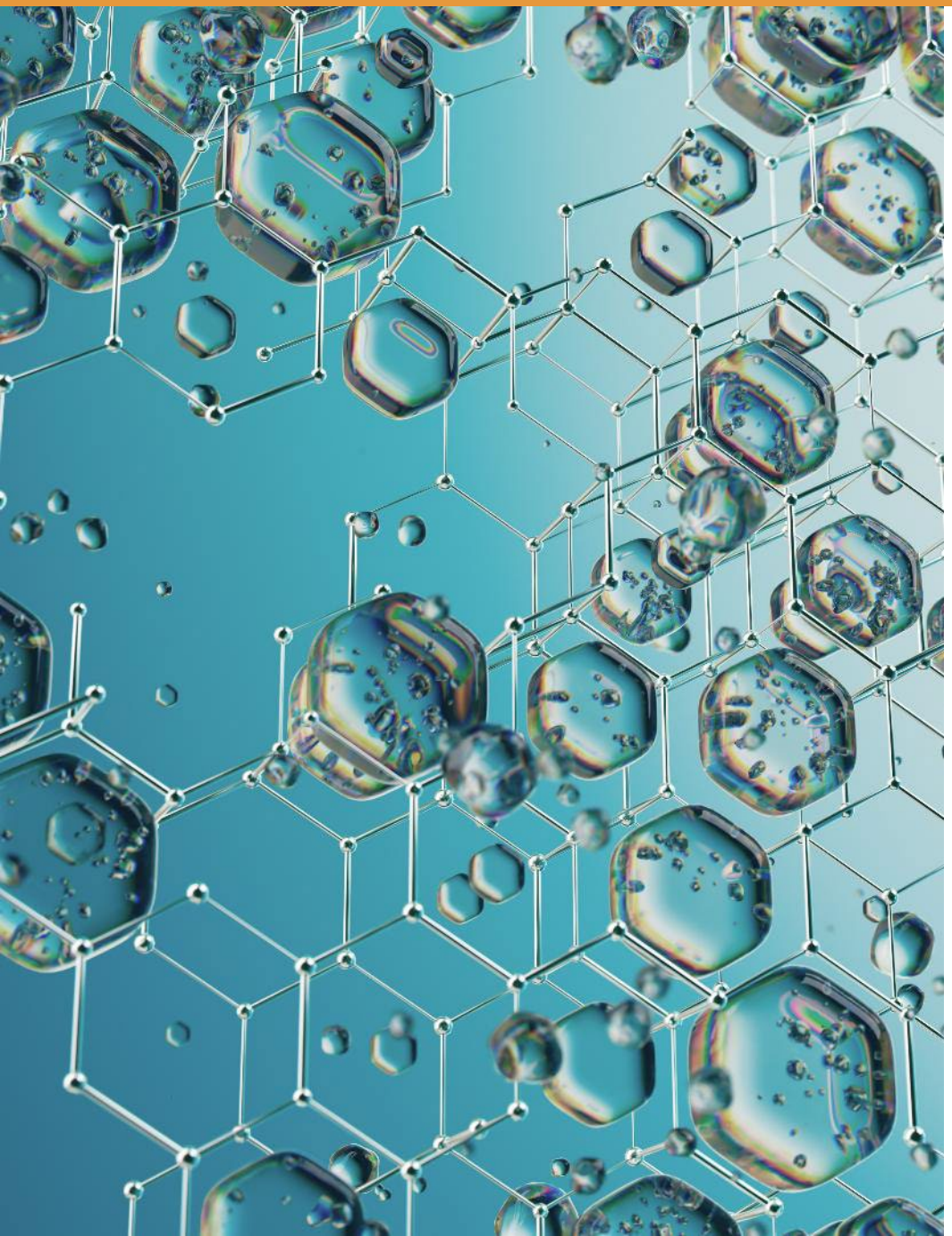
- Headline positive data
- Media coverage
- FDA approval announcements

RETAIL FLOWS CAN:

- Increase volatility
- Create price spikes
- Increase social media-driven trading

IPO IMPACT

- **While IPO allocation is typically institutional, retail participation often increases after**:
  - First major data readout
  - Regulatory approval
- **Companies must ensure**:
  - Press releases are carefully drafted
  - Headlines do not oversimplify results
  - Social media narrative is monitored
- Retail volatility increases litigation risk if expectations are inflated.



Strategic Takeaways

UNDERSTANDING INVESTOR MIX AFFECTS:

- IPO pricing stability
- Aftermarket support
- Volatility management
- Secondary offering timing

BOARDS SHOULD ASK:

- Who is anchoring the book?
- What percentage is long-only?
- How much is event-driven?
- Are crossover investors committed?

Preparing For & Managing the Binary Event Cycle

- Biotech companies operate in what we call: **The Binary Event Cycle**
- These are events where outcomes materially change valuation in a short period:
  - Phase 2 readout or Phase 3 readout
  - Advisory Committee vote
  - PDUFA decision
  - CRL issuance

Proper preparation before IPO is critical.

KEY CONSIDERATIONS

- Blackout planning
- Reg FD compliance
- Crisis communications playbook
- Media narrative control
- Post-readout capital planning

Blackout Planning

- **A blackout period restricts insider trading around material events**:
  - Trial data release
  - Regulatory decisions
  - Major scientific conferences

IPO IMPACT

- **Pre-IPO *and post-IPO*, companies must**:
  - Coordinate blackout calendars
  - Train executives on material nonpublic information (MNPI)
  - Monitor access to clinical data
- **Improper trading before data release is**:
  - High enforcement risk
  - High reputational risk
  - High litigation exposure
- Boards must oversee insider trading compliance robustly.

Rule 10b5-1 Trading Plans

SEC AMENDMENTS (EFFECTIVE 2023) REQUIRE:

- **Cooling-off periods**:
  - 90 days for officers/directors
- Written certification at adoption
- Limits on overlapping plans
- Limitation on single-trade plans (one per 12 months for officers/directors)
- Enhanced Form 4 disclosure
- Annual 10-K disclosure of plan usage

WHY THIS MATTERS IN BIOTECH

- Binary events complicate insider liquidity planning.
- **Executives must**:
  - Adopt plans well in advance of readouts.
  - Avoid modifications near MNPI events.

IPO IMPACT

- IPO readiness checklist must include 10b5-1 education.
- Insider trading policy must reflect amended rules.
- Disclosure controls must capture plan adoption and termination.
- D&O insurers evaluate insider sale timing patterns.
- Failure to properly implement plans can create enforcement and reputational risk.

Reg FD Compliance

- Reg FD (Regulation Fair Disclosure) requires: Material information be disclosed publicly, not selectively.
- **In biotech, risk arises when**:
  - Executives speak at investor conferences
  - Scientists present data informally
  - One-on-one investor calls occur

IPO IMPACT

- **Companies must**:
  - Ensure roadshow messaging matches S-1
  - Avoid selective disclosure of data interpretation
  - Carefully script Q&A responses
- **Reg FD violations can trigger**:
  - SEC enforcement
  - Credibility damage and Investor distrust

Crisis Communications Playbook

BIOTECH COMPANIES SHOULD PREPARE IN ADVANCE FOR:

- Negative trial results
- Unexpected adverse events
- Regulatory rejection

THIS INCLUDES:

- Drafting template disclosures
- Coordinating legal + IR (Investor Relations) + scientific messaging
- Preparing FAQ documents
- Preparing board-level response plan

IPO IMPACT

- Companies without a crisis plan often:
- Overreact publicly
- Provide inconsistent messaging
- Invite litigation
- Preparation reduces:
- Disclosure inconsistency
- Regulatory scrutiny
- Reputational damage

Media Narrative Control

In biotech, media coverage often simplifies complex science.

EXAMPLE:

- Headline: “Drug Fails in Late-Stage Trial”

EVEN IF:

- Secondary endpoints were met
- Subgroup data was promising

COMPANIES MUST:

- Draft press releases carefully
- Anticipate media interpretation
- Avoid promotional framing

IPO IMPACT

- Media narrative influences:
  - Retail participation
  - Short-term volatility
  - Follow-on window timing
- Misleading headlines can create expectations misalignment.

Post-Readout Capital Planning

- **Positive data often opens**:
  - Follow-on offering window
  - ATM opportunity
  - Strategic partnership negotiations
- **Negative data may**:
  - Close capital markets access
  - Require PIPE financing
  - Force restructuring

IPO IMPACT

- **Boards must pre-plan**:
  - Capital raise timing post-data
  - Shelf registration readiness
  - Underwriter re-engagement
- Companies that act quickly after positive readouts often secure better pricing.
- **Delay may result in**:
  - Market digestion
  - Competitor news overshadowing
  - Lost momentum

Strategic Takeaways

- Biotech IPO success does not end at pricing.
- **It depends on**:
  - Investor mix discipline
  - Communication rigor
  - Volatility planning
  - Legal compliance
  - Capital window readiness
- Boards should treat each major clinical or regulatory milestone as a mini-IPO event.
- **Preparation reduces**:
  - Litigation exposure
  - Regulatory scrutiny
  - Capital inefficiency
  - Credibility erosion

Board-Level Questions to Ask

- Do we understand who our investor base is?
- Is our blackout policy robust and enforced?
- Do we have a pre-drafted crisis communications plan?
- Are we prepared to raise capital quickly after positive data?
- Are our disclosure controls strong enough for binary events?

Key Takeaways

Biotech IPOs Require an Integrated, Event-Driven Strategy

- A **clinical credibility** event
- A **regulatory positioning** event
- A **capital runway engineering** event
- A **litigation risk inflection** point
- A **long-term investor base formation** moment

Clinical Strategy Is the IPO Strategy

IN BIOTECH, THE IPO IS FUNDAMENTALLY TIED TO:

- Clinical trial timing
- Data quality
- Regulatory feedback
- Probability of approval

VALUATION IS NOT DRIVEN BY HISTORICAL FINANCIALS — IT IS DRIVEN BY:

- Future clinical success
- Regulatory pathway clarity
- Time to commercialization

BOARD TAKEAWAY

IPO TIMING MUST ALIGN WITH CLINICAL INFLECTION POINTS, NOT MARKET ENTHUSIASM ALONE.

Disclosure Discipline Is Paramount

BIOTECH S-1 DISCLOSURES MUST BALANCE:

- Scientific enthusiasm
- Regulatory uncertainty
- Statistical nuance
- Manufacturing risk
- Competitive dynamics

BECAUSE:

- Section 11 liability applies to registration statements
- Safe harbor does not protect IPO filings
- Binary outcomes frequently trigger stock-drop litigation

BOARD TAKEAWAY:

- Assume that every clinical statement may later be examined in litigation.
- Conservative, precise drafting protects long-term credibility.

IP Durability & Pricing Window Determines Valuation Ceiling

- **Biotech valuation depends heavily on**:
  - Composition-of-matter protection
  - Duration of exclusivity
  - Freedom to operate
  - Global enforceability
- Even strong clinical data cannot overcome weak IP.
- AND Medicare negotiation eligibility may compress effective pricing window independent of patent life

BOARD TAKEAWAY: **Before IPO, understand patent expiration timelines and competitive vulnerability.**

Manufacturing & CMC Failures Can Derail Success

- **Strong trial data is insufficient if:**
  - Scale-up is incomplete
  - Comparability studies are unresolved
  - CDMO reliance is fragile
  - Inspection risk exists
- CMC failures frequently delay approval and trigger litigation.

BOARD TAKEAWAY: **Commercial manufacturability is part of IPO readiness — not a post-IPO issue.**

Governance Is Part of the Investment Thesis

IN BIOTECH:

- Scientific credibility matters
- Regulatory experience matters
- Commercial expertise matters
- Compensation alignment matters

EQUITY BURN RATE AND OVERHANG DIRECTLY INFLUENCE:

- Investor demand
- Proxy advisory support
- Long-term dilution

BOARD TAKEAWAY: **Board composition and compensation structure impact IPO pricing and aftermarket performance.**

Litigation Is Not Hypothetical — It Is Probable

BIOTECH IPOS FACE ELEVATED RISK OF:

- Section 11 claims
- Stock-drop litigation
- Post-data securities suits

- D&O insurance must be robust.
- Risk factors must be specific.
- Binary events must be anticipated.

BOARD TAKEAWAY: **Plan for litigation before it happens.**

Volatility Is Structural, Not Accidental

- Biotech companies operate in a Binary event cycle.
- Clinical readouts, advisory votes, and regulatory decisions can move valuation dramatically.

PREPARATION REQUIRES:

- Blackout discipline
- Reg FD compliance
- Crisis communications planning
- Post-readout capital readiness

BOARD TAKEAWAY: **Every major milestone should be treated like a mini-IPO event.**

Final Framing for Boards & Management

BEFORE LAUNCHING AN IPO, LEADERSHIP SHOULD BE ABLE TO CLEARLY ANSWER:

- What milestone are we funding?
- How durable is our exclusivity?
- Are we commercially manufacturable?
- Are our disclosures litigation-ready?
- Do we have 18–24 months of credible runway?
- Is our board scientifically and regulatorily credible?
- Are we prepared for volatility and litigation?
- Are we pursuing accelerated approval, and what is our confirmatory trial risk?
- When would our product become eligible for Medicare price negotiation?
- Have we modeled Section 382 limitations on NOL usage post-IPO?
- Are proposed insider 10b5-1 plans compliant with amended SEC rules?
- Should we adopt a classified board or dual-class structure before IPO?
- Does our life cycle strategy extend valuation beyond initial approval?

IF THOSE ANSWERS ARE STRONG AND INTEGRATED, THE IPO HAS A MUCH HIGHER PROBABILITY OF LONG-TERM SUCCESS.

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