May 2023

Biotech Paths for Growth: Structuring Considerations

Key Drivers of Deal Structure

1. Financial terms
2. Control
3. Risk allocation
4. Tax efficiency
5. Pipeline Programs
6. Financing/ liquidity for investors
7. Accounting treatment

Deal Structures

Venture and Strategic Investment Structures

Typical Equity and Convertible Equity Instruments

Preferred Stock

- Convertible preferred stock issued in a financing round with a *pari passu* or senior liquidation preference
- Customary contractual rights (*e.g.*, registration rights; information rights; anti-dilution protection)
- Board seat/observer seat
- Notice right/ROFN/ROFR (sale transactions)
- Downward pressure on valuations; increasingly investor-favorable deal terms

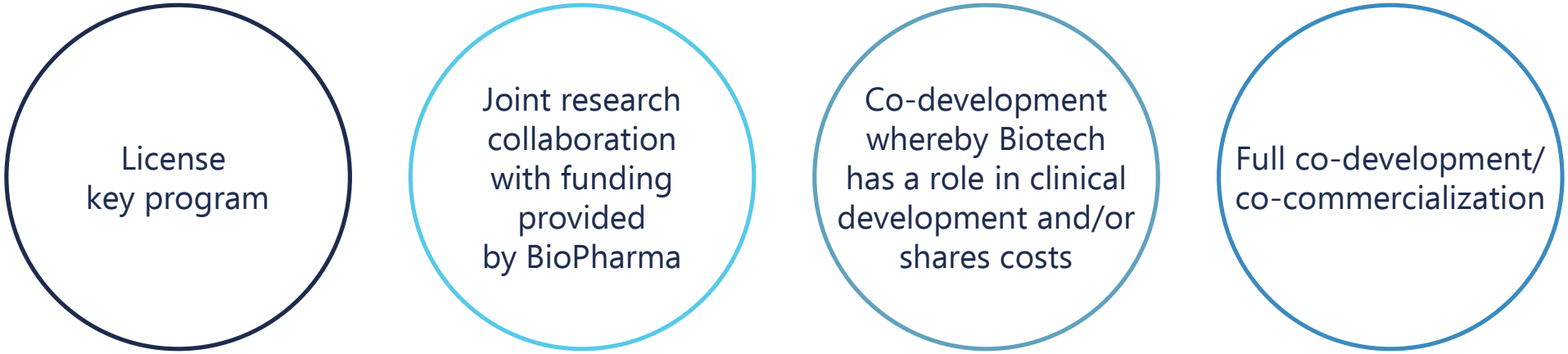
Financings (continued)

Rights and Responsibilities of Directors and Observers

Rights and Obligations	Director	Observer
Fiduciary Obligations	X	-
Can Vote on Board Actions	X	-
Protected by Company Attorney-Client Privilege	X	-
Receives Notices of Board Meetings	X	X
Receives Board Packages*	X	X
Attends Board Meetings*	X	X
Participates in Board Discussions*	X	X
Subject to Confidentiality Obligations	X	X

* Subject to exclusions

License/Collaboration



License/Collaboration

Key Considerations

Pharma

- Enables targeted acquisition of rights to product or technology of interest
- No assumption of undisclosed liabilities
- Lack of full control
  - Committee and reporting obligations can be burdensome, even with tie-breaking vote
  - Diligence obligations limit freedom and can create risk
- Return of asset if program terminates

Biotech

- Retain other pipeline programs
- Source of non-dilutive financing
- Shift of risk to licensee (although much retained through milestone/royalties)
- No exit or liquidity for investors
- Return of asset if program terminates

Payment and Other Forms of Consideration

Upfront Payment	One-time, non-contingent consideration paid on or shortly after closing
Equity	One-time (often minority) investment (common or preferred stock, convertible promissory note or warrant) in the licensee
Option Fee	Payable upon exercise of an option to license IP
Development/ Regulatory Milestones	Contingent consideration, payable on licensee's accomplishment of specified development milestones (e.g., start of Phase 1, first BLA approval) **Practice Tips:** Define milestone triggers carefully (e.g., what is "successful completion" of a Phase 1")! Define scope of products that trigger the milestones carefully.
Sales Milestones	Contingent consideration, payable on licensee's first achievement of certain cumulated annual net sales target (e.g., $100M of annual net sales).

Royalties	Contingent consideration, payable as a percentage of licensee's net sales of licensed products
	• Percentage is typically tiered, based on annual sales volume
	• Royalty term typically spans for the longest of (per product and country): (i) expiration of last patent covering the product, (ii) expiry of regulatory data exclusivity and (iii) 10/12 years from first commercial sale
	• Often subject to a variety of deductions, e.g., "anti-stacking" amounts paid to license third party IP needed for the licensed product
	  • **Practice Tip:** Consider what the deductions are for (any amounts paid or only royalties paid?) and what amounts they apply to (royalties only or milestones too?)
	  • For multi-component products (e.g., gene therapy), royalty anti-stack calculations can get highly complex.
	• Often also subject to a variety of step-downs (reductions in royalty percentage), e.g., expiration of patents that cover the licensed product (antitrust issues) and entry of generic competition
	  • **Practice Tip:** Consider the aggregate based on specific product. What is "market" is relevant but doesn't always answer the question.

Diligence Obligations

In return for granting exclusive rights, and because many payments are contingent on licensee's performance, licensor will typically require that licensee actively develops/commercializes the product

All of these phrases mean different things to different people in different jurisdictions!

In practice, parties usually expressly define "Commercially Reasonable Efforts" in the agreement

Practice Tips:

When drafting a CRE standard, consider:

- What's commercially reasonable?
- Who do you get measured against? Internal standard (your company) vs. external standard (other similarly situated companies in biopharma/MedTech)
- Which factors you should be required to take into consideration, e.g., if you have a competing product that's better, how much money you have to pay under the agreement, or expected profitability of the product

When drafting a CRE requirement, specify the specific obligations to which CRE applies[9]

- Milestones, number of products/indications, specific countries/jurisdictions (e.g. US, EU, Japan)

Diligence Obligations (continued)

What is "commercially reasonable" will always remain vague and a risk for disputes. Therefore:

- **Licensee will try to avoid being caught in breach claims unnecessarily, e.g.:**
  - Consider adding that interim hold of development program for evaluation/decision-making purposes does not constitute breach
  - Require warning notice with long cure periods prior to termination right
  - Require that termination is only effective if confirmed by competent court/arbitration
- **Certain licensors will seek to obtain firm commitments, e.g.:**
  - Maximum time to reach certain development milestones
  - Minimum budgets to invest in development
  - Minimum number of FTEs to work on development
  - Minimum requirements for launch preparation and commercialization

Practice Tips:

- Keep in mind that a requirement to use CRE to perform is not an absolute requirement to perform. For example, licensor may have a CRE obligation to commercialize in a specific country, but may nevertheless elect not to do so if the pricing and reimbursement approval received in such country is too low, therefore making it commercially unreasonable to sell.
- Licensors to consider ways in which you can monitor compliance with CRE obligations, e.g., governance meetings or reporting requirements

Termination Rights & Effects of Termination

Unlike M&A deals, most licensing deals "live" for an extended period of time – so what happens if the parties change their minds? Consider what happens when you walk away.

- Is the agreement terminated as a whole or only with respect to a particular product/offering or particular country(ies)?
- Who can continue to practice the developed (foreground) technology?
- Has any of your pre-existing technology been affected?
- Do you need continued access to any other party's IP, data or technology, for your rights to be meaningful?
- Consider how termination plays out at each phase of the project (pre-launch vs. post-launch)

Termination for Convenience	• If present, usually only the licensee can terminate for convenience, NOT the licensor • In biopharma deals, usually the licensor tries to limit the right, or require a reasonable notice period **Practice Tip:** Consider bifurcating different notice periods for different stages of the collaboration. For late stage products, termination may trigger a termination fee.
Termination for Patent Challenge	• Usually the licensor requires a termination right in case licensee starts to challenge the validity of the licensed patents **Practice Tip:** Keep in mind that many patent challenge clauses are likely unenforceable.
Deal-specific Termination Rights	• Termination for safety concerns • Termination for bankruptcy of the counterparty (not valid in many countries) • Changed support for the offering
Termination for Material Breach	• Often separate clauses for breach of diligence obligations with longer notice and cure period • Licensee will often request tolling provisions during which agreement doesn't terminate during pendency of dispute

Additional Effects of Termination

Common Effects of Termination (irrespective of termination trigger)

- Original licenses and payment obligations will terminate; complete, transition or wind down any clinical trials/ongoing users
- Licensee may have the right to sell-off remaining inventory
- Exclusivity obligations may survive for some period after termination (a "tail period")
- Could involve a "reversion license" – a transfer or license of the program (including new IP) back to the non-terminating party
- **Practice Tip:** Even though parties getting married don't like discuss divorce, to avoid future renegotiation and disputes, it pays to take the time to get these right!

Special Case: If licensor breaches, and licensee terminates, licensee will lose its license. Poor outcome for licensee…

Licensees often try to negotiate an "alternative remedy" – instead of terminating for breach:

- The license would become perpetual and irrevocable
- Milestone/royalty amounts/other ongoing payments would be reduced (typically starts at 50%)
- Licensee would have the right to offset damages against future payments
- Licensee would have the right to step-in to perform certain activities of the Licensor

BioPharma Licensed Product/IP Reversion Rights

Reversion License

- Scope of rights granted
- Survival of existing sublicenses
- Consideration in favor of licensee
  - Reverse royalties
  - **Practice Tip:** Consider negotiating upfront vs. negotiating at termination (with dispute resolution procedure if parties cannot agree).
- Critical IP created by licensee that extends patent life cycle
  - Improvements to foreground IP only or background IP too

Context Matters

- Stage of product when agreement is executed
  - Drug/target discovery collaborations
- Scope of technology licensed
  - Cell and gene therapies
  - Component licenses – capsid, promoter, transgene
- Manufacturing technology
- Reason for termination
  - Generally no reversion rights for termination for safety concern

Program Acquisition

Acquisition of assets related to key program - Key Considerations

Pharma

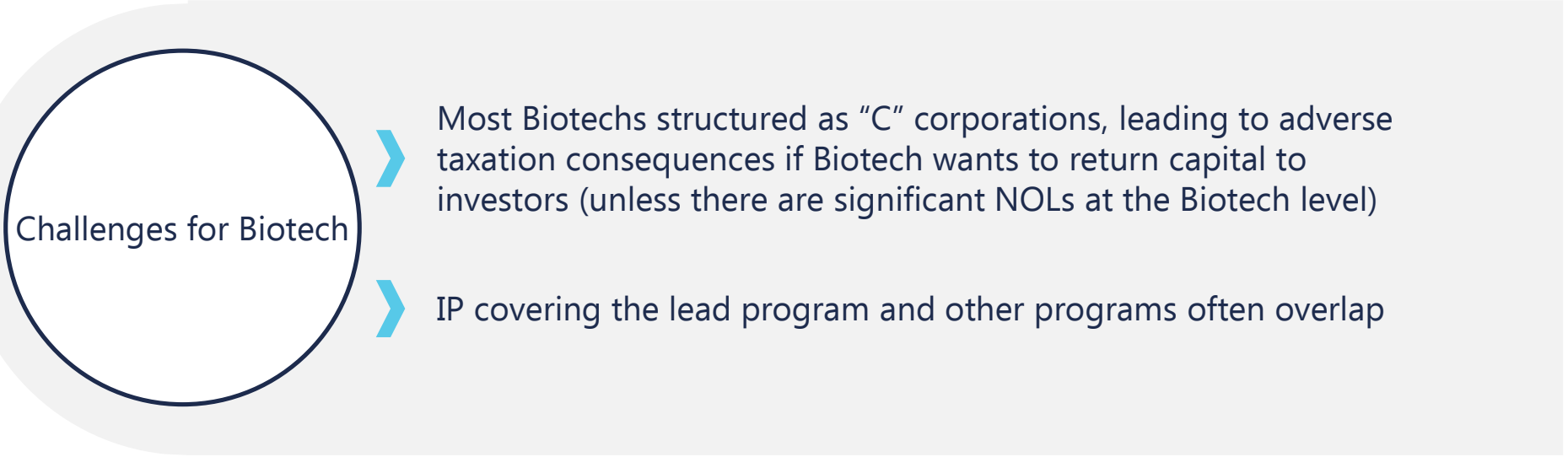
- Targeted acquisition of program or technology
- Ownership of key assets vs. license
- No assumption of undisclosed liabilities
- Full control/assumption of risk of program
  - Diligence obligations
  - Risk sharing through milestones/royalties
- Tax: step up in tax basis for acquired assets

Biotech

- Retain other pipeline programs
- Source of non-dilutive financing
- Retain pre-closing liabilities
- Shift of control/risk to purchaser
  - Diligence obligations
  - Risk sharing through milestones/royalties
- Tax: potential significant tax liability if low basis
- No exit or liquidity for investors

Asset Acquisition

Continued



M&A

Acquisition of the Biotech as an entirety (stock deal)

Typically structured as a merger, given number of stockholders

M&A

Key Considerations

Pharma

- Full control/assumption of risk of program
  - Diligence obligations
  - Risk sharing through milestones
- Assumption of all pre-closing liabilities
  - Indemnification for breach of reps/warranties
- Tax: no "step up" in basis of assets
- No mechanism to return asset

Biotech

- Shift of control/risk to purchaser
  - Diligence obligations
  - Risk sharing through milestones
- Trend to limit indemnification
- Exit for investors
- Tax: Gains on stock taxed as capital gain
- No mechanism to retake control

M&A

Current Issues

- Current antitrust environment
  - Complexity in negotiating risk allocation provisions
  - Impacts deal even where antitrust risk considered low
- Financing considerations
  - Can impact M&A deal terms
- Spin off of non-core pipeline assets
  - Often not valued by purchaser
  - Can be used to bridge value gaps
  - Execution can be complex
  - Tax: Spin-off is viewed as a taxable event to the Biotech
- Diligence (CRE)

Option to Acquire

- Option for Pharma to acquire Biotech as an entirety on pre-negotiated terms
- Up-front option fee
  - Non-dilutive
  - Used to fund development through to exercise trigger
- Tax:
  - Potential phantom income for investors if not exercised
  - Structuring can be complex
- Often paired with financing round

Option to Acquire

Key Considerations - Complexity

Pharma

- Lock up asset on pre-negotiated terms
- Hedge risk to next inflection point
- Minimal control pre-exercise
  - However, some influence
- If exercised, same as M&A

Biotech

- Essentially caps the value of the company
- Retain control of asset prior to exercise
- Frequently not exercised or re-negotiated
  - Can hamstring company going forward
- If exercised, same as M&A


Thank you
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