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THE LIFE SCIENCES GROWTH SERIES

Preparing for a Series A Investment and Due Diligence

Tony Chan, Robin Silva | January 15, 2019

Agenda

- Introduction
- General overview of corporate process
- Getting your corporate house in order
- Getting your IP house in order
  - Patent portfolio
  - Freedom to operate (FTO)
- Questions

The Basic Process

- Generally the business and technical due diligence goes first
  - Once the business case has been made, and the technology vetted, then corporate and IP due diligence is done
    - Sometimes this makes for a fast timeline, so letting counsel know early that the process is starting allows for better preparation
- Corporate due diligence is similar for tech and life sciences startups
- IPDD generally is much deeper for life sciences
- Building a good process and documentation for Series A means you will be better prepared for later financings

SECTION 01

SERIES A FINANCING AND DUE DILIGENCE

Series A Financing

- Series A financings are more complex than Angel or Seed financings:
  - Will usually involve an "anchor" or "lead" investor who will lead the diligence and negotiation on behalf of the other investors in the financing round
  - Several different constituencies, perhaps with interests which are not aligned: management, common stockholders, and different series of preferred stockholders
  - The rights and preferences of each of these constituencies must be balanced carefully in order to achieve a successful transaction
  - Timing is usually 3-4 months
- Transaction Mechanics and Process, including due diligence
- Intellectual Property

Typical Documentation

- NVCA
- Term Sheet
- Amended and Restated Certificate of Incorporation
- Preferred Stock Purchase Agreement
- Investors' Rights Agreement
- Voting Agreement
- Right of First Refusal and Co-Sale Agreement
- Management Rights Agreement
- Director Indemnification Agreement

Preferred Stock

- Series A financing will almost always involve the issuance of preferred stock, ranking senior in terms of liquidation priority to all of the other equity securities of the corporation.
- This means that, when the corporation is sold, the investors in the round get their money back, typically plus a dividend, before other stockholders receive anything

Term Sheet

- Principal Terms
- Amount Raised
- Price Per Share
- Capital Structure
- Documentation
- Confidentiality
- Exclusivity
- Governing Law

Stock Purchase Agreement

- Valuation
- Representations and Warranties
  - Intellectual Property representation is often the most heavily negotiated
- Transaction Mechanics
- Conditions to Closing
  - Option Plan
  - Invention Assignment Agreements
- Reimbursement of Fees

Valuation

- Pre-money valuation is a central issue in the transaction, although many of the other terms we will discuss will have a direct impact on valuation.
- The pre-money valuation is used to determine the share price the investor will pay in the round.
- The share price is determined by dividing the pre-money valuation by the number of "fully diluted" shares outstanding. The pre-money valuation, plus the amount of the investment is referred to as the post-money valuation.
- "Fully diluted shares outstanding" is a very important concept and can include shares issuable upon exercise or conversion of a variety of different securities: outstanding options, unissued option pool, warrants, convertible notes and preferred stock, all with potentially complex exercise and conversion terms.

Certificate of Incorporation

- Preferred Stock Provisions
  - Liquidation Preference
  - Seniority
  - Definition of Liquidation Event
  - Participating or Non-Participating
  - Protective Provisions
    - Approval over:
      - Acquisitions
      - Amendments to Charter and Bylaws
      - Authorization of senior securities
      - Increases in option pool
      - Others

Certificate of Incorporation

- Preferred Stock Provisions
  - Conversion
    - Mandatory
    - Voluntary
  - Anti-dilution
  - Pay to Play
  - Board of Directors
  - Voting
  - Redemption Rights
  - Indemnification
  - Exculpation

Certificate of Incorporation – Board of Directors

- The Board of Directors manages the corporation. "*The business and affairs of every corporation organized under this chapter shall be managed by or under the direction of a board of directors . . .*" Del. Sec. 141. All major decisions, such as raising capital or selling the corporation, require approval of the Board of Directors as a first step.
- Each member of the Board of Directors has a fiduciary duty to all stockholders, not just to the group that designated the Board member for election.
- Board members must be careful to separate their actions as Board members from their actions as stockholders.

Investor Rights Agreement

- Registration Rights
  - Demand Rights
  - Piggyback Rights
  - S-3 Rights
- Preemptive Rights
  - Major Investors
- Information Rights
- Preferred Investor Approval
- Board Observer Rights
- Ongoing Covenants
- QSBS

Voting Agreement

- Board Composition
  - Common
  - Preferred
  - Independent
  - CEO
- Drag-Along Rights
  - Forced sale of Company
  - Who can trigger?
  - Thresholds/limitations
  - Fiduciary Duties?
- Bad Actor

Right of First Refusal and Co-Sale Agreement

- Restrictions on key employee equity
- Right of First Refusal on Proposed Transactions
- Co-Sale if ROFR is not exercised
  - Standard Exceptions
- Exercisable by Company and Major Investors
- Interaction with other Transfer Restrictions?
- Lock-Up

Other Documents

- Management Rights Letter
- Indemnification Agreement
- Option Plan and Grant Agreement
- PIIA
- Legal Opinion(s)
- Certificates
- Employment Agreements
  - Consulting Agreements (SAB members)

Due Diligence

- What is it?
- Why is it important?
- What are some of the pitfalls?
  - Often overlooked until late in the process

Be Prepared

- Maintain central repository for all company documents
- Organize, collect, and maintain all contracts
- Clean up and verify capitalization (particularly options, warrants, and any other securities)
- Gather all board of director and shareholder minutes, including all board packet and shareholder communications
- Have ready all [un]audited financial statements

Due Diligence Request Lists

- Investors typically offers up a relatively standard list of requested documents
- Appoint one person to manage incoming requests, communicate with appropriate internal teams, and coordinate external responses
- Be internally prepared with messaging on any problematic items before they are presented to the other side; there should not be any surprises—find them yourself first!

Scope

- Corporate Records and Charter Documents
- Business Plan and Financials
- Material Contracts
- Intellectual Property
  - A list of the Company's trademarks, patents, copyrights and domain names (or any applications therefore) including documentation of filing or registration with the appropriate governmental entities.
  - If any of the foregoing were assigned to the Company, please so state and provide documentation of the assignment and recordation with the appropriate governmental entities.
- Security Issuances and Agreements Concerning Securities
- Disputes and Potential Litigation
- Employees and Employee Benefits

How to Best Organize/Share Contracts

- Work with business team and counsel to prioritize material or critical information for buyer
- Group contracts in logical sets based on type using a form diligence request
- Work with business team to discuss any commercially sensitive information that will not be provided up front or will be provided pursuant to special procedures

Setting Up a Data Room/Site

- Pick a vendor
  - Be aware that there are many providers; not all may be appropriate
  - Consider both security and product functionality
- Search capabilities of data room
  - Ensure that searching is enabled and efficient
  - Consider printing enablement

Setting Up a Data Room/Site (cont.)

- Managing uploads
  - Appoint a single account administrator at the company and/or counsel who manages uploads—again, organization is key here
  - Enable email alerts regarding new uploads
- Legal vs. business due diligence
  - Need adequate communication across all diligence teams to ensure everything is looked at by appropriate parties
  - Issues lists and diligence trackers are often used to keep a full record of what was reviewed and any follow-up diligence necessary

Don’t Provide (Without a Game Plan)…

- Demographics about employees
  - If necessary, include in folder with privacy settings (be aware of, and confirm, state law privacy requirements)
- Board minutes that discuss current deal or other deals
  - Redact minutes but indicate what is being withheld
- Confidential contracts
  - If necessary, prepare anonymous summaries or redact certain provisions

Don’t Provide (Without a Game Plan)… (cont.)

- Competitively sensitive information
  - Consider antitrust issues around providing certain types of information to competitors
- Attorney/client privileged documents
  - Consult counsel on these materials
- Diligence logs and issues trackers
  - Sharing issues lists with the other side should be approached with caution

Preparing Schedules

- At a minimum, all business people within "knowledge" definition need the current representations, warranties, and schedules
- What needs to be listed on disclosure schedules?
- Information must be responsive to representations and warranties in the agreement

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IPDD

Basic Overview of IPDD

- There are two main components:
  - What IP does the company have?
    - What licenses, NDAs, etc. are in place and how will that effect the investor(s)?
      - Many companies have a founding technology that is assigned to someone else
  - Does the company have freedom-to-operate?
- General advice: company does not have to have all the answers, but an articulated plan moving forward is key
- Then generally a big list of "housekeeping" issues (see later slides)
- Investors will talk to counsel so involve them! Early!
  - Company side is frequently outside counsel for start-ups
    - Note coordination between licensor's IP counsel and licensee's IP counsel
      - University out-licenses as foundational IP, etc.

IPDD: Review of Company's IP Portfolio

- What IP is on file?
  - Generally a schedule needs to be provided
    - Goes to Tony's point: who is the keeper of this list?
    - Don't feel badly if the list is short, everyone started out small
- What was in-licensed and under what terms?
  - Close review of technical definitions, field and scope of license, milestones, royalty rates, ability to sublicense and to whom
  - Patent prosecution control and enforcement
- Any out-licenses?
  - Why? To whom? Under what terms? Still sublicenseable?
- Where is the company planning on filing for foreign coverage?

IPPD: Company Portfolio, cont.

- What is the portfolio strategy moving forward?
  - Having a plan, even if not yet fully executed, is key
    - Example: Original platform technology filings followed by "species" filings for discovered drugs
    - Example: Separation of the original in-licensed technology with later filed improvements, combinations, etc.
  - Understanding, identifying and being able to articulate the known issues
    - Even if there are no immediate solutions to offer
    - Example: how to address "inventive step of antibodies" in Europe

A Note about "Patent Life Cycle Management" (LCM)

- In Life Sciences, the goal is to have exclusivity on the product for as long as possible
  - This strategy involves a combination of patent and regulatory exclusivities
    - Patent Term Extension (PTE), 5 year, 12 year market exclusivities
      - There are some equivalents to this in some foreign jurisdictions
    - (Note: this is a whole webinar by itself!)
- Early companies (and universities) often think a "land grab" of IP is desirable
  - However, the ability to hold off on some types of coverage until later can be extremely valuable, particularly to partners
  - We call this "life cycle management"

First Generation Protection

- "Picture claims" (species claims)
  - Exact sequences/compositions
    - May be interesting to define with cell therapy or gene therapy (AAV particles?)
  - Very narrow scope, which makes it difficult to invalidate based on obviousness
    - Makes claim interpretation easier
    - First office action allowance means less file history estoppel issues (FHE)
      - Although note FHE attaches to anything in priority chain
      - Strategy: if we know the commercial product, maybe file two provisionals, one for picture purposes and one for everything else
  - Single molecule composition claims
  - Nucleic acids encoding, expression vectors comprising, host cells containing
  - Method of making
  - Methods of using/treatment
    - "Cancer" versus "breast cancer" discussion
    - Easy to argue breast cancer and lung cancer are two different diseases
      - But you might need to do a terminal disclaimer if claim broadly early!
  - One of these is generally the PTE choice

A special note about written description in biologics

- The written description requirement in biologics may result in significant patent vulnerabilities
- Claims defined solely by function are quite vulnerable
  - And probably not patentable in the US under the new guidelines
- Case law developing, see antibody issues
  - The difficulty is "describing" what antibodies will fit the function
    - "Epitope" claims and Amgen v. Sanofi
      - Denial of cert. to SCOTUS so FC decision stands
- Remember, framework regions contribute function as well
  - Thus I worry that CDR claims will be more vulnerable in the future
- This is a whole talk in itself
  - For a later date, if necessary!

Second Generation Protection

- Goal: have later filed patents that will still cover the making, using or selling of the product as long as possible
- Dosing amounts
- Dosing regimes
  - note that moving from IV to subQ for antibodies is not always obvious, so don't put in original applications!
- Combinations of drugs
  - But careful, as we don't want to prior art ourselves unnecessarily
- Formulations
- Methods of making
  - For some areas, like cell therapies or gene therapy, this may be a significant area of protection
- Methods of treating new indications
  - Again, narrow claims are harder to invalidate
  - Maybe don't claim diseases so broadly
- Goal: prevent biosimilar from being able to sell in same markets or same patients, etc.
- Goal: have patents for which the safe harbor does not apply
  - E.g. things like assays, manufacturing, etc.

The best LCM example . . .

- Humira® is a >$16B/year US drug
- Abbvie did extensive LCM filings over the decade
  - Have over 60 granted US LCM patents
- A particular formulation patent, expiring 2023, was attacked >3 times by Amgen and others in Inter Partes Review (IPR) but withstood the challenges
- Settlement between Abbvie and Amgen:
  - Amgen agreed to not sell Humira® biosimilar in the US until 2023
    - Do the math . . . .

TAKE HOME: DON'T THINK THAT BROAD PATENT COVERAGE IS ALWAYS BETTER THAN NARROW COVERAGE!

IPDD Issues: FTO Analyses

- Remember the difference between "patentability" and "freedom-to-operate"
  - Having a patent does not give you the right to practice your invention
    - Only the right to exclude others from doing so
- Most investors care far more about FTO than patentability
  - FTO risks feed into the asset valuation and the business plan
  - General assumption is that something will be patentable
- So make sure you are prepared:
  - Understand the general competitive field
  - Have done some FTO searching
    - Platform versus lead candidates, etc.
  - Identify the potential (e.g. pending claims) or issued claims to the investors

FTO Issues, cont.

- Full FTO is generally done once leads are selected
  - "Does this specific molecule for this specific use/disease have FTO based on publicly available patents?"
    - Brief discussion re: foreign jurisdictions (EP and Asia)
- When you have an FTO issue*:
  - An initial analysis should be done
    - Non-infringement arguments?
    - Invalidity arguments?
- The worst situation is when the investor brings up a patent family that you didn't know about
- Don't downplay relevance of FTO issues
  - There needs to be an accurate discussion of risks

*And if you have none, I'd question your search

FTO Issues, cont.

- Our experience: you need a narrative but not necessarily a final answer
- Possible narratives:
  - "We are aware of US Patent No.X, assigned to Company Z. We believe that we don't infringe X because of these 4 reasons, and also that X is invalid based on prior art A. However, you need to make your own evaluation."
  - "The pending claims of X are currently broad enough to potentially cover our proposed molecule, but we have not yet done an analysis, since [it's too early/we don't have a defined lead yet]. We are monitoring the prosecution moving forward."

General "Housekeeping" IPDD issues

- Schedule of IP and licenses always needed
- Confirmation that there are no:
  - Inventorship disputes
  - Oppositions, litigations, IPRs, etc.
  - Ownership issues
  - FTO issues (see above)
    - Again, provide all relevant issues and let the investor decide
- Assignment of patents documentation
- Verification that employment contracts assign IP rights
  - Including SAB, consultants, CROs, etc.
- Internal procedures regarding invention disclosures, confidentiality, trade secrets, etc.

Don’t forget other types of IP

- Trade secret coverage
  - For some types of technology, high value in keeping processes as trade secrets
    - Bioinformatic analysis algorithms for the identification of biomarkers
    - Identification of a novel pathway may enable new methods of screening
      - Think whether or not to file patent applications
    - Manufacturing for cell therapies or viral vectors
      - In some cases, the “manufacturing magic” can be the real value and patents might not be the best coverage
  - At least have a discussion about this concept
    - An affirmative decision rather than a default position that patents are always filed
- Trademarks
  - Generally pretty straightforward

Biography

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Tony Chan has more than 15 years of experience advising companies on mergers and acquisitions (M&A), private equity, growth equity, and venture capital transactions, as well as on corporate governance, emerging company representation, and corporate finance. Tony's clients include strategic buyers and sellers as well as financial sponsors and their portfolio companies in the life sciences, investment management, technology, and video game sectors. He also regularly advises on complex international and cross-border matters.

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With an emphasis on emerging biotechnology and biopharmaceutical companies, Robin M. Silva manages and counsels clients in domestic and international issues, focusing on IP portfolio strategic development. Her background includes patent prosecution, IP due diligence (opinions, financings, evaluating IP portfolios in connection with due diligence for acquisitions, mergers, financings, collaborations, and partnering deals), global portfolio management and mining, technical litigation support, and working with business development personnel and licensing managers to maximize portfolio value.

Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Almaty
Astana
Beijing*
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Century City
Chicago
Dallas
Dubai
Frankfurt
Hartford
Hong Kong*
Houston
London
Los Angeles
Miami
Moscow
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Orange County
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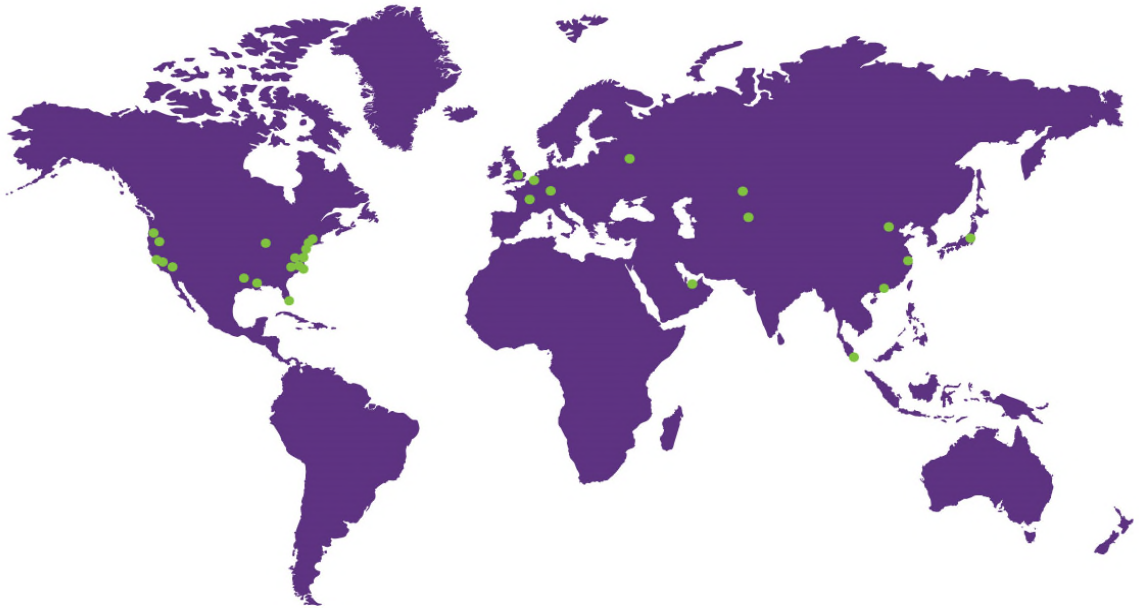

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