Life sciences licensing : a generic checklist ☑

1. Preparing to partner

What are the immediate and longer-term strategic objectives of your business?

- What is the potential financial benefit of partnering?
- What are the potential strategic benefits of partnering?
- What can you learn from other deals that have been concluded in your sector?

Which potential partners and deal structures might fulfill your objectives?

- Strong in development, marketing or both?
- Global or strong national player?
- Innovation or market-driven partner?
- Option agreement, co-development agreement or grant of full control of the asset to the licensor?

- **What is your value proposition?**
  - What are the unique characteristics of your asset which serve to distinguish it from competing offerings?
    - Is the offering "evolutionary or revolutionary"?
    - What are the strengths and shortcomings of your competitors?
  - How will unique characteristics of your proposition create value for the licensee?
  - What qualitative and quantitative support is there for your position?
    - Meets unmet needs?
    - What are the hurdles to market access?
    - Will it meet payor/reimbursement criteria?
- **How is the asset defined?**
  - By granted or filed intellectual property?
  - By know-how and unique expertise?
  - By data?
- **Are there sufficient management resources available to initiate, execute and secure a licensing agreement in the desired timeframe?**

2. Finding a partner

- **Have you defined and weighted the criteria that a prospect must fulfill in order to meet your strategic objectives?**
    - Market presence and sales?
    - Licensing history?
    - Cash and development resources?
    - Track record in gaining regulatory approvals?
    - Territorial presence?
- **Have you defined a search strategy to identify prospective partners?**
    - Own endeavors, subscription to partnering databases, and attendance at partnering meetings or reliance on advisors?
- **Have you improved your chance of making the most appropriate contact by learning something of a prospective partner's structure and process?**
    - Is the licensing function centralized or are there designated licensing executives for different therapeutic categories?
- **Is your marketing collateral of sufficient quality and have the right content to appeal to a prospective partner?**
    - Is your website informative and easy to navigate?
    - Does your printed or electronic collateral capture and communic ate the value proposition?
- **Are you able to follow-up and consolidate any initial interest quickly and effectively?**
    - Is there a template confidentiality agreement to hand?
    - Have you prepared and rehearsed a detailed presentation outlining the value proposition, the required level of technical detail and your partnering requirements?
    - Do you have short-form detailed technical information (laboratory, preclinical and manufacturing data, for example)
    - Do you have a summary of the status of your intellectual propert y to hand?
        - Filing status?
        - Breadth and scope of claims?

3. Negotiation & term sheet provision

- **Have you defined the desired licensing structure and financial terms and an acceptable compromise position internally?**
  - What are your go/no-go decision points in the negotiation process?
- **What is your perceived value of the asset?**
  - Which valuation methodology do you intend to use?
    - NPV based (risk-adjusted or extended NPV)?
    - Benchmarking?
      - Do you have enough data for a robust comparison?
  - Are your valuation model inputs (market forecast, rate of uptake, time and cost to market) credible?
  - Are you able to define credible opening terms?
    - What is the basis for the calculated value split?
- **Does your opening term sheet represent an accurate and comprehensive description of the asset and its use, a complete view of the deal structure, of the responsibilities of the parties and of the financial terms ?**
  - Asset, field of use and any restrictions (therapeutic but not diagnostic, or restricted to a specific disease, for example)
  - Territory in which the license is valid
  - Exclusive or non-exclusive grant?
  - Are there any existing third-party rights?
  - Is the license sublicensable?
  - What are the developmental milestones?
    - Who is responsible for development?
  - What are the regulatory milestones?
    - Who is responsible for regulatory submissions?
  - What happens to license rights if the responsible party is unable to fulfill its development or regulatory milestones?
  - What are the partner's obligations with regard to product launch, marketing and promotion?
  - Who owns and has the right to exploit improvements in the intellectual property?

        - Who is responsible for future patent filing and prosecution?
    - What are the payment terms?
        - Signature or upfront fee?
        - Progress-related milestones
        - Royalty payments
            - Fixed or related to level of sales ?
            - Flexibility in case of royalty stacking?
        - Share of sublicensing revenue?
        - Sales-related milestones
            - On meeting agreed minimum annual net sales?
            - On meeting agreed cumulative net sales?

- **Have you assembled an appropriate negotiating team representing the neces sary commercial, legal and technical skills to support the process?**
    - Are your team members aware of their respective roles, responsibilities and limits?
- **Have you collated and organized all necessary documentation to support the counterparty's due diligence process?**
    - Who is managing and monitoring the diligence process?
    - Single physical resource to be consulted by the counterparty on -site?
        - Signature/access-tracking in place?
    - Electronic virtual data room?
        - Mechanism for updating and monitoring in place?
- **Will your premises provide the counterparty with sufficient space, privacy and administrative assistance to conduct due diligence on-site?**

4. The agreement and beyond

- **Which party is responsible for turning the binding term sheet into an agreement?**
    - What is potentially rate-limiting?
        - Legal resource, management resource or experience?
        - Counterparty process?
- **If you are responsible for drafting the agreement:**
    - Has your legal counsel been fully briefed and have all pertinent documents and communication been made available?
    - Have you provided your counterparty with an anticipated time to receipt of first draft and of your internal process?
    - Have you been advised of the counterparty's review and sign-off process?
- **Will the partnership be announced?**
    - Which party is responsible for drafting of the press release and have you communicated your respective review and sign-off process?
- **Have you defined a pragmatic dispute resolution process?**
    - Mediation and criteria for mediator selection?
    - Arbitration and criteria for arbitrator selection?
    - Under which jurisdiction- yours or the counterparty's?
- **Have you rigorously defined the grounds for termination?**
- **Have you rigorously defined reversionary rights in the event of termination**
    - Data ownership?
    - Rights to exploit (including any improvements)?

Alexander Yule Consulting works with businesses at all stages of their commercial and corporate development, and particularly in the provision of cost effective business development support and interim leadership to early-stage enterprises. The principal has over 20 years experience in commercial and corporate support, working at senior level on behalf of life science and pharmaceutical companies (UK, Scandinavia and North America) and investors across a range of product categories including oncology, CNS, urology, vaccines, infectious disease, medical devices and OTC/consumer healthcare

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