



A Checklist for Life Sciences Licensing Agreements

1. Types of Licensing Arrangements

- Traditional License Arrangements include: (i) market valuation based on current stage of development; (ii) asset removed from control of licensor; (iii) long term commitment/relationship between licensor/licensee.
- Soft Licenses include: (i) co-promotions; (ii) co-developments.

2. Positioning to License

- Define the asset to be licensed.
- Have all intellectual property claims established (the structure and breadth of claims make a difference).
- Be prepared to “partner”: (i) establish quality management; (ii) distinguish the asset to license (and the company); (iii) update your strategic business plan; (iv) research comparable deals; and (v) set reasonable expectations on terms.

3. Meeting With a Licensee

- Be prepared to respond quickly to reasonable requests of a potential licensee.
- Have prepared a nondisclosure/confidentiality agreement.
- Present the asset in a realistic, positive manner.
- Have an internal working term sheet based on the company’s needs, comparable deals and a reasonable valuation.
- Define the type of license that best fits the assets: (i) co-promote; (ii) co-development; (iii) exclusive license; or (iv) nonexclusive license.

4. Scope of License

- Define whether the license is exclusive or nonexclusive.
- Define the geographic scope of the license.
- Define options to expand the geographic scope of the license if appropriate.
- Define the indicated use of the asset in the license.
- Set out clear terms on off-label promotions and secondary post market approvals for additional indications of the asset and which party is entitled to develop such post market indications.
- Define whether the license extends to affiliates, wholly owned subsidiaries or independent contractors (in the case of outsourced marketing and advertising).
- Define whether the licensed rights are transferable in the event of a sale of the licensee, a merger or divestiture.



- Define the scope for any sublicensing rights.
- Define any reversionary interests in the licensed asset in the event of a sale, merger, divestiture or bankruptcy.
- Define any reversionary interests in the event that developmental or marketing milestones are not met by the licensee.
- Define developmental milestones by clearly articulating each milestone. Common milestone definitions include permission to commence clinic trials, permission to move from one phase of clinical trials to the next, the filing of New Drug Applications and approval to market.
- If the license includes post approval sales, set targets for sales performance.
- Depending on the type of license, define whether the licensee is solely responsible for the regulatory filing costs and fees.
- Define any reversionary interests should the licensee fail to obtain regulatory approval to market the asset.
- If the deal is a co-promotion arrangement, define the resources needed to promote the asset and each Party's responsibility in how the promotion is done, both geographically and in the marketing and sales techniques to be used.

5. Payment Terms

- Define upfront payments. These payments should be reasonably related to the stage of the assets development when licensed.
- Set forth milestone payments.
- Define royalty payments. If royalties are based on sales, be careful to include certain performance criterion which includes a required threshold market penetration. Also define whether royalties are based on gross or net sales values and if net, then define net sales.
- Define the currency to be used for payment, and account for exchange rate fluctuations if applicable.

6. Term, Termination and Renewal

- Define the initial term of the license.
- Define renewal terms.
- Define the grounds for termination for cause, without cause and immediate termination.
- Define the effects of termination including, but not limited to, the disposition of the asset in development, ownership of clinical data developed during the license and ownership of any information related to the regulatory filings.

7. Confidential and Proprietary Information and Intellectual Property

- Define confidential and proprietary information. Define the intellectual property which is the subject of the license.
- Define the standard of care with respect to all such information.



- Provide for the disposition of confidential information upon the termination of the license.
- Define which party owns improvements or new inventions related to the asset or which are discovered during the development of the asset.
- Define who is responsible for all intellectual property maintenance fees.

8. Disputes

- Define how disputes between the parties are to be resolved.
- If the dispute resolution provision contains a mediation or arbitration procedure, be sure to define: (i) what rules apply to the arbitration; (ii) how is the mediator or arbitrator chosen; (iii) the controlling law; and (iv) the place that the mediation or arbitration is to be held.
- When the parties choose not to include an arbitration proceeding, then for purposes of litigation define the applicable law and the jurisdiction in which the litigation is to take place.

9. Indemnification and Hold Harmless Clauses

- Decide whether the terms of the license require an indemnification provision and/or hold harmless clause. If such a clause is determined to be desirable, then consider under what circumstances one party will indemnify and hold harmless the other party.
- Define the limitations on indemnification: (i) what and who is covered; (ii) all costs incurred versus final judgment; and (iii) process and procedures.

10. General Contractual Terms

- Include language which indicates that the license agreement is the entire agreement between the parties and supersedes any and all other agreements, whether oral or written.
- Include assignment language defining whether and under what circumstances the license can be assigned.
- Include how the license can be amended.



Life Sciences

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- Corporate Issues
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- Intellectual Property Protection
- Clinical Development
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- Post-Approval or Commercialization Issues
- Risk Management and Litigation

For more information on how the Troutman Sanders Life Sciences Practice Team can assist you, contact Diane Romza-Kutz at 312.759.1922 or diane.kutz@troutmansanders.com.