LEAD Process
Licensing **E**valuation **A**nd **D**iligence

- Zebra assists its Clients to create sustainable pipelines through inlicensing of products.
- The LEAD process is structured as a stage method; the initiation of each stage is dependent on Client's decision to proceed based on the outcome from the previous one.

LEAD Stage	Activities
Scout and Contact	✓ Identify opportunities that meet the Client's requirements ✓ Contact potential partners, discuss product availability and preferred partnering arrangement ✓ Shortlist opportunities for further evaluation
Non Confidential Evaluation and Screening	✓ Collect non confidential information ✓ Define targeted product profile ✓ Identify strengths and weaknesses ✓ Prioritize projects for further evaluation
Confidential Data and Q&A	✓ Support execution of confidentiality agreements ✓ Review confidential information and engage in Q&A discussions
Valuation and Non Biding Term Sheet Discussions	✓ Generate NPV model to support product valuation ✓ Collect benchmark data on comparable deals ✓ Prepare term sheet proposal
Due Diligence	✓ Assemble multi-functional team ✓ Coordinate IP evaluation including Freedom to Operate and Patent Validity ✓ Conduct or commission primary market research ✓ Manage the due diligence process
Final Recommendation	✓ Draft final report with recommendations ✓ Adjust NPV model and Term Sheet based on revised product profile
Contract Negotiation Support	✓ Coordinate and/or support contract drafting activities

PIPELINE DIVERSIFICATION

Long term risk dilution through acquisition of additional product opportunities with diverse mechanism of action or development stage

LICENSE

Common business arrangement in the drug development field that regulates the exploitation of intellectual property around a product between the party who sells the rights and the one who acquires them

DUE DILIGENCE

Scientific, technical and legal evaluation of a product before the execution of a commercial agreement

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Case Study

Zebra's Client was looking for a clinical asset in auto-immunity and inflammation that had achieved at least Proof-of-Concept stage in patients.

Zebra identified 20 different lead opportunities from our network and subscription based databases and conducted a full on site due diligence on one product opportunity (Big Pharma, US offices).

Multifunctional team included:

- Regulatory Expert, formerly Senior Vice President Worldwide Regulatory Affairs Schering Plough
- Preclinical and Safety Expert, formerly Vice President of Regulatory Affairs at Human Genome Sciences Senior Biomedical Research Service Officer at FDA
- CMC Expert, formerly Senior VP GQAC Schering Plough
- Clinical Development Expert, former Chief Medical Officer and Senior Vice-President at Trubion Pharmaceuticals, and former Vice-President at Amgen Corporation
- IP Consultancy Firm (UK), Zebra's strategic partner company
- Key Opinion Leader, Principal Investigator for a competing product in the same therapeutic area and recognized expert for the specific Mechanism of Action.

The Client and Big Pharma executed a Non-Binding Term Sheet Agreement based on the outcome of the Due Diligence and the product valuation performed by Zebra.

TERM SHEET

A document that outlines key issues in a potential deal such as: the licensed product or process, licensed territory, fees and royalties, technical information required to develop, make and sell the licensed product

FREEDOM TO OPERATE

The ability to develop and market a drug or device without infringing the valid and enforceable patent rights of others

NET PRESENT VALUE

Mathematical formula to calculate the value of a product at a given time based on expected future costs and revenues

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