

CRITERIA FOR SELECTION OF
IN-LICENSING OPPORTUNITIES IN LEAD
CANDIDATE DEVELOPMENT



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OVERVIEW

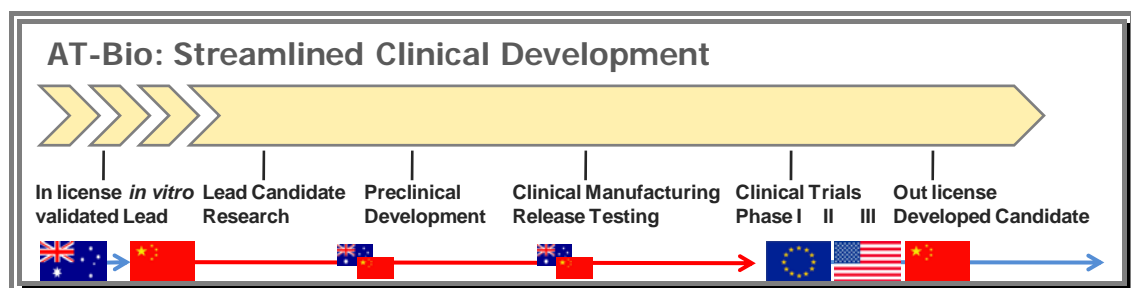
AT-Bio follows a model of clinical development similar to many biotech companies. We will license-in chemical-drug therapeutic candidates at discovery stage from research institutions, universities and other biotech companies. The preclinical and early clinical development will then be conducted in China by AT-Bio's development partner, TIPR, according to international standards. Human clinical trials will be conducted in China and in Western countries, according to the study design requirements of each particular drug candidate. We will then seek international partners for late stage development and commercialisation.

AT-Bio's development partner, the Tianjin Institute for Pharmaceutical Research (TIPR), has proven capabilities in developing early stage lead candidates for clinical applications. TIPR follows a robust, industry-compliant multi-faceted development routine that includes:

1. Technical and Pharmaceutical chemistry
2. Experience and expertise in GMP-compliant industrial scale production
3. Drug analysis and testing
4. Pharmaceutical research and engineering
5. Pharmacology and Pharmacodynamics
6. Bioanalytical testing

Some of the key differences in AT-Bio's clinical development path are:

- Greater potential market coverage - Our successful candidates will not only be available for sale in the US and European markets, but we can also provide access to the Chinese market. China's pharma market is currently the 9th largest in the world and is predicted to rapidly rise to the 5th largest by 2010.
- The work is not interrupted by the need for multiple funding rounds (VC funding or IPO). AT-Bio has the capacity to take candidates all the way to Phase II trials.
- Much of the work is completed within the one large organisation.



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In-licensing opportunities, from the therapeutic areas of interest of Oncology, Antiviral / Anti-infective, Anxiety / Depression and Endocrine will be assessed on the following criteria:

1. **Commercial Potential.** We are seeking candidates that have world market potential. Our selection of therapeutic areas is based on conditions that are of concern in China and the rest of the world. Each candidate will be evaluated on standard commercial factors such as; market size, technical risk, competitiveness, patient benefit, regulatory acceptance and reimbursement potential.
2. **Therapeutic / Diagnostic:** AT-Bio will focus on **therapeutic candidates**. The focus on therapeutic candidates will benefit the most from TIPR's expertise in drug development and manufacture.
3. **Chemical / Biological Therapeutics:** Initially, AT-Bio will focus on **chemical-drug therapeutics**.
 - One of the key features of AT-Bio is the in-house capability of developing early-stage chemical-drug therapeutic leads all the way through to human trials. TIPR has extensive experience in the in house optimization of chemical entities in order to meet desired manufacturing, in vivo or efficacy properties. Since this experience resides wholly in-house, it allows AT-Bio to in license clinically relevant candidates at an earlier stage of development and efficiently (co-)develop them for human clinical trials.
 - Very early stage development of biological therapeutics is not as linear, due to the intricacies of biological therapeutic protein expression and stability testing. However, TIPR can offer an efficient, industry standardized, in vivo/ toxicological / biodistribution / pharmacokinetic and formulation testing service to biological therapeutics. Such lead candidates would be brought into TIPR under a Contract Research Organization model.
4. **Stage of Target Validation and Lead Development:** AT-Bio will focus on developing chemical-drug therapeutics that meet the following criteria:
 - Ideally, AT-Bio is seeking to in license chemical-drug leads against **well validated and clinically relevant targets**. The lead will optimally have been selected through the primary screening of a chemical-library and further validated by optimized in vitro and in vivo assays. The licensee will not have performed any scale-up manufacturing or any formal formulation chemistry, pharmacology or pharmacodynamics, dosing optimization or toxicology testing.
 - AT-Bio is also seeking single or multiple chemical-drug therapeutic candidates which have been identified through a primary screening and subsequently validated for efficacy in vitro. Further in vivo validation may be lacking at this stage of development. AT-Bio and TIPR will be able to provide strong in vivo efficacy studies and subsequent lead selection and optimization.

- AT-Bio may also enter negotiations with research bodies with proprietary access to high-value, novel, clinically relevant targets, irrespective of clinical lead development. In such cases, primary hit screening and validation of chemical drugs against high value targets can be efficiently performed at TIPR. In such cases, AT-Bio will co-develop functional and efficacy assays with the licensee.
- Due diligence by both AT-Bio (Australia) and TIPR (China) will be undertaken for all in licensing opportunities. All due diligence will be undertaken following an appropriate confidentiality framework.

