



CAPABILITIES DOCUMENT

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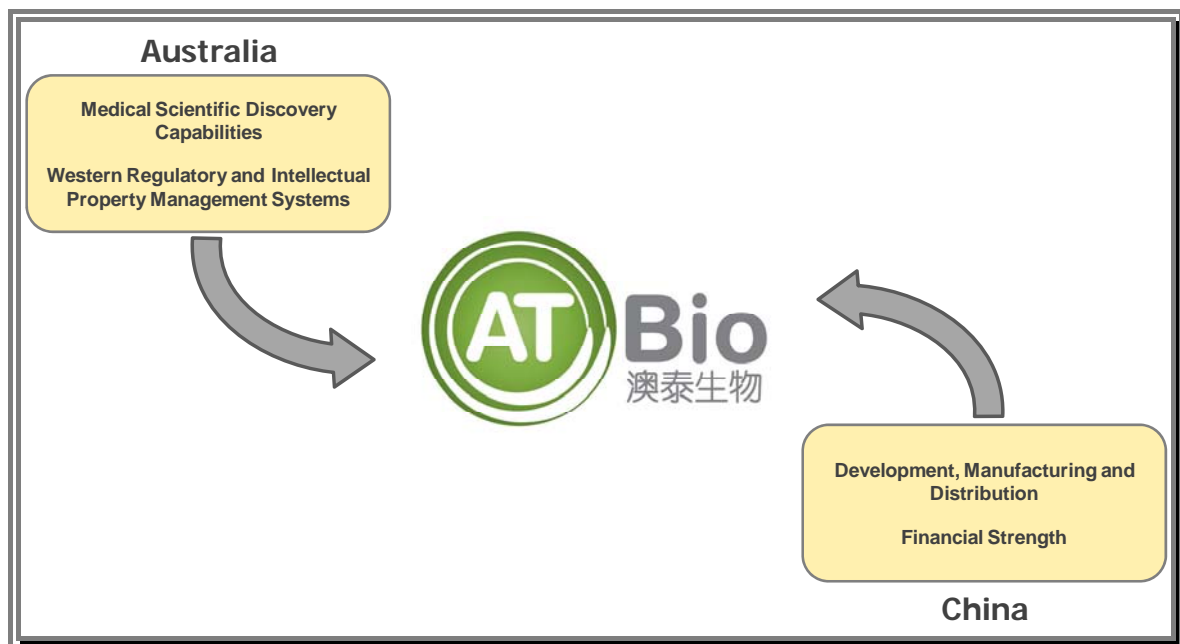
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OVERVIEW:

AT-BIO PTY LTD

AT-Bio is a joint venture drug development company of the Tianjin Institute of Pharmaceutical Research (TIPR), (Tianjin, China) and Atholl Management (Melbourne, Australia). The objective of AT-Bio is to develop small molecule western medicines for global markets, according to international regulatory and intellectual property standards. Our business model combines the scientific discovery capabilities of Australia and its knowledge of Western management systems, with the development, manufacturing and financial strength of China. AT-Bio is an officially approved Chinese foreign joint venture company. It represents TIPR's interests outside of China. All business in Australia is conducted in Australian currency and under Australian commercial laws. Our mandate is to license-in discoveries from Australia and complete the preclinical and clinical development collaboratively in China. Drug development is carried out in China in the laboratories of TIPR.



TIANJIN INSTITUTE OF PHARMACEUTICAL RESEARCH

Tianjin is China's fourth largest city, after Shanghai, Beijing and Hong Kong. It is situated directly between Beijing and the coast, with a population of over 10 million people. It is the pharmaceutical industry centre for Northern China.

The Tianjin Institute of Pharmaceutical Research (TIPR) is a prestigious research organisation affiliated with the State Food and Drug Administration of China (SFDA) and has more than 50 years of pharmaceutical research history. It was one of three pharmaceutical laboratories originally established by the SFDA. It is now a State Owned Entity with over 400 staff. TIPR has net assets in excess of AU\$1.86 billion and annual revenues in excess of AU\$380 Million. It is important to note that TIPR has substantial experience in Western medicines as well as Traditional Chinese Medicine.

The mission of the institute is to develop new therapeutic drugs for specific pathologies including cancer, cerebral and cardiovascular disease, hepatitis and other viral diseases, disorders of nervous system, anti-inflammatory and immune diseases, and diabetes. With a full range of capabilities in preclinical development and GMP manufacturing. TIPR has the financial resources and scientific capabilities to take candidates all the way from early discovery stage through to clinical trials.

TIPR has modern research facilities and ranks top among the institutions of pharmaceutical industry in China.

TIPR comprises:

- The State Key laboratory of Pharmacokinetics and Pharmacodynamics
- Tianjin Key Laboratory of Molecular Design and Drug Discovery
- The Tianjin Center for New Drug Safety Evaluation and Research (TCNDSER)

Therapeutic Areas of Interest

- Oncology
- Antiviral, Anti-infective
- Anxiety, Depression
- Endocrine

KEY PEOPLE

There are four Directors of AT-Bio Pty Ltd

Jim Murray is the CEO of AT-Bio. Jim is an experienced developer of technology businesses for over 20 years. Jim is on the Board of Directors of the BioMelbourne Network, Victoria's biotechnology industry association and was most recently its Acting CEO. His background includes four years as General Manager of the Melbourne Neuropsychiatry Centre at the University of Melbourne; five years as Director, Business Strategy at Ernst & Young and six years in Business Development roles across Australia and Asia with IBM. Jim has a Bachelor's Degree in Commerce, a Masters Degree in Innovation Management and a Graduate Diploma in Applied Finance.

Ms Hongying (Theresa) Sun is AT-Bio Director of Business Development. Theresa specialises in developing business relationships between Australian and Chinese industry. Theresa has a double Master's degree from RMIT University (MBA Marketing Management and Master of Professional Accounting). She also has a Bachelor of Economics from Heilongjiang University. Ms Sun has held senior business development roles in Beijing and Tianjin for international companies Bosch-Siemens and Samsung.

Professor Tang Lida is the President of TIPR. Prof Lida gained his Bachelor's Degree in Biochemistry in 1986, a Masters Degree in Pharmacology in 1990 and Doctor's Degree in Organic Chemistry in 2006. Prof Lida also trained in Intellectual Property Management for one year at the University of California, Berkeley, USA.

Professor Meixiang Zou is the Chief Engineer of TIPR. Prof Zou received her Bachelor's Degree in Pharmaceutical Engineering in 1982. Ms Zou also has an Executive MBA in Pharmaceuticals from Peking University, China's top ranked medical university and has studied Project Management at RMIT University in Melbourne, Australia.

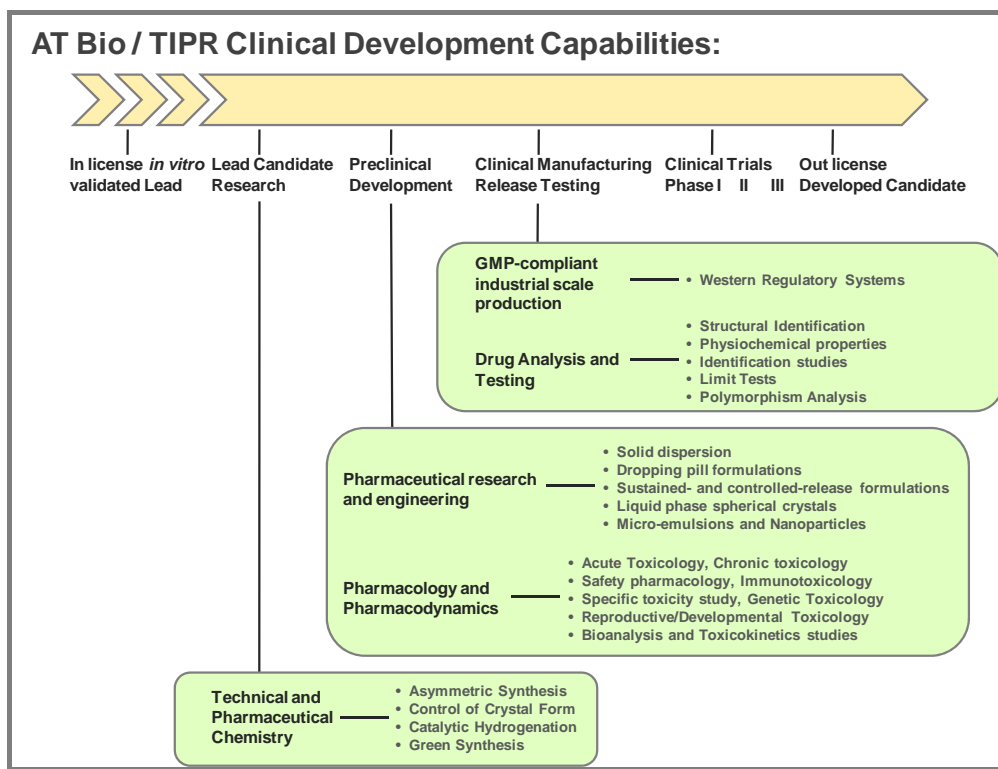
KEY CAPABILITIES

TIPR hosts more than 400 staff members, including more than 200 scientists and technicians, nearly 100 Professors and Associate Professors.

Individual research departments in TIPR are staffed by 20-30 employees, divided into 3-5 groups. A typical research group has 5-10 staff, including 1 Professor and 2 Associate Professors. Generally, new staff recruits are high level pharmaceutical university graduates from well-regarded universities. Some staff have had experience in other research institutes or companies. A significant percentage of employees are not native to the Tianjin area and some of them have also studied or worked overseas.

TIPR has outstanding and well-recognized expertise in early phase development of new drugs in China, with extensive capabilities in:

- Synthetic chemistry.
- Drug delivery formulations.
- Drug quality control.
- New drug evaluation (including pharmacology, safety evaluation, pharmacokinetic and clinical pharmacology).
- Pharmaceutical informatics.
- Traditional Chinese Medicines.



TIPR plays host to state-of-the-art scientific equipment including NMR, HPLC, GC, HPCE, LC/MS/MS, LC/MS, Atomic Absorption Spectrometer, Differential Scanning Calorimeter and Dissolution Test Apparatus. This raw technical power, the scientific expertise and preclinical/clinical track record, sets TIPR apart from other institutes in China.

ANIMAL CARE FACILITIES

TIPR has well-established animal facilities that were designed and constructed in accordance to international standards, especially AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care) requirements. These facilities include a Specific-antigen-free (SPF) small-animal barrier facility, a clean grade animal facility and several affiliated facilities including animal anatomy, animal behaviour and sterilization facilities. These facilities are all equipped with advanced climate control systems and closed circuit camera monitoring systems.

- **SPF Small-Animal Facility:** is contained over 550 square meters and can perform six evaluation studies concurrently. Lead candidate preclinical validation studies can be performed on rat, mouse and guinea pig models.
- **Conventional Big Animal Facility:** is over 500 square meters in size and allows four concurrent evaluation studies. Studies can be performed using canine and monkey models. Specialized preparation and necropsy rooms are associated to this facility.

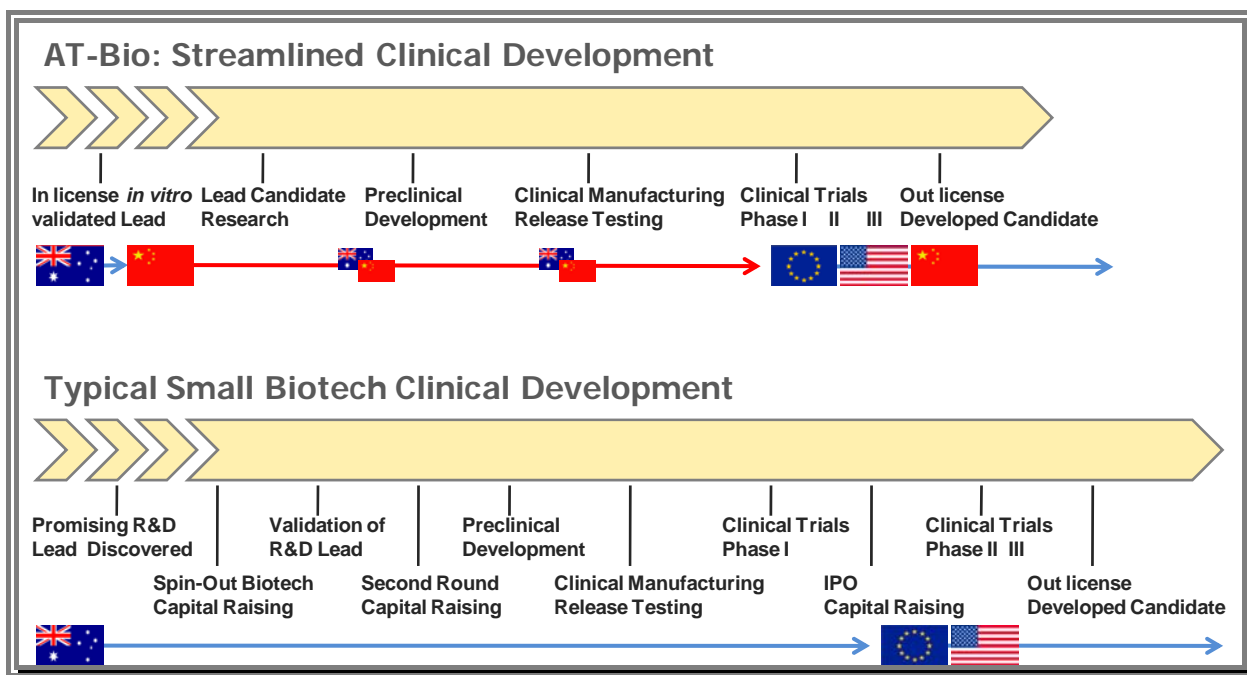
Animal experimentation is governed by the Institutional Animal Care and Use Committee (IACUC). This committee has seven members; two members are public, two members are non-affiliated experts in veterinary science (i.e. Veterinarians working in TIPR, who are in charge of animal care but take no part in any animal experiment) and the remaining three members are intuitional scientific researchers (TIPR employed toxicologists) with well-documented expertise in animal experiments.

The responsibility of the committee includes the supervision and evaluation of animal usage, review and standardization of operating procedures and assessment of facilities. This committee ensures conformity to all relevant legal requirements and ensures animal welfare meets AAALAC requirements.

DEVELOPMENT OF EARLY PHASE LEAD CANDIDATES

AT-Bio follows a model of clinical development similar to many biotech companies. It intends to license-in small molecule candidates at discovery stage from research institutions, universities and other biotech companies. The preclinical and early clinical development will then be conducted by TIPR in China, according to international standards. We will then seek international partners for late stage development and commercialisation. Some of the key differences 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 and TIPR have the capacity to take candidates all the way to Phase II trials.
- Much of the work is completed within the one large organisation.



TIPR has proven capabilities in developing early stage lead candidates for clinical applications. The institute follows a robust, industry-compliant multi-faceted development routine that includes:

1. **Technical and Pharmaceutical Chemistry:** Innovative development of synthetic drugs and their intermediates. TIPR has extensive know-how in developing a simple lab-scale process into a system suited to GMP-compliant industrial scale production. The institute has well documented successes in the fields of cardiovascular agents, analgesics, psychopharmacological drugs, anti-infective agents, and endocrine drugs. TIPR has well-recognized experience in:
 - Asymmetric Synthesis.
 - Control of Crystal Form.
 - Catalytic Hydrogenation.
 - Green Synthesis.

2. **Experience and expertise in GMP-compliant industrial scale production:** 98% of TIPR's achievements have been extended to commercial production. Some of these success stories include:
- Cardiovascular agents: Gemfibrozil capsule, Oxymetazoline nasal spray, Ticlopidine tablet and Amlodipine tablet.
 - Analgesics: Buprenorphine Hydrochloride and injection, Oxybutynin and tablet, Nimesulide and tablet etc.
 - Psychopharmacological drugs: Pergolide tablet, Glutethimide tablet and Qietiapine tablet.
 - Anti-infective agents: Gatifloxacin tablet and Prulifloxacin tablet.
 - Endocrine drugs: Glipizide tablet and Gliquidone tablet.
3. **Drug Analysis and Testing:** Lead candidates developed in systems suited to GMP-compliant scale-up can be functionally and analytically verified for quality, stability and physiochemical properties. TIPR also has extensive experience in structure elucidation of pharmaceutical compounds, characterization of chiral compounds and the determination of residue solvents in pharmaceutical compounds. Some clinical examples of this expertise include:
- **Aildenafil Citrate:** TIPR applied for a New Drug Application to the SFDA for this product. In the Application Dossier, the following characterizations were disclosed:
 - Structural Identification: Elemental analysis, NMR, MS, XRSD (X-ray single crystal diffraction), UV, IR, DSC/TGA, XRPD (X-ray powder diffraction).
 - Physiochemical properties: Solubility, melting point/range, Optical rotation, Extinction coefficient, pH.
 - Identification studies: IR, HPLC/UV.
 - Limit Tests: Product-related substances, Residual solvents, Loss on Drying, Ash, Heavy Metals, Chlorides, Citrate.
 - Polymorphism Analysis: HPLC, Non-aqueous Titration, Stability studies, Accelerated testing, Long-term testing, Stress testing.
 - **Chiral Separation of Sertraline Hydrochloride with Its Isomers by Capillary Electrophoresis:**
 - Instrumentation: Beckman Coulter P/ACE™ MDQ Capillary electrophoresis, diode-array detection.

- Capillary electrophoresis was applied to the chiral separation of Sertraline Hydrochloride from its isomers. The separation was performed on a fused-silica capillary.
 - **Headspace GC Determination of Residual Organic Solvents in Pazufloxacin Mesylate:**
 - Instrumentation: Agilent 6890N Gas chromatography, Headspace autosampler, FID.
 - TIPR established a method for determining the residual organic solvents in pazufloxacin mesylate.
- 4. **Pharmaceutical research and engineering:** The early stage development of Lead candidates can be further progressed by assessing advanced dosage forms and new drug-delivery-systems. TIPR has detailed know-how in developing drug- and pathology-specific delivery systems, of which some include:
 - Solid dispersion
 - Dropping pill formulations
 - Sustained- and controlled-release formulations
 - Liquid phase spherical crystals
 - Micro-emulsions and Nanoparticles
- 5. **Pharmacology and Pharmacodynamics:** Robust and industry-standardized early stage preclinical pharmacology, pharmacodynamics (efficacy-studies) and pharmacokinetic-pharmacodynamic combination investigations are invaluable to the comprehensive assessment of therapeutic candidates. TIPR is the leader in preclinical analyses in China. The institute is well known for "thinking outside the box" in order to provide efficient and scientifically sound methodologies.
- 6. **Bioanalytical Testing:** Selective and sensitive analytical methods for the quantitative evaluation of drugs and their metabolites are a critical component of a successful preclinical screening program. Pharmacokinetic and toxicokinetic analyses are key to developing a pharmacological profile for the candidate compound.

PRECLINICAL TOXICOLOGY

In further developing early phase Lead candidates for the clinic, TIPR specializes in detailed GLP-compliant preclinical toxicological studies. These studies are designed to meet the preclinical needs for filing an Investigational New Drug Application (IND) with the FDA or similar clinical dossiers. Some clinical examples of TIPR's expertise are Aildenafil citrate and Batifiban. TIPR has industry standardized assays for:

- General Toxicology: Acute Toxicology (single dose) and chronic toxicology (repeat dose), in rodents and non-rodents.
- Safety pharmacology: Detailed analysis of the central nervous system, cardiovascular system, respiratory system, gastrointestinal system or other safety pharmacology.
- Immunotoxicology.
- Specific toxicity study: Irritation, allergy and haemolysis testing.
- Genetic Toxicology: Salmonella/E.coli reverse mutation assay, chromosomal aberrations testing and mouse micronucleus assay.
- Reproductive/Developmental Toxicology: Segment I (male and female fertility and early embryonic development to implantation), II (embryo-foetal development) and III (pre-and postnatal development, including maternal function) testing.
- Bioanalysis and Toxicokinetics studies.
- Toxicokinetics studies and bioanalytical support for samples generated in toxicology studies.

PRECLINICAL/CLINICAL PHARMACOKINETICS

In addition to preclinical toxicity studies, TIPR has a proven track-record for preclinical and clinical pharmacokinetic studies. Pharmacokinetic data from animal and human radiolabelled studies, human clinical trials and veterinary clinical studies can be assessed utilizing industry-standard software and analyses. TIPR has extensive experience in providing:

- Input into study design, including preclinical-to-clinical considerations (allometric scaling) utilizing information from preclinical toxicokinetic studies.
- Non-compartmental pharmacokinetics in mice, rats, dogs, monkeys or other animals, and healthy volunteers and patients.
- Compartmental pharmacokinetics/ simulations in mice, rats, dogs, monkeys or other animals, and healthy volunteers and patients.
- Ascending dose (assessment of dose proportionality).
- Repeat dose (assessment of multiple dose linearity).
- Bioavailability and bioequivalence for drug formulation in animals.
- Drug interaction studies.
- Special populations.

- Pharmacodynamic and PK/PD modelling.

MODERNIZATION OF TRADITIONAL CHINESE MEDICINES

The department of modernization of traditional Chinese medicines is the center where the research of Chinese medicines is engaged. It is well-staffed by a team of qualified scientists specialized in phytochemistry, phytochemistry, pharmacology and drug analysis in regard to Chinese medicines. This department is responsible for the development of a number of new drugs. In order to improve its research capabilities and the level of innovation in the field of traditional Chinese medicines, specific technological platforms have been built, including:

- **New drug screening platform:** Responsible for screening for active constituents and assessing efficacy of minority medicines, folklore medicines and herbal medicines adopted abroad.
- **Novel purification technologies:** Involved in the modernization of traditional Chinese formulations through the use of modern purification techniques.
- **Dosage form investigation:** Determines and develops new dosage forms for phytopharmaceutical formulations.

CLINICAL TRACK RECORD

Over 30 years, TIPR has been the leader in providing quality testing services to the pharmaceutical, biotech, medical device, chemical, and consumer products industries in China. The highly experienced scientists and technical staff have helped TIPR acquire over 200 new drug certificates, including 161 generic chemical drugs, 33 Chinese medicines and 1 biological drug. Some of the core competitive products include:

- **Adefovir:** An orally-administered nucleotide analogue reverse transcriptase inhibitor (ntRTI) used for treatment of hepatitis B. This is one of the core competitive products of TIPR Pharmaceutical Responsible Company Ltd. Sales of this drug in 2007 were in excess of AU\$75 million.
- **Complex Radix Danshen dripping pills:** Used for the treatment of cardiovascular diseases. This is the core competitive product of Tianjin TASLY Pharmaceutical Co. Ltd; privately owned company that is one of China's top ten pharmaceutical companies. The annual sales of this drug in the last five years are more than AU\$155 Million.
- **Sulphuric acid clopidogrel:** Used for the treatment of coronary heart disease. This drug is the core competitive product of Shenzhen Salubris Pharmaceuticals Co. Ltd. TIPR were the first to develop this drug in China and, through the collaboration with Shenzhen Salubris Pharmaceuticals Co. Ltd, were the only company to receive approval from the SFDA.
- **Cefdinir:** An antibiotic. This is the core product of Tianjin Jinkang Pharmaceutical Co. Ltd.

Other clinical milestones include:

1. The **Technical and Pharmaceutical Chemistry** division has seen more than 60 achievements extended to commercial production and 11 of these achievements have received scientific and technological progress prizes awarded by the government. Major achievements include the release of new generic drugs, the synthesis of new compounds and intermediates, the development of new pharmaceutical technologies and the development of novel research platforms.
2. The **Pharmaceutical Research and Engineering** division has taken nearly 100 dosage formulations to clinical production. Many of these formulations have been exported to Japan, Korea, and Southeast Asian countries and won a very good reputation.

TIPR's clinical track record has seen many of its scientific and quality achievements adopted in production regimes by numerous pharmaceutical manufacturers and thus, TIPR is considered one of the major contributors to the Chinese pharmaceutical industry.

One example is in the manufacture of GCLE, which is an important intermediate for antibiotic drugs. GCLE is now manufactured in Tianjin city at the Tianjin Jinkang Pharmaceutical Co. Ltd. TPIR is the technology supporter of this antibiotic production base and now is responsible for exporting GCLE to India.

CERTIFICATION AND STANDARDS

TPIR has a well-developed understanding of regulatory requirements because of its origins with the SFDA and its long history of involvement with Western medicines. TPIR is implementing a program of compliance with international standards, including the OECD and the US FDA. China is currently in negotiations to adopt OECD standards for GLP and GMP. That will bring it under the same standards regime as Australia. While these negotiations are being concluded, TPIR is already putting in place a program to follow these international standards. It means that drugs developed in their labs will be ready to undergo an external audit from any OECD country or an audit by the US FDA.

In meeting GLP compliance, over 766 Standard Operating Procedures (SOPs) have been established in the institute, including SOPs for laboratory management, quality assurance, animal experimentation, environmental protection and experimental technologies. These SOPs are routinely amended, supplemented and revised to meet the changing technological face of the institute. The most recent complete update and revision of all SOPs was in 2006. Every procedure undertaken within the institute has been defined by a SOP.

Regulatory compliance is controlled by the independent Assurance Unit (QAU). The QAU is composed of one quality assurance manager (QAM) and two quality assurance inspectors (QA), with the role of ensuring that facilities, equipment and management meet GLP requirements. Each member of the QAU has received special domestic or overseas training. They are directly involved in the formulation of standard operating procedures, data handling and reporting.

FUNDING STRUCTURE

Most of the research projects undertaken by TPIR are self-financed or may also be partly supported by various national funds.

The most recent financial statements for TPIR show that TPIR's total assets are worth close to AU\$2.8 billion and net assets are in excess of AU\$1.86 billion. Recent figures show that revenue is in excess of AU\$382 Million, which is consistent with previous financial years. Revenue generation can be broken down into:

- 58% from TPIR's competitive research and payments from customers for TPIR's technical services.
- 3.5% from royalties.
- 24% from profits on investments.
- 14% from government funding.

ALLIANCES

TIPR is both well recognized and has well established alliances with key players in the Chinese pharmaceutical industry, major universities and research institutes. These alliances include:

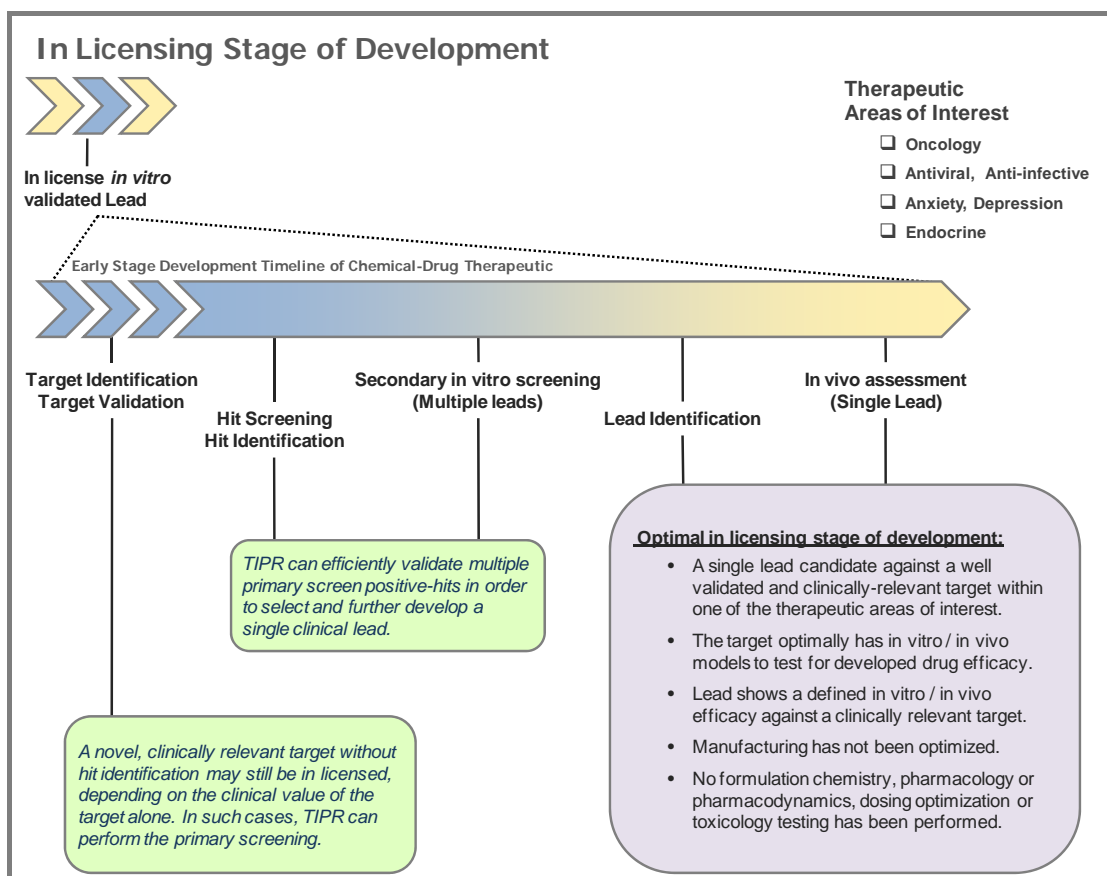
- **SFDA and other government organizations:** Numerous staff members of TIPR are enrolled and/or formally recognized by the SFDA or other governmental pharmaceutical regulatory bodies. These recognitions include:
 - 37 staff which are recognized as experts in their field by the Tianjin Food and Drug Administration.
 - 2 committee members of Chinese Pharmacopoeia Commission.
 - 3 drug price experts of the National Development and Reform Commission.
 - 1 academic of the Chinese Academy of Engineering.
 - 10 State-assigned experts for New Drug Assessment.
 - 3 scientific personnel conferred the title of “expert of Tianjin City”.
 - 34 experts holding a special subsidy granted by the State Council.
- **Relationship with major universities and research institutes:** Due to TIPR’s important role in the Chinese Pharmaceutical industry, it is well positioned to play an important role in universities and research institutes. Some of these relationships are:
 - TIPR has established the Pharmaceutical Science and Technology College with Tianjin University.
 - TIPR is a continuing supporter and co-lecture partner for:
 - Bachelor, Master and Doctors Degrees held at the Pharmaceutical Science and Technology College of Tianjin University;
 - Doctor’s Degree in Pharmacology within the Tianjin Medical University;
 - Master’s Degree in Chinese *Materia Medica* within the Tianjin University of Traditional Chinese Medicine
 - Master’s Degree in Pharmaceutics and Pharmacology within Henan University and Shandong University.
 - TIPR is establishing a combined Academy with Nankai University in the New Binhai District.
 - TIPR also oversees numerous Postdoctoral programs.

CRITERIA FOR SELECTION OF LICENSING CANDIDATES

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.

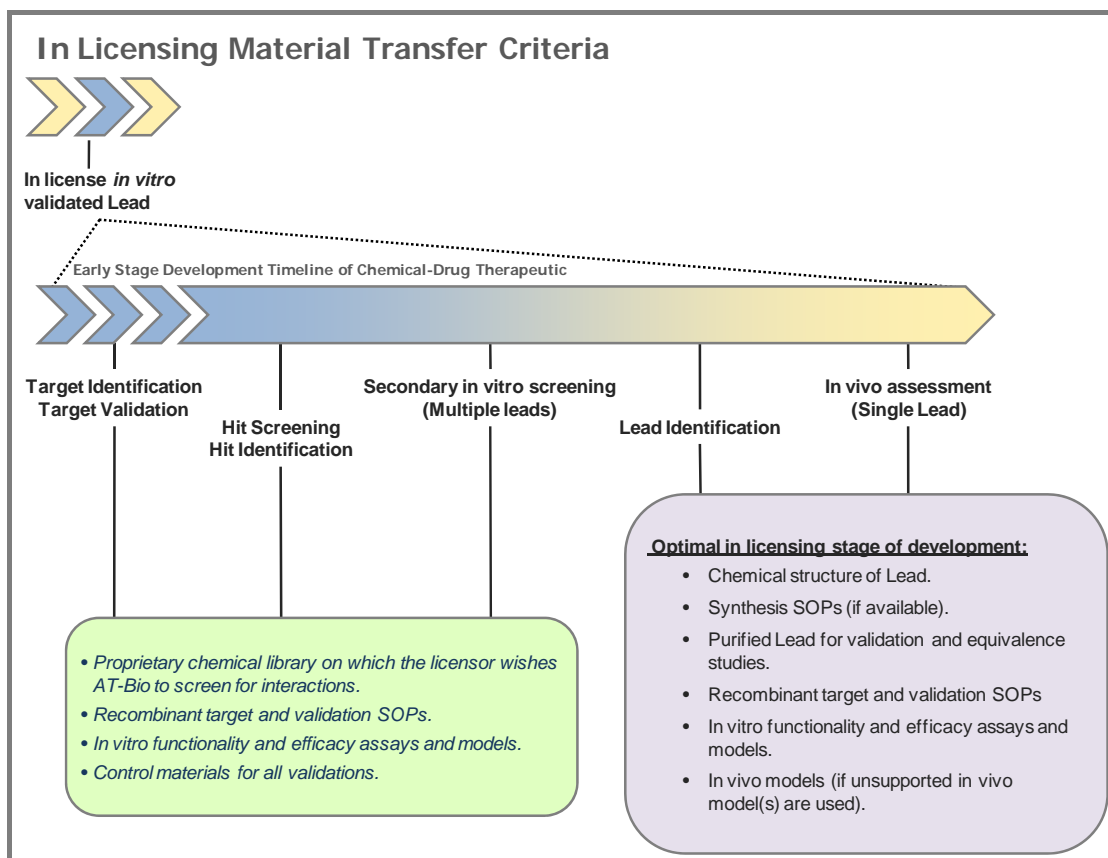


MATERIAL TRANSFER CRITERIA

On successful in-licensing of a specific therapeutic Lead, AT-Bio will assist the licensor in transferring the correct technical and chemical information, reagents and knowhow essential to Lead development. AT-Bio will provide a strong technical team to assist in this transfer. Although highly Lead specific, a typically technology transfer scenario would encompass:

1. **Chemical structure of Lead:** The chemical structure of the in-licensed clinical Lead is critical to AT-Bio. Together with the chemical structure, proprietary information regarding proposed mode of activity will allow AT-Bio to further develop this activity in a clinically relevant chemical entity.
2. **Small scale purified Lead and recombinant target:** If available to the licensor, a sample of the purified lead candidate will allow AT-Bio to perform equivalence assessment between Lab-produced material and material generated in a GMP-compliant system. Similarly, in order to reproduce functionality and efficacy assays, AT-Bio will require access to a recombinant form of the target (if applicable), or the materials that constitute all in vitro models used by the licensor to assess for functionality and efficacy.
3. **Relevant standard operating procedures:** Together with physical reagents, AT-Bio will require all relevant SOPs. These SOPs are critical to reproducing and confirming results obtained by the licensor. All relevant SOPs will be evaluated by our technology transfer team and a gap-assessment will identify any information, reagents or in vitro models that may be further required.
4. **In vivo models:** In cases where in vivo assessment of functionality and efficacy makes use of an in vivo system not currently present at AT-Bio, all materials that constitute this system(s) should be made available to AT-Bio. This is critical to allowing AT-Bio to reproduce in vivo models and progress clinical development. AT-Bio already has access to many in vivo systems and models.
5. **Chemical library for interaction screening:** Under exceptional circumstances, a proprietary target of key clinical value may be in-licensed by AT-Bio at a very early stage of development. To advance development, AT-Bio will perform initial interaction screening, interaction validation and secondary screening. In this case, AT-Bio must be provided with the chemical library that the licensor wishes AT-Bio to screen for interactions. Clinical Leads falling within the optimal stage of development outlined by AT-Bio will not require this.

The list of materials assessed as essential to Lead development by AT-Bio's technical team will be forwarded to the licensor. Conditions of transfer and use will be encompassed within the in-licensing agreement. Materials outside of this agreement that, during the course of Lead development, become essential to AT-Bio will be managed through standard material transfer agreements.



GMP MANUFACTURING

As a key player in the Chinese Pharmaceutical industry, TIPR has a full GMP production and fill-finish suite. This GMP manufacturing capability is supplied to TPIR through Tianjin Pharmaceutical Holdings, a wholly-owned subsidiary of TPIR. The raw material medicine refining-drying-packing workshop, solid preparation workshop and small-dose injection workshop have all passed GMP authentication with the SFDA.

CORE GMP CAPABILITY:

The raw material medicine production base includes four synthetic workshops and two refining-drying-packing workshops. The No. 1 refining-drying-packing workshop is located in a separate, single-storey building, equipped with one (2 tonne) production line. Similarly, the No. 2 refining-drying-packing workshop is also housed in a separate single-storey building and is equipped with three production lines of 1.5 tonne, 0.5 tonne, and 10 litre.

The General Production Area houses many of the key GMP services including the:

- Material preparation, weighing, discoloring, carbon filtration, crystallization operation suites.
- Purified water suite.

- Crude material medicines preparation room.
- Packaging material and finished product packaging/storage rooms
- Plant/Power machinery room.

Detailed and complete SOPs are in place for all processes and procedures undertaken in the GMP suite. Furthermore, exhaustive routine validations on the air and water purification systems, crystallization tank, centrifuge, heated air circulation oven, grinder, mixer, technical procedure and equipment cleaning methods are performed.

OUTPUT PRODUCTION:

Annual production capacity is approximately 10 hundred million tablets of solid preparations, 60 million injectables and 100 tonnes of raw material medicine.

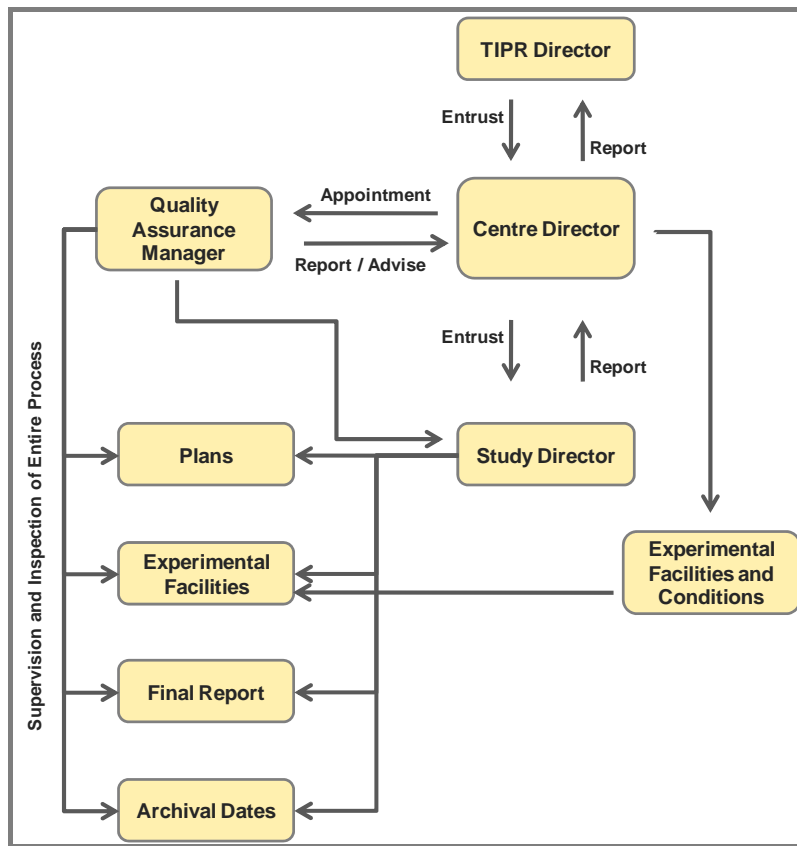
OVERVIEW OF SCALE-UP EXPERIENCE:

- **Adefovir Dipivoxil Tablets:** An anti-hepatitis B virus drug, a new generation of nucleotide analogues.
 - Production at TIPR was a Science and Technology Innovation Project funded by the Tianjin Municipal Science and Technology Commission.
 - Annual production output: 60,000,000 tablets.
- **Pu Wei[®] (Nimesulide tablets):** A new, non-steroidal anti-inflammatory, antipyretic and analgesic drug.
 - Pu Wei was initially researched and developed by TIPR and was one of the first drugs to enter production for TIPR.
 - The Ministry of Science and Technology regarded the development of this drug as of highest importance. TIPR's development and manufacture by the State Drug Administration in 1998.
 - Annual production capacity: 10,000,000 tablets.
- **Buprenorphine hydrochloride injection, sublingual tablets:** A mixed opioid receptor-agonist and receptor-antagonist. This is a new form of long-lasting analgesic.
 - TIPR was the sole domestic pharmaceutical company to research and develop this drug.
 - In 1995, this project was listed in the National Torch Plan. In 1997, it was awarded a Scientific & Technological Achievement Award by the State Science and Technology Commission and in 2000, was recognized as a key new product by State Ministry of Science and Technology.
 - Annual production capacity: 5,000,000 tablets and 1,000,000 injections.
- **Ambroxol hydrochloride injection:** A drug for the treatment of chronic respiratory diseases.

- This exclusive domestic product is produced with a mature technology.
- Annual production capacity: 50,000,000 injections.
- **Risperidone tablets:** A new antipsychotic drug.
 - Compared to conventional antipsychotic drugs, Risperidone tablets have efficacy on both the positive and negative symptoms of schizophrenia.
 - Annual production capacity: 30,000,000 tablets.

RESEARCH MANAGEMENT SYSTEM

A well-defined management system has been adopted by the centre. All technical work is under the direct supervision of study directors and study directors report directly to the center director. The management system implemented is compliant with the GLP regulations and is continuously monitored by the quality assurance department and the Animal Regulation Association.



ORGANIZATION OF TCNDSER

Professor Liu Changxiao is the Director of TCNDSER and Tianjin State Key Laboratory of Pharmacodynamics and Pharmacokinetics. He is also the Director of the Academic Committee of Tianjin Institute of Pharmaceutical Research. In 1968, Prof. Liu established the first pharmacokinetics laboratory in China and has published numerous books on the topic. Liu was the first among his Chinese peers to apply pharmacokinetics to the research of new drugs. He has led 25 research projects for the national key scientific and technological plans, new drug funds and pharmacokinetic studies in key projects for the “863” and “973” plans. Liu took part directly in drafting China’s GLP Guidelines. Prof. Liu has been awarded numerous prizes in China, Thailand and Germany and has published more than 240 papers and 14 books in English and in Chinese.

TCNDSER, the research department of Tianjin Center of Pharmaceutical Research includes:

- Institutional Animal Care and Use Committee (IACUC)
- Quality Assurance Unit (QUA)
- DMPK Research Unit
- Pharmacodynamic Research Unit
- Toxicology Research Unit

