

# Syntara Limited

## Risk Management Statement

### 1. Board responsibility

The Syntara Board is responsible for ensuring the Company establishes and maintains a risk management framework for the oversight and management of risk consistent with the risk appetite set by the Board.

The Board reviews risks to the Company's business plan at its scheduled meetings.

The Audit Committee, at least annually:

- reviews and updates the risk profile of the Company
- reviews the Company's policies and procedures for identifying and managing risk
- makes recommendations to the Board concerning the Company's risk management framework

### 2. Risk appetite

Syntara seeks high returns from its high risk biotech business model. While the Board therefore adopts a high risk appetite to the Company, the higher risk appetite is not applicable to all activities of the business. The higher risk appetite particularly applies to the likelihood of success of preclinical and clinical programs of the therapeutic targets which are the focus of the research programs, rather than to the manner in which the research programs are conducted. The Company conducts extensive reviews before embarking on a research program, seeking input its Scientific Advisory Board and other external key opinion leaders. The Company's research programs are informed by an understanding of the data packages required by big pharma companies who are the likely eventual partners of successful research programs – gained from experience of the Company's key researchers working within big pharma and by regular engagement with big pharma scientific and business development representatives.

### 3. Senior executive responsibility

The Chief Executive Officer and the Chief Financial Officer are responsible for profiling the Company's risks and ensuring appropriate risk management procedures are in place and operating effectively consistent with the risk appetite set by the Board. Within this framework, areas of risk are monitored as a part of the regular reporting to the Board.

### 4. Risk profile and management

While capital markets are an important and appropriate source of funds for a clinical stage development company, Syntara seeks to maximise the use of internal and external non-dilutive sources of funds to pursue the development of its drug pipeline. The Company has been successful in obtaining grants to fund clinical trials for its dual SSAO/MAOB inhibitor in iRBD/Parkinsons' disease, low to intermediate risk MDS and high risk MDS. The Company also accesses R&D tax credits.

#### 4.1 Funding risk

The largest opportunities pursued by the Company arise from its new drug development program. Syntara will aim to partner new drugs when they have achieved clinical proof of concept which in most cases will be at phase 2 or more rarely phase 3 stage of development, but does not plan to undertake

regulatory approval and reimbursement processes. These stages of development and commercialisation will be the responsibility of partners. The expenses associated with new drug development are small in the early stages compared to the clinical development phase and the costs only increase as the results of research work justify advancing the specific project towards the clinic. The process to partner is complex, expensive and not quickly achieved. Revenue from partnering new drugs typically takes the form of large payments at irregular intervals, the payment of which is triggered by development milestones over which the Company has no direct control. Syntara seeks to manage the uncertainty of these risks by:

- Focusing its new drug development on biological targets that are of interest and value to potential big pharma partners
- Initiating early engagement with potential partners to inform the drug development process and build scientific credibility
- Leverage the Company's proven research expertise in drug and clinical development to deliver multiple new drug candidates to enter phase 1 & 2 clinical trials
- Selection of partners that are committed to a rapid development of the drug acquired from the Company
- Review of drug development projects by the Company's Scientific Advisory Board
- See also 4.2 Research Risk below

#### R&D tax credit

The Company was entitled to an Australian research and development tax credit of \$4.6 million in the 2024 financial year, \$5.2 million in the 2023 financial year and \$4.9 million in the 2022 financial year. The Company expects to be eligible for the tax credit in future years depending upon its ability to meet eligibility criteria, in particular the limit on total revenue of \$20 million cap.

#### 4.2 Research risk

Risk is inherent in the research and development process. Nevertheless, that risk requires management to ensure adequate justification exists before proceeding to the next phase of development. Syntara manages the risks associated with its research and development activities by:

- Syntara staff having the experience and capability to design and manage its drug development programs to deliver drugs and supporting data packages acceptable to large pharma companies.
- Interacting with large pharma companies as projects proceed to understand their objectives and requirements for new drugs they are looking to acquire.
- Fully documenting all research project plans and monitoring performance against plan on a regular basis.
- Phasing expenditures on individual projects such that continued expenditure is dependent on achievement of milestones.
- Regular reports to and review by Senior Management and Board of Directors.
- Periodic evaluation of proposed research projects against expected business returns.

- Review of research projects by the Company's Scientific Advisory Board and independent consultants.

#### 4.3 Clinical & preclinical risk

Approval of a therapeutic product by a regulatory agency requires the submission of an extensive clinical, preclinical (safety) and manufacturing dossier. The dossier includes the results of the supporting clinical trials and preclinical studies. While the Company's business plan is to partner drug discoveries at either phase 1 or phase 2, the design and completion of these trials must support future phase 3 trials to be completed by partners. In designing clinical trials and preclinical studies it is therefore important to ensure that the endpoints of the trials/studies will be acceptable to potential partners as well as the regulatory agencies in all of the countries where registration will be sought; that the trials/studies will support the desired label claim of the product, and that the trial/study end points to be completed by Syntara are achievable in an acceptable timeframe and at an acceptable cost.

Successful execution of clinical trials and preclinical studies requires negotiation of contracts with acceptable timetables, costs and risks with the various investigators, institutions and clinical research service providers necessary to conduct a clinical program; sourcing and supply of clinical trial drug; and constant monitoring of contract performance over the course of the trial/study.

The conduct of preclinical studies involves animal testing at third party research organisations and potentially exposes the Company to adverse publicity or interruption to research activities as a result of activities by animal rights organisations.

The clinical/preclinical program risk is managed by:

- Syntara staff having the experience and capability to design and manage its clinical and preclinical program.
- Regular internal cross functional meetings review both trial/study design and ongoing performance.
- Finalising clinical and preclinical study designs in collaboration with contract research organisations, investigators, regulators and experienced consultants.
- Engaging clinical research organisations with relevant disease experience and global capability to run clinical trials.
- Negotiating contractual arrangements such that payments are, wherever possible, tied to contractual performance.
- Minimising preclinical studies involving animal testing and only conducting such studies at organisations and facilities that meet both industry and Syntara standards of animal welfare.
- Regular reports to and review by Senior Management and Board of Directors.

#### 4.4 Financial risk

Financial risk includes:

- Safeguarding of Syntara physical assets.

The Company takes a range of measures to effectively safeguard physical assets. The Company maintains an appropriate level of insurance covering physical loss of assets.

- Safeguarding against fraud.  
An expenditure approval policy delegating spending within budget and up to set limits to various levels of management supported by a robust financial control system is in place. The Board of Directors receive regular reporting of financial performance against an approved budget. Cash investments are managed within Board approved procedures and policies.
- Credit risk  
The credit risk on both the invested cash funds and the interest on the underlying funds is managed in accordance with a Board of Director approved policy that limits the approved investment instruments to bank deposits and bank accepted commercial bills, limits the term of the investment period, specifies the acceptable counterparty banks and requires monthly reporting of investment details to the Board of Directors. The credit risk on accounts receivable is managed by assessment of financial condition before supplying to major customers and regularly monitoring of outstanding receivables from customers.
- Foreign exchange risk.  
The Company contracts with a number of international organisations and institutions to provide a range of services. In most cases these organisations require payment in their local currency. Syntara does not generally hedge the long term purchasing power of its Australian dollar funds which it uses to pay for this clinical research. However, the Company does limit its exposure to amounts due under contracts by paying non Australian dollar liabilities as soon as possible after receipt of an invoice and by retaining foreign currency receipts to meet expected short term payment obligations. The Company effectively hedged the majority of its currency risk in relation to the Phase 3 clinical trial in cystic fibrosis as both the payments to the clinical research organisation and the reimbursement from Chiesi were denominated in US dollars.  
The Company invoices large foreign currency amounts in relation to assets it has partnered to international pharmaceutical companies and also in relation to the supply of product to certain international markets. Such invoices are monitored and where the size is significant and the settlement date can be reliably predicted the Company utilises foreign exchange forward rate agreements to hedge the receivables. The Company's policy will continue to be reviewed as these cash flows increase.
- Financial and IT risks  
The Company has a financial and management system that provides comprehensive management and oversight of the Company's financial and IT risks. This system is reviewed and tested annually.

#### 4.5 Human resources risk

The success of Syntara depends on its ability to recruit and retain employees with relevant expertise and experience throughout all levels of the Company. High calibre employees are attracted to Syntara by a number of factors

including working environment, career opportunities, personal contribution to growth, responsibility and remuneration.

Syntara has a formal annual employee performance appraisal policy which is linked where appropriate to the payment of performance related bonuses and equity plans.

#### 4.6 Intellectual property risk

Syntara must appropriately protect and safeguard the intellectual property that underpins the future growth and success of the Company. The Company therefore:

- Maintains appropriate records of its research and development activities.
- Patents innovations it considers have possible commercial value.
- Engages appropriately qualified and experienced patent attorneys.
- Requires all employment agreements to contain confidentiality and intellectual property ownership provisions or to sign confidentiality and intellectual property ownership agreements, as a condition of employment.
- Establishes confidentiality agreements with outside parties before discussing any matters of a confidential nature.
- Monitors developments in competing technologies that seek to address the same or similar clinical end points through different means.

#### 4.7 Public liability risk

Syntara is exposed to certain risks associated with the conduct of its clinical trials. This risk is managed by:

- Employing appropriately qualified and experienced staff. Clinical operations are led by a Chief Medical Officer with extensive experience in designing and running clinical trials.
- Engaging suitably qualified and experienced contract research organisations to manage clinical trials overall or for defined components of the trial.
- Designing its clinical trials to comply with Good Clinical Practice, which incorporates review and approval of clinical trial protocols by independent investigators as well as ethics committees of each site where clinical trials are conducted.
- Clinical trials are monitored whilst in progress by a safety review board.
- Agreement of clinical trial protocols by relevant regulatory agencies.
- Obtaining an appropriate level of clinical trial insurance from a reputable underwriter.
- Seeking expert advice on clinical trial designs.

The Company is also exposed to certain risks associated with the manufacture and sale of its products for both clinical trials and for commercial sale. This risk is managed by:

- Employing appropriately qualified and experienced management and staff.
- Quality management systems that encompass the entire production process and meet the regulatory agency requirements for a licence to manufacture under Good Manufacturing Practices. The Company's

manufacturing plant is audited by the regulatory agencies as part of its licence conditions.

- Obtaining an appropriate level of product and public liability insurance from a reputable underwriter.
- Engaging external consultants to provide expert industry advice on systems and controls processes.

#### 4.8 Other

- Economic, environmental and social sustainability risks.  
At its current size, scope of operations and stage of development the Company does not have any material exposure to any economic, environmental (including climate change) or social sustainability risks.
- Continuous Disclosure. However, the Company has recently initiated a program to prepare for future climate reporting which will provide guide to both future planning and reporting.  
As a listed public company Syntara has externally imposed disclosure requirements by the ASX and its own internal standards of shareholder communications. The Continuous Disclosure and Shareholder Reporting Policy sets out the Company's approach to management in this area. The policy is reviewed and amended each year.
- Insider Trading.  
The Share Trading Policy sets out the Company's approach to management in this area, including appropriate trading black-out periods. The policy is reviewed and amended as necessary each year.
- Cyber security risk.  
Syntara is exposed to cyber security risk in relation to its IT infrastructure which is a mix of internal resources and externally hosted applications. The Company reviews the security measures employed by external service providers and utilises a range of measures to protect its internal IT resources, including specific security hardware and software, physical security surrounding IT infrastructure and staff training.

### **5. Effectiveness of risk management**

This Syntara risk management statement is annually updated by management and reviewed by the Audit Committee in conjunction with a review of the Syntara risk profile. The CEO and CFO must annually attest to the effective operation of the Company's system of risk management.