

## EXECUTIVE SUMMARY

### MISSION AND BUSINESS MODEL

The Austrian Translational Research Centre (TRC) will serve as the national drug development and commercialisation enterprise translating breakthrough academic discoveries into innovative products. Striving towards sustainable and trustful partnerships with all universities and research institutes across the country, the TRC intends to become the one-stop-shop for biomedical innovations 'Made in Austria'.

Along the extensive pharmaceutical value chain, the TRC emphasises on early-stage drug development independent of disease area and type of drug. Thereby, the TRC employs a systematic and innovative sourcing and de-risking approach leading to an exclusive portfolio of promising preclinical drug candidates.

Early alliance with industry further fuels the translational efforts of the TRC and facilitates the commercialisation of its valuable assets. Licensed or sold products, respectively are then further advanced by the pharmaceutical and biotech industry towards market.

### OPERATIONAL CONCEPT

The Austrian TRC proposes a unique and highly collaborative Business Model bundling and using already existing infrastructure and expertise in academia and industry. The model is based on a flexible and modular scalable, tiered structure. Project Sourcing and Validation is pursued in collaboration with Austria's academia, subsequent design of drug candidates with renowned, (inter)national industry partners. Eventually, commercialisation of successfully developed assets is promoted by the TRC's seasoned Business Development Team (BD Team). The main process steps are summarised in the following:

#### **Project Sourcing:**

Breakthrough scientific discoveries originating from Austria's academia are identified by a team of experienced Translational Guides (TGs) operating from hot desks within Austria's biomedical centres of gravity. In a transparent and objective evaluation procedure, under the surveillance of an independent Evaluation Board (EB), a limited number of most promising projects are selected for translation.

#### **Project Validation:**

Subsequently, selected projects are challenged regarding reproducibility of data and disease relevance of the biological hypothesis using state-of-the-art predictive models. TGs establish and moderate project-specific, Multidisciplinary Research Teams (MRTs) with members remaining embedded in their original academic environment.

This approach ensures access to scientific excellence and highly specialised infrastructure for a wide range of biomedical research areas. The teams work along a predefined research plan maintaining stringent industry standards. Progress is regularly monitored by the EB.

#### **Product Development:**

Successfully validated projects are eventually advanced into Product Development, where first chemical and biological entities are identified and further refined into realisable candidate medications. This development phase requires structures and processes, which are only scarcely established in the academic environment if at all. Thus, the Austrian TRC strives towards close collaborations with world leading TRCs and the (inter)national pharmaceutical and biotech industry.

#### **Business Development:**

The primary objective of the BD Team is to successfully commercialise assets of the TRC. Identifying appropriate partners and establishment of early alliances with future customers are key success factors providing additional infrastructure, know-who, material, scientific and strategic guidance, and last but not least additional project funding fuelling the translational efforts of the Austrian TRC. A balanced exit strategy and close monitoring of assets upon commercialisation aim at generating predictable revenue streams. A significant part of the profit is returned to the Austrian academia.

### COLLABORATION AND IP STRATEGY

The TRC maintains a highly collaborative, open innovation network fusing Austria's academic strength in the biosciences with global pharmaceutical industry excellence. This approach requires strong management capabilities to exploit the enormous potential of this proposition. Therefore, the Austrian TRC strives to establish clear rules for collaboration with all partners. A Framework Agreement has been mutually elaborated regulating the main principles of collaboration with the Austrian TRC. Prior to starting a selected project for translation with the TRC, specific Project Agreements are concluded with the involved parties. Furthermore, collaboration principles regarding Preferred Partnership Agreements have been negotiated with the Lead Discovery Centre, Dortmund and the Medical Research Council Technology, London.

An important part of the collaboration relates to the handling of Intellectual Property (IP) and participation on future proceeds upon successful commercialisation of assets by the Austrian TRC. Transparent and fair rules for IP

handling have already been drafted together with an attorney. They are further refined during the negotiation of the general Framework Agreement with Austria's academia and term sheets with preferred TRC partners.

Profits generated by the Austrian TRC are fairly distributed between all parties that provide IP as well as infrastructure and specific know-how with some degree of risk sharing being taken into consideration. In general, the TRC proposes to compensate Project Partners for incurred direct costs; however, other cost-and-revenue sharing models are possible. Profit-oriented partners such as Contract Research Organisations (CROs) are not participating on future proceeds.

## ORGANISATIONAL STRUCTURE

The legal structure for the Austrian TRC is built upon two separate organisational entities: i) the Operating Unit that runs the operations and ii) a Steering Unit that acts as the single shareholder and funding vehicle for the Operating Unit. The decision for this 2-tier legal architecture has been mainly driven by the complex stakeholder structure, the need for a high-level of independence, flexibility, and streamlined decision making on the operational level.

The Steering Unit is set-up as a foundation, which is considered the most common and appropriate legal vehicle for holding shares in business-oriented companies. The Austrian Law for foundations –either private or federal - allows much higher flexibility with regard to customizing the bylaws for the specific needs of potential donors.

The Operating Unit is established as a standard limited liability company (GmbH) with statutes qualifying it as a research organisation oriented towards the public welfare. With this status, the Austrian TRC is eligible for 12% tax allowance for R&D expenses and for input tax reduction.

A lean management team of seasoned experts in the biomedical field, consisting of Managing Director, Head of R&D, and Head of Finance is leading the Operating Unit. After a ramp-up phase of four years, a total of 35 FTEs are employed at the TRC, whereas 20% are structure-related and 80% project-related FTEs.

## MARKET

The pharmaceutical industry has realised that outstanding academic research may provide a strong base to cope with the enormous future health care challenges. Thus, open innovation models have been growing extensively over the last decade with research centres fully dedicated to translational medicine playing a principle role as hub for industry into basic research.

Several of these TRCs have been established mainly in the UK, Benelux, Germany, and Sweden. Although some of these foreign institutions have already started sourcing for disruptive discoveries in Austria's academia, their efforts here are neither systematic nor sustainable. This can only be accomplished by a national initiative establishing strong and trusted relationships with local scientists and TTOs, an element that has been given special emphasis in the business concept of the TRC. Eventually, instead of competing with leading institutions in translational biomedicine, the Austrian TRC rather seeks for their partnership accessing internationally existing infrastructure and expertise. A participation in such a network of excellence is assumed to further leveraging the TRC's efforts in conveying Austria's fundamental research to the market, which still has an enormous demand for novel, safe, efficacious, and affordable drugs.

## FINANCE

For a base case scenario with eight running projects in parallel and a staff of 35 FTEs in steady-state, the TRC's total operational expenses amount to around 7 mEUR. Considering a five-year ramp-up phase and inflation of 2.5%, total costs of 226 mEUR are incurred over a period of 25 years.

Assuming license deals being the predominant exit avenue, revenues from successfully commercialised projects amount to 386 mEUR over 25 years. Around 124 mEUR are returned to Project Partners with Austria's academia receiving around 75%. Approx. 31 mEUR are reserved to compensate a potential private investment of the European Investment Fund (EIF). The remaining exit revenues of 230 mEUR are retained by the TRC and used together with ca. 17 mEUR from industry project funding for financing operations and long-term corporate development as well as a success-dependent employee bonus scheme.

Over the first 10 years of operations, external funding is required in the range of 39 mEUR to reach cash-flow break-even. Therefore, a private/public financing mix is suggested with funds coming from the Federal Government and States, the pharmaceutical industry and the EIF.

## CONTACT DETAILS

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