

Case Study

Specialised Therapeutics benefits from a lean business model

Specialised Therapeutics is a privately-held biopharmaceutical company that partners with international biotech and pharmaceutical businesses without a presence in Oceania. It then in-licenses, commercialises and champions partners' products, as if they were their own.

As its name suggests, Specialised Therapeutics focuses on products that have a unique proposition in fulfilling an unmet medical need. The medicines are typically low-volume, high-value products. For example, even if only 100 units are sold each year, this could represent revenue in excess of a million dollars.



“We are very selective in the products we take on. We must know and understand a product intimately before we make the decision to license

and our team can spend months undertaking appropriate due diligence, which involves not only knowing how a therapy works, but who it will benefit, what other products are its competitors and at what stage of the disease do patients need this therapy

Carlo Montagner

Chief Executive Officer, Specialised Therapeutics

Specialised Therapeutics looks after all the medical, regulatory and commercialisation activities for these products, including logistics, distribution and marketing.

“So, while we don't conduct the original the research and development underpinning our products, we treat all of them as if they were developed by us. “We don't want ‘me-too’ therapies. We always look to license products where there is a genuine unmet clinical need.” The first product Specialised Therapeutics commercialised 15 years ago was Abraxane, which today is a standard treatment for breast and pancreatic cancer – becoming one of the most successful chemotherapies ever commercialised in Australia. Since then, the business has formed relationships with more than 10 partners spanning Europe, the US and Asia and expanded its product portfolio across a number of

diseases.

China represents a huge opportunity for the business, with companies based in this jurisdiction disrupting the global pharmaceutical market with high tech drugs at low price points.

“We want to be at the forefront of this. We have a partnership with a Chinese company which will evolve into taking on several of their other pipeline products. We are also talking to other Chinese companies to bring their products to market,” says Montagner.

Specialised Therapeutics constantly faces challenges bringing products to market, the most significant of which is patients' capacity to afford specialist therapies and technologies. Consequently, registering its products with the Pharmaceutical Benefits Scheme (PBS) is a priority, given patients are only required to make a small co-payment to access drugs on the PBS, which may otherwise cost many thousands.

Another challenge is each product's lengthy payback period. The business invests between \$1 million and \$2 million per product applying for regulatory and reimbursement approvals, and even then, there is no guarantee of success. It can take several years between the time a drug is approved by the TGA and it being fully commercialised, generating meaningful revenue.

“There are many barriers to entry for newcomers and these can only be overcome by having a solid capital base, positive cash flow and disciplined business management selecting and commercialising medicines,” says Montagner, who explains the business suffers what he calls ‘leaky bucket syndrome’. Our products have finite patent lives of between 10 and 15 years. There are always new competitors taking market share, as well as price erosion to consider. So we have to keep topping up the bucket with new products,” he adds.

The business has always been cash flow positive and profitable, and has never relied on debt or other investors. "Our cash flow has funded our growth and sustainability," says Montagner. Finding the right products that are available for licensing for this region, which are commercially viable, and which can be sold at a reasonable price with reasonable market uptake, is another hurdle.

To this end, Montagner spends up to 60 per cent of his time on business development to bring in new products. "This is very resource intensive and not all products will be commercially feasible," he says.

Foreign exchange risk poses another barrier and future revenue streams are adjusted for commercial, regulatory, price and product risk. The team operates a zero-based budgeting model, working on a rolling 18-month budget, reviewed monthly and quarterly.

"We run the organisation as if it's a listed, multinational company. That has been the key to our longevity and survival," says Montagner. While access to talent is a typical challenge for health businesses, Specialised Therapeutics has put together a stellar team of highly experienced people with outstanding capability and expertise.

"We position ourselves as an attractive and enjoyable place to work. We're focused on bringing people into the business we think would enjoy working with each other because they are aligned to our values," says Montagner.

RSM has provided invaluable assistance to Specialised Therapeutics with general compliance advice, as well as expert knowledge on transfer pricing and working internationally.

"As our business grew and expanded internationally, we realised we needed accountants like RSM with broad, multi-country expertise who were adept at navigating complex global markets," says Montagner.

"At the moment, RSM is helping us with a corporate restructure. The team also has the expertise to work on our long-term positioning on a local and a strategic level and they understand our business. They have expertise in Asia, so they tick all our boxes and have been extremely helpful," he adds.

"Our business relationship with RSM is enduring. We are always impressed by how responsive they are. If we need an answer to what may be a complex query, we know we can just pick up the phone and ask. Our account manager is fantastic and always makes himself available. Our transition to RSM was seamless and they rapidly developed an understanding of our business model, operating in very complex markets."