One to Watch

Acrux

Chasing a US$1.1 billion market opportunity

12th November 2024

Venn Brown sat down with Michael Kotsanis, CEO of Acrux, to discuss the company's growing portfolio of generic topical pharmaceuticals.

Growing generics portfolio: Acrux has brought five products to market, with a further ten in various stages of development, including two the company expects to launch by March 2025.

Like all generic drug developers, Acrux is focused on building value through a portfolio of topical pharmaceuticals rather than developing one high-return single drug. Acrux assesses each drug based on a business case assuming only a five-year product life, leaving significant upside as the drugs are expected to remain on the market for substantially longer.

Topicals have less competition: Topical pharmaceuticals are more complicated than oral and injectables, resulting in fewer competitors in the generics space. With generics representing approximately 90% of all US subscriptions, fewer competitors mean larger market share opportunities and less pricing pressure.

Market size: Acrux is targeting a US$1.1 billion US market for its topical drugs, more than 50% of which have no existing generics. As a single market with structurally higher pricing, Acrux is focused on the US but can leverage FDA approvals to expand into other geographies.

Cash flow: Acrux has had positive cash flow for four of the last eight quarters. Cash flow will continue to fluctuate as the company builds out its portfolio. The company has a medium-term goal to be cash flow positive but is focused on building value by growing its portfolio rather than achieving immediate profitability.

Beneficial tax structure: Acrux is a pooled development fund, an old Australian tax structure that means all distributions and capital gains are tax-free. [1]

Outlook: Acrux is looking to build a steady cadence of launching around two new products a year. Over the next five years, it expects to bring its remaining eleven products to market while replacing them with ten new drugs in its development pipeline.

[1] This is not tax advice. Investors should seek their own individual tax advice.

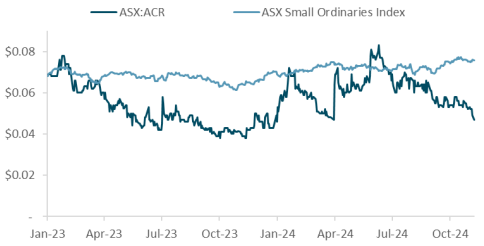
Acrux

ASX:ACR

Sector	Pharmaceuticals
Date	11-Nov-24
Share price	$0.047
52-week range	$0.035 / $0.099
Market cap	$13.7m
Free float	68.4%
Dividend	-
Yield	-

Year-end 30 June	FY21	FY22	FY23	FY24
Revenue	$5.2m	$5.1m	$11.9m	$8.1m
EBITDA	-$11.8m	-$8.9m	$0.4m	-$5.1m
EBIT	-$12.4m	-$9.6m	-$0.2m	-$5.6m
Net profit	-$12.6m	-$9.8m	-$0.8m	-$5.8m
Earnings per share	-$0.06	-$0.04	-$0.00	-$0.02
Operating cash flow	-$11.4m	-$8.8m	$0.7m	-$4.3m
Free cash flow	-$11.5m	-$9.3m	$0.6m	-$4.6m
Cash & equiv	$15.3m	$5.8m	$6.2m	$2.9m
Net debt	-$15.3m	-$5.8m	-$6.2m	-$1.5m
Net debt / EBITDA	-	-	-	-

3-year Price Chart



Analysts

Andrew Wilkinson awilkinson@vennbrown.com

Thanks for being with us today, Mike. First, can you give us a brief overview of Acrux?

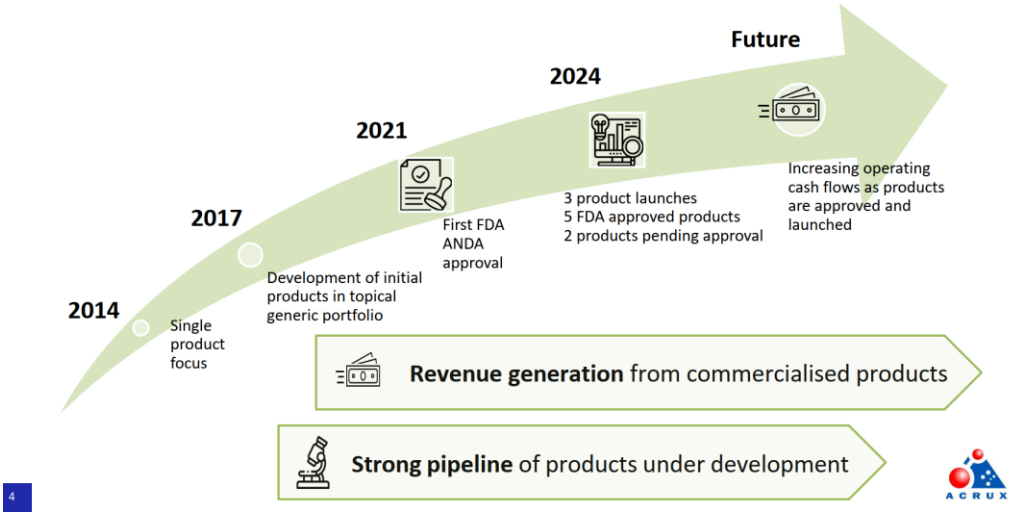
Acrux is a Melbourne-based pharmaceutical company. We were founded in 1998, and ever since, our focus has been on developing topical pharmaceuticals that are applied to the skin that either act locally or through the bloodstream.

We've had a series of product approvals in the major markets of the US, Europe and several other countries. These approvals demonstrate our capability to develop products for the US, which is our major focus market.

We run lean by outsourcing the manufacturing and sales. We have a network of manufacturers, most of which are licenced to manufacture products for the United States market. We also use commercial partnerships to distribute our products in each market, negating the need for an on-the-ground sales force in each region.

I also want to add that we're a revenue-generating company. Over the last two years we've generated $20 million[2] in revenue, and we have been cash flow positive for four of the last eight quarters.

Figure 1: Acrux has a long history of gaining FDA approval & bringing drugs to market



Source: Acrux

Given you're making generics rather than novel pharmaceuticals, how do you choose which products to take to market?

That's a huge focus for us. We put together a business case for each product to see if it's worthwhile from a returns perspective. We look at all the relevant factors, including market size, competition, cost to develop, timing of product approval, input costs, pricing and expected revenue. We have a lot of experience developing products and bringing them to market, so we can estimate the costs pretty well.

We then use these inputs to calculate an NPV for each product, assuming just a ten-year product life, five years for development and five years for commercialisation. If the figure stacks up after our stress test, then we will go ahead.

[2] FY23 - $12.0 million and FY24 - $8.1 million

Five years of commercialisation seems very short.

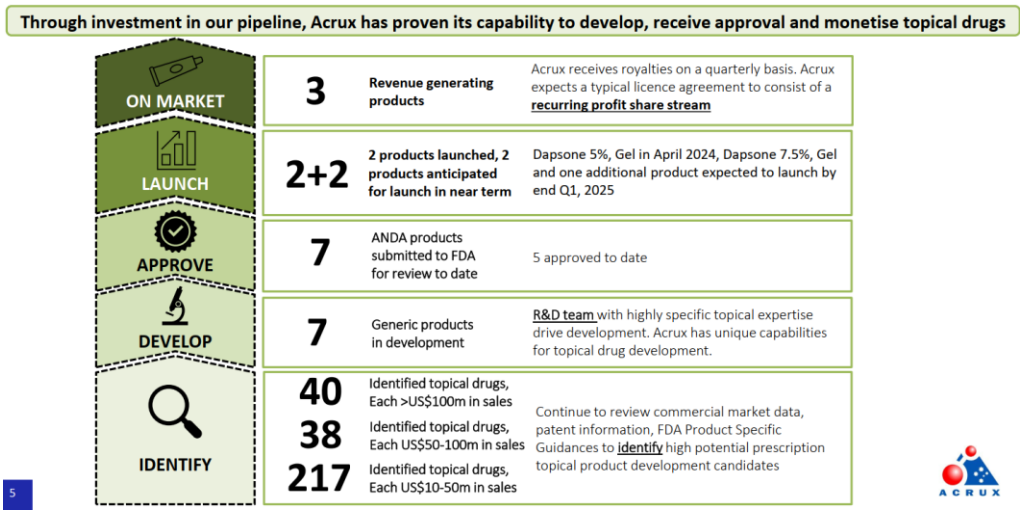
Predicting anything ten years in the future is difficult, but our ten-year product life assumption provides a significant safety buffer. That said, we don't go into a product with a five-year view. We expect all products to have a much longer product life. Some generics have been in the market for 20, 30 or 40 years, so any cash flow beyond the five years of commercialisation is pure upside to our NPV.

Does that mean that you've got a funnel of products that you're working on bringing to market?

Yes, we always have a funnel of products we're comparing and working up in terms of the next ones to add to our development pipeline. We're constantly comparing them, assessing each one's value, timing, complexity and other factors. A bunch of products are competing to be the next cab off the rank.

A key factor is value, but also complexity. Often, not surprisingly, the more complex products are difficult for everybody and, therefore, provide more value. But we don't put everything really difficult into our pipeline and make life difficult for ourselves. We try to balance risk and reward as well.

Figure 2: Acrux has a portfolio of 16 products & expects to add two new ones a year[3]



Source: Acrux

How much competition do the five drugs that you have in the market face?[3]

Generally, topical drugs have less competition than oral or injectable drugs of a similar market size. This is due to the complexity of topical pharmaceuticals. Fewer companies have the expertise to develop topical drugs. Every generic company knows how to create an oral drug, but topical drugs require different manufacturing equipment, different development skills and have different bioequivalence pathways.

[3] Acrux, has three products generating revenue, another that's approved but not yet commercialised so not generating revenue, and a fifth that's generating revenue in 40+ countries but Acrux stopped earning royalties from in 2023.

To address your question, though, we have some products with two competitors and some with five competitors.

We're looking at getting approval fairly shortly for one with only one competitor. So it varies quite a lot. If you compare that to orals, you'll often see tablets and capsules have 10 to 20 generic competitors over the life of the drug, particularly the bigger ones. So topical drugs are less competitive than orals and injectables.

I've been looking at generic products for a long time. I'm consistently amazed that we come across products that are off patent with maybe one or no generics and it's primarily due to complexity.

And we consistently see products that have no competition. It doesn't mean a competitor won't be approved tomorrow, but there's no reason to believe that a product will only last five years. Some products we've seen have had only one generic for 20, 30, 40 years. They're sitting there, probably with an equal share of the market with the branded product and maintain fairly consistent pricing. That's a very valuable product that the company is marketing.

What's the marketing process to get your product on pharmacy shelves and how do you compete with other generics?

Firstly, the US market is very efficient for generics. Generics represent nine out of ten prescriptions that are dispensed. That's because most drugs have come off patent, so generics are available.

The key customers for generic companies are the wholesalers. Three wholesalers control about 85% of the US market, each generating billions in annual revenue. Roughly speaking, if you are successful in listing your drug with one of those wholesalers, you can get 30% market share. Often, when the first generic launches, it captures market share incredibly quickly. On average, the generic will capture 50% market share within six weeks.

The customers of the branded companies are generally prescribing physicians, as well as the payors [US insurance companies]. In contrast, generic companies offer consumers a very simple value proposition: "Would you like the same drug at a cheaper price?"

The difference between the US prices for branded and generic drugs can be substantial. Far larger than in Australia and Europe. So, when it comes to generics, it's a patient and wholesaler-driven model.

If there are already generics in the market, doesn't it simply become a race to the bottom in terms of pricing?

That's a fair question. When you look at oral products, tablets, and capsules, where there are a lot of competitors, it often becomes a commodity-based market where, over time, the lowest-cost, largest-scale manufacturer will get a dominant position.

I think you see more rational behaviour in a market with fewer competitors. Generics compete on price, no question about that. They offer value through pricing. At the same time, generic companies aim to sell at as high a price as possible to obtain their targeted market share.

Of course, wholesalers have enormous power; their contracts are critical to generic companies and will wield that power. But at the same time, they want a competitive generic

market. They don't want to force companies out by pushing prices beyond cost because then their own competitiveness will decline. There's a balance that's eventually found.

If you've got ten competitors in a market, that's a really difficult market to enter, and we will immediately avoid it. But we are very interested in markets with low competition because they lend themselves to a more equal and fair share type of market over time where the companies and the competitors will respect each other's market share and won't just chase volume for volume's sake.

Do you sell directly to the wholesalers?

No, we don't. We operate using a very lean model. We outsource our manufacturing and use commercial partners with their own sales and market teams in the US to market to the wholesalers. These partners have their own generic portfolios and use ours to fill them out, so it's beneficial for both parties.

Are you focused on the US simply because it's the largest market governed by a single regulator, or are there pricing differentials within the US market that are also appealing?

Both. The US represents approximately 50% of the world pharmaceutical market. So targeting a large market operating under a single regulator makes sense for a small company like Acrux. The FDA is quite transparent in its regulatory process, making it easier to manage and more predictable.

At the same time, we are exploring other geographies. When we get approvals in the US, we're often contacted by companies outside the US interested in leveraging those approvals into their own markets. We are currently having discussions with companies in the UK, the Middle East, Brazil, and other countries as well.

And yes, pricing in the US is higher than in other countries, but there's definitely value outside the US. Our strategy is to focus on the US first, but I think it's inevitable that we'll grow by adding geographic territories to our products.

What is the process for gaining FDA approval for generic drugs, and how long does it take?

Our business cases assume five years of development, which includes regulator approval. The FDA regularly publishes its review times, which are currently around two and a half to three years. That said, the FDA considers topical drugs to be niche and complex, so approvals can take longer.

Sometimes, clinical trials are required, which can involve human trials, and sometimes in vitro tests [non-human trials] are sufficient. It depends on the specific drug being tested. For example, sometimes, a clinical study on a large group of patients is required if the drug is poorly absorbed, such as in the case of acne treatment.

We always examine the FDA guidelines and factor in the cost, complexity and duration of trials in our business cases. If the costs are too large or the process is expected to be too long, then we won't proceed with the drug.

One of the things we've tried to do a lot more of is engage with the FDA. We use various avenues of engagement to maximise our chances of success and minimise the time to approval. These include control correspondence, pre-submission meetings and mid-cycle meetings during the submission. I think we probably had a couple of hundred such

engagements last year. And for us, it's all about trying to learn what the FDA needs so that we can have faster approvals.

Can you speak to the size of the total addressable market for the five drugs you already have in the market?

Like all generic drug companies, we're building a product portfolio. We're not working on a single drug hoping it will be a blockbuster. Instead, we're building a portfolio that collectively targets US$1.1 billion in annual revenue. Some of the products operate in a segment with five existing generics, and some don't have any existing generics, so that opportunity is substantial.

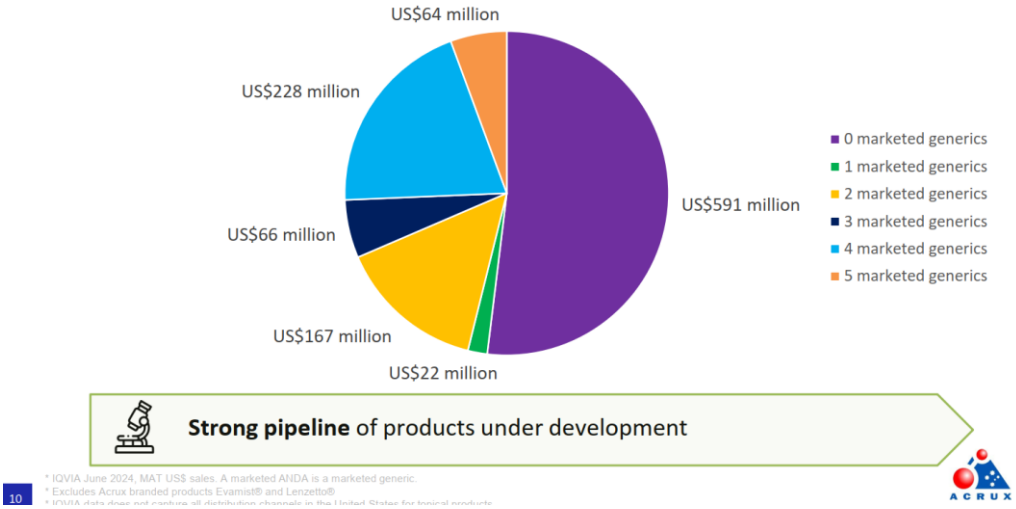
Some of our existing products operating in markets ranging from US$15 million to $38 million in annual revenue:

- Dapsone 5% US$16 million
- Dapsone 7.5% US$38 million
- Prilocaine/Lidocaine Cream US$24 million

We have an approved product but can't market it until we sort through some patent issues. It's targeting a US$468 million market. Our Nitroglycerin ointment, under FDA review, is targeting a $22 million market, and there's only one existing generic. We expect FDA approval soon.

With our current pipeline, we expect to launch two new products onto the market within the next five months.

Figure 3: Acrux topical generic portfolio is targeting US$1.1 billion market



Source: Acrux

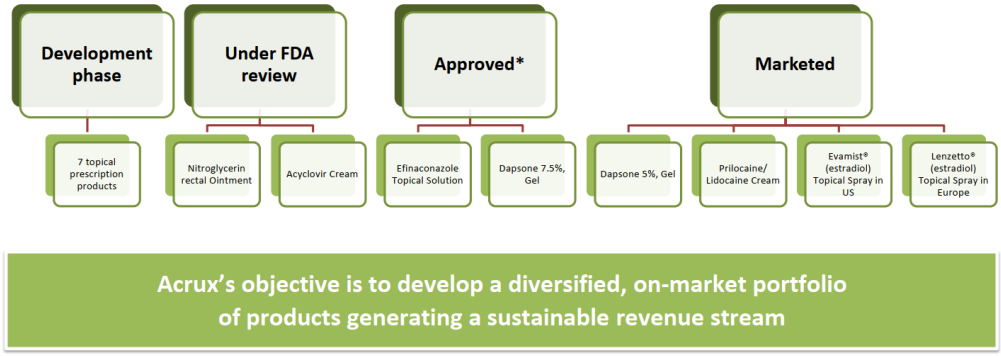
Where do you see the business in three to five years?

Five years is an interesting timeframe because the general project plan for a product from start to launch is five years. We currently have 16 products in our portfolio. Five are on the market, and the others are in various stages of development, review and approval. After five years, 15-16 of these existing products will be on the market, and we'll have added more

products to the development pipeline. We look to add two new products a year. We added two this year, and we've already identified one to add early next year.

So, after five years, we've got our existing 15-16 products all on market, plus ten more in various stages of development.

Figure 4: Acrux has five products on market and eleven more in development



Source: Acrux

Can you give any guidance as to when you expect to be completely cash flow positive?

Being cash flow positive is a core goal, and we've been cash flow positive for four of the last eight quarters. We could be cash flow positive now if we stopped product development and simply milked the existing five products, but that doesn't maximise our company value.

Currently, we're more focused on bringing more products to market rather than minimalising expenses. As the portfolio grows, we will become cash flow positive. In the meantime, it's important to realise that our expenses can be quite lumpy depending on when the products are going through the manufacturing phase.

Looking ahead to the five-year stage, where a topical generics company has 16 products on the market with another ten or so in its pipeline, what sort of EBIT margin could a company like that achieve?

The industry averages are around 20% - 25% EBIT margin, but they vary according to the type of company and the industry sector in which they operate. There's been a lot of consolidation in the generic industry, so there are fewer data points. The larger companies with sizeable oral commodity portfolios tend to have lower EBIT margins than the more specialised generic companies that operate on what I would call more sustainable type sectors of the generic industry, like topicals.

What's the biggest risk to Acrux reaching these five-year goals?

The two key risks we face are time to market and market competition:

- We're always talking about and focusing on getting products to market as quickly and efficiently as possible. The drug development process is complex. There are always challenges when you get to the FDA. We've never had to change the formulation of a product, so when we submit a drug, the formulation is inevitably approvable. But that doesn't mean that the FDA won't ask questions about the data

supporting it or ask for more data or a different view of the same data we've already supplied.

We have a lot of experience and undertake detailed planning, but we only control part of the process. Manufacturers control part of it, and the regulator controls part of it, so we don't have absolute control over timing.

- Market competition is also critical. As I mentioned, a drug development path is five years, and most manufacturers don't publish their pipeline, so a market can change significantly during the development phase. If we misread the market competition or far more competition appears, then we might get more pricing pressure than we anticipated.

As I mentioned, there are several products that we're working on where there are no generics or only one generic, and that's been the case for many years. Our business cases always assume competition, but if there is none, or only one, that offers significant upside.

What's the most misunderstood part of Acrux?

I'm always asked, "What's the next really big product for Acrux?". That's a widespread misunderstanding about generic pharmaceuticals. We're not trying to hit it out of the park with one groundbreaking drug. We're building a portfolio of generic topical medicines, each adding value. No one product is going to provide the majority of our revenue, but collectively, we're building a really nice business. The portfolio approach means that at any one time, we have several products in development, a number under regulatory review and a number on the market.

Generic companies don't focus on one product, which is how we differ from most of the other listed Australian life sciences companies. Most of these companies are focused on a single drug or treatment, leading to misunderstandings when investors look at us.

What is it that you wish more investors understood about the business?

There are a few things. Firstly, all dividends and capital gains made on Acrux are tax-free. [4] Acrux is a pooled development fund, an old Australian tax incentive structure formed in the 1990s that made all dividends and capital gains of Acrux tax-free.

The other is that we have a track record of getting products approved by the FDA, which is universally recognised as one of the most challenging regulators. We're not a large company, but we're consistently submitting products and getting products approved. If you look at the number of companies in Australia with FDA approvals, that's pretty limited, so we have some valuable skills and capabilities.

A third thing that the market doesn't appear to understand or appreciate is that we have commercial partners for all our near-term products. We don't struggle to find commercial partners. We're not shopping around desperate to find someone to take our products. On the contrary, we often have multiple companies interested in our products. It's a great position to be in and removes a lot of risk.

[4] This is not tax advice. Investors should seek their own individual tax advice.

Share price performance

Source: S&P Global

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