ASX Release: Acrux Limited (ASX:ACR)

ASX Market Announcements Office, Melbourne
Level 4, North Tower, Rialto
525 Collins Street
MELBOURNE VIC 3000

21 November 2024

In accordance with ASX Listing Rule 3.13.13, Acrux Ltd is pleased to release the addresses to be given by our Chairman, Ross Dobinson, and our Chief Executive Officer and Managing Director, Michael Kotsanis, at the Company's AGM to be held at 10:00am this morning.

Authorised for release by the Board of Acrux Limited.

For more information, please contact:
Michael Kotsanis
Acrux Limited
CEO & Managing Director
P: + 61 3 8379 0100
E: michael.kotsanis@acrux.com.au

About Acrux

Acrux is a specialty pharma company with a successful track record of developing and commercialising a pipeline of topically applied pharmaceutical products. Drawing on 25 years of experience, Acrux has successfully marketed through licensees a number of products worldwide with emphasis on the United States.

Acrux is formulating and developing a range of topical generic products by leveraging its highly skilled workforce, on-site laboratories, GMP manufacturing suite, technical, clinical and commercial experience to bring affordable products to market. Acrux encourages collaboration and is well positioned to discuss commercial partnering and product development opportunities.

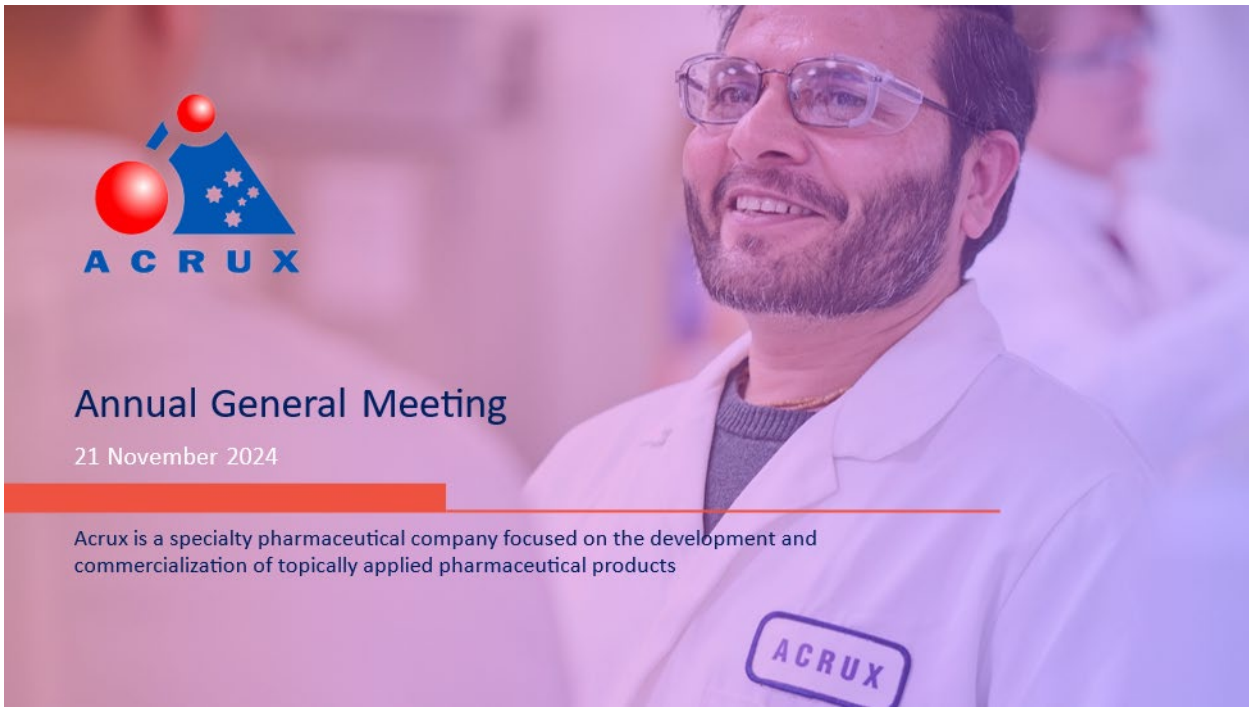
For further information on Acrux, visit www.acrux.com.au

Acrux Ltd
Annual General Meeting Presentation
21 November 2024

Good morning ladies and gentlemen. My name is Ross Dobinson and I am the Chairman of Acrux Limited.

It is my great pleasure to welcome Acrux shareholders and guests to our 2024 Annual General Meeting, which is being held today in the offices of our auditors, Pitcher Partners.

This AGM is convened to address the items detailed in the Notice of 2024 Annual General Meeting which was circulated to shareholders on 15 October 2024.



I am joined by my fellow Directors, Michael Kotsanis, our Chief Executive Officer and Managing Director, and Non-executive Directors: Geoff Brooke, Tim Oldham and Don Brumley. Also attending are Joanna Johnson, our CFO & Company Secretary, and representatives from our auditor, Pitcher Partners and our Share Registry, Link Market Services, to conduct the polls.

The agenda for today's Meeting is as follows:

- Firstly, I will present my address
- Michael Kotsanis will then review the Company's activities and milestones achieved over the past 12 months in the CEO's Report
- We will then conduct the formal business of the Meeting.

Acrux is a specialty pharmaceutical company with a team of specialised scientists focussed on developing a range of topically applied generic prescription pharmaceutical products which will be predominantly commercialised in the United States. The Company has a successful track record of obtaining product approvals in the US which reflects our expertise in submitting dossiers that meet the US FDA's complex Product Specific Guidance for generic products. Our in-house expertise is complemented by our network of contract manufacturing and development organisations and commercial licensees.

This commercial strategy remains unchanged since Q4, 2017. The Company's objective is to create a diversified on-market portfolio of topically applied products generating sustainable revenues and to concurrently maintain a broad development pipeline which generates regular regulatory submissions, approvals and future product launches.

As evidence of the continuing execution of this strategy, the following milestones were achieved during the FY24 financial year:

- Acrux submitted and had accepted for FDA review Nitroglycerin 0.4%, Rectal Ointment at the start of the financial year. This was the seventh regulatory dossier submitted by Acrux since 2017 and this product is now one of three which are progressing through the FDA's review processes. The product, when approved, will be used to treat moderate to severe pain associated with anal fissure.
- In April 2024 we launched Dapsone 5%, Gel into the United States market following its approval by the FDA. The product is approved for the treatment of acne vulgaris.
- We divested our Testosterone Topical Solution product in the United States because this ANDA no longer had any commercial value to Acrux due to a rapidly declining market characterised by low in-market pricing. The divestment was executed in the June quarter of 2024.

The outlook for product derived revenue growth in FY25 is encouraging as Dapsone 5%, Gel was launched in April 2024 and we have 2 further products planned for launch in FY25, one of which is dependent on the timely receipt of FDA approval.

The Company today has a portfolio of 16 products with three of those on market generating revenue for the Company. Currently 2 products are in late stages of review by the FDA. Over time, as our products are approved, Acrux will add new projects in order to maintain a similar number of products in active development.

The number of commercialised products will continue to expand following the recent launches of Prilocaine 2.5% and Lidocaine 2.5%, Cream and Dapsone 5%, Gel as we have a further 2 products that we expect to launch in the next 4 months.

During the year, the Board has reviewed and updated all Corporate Governance policies as part of the routine review cycle. Corporate Governance policies can be viewed on the Acrux website under the Corporate Governance tab.

The Board has also reviewed the qualities that each Director brings to the Board to ensure the Board has the appropriate skills and experience to lead the company both now and in the future and to identify potential or emerging gaps in skill sets, any areas for improvement and to support succession planning.

We would like to personally thank the Acrux team of employees and the Board for their valuable contributions, their sustained efforts to progress ANDA's through the FDA review process and the focus on the company's revenue growth objectives.

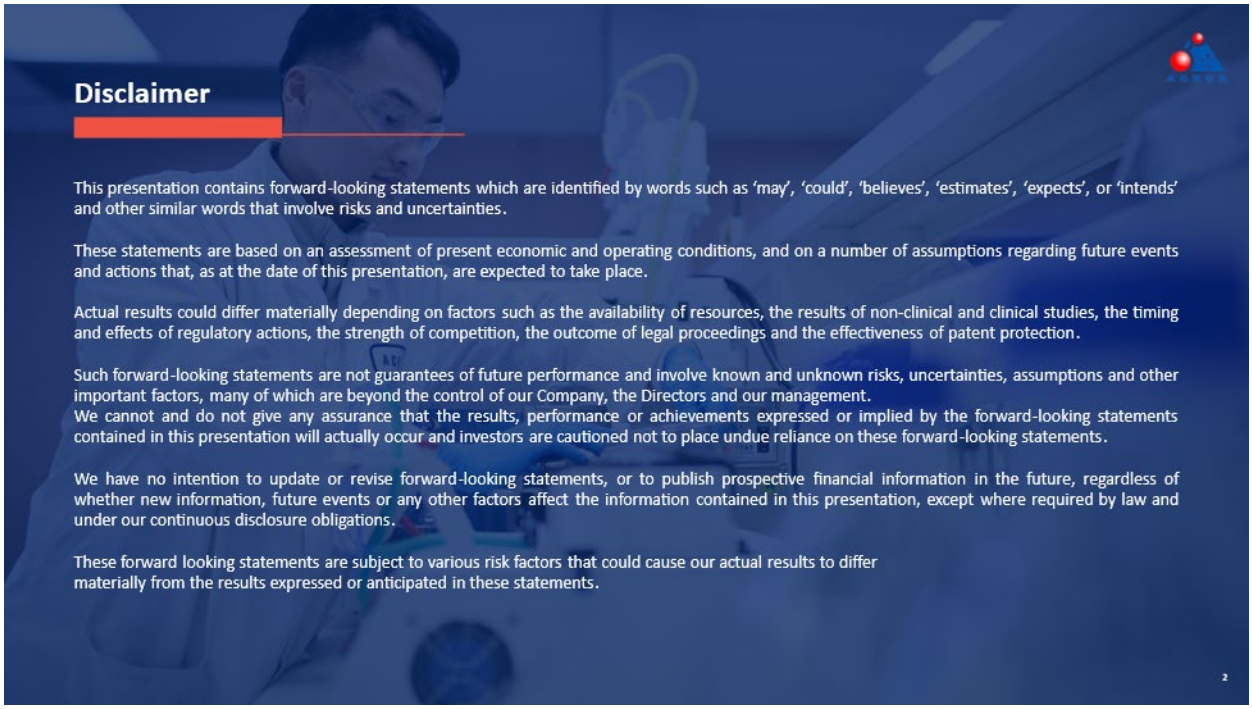
Finally, we would like to thank you, our shareholders, for maintaining faith in Acrux which will be warranted as we progress into the revenue growth phase.

I now ask Michael Kotsanis to further detail this progress in the CEO's report.

Michael Kotsanis – Chief Executive Officer and Managing Director

Good morning. I'd also like to give a warm welcome to all shareholders and guests who join us this morning at this year's Annual General Meeting. Thank you for attending.

Before I start my presentation, I refer you to our Disclaimer Statement. Please review this statement carefully.



The Acrux pipeline is strong and progressing and we are close to a tipping point in terms of our goals to grow recurring revenue streams and to generate consistent positive cash flow for our Company. This is underpinned by a strong company core.

Acrux has a 25+ year history of developing topically applied pharmaceutical products. We were founded in 1998 and have a strong track record of products approvals from the major regulatory agencies. Acrux has the skills and competence to develop topical pharmaceutical products through to regulatory approval and to subsequently launch these products.

Our network of 8 contracted, contract manufacturing organisations (CMO) are all FDA inspected and manufacture different and specific products from within the Acrux portfolio. We initially contract with a CMO to transfer our product formulation to them and to subsequently manufacture product for regulatory and bioequivalence purposes. The same CMO then provides our commercial licensees with manufactured product to sell into the market once the product has been approved.

We have a number of licensees that we contract with for the commercial sale of our products into the United States and other markets. Our commercial licensees are well established pharma companies with existing portfolios of on market products. Our commercial licensees pay us a royalty or profit share on a quarterly basis.

The information on this slide gives an overview of key data about the Company.

Our largest shareholder is Bioscience Managers and the top 20 shareholders hold 34.6% of shares on issue.

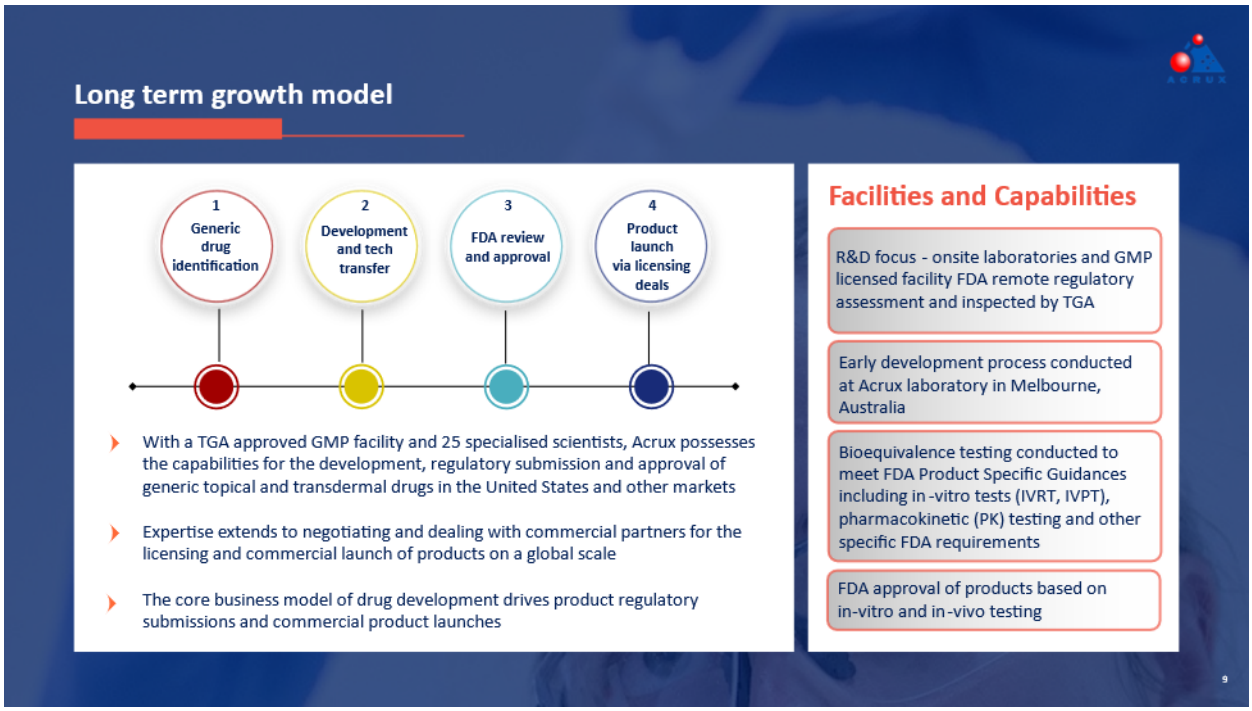
The Board and Management of Acrux are highly experienced with significant levels of industry relevant experience. They are all in the audience this morning and you are welcome to interact with them following today's Annual General Meeting.

Over the last two years, Acrux has generated $20 million in revenue. The majority of this is revenue from our commercialised products.

We currently have 3 products that generate revenue for Acrux through contractual royalty and profit share agreements and we have another two products that are under review by the United States regulator, the FDA. We expect to launch two additional products to add to the three products on market within the next 4 months.

We have another 8 products in various stages of development. I will go into more detail about our portfolio and pipeline of products over the course of this presentation

The products that we choose to develop are chosen from a group of 295 marketed topical and transdermal products in the United States that each generate over US$10 million in annual sales. In the United States, based on IQVIA sales data *[IQVIA data is a subscription database of commercial sales data used widely by the pharma industry]* there are 40 different topical products that generate annual sales of over US100 million. There are an additional 38 products that generate between US$50 million and US$100 million in annual sales and there are 217 different products that have annual sales of between US$10 million and US$ 50 million.



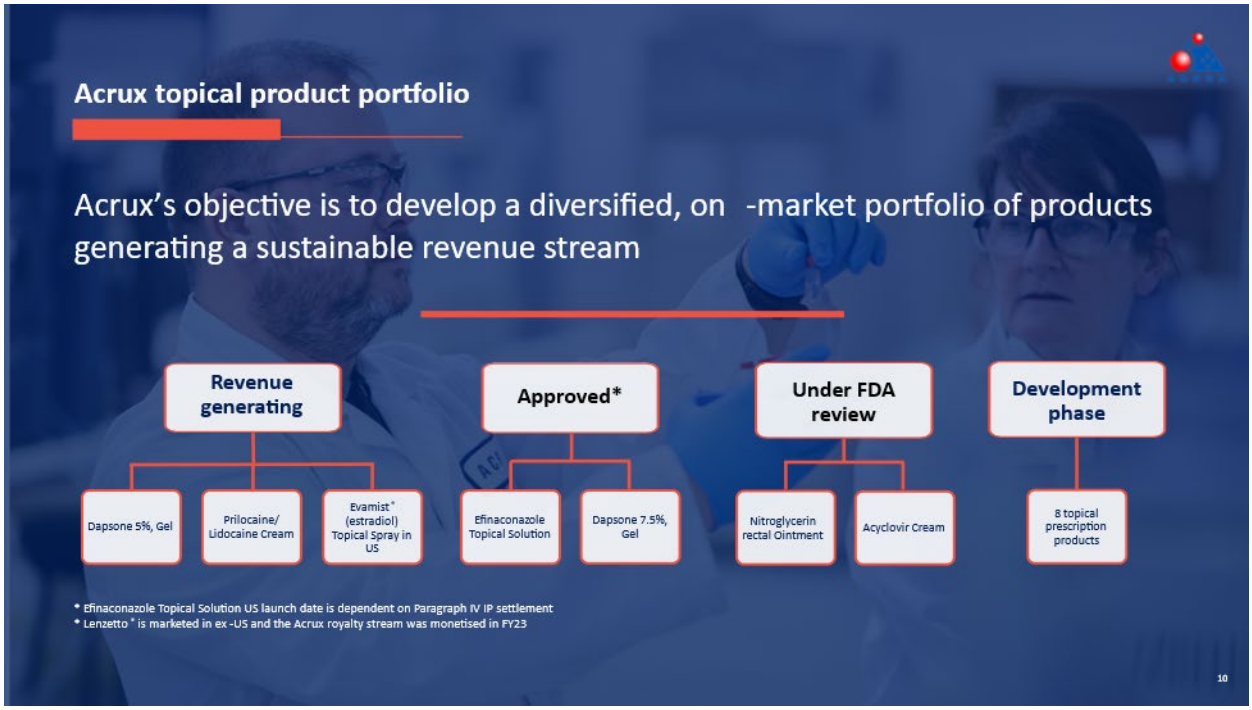
Our business model is depicted in this slide.

We spend considerable time and effort in the selection of products to add to our pipeline. We use publicly available data sources such as the FDA Orange Book which lists products approvals, market exclusivities and patent status for each product. We also fully assess the FDA Product Specific Guidances that the FDA publishes on their website which guides pharmaceutical companies on the methods recommended for bioequivalence testing. We engage with the FDA early in our selection process through Controlled Correspondences and meeting requests under their formal meeting processes. Over the course of the 2024 financial year, the Company has submitted 94 Controlled Correspondences, including 40 addressing potential new product candidates. In that period, the Company has also had 40 other interactions with the FDA via video, teleconference, or written correspondence.

We use paid subscription databases, including for IQVIA data, for commercial sales for every topical drug sold in the United States and combine this with market intelligence from our partners as well to determine the next products that we will add to our pipeline.

Once we select a product for development, our 25 scientists go to work to develop the formulation with a goal to match the reference drug. This is an extensive process which involves our formulation, analytical and stability teams. Once we are satisfied with the formulation, we move to the next step in our product development process where we identify a contract manufacturing organisation (CMO) with a successful FDA inspection record and contract with them to transfer our formulation and subsequently manufacture the product for both regulatory and bioequivalence purposes. The product that is manufactured for regulatory purposes is then tested by us and selected external laboratories to demonstrate bioequivalence of our product comparted to the reference listed drug in the United States. The same CMO is also contracted to manufacture commercial product for our commercial licensee once that product is approved by the regulator.

Clearly we have demonstrated our ability to develop and receive approval for our products as evidenced by the 5 product approvals we have received from the FDA since 2001.



Summarising our portfolio today, Acrux has 16 products in its portfolio.

Five of these products are approved in the United States and three of these are generating revenue for the Company – Prilocaine and Lidocaine Cream, Evamist® and Dapsone 5%, Gel. Over the last 2 years, Acrux made strong progress towards its goals of launching multiple products and building a sustainable revenue stream.

In December 2022, through Padagis, our licensee, Acrux launched Prilocaine and Lidocaine Cream. This product is used as a local anaesthetic in the United States. In February 2023, one of the competitors in that market with 60% market share, announced their bankruptcy and cessation of supply of their extensive range of products to the US market. That event caused considerable disruption to supply chains for this and other products for a lengthy period of time with limited stock available for sale for a number of months and this hampered our licensees efforts to drive market share of the product. Recent IQVIA sales volume data shows that for the 3 month period to end August 2024, the Padagis market share is growing and is higher than at any other equivalent period since launch.

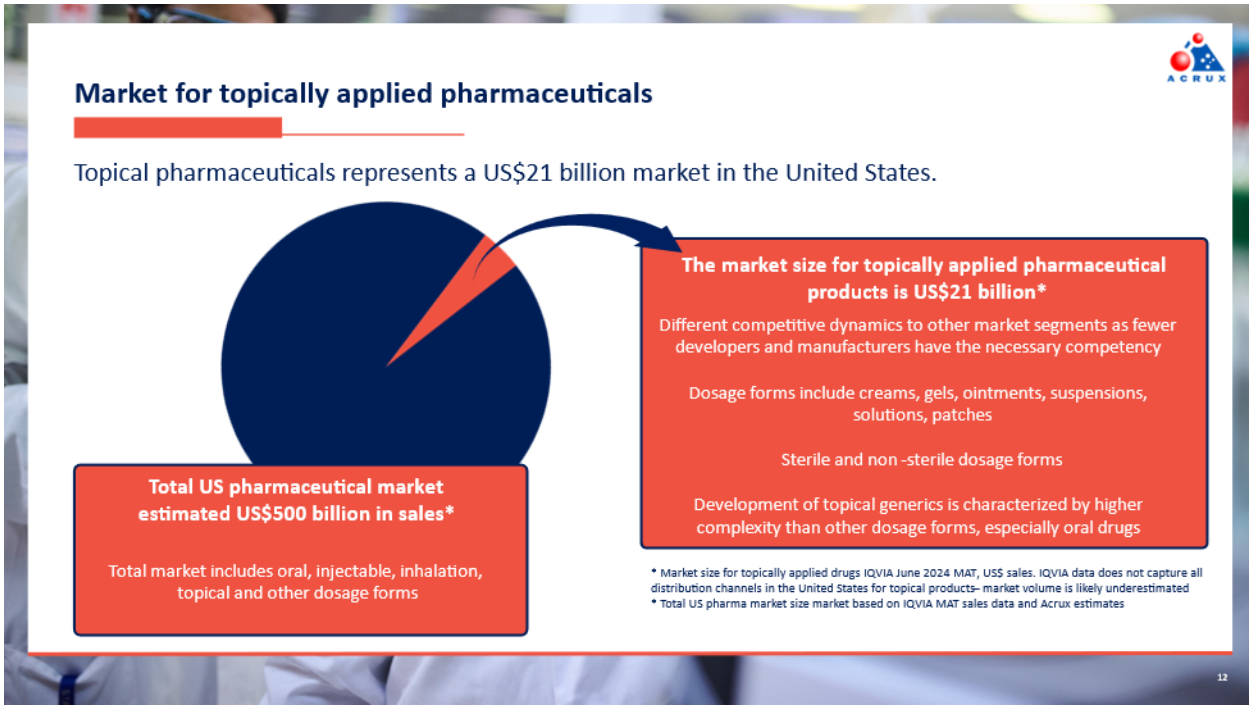
In the second quarter of this calendar year, through TruPharma, our licensee, Acrux launched Dapsone 5%, Gel. Our market share to date is low, however, our partner intends to launch an additional product presentation to complete the range and improve their market competitiveness over the coming weeks.

We have two more products scheduled for launch in the next 4 months and look forward to announcing the details of these launches as they occur.

Acrux has two products currently under FDA review 8 additional products in our development pipeline.

Our key focus is on developing products for the US market and commercialising these through our long term relationships with licensees. Now that we are starting to achieve regular product approvals and launches, we are increasingly engaging with pharmaceutical companies in other countries who are expressing an interest in marketing our product outside the United States. Commercial discussions are underway in a number of countries for commercial rights to our products.

This offers Acrux the opportunity to expand its existing US approved product portfolio into new markets and to leverage the Company's regulatory and development efforts involved in achieving FDA approvals.



Our competence and focus since our inception as a company over 25 years ago, has been the delivery of drugs that are applied topically – on part of the human body.

The market for topically applied pharmaceutical products that Acrux targets is focussed and niche, but substantially large enough to be attractive for Acrux to target. At US$21 billion in size in the United States alone, we believe this market segment is attractive on the basis of generally lower numbers of generic products, including products that generate reasonable annual sales that have very limited or no generic competition despite no patent protection for many years.

The total pharmaceutical market in the United States exceeds US$500 billion in sales, as measured by IQVIA. Generic development techniques vary by dosage form and indication. Acrux does not target the entire generic market, as this slide illustrates. The biggest sector for the pharmaceutical market in the United States is the market for drugs taken orally, usually by tablet or capsule or by injection.

Acrux targets pharmaceutical products in the sector that are applied topically. This is where our collective experience makes a positive difference. Products in the topical sector are generally less competitive compared to oral drugs and bioequivalence techniques are variable depending on the drug, the dosage form and the therapeutic use of the product.

Topically applied drugs are available in a number of dosage forms, including creams, ointments, solutions, pastes, gels and suspensions. They can be applied to a variety of areas of the body including the skin, eyes, ears, nose and other parts of the body. The topical category of products includes some topically applied products that require sterile manufacturing techniques in the case of ophthalmic and some otic products or non-sterile manufacturing processes for most products with application sites on the skin. This variety of dosage forms and therapeutic uses results in a high degree of variability of bioequivalence technique that the FDA expects generic companies to use to demonstrate bioequivalence which the FDA often describe in their published Product Specific Guidances. This is where Acrux's experience in the development of topically applied pharmaceuticals is important as we have a demonstrated capability to do this.

Acrux can target a significant number of topically applied pharmaceuticals

US$21 billion* market has a broad range of development targets for topically applied pharmaceuticals

Acrux is focussed on the specialty sector of topically applied pharmaceuticals

Why topicals? Generally smaller market size (volume and total market value) but generally fewer generic competitors and therefore lower price discounting.

Opportunity to develop products for established but low competition generic products as well as newly genericised.

Application site	>US$100m	US$50m-100m	US$10m-50m
TOPICAL DERMATOLOGICALS	13	11	81
TOPICAL OPHTHALMIC	14	11	48
TRANSDERMAL PATCHES	4	8	32
TOPICAL EXTERNAL		3	8
TOPICAL NASAL	2	1	11
MOUTH/THROAT TOPICAL			9
TOPICAL RECTAL			8
TOPICAL VAGINAL	6	3	11
TOPICAL OTIC	1	1	5
TOPICAL UROLOGICAL			3
TOPICAL ALL OTHERS			1
Number of products - Total	**40**	**38**	**217**

* Market size for topically applied products. One product is a drug substance in one strength. IQVIA June 2024 MAT, US$ sales

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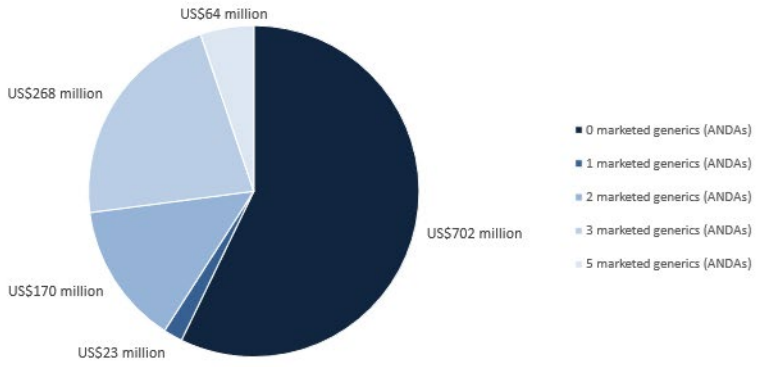
The products we continually assess for product development candidates are categorised in this table by site of administration and sales. This is the group of products that we regularly review and we maintain a database on each of these products and assess them on a very regular basis.

There are 295 topical products that generate annual sales of over US$10 million. Of those, 40 are generating over US$100 million in annual sales and 38 are generating annual sales of between US$50 and US$100 million.

Acrux portfolio – addressable market is over $1.2 billion*

Acrux products are targeting topical markets with limited competition



* IQVIA August 2024, MAT US$ sales. A marketed ANDA is a marketed generic. The graph excludes branded products Evamist * and Lenzetto * (Estradiol Spray products) which have no generic competitors in Europe or the United States..

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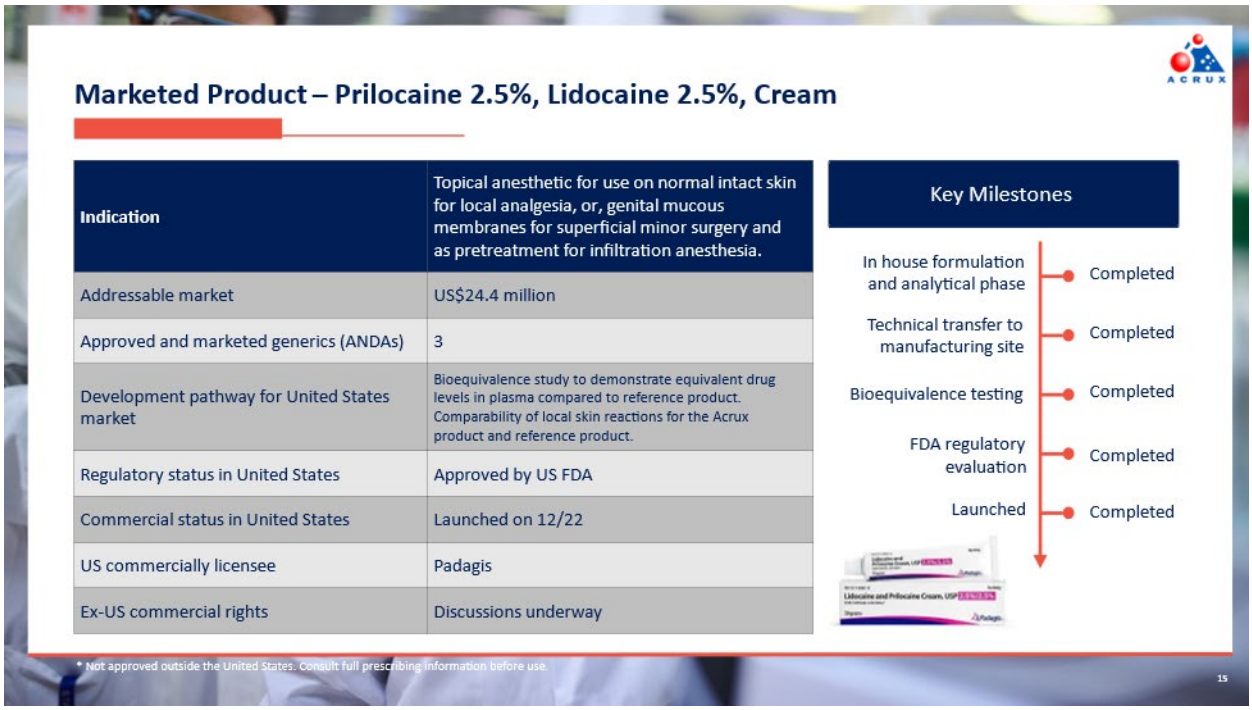
Our portfolio of products, including those marketed and those under development, target US$1.2 billion in current annual revenue across the 16 products in our portfolio. One of the key

factors we consider when choosing to develop a drug is the level of competition that exists and that may be expected on launch.

Most generic companies do not share details of their pipeline products and competition can be difficult to determine in advance of a product approval. Nonetheless, we are encouraged by the generally low levels of generic competition that we note for various topically applied drugs in our portfolio of products targeting the US market. The slide shows that in general our portfolio faces low levels of competition.



In the next few slides, I will outline selected products that we have developed including the bioequivalence process that that the FDA recommends we follow, the size of the market according to annual IQVIA sales data, the number of competitors and the development status of the product.

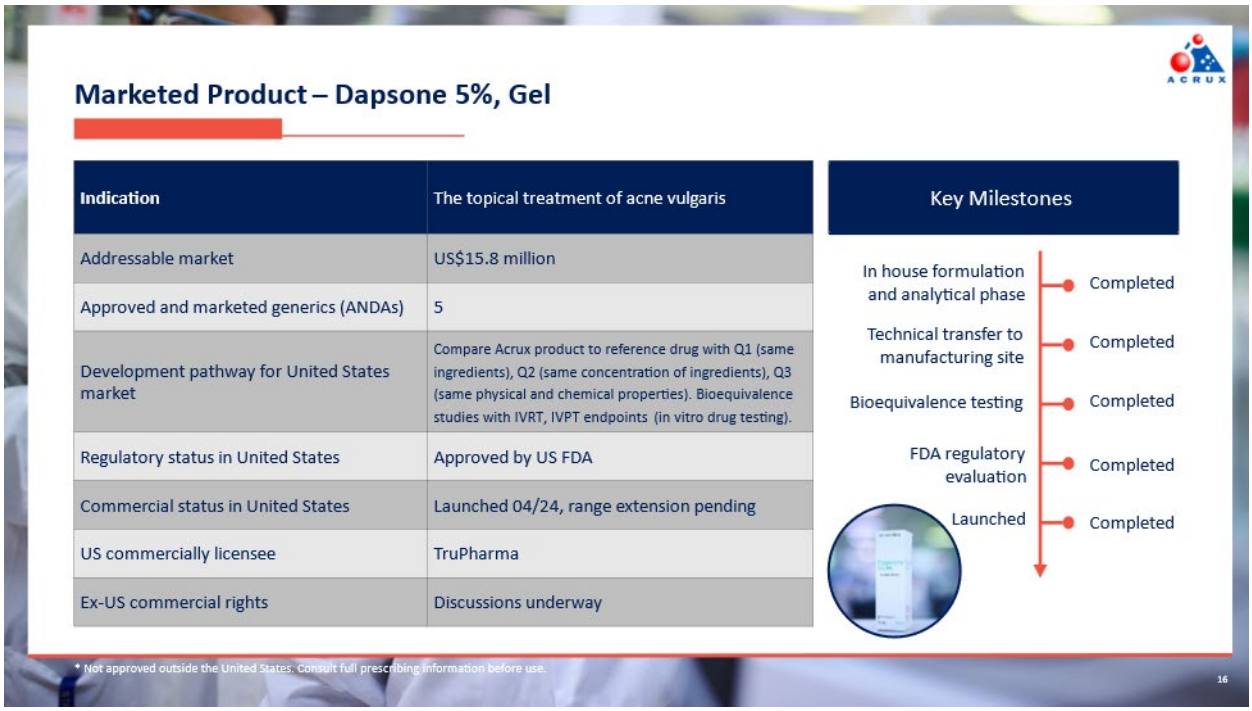
The first product is Prilocaine and Lidocaine Cream.

The product is approved for use in the United States as a topical anesthetic for use on normal intact skin for local analgesia, or, genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia.

The market in which it competes, also called the addressable market, generates annual sales of US$24.4 million. There are 3 approved and marketed ANDAs in that market.

The product was launched in December 2022 by our partner Padagis.

We also have a number of discussions underway for the licensing and commercialisation rights for this product in countries outside the United States.



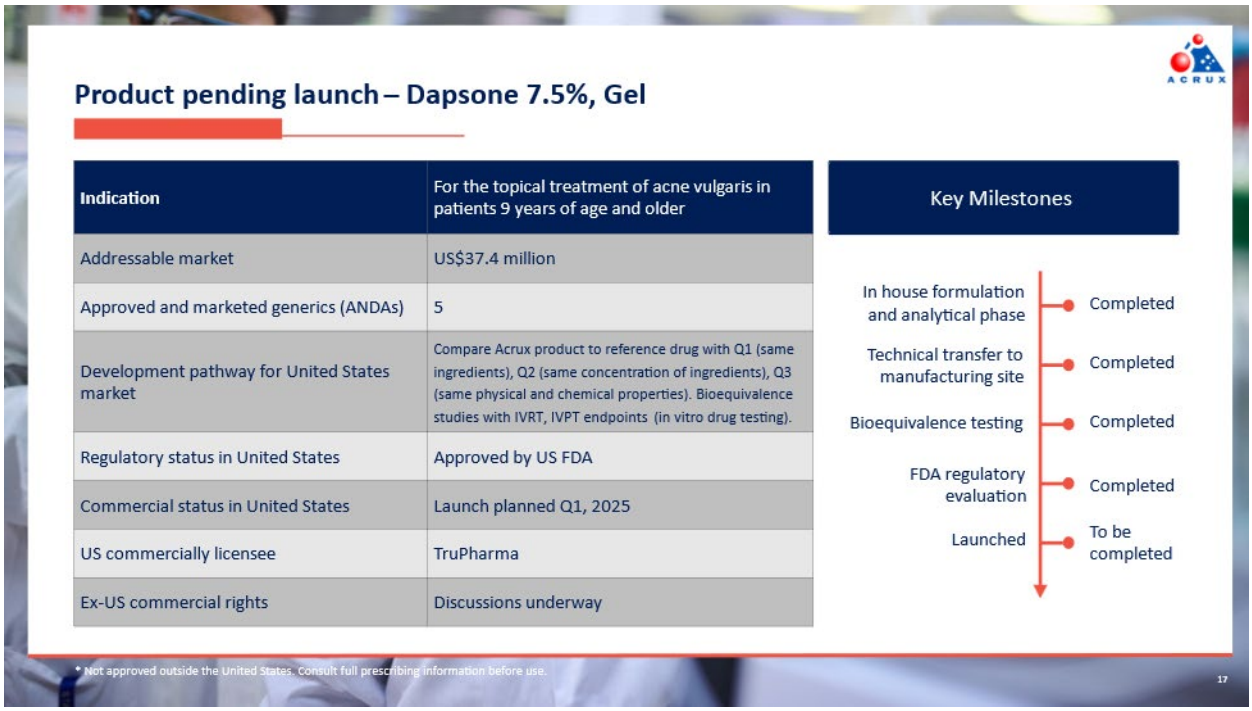
The next product is Dapsone 5%, Gel.

The product is approved for use in the United States in the topical treatment of acne vulgaris. The FDA mandated a complex bioequivalence pathway including in-vitro release testing compared to the United States Reference Listed Drug (RLD), in-vitro permeation testing also versus the RLD and other testing. More recently, the FDA has evolved their Product Specific Guidance further and modified the requirements for in-vitro testing. The FDA requirements for in-vitro testing continue to evolve and we carefully assess the ongoing evolution of the Product Specific Guidances for other products as well. The in-vitro bioequivalence pathway is complex and Acrux has shown that it has the capabilities of receiving FDA approvals based on this requirement, which a limited number of companies have demonstrated.

The market in which it competes, also called the addressable market, generates annual sales of US$15.8 million. There are 5 approved and marketed ANDAs in that market.

The product was launched in the second quarter of the 2024 calendar year by our partner TruPharma.

We also have a number of discussions underway for the licensing and commercialisation rights for this product in countries outside the United States.



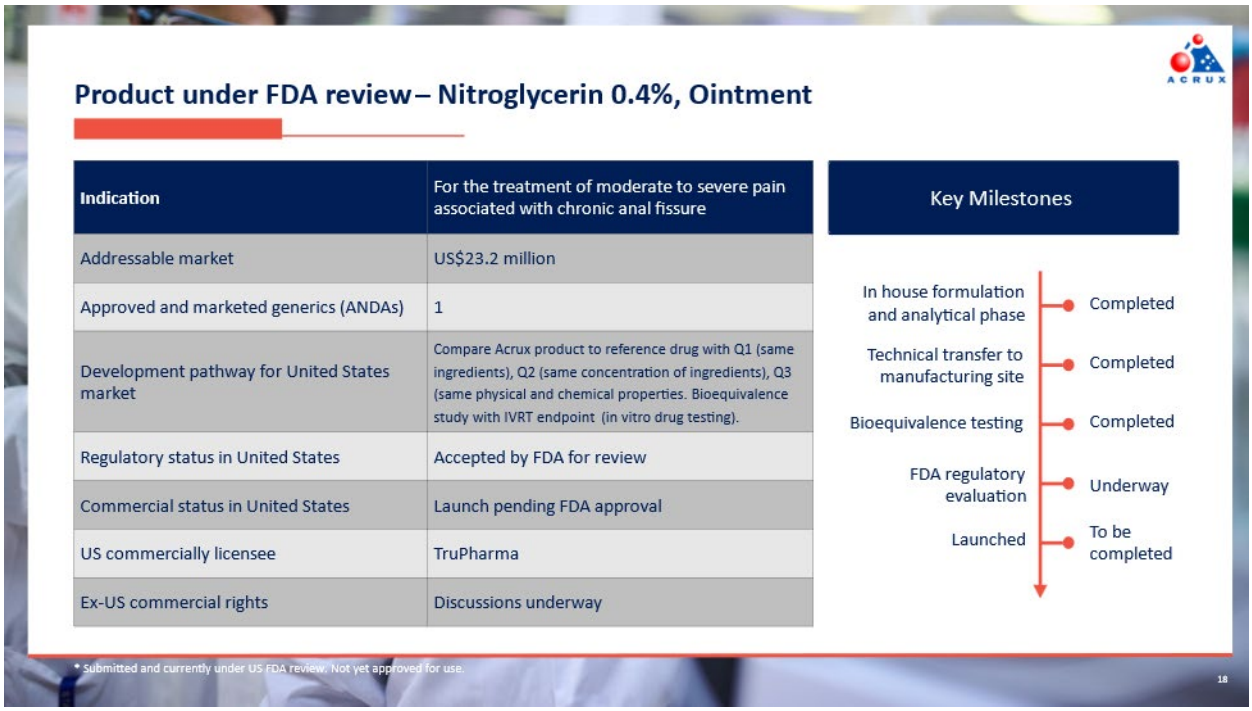
We also have a higher strength Dapsone product soon to be commercialised which is Dapsone 7.5%, Gel.

The product is also approved for use in the United States as a topical treatment for acne vulgaris in patients 9 years of age or older.

Similar to the previous product (Dapsone 5%, Gel), the FDA also mandated a complex bioequivalence pathway including in-vitro release testing compared to the United States Reference Listed Drug (RLD), in-vitro permeation testing also versus the RLD and other testing. More recently, the FDA has removed some requirements from the Product Specific Guidance further and by modifying the extent of in-vitro testing required.

The market in which it competes, also called the addressable market, generates annual sales of US$37.4 million. There are 5 approved and marketed ANDAs in that market. The product was approved in Q3, 2024 and we will launch our product into this market in the new year through our licensee TruPharma.

We also have a number of discussions underway for the licensing and commercialisation rights for this product in countries outside the United States.



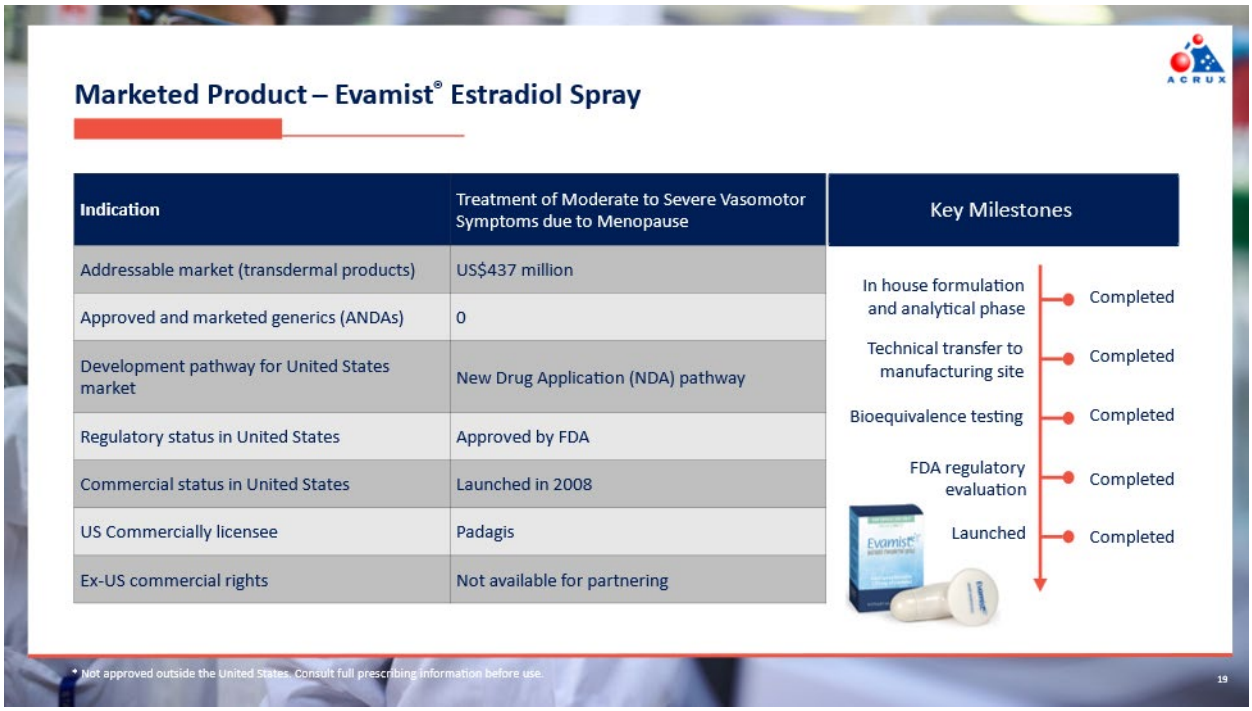
An additional product that is under FDA review is Nitroglycerine 0.4%, Ointment.

The branded reference product is approved for use in the United States as a topically applied treatment for moderate to severe pain from anal fissure. The Acrux product again requires complex in-vitro bioequivalence testing which Acrux performed to show bioequivalence compared to the reference product in its own Australian laboratories.

The market in which it competes, also called the addressable market, generates annual sales of US$23.2 million. There is 1 approved and marketed ANDA in that market.

The product is not yet approved by the FDA.

We also have a number of discussions underway for the licensing and commercialisation rights for this product in countries outside the United States.



One of our earlier approved products is Evamist® which is marketed by our licensee Padagis in the United States.

The product is approved for use in the United States for the treatment of moderate to severe vasomotor symptoms due to menopause.

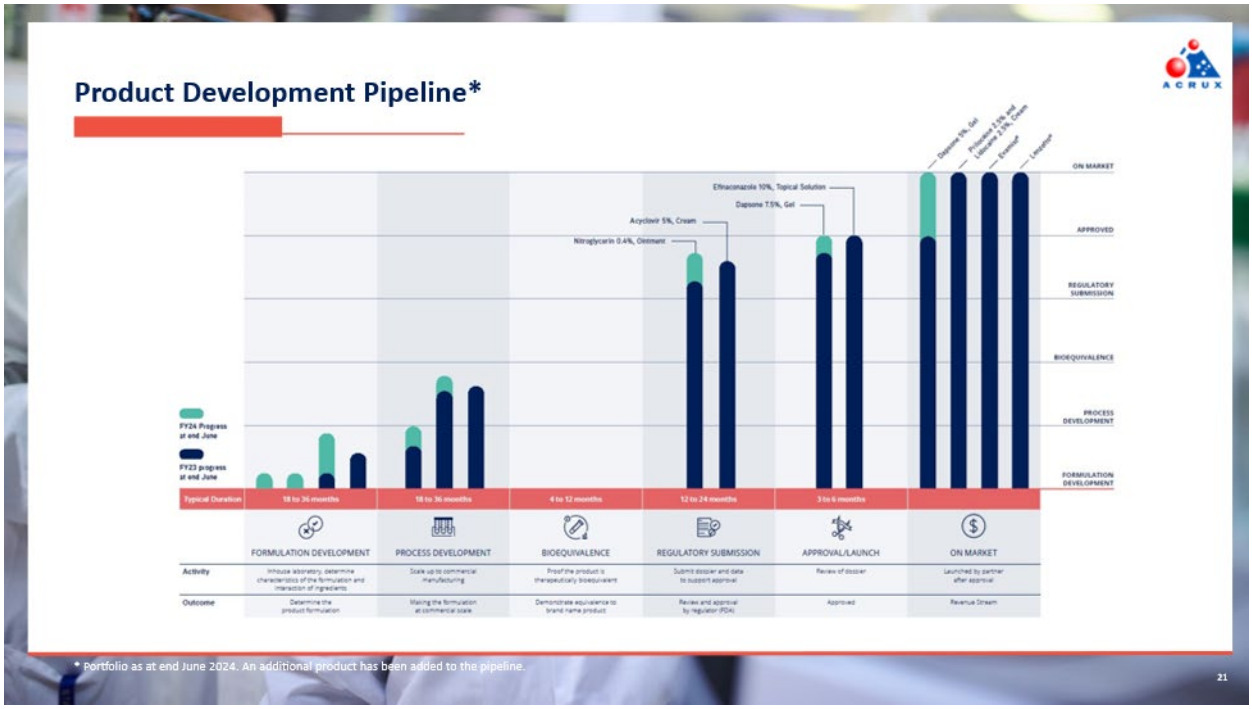
The market in which it competes, including other dosage forms of estradiol such as patches and gels generates annual sales of US$437 million in annual sales. There are many approved and marketed products in that market and sales of our product are relatively stable.

The commercial rights in most of the rest of the world, including Europe, for our similar product Lenzetto® are held by our licensee Gedeon Richter.

We currently have 3 revenue generating products and will launch 2 more products in the United States in the next 4 months. That is a good opportunity for the Company.

The addressable market, in Australian dollars, for annual sales of the generic products we have on market as well as the products we are about to launch, is approximately US$150 million.

In addition, we will continue to add products to our pipeline and to date this year we added 1 product in October and one earlier in the year in July.



Our pipeline is illustrated above, showing the stage of development of each product through to the commercialisation stage.

We disclose the details of the products which have been accepted for review by the FDA, those that have been approved and those that have been commercialised.

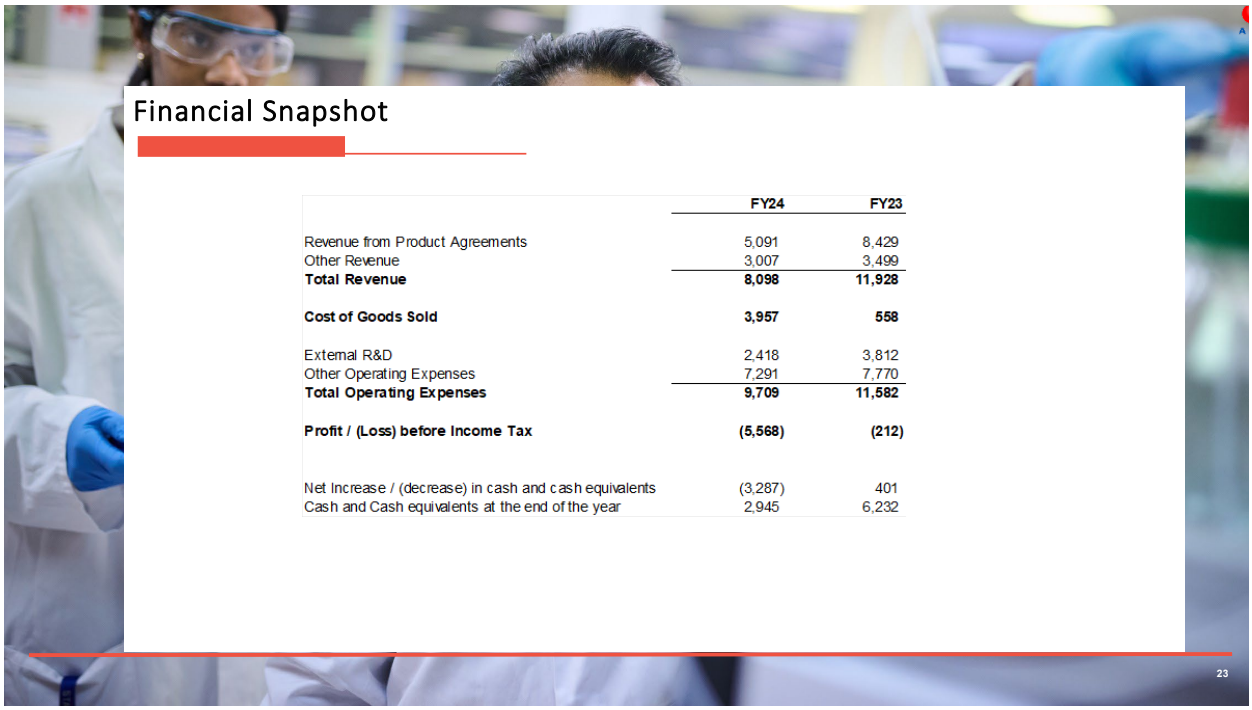
There are a further 7 products depicted on this slide with one additional product added in October to make 8 in development. The development projects which are in our development pipeline are at various stages of either formulation development or process development as can be shown by the size of the column for each product.

Our intention is to continue to progress products from early stage development through to FDA submission, review and ultimately commercialisation. Although we have focussed our development efforts on later stage products in recent times, as well as monetising the future royalty stream from Lenzetto® in early 2023 and divesting our testosterone product in mid 2024, our intention is that we will maintain a balanced number of products through the various stages of development, so that a regular number of products reach commercialisation and add to our growing recurring revenue stream.

We also intend to leverage our development efforts into new territories as evidenced by the commercial discussions that are underway for products in markets outside the United States.

I now invite our Chief Financial Officer, Joanna Johnson, to present the FY24 financial results of the Company.

Joanna Johnson – CFO and Company Secretary



Thanks Mike and good morning everyone.

The generation of revenue from product agreements is key to Acrux's long term success.

FY23's revenue includes EUR4.1 million / AUD6.3 million for the monetisation of advance royalties for Lenzetto®.

FY24's revenue reflects our partners' sales of Prilocaine and Lidocaine Cream as well as Estradiol Spray.

Revenue growth is expected for FY25 and beyond following the launch of Dapsone 5%, Gel in the second quarter of this calendar year, plus the impact of 2 products planned to be launched within the next 4 months, including Dapsone 7.5%, Gel which was approved by the FDA in August 2024.

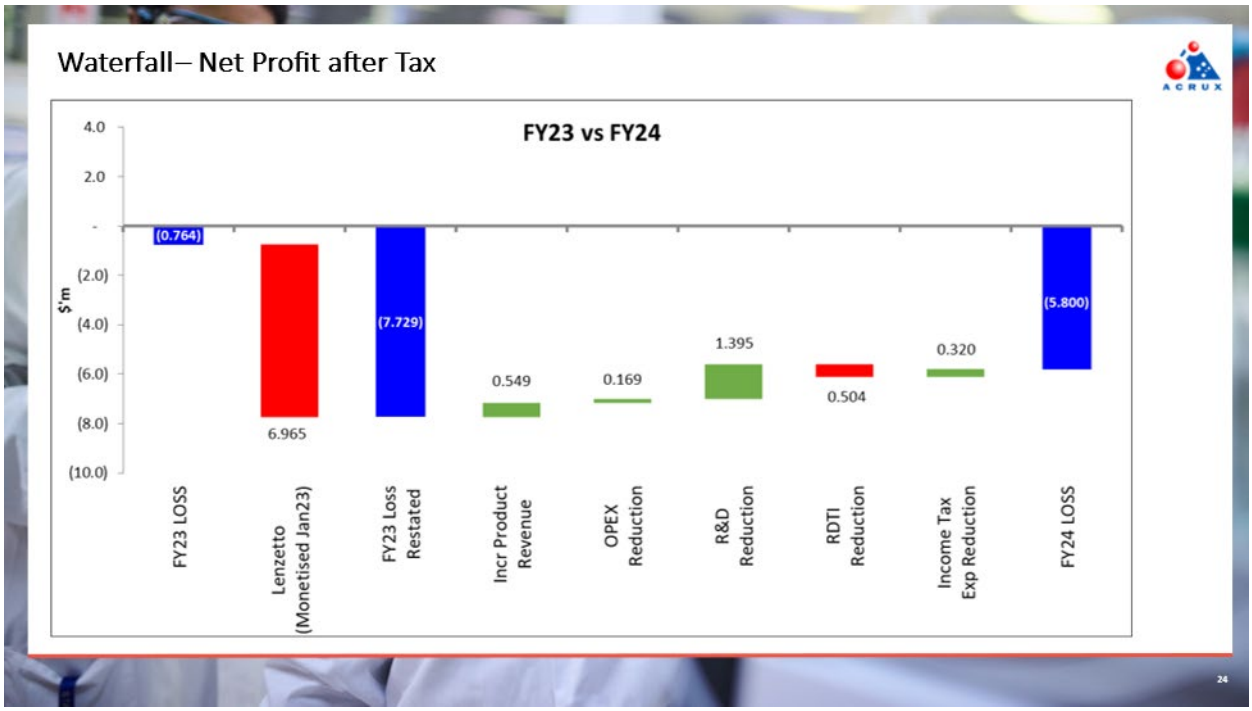
Other Revenue reflects RDTI which will vary from year to year depending on the level of eligible domestic and overseas R&D expenditure. In June 2024 we entered a short term funding facility for this receivable balance and these loan funds were repaid in full in October following receipt of the RDTI rebate from the Australian Tax Office.

Cost of Goods Sold is a pass through expense relating to the purchase of API to maximise continuity of supply and support the manufacture of Prilocaine and Lidocaine cream during FY23 and FY24. Padagis have now assumed responsibility for this procurement and our involvement in purchasing and coordinating API has ceased.

Our Revenue growth supports ongoing investment in our product pipeline through external R&D expenditure which varies from year to year due to the stages of the products in the pipeline. Typically, the more costly phases are conducted at our CMO's just before dossier submission to the FDA where we are most actively engaged in proving bioequivalence of our products to the branded equivalent and scaling up manufacture to commercial scale.

Salaries and Oncosts comprise approximately 2/3 of our Other Operating Expenses. We are not a virtual company and have 32 employees, including 25 technical staff who are employed in our laboratories in West Melbourne. As these technical staff are responsible for determining the formulation for each of our development products as well as managing the development of each product and dossier submission most of these salary costs are eligible for RDTI claims.

In FY23 we generated a net increase in Cash and cash equivalents due to the Lenzetto® royalty monetisation and our investment in our product pipeline resulted in a net reduction in cash reserves for FY24.



This slide highlights the progress towards Acrux's objective of sustainable revenue growth from the currently marketed products, Prilocaine and Lidocaine Cream, Dapsone 5%, Gel and Evamist®.

Firstly, we have excluded the impact of Lenzetto®, specifically the FY23 royalties received and the onetime impact of monetising the future royalty income, in order to restate FY23 to be comparable to FY24.

Therefore, excluding the impact of Lenzetto®, Total Revenue from Product Agreements for FY24 increased by $549 thousand to $5.091 million due to revenue derived from Prilocaine and Lidocaine Cream and which is expected to continue to grow as new products are launched.

It is also important to note that R&D Expenditure, and therefore RDTI Income, was lower in FY24. This is due to the stages of product development with typically lower expenditure in the initial stages of formulation and also at the time of dossier review by the FDA. This is a timing difference and our expenditure varies as projects reach the stage where we are working on bioequivalence and pilot batches with our contract manufacturers.

Thank you, I will now hand back to **Michael** to conclude the presentation.

To summarise our presentation, Acrux has a strong track record of developing and commercialising products. We have had 5 products approved since 2021 and we have had 2 recent product launches that will be joined by an additional two new products in the next 4 months. We look forward to executing these launches.

Our pipeline is strong and progressing and we are close to a tipping point in terms of our goals to grow recurring revenue streams and to generate consistent positive cash flow for our Company.

In closing, I would like to thank our shareholders for their support of the Company and also Acrux's employees and the Board for their continued efforts and focus on moving our products through development phases to commercialisation.

The whole Acrux team looks forward to the opportunities and challenges ahead.