ASX Release

23 November 2022

Address of Chairman and CEO to Annual General Meeting

Melbourne, Australia; Acrux Limited (ASX:ACR): 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 from 10:00am this morning.

Authorised for release by the Board of Acrux Limited.

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About Acrux

Acrux (ASX: ACR) is a pharmaceutical company dedicated to developing and commercialising topical pharmaceuticals. Drawing on 25 years of experience and using in house facilities and capabilities, Acrux has successfully developed and commercialised through licensees a number of topically applied pharmaceutical products in the US and Europe. Acrux is developing of a range of generic products for the US market by leveraging its on-site laboratories, GMP manufacturing suite, clinical and commercial experience to bring affordable products to market. Acrux encourages collaboration and is well positioned to discuss partnering and product development.

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

Acrux Ltd
Annual General Meeting Presentation
23 November 2022

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

Today it is my pleasure to welcome shareholders and guests to Acrux's 2022 Annual General Meeting, which this year is being conducted in a hybrid format with some shareholders attending in person and others joining us virtually.

All shareholders will have the same opportunity to participate in this meeting, including voting and the ability to ask questions.

Today I am joined by my fellow Directors:

- Our Chief Executive Officer and Managing Director, Michael Kotsanis
- Non-executive Directors: Geoff Brooke, Tim Oldham and Don Brumley

Also attending today are

- Our CFO & Company Secretary – Joanna Johnson
- Our auditor, Nick Bull from Pitcher Partners and
- Representatives of our Share Registry - Link Market Services

The agenda for today's Meeting is as follows:

- Firstly, I will present my address
- Following that Michael Kotsanis will present his review of activities
- We will then proceed to the formal business of the Meeting

Address

We enter our 25th year at a pivotal point in the Company's transformation as we grow our revenue from currently marketed products, as well as progress our near-term product development candidates through the regulatory approval process and into commercialisation.

Acrux has three commercialised topical products, two products nearing regulatory approval and an additional product that has recently been accepted for review by the FDA. Acrux expects to receive regulatory approval for two of its topical generic products this financial year. This will lead to further product launches as all products under FDA review have existing commercial licensing arrangements in place.

We are advancing our product pipeline through the varying stages of development, either at Acrux or with our contracted manufacturing partners. Our main priority is on

later stage projects that will reach commercialisation in the short term, while continuing development of earlier-stage topical generics to ensure breadth of our product pipeline.

The Company now has 16 products in its portfolio, including 5 approved products and 3 dossiers currently being reviewed by the FDA and we intend to maintain a development pipeline of 10–12 topical generic products. Since the date of the last Directors' Report, we added 1 new development project to the pipeline and ceased development on 2 projects where it was considered that the estimated future commercial returns were unlikely to adequately cover development costs. This is a normal and expected outcome of our continuous portfolio review process.

Our operational structure has the processes in place to deal efficiently and effectively with our organisational priorities to achieve our revenue generation targets.

Our three key priorities are:

1. Revenue realisation
2. Operational efficiency
3. Optimal portfolio management

Revenue realisation is the transformation driver for the Company. We have one product which has been approved with prelaunch activities in progress and there are a further 2 products which are in late-stage review by the FDA. Each of these products has a commercial licensee in place. We're continuing development of earlier-stage products to maintain the depth/breadth of our pipeline.

Operational efficiency, supported by resource and cost management will deliver a diversified portfolio of products to commercialisation, with revenue generation over the next three years.

Portfolio management based on strategic product selection will maximise commercial returns. Consistent intelligence gathering and assessment in a rapidly changing product and market landscape is a key component of successful portfolio management.

The Company has invested to procure and maintain the necessary blend of skills, knowledge and experience to deliver on our key priorities.

BOARD AND CORPORATE GOVERNANCE

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

The Board also reviewed the skills that each Director brings to the Board through the Board Skills Matrix. This is a necessary process to identify potential gaps in Board skill sets, areas for improvement and future skill requirements.

The Directors consider that Acrux has complied with all applicable environmental laws and regulations throughout the year ended 30 June 2022.

The Company promotes a supportive, equitable and inclusive culture where the need for diversity is recognised.

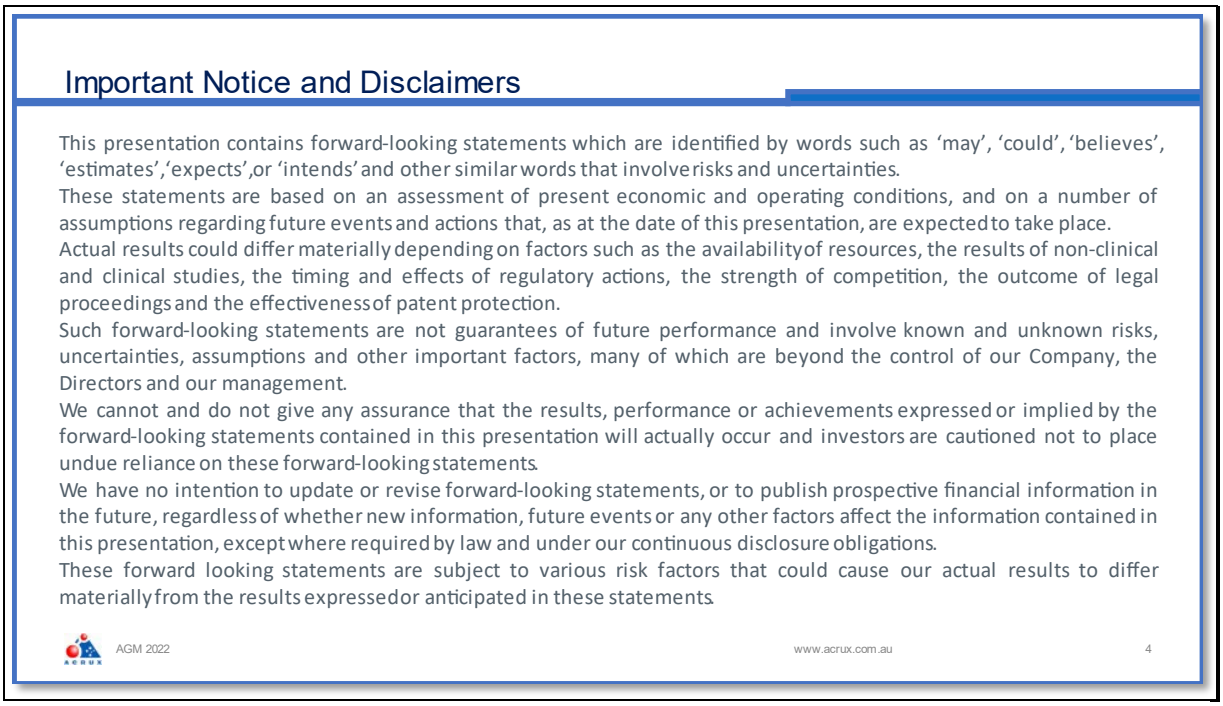
I will now hand over to Michael Kotsanis to provide the CEO's report.

CEO's Address

Thanks Ross.

Good morning and thank you for attending this year's Annual General Meeting. We welcome your attendance today and your participation.

Before I start, I refer you to our Disclaimer Statement which is included in this slide deck.



Important Notice and Disclaimers

This presentation contains forward-looking statements which are identified by words such as 'may', 'could', 'believes', 'estimates','expects',or 'intends' and other similar words that involve risks and uncertainties.
These statements are based on an assessment of present economic and operating conditions, and on a number of assumptions regarding future events and actions that, as at the date of this presentation, are expected to take place.
Actual results could differ materially depending on factors such as the availability of resources, the results of non-clinical and clinical studies, the timing and effects of regulatory actions, the strength of competition, the outcome of legal proceedings and the effectiveness of patent protection.
Such forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of our Company, the Directors and our management.
We cannot and do not give any assurance that the results, performance or achievements expressed or implied by the forward-looking statements contained in this presentation will actually occur and investors are cautioned not to place undue reliance on these forward-looking statements.
We have no intention to update or revise forward-looking statements, or to publish prospective financial information in the future, regardless of whether new information, future events or any other factors affect the information contained in this presentation, except where required by law and under our continuous disclosure obligations.
These forward looking statements are subject to various risk factors that could cause our actual results to differ materially from the results expressed or anticipated in these statements.

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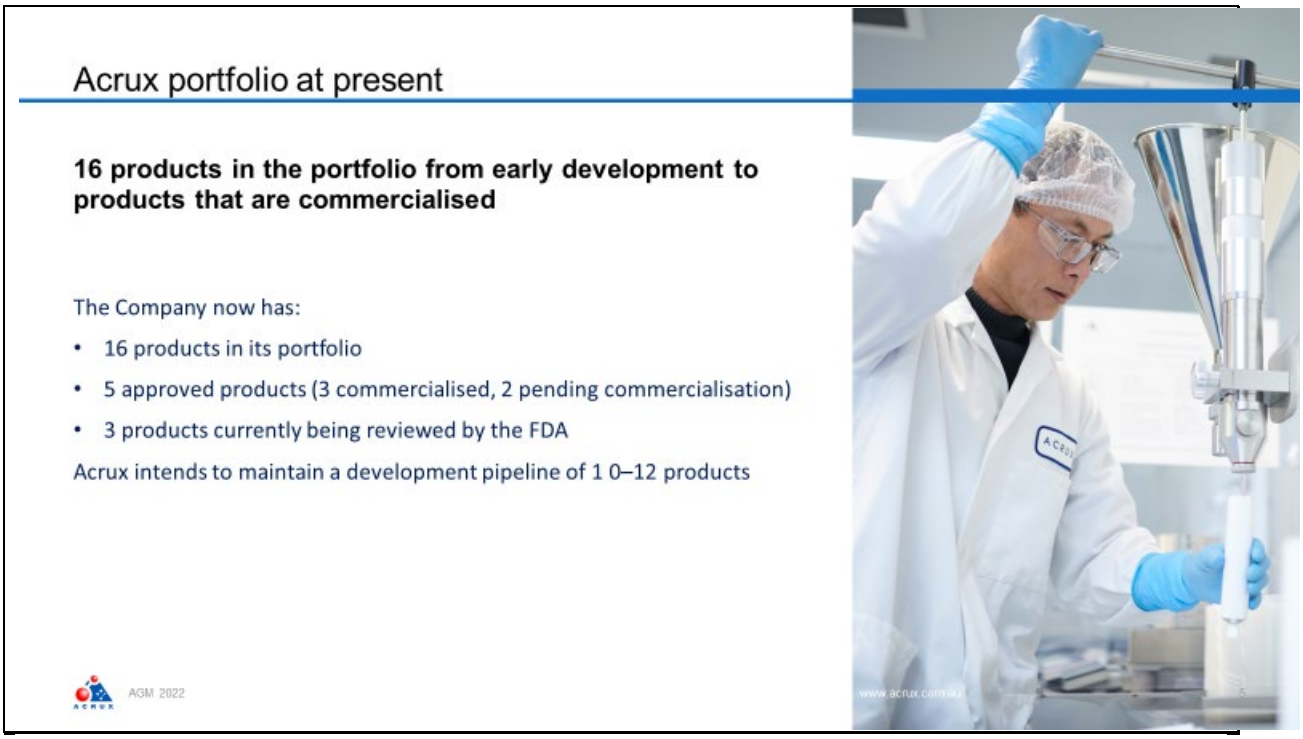
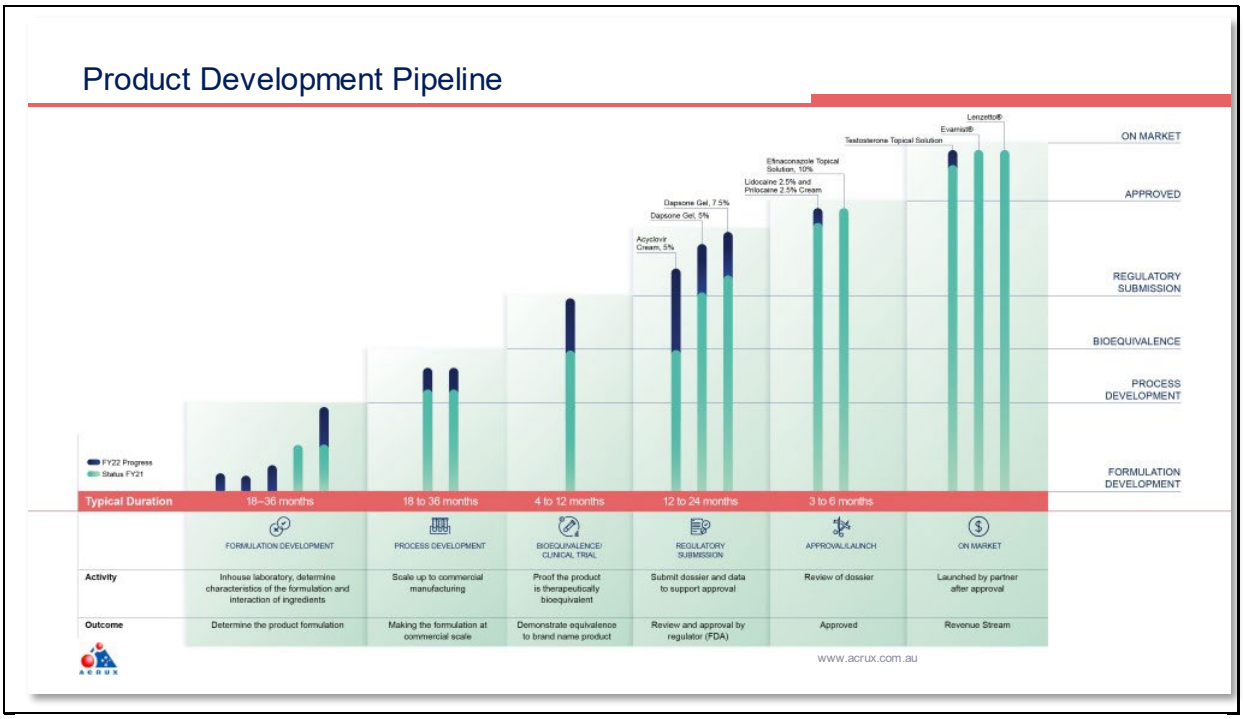


At present, Acrux has 16 products in its portfolio, ranging from early stage development projects through to commercialised products

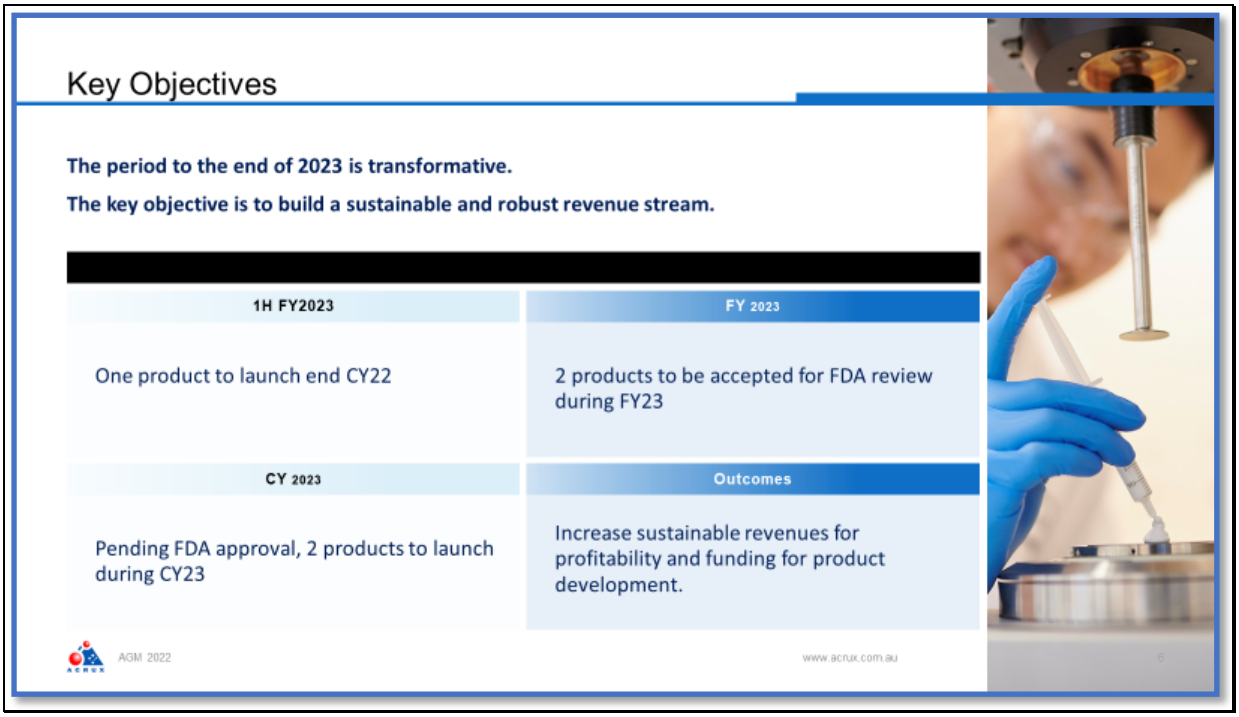
We have a total of 5 products that have regulatory approval, 3 of which have been launched and two products that are awaiting launch.

Three of our topical generic products are currently under FDA review, being dapsone 7.5% gel, dapsone 5% gel and acyclovir cream.

Our intention is to maintain a development pipeline of 10-12 products, which range from early stage development where we are establishing the project plan, through to products which are currently under FDA review. It is worth reinforcing that 11 of our 16 products have existing commercial license contracts in place.



Our portfolio of products and the various stages of development, regulatory review and commercialisation are shown on this table. Importantly, the dark blue shows progress over the prior year. The table can also be found in our Annual Report.



The year 2023 is a transformative year for the Company. Our primary objective has been and continues to be to build a sustainable and robust revenue stream derived from a range of commercialised products. Today we have three products commercialised, with the bulk of our revenue driven by Lenzetto® which is marketed by our Licensee Gedeon Richter in over 40 countries.

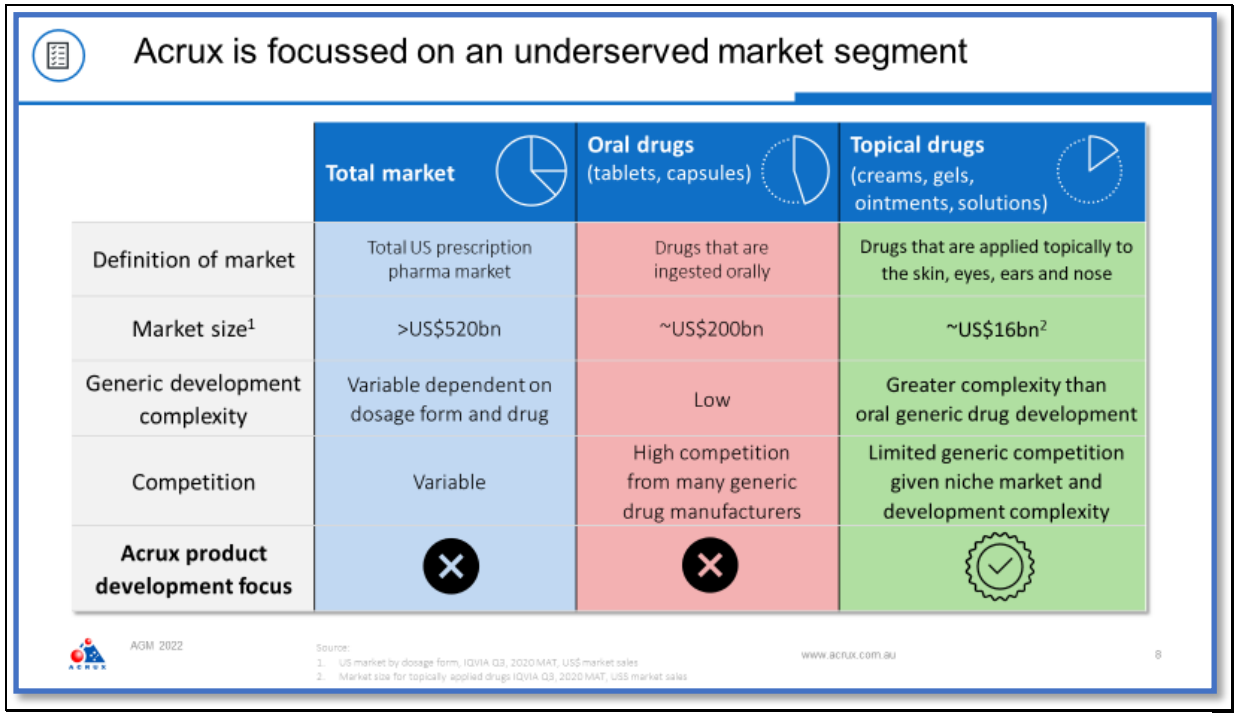
We expect to launch an additional product through our licensee Padagis in the United States market by the end of 2022. During the current financial year, we expect to have 2 topical generic products accepted for review by the FDA, one of which is acyclovir cream, which has already been submitted and accepted for review and was announced to shareholders in August this year.

During the 2023 calendar year we intend to launch 2 additional products, both of which are pending FDA approval. The products that we have under review by the FDA include dapsone gel 7.5%, which was accepted for review by the FDA in April 2021. We also have a second dapsone product, which is a 5% gel that was accepted for review by the FDA in September 2021. Both products target the significant acne market in the United States. For both products, the FDA has recommended a combination of *in vitro* and *in vivo* studies with pharmacokinetic endpoints.

Importantly, for both products we have successfully completed *in-vitro* permeation testing, also known as IVPT, to demonstrate bioequivalence. This is recognised in the pharmaceutical industry as a very challenging technical hurdle and we are very pleased with the bioequivalence evidence we have achieved for both products. We believe this is becoming a core and unique competence that differentiates us from others in the topical generic field.

We have also had our acyclovir cream product accepted for review by the FDA in August this year.

[Introduce management team]
In addition to our Management Team, we have 25 extremely capable scientific staff who have continued to work hard to progress our products through the development process to regulatory approval.



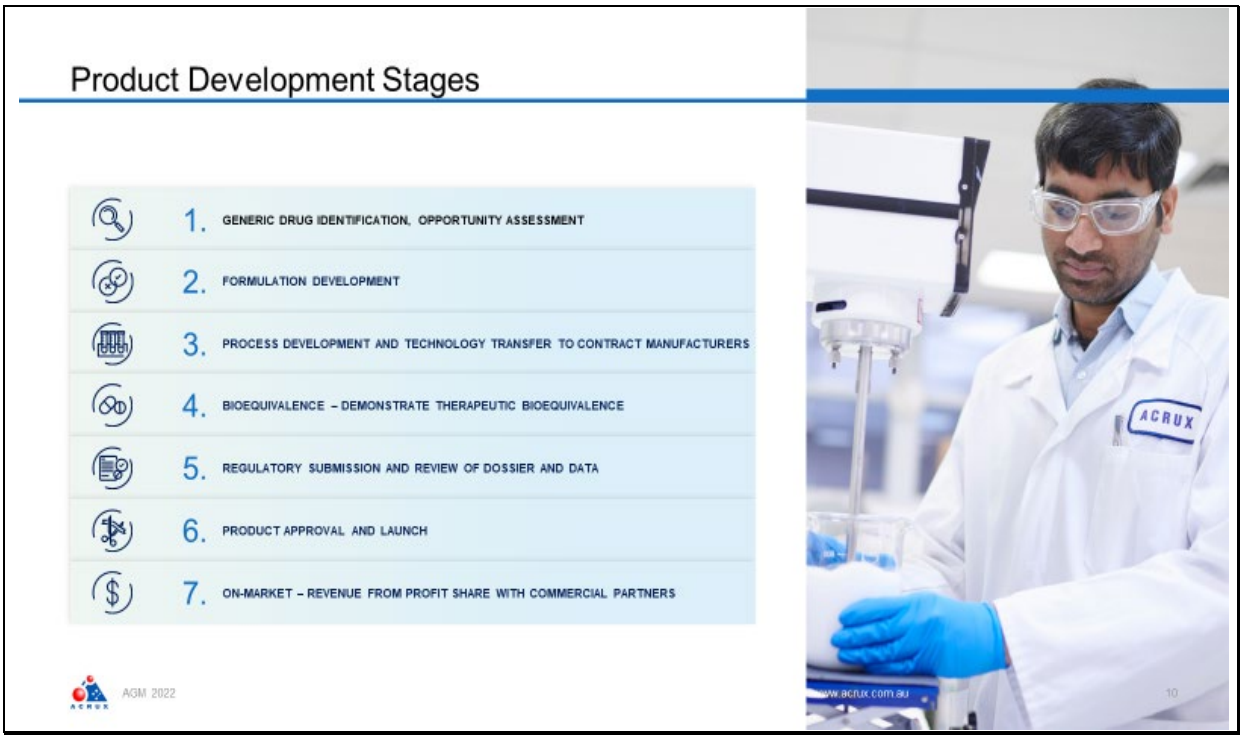
We believe the topical pharmaceuticals market is substantially differentiated from the other larger segments of the total US pharmaceuticals market.

The total market (which excludes Covid 19 vaccines) in the United States generates over US$520 billion in annual sales based on IQVIA data. The market for oral tablets and capsules forms the largest segment of the total market and generates approximately US$200 billion in sales. In the United States, 90% of prescriptions dispensed to patients for tablets and capsules are for generic products. Branded products in the United States rapidly lose market share to generic competition once the generics are launched. The market for oral tablets and capsules contrasts with the smaller and less competitive market for products that are applied topically onto the skin or some type of mucosa such as the eyes, ear, nose or rectum. The topical market generates approximately US$16 billion in sales, but has a lower level of generic competition and market penetration than is experienced in the oral market.

Differentiating factors for the oral market compared to the topical market are the overall size of the market, the relative size of individual products, the differing dosage forms and the more complex development processes and methods for demonstrating bioequivalence of the generic product to the on-market brand. Oral generic drugs are often approved on the basis of pharmacokinetic studies that compare the branded product to the generic product. The oral products that have generic competition generally experience heavy substitution by those generics in the United States.

For topical drugs there are significant barriers to market entry including the wide variety of techniques that the FDA requires to demonstrate bioequivalence as a precursor for FDA approval and in which Acrux has, and continues to develop leadership. These include *in vitro* permeation testing and *in vitro* release testing, both of which are challenging techniques to master and with which Acrux now has considerable experience, after having repeatedly demonstrated success with both. The FDA also recommends that applicants conduct pharmacokinetic studies, clinical endpoint studies and vasoconstrictor studies for some products that are applied topically. These methods are recommended by the FDA for applicants to demonstrate bioequivalence as well, depending on the type of dosage form, the indication (or use) of the product and the systemic absorption profile of the (topically applied) product.

This topical pharmaceutical market segment is the exclusive focus of Acrux as it reflects our depth of experience and specialised skill sets. We believe that this segment is an underserved segment of the US generic pharmaceuticals market.



Our business model is summed up by this slide. We spend a significant amount of time evaluating different products as potential product development candidates. All of the products we assess are topically applied prescription pharmaceutical products which are marketed in the United States. Our assessment of a product candidate includes a commercial and patent assessment, a technical feasibility assessment as well as an overall financial assessment.

Once we identify and assess a product for development, we begin the analytical and formulation work that underpins our scientific development process. We routinely engage with the FDA. We do this through Controlled Correspondences, pre-submission meetings and pre-development meetings with the FDA under their processes for industry engagement. We note that recently, the FDA has acknowledged the need for greater industry engagement [under the FDA GDUFA III Commitment Letter].

Once our analytical and formulation work is at an advanced stage, we contract an FDA approved manufacturer to transfer our formulation knowhow in what is termed a technology transfer to this manufacturer for the product. The data we generate from batches of our product that are manufactured at the contract manufacturer are then included with our analytical and formulation development reports, as well as our bioequivalence studies which are then submitted as part of the dossier provided to the FDA for review. Our development process for each product is governed by a well documented project plan. These project plans guide our teams on the development steps for each product under development.

Our licensing deals with companies that market generics in the United States are for the rights to commercialise and sell our products in the United States after the products are approved by the FDA. These licensing contracts will generate the recurring revenue that will drive our business forward. Our business model's success will be demonstrated when recurring revenue streams consistently exceed our R&D expenditure necessary to develop new products. With our growing revenue streams from existing products, products close to receiving FDA approval and subsequent launches, we are on the cusp of achieving this.

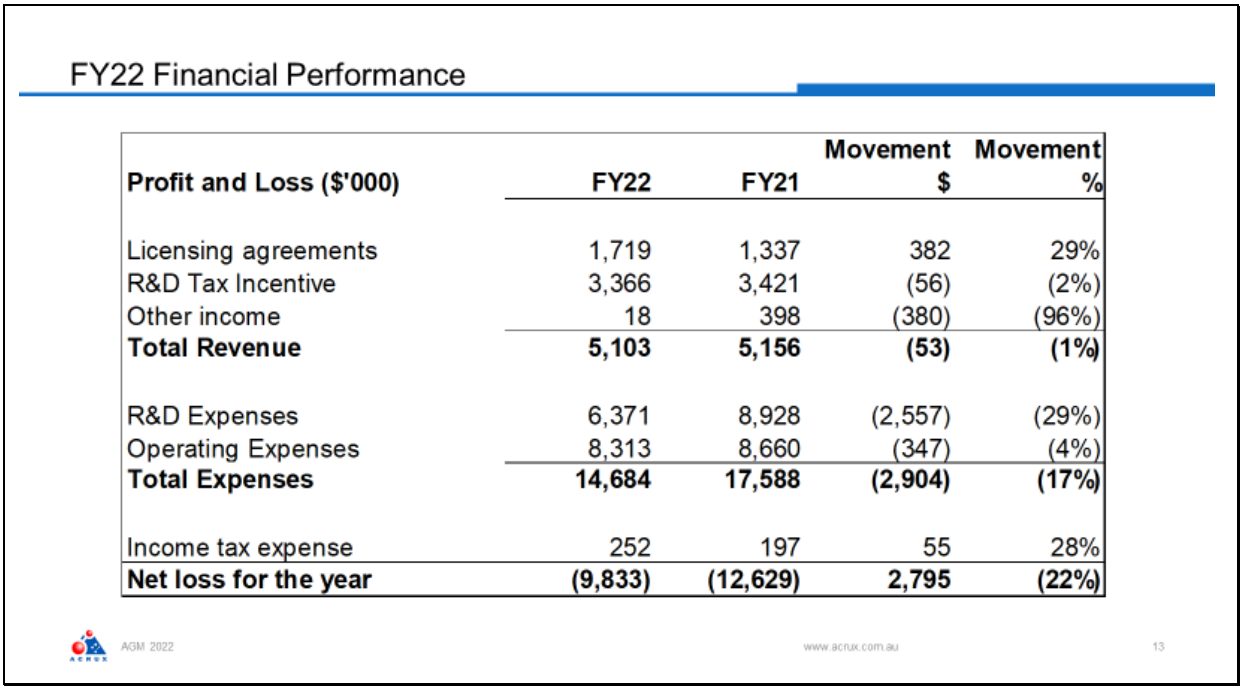
Acrux currently markets three of its products through three different licensees. Padagis markets Evamist® in the United States and will soon launch another product that Acrux has developed. Gedeon Richter markets Lenzetto® in over 40 countries and the revenue that Acrux received grew by 35% last financial year over the prior corresponding period. Our Testosterone Solution product was launched by our licensee Dash Pharmaceuticals in August 2021 and most of our later stage development products have already been licensed to generic marketing companies for distribution in the United States.

Our products in development are initially exclusively targeting the United States market for topically applied prescription pharmaceuticals. One additional point I would like to make is that we are approached regularly by companies seeking licenses to our topical products for commercialisation in countries outside the United States and we will continue to explore the benefits of working with these companies on a case by case basis. The potential commercial benefit that Acrux could receive from these discussions needs to be balanced against the additional effort required to

conduct the development work that is usually needed to register products in markets outside the US.

We are at an exciting stage of Acrux's transformation as we are now beginning to commercialise a range of additional products. Our launch planning is underway for these further product launches and we are looking forward to these additional FDA approvals and subsequent product launches in the near future.

I will now hand over to our Chief Financial Officer and Company Secretary, Joanna Johnson to discuss the FY22 financial outcomes for the Company.



FY22 Financial Performance

Profit and Loss ($'000)	FY22	FY21	Movement $	Movement %
Licensing agreements	1,719	1,337	382	29%
R&D Tax Incentive	3,366	3,421	(56)	(2%)
Other income	18	398	(380)	(96%)
Total Revenue	**5,103**	**5,156**	**(53)**	**(1%)**
R&D Expenses	6,371	8,928	(2,557)	(29%)
Operating Expenses	8,313	8,660	(347)	(4%)
Total Expenses	**14,684**	**17,588**	**(2,904)**	**(17%)**
Income tax expense	252	197	55	28%
Net loss for the year	**(9,833)**	**(12,629)**	**2,795**	**(22%)**

Thanks Michael.

Thankyou to all shareholders who join us today. This slide summarises our financial performance for FY22 and importantly, shows that revenue from licensing agreements increased by 29% and the reported net loss declined by 22% due to:

- Meaningful growth in income from product licensing arrangements from both existing and new products and
- Closely managed operating and project based expenses

Additionally:

- Whilst reported Research and Development Tax Incentive income ('RDTI') was consistent on a year on year basis, an additional $454k has been received in FY23 for the FY22 Overseas Finding ('OSF'), which was not

accrued as at 30/6/22 due to uncertainty in the value and timing at the time. A total of $3.742m has been received for FY22 RDTI.

- Other Income declined due to the one time receipt of the JobKeeper support entitlement received from the Federal Government during FY21.

Reported Cash Reserves were $5.831m as at 30 June and $3.329m as at 30 September.

Acrux expects to deliver on its indication of increasing cash reserves during the current December quarter. Of the $3.742m FY22 R&D Tax Incentive Rebate received, $2.749m was received in the December Quarter. Additionally, revenue from client contracts continues to grow and these combined inflows are expected to exceed cash outflows during this period.

Looking beyond December, our forward cash projections reflect new sources of operating revenue to be derived from the products launched in CY 2022 and CY 2023.

I now hand back to Michael for the conclusion of the presentation.

In summary, Acrux has:

- Increasing revenue from marketed products
- A broad product development pipeline
- FDA approval received for 3 products in 2021
- An additional product launch planned in 2022
- A strong and experienced management team
- A robust track record of developing and launching products

In closing, I would like to thank our shareholders, the Acrux team and the Acrux Board for their efforts and support of the Company.

I would like to personally thank the Acrux team of employees and the Board for their continued efforts and focus on moving our products through the development and into the commercial phase. The Acrux team is looking forward to the opportunities and challenges ahead.