ASX/Media Release

20 December 2018

Excellent progress in 2018, approaching commercialisation in 2019

Melbourne, Australia; 20 December 2018: Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**") is pleased to release an end of year update and operational review. During calendar year 2018 Acrux made excellent progress across all key operational aspects and is well positioned to meet its objective of beginning commercialisation of the topical generic portfolio in 2019.

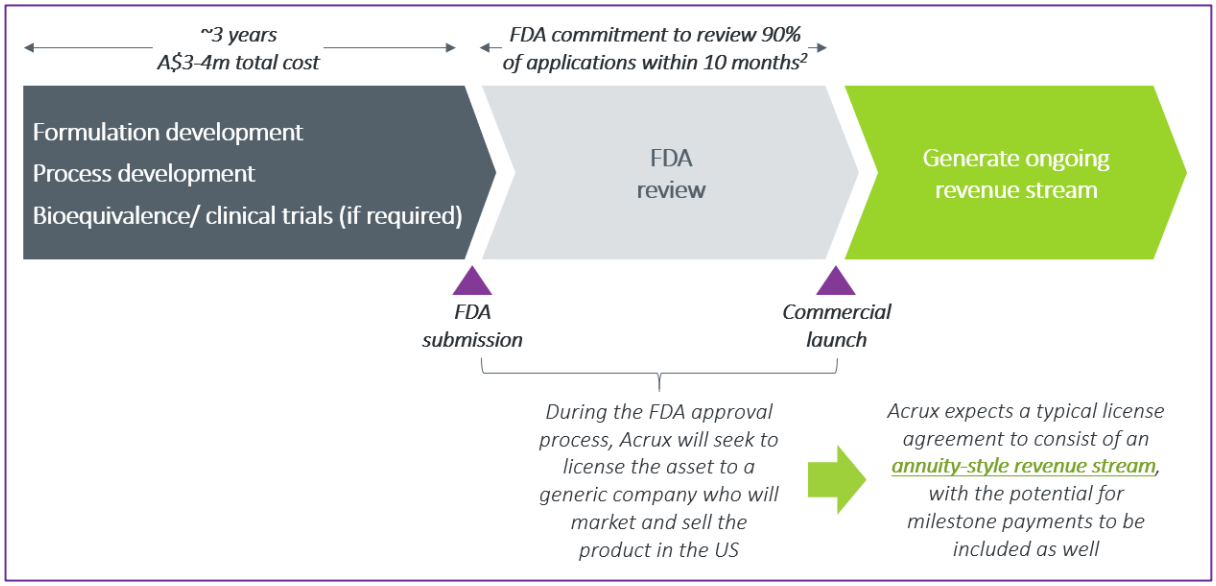
ACHIEVEMENTS AND HIGHLIGHTS IN 2018

- Successfully submitted two Abbreviated New Drug Applications (ANDA) to the FDA:
  - A generic version of Julia® (efinaconazole)
  - A generic Testosterone Topical Solution
- Engaged additional FDA-approved Contract Manufacturing Organisations
- Expanded generic topical portfolio from 10 to 13 products:
  - Market screening to identify high potential topical products
  - Successful formulation development of multiple products in the portfolio
- Commercial interest in the portfolio from several parties

ACRUX IS RAPIDLY APPROACHING COMMERCIALISATION OF ITS PORTFOLIO

As products near FDA submission, it is important to recognise the near-term nature of the associated revenues. The below diagram illustrates Acrux's typical commercialisation pathway for a drug in its development portfolio. This commercialisation pathway is representative of 11 of the 13 products in the topical portfolio[1].

Figure 1: Illustrative generic drug development pathway

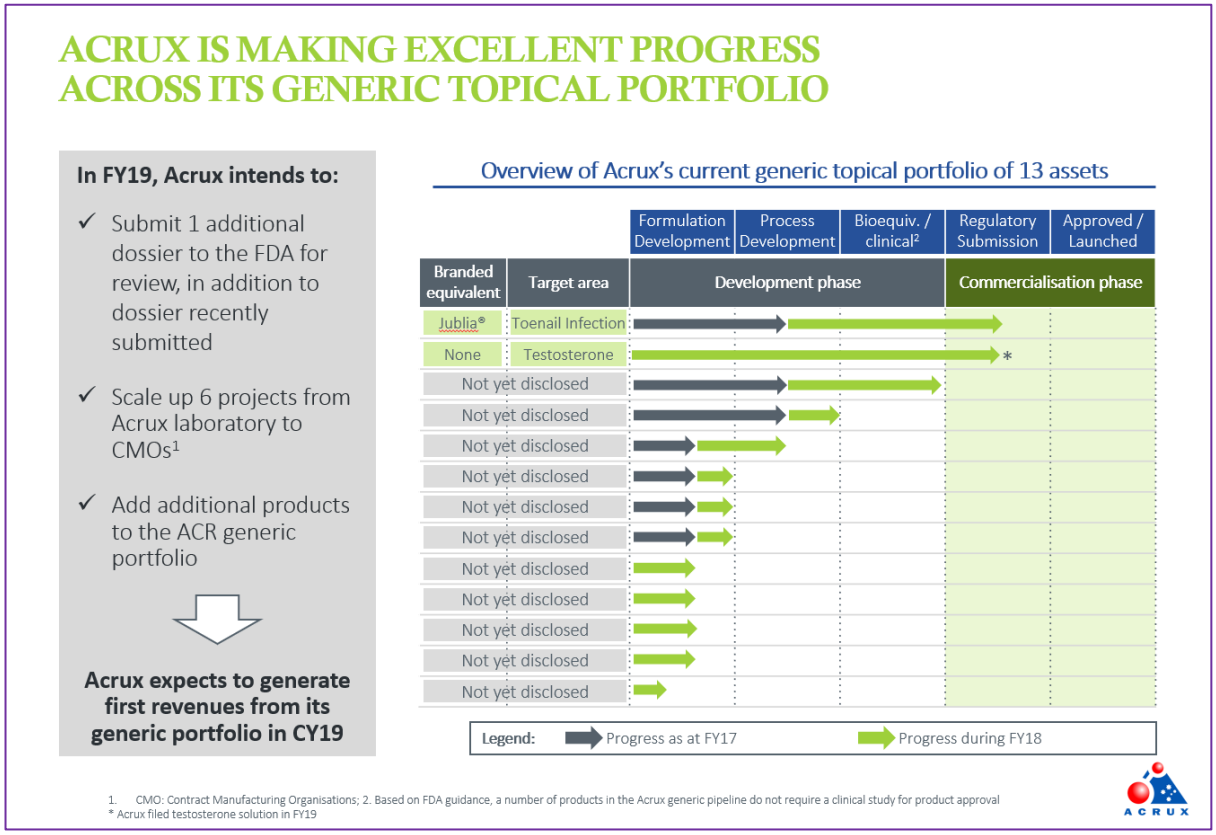


[1] Two products will include a Paragraph IV Abbreviated New Drug Application to the US Food and Drug Administration (FDA), which may include an additional litigation process not shown in Figure 1.

[2] The FDA has committed to review 90% of ANDA applications within 10 months. ANDA approval will follow if the FDA is satisfied during the review process.

EXCELLENT PROGRESS MADE ACROSS THE TOPICAL GENERIC PORTFOLIO

Figure 2: Recap of progress across topical generic portfolio – shared at 2018 AGM



Jublia FDA submission:

In August 2018, Acrux announced the acceptance of the ANDA submission for review by the US Food and Drug Administration (FDA) for a generic version of Jublia® (efinaconazole) topical solution. The FDA's acceptance represented a key milestone for Acrux, being the first of 13 generic compounds in the Company's pipeline to reach this stage of development.

Testosterone Topical Solution submission:

Marking the second milestone of its kind for Acrux, the Company announced in October 2018 that the FDA accepted for review the ANDA submission for its generic product based on Perrigo's Testosterone Topical Solution. The FDA has committed to review and act on 90 percent of all complete electronic ANDAs within 10 months after the date of submission. Once approved by the FDA, Acrux will be able to commence marketing and sales for the product in the United States. The market is currently occupied by 4 other generic versions with no branded products in existence. Acrux is having ongoing discussions with potential commercial partners.

Continued progression of drug development portfolio:

During the calendar year, Acrux successfully expanded its generic topical portfolio from 10 to 13 products, headlining strong recent developmental progress and demonstrating effective execution of operational strategies.

OUTLOOK

Following the successful achievement of operational objectives in CY18, Acrux remains strongly positioned for continued progress in CY19. The company has made excellent progress across its near term objectives and is on track to meet all expectations set:

Near Term Objective	Timing	Progress
Submit two additional dossiers to the FDA for review	FY19	1 dossier submitted in FY19 (Efinaconazole was submitted prior to FY19)
Scale up 6 additional projects from laboratory stage to CMOs	FY19	On track
Add further products to the ACR generic portfolio	FY19	New high value opportunities have been identified for inclusion into the portfolio.
First revenues from the generic portfolio	CY19	Discussions with potential partners are ongoing

Acrux CEO and Managing Director, Michael Kotsanis said:

"We are pleased with the strong operational performance achieved by the Company in 2018. The acceptance for review from the FDA for our first two generic products highlights the significant progress made in the transformation of Acrux this year.

Our R&D and product development teams continue to achieve their operational targets and we are confident in the progression of our generic product portfolio towards commercialisation in 2019."

For more information, please contact:

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About Acrux

Acrux (ASX: ACR) is a pharmaceutical company dedicated to developing and commercialising topical pharmaceuticals. Incorporated in 1998 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