

ACRUX GENERIC STRATEGY AND AXIRON PATENT LITIGATION UPDATE

Acrux generic pipeline

In mid-2015, Acrux (ASX: ACR) embarked on a new strategy leveraging its existing capabilities as it began development activities on a pipeline of topical and transdermal generic products. The generic pipeline is being developed in addition to our activities developing topical specialty products, in particular our onychomycosis development project for the treatment of fungal infections of the nail bed. Acrux has traditionally reformulated generic drugs incorporating an improved delivery profile that has provided new intellectual property and forms part of our topical specialty product portfolio. The key difference with our new generic program is that we are not developing new formulations to create new intellectual property. Our expertise is being used to recreate formulations of proven actives that have an existing market position and an attractive commercial profile.

We are excited by the potential of this generic portfolio and are pleased to confirm that product formulation and development activities are progressing to plan. We have completed formulation development activities for our first three generic projects and are now moving forward with scale up plans. Identification and selection of contract manufacturing organisations for these products is proceeding in parallel and manufacture of our first exhibit batches is expected to occur in FY2017.

The Board approved a budget allocation for the development of this generic pipeline, based on attractive projected internal rates of return, with a collectively lower risk profile and faster pathway to approval than could be achieved with product development of new chemical entities. Each of the topical or transdermal generic products in the pipeline has been assessed for its commercial prospects in the US market. Collectively, annual sales of topical and transdermal products in the US exceeds US\$18 billion of sales. The addressable annual market in the US for the first three topical generic projects in our program is collectively over US\$500 million.¹

Acrux has continued to evaluate additional generic topical and transdermal projects and has identified a number of additional generic development projects. These additional generic projects will be developed under our program in a sequential manner as our analytical and formulation development capacity allows. The timing of the development of these additional generic products will also be based on cash flow projections following receipt of royalties on our commercialised portfolio of products. By the end FY2017, we expect to have between 5 and 7 generic projects in active development. Our goal is to develop a portfolio of topical and transdermal generics and develop these into a strong, sustainable revenue stream for Acrux. We believe that by the early part of the next decade that revenue from our commercialised generic products could match the revenue that is currently generated from Axiron.

Axiron® patent litigation

Our largest commercial product – Axiron has attracted the interest of generic companies in the United States. The market remains attractive with net sales of Axiron in the US alone exceeding US\$145 million in 2015. As has been previously communicated, we and our partner Eli Lilly and Company have filed lawsuits against a number of companies that have filed an application for a generic of Axiron for infringement of specified issued US patents. Formal litigation proceedings began this month in the United States District Court for the Southern District of Indiana against these generic companies, with a decision expected sometime after the case has been completed. The relevant patents include claims relating to the formulation (expiry 2017), application of testosterone to the axilla (expiry 2027) and to the applicator used to apply Axiron (expiry 2030). The court will rule on the validity and infringement of those patent claims by the generic challengers' proposed products. Lilly and Acrux are represented by Finnegan, Henderson, Farabow, Garrett & Dunner, LLP which is a firm with significant expertise in patent litigation in the United States. The conduct of the lawsuit will not have a material impact on Acrux operating expenditure.

Lilly and Acrux are committed to asserting their intellectual property rights for Axiron. Should the relevant patent families for Axiron be found to be invalid, then the result could be the potential launch of generic competition to Axiron in the United States, which would cause a decline in Axiron's net sales and the resulting royalties received by Acrux.

Acrux will keep shareholders informed of developments in both our generic pipeline as well as our patent litigation.

1. IMS June 2015 data, Acrux analysis.

For further information, contact

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About Acrux

Acrux (ASX: ACR) is a drug development company focused on commercialising topical products using its proprietary drug delivery technology. Incorporated in 1998 and using in house facilities and capabilities, Acrux has successfully developed and licensed a number of pharmaceutical products in the US and Europe using the Patchless Patch™, a fast-drying and invisible topical application technology. Acrux will continue to innovate and bring its developed products to the market in collaboration with licensees.

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

