Cite as: John Kurek, Peter Devine, Hatchtech – the Long Road From Drug Discovery to FDA Approval, Innovation & Impact, 2020
URL: http://iai.digital/2020/hatchtech

Hatchtech–the Long Road From Drug Discovery to FDA Approval

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Abstract: Hatchtech, an Australian pharmaceutical company, has become the first Australian company to have a drug approved by the US Food and Drug Administration (FDA) for the treatment of head lice.

Keywords: Hatchtech, head lice, Xeglyze.

1. The success story—Hatchtech

Hatchtech was borne out of the need to develop new control strategies for parasites of an importance to humans and livestock. The focus on head lice was based on the need for improved products that were effective against the lice and, more importantly, their eggs, since available products, in general, are not highly effective at killing lice eggs, although they are promoted as such.

The company's lead product is Xeglyze®, a single application head lice control agent safe for use in children. In 2015, Hatchtech signed an agreement with the integrated pharmaceutical company Dr 'Reddy's Laboratories for up to $279m to commercialise this product.

2. Where did it start and the motivation?

Hatchtech was founded in 2001 by Dr Vern Bowles from the University of Melbourne. Hatchtech is an Australian venture-backed speciality pharmaceutical product company that is developing technologies for the control of invertebrate pests. The product is presently awaiting regulatory approval from the FDA in the United States, where it will be sold as a prescription head lice product.

3. The journey so far

Initial seed funding for developing the lead program was obtained from Uniseed, which was later matched with Government funding through the Biotechnology Innovation Fund in 2002. From 2005 to 2009, Uniseed assisted Hatchtech in securing additional investment from other venture capital firms, including GBS Ventures, QIC Bioventures, and Biocomm, with the

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University Melbourne also investing from their endowment fund. Subsequent investors in Hatchtech's development included OneVentures in 2010 and Blue-Sky Venture Capital in 2013. The company was a recipient of further non-dilutive funding from the Australian Government's Commercial Ready scheme, Export Market Development Grant, as well as the R&D tax incentive scheme. The company ran almost like a virtual company with a COO and CSO in the first 4–5 years and subsequently engaged a CEO, with the current CEO Hugh Alsop joining Hatchtech in 2013.

Figure 1. R Hatchtech CEO Hugh Alsop, Associate Professor Vern Bowles and Hatchtech Chairman Paul Kelly.

Hugh further expanded the team to include members with enhanced regulatory and clinical expertise, who oversaw the development and regulatory strategy of the company. A significant amount of Hatchtech's development was outsourced as needed. The focus was always on identifying excellent contractors to undertake the required work which would meet FDA requirements. In 2014, the company achieved a key milestone by successfully completing two phase 3 studies in the US The studies conclusively demonstrated that Hatchtech's head lice product was highly effective in killing both the lice and their eggs with a single 10-minute treatment, without the need for combing. On the back of these results, Hatchtech was able to attract commercial interest leading to the deal with Dr Reddy's to take the product through the regulatory approval process and onto the market when the New Drug Application was filed with the FDA (headline deal value US$200m).

After submitting the NDA to the US FDA in 2015, Hatchtech finally received regulatory approval of its head lice product Xeglyze® in July 2020. FDA approval had been delayed due to deficient quality practices cited by the FDA during audits at Dr Reddy's manufacturing plants in India. Whilst none of the quality issues involved 'Hatchtech's product, the agency would not approve any new products from the facilities in question until the remediation was complete. This delay, which was outside Hatchtech's control, highlights the risk that exists right through the drug development process.

4. Look into the future

To give context to the significance of this achievement—the number of drugs approved by the FDA that have been developed, or substantially developed, by Australian companies is 12, and of these, there are only five new molecular entities such as Hatchtech's.

With FDA approval secured, it will be of interest to see how the Hatchtech drug penetrates to the US$200+ million prescription headlice market in the USA.

Key insights from this journey are that successful deals do not just happen. Drug development is always about managing risks and adopting a disciplined approach and strategically thinking about all that could go wrong, and mitigating risk by implementing plans where possible to reduce that probability and reduce the potential impact. It would help if you also were prepared for the curveballs… they are on their way, and you will need to meet them head-on! Adopting the excellence mindset is also essential: to the team, in planning, in execution, in advisers, and providers.

The company

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References

[1] Bowles V.M., VanLuvanee L. J., Alsop H., Hazan L., Shepherd K., Sidgiddi S., Allenby K., Ahveninen T., and Hanegraaf S., Clinical studies evaluating abametapir lotion, 0.74%, for the treatment of head louse infestation. Pediatric Dermatology 2018, 35, 616-621.

John Kurek is the Biotechnology Investment Manager at Uniseed, Australia's longest-running venture fund, operating at the Universities of Melbourne, Queensland, Sydney & New South Wales, and the CSIRO, with investment capital provided by these research organisations. At Uniseed, John is responsible for identifying new investment opportunities from the five research partners, and also covers Uniseed's overall biotechnology and life sciences portfolio. Uniseed has returned significant capital to its investors, including Novartis acquisition of Spinifex for US$700m; Shire plc acquisition of Fibrotech Therapeutics for US$557m; and Hatchtech sale to Dr Reddy's Laboratories for ~US$200m.

John brings 20 years of industry experience as a Biotechnology Manager with a focus on the strategic design and implementation of drug development programs. John's previous roles have been with ASX listed biotech companies BioDiem Ltd and Amrad Corporation Ltd., where he was responsible for the management of preclinical and early clinical stage drug development projects. His experience extends from late drug discovery to the phase I-II clinical phases of drug development. John's experience covers a range of areas, including 1) Acting as Director on investee company boards, 2) Biotechnology project management, 3) Investment analysis and due diligence, 4) Financial modelling, 5) Intellectual property management, 6) Business development, 7) Risk management, and 8) Relationship management.

John has a PhD in Neuroscience and a Post Graduate Diploma in Drug Evaluation & Pharmaceutical Science, both from the University of Melbourne, and is a graduate of the Australian Institute of Company Directors.

Peter Devine is CEO of Uniseed and has extensive experience at board and executive management levels in the commercialisation of early-stage technologies, having held senior R&D, business development and commercialisation positions in several Australian companies and Australian universities. Has served on the Board of numerous start-ups which have collectively raised over AU$300m, with a number of these being successfully sold to large multi-nationals in deals collectively worth over AU$1.75b.

Peter holds a PhD from the University of Queensland and received the Dean's Prize for his MBA studies at the Australian Graduate School of Management. He is a Graduate and Fellow of the Australian Institute of Company Directors and holds a Diploma of Financial Services (Financial Markets) and a Graduate Diploma in Applied Finance from Kaplan Professional. Peter was previously VP of Business Development at ASX-listed Progen Industries Ltd. He was Research, Development and Commercialisation Manager at Brisbane-based PanBio Pty Ltd from 1996 to 2000, which ultimately was sold to Inverness Medical. He received a Federal Government Centenary Medal in 2003 for outstanding contribution to the business of biotechnology.

Recent Uniseed successes include Fibrotech Therapeutics' sale to Shire in 2014; the Spinifex Pharmaceuticals sale to Novartis in 2015; the Hatchtech sale to Dr Reddy's in 2015 and FDA approval in 2020; the Smart Sparrow sale to Pearson on 2020 and Exonate's collaborative agreement with Janssen in 2020.