



## **ASX Announcement**

**25 May 2021**

### **ShareCafe Presentation**

MELBOURNE, AUSTRALIA (25 May 2021): Hexima Limited (ASX:HXL) a clinical stage biotechnology company developing HXP124, a new prescription topical treatment for onychomycosis, presented to investors and shareholders at the ShareCafe Hidden Gems Webinar at 12.30pm (AEST) on Friday 21 May.

A copy of the presentation is attached, and the complete audio and visual presentation can be accessed via the Hexima website or at the following link <https://investors.hexima.com.au/investor-centre/?page=presentations-and-media>.

#### **About Hexima**

Hexima (ASX:HXL) is a clinical stage, anti-infectives focused biotechnology company engaged in the research and development of defensin peptides for applications as human therapeutics. Our lead product candidate, pezadeftide (previously referred to as HXP124) applied in a topical formulation, is a potential new prescription treatment for toenail fungal infections (or onychomycosis). Hexima is currently conducting an Australian phase IIb clinical trial testing pezadeftide for the treatment of onychomycosis. Hexima holds granted, long-life patents protecting pezadeftide in major markets globally. For additional information about Hexima please visit [www.hexima.com.au](http://www.hexima.com.au). You can also find us on [Twitter](#) and [LinkedIn](#).

#### **About Onychomycosis**

Onychomycosis is a common fungal nail infection in the nail plate and nail bed. Prevalence of onychomycosis has been estimated at between 10% (Japan) and 13.8% (USA).<sup>[2]</sup> Onychomycosis is an infectious disease and is difficult to treat with significant healthcare burden. It causes pain in approximately 50% of patients and in the US results in close to four doctor's visits annually for treatment.<sup>[3]</sup> Onychomycosis impacts a patient's quality of life with 51% unable to wear the shoes they would prefer and 66% distressed by the appearance of their nail.<sup>[4]</sup> It is important to treat onychomycosis as the fungi in the nail and can be a source of secondary infection in other areas of the body or infect family members and spread to the environment.

Onychomycosis is the most common nail disorder accounting for 50% of all nail diseases. It is particularly prevalent in older, diabetic and immune compromised populations.<sup>[3]</sup> The global market for treatments for onychomycosis was approximately US\$3.7 billion in 2018.<sup>[5]</sup>

#### **Treatment of Onychomycosis**

Approved prescription therapies for onychomycosis comprise either oral or topical medications. Oral medications are associated with adverse effects such as nausea, taste disturbance, and flatulence. They can also severely impact liver function and so often require liver function monitoring. The clinical and



commercial success of topical medications has been constrained by an inability of anti-fungal agents to effectively penetrate the human nail and the lack of sufficient anti-fungal activity when in contact with the target pathogen.<sup>[6]</sup>

### **Hexima's Approach**

Hexima embraces the significant challenge of new product development for onychomycosis. Hexima has taken a very different approach, building on its many years of ground-breaking research into the evolutionary tools that plants use naturally to fight fungal infections. The result is pezadeftide, a new topical treatment for onychomycosis, with a novel and powerful fungicidal mode of action.

Historically, therapies for onychomycosis have generally focused on new forms of the azole class of antifungal agents or improving the topical delivery of systemic antifungal agents. Hexima's technology is a completely novel approach with fundamental differences that address the well-documented limitations of these traditional technologies.

Pezadeftide penetrates the nail more effectively than existing topical treatments and so can more readily target the fungal cells which proliferate in the nail bed. It is also more effective at rapidly killing fungal cells on contact. Together, these properties mean that pezadeftide has the potential to resolve the fungal infection more quickly, leading to faster and more complete clearing of the infected nail area. Consequently, pezadeftide offers the promise to capture significant value in a large and poorly served market.

#### Notes:

1. ClearView Healthcare Partners proprietary market research, 2019
2. Tatchibana et al., Journal of Fungi, 2017
3. Joseph et al, Supplement to Podiatry Today, 2013
4. Milobratovic et al., Mycoses, 2013
5. Persistence Market Research 2018
6. Wang et al., Onychomycosis: Diagnosis and Effective Management, 2018

**This announcement is authorised for release to ASX by Michael Aldridge, CEO**

#### ***Enquiries:***

Dr Nicole van der Weerden

Chief Operating Officer

[n.vanderweerden@hexima.com.au](mailto:n.vanderweerden@hexima.com.au)

***Join our email database to receive company announcements:***

[info@hexima.com.au](mailto:info@hexima.com.au)

[www.hexima.com.au](http://www.hexima.com.au)



# Hexima Limited (ASX:HXL)






## A game-changing treatment for onychomycosis

21 May 2021

# Hexima Limited (ASX:HXL)

*Novel topical product addresses clear unmet need in large and growing market*



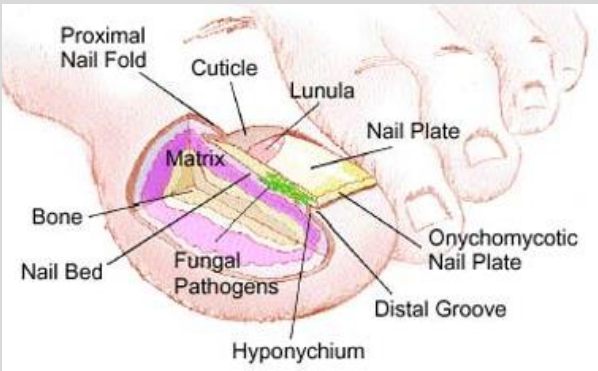
	<b>Clinical-stage, infectious disease</b> focused biotechnology company	Lead program is pezadeftide (HXP124), a <b>potential new topical treatment for onychomycosis</b> (fungal nail infections) Also exploring other applications for anti-fungal peptide platform
	Large and growing market with <b>substantial unmet need</b>	Onychomycosis <b>affects ~14% of the US population</b> Global market for treatments for onychomycosis <b>US\$3.7 bn</b> <b>Clear shortcomings of current treatments</b> <ul style="list-style-type: none"><li>• topical drugs - long course of treatment, limited efficacy</li><li>• oral drugs - more effective but risk of toxic side effects</li></ul> Patients and clinicians have a <b>clear preference for a safe topical product</b> with a more convenient <b>shorter course of therapy</b> and <b>better efficacy</b>
	<b>Novel, proprietary</b> molecule with unique MOA	Pezadeftide is a patented biologic and the first in a new class of antifungals with a <b>novel and powerful fungicidal mode of action</b> <b>Rapidly penetrates the human nail</b> to target the site of infection
	HXP124 addresses a clear unmet need and promises to be the <b>treatment of choice for this large and growing market</b>	Demonstrated in a phase I/IIa clinical trial to have a favourable safety profile and deliver effective and rapid anti-fungal treatment <ul style="list-style-type: none"><li>• <b>Safe and well tolerated</b></li><li>• <b>High efficacy</b> via consumer-friendly topical application</li><li>• <b>Short, convenient course of therapy</b>, delivers rapid resolution of disease</li></ul>
	<b>Well-defined development path</b>	Currently in Australian phase IIb clinical trial – results Q2 2022 File IND with FDA in Q4 2021

# Onychomycosis (fungal nail infection)

*Common infectious disease with a significant healthcare burden*



## Pathophysiology



Dermatophytes (fungi that cause skin disease) typically enter through the distal groove at the end of the nail and proliferate in the nail bed.



Onychomycosis of the toenail is estimated to affect **10-14% of the US population**, growth in the market is primarily driven by an ageing population.



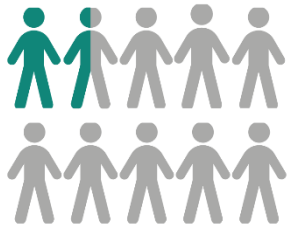
Left untreated, the **nail becomes thick and brittle and easily separates from the nail bed**, causing pain. Also serves as a reservoir for further infections.



**Infectious disease: risk factors include increasing age, athlete's foot, diabetes, and immunodeficiency.**



**Patients experience pain, discomfort and difficulty wearing shoes.** Quality of life is affected by nail dystrophy and unacceptable cosmetic appearance.



Onychomycosis is estimated to affect 10-14% of the population and is the most common nail disorder.

# 4 p.a.

Onychomycosis is responsible for an average of 4 doctors visits annually by patients seeking treatment.





# Existing therapies do not meet consumer needs

*Clear market need for a safe, convenient and more effective topical product*

**Topical treatments** = long treatments, poor efficacy

**Oral drugs** = better efficacy but potential for serious adverse events

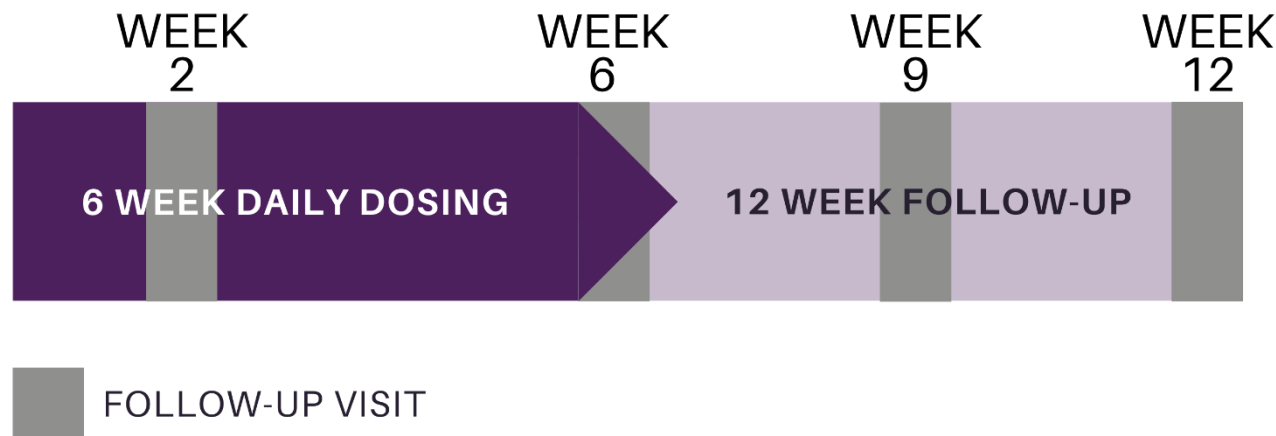




# Successful phase I/IIa clinical trial

## *HXP124-ONY-001 – Trial design*

- Randomised, double blind, vehicle-controlled, ascending dose cohort study
- Patients treated nails daily with pezadeftide (or vehicle) for 6 weeks with follow-up at 12 weeks
- 36 patients treated with pezadeftide, 12 treated with vehicle





# Safe and well tolerated

*HXP124-ONY-001 – No systemic absorption and no local redness or irritation*

---

**The primary endpoint for the phase I/IIa study was safety and tolerability**



Pezadeftide is **safe and well tolerated** when applied daily for 6 weeks.  
No drug-related adverse events.



Pezadeftide **did not cause local redness or irritation** and was not detected in the bloodstream.  
**No systemic toxicity.**





# Rapid and dramatic improvement in appearance of nails

*HXP124-ONY-001– Noticeable improvement in 2 weeks, almost clear in 12 weeks*

---



## Two stage process:

1. Penetrate the nail and kill the fungal infection
2. Healthy, uninfected nail grows clear



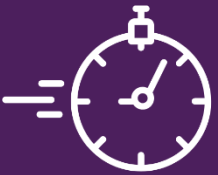
# Effective and rapid anti-fungal activity

*HXP124-ONY-001 – Mycological cure rate 2-fold higher than current treatments*

## Key Insights from HXP124-ONY001 – Phase I/IIa clinical trial

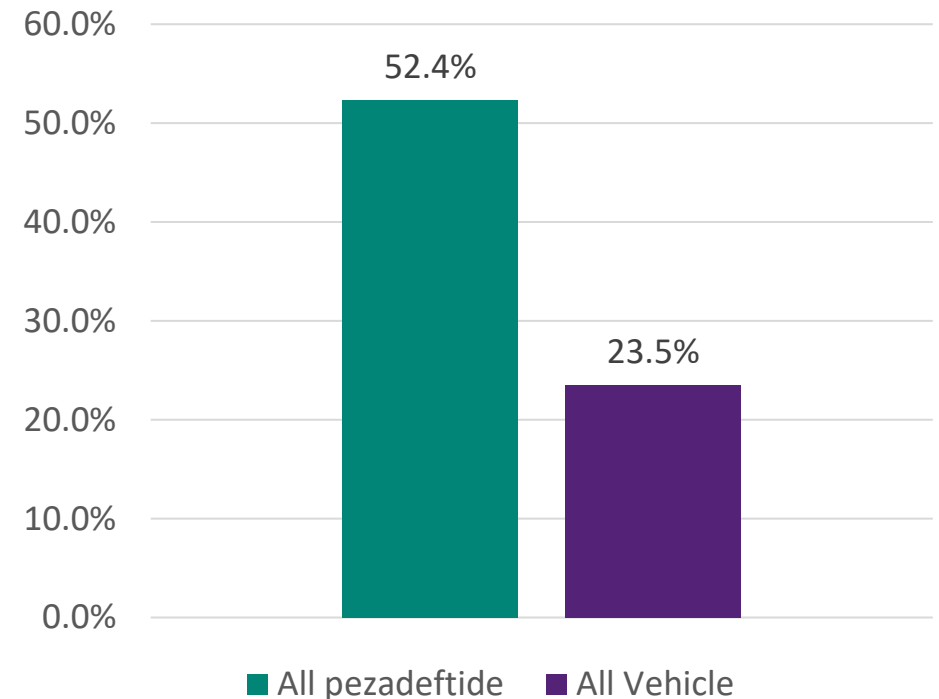


**Mycological cure\*** was achieved in **52% of pezadeftide-treated nails** within 12 weeks (vehicle 24%)



**Mycological Cure\*** rate at 12 weeks, ~2-fold higher than current treatments, after only 6 weeks of daily treatment

Mycological Cure at 12 weeks



\*Mycological Cure = clearance of fungi from the nail as assessed by microscopy and culture

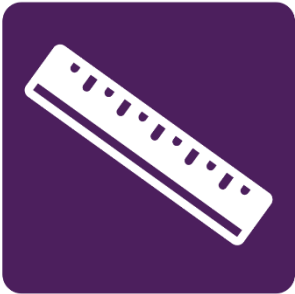


# Rapidly cleared the affected nail area

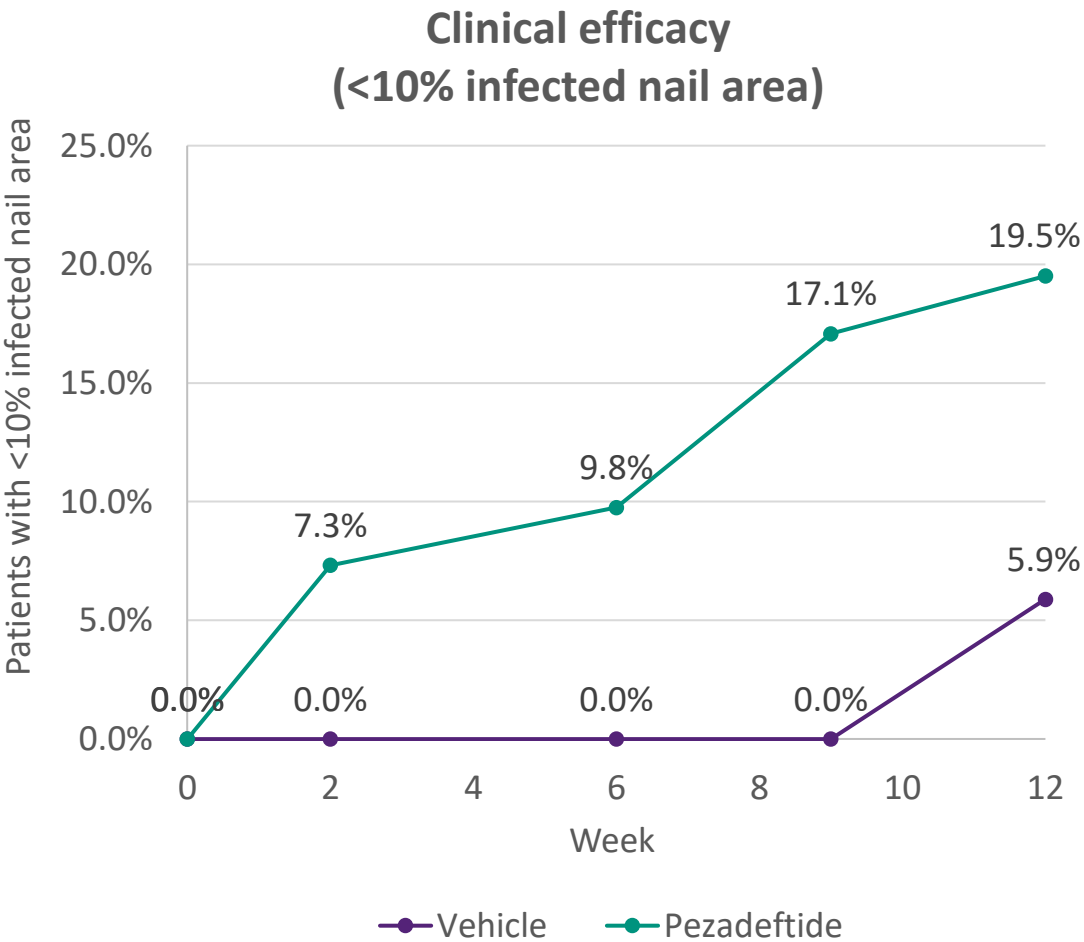
*HXP124-ONY-001 – Clear nail growth continued after dosing complete*



**Pezadeftide cleared the affected nail area** more effectively than formulation not containing HXP124



**Clinical efficacy was achieved in 20% of pezadeftide-treated nails** within just 12 weeks (vehicle 6%)



\*Clinical efficacy = <10% of the nail area infected.

# Pezadeftide: demonstrated potential to deliver the preferred solution in a consumer-driven market



**Safe**, topical medication



**Convenient**, short course of therapy



**Effective**, best-in-class mycological cure



## For patients who want...

An easy-to-apply topical solution

Rapid improvement in the appearance of the nail

Early affirmation the drug is working

A short course of effective treatment



## For physicians who want...

An effective product that will cure the infection

A safe product

To quickly know a patient is responding to therapy



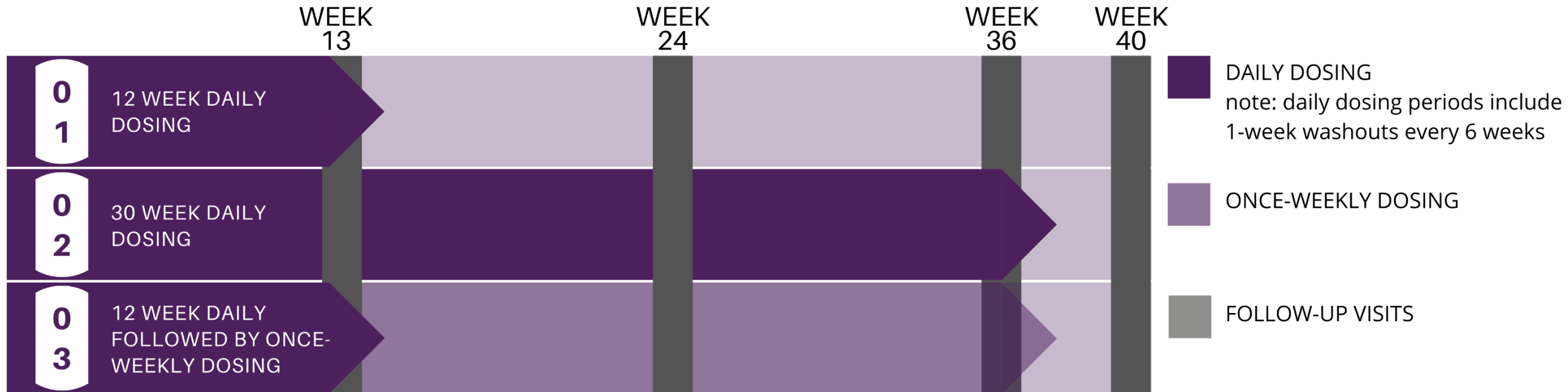
## For payers who want...

An effective product that patients will not abandon

A competitively-priced product

# Australian Phase IIb clinical trial

HXP124-ONY-002

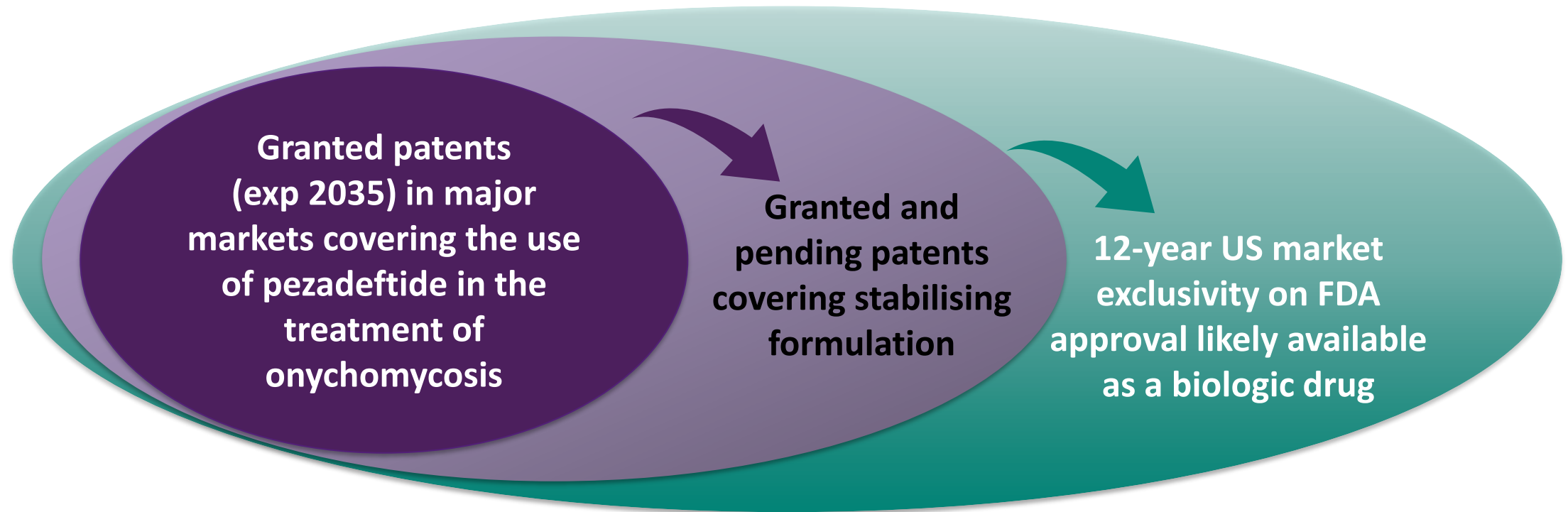


- Three active arms versus vehicle to test optimal dosing strategy
- Safety & efficacy assessed at 13, 24, 36 and 40 weeks, data expected Q2 2022
- Multi-center, randomised, double blind, vehicle-controlled study
- Primary endpoint safety and tolerability, secondary endpoints mycological cure and clinical efficacy



# Granted patents in major markets

*Additional protection via formulation patents and market exclusivity for biologics*



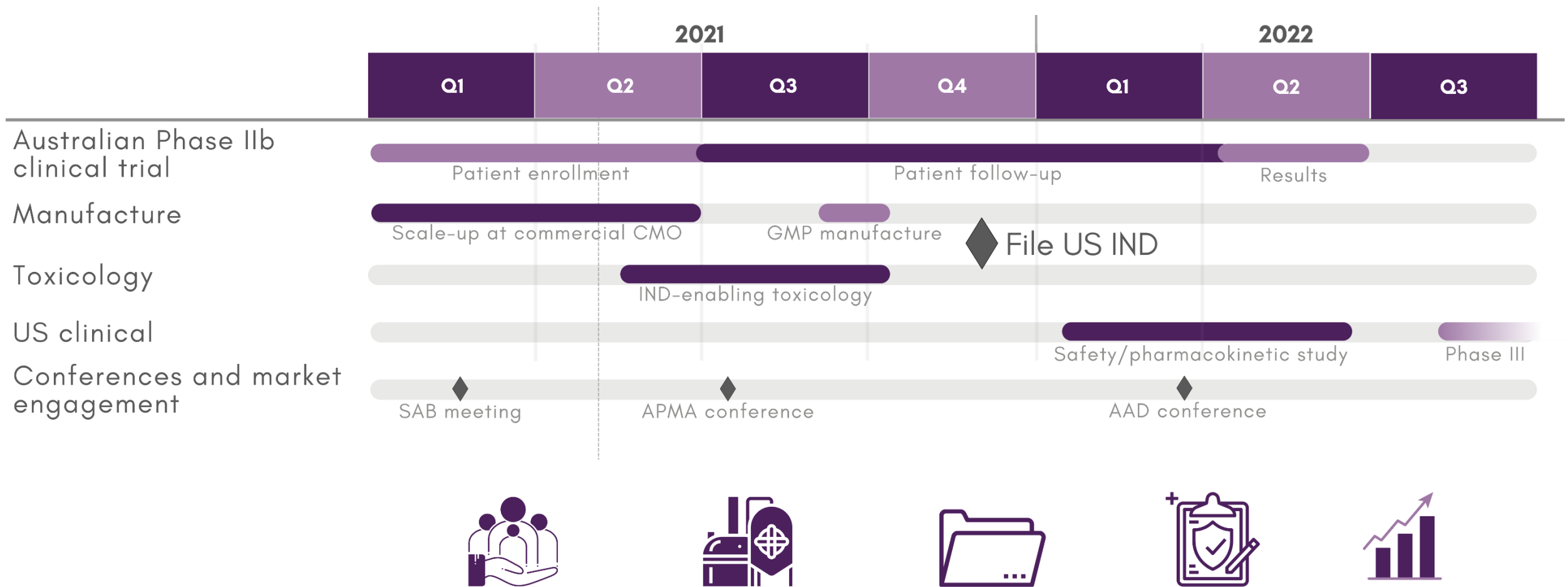
**Clearly defined  
growth strategy**



- Develop independently in US and EU (ICH) markets
- License and collaborative development in Japan

# Development plan

*Well-defined development path and clearly-defined milestones*







# Pezadeftide: a potential solution for a large and poorly served market



POORLY-SERVED, CONSUMER-DRIVEN MARKET	NEW AND UNIQUE	SAFE	CONVENIENT	EFFECTIVE
Affects ~14% of the population Strong consumer preference for topical products Clear unmet medical need	Novel molecule with unique mode of action Strong patent protection & long patent life	No systemic effects No local redness or irritation	Easy to apply Short treatment duration Rapid clearing of infected nail	Efficiently penetrates the nail Rapidly kills fungus Best-in-class mycological cure





# Experienced management team

*Proven track record of delivering value*



**Michael Aldridge**  
Chief Executive Officer

- CEO Peplin, sold to Leo Pharma in 2009 for \$300M
- SVP Corporate Strategy Questcor, sold to Mallinckrodt in 2014 for \$5.6B
- SVP Corporate & Strategic Development Codexis, \$357M partnership with Nestle in PKU in 2017



**Prof. Marilyn Anderson**  
Chief Science Officer

- Founding scientist of Hexima
- Fellow of the Australian Academy of Science and Australian Academy of Technological Sciences
- Member of Hexima board of directors since 2010



**Dr. Nicole van der Weerden**  
Chief Operating Officer

- Inventor on all Hexima's key patents
- Led discovery and development program for pezadeftide
- CEO of Hexima 2015-2020



**Dr. Peter Welburn**  
Chief Development Officer

- CSO and VP R&D at Peplin, NDA for Picato (PEP005 Gel) approved 2012
- General Manager Leo Pharma (Australia)
- Consultant to Codexis on CDX6114 for PKU

# Contacts

---



- Michael Aldridge, Chief Executive Officer  
[m.aldridge@hexima.com.au](mailto:m.aldridge@hexima.com.au)  
+1 650 452 4684
- Dr Nicole van der Weerden, Chief Operating Officer  
[n.vanderweerden@hexima.com.au](mailto:n.vanderweerden@hexima.com.au)  
+61 407 039 983

Further information is available at:  
[www.hexima.com.au](http://www.hexima.com.au)