



## **ASX Announcement**

27 September 2021

### **Hexima to present at Switzer Small and Micro-Cap Virtual Investor Day**

MELBOURNE, AUSTRALIA (27 September 2021): Hexima Limited (ASX:HXL) is pleased to announce that Michael Aldridge, CEO will present on Tuesday 28 September at 9:25 AM (AEST) at the Switzer Small and Micro-Cap Virtual Investor Day. Hexima will present an update to pezadeftide's development program, give an outlook of the company's future plans and answer conference attendees' questions. Hexima's corporate presentation is attached.

To register to attend this free event please visit the following link.

<https://www.switzerevents.com.au/events>

**This announcement is authorised for release to ASX by Michael Aldridge, Chief Executive Officer and Managing Director.**

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

Dr Nicole van der Weerden

Chief Operating Officer

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

#### **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 (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 please visit [www.hexima.com.au](http://www.hexima.com.au). You can also find us on [Twitter](#) and [LinkedIn](#).

SEPTEMBER 2021

# HEXIMA LIMITED (ASX:HXL)

A game-changing treatment for onychomycosis



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# HEXIMA LIMITED (ASX:HXL)

DEVELOPING A NOVEL TOPICAL PRODUCT ADDRESSING A CLEAR UNMET NEED IN A LARGE AND GROWING MARKET



**CLINICAL-STAGE, INFECTIOUS DISEASE-FOCUSED BIOTECHNOLOGY COMPANY**



**LARGE AND GROWING MARKET WITH SUBSTANTIAL UNMET NEED**



**NOVEL, PROPRIETARY MOLECULE WITH UNIQUE MOA**



**PEZADEFTIDE ADDRESSES AN UNMET NEED. GOAL TO BE THE TREATMENT OF CHOICE**



**WELL-DEFINED DEVELOPMENT PATH**

Lead program is pezadeftide (HXP124), a **potential new topical treatment** for onychomycosis (fungal nail infections)

Exploring other applications for its anti-fungal peptide platform

Onychomycosis **affects ~14% of the US population**. Global market for treatments for onychomycosis **US\$3.7 bn**

Current treatments do not meet patient needs

- Topical drugs - long course of treatment, limited efficacy
- Oral drugs - more effective but risk of toxic side effects

Patients and clinicians have a **clear preference for a safe topical product** with a more convenient **shorter course of therapy and better efficacy**

Pezadeftide is a patented biologic with a **novel fungicidal mode of action**

**Rapidly penetrates the human nail** to target the site of infection

Demonstrated in a phase I/IIa clinical trial to have a favourable safety profile and deliver effective and rapid anti-fungal treatment

**Safe and well tolerated**

**High efficacy** via consumer-friendly topical application

**Short, convenient course of therapy**, delivers rapid resolution of disease

Currently in Australian phase IIb clinical trial – results Q2 2022  
File IND with FDA in Q4 2021  
Phase III 2022



# PEZADEFTIDE IN ACTION

[Click to play animation](#)



# 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



Patients with onychomycosis reluctant to use **oral drugs** because of **potential toxicity**



**Topical products** are therefore **strongly preferred**



However, **existing topicals** suffer from **low efficacy** rates and **long courses of therapy**



Patients often **stop treatment** because the appearance of the nail does not improve for many months



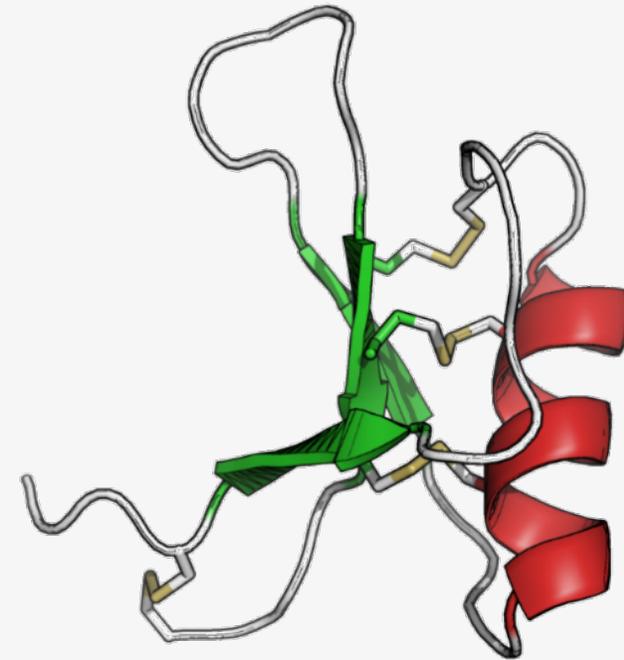
# OUR SOLUTION: PEZADEFTIDE IS A NATURALLY OCCURRING PEPTIDE

ITS UNIQUE PROPERTIES ENABLE RAPID  
NAIL PENETRATION AND FUNGAL KILLING

**Pezadeftide is a potent broad-spectrum antifungal peptide that has evolved to kill fungal pathogens**

- Hydrophilic & highly soluble – drives nail penetration
- Resistant to proteases & extremely stable
- Regulated as a biologic
- Excellent safety profile
- Does not pass through human skin

PEZADEFTIDE MOLECULE



# SUCCESSFUL PHASE I/IIA CLINICAL TRIAL

HXP124-ONY-001 – TRIAL DESIGN

**Randomised, double blind, vehicle-controlled, ascending dose cohort study**

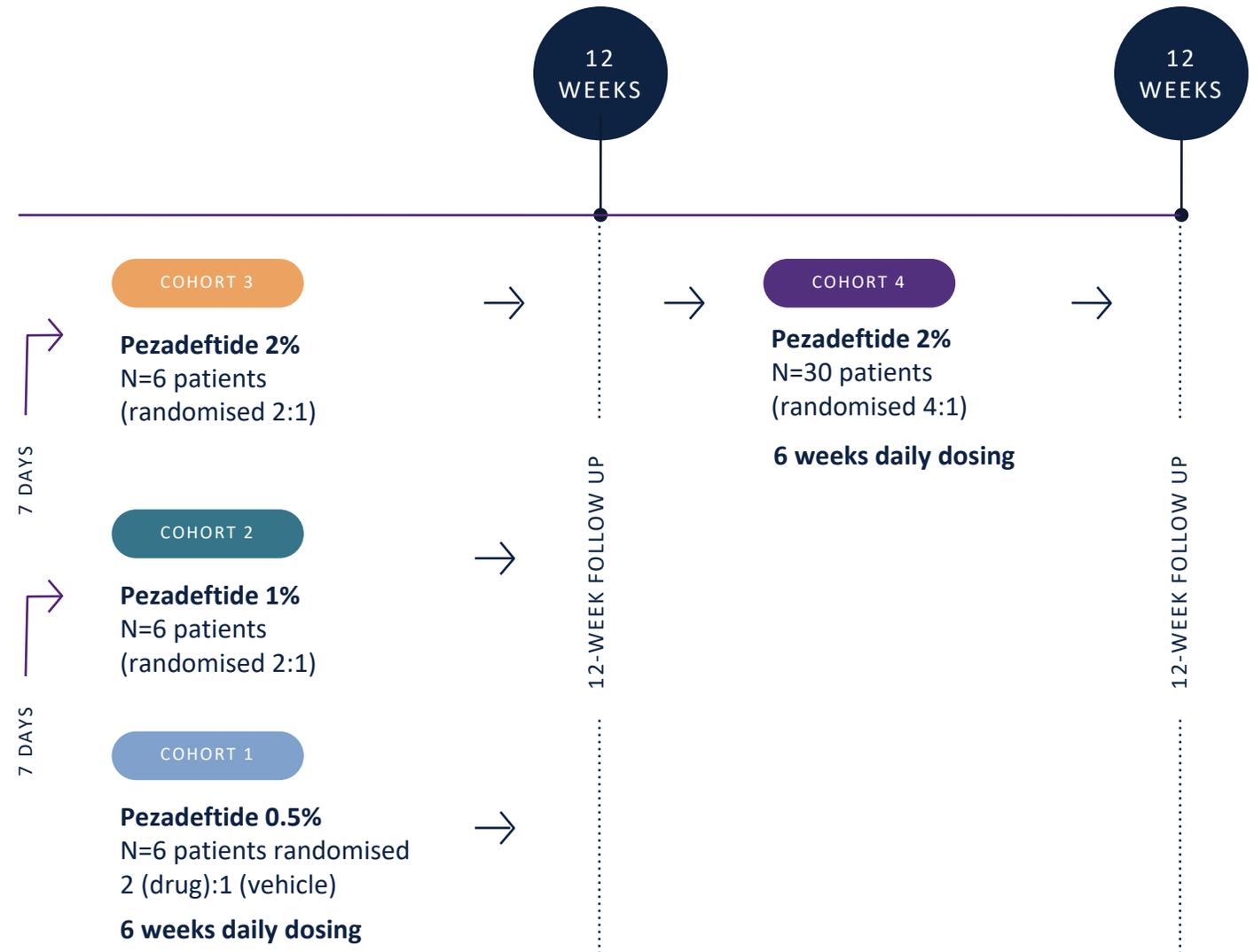
**Patients treated nails daily with pezadeftide (or vehicle) for 6 weeks with follow-up at 12 weeks**

- 36 patients treated with pezadeftide, 12 treated with vehicle

**Cohort 1, 2, 3 escalation cohorts**

**Cohort 4 expansion cohort**

- 30 patients, pezadeftide 2% vs vehicle, 6 weeks dosing



# PRIMARY ENDPOINT SAFETY AND TOLERABILITY

HXP124-ONY-001 – NO SYSTEMIC ABSORPTION  
AND NO LOCAL REDNESS OR IRRITATION

## Pezadeftide is safe and well tolerated

### NO DRUG-RELATED ADVERSE EVENTS

Pezadeftide is safe and well tolerated when applied daily for 6 weeks.

### NO SYSTEMIC TOXICITY

Pezadeftide accumulated in nails and was still detectable 6 weeks after dosing but was not detected in the bloodstream.

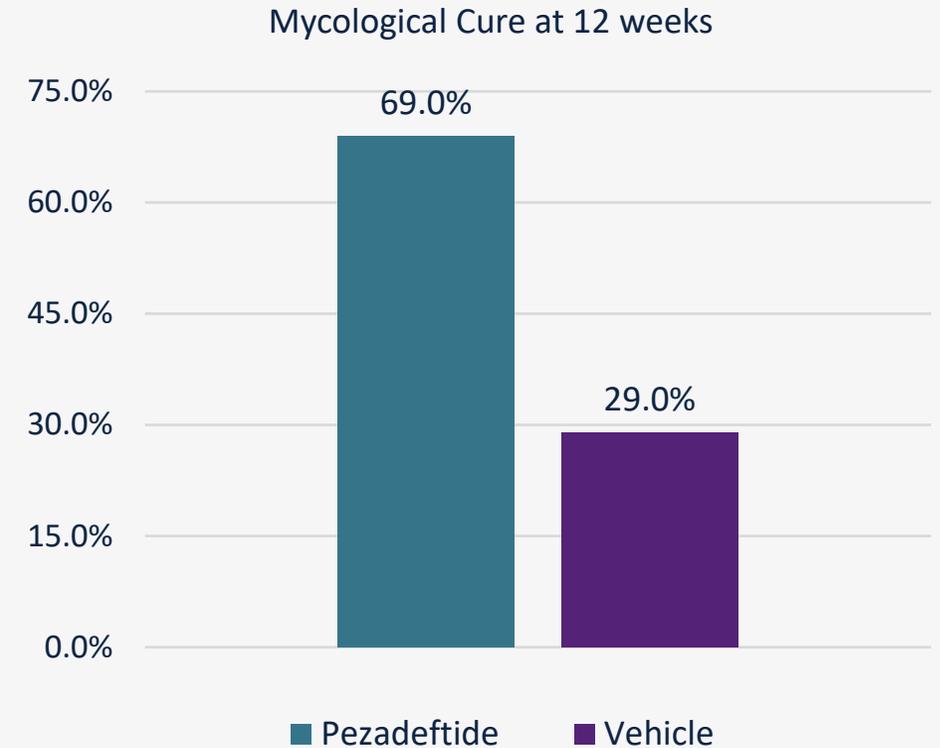


# EFFECTIVE AND RAPID ANTI-FUNGAL ACTIVITY

HXP124-ONY-001 – MYCOLOGICAL CURE RATE FOR COHORT 4  
30 PATIENTS TREATED AT HIGH DOSE (2%) FOR 6 WEEKS

**Mycological cure\* was achieved in 69%  
of pezadeftide-treated nails in Cohort 4 within  
12 weeks (vehicle 29%)**

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



\*Mycological cure: KOH stain negative and culture negative

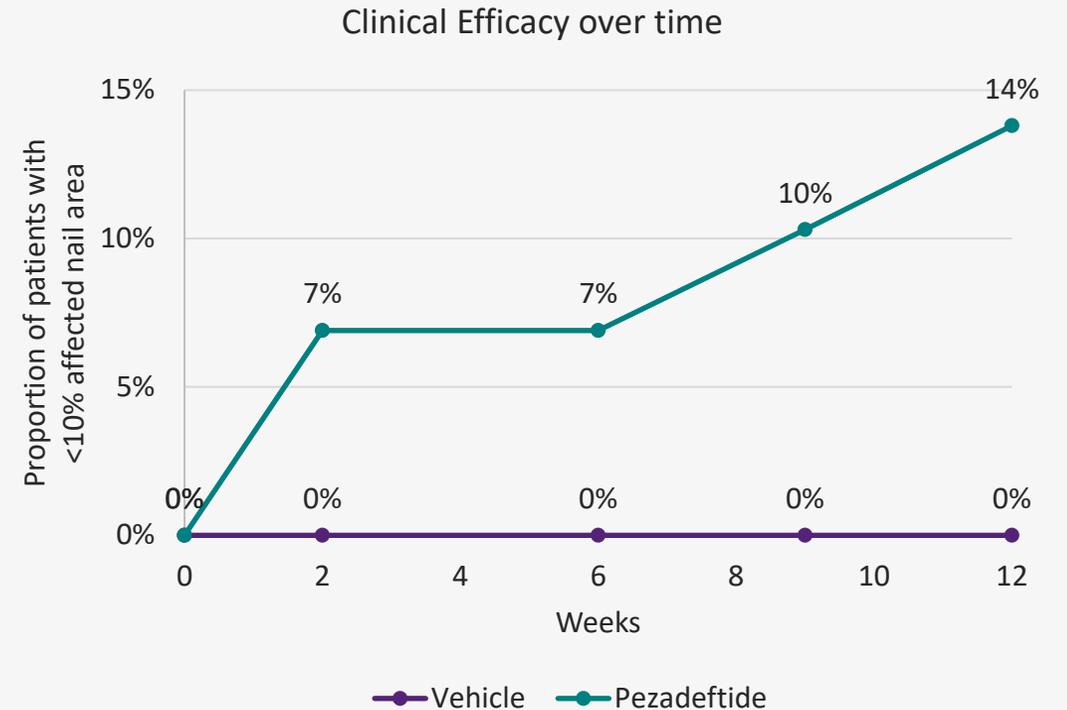


# PEZADEFTIDE RAPIDLY CLEARED THE AFFECTED NAIL AREA

HXP124-ONY-001 – CLEAR NAIL GROWTH FOR COHORT 4  
30 PATIENTS TREATED AT HIGH DOSE (2%) FOR 6 WEEKS

## Pezadeftide cleared the affected nail area more effectively than vehicle (formulation not containing pezadeftide)

- **Clinical Efficacy\*** was achieved in **14%** of **2% pezadeftide-treated nails** within just 12 weeks
- No vehicle-treated nails achieved Clinical Efficacy



\*Clinical Efficacy = <10% of the nail area affected.



# RAPID AND DRAMATIC IMPROVEMENT IN APPEARANCE OF NAILS

NOTICEABLE IMPROVEMENT IN JUST 2 WEEKS,  
ALMOST CLEAR IN 12 WEEKS

**Pezadeftide penetrates the nail to kill the fungus, allowing healthy, uninfected nail to grow out**

- Clear nail growth continues after dosing has finished

[Click to play animation](#)



# PATENT FILED ON COMPLIANCEPAK ASSOCIATED MOBILE APPLICATION

CompliancePak  
benefits &  
highlights



## CompliancePak

- No spill / difficult to misplace
- Easy to open / child resistant
- Reinforces FDA use directions
- Connects by QR code to mobile app

Mobile App  
benefits &  
highlights



## Mobile app

- Reinforces FDA use directions (with video)
- Compliance reminders / confirmation of treatment
- Visual tracking of treatment progress
- Teledoc: diagnosis, prescription and refills



# 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

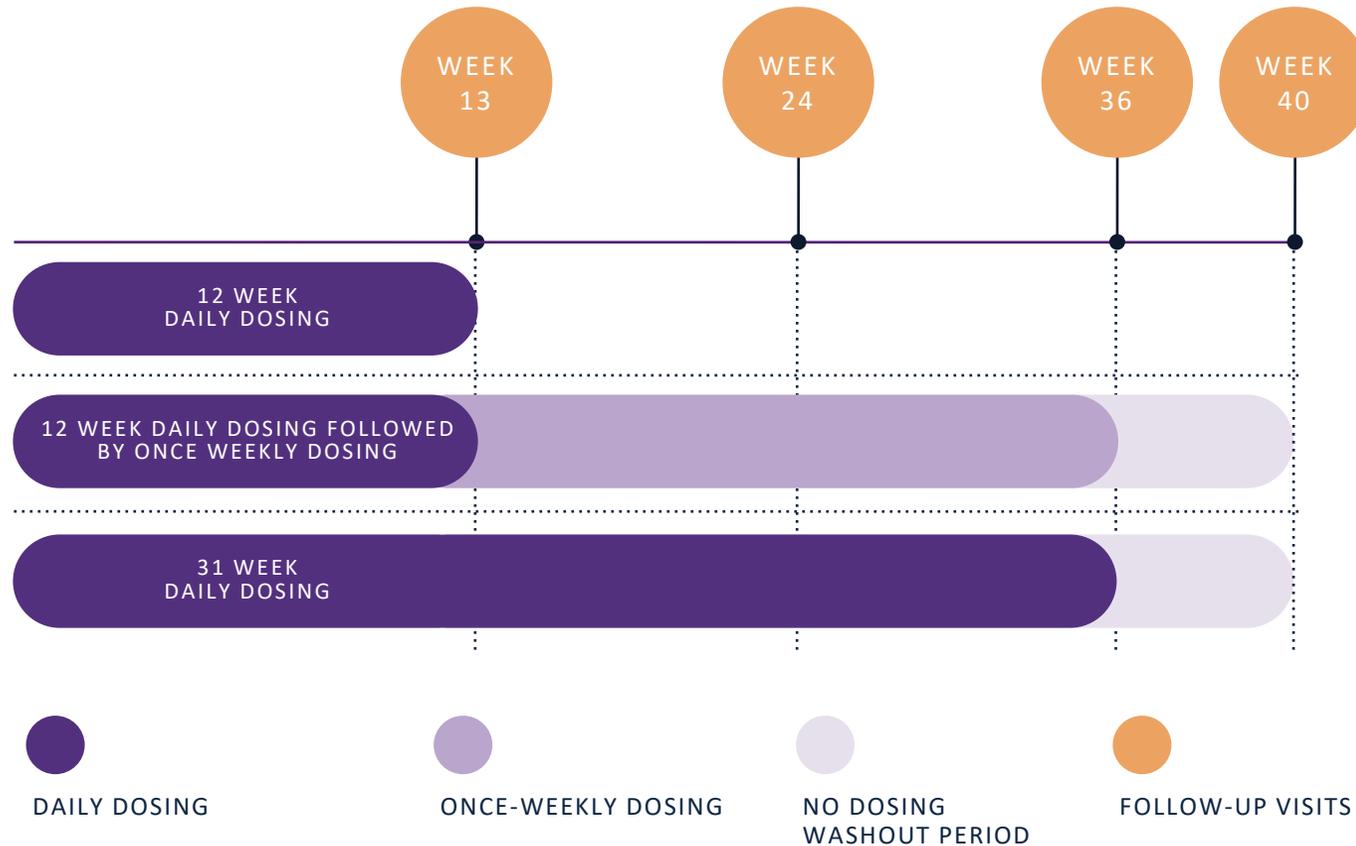
## FOR PAYERS WHO WANT

- An effective product that patients will not abandon
- A competitively-priced product



# AUSTRALIAN PHASE IIB CLINICAL TRIAL

HXP124-ONY-002



NOTE: DAILY DOSING PERIODS INCLUDE 1-WEEK WASHOUTS EVERY 6 WEEKS

Enrolment completed  
July 2021

- Multi-center, randomised, double blind, vehicle-controlled study
- Primary endpoint safety and tolerability, secondary endpoints Mycological Cure and Clinical Efficacy
- Three active (2% pezadeftide) versus vehicle arms to test optimal dosing strategy
- Safety & efficacy assessed at 13, 24, 36 and 40 weeks, data expected Q2 2022



# PEZADEFTIDE: A POTENTIAL SOLUTION FOR A LARGE AND POORLY SERVED MARKET



## POORLY SERVED MARKET

Affects 14% of the population

Strong consumer preference for topical products

Clear unmet medical need



## NEW AND UNIQUE

Novel molecule with unique mode of action

Strong patent protection and long patent life



## SAFE

No systemic effects

No local redness or irritation



## CONVENIENT

Easy to apply

Short treatment duration

Rapid clearing of infected nail



## EFFECTIVE

Efficiently penetrates the nail

Rapidly kills fungus

Best-in-class mycological cure



# CONTACTS

MICHAEL  
ALDRIDGE

CHIEF EXECUTIVE OFFICER

m.aldridge@hexima.com.au  
+1 650 452 4684

DR NICOLE  
VAN DER WEERDEN

CHIEF OPERATING OFFICER

n.vanderweerden@hexima.com.au  
+61 407 039 983

**hexima.com.au**

