



ASX Announcement

14 September 2021

ASX Small and Mid-Cap Conference Presentation

MELBOURNE, AUSTRALIA (14 September 2021): Hexima Limited (ASX:HXL) a clinical stage biotechnology company developing pezadeftide (formerly HXP124), as a potential new prescription topical treatment for onychomycosis, encloses its presentation that is available from today as an on demand presentation at the ASX Small and Mid-Cap Conference.

The registration link for the conference is available below.

<https://www2.asx.com.au/investors/investment-tools-and-resources/events/smid>

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

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. 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



SUCCESSFUL PHASE I/IIA CLINICAL TRIAL

HXP124-ONY-001 – TRIAL DESIGN

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

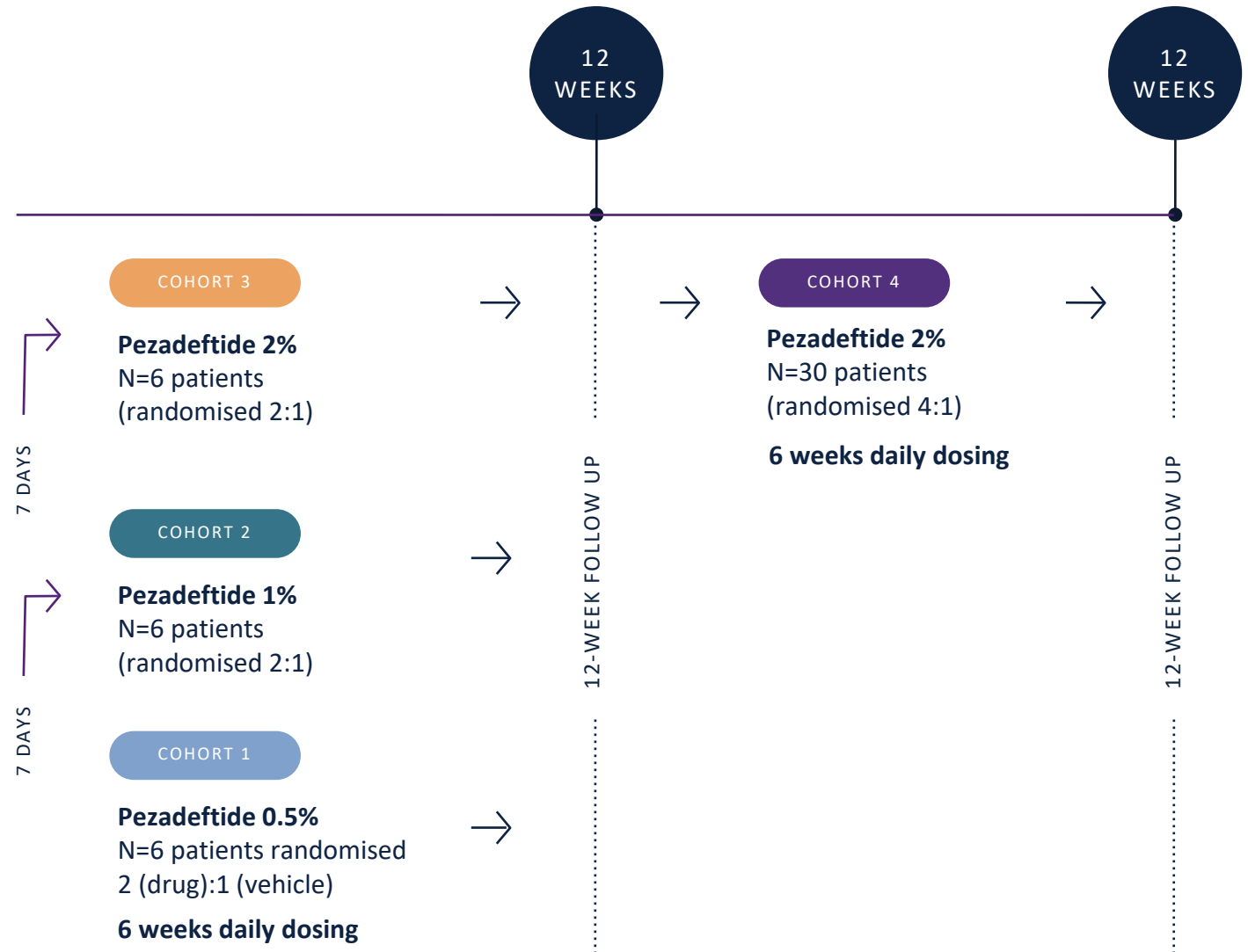
Patients treated nails daily with pezadeftide (or vehicle) for 6 weeks with follow-up at 12 weeks

- 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.

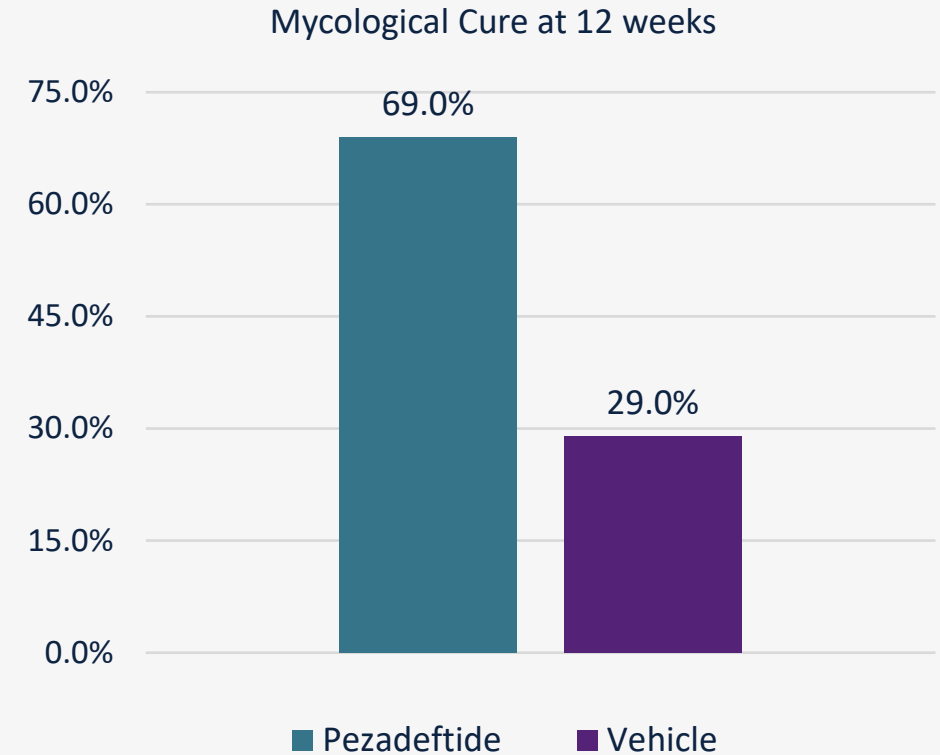


EFFECTIVE AND RAPID ANTI-FUNGAL ACTIVITY

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

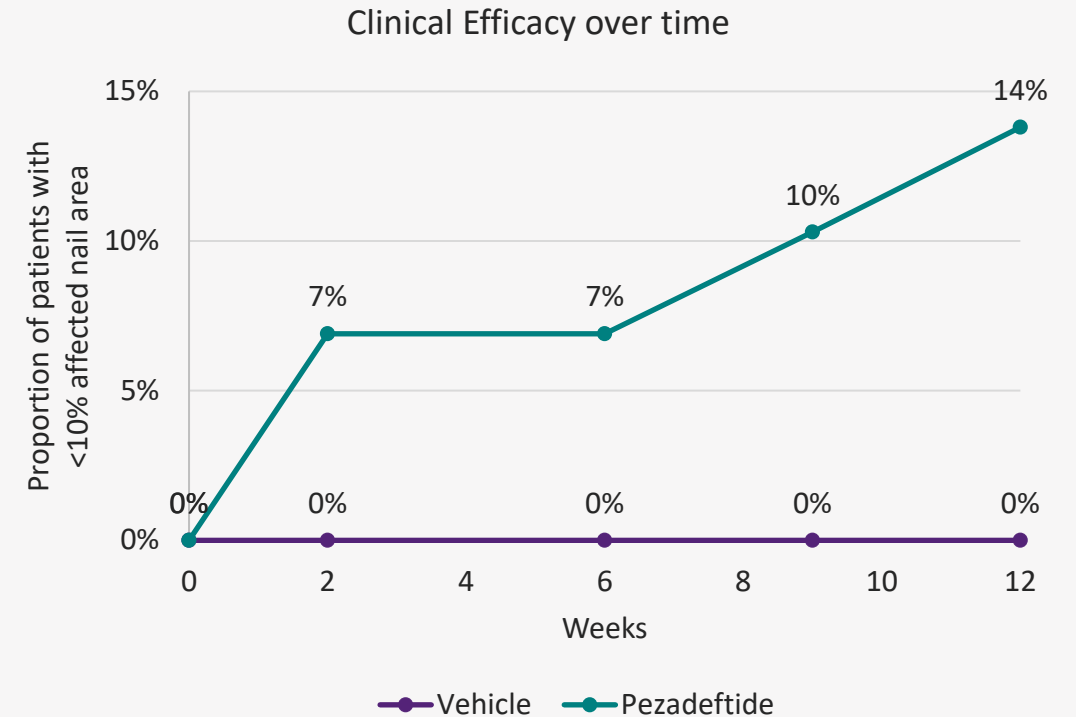


PEZADEFTIDE RAPIDLY CLEARED THE AFFECTED NAIL AREA

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](#)



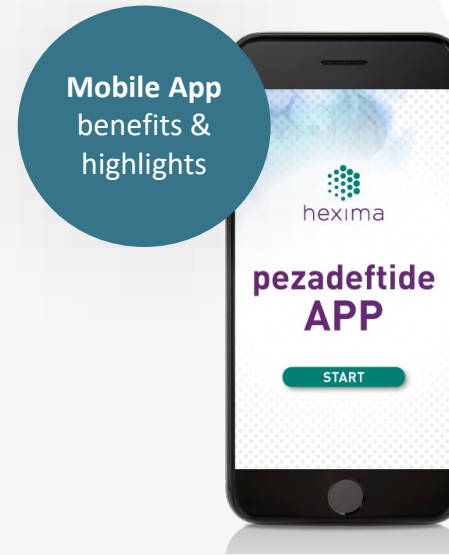
PATENT FILED ON COMPLIANCEPAK ASSOCIATED MOBILE APPLICATION



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

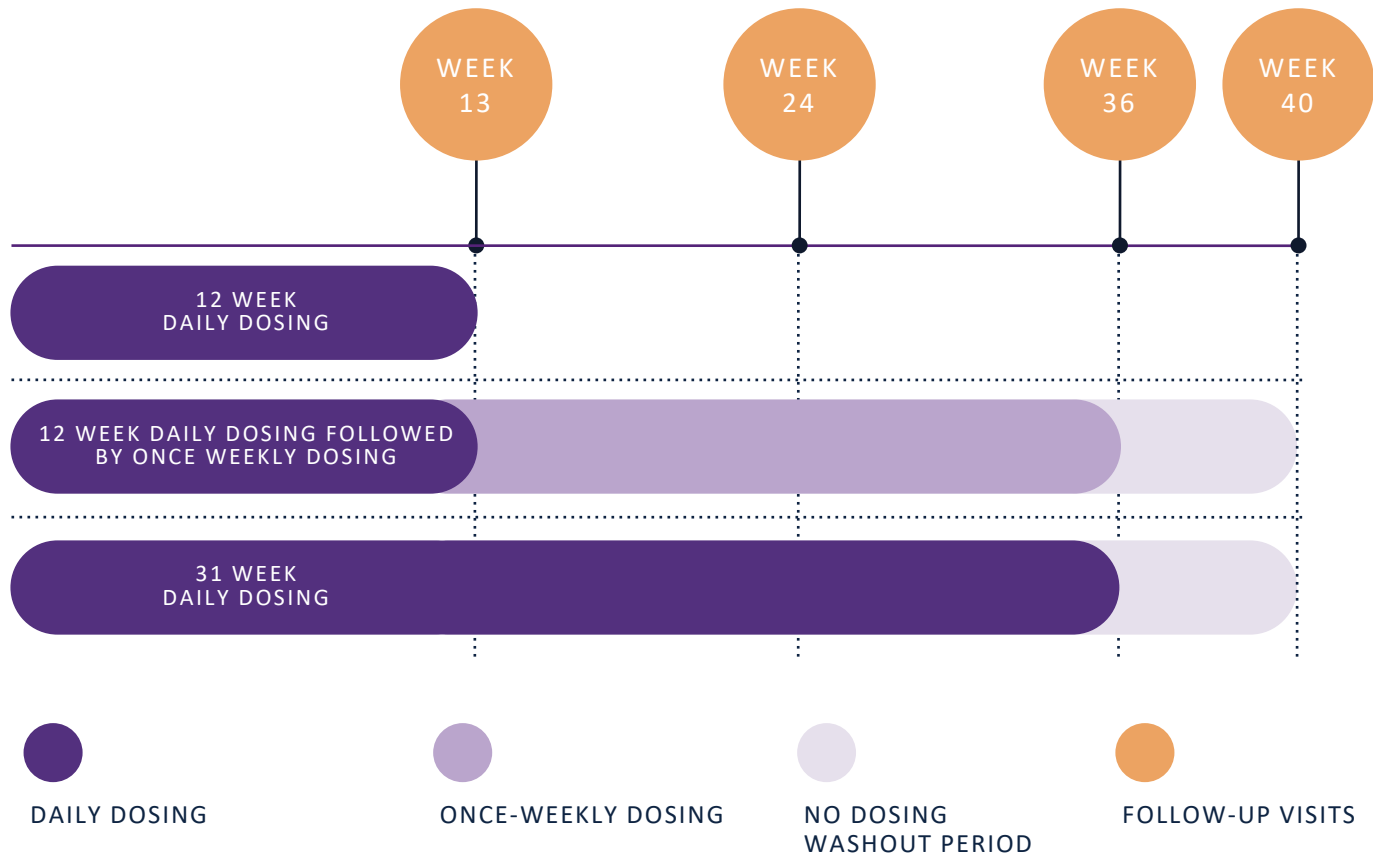
FOR PAYERS WHO WANT

- 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

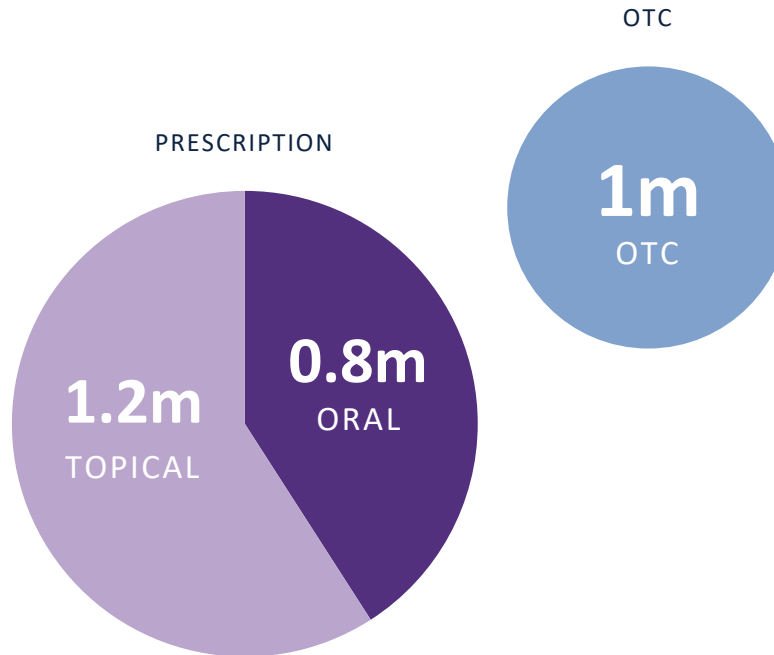
- Multi-center, randomised, double blind, vehicle-controlled study
- Primary endpoint safety and tolerability, secondary endpoints Mycological Cure and Clinical Efficacy
- Three active (2% pezadeftide) versus vehicle arms to test optimal dosing strategy
- Safety & efficacy assessed at 13, 24, 36 and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



~23M PATIENTS WITH ONYCHOMYCOSIS IN THE US

~3M PATIENTS ARE TREATED WITH OTC OR RX PRODUCTS

Target markets



TOPICAL RX MARKET

Better efficacy and a shorter, more convenient treatment, **pezadeftide expects to be the leader in this market.**

ORAL RX MARKET

Better safety profile, similar efficacy and course of therapy, **pezadeftide competitive with oral Rx products.**

OTC MARKET

The availability of a **safe, effective and convenient Rx-strength therapy will appeal to patients who want to get serious about treating their fungal infection**

20+m

UNTREATED

Onychomycosis is an infectious disease which needs to be treated with a clinically-proven, safe and effective product



STRONG PATENT POSITION

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

Granted patents (exp 2035) in major markets covering the use of pezadeftide in the treatment of onychomycosis



Granted and pending patents covering stabilising formulation for pezadeftide



12-year US market exclusivity on FDA approval likely available as a biologic drug



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

