ASX Announcement

29 July 2021

APMA Presentation and Investor Webinar

MELBOURNE, AUSTRALIA (29 July 2021): Hexima Limited (ASX:HXL) a clinical stage biotechnology company, will present clinical data from its phase I/IIa clinical trial of pezadeftide (HXP124) for the treatment of onychomycosis[1] at the annual meeting of the American Podiatric Medical Association (APMA) on 29 July 2021 in Aurora, Colorado.

The APMA annual meeting represents an important venue for the presentation of pezadeftide's potential in the treatment of onychomycosis. Podiatrists are the specialist group which tend to diagnose and manage most cases of onychomycosis and importantly write 80% of all prescriptions for onychomycosis in the US.[1]

The abstract, which describes the poster being presented, is included in this announcement. A copy of the APMA poster is available on the Hexima website. Important highlights include a 69% mycological cure rate observed in the high dose (2% pezadeftide) group compared to 29% in the vehicle group. In the same high dose group, clearance of >40% of the infected nail area was observed in 26% of the pezadeftide-treated nails compared to 0% in the vehicle group.

Hexima COO Dr Nicole van der Weerden commented "The mycological cure rate for our high-dose group is more than two-fold higher than that reported for other onychomycosis treatments at the same time point which represents the potential for dramatically higher efficacy."

Hexima CEO Michael Aldridge added "We look forward to presenting pezadeftide's impressive safety and efficacy data from our phase I/IIa clinical trial to this important group of prescribers as we ensure our development of pezadeftide effectively meets the needs of patients with onychomycosis."

To hear more about the presentation at the APMA meeting be sure to attend our investor webinar at 9 AM AEST today. Attendees can register to attend using the link below. A copy of the presentation is appended to this announcement.

Investor Webinar: 29 July 2021, 9 am AEST
Registration link: https://zoom.us/webinar/register/WN_Ixv6voHySM-bsm6C6xgC8A

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
Join our email database to receive company announcements: info@hexima.com.au

[1] Clinical study HXP124-ONY-001; ANZCTR registration number: ACTRN12618000131257

APMA 2021 ABSTRACT

A phase I/IIa, randomized, double-blind, vehicle-controlled study of pezadeftide (HXP124), a novel topical treatment, in patients with onychomycosis.

Van der Weerden N.[1], Gaspar Y. [1], Anderson M. [1], Xie, A.[2], Aldridge, M.[1] and Welburn, P.[1]

1. Hexima Limited, La Trobe Institute for Molecular Science, La Trobe University, Melbourne, Australia. 2. Linear Clinical Research, QEII Medical Centre, First Floor, B Block, Hospital Avenue, Nedlands WA 6009, Australia.

Background: Onychomycosis, or fungal infection of the nail, affects about 14% of the population. These infections are long-term, hard to treat, can be painful and have a cosmetic impact to the patient. Pezadeftide, a plant defensin, has potent fungicidal activity against a range of human fungal pathogens including Candida spp, dermatophytes and non-dermatophytic moulds. In particular, pezadeftide demonstrates excellent activity against dermatophytes that infect skin and nails and efficiently and rapidly penetrates human nails, making it an ideal candidate for development of a novel treatment for onychomycosis.

Objective: To assess the safety and efficacy of a topical formulation of pezadeftide in a randomized, double-blind, vehicle-controlled phase I/IIa clinical trial in patients with onychomycosis.

Methods: Patients aged 18 - 65 years who had 20 – 70% mycotic involvement of one (or both) great toenails were randomized to receive either 2% pezadeftide or vehicle, applied daily to all 10 toenails for 6 weeks. The patients were then followed for a further 6 weeks. Resolution of infection was evaluated at 12 weeks by assessing mycological cure (negative KOH stain and culture of nail scrapings and clippings) and visual appearance of the infected nail area.

Results: Pezadeftide was well tolerated with no reported treatment-related adverse events and pezadeftide was not detected in the bloodstream. At 12 weeks, pezadeftide demonstrated mycological cure (culture and KOH stain negative) in 69% of the nails treated compared with 29% in the vehicle group. Clearance of >40% of the infected nail area was seen in 26% of the pezadeftide-treated nails compared to 0% in the vehicle group.

Conclusions: Topical treatment with 2% pezadeftide resulted in a high nail clearance rate, and mycological cure when compared to vehicle. Pezadeftide also demonstrated a favourable safety profile and warrants further development as a novel, convenient treatment for onychomycosis.

JULY 2021

HEXIMA LIMITED (ASX:HXL)

A game-changing treatment for onychomycosis

hexima

DISCLAIMER

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AGENDA

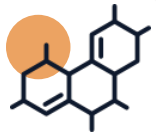
REVIEW OF QUARTERLY ACTIVITIES

Significant progress in Q2 2021

- Presenting at APMA in Denver, CO
- Completion of enrollment in phase IIb
- Completion of large-scale manufacturing
- Key patents granted in Europe and Mexico
- INN designation for pezadeftide

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

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

Exploring other applications for its anti-fungal peptide platform

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

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**

NOVEL, PROPRIETARY MOLECULE WITH UNIQUE MOA

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

Rapidly penetrates the human nail to target the site of infection

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

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

WELL-DEFINED DEVELOPMENT PATH

Currently in Australian phase IIb clinical trial – results Q2 2022

File IND with FDA in Q4 2021

Phase III 2022

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

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

AMERICAN PODIATRIC MEDICAL ASSOCIATION

apma
Advancing foot and ankle medicine and surgery

NATIONAL ORGANIZATION REPRESENTING
DOCTORS OF PODIATRIC MEDICINE

Critical prescriber base for the diagnosis and management of onychomycosis

APMA

Represents the vast majority of ~18,000 podiatrists in US

PODIATRISTS

Write 80% of the prescriptions for onychomycosis [1]

"I see onychomycosis in my practice, every day, every hour. It is something that is so common to what I do as a podiatric physician. Patients come to see me specifically for it, patients are sent to me for it and I discover it on patients who didn't even know they had it"

- Dr Tracey Vlahovic [2]

1. ClearView Healthcare Partners proprietary market research, 2019,
2. Dr Tracey Vlahovic, Clinical Professor at Temple University School of Podiatric Medicine and Member of Hexima's Scientific Advisory Board

PHASE I/IIA CLINICAL TRIAL

HXP124-ONY-001 – TRIAL DESIGN

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

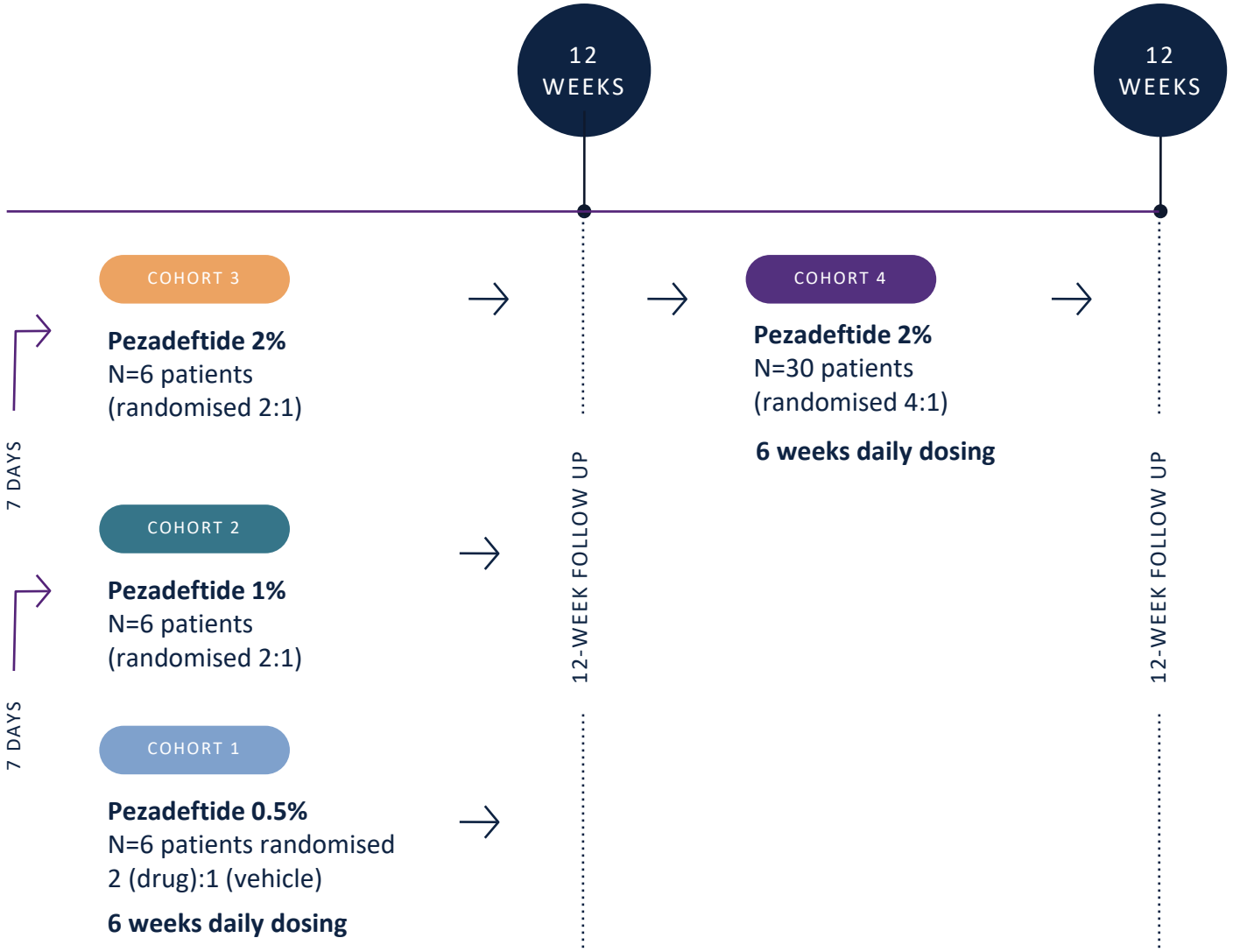
Patients treated nails daily with pezadeftide (or vehicle) for 6 weeks with follow-up at 12 weeks

- 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



ANZCTR registration number: ACTRN12618000131257

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 ABSORPTION

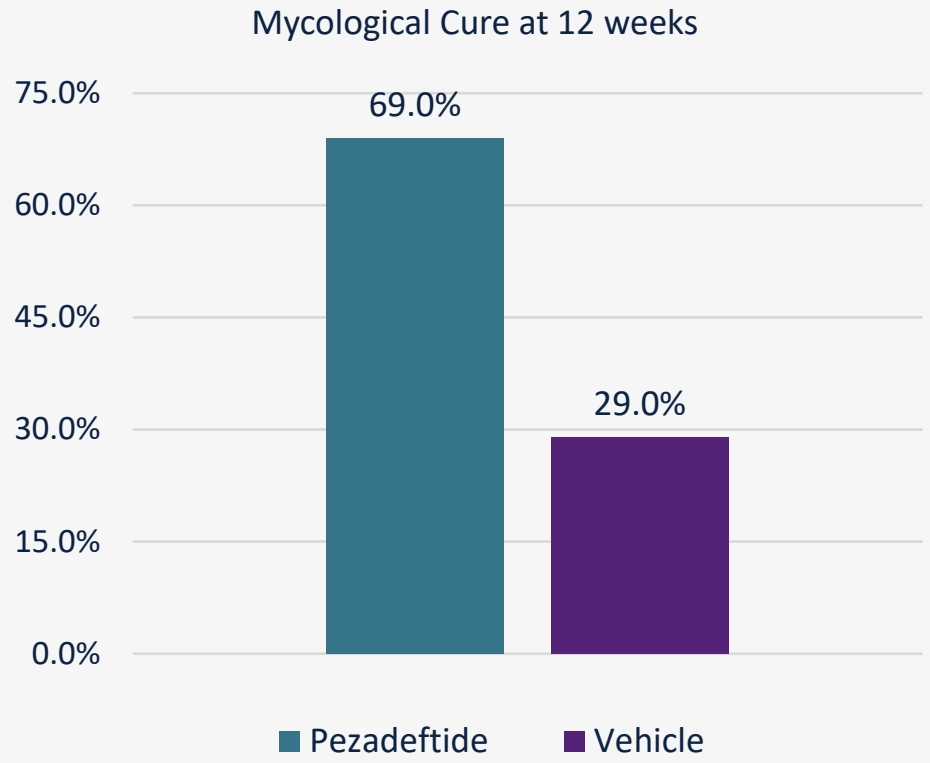
Pezadeftide accumulated in nails and was still detectable 6 weeks after dosing but was not detected in the bloodstream.

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



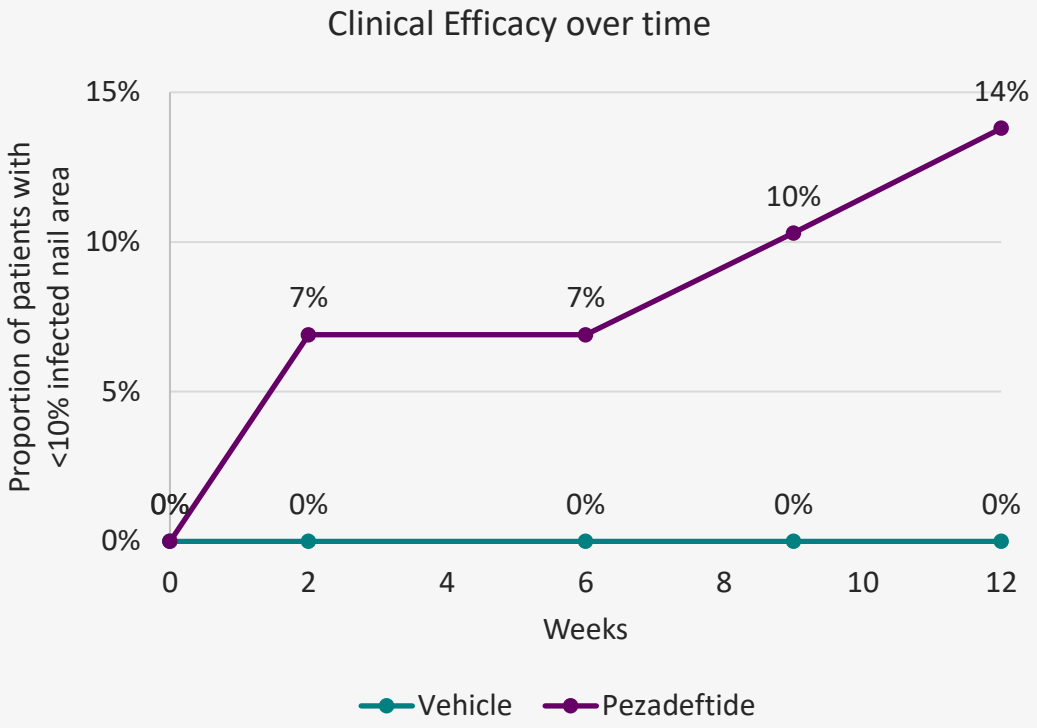
*Mycological cure: KOH stain negative and culture negative

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



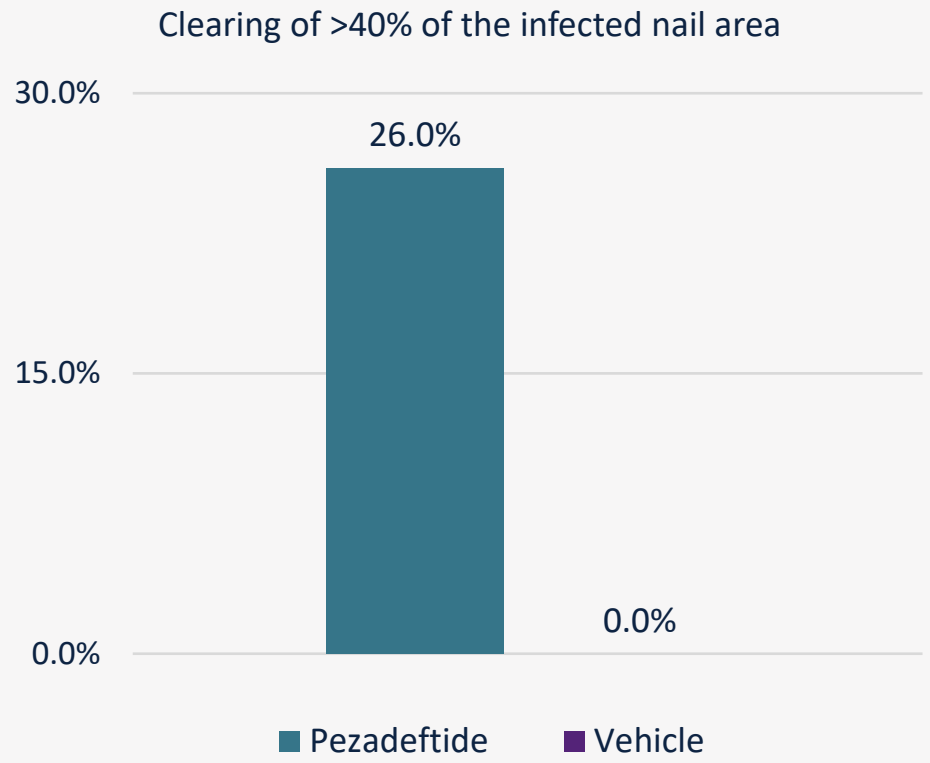
*Clinical Efficacy = <10% of the nail area infected.

EXTENSIVE NAIL CLEARING IN JUST 12 WEEKS

HXP124-ONY-001 – PERCENT CLEARING OF INFECTED NAIL AREA FOR COHORT 4 PATIENTS TREATED AT HIGH DOSE (2%) FOR 6 WEEKS

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

- More pezadeftide-treated nails in Cohort 4 showed a greater than 40% reduction in the infected nail area (26%) than vehicle-treated nails (0%)

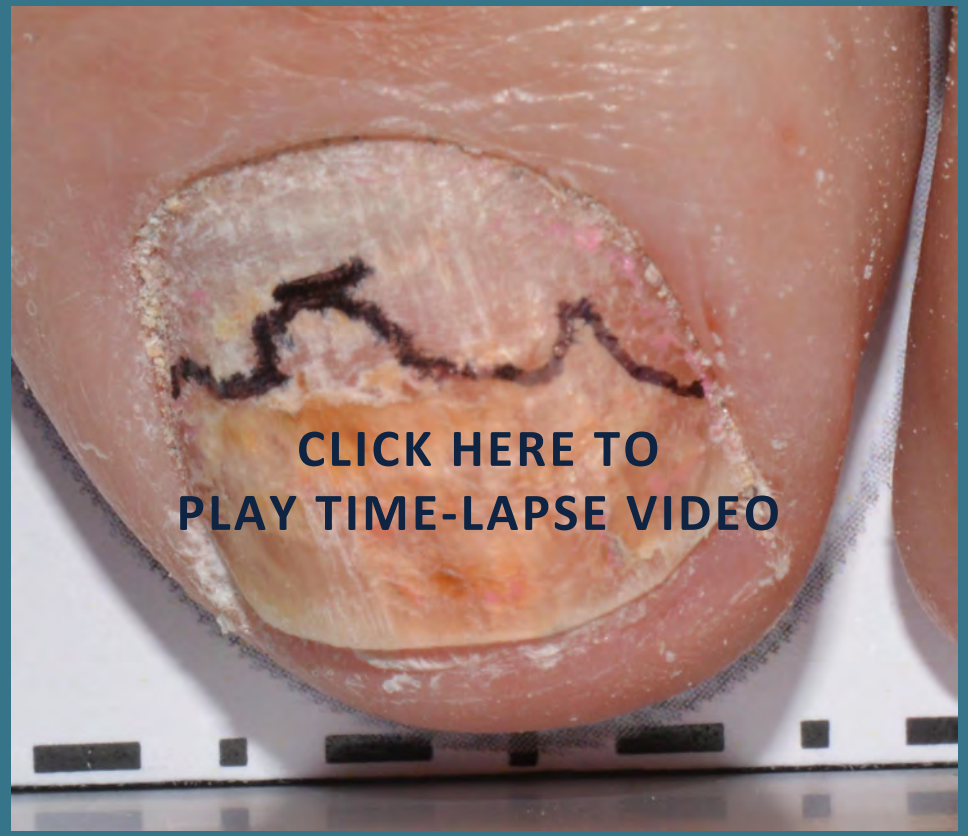


RAPID AND DRAMATIC IMPROVEMENT IN APPEARANCE OF NAILS

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

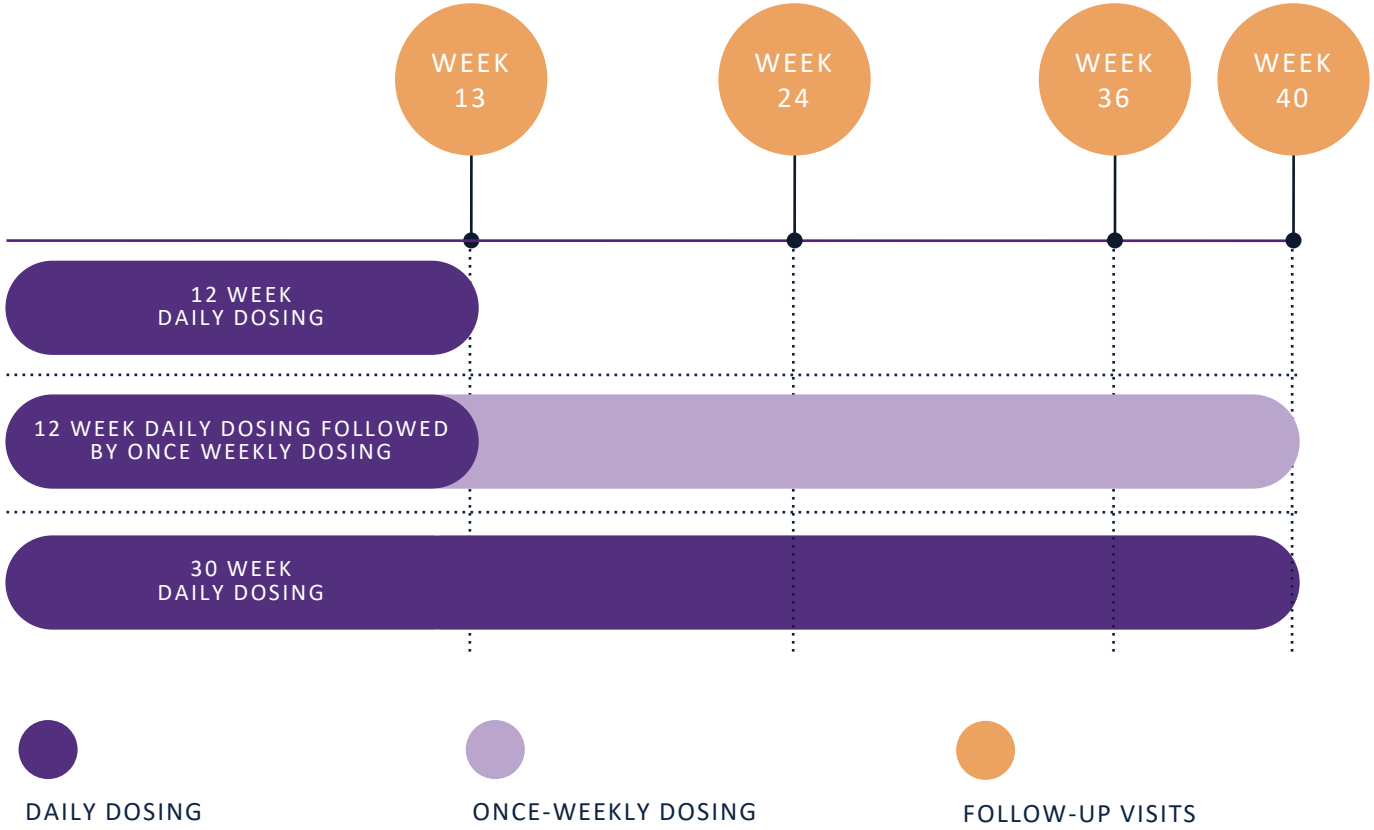
Pezadeftide penetrates the nail to kill the fungus, allowing healthy, uninfected nail to grow out

- Clear nail growth continues after dosing has finished



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

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

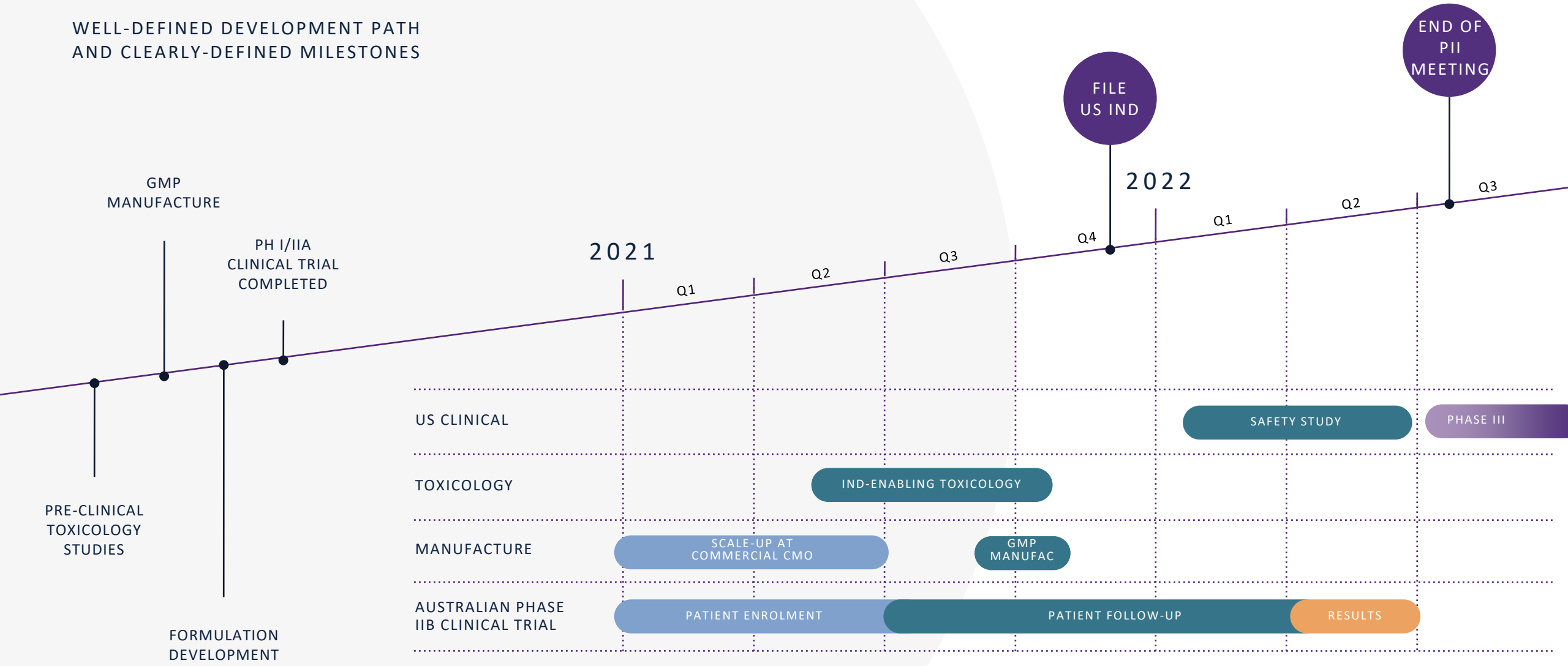
FOR PAYERS WHO WANT

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

ClearView Healthcare Partners proprietary market research, 2019

DEVELOPMENT PLAN

WELL-DEFINED DEVELOPMENT PATH
AND CLEARLY-DEFINED MILESTONES



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

PEZADEFTIDE IS MANUFACTURED RAPIDLY AND ECONOMICALLY

SCALE-UP WITH EUROPEAN CMO
ON-TRACK

Pezadeftide is produced in a yeast expression system with a highly competitive cost of goods

- Pezadeftide has been manufactured to GMP.
- Commercial-scale contract manufacturer engaged
- Pezadeftide successfully produced at large-scale
- Drug product retains activity when stored at room temperature for 24 months

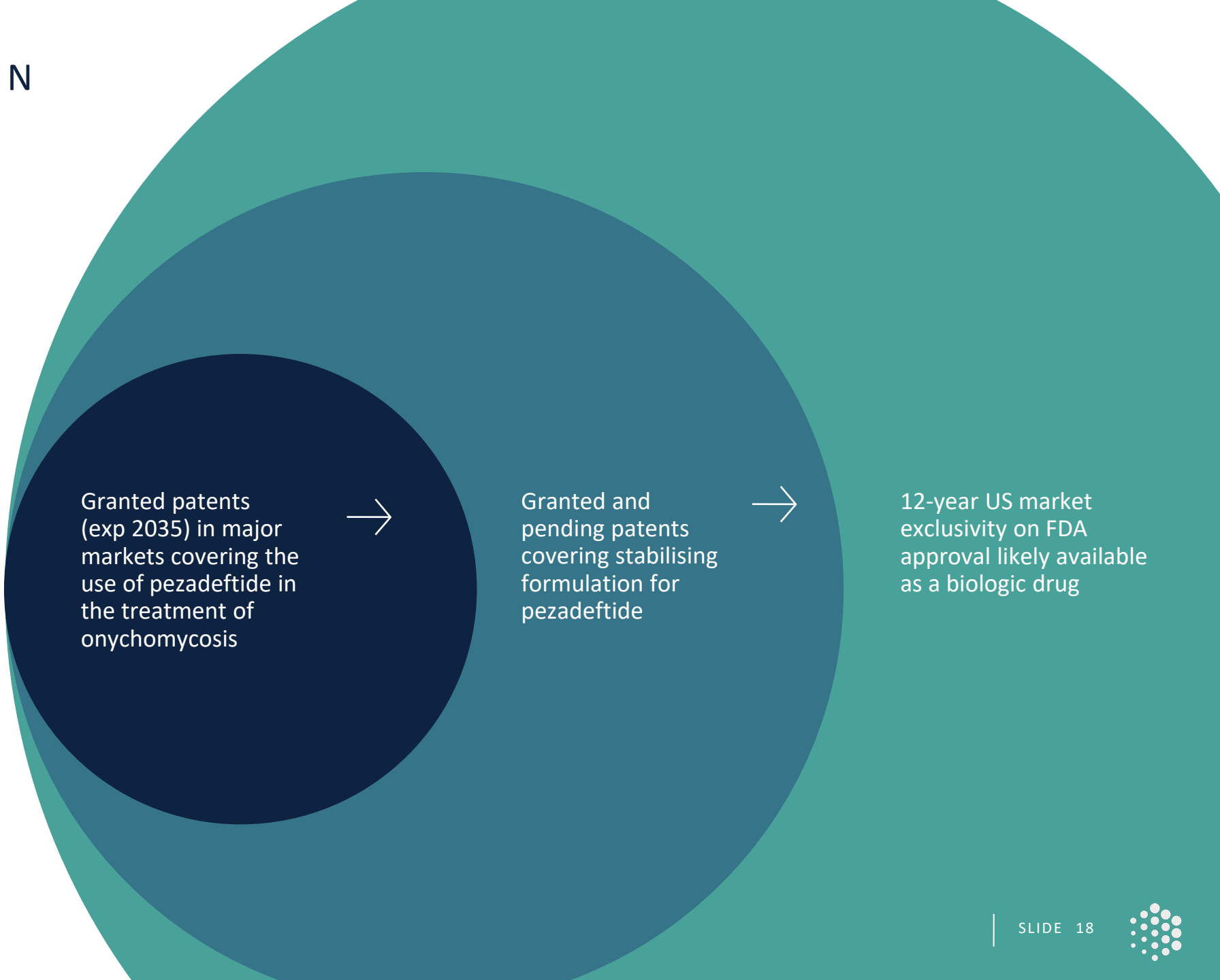
PICTURED
Fermenter and Chromatographic purification at European CMO

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



RAPID AND DRAMATIC IMPROVEMENT IN APPEARANCE OF NAILS

HXP124-ONY-001– NOTICEABLE IMPROVEMENT IN 2 WEEKS, ALMOST CLEAR IN 12 WEEKS

BEFORE

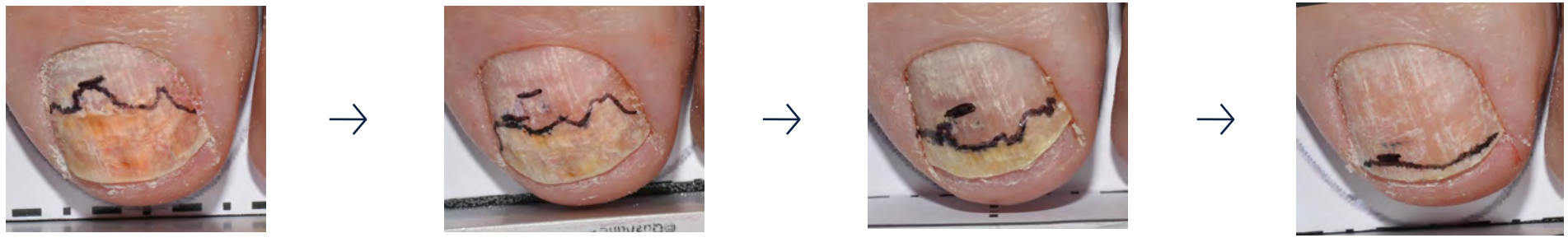
2 WEEKS

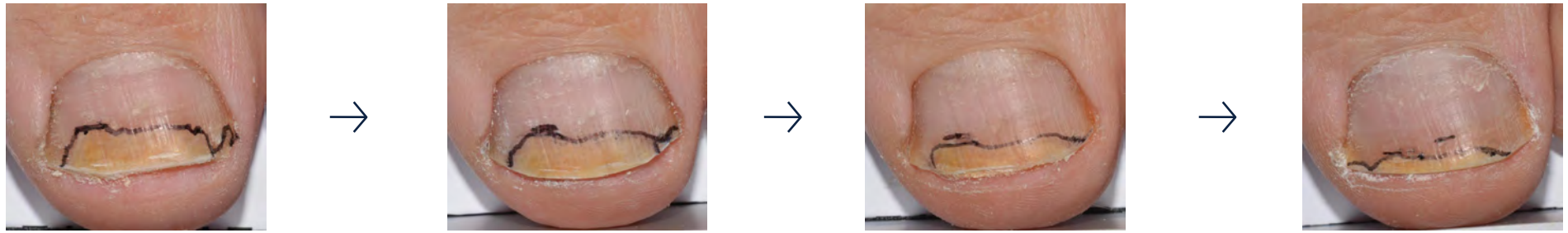
Noticeable improvement in just 2 weeks

6 WEEKS
END OF TREATMENT

12 WEEKS

Almost clear nail in 12 weeks





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

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 please visit 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).[2] Onychomycosis is an infectious disease and is difficult to treat with a 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.[3] 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.[4] It is important to treat onychomycosis as the fungi in the nail 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 more prevalent in older, diabetic and immune compromised populations.[3] The global market for treatments for onychomycosis was approximately US$3.7 billion in 2018.[5]

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.[6]

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 effective at rapidly killing fungal cells by a novel fungicidal mode of action. 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