

JULY 2021

HEXIMA LIMITED (ASX:HXL)

A game-changing treatment for onychomycosis



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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



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



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



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

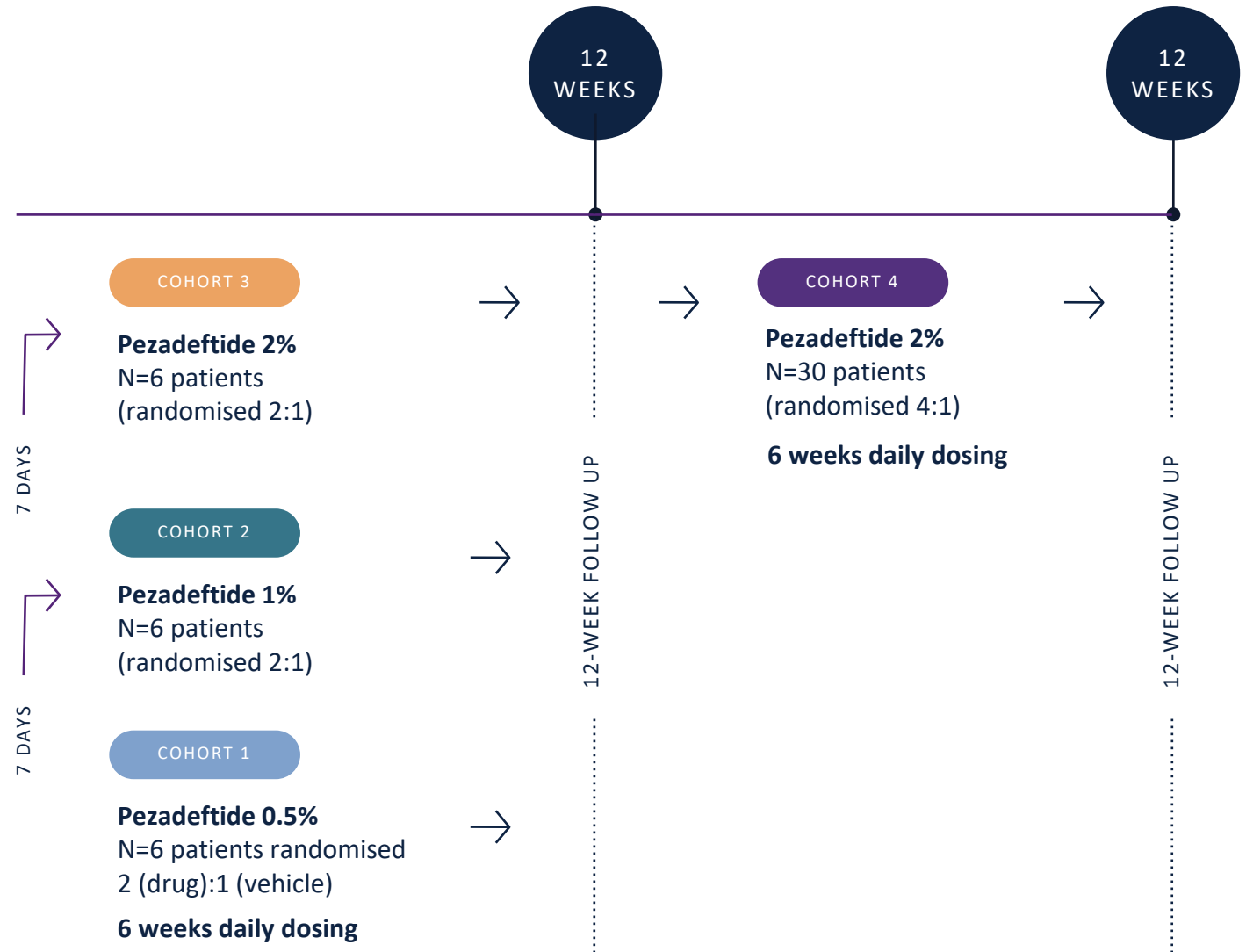
Patients treated nails daily with pezadeftide (or vehicle) for 6 weeks with follow-up at 12 weeks

- 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



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.

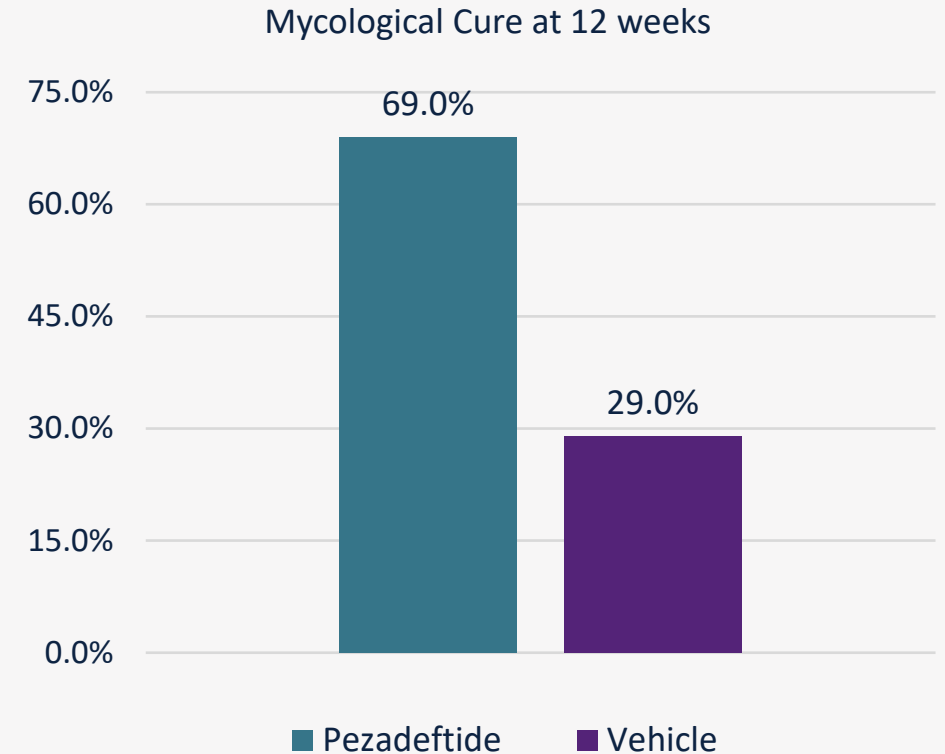


EFFECTIVE AND RAPID ANTI-FUNGAL ACTIVITY

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

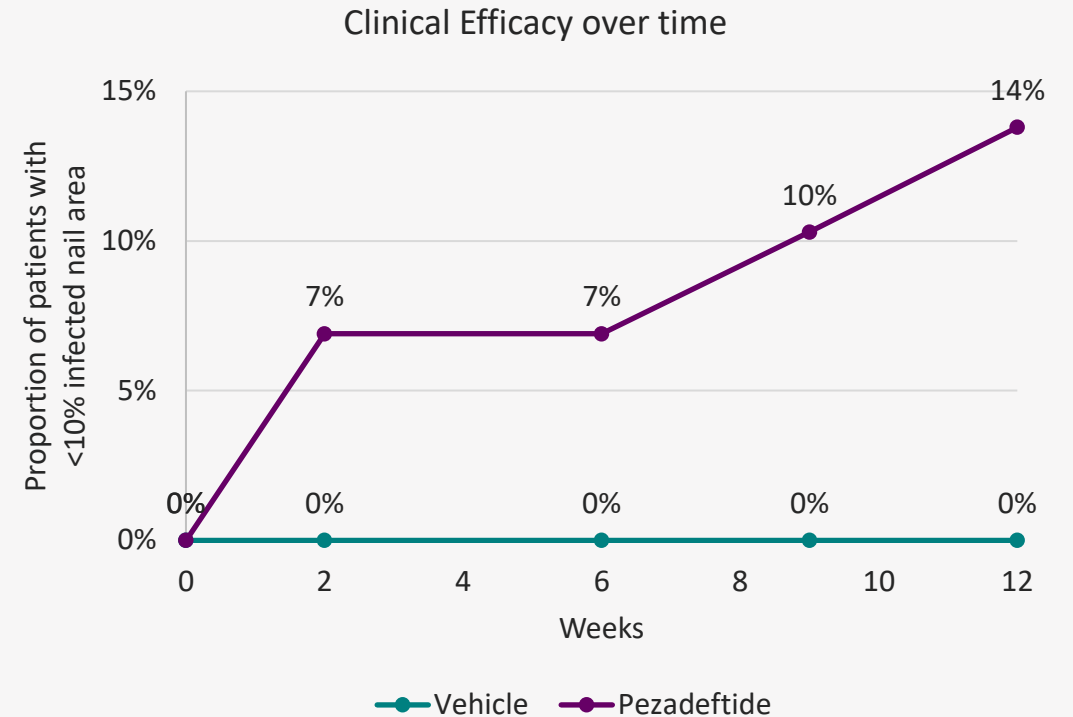


PEZADEFTIDE RAPIDLY CLEARED THE AFFECTED NAIL AREA

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.

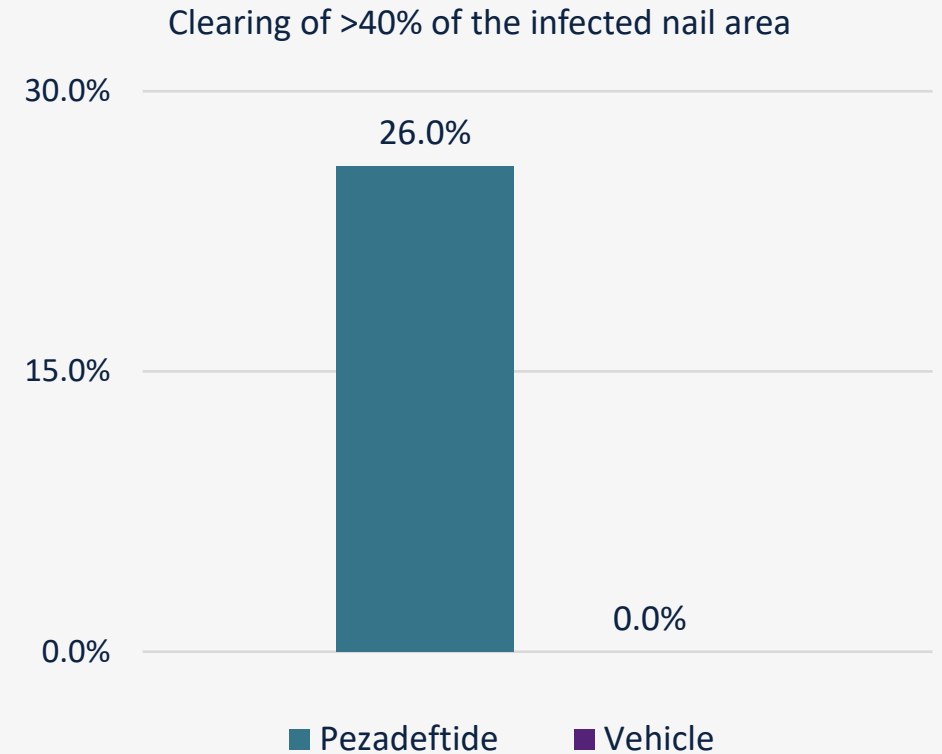


EXTENSIVE NAIL CLEARING IN JUST 12 WEEKS

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

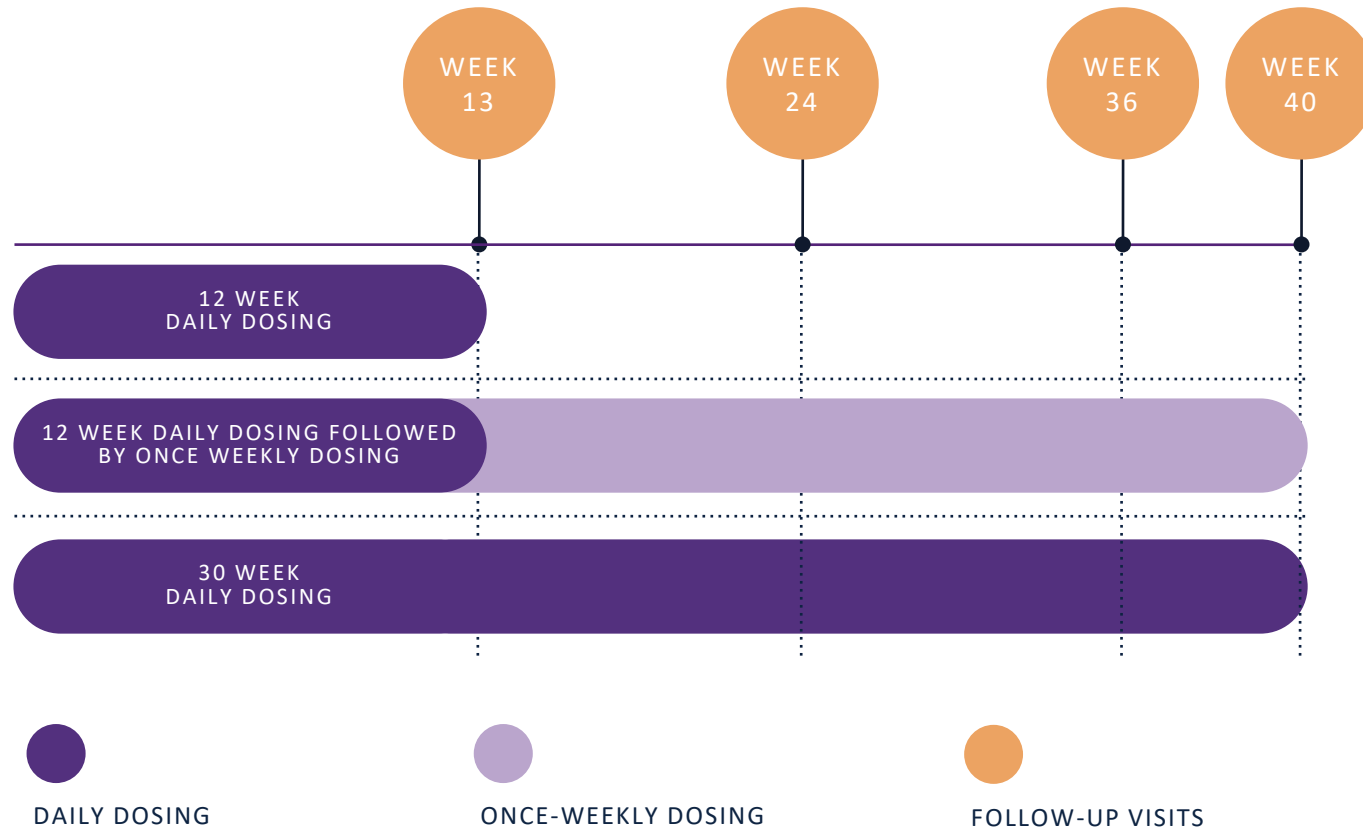
Pezadeftide penetrates the nail to kill the fungus, allowing healthy, uninfected nail to grow out

- 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

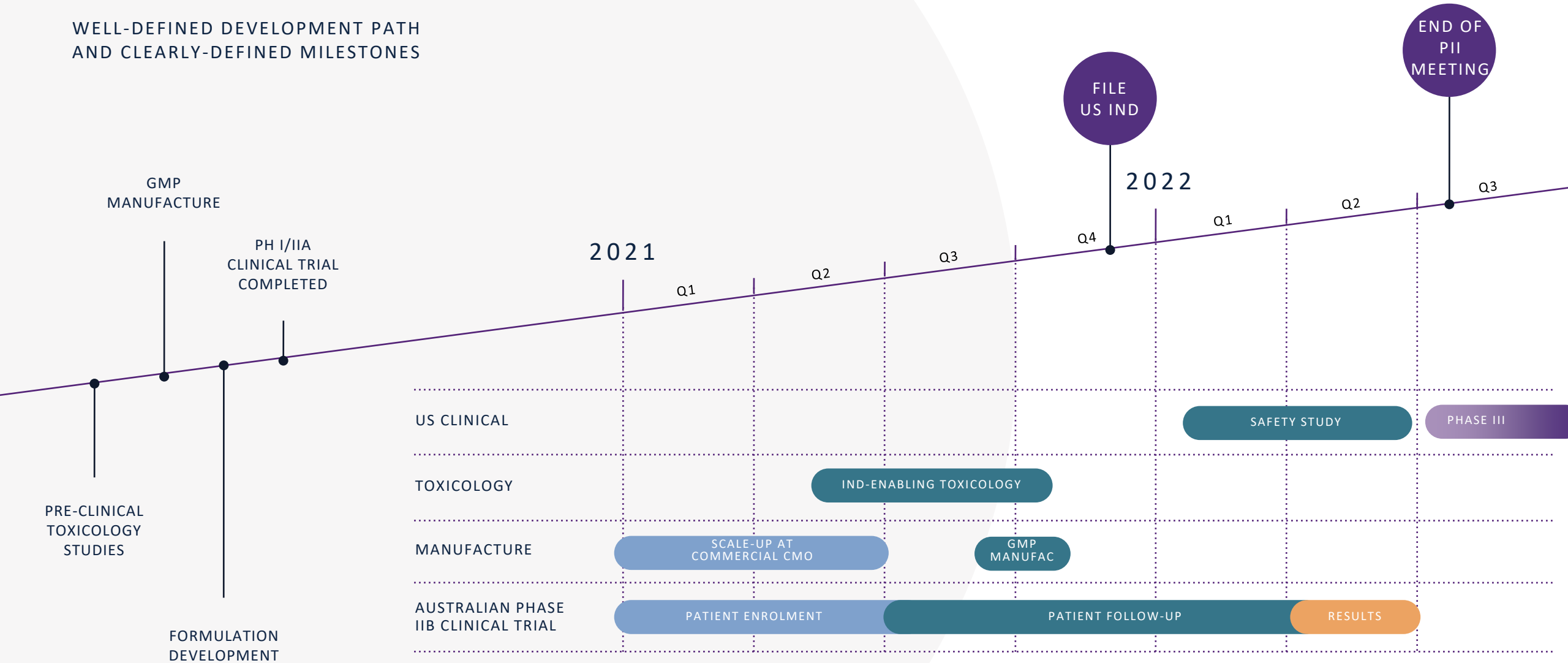
FOR PAYERS WHO WANT

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



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

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



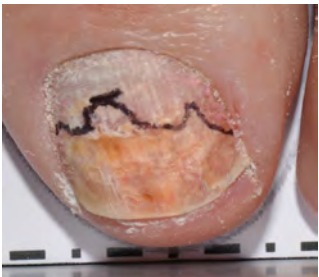
12-year US market exclusivity on FDA approval likely available as a biologic drug



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



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