Hexima Limited

HXP124: a game-changing treatment for fungal infections

Public Offer and ASX Listing
October 2020

Hexima Limited

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Overview

- **Hexima is a Melbourne-based biotechnology company developing HXP124, a potential new topical treatment for onychomycosis**

- **Onychomycosis (fungal nail infection) represents a large and growing market with substantial unmet need**
  - Estimated to affect up to 14% of the population, **globally the market for treatment of onychomycosis has been estimated at US$3.7 bn.**
  - Well developed market in US and Japan with sales of the leading topical product, efinaconazole, exceeding US$320m in 2019
  - Current topical products suffer from poor efficacy rates and long treatment durations, oral treatments are more effective but can have toxic side effects
- **HXP124 is a potentially game-changing treatment**
  - Demonstrated in a phase I/IIa clinical trial to have a favourable safety profile and deliver effective and rapid anti-fungal treatment
    - **High efficacy** via a topical application with novel mode of action
    - **Fast acting treatment** reducing treatment duration
    - **No toxic side effects**
  - Currently in an Australian phase IIb clinical trial for onychomycosis
- **Hexima's highly experienced management and scientific team and commercial board of directors have a strong track record in bringing novel biotech solutions to market**
  - >$25 million invested in research and development of HXP124 to date
- **HXP124 represents a compelling commercial opportunity in the US and globally**
  - Hexima aims to position HXP124 to be the **treatment of choice for an unsatisfied, consumer-driven market**
- **Hexima is currently seeking to raise $3.0 million in conjunction with a re-listing on the ASX in Q4 2020**
  - Existing shareholders will be provided with a sale facility, and with a priority under the public offer

Investment highlights

1. **The market for onychomycosis treatments is large and growing**
   The global market for all forms of onychomycosis treatments in 2018 was estimated at US$3.7 billion, the disease impacts >500 million people
2. **There is a well defined and unmet medical need for a safe, effective and rapidly acting topical product**
   Clinicians and patients are frustrated by the long treatment times and modest efficacy rates of current topical treatments
3. **HXP124 poised to become the best-in-class onychomycosis treatment**
   HXP124 has shown 2-fold better Mycological Cure* at 12 weeks than current topical treatments, following 6-weeks treatment with a better safety profile
4. **HXP124 promise of excellent efficacy without toxic side effects**
   HXP124 promises to deliver cure rates approaching oral drugs but without their attendant toxic side effects
5. **The market opportunity in the US for HXP124 has been independently tested and verified**
   Specialist healthcare market research firm ClearView Healthcare Partners assessed the market opportunity for HXP124 in the U.S.
6. **HXP124 represents a compelling commercial opportunity in the US and globally**
   HXP124 has the potential to drive significant worldwide sales
7. **Hexima has a strong, long life, global portfolio of intellectual property**
   Patents granted in the US, Japan and Europe; patents pending in other key jurisdictions including China
8. **Hexima is managed by a highly experienced senior leadership team with substantial equity ownership**
   Hexima's senior leadership team has significant clinical trial and product development experience, and currently owns 23%** of the company

Note: *Mycological Cure = no fungus in samples collected from underneath the nail as assessed by stain (microscopy) and culture (growth); ** On a fully diluted basis

The market for onychomycosis treatments is large and growing

Key Insights

Onychomycosis of the toenail is estimated to affect up to 14% of the population, growth in the market is primarily driven by an ageing population

Risk factors include increasing age, athlete's foot, diabetes, and immunodeficiency.

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

Only ~35% of patients seek treatment. Large potential for growth with an effective product

Source: Gupta. J Eur Acad Dermatol Venereol. 2016; ClearView Healthcare Partners

Topical products are preferred over oral treatments, but existing products fail to meet fundamental patient needs

Patients with onychomycosis do not want to use the more effective **oral drugs** because they are **potentially toxic**

Topical products are therefore **strongly preferred**

However, **existing topicals** suffer from **low efficacy** rates and **protracted timelines** for treatment

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

There has been a sustained shift in the market to favor prescription of topical agents over oral agents, demonstrating growing **demand for safe and effective topical therapies**

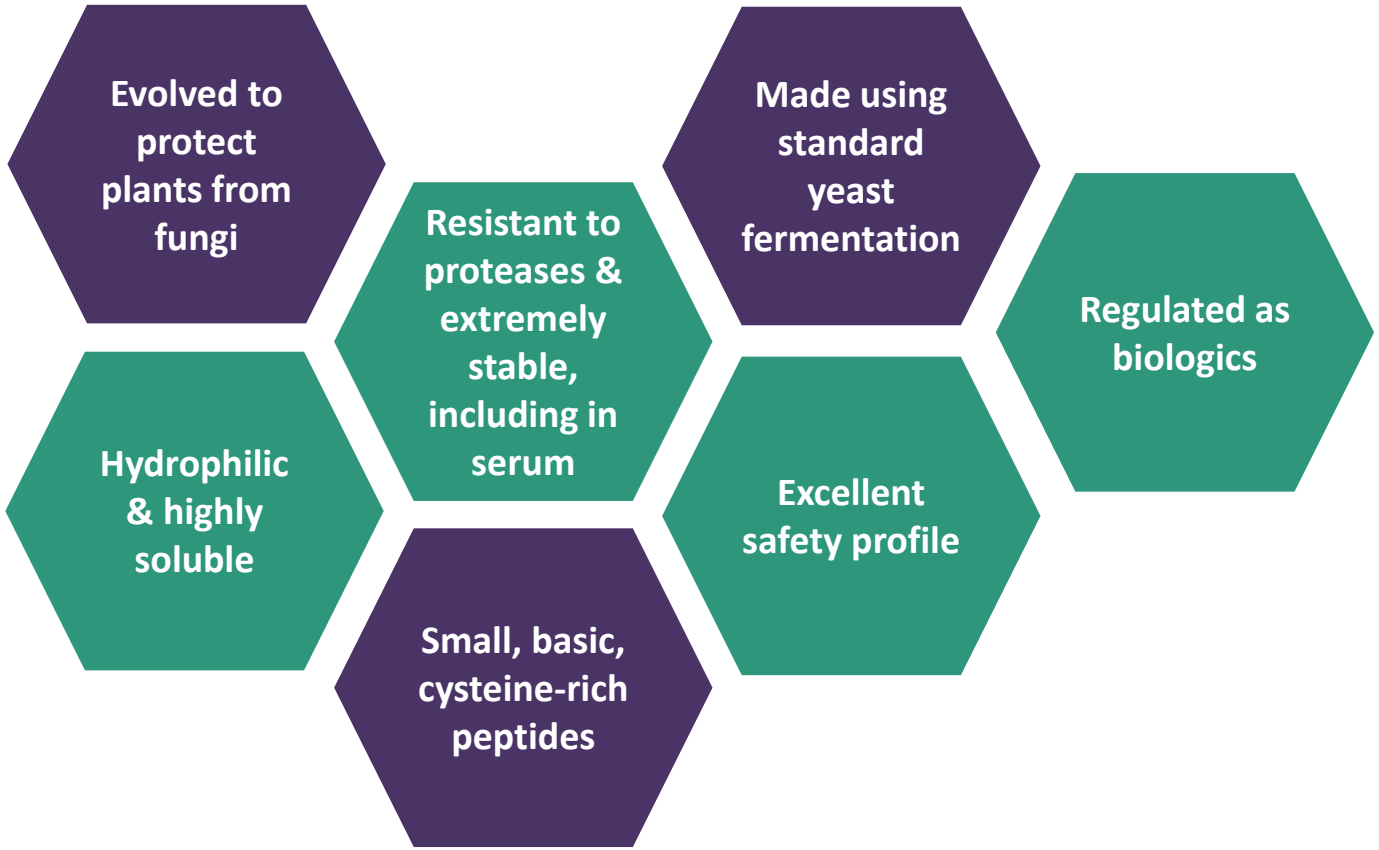
HXP124 has the potential to become a game-changing, best-in-class treatment given its efficacy, safety and speed of action

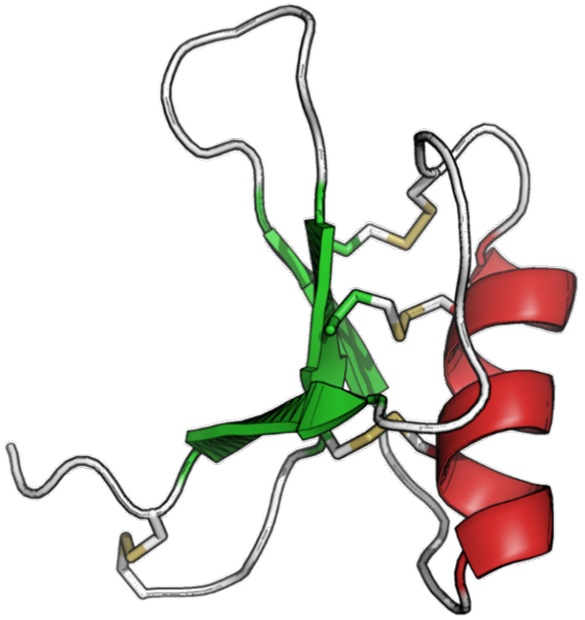
Best-practice treatment features	LAMISIL *Terbinafine*	Kerydin™ *Tavaborole*	JUBLIA® *Efinaconazole*	Penlac™ *Ciclopirox*	hexima *HXP124*
Product type	***Oral***	***Topical***	***Topical***	***Topical***	***Topical***
Fast acting	✓	✗	✗	✗	✓
Efficacious	✓	✗	✗	✗	✓
No systemic toxicity	✗	✓	✓	✓	✓
No local side effects	*N/A*	✗	✗	✓	✓

HXP124 has the potential to become the best available treatment on the market: better response than current topical treatments (approaching that of oral drugs), but with a substantially shorter treatment time and a much improved safety profile

Plant defensins

- The unique physical properties of defensins lend HXP124 to the task of safely penetrating the nail and clearing infection

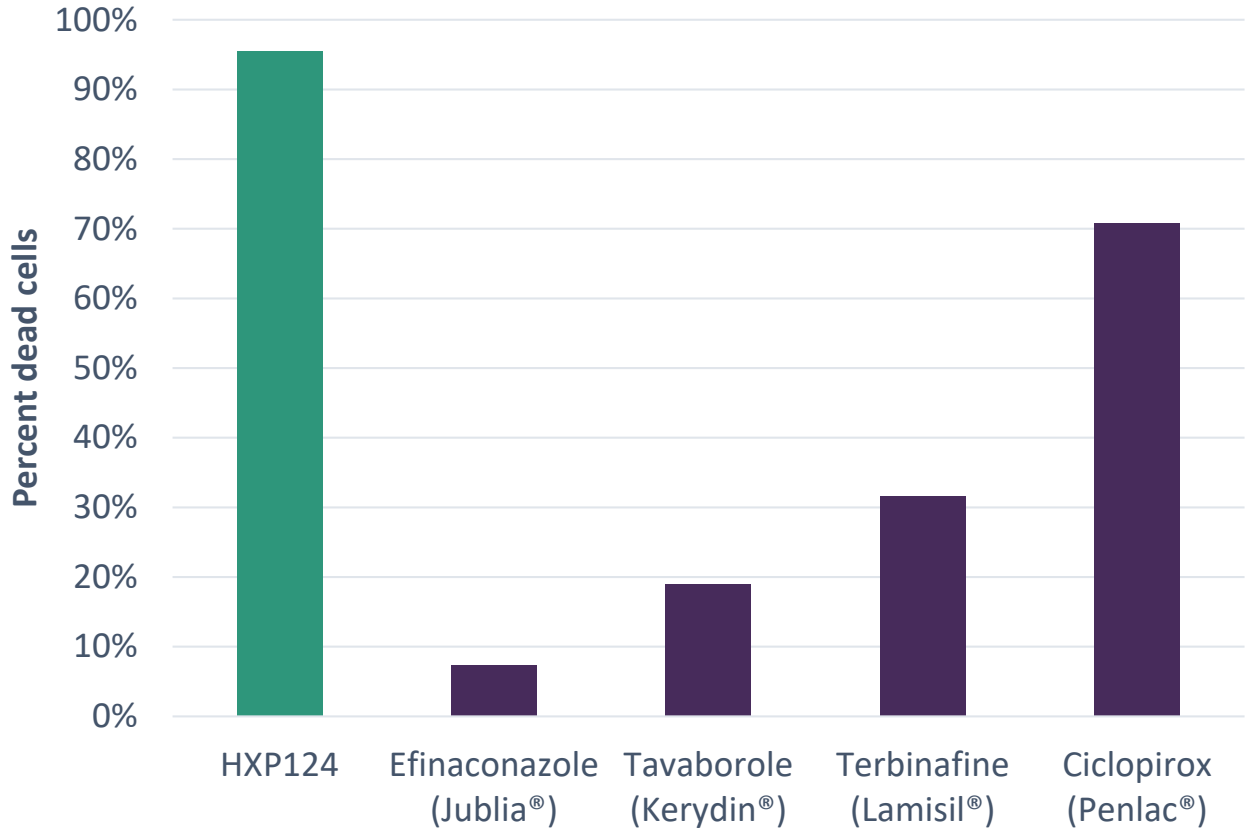




NMR structure of HXP124

HXP124 kills fungi more readily than other treatments for nail infections

- HXP124 kills fungal cells within 30 minutes via a novel mode of action
- Ineffective killing by drugs currently on the market means the fungus often regrows when treatment is stopped
- HXP124 is specific for fungal cells and does not impact the viability of human cells

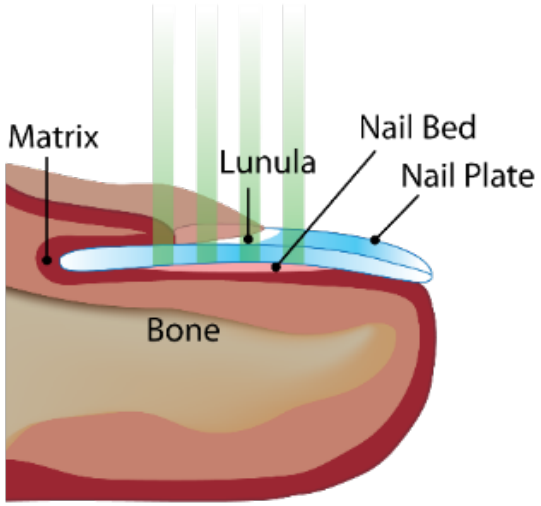


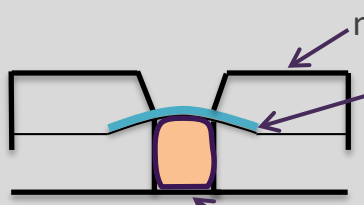
Fluorescence Associated Cell Sorting (FACS) of Propidium Iodide stained cells was used to identify living and dead *Candida albicans* cells after 30 min treatment with antifungal agents

Note: Internal Hexima Study

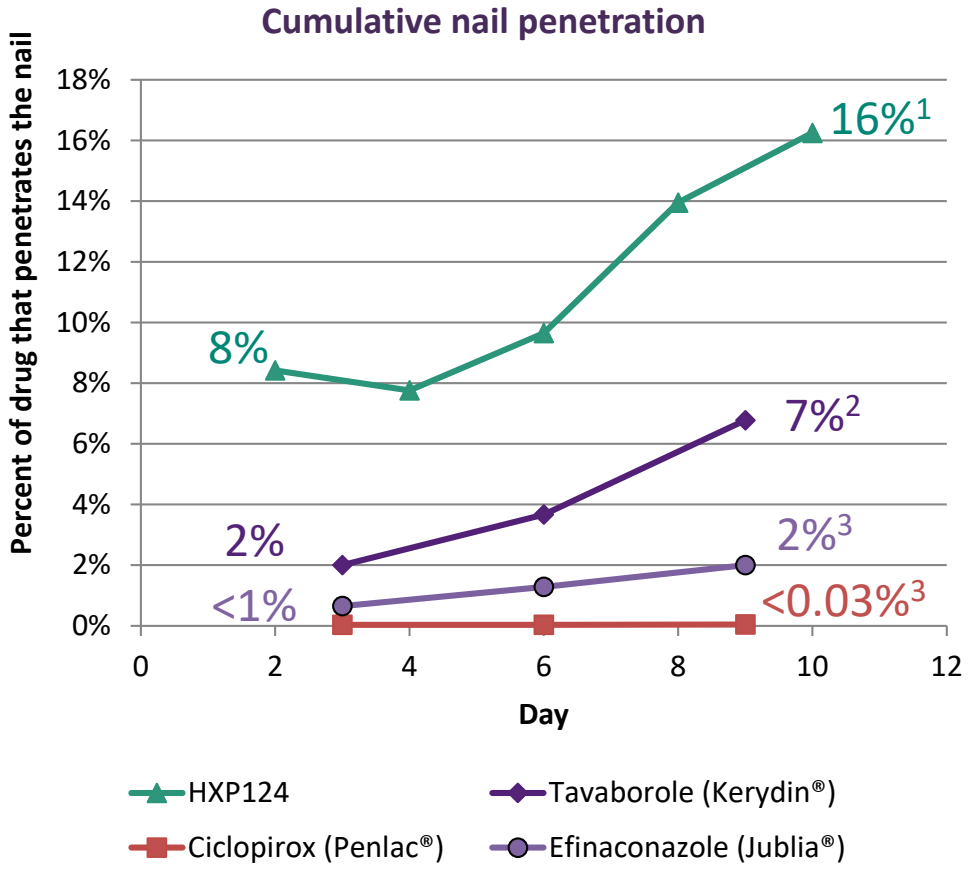
HXP124 penetrates nails faster and more efficiently than current marketed products

- Topical treatments for fungal nail disease must penetrate human nails to reach the nail bed, the main site of infection
  - Nail penetration of existing topical drugs is a major barrier to treatment efficacy





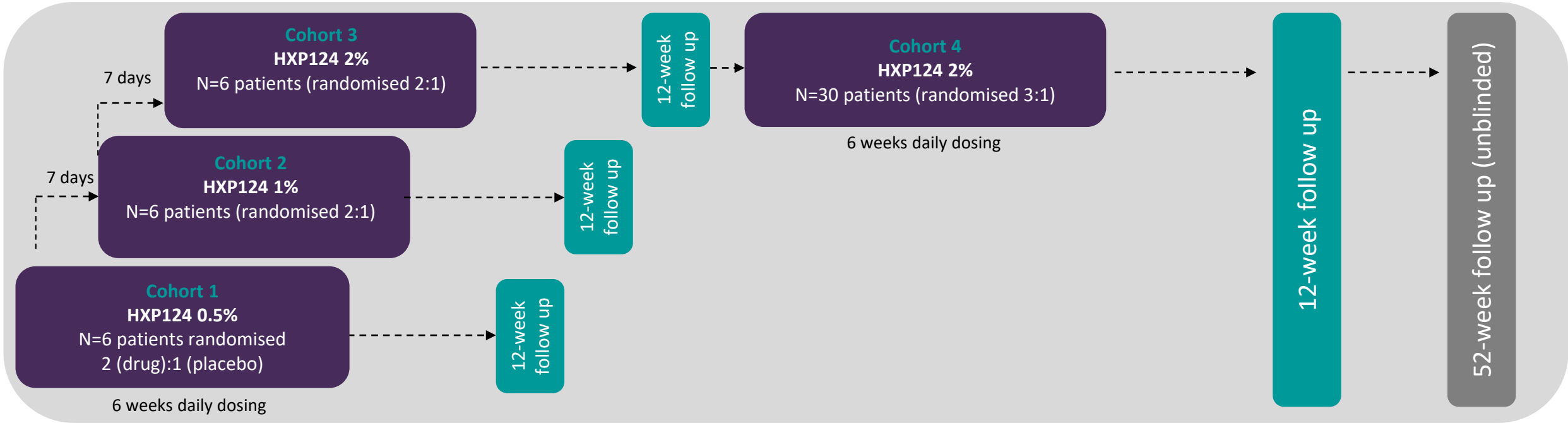
Permeation model based on method developed by Dr. Howard Maibach. (UCSF Medical Center, Hui et al., 2007)



Note: 1 Internal Hexima Study
2 Kaken Pharma and Dow Pharma, Sugiura et al., 2014;
3 UCSF Medical Center, Hui et al., 2006

Successful phase I/IIa clinical trial

- Randomised, double blind cohort study
- Patients treated nails daily with HXP124 (or vehicle) for 6 weeks with follow-up at 12 weeks
  - Total of 48 patients – 36 treated with HXP124, 12 treated with vehicle
  - Unblinded follow-up at 52 weeks only for Cohort 4



HXP124 is safe when applied to nails daily for 42 days

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

HXP124 is **safe and well tolerated.** No drug-related adverse events.

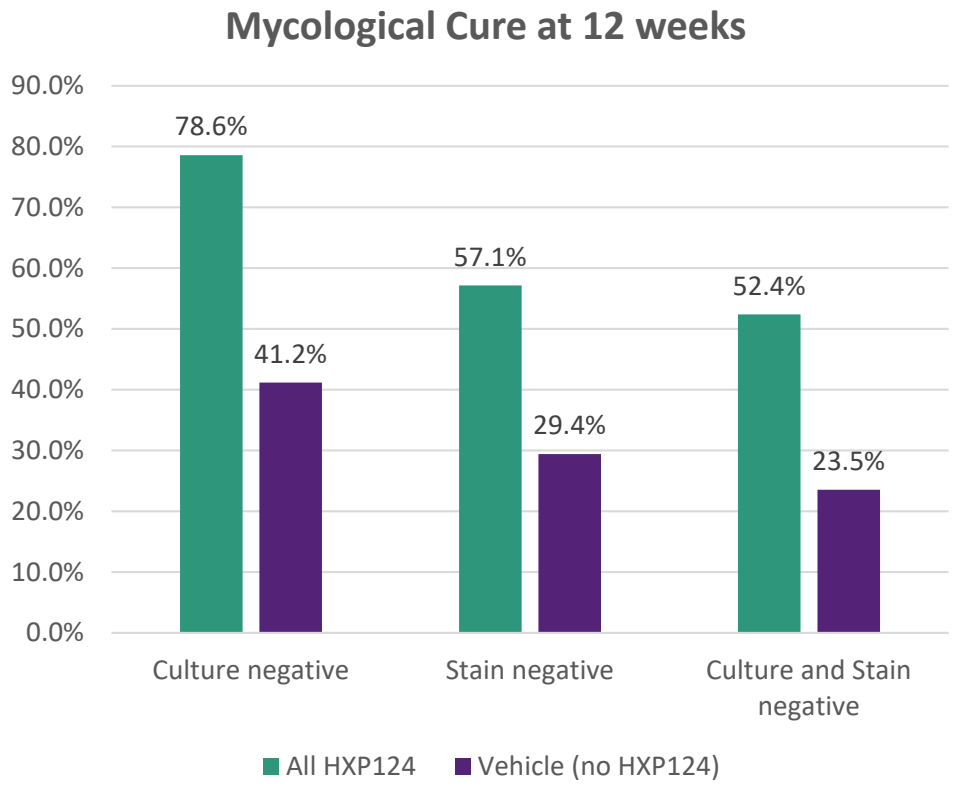
HXP124 **did not cause local irritation** and did not enter the bloodstream.
There was **no systemic toxicity.**

During a phase I/IIa trial HXP124 delivered effective and rapid anti-fungal treatment for patients

Key Insights from Phase I/IIa clinical trial

Mycological cure (culture and stain negative) was achieved in **52% of HXP124-treated nails** within 12 weeks (vehicle 24%)

HXP124 produced a high Mycological Cure* rate at 12 weeks, ~2-fold higher than current treatments, after only 6 weeks of treatment

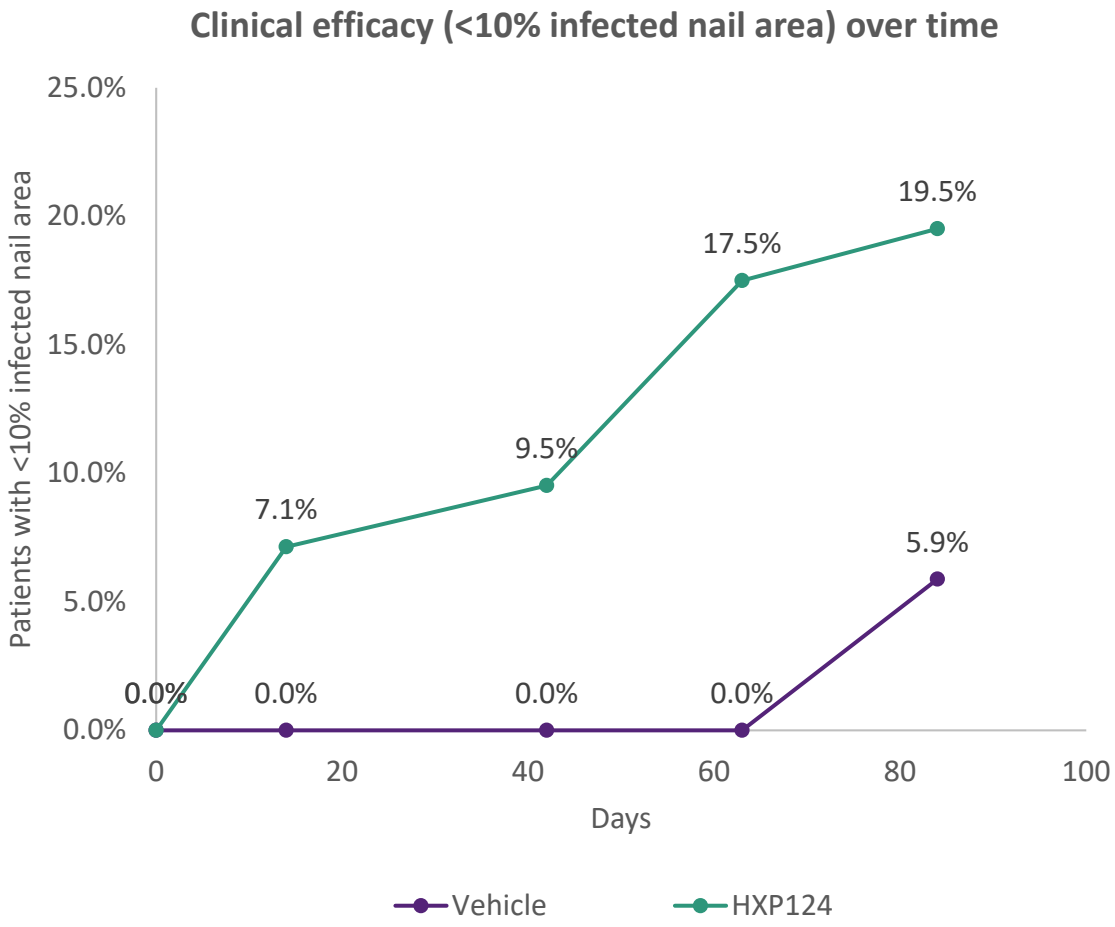


Note: *Mycological Cure = no fungus in samples collected from underneath the nail as assessed by stain (microscopy) and culture (growth).

During a phase I/IIa trial HXP124 substantially improved onychomycosis symptoms

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

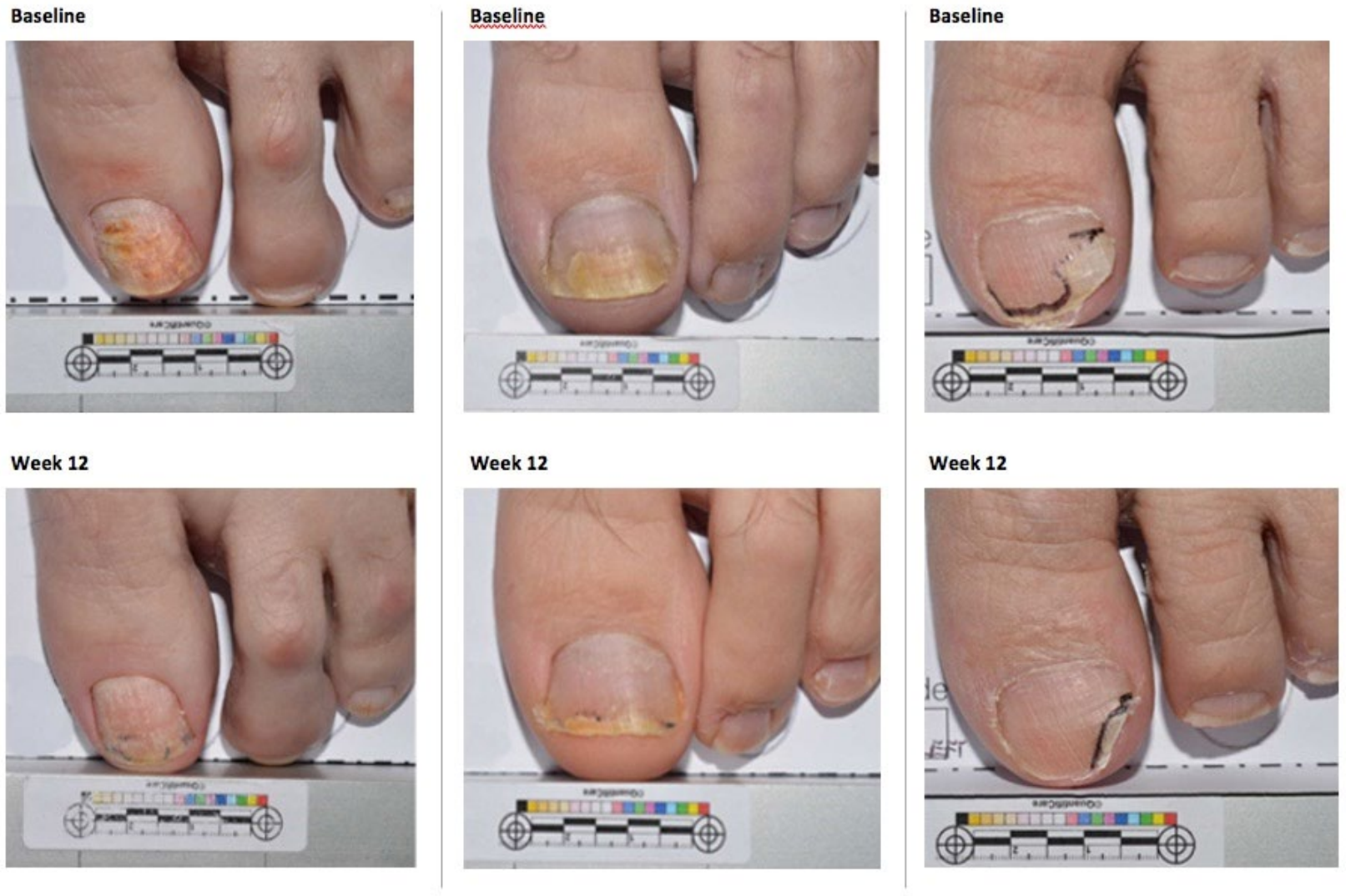
Clinical efficacy (defined as <10% of the nail area affected) was **achieved in 20% of HXP124-treated nails** within just 12 weeks (vehicle 6%)



During a phase I/IIa trial HXP124 delivered significant improvement in nail appearance within 12 weeks

Prior to treatment

12 weeks after treatment commenced

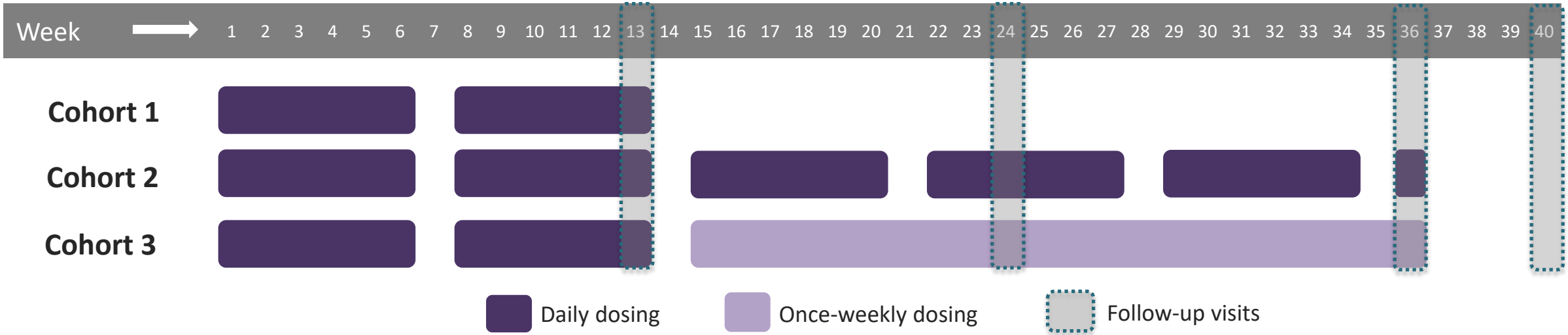


Given HXP124's safety & efficacy profile, Hexima believes it has the potential to deliver best-in-class cure rates without the toxic side effects of oral alternatives

Proposed Australian Phase IIb clinical trials

- Multi-center, randomised, double blind, vehicle-controlled study
- Three active arms versus vehicle (132 subjects)
  - Comparing three dosing strategies
- Safety & efficacy assessed at 13, 24, 36 and 40 weeks
  - Assessments align with those used for Julia® during phase II study
- Inclusion/exclusion criteria align with those used for Julia® phase III study

36 week treatment – 40 week follow-up



HXP124 can be produced rapidly and economically

HXP124 is produced in a non-proprietary yeast expression system with a **highly competitive cost of goods**

HXP124 has been **manufactured under Good Manufacturing Practice (GMP)** conditions. Commercial-scale contract manufacturer engaged.

Drug product **retains activity when stored at room temperature for 24 months**

Hexima has developed strong protection for its world-leading Intellectual Property, creating a strong foundation from which to launch HXP124

World-leading IP portfolio

Hexima has built a **world leading competency in plant defensins** and a broad IP portfolio

Globally recognised scientists

Extensive IP protection in key international markets

Patents granted in the US, Japan and Europe for HXP124 to treat fungal nail infections, patents pending in several other major jurisdictions, including China

- 15 years patent life remaining, plus any available patent term extensions

HXP124 is a biologic, eligible for 12 years marketing exclusivity in the US

30 patents for HXP124 in 2 patent families

Clearly defined growth strategy

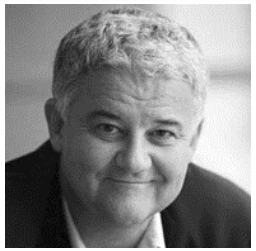
Strategy is to **develop independently in US and EU markets**

- Considering a licensing strategy in non-US and non-EU countries

$>25m invested in research and development of HXP124

Hexima is run by an experienced senior executive team who are invested in the success of the company

Board of Directors and Senior Executive Team



Prof. Jonathan West
Non-Executive Chair

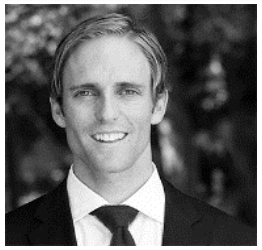
- Former Assoc. Prof. at Harvard Business School
- Founding Director of Australian Innovation Research Centre
- Advisor to major corporates including DuPont, Roche, Novartis and Syngenta.

3.3% ownership

Mr Justin Yap
Non-Executive Director

- Non-Executive Director of CathRx Limited
- Non-executive Director Wilhelm Integrated Solutions
- Formerly at Mosaic Risk Management (Wilson HTM)

10.5% ownership



Scott Robertson
Non-Executive Director

- MBA (Haas School of Business)
- Former Business Development Director at DuPont Pioneer
- Former investment professional at MPM Capital, a life science-dedicated venture capital fund
- Current CFO at DiCE Molecules

0.2% ownership

Michael Aldridge
Executive Director
Chief Executive Officer

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

1.8% ownership

Dr. Nicole van der Weerden
Executive Director
Chief Operating Officer

- PhD (La Trobe University)
- MBA (Melbourne Business School)
- Inventor on all of Hexima's key patents
- Led discovery and development program for HXP124
- CEO of Hexima 2015 -2020

1.3% ownership

Prof. Marilyn Anderson AO
Executive Director
Chief Science Officer

- Founding scientist of Hexima
- Fellow of the Australian Academy of Science and Australian Academy of Technological Sciences
- Executive Director of Hexima since 2010

1.7% ownership

Dr Peter Welburn
Chief Development Officer

- CSO and VP Research & Development Peplin Inc., NDA for PEP005 Gel approved 2012
- General Manager Leo Pharma (Australia)
- Consultant to Codexis on CDX6114 for PKU

0.4% ownership

Note: * Shareholding includes ownership by entities associated with listed individuals, and is on a fully diluted basis post Offer

Hexima considers that HXP124 presents a highly compelling commercial opportunity

Strong Clinical Profile

Market demand for greater efficacy with shorter treatment durations than current topical agents, ***indicates potential for HXP124 to become their preferred topical product***

Ability to Differentiate vs. Standard of Care

The limited efficacy and long treatment durations required by current topical drugs creates the ***opportunity to differentiate HXP124 from current drugs and drive uptake***

Potential for Antifungal Market Growth

Historic responsiveness of the market to the Julia® product launch and promotional campaigns highlights ***potential for growth in overall prescription market with HXP124***

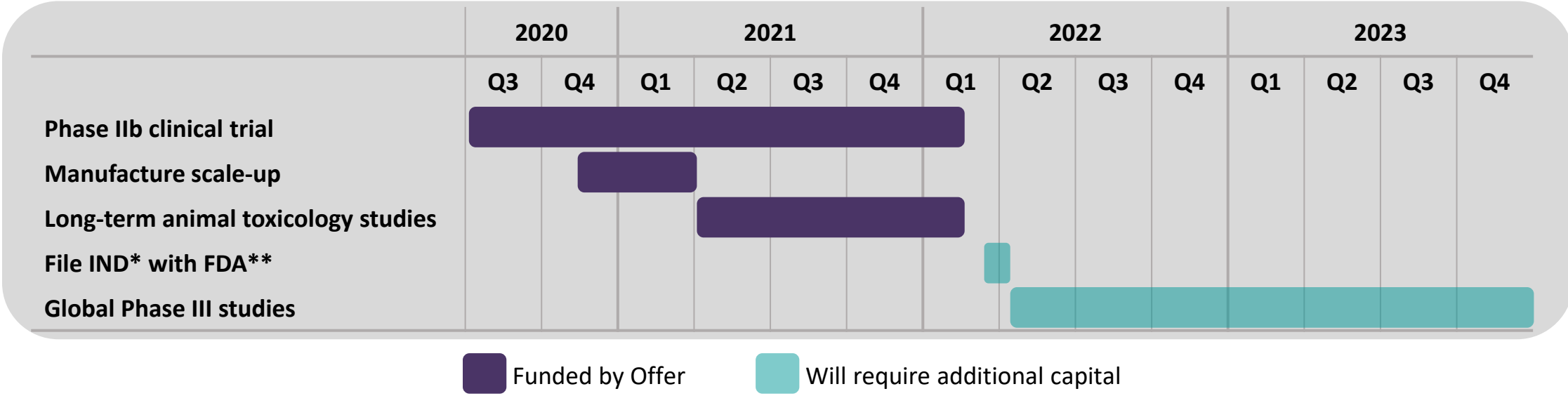
Implications

HXP124 has a meaningful and achievable commercial opportunity

Based on the expected profile and phase I/IIA results, HXP124 has the potential to ***outperform existing topical antifungal therapies***

The product development roadmap of HXP124 involves several clearly defined activities over the mid-term

Detailed product development timeline



Note: * IND = Investigational New Drug Application, required to conduct clinical trials in the US; ** FDA = US Food and Drug Administration;

Hexima is committed to the execution of a sound strategic plan, whilst preserving options to maximise shareholder returns

High-level strategic roadmap

- Raise capital for, conduct, and complete Phase IIb clinical trials in Australia
- Secure collaborative partnership in Japan
- Secure funding for, undertake, and complete Phase III clinical trials in the US
- Maintain dialogue with potential partners (or acquirors) for HXP124 in US & EU

Flexibility to pursue other strategic alternatives

Strategic alternatives designed to retain flexibility and maximise shareholder returns / value

- Trade sale of HXP124 (or Hexima) to an international pharmaceutical company at inflection points (including completion of Australian Phase IIb trials; or completion of US trials)
- Pursue a licencing arrangement of HXP124 for onychomycosis in Japan (process underway), or in the US, EU or Globally

Public Offer Indicative Capital Structure

- Hexima is raising A$3.0 million via a Public Offer at $0.20 per share and re-listing on the ASX
- A priority will be given to existing shareholders under the Public Offer
- A share sale facility will also be included in the Offer for existing shareholders at the same price as the Public Offer for up to 22.5 million shares

Indicative Capital Structure	Shares	% Ownership (Undiluted)	Gross Amount Raised	Implied Market Cap at Public Offer Price
Existing Shareholders	115.9m	88.5%	-	$23.2m
Public Offer Capital Raising	15.0m	11.5%	$3.0m	$3.0m
Total Post Offer	**130.9m**	**100.0%**	**$3.0m**	**$26.2m**

- Hexima has a Long Term Incentive Plan (LTIP) under which the Board may issue share, options, performance rights or share appreciation rights to employees, directors and consultants
- The total number of shares to be issued under the LTIP is limited to 10% of the total number of issued Shares at the time of granting the Awards.

Use of Funds & Indictive Timetable

USE OF FUNDS AND EXISTING CASH	A$
Existing Cash Balances as at 30 September 2020*	$5.5m
R&D tax incentive refund (expected November 2020)	$1.9m
Gross Proceeds of the Offer	$3.0m
Total Cash on Completion of the Offer	**$10.4m**
Phase IIb clinical trial	$3.4m
Scale-up of HXP124 manufacture	$1.2m
Formulation, stability & chemistry, manufacture & controls	$0.7m
Toxicology studies	$2.0m
Market research	$0.1m
Costs of the Offer	$0.7m
Working capital	$2.4m
TOTAL	**$10.4m**

INDICATIVE TIMETABLE	2020
Prospectus Lodgement	Mid October
Offer opens	Late October
Share Sale Facility closes	Early November
Public Offer closes	Mid November
Shares commence trading on ASX	Late November

Indicative timetable is subject to change

HXP124 is well-positioned to become the market-leading treatment for onychomycosis globally

Hexima has extensive understanding of the HXP124 molecule, and is the world leader in this class of proteins

HXP124's high (>50%) mycological cure rate after just 6 weeks of daily application.
The Australian phase IIb trial will assess 12-30 week courses of treatment.

HXP124 has the potential to address the well-defined and unmet medical need of millions of patients suffering from the disfiguring and often painful disease, and who are inadequately served by existing treatments. It is also highly cost-effective to manufacture

Medical practitioners surveyed have indicated a product with HXP124's characteristics (efficacy, treatment duration, safety, etc.) would likely be prescribed as a priority ahead of competing products

Historically the failure in onychomycosis product development and commercialisation has occurred because of:

- potential toxicity through ingesting a tablet with harmful side effects;
- limited efficacy;
- inability to kill fungus; and
- inability of topical products to penetrate the nail

Based on documented studies, HXP124 does not suffer any of the above limitations

Hexima has strong patent protections in all key markets, and a clear roadmap for successfully developing HXP124

Through HXP124, Hexima is positioned to deliver meaningful solutions to patients and significant value to its investors

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