

Q3 2021

NAILMAIL

INVESTOR NEWS

QUARTERLY NEWSLETTER TO SHAREHOLDERS, INVESTORS AND INTERESTED PARTIES. FOR FURTHER INFORMATION VISIT OUR WEBSITE AT HEXIMA.COM.AU.



MAJOR ACHIEVEMENTS COVERED IN THIS REPORT

- ✓ Filed design patents covering important consumer-orientated elements of CompliancePak, Hexima's novel secondary packaging system for pezadeftide;
- ✓ Completed patient enrolment in its phase IIb clinical trial, which sets the timeline for the delivery of results, expected in Q2 2022;
- ✓ Presented new clinical data from its phase I/IIa clinical trial at the annual meeting of the American Podiatric Medical Association (APMA) in Denver, CO.;
- ✓ Received notice of grant for patents covering the therapeutic use of pezadeftide for onychomycosis in both Europe and China;
- ✓ Presented at the ACCESS CHINA Biotech Forum and initiated a program of outreach to potential corporate partners in China; and
- ✓ Complemented the strength of its existing board with the appointment of Mr Jake Nunn.

ABOUT HEXIMA

Hexima 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 (formerly 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.

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IMPORTANT DEVELOPMENTS AND MILESTONES Q3 2021

The September 2021 quarter reflects a period of important progress towards our goal of delivering a new, safe, and effective topical treatment for onychomycosis with a more convenient shorter course of therapy.

Many of the activities currently being conducted by the Company are designed to accelerate its business plan into the US, as Hexima prepares for its US phase III program in 2022.

CompliancePak and Mobile App

In August, Hexima announced that it had filed a design patent covering important consumer-orientated elements of its CompliancePak secondary packaging system.

Hexima is also developing a mobile application intended as a companion application to assist patients in treating their onychomycosis.

The treatment of onychomycosis is a consumer-driven market and CompliancePak and the mobile app are intended to enhance the experience of patients using pezadeftide to treat their onychomycosis.

Hexima unveiled both the mobile application and CompliancePak (see images below) as part of a



webinar held in early September. A recording of this webinar is available on the Hexima website and [from this link](#).

Hexima is focused on completing the design and engineering of this packaging system to test it comprehensively in its phase III trials. By including it in the phase III trial, Hexima intends to demonstrate how the improved patient experience leads to better treatment compliance and thus better overall health outcomes.

Hexima is confident that its complete product solution can deliver both an improved treatment experience and disease resolution currently missing in existing treatment alternatives.



COMPLIANCEPAK

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



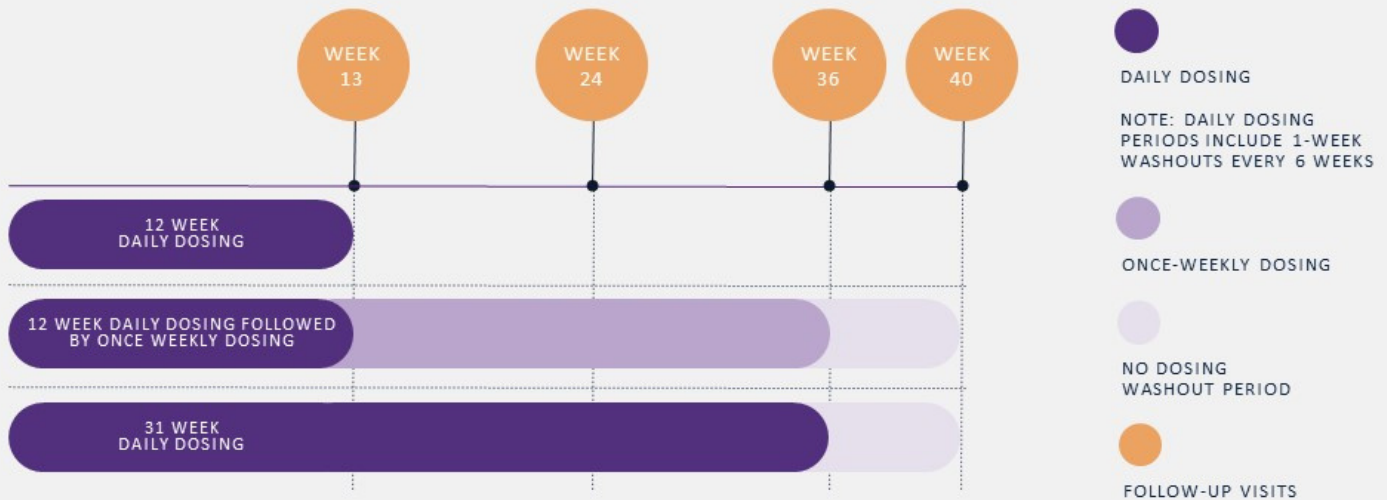
MOBILE APP

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

PHASE IIB CLINICAL TRIAL



In July, Hexima announced the completion of patient enrolment in its phase Iib clinical trial. All patients enrolled in this trial are now in their treatment or follow-up phase and this sets the timeline for the delivery of results in Q2 2022.



This phase Iib clinical trial is a multi-centre trial being conducted across 14 clinical sites in Australia and New Zealand. Subjects with onychomycosis are randomly assigned to one of three treatment arms i) 12 weeks; versus ii) 31 weeks of daily therapy; versus iii) 12 weeks of daily therapy followed by once a week therapy out to 36 weeks.

The study is vehicle-controlled where 25% of subjects will receive the vehicle which is the formulation with no pezadeftide in it. Both patient and evaluating professional are blinded to the active / vehicle identity.

By comparing the results in each arm of this trial we intend to identify the optimum dosing regimen to take into Hexima's US phase III clinical trial program.

KOL Commentry

Hexima recently took the opportunity to speak with certain of its Scientific Advisory Board members about Onychomycosis: the disease, its treatment and the potential for a new therapy like pezadeftide. We captured videos of these interactions and have made them available to [view on our website](#). In this NailMail we highlight one of Dr Tracey C. Vlahovic's comments. You can see her [full response here](#).

"If we had a topical medication that approached the therapeutic efficacy of the oral anti-fungals but had the safety of the topical anti-fungals, that would be a slam dunk"

- Dr Tracey C. Vlahovic

European and China Patents Granted

During the quarter Hexima received notice that patents covering the therapeutic use of pezadeftide for onychomycosis were granted in both Europe and China.

These patents add to Hexima's existing patent portfolio for other regions in the United States, Japan, Singapore and Australia, and protect the Company's innovations in the EU and China, until 2035.

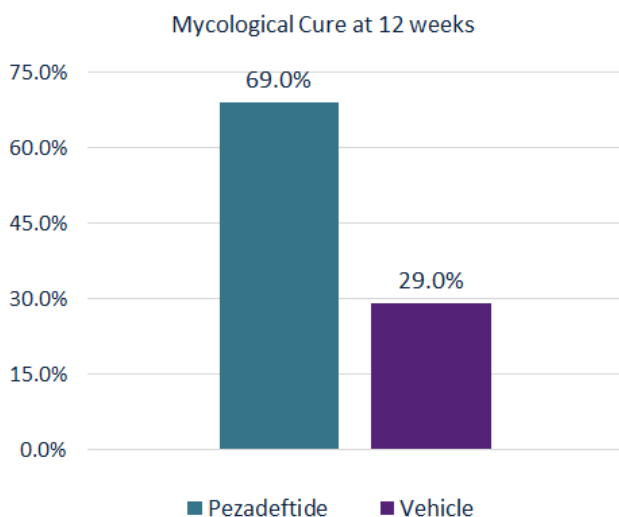
Beyond that, Hexima continues to add further intellectual property protection to this patent estate which covers important innovations we have made in our R&D program.

Presentation at American Podiatric Medical Association Conference

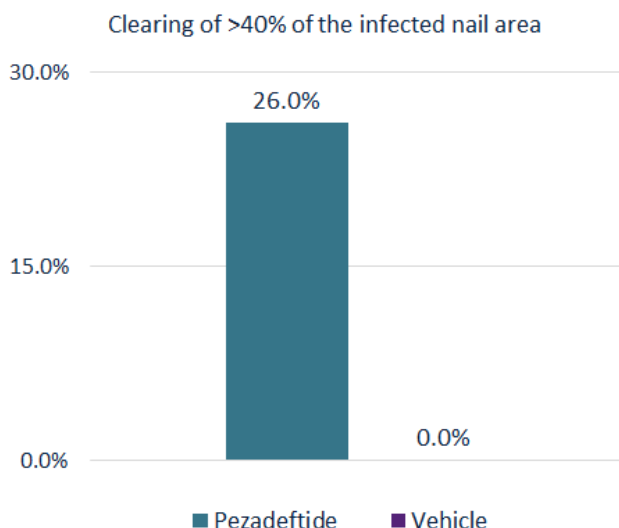
Hexima presented clinical data from its phase I/IIa clinical trial of pezadeftide for the treatment of onychomycosis at the annual meeting of the American Podiatric Medical Association (APMA) in Aurora, Colorado in July 2021.

The APMA represents an important venue for the presentation of pezadeftide's potential in onychomycosis. Podiatrists are the specialists who manage most cases of onychomycosis and importantly write 80% of all prescriptions for onychomycosis in the US.[1]

The data is impressive, particularly at this early stage of development. In Cohort 4 (comprising 30 patients) 69% of subjects treated with pezadeftide (2%) daily for just 6 weeks achieved a mycological cure at 12 weeks, compared to just 29% of vehicle-treated patients.



Further, 25% of these subjects were able to clear more than 40% of their original infected nail area, compared with 0% of the vehicle-treated patients at the same time point.



Initiated China BD Program

In late September, Hexima presented at the ACCESS CHINA Biotech Forum and initiated a program of outreach to potential corporate partners in China. This program has already begun to yield results for the Company, as Hexima has entered into preliminary discussions with a potential China partner.

Board

In September, Hexima complemented the strength of our existing board with the appointment of Mr Jake Nunn to our Board of Directors.

Mr. Nunn brings more than 25 years of experience in the life science industry as an investor, independent director, research analyst and investment banker. Jake is currently an independent advisor to several life-science companies and a venture advisor at New Enterprise Associates (NEA), where he was an investing partner from 2006 to 2018 focused on the biopharmaceutical and medical technology sectors. Jake will be a critically important advisor to the Company as we plan our US growth and development.

MILESTONES TO LOOK FORWARD TO IN Q4 2021

File IND with FDA: Hexima anticipates completing and compiling its manufacturing and toxicology information ahead of filing our Investigational New Drug (IND) Application with FDA in Q4 2021.

This filing is critical to initiating our US development program. We anticipate the first trial will be a short single-centre safety clinical study in the US necessary prior to proceeding to phase III.

Toxicology studies: Having completed the necessary toxicology studies and reports, Hexima's toxicology program remains on track. Hexima will include the information in the toxicology section of our upcoming IND filing. The Company expects to file the IND with FDA in Q4 2021.

Manufacturing: Hexima completed the last of its large-scale engineering manufacturing batches. It expects to manufacture pezadeftide under GMP manufacturing conditions in Q4 2021 to support the filing of an IND and US clinical trials in early 2022.

Notes:

1. ClearView Healthcare Partners proprietary market research, 2019