ASX Announcement

28 July 2021

Quarterly Activities Report and Appendix 4C

Enrolment in phase IIb clinical trial completed in July

INN designation received for pezadeftide

Key patents granted in Europe and Mexico

Large-scale manufacture complete

MELBOURNE, AUSTRALIA (28 July 2021): Hexima Limited (ASX:HXL) a clinical stage biotechnology company developing pezadeftide (formerly HXP124), as a potential new prescription topical treatment for onychomycosis, today files its Appendix 4C and quarterly activities report for the quarter ended 30 June 2021. Quarterly activities are set out in the attached NailMail, Hexima's quarterly communication to shareholders.

Hexima will hold an investor webinar at 9 am AEST on 29 July to share clinical data from its phase I/IIa clinical study that will be presented at the American Podiatric Medical Association (APMA) Annual Meeting in Colorado on 30 July 2021. The Company will also give an update on progress of its phase IIb clinical study. Attendees can register to attend using the link below.

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

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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.

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

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.[5]

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 more effective at rapidly killing fungal cells on contact. Together, these properties mean that HXP124 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.

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[1] Tatchibana et al., Journal of Fungi, 2017
[2] Joseph et al, Supplement to Podiatry Today, 2013
[3] Milobratovic et al., Mycoses, 2013
[4] Persistence Market Research 2018
[5] Wang et al., Onychomycosis: Diagnosis and Effective Management, 2018

Q2 2021

NailMail

Investor News

NailMail is Hexima's regular quarterly newsletter to shareholders, investors and interested parties. For further information visit our website at hexima.com.au.

Major achievements covered in this report

- **Completing enrolment** in phase IIb clinical trial for pezadeftide (formerly HXP124) as a treatment for onychomycosis;
- **Receiving the INN designation** for pezadeftide and establishing it as the first in a new class of antifungal molecules;
- **Receiving the notice of grant** of key patents covering the use of pezadeftide in both Europe and Mexico;
- **Completing large-scale manufacture** at a commercial-scale contract manufacturer in Europe; and
- **Acceptance to present at the American Podiatric Medicine Association (APMA)** annual meeting in Denver, Colorado.

Hexima is on-track to file an IND with FDA in Q4 2021 and to report results from its phase IIb clinical trial in Q2 2022.

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.

Hexima Limited

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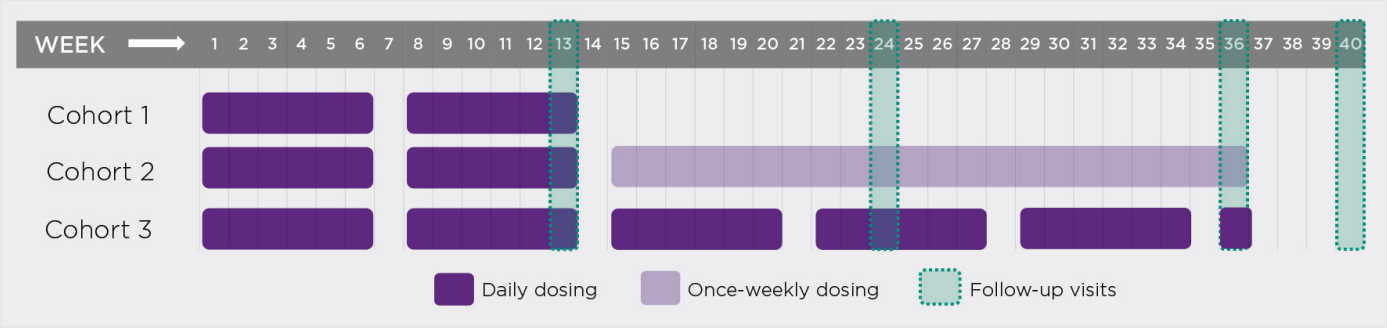
Phase IIb clinical trial (HXP124-ONY-002)

Hexima is conducting a phase IIb clinical trial at 15 sites in Australia and New Zealand. The trial has enrolled 117 patients with onychomycosis and seeks to identify the optimal course of therapy for pezadeftide. This study is comparing 12 weeks versus 30 weeks of daily therapy as well as 12 weeks of daily therapy followed by weekly maintenance therapy out to 36 weeks. The patients receiving treatment with pezadeftide are being compared to patients being treated with a formulation not containing pezadeftide at a ratio of 3:1.

The results of this clinical trial are intended to identify the optimum dosing regimen to take into Hexima's US phase III clinical trial program. Hexima expects this phase IIb clinical trial (HXP124-ONY-002 [7]) to represent its last large, multi-centre clinical trial ahead of initiating its phase III program.

Our goal is to demonstrate the potential of pezadeftide to be a safe and effective treatment in a convenient, consumer friendly, topical format for this very common and difficult to treat infectious disease.



Important developments and milestones in Q2 2021

Completion of enrolment in phase IIb clinical trial

Shortly after the quarter end, Hexima completed enrolment of patients into its phase IIb clinical trial of pezadeftide for onychomycosis.

This is an important achievement in pezadeftide's development program. A total of 15 clinical sites across Australia and New Zealand recruited, screened, and enrolled 117 eligible patients to evaluate pezadeftide as a new topical treatment for onychomycosis in three different treatment arms, with a vehicle control. All patients have now started treatment and will be followed for safety and efficacy, we are also collecting patient satisfaction measures.

Hexima expects this study to build on the very promising evidence of efficacy demonstrated in its phase I/IIa clinical trial. The Company's goal is to demonstrate the potential of pezadeftide to be a safe and effective treatment in a convenient, consumer friendly, topical format for this very common and difficult to treat infectious disease.

Hexima expects to announce the results of this study, as previously indicated, in Q2 2022. These results will be pivotal in determining the optimal dosing strategy for its final phase III program in the US. The phase III program in the US is expected to begin in the later half of 2022.

INN designation

The International Nonproprietary Names (INN) Programme and Classification of Medical Products of the World Health Organization (WHO) has selected "pezadeftide" as the non-proprietary name for Hexima's HXP124. The suffix "-deftide", representing defensin-derived anti-microbial peptides, establishes pezadeftide as the first in a new class of anti-fungal molecules.

The designation of pezadeftide as the first in a new class of anti-microbial peptides highlights the important role that Hexima is playing in developing novel, powerful and broad-spectrum fungicidal molecules as potentially valuable tools in the ever-escalating battle with constantly evolving fungal pathogens.

Hexima expects "pezadeftide" to be included in List 126 of proposed INN, to be published in WHO Drug Information and to be confirmed following a four month public review and comment period.

Selection to present at American Podiatric Medical Association Conference

Hexima has been selected to present 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 tend to manage most cases of onychomycosis and importantly write 80% of all prescriptions for onychomycosis in the US.[3]

Dr Tracey Vlahovic, Clinical Professor at Temple University School of Podiatric Medicine and Member of Hexima's Scientific Advisory Board, says:

"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".

Presenting at the APMA will provide an opportunity to share pezadeftide's data and further engage with this important group of prescribers as we ensure the development of pezadeftide effectively meets the needs of patients with onychomycosis.

Completion of manufacturing scale-up

Hexima completed multiple large-scale manufacturing batches with its European CMO to produce pezadeftide for toxicology studies. In this scale-up process Hexima has resolved the challenges in manufacturing pezadeftide at scale and can now point confidently to both commercial-scale and low-cost manufacturing of pezadeftide.

Grant of pezadeftide patents in Europe and Mexico

Patents covering the use of pezadeftide for the treatment of onychomycosis were granted in Europe and Mexico. The patents, described as "A Method of Treatment", provide broad protection covering the therapeutic use of pezadeftide, as well as topical formulations containing pezadeftide, for the treatment of onychomycosis. The patents provide protection until 2035.

Hexima also expects to benefit from up to an additional five years of market exclusivity in Europe through the supplementary patent certification available for medicinal products in member states of the European Union.

The award of the European and Mexican patents further strengthens Hexima's patent portfolio which includes similar granted patents in the United States, Japan, Singapore and Australia. Hexima continues to pursue additional layers of patent protection in these and other jurisdictions.

Milestones to look forward to in 2021

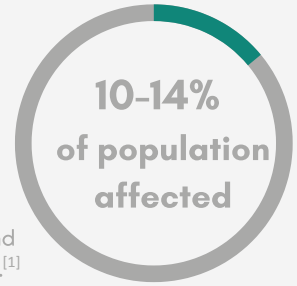
Toxicology studies: Our toxicology program is on track and we plan to complete necessary toxicology studies in Q3 2021.

Manufacturing: Hexima expects to manufacture pezadeftide under GMP manufacturing conditions in Q4 2021, to support US clinical trials in early 2022.

File IND with FDA: We anticipate completing and compiling our manufacturing and toxicology information and to file an 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.

ONYCHOMYCOSIS AT A GLANCE

Onychomycosis is estimated to affect 10-14% of the population and is the most common nail disorder.[1]



$3.7b

The global market for treatments for onychomycosis was approximately US$3.7 billion in 2018.[2]

3.1M

Number of patients treated annually in the US.[3]

"Topical products are preferred by many patients"

Boni Elewski MD, [4]

~70% of onychomycosis scripts in the US are for topical products.[2]

Onychomycosis has a substantial healthcare burden[5,6]

Onychomycosis is responsible for an average of 4 doctors visits annually by patients seeking treatment.

4 p.a.

50% EXPERIENCE PAIN

51% ARE IMPACTED WEARING SHOES

66% DISTRESSED BY APPEARANCE OF THEIR NAILS

Patients prefer topical products because oral products can have serious side effects but they are left frustrated by the long treatment duration and limited efficacy of current treatment options.

Notes:
1.Tatchibana et al., Journal of Fungi, 2017; 2.Persistence Market Research 2018; 3.ClearView Healthcare Partners proprietary market research, 2019; 4. Infection Inspection, Dermatology World, 2017; 5 .Joseph et al, Supplement to Podiatry Today, 2013;
6. Milobratovic et al., Mycoses, 2013; 7.ANZCTR Registration Number: ACTRN12620000697987

Expected and Actual Use of Funds			
Categories	**Expected Use of Funds [1, 2] $000's**	**Actual Use of Funds 1 October 2020 to 30 June 2021 $000's**	**% of total**
Phase IIb clinical trial	3,400	2,154	63
Scale-up of HXP124 manufacture and production of material for toxicology studies	1,200	1,782	148
Formulation, stability and chemistry, manufacture and controls	700	465	66
Toxicology studies	2,000	248	12
Market research	100	67	67
Costs of the offer	700	703	100
Working capital	2,300	1,971	86
Totals	**10,400**	**7,390**	**71**

Note 1. Expected Use of Proceeds and Current Cash as set out on page 10 of the Company's Prospectus dated 15 October 2020

Note 2. Expected Use of Funds is net of the estimated R&D Tax Incentive rebate

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Hexima Limited	
ABN	**Quarter ended ("current quarter")**
64 079 319 314	30 June 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	108	540
1.2	Payments for		
	(a) research and development	(2,235)	(5,990)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		(3)
	(d) leased assets		
	(e) staff costs	(301)	(1,159)
	(f) administration and corporate costs	(194)	(1,362)
1.3	Dividends received (see note 3)		
1.4	Interest received		1
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		(25)
1.7	Government grants and tax incentives		1,988
1.8	Other – GST Refund	85	470
	Other – Reimbursement of LT receivable	23	23
1.9	**Net cash from / (used in) operating activities**	**(2,514)**	**(5,517)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments		
	(e) intellectual property		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(f) other non-current assets		
2.2	Proceeds from disposal of:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		
2.3	Cash flows from loans to other entities		
2.4	Dividends received (see note 3)		
2.5	Other (provide details if material)		
2.6	**Net cash from / (used in) investing activities**		

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		8,700
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		
3.4	Transaction costs related to issues of equity securities or convertible debt securities		(1,065)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings		
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (provide details if material)		(9)
3.10	**Net cash from / (used in) financing activities**	**-**	**7,626**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	5,880	1,357
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,514)	(5,518)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)		7,626
4.5	Effect of movement in exchange rates on cash held	56	(43)
4.6	**Cash and cash equivalents at end of period**	**3,422**	**3,422**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	3,421	5,879
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other – Petty cash	1	1
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**3,422**	**5,880**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other – NAB Credit card facility	300	5
7.4	**Total financing facilities**	300	5

7.5	**Unused financing facilities available at quarter end**	295

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,514)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,422
8.3	Unused finance facilities available at quarter end (item 7.5)	295
8.4	Total available funding (item 8.2 + item 8.3)	3,717
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.4

NOTE: Item 1.9 does not include the receipt of the annual R&D Tax Incentive. The calculation of item 8.5 has been adjusted to include amortisation of the R&D Tax Incentive receivable over 12 months to more appropriately reflect the quarterly cash flow.

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: ..28 July 2021.....

Authorised by: ....Michael Aldridge, Managing Director and CEO.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.