HEXIMA LIMITED

ASX ANNOUNCEMENT

28 October 2021

QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

- ***Completed enrolment in phase IIb clinical trial***
- ***Filed design patents on CompliancePak***
- ***Received notice of grant of Europe and China patents***

MELBOURNE, AUSTRALIA (28 October 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 September 2021. Hexima finished the quarter with cash plus R&D Tax receivable of $4.9 million. Hexima's R&D Tax receivable of $3.66 million was received in October 2021.

Quarterly activities are set out in the attached NailMail, Hexima's quarterly communication to shareholders.

This announcement is authorised for release to ASX by Michael Aldridge, Managing Director & 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 or email us at info@hexima.com.au.

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.

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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).

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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

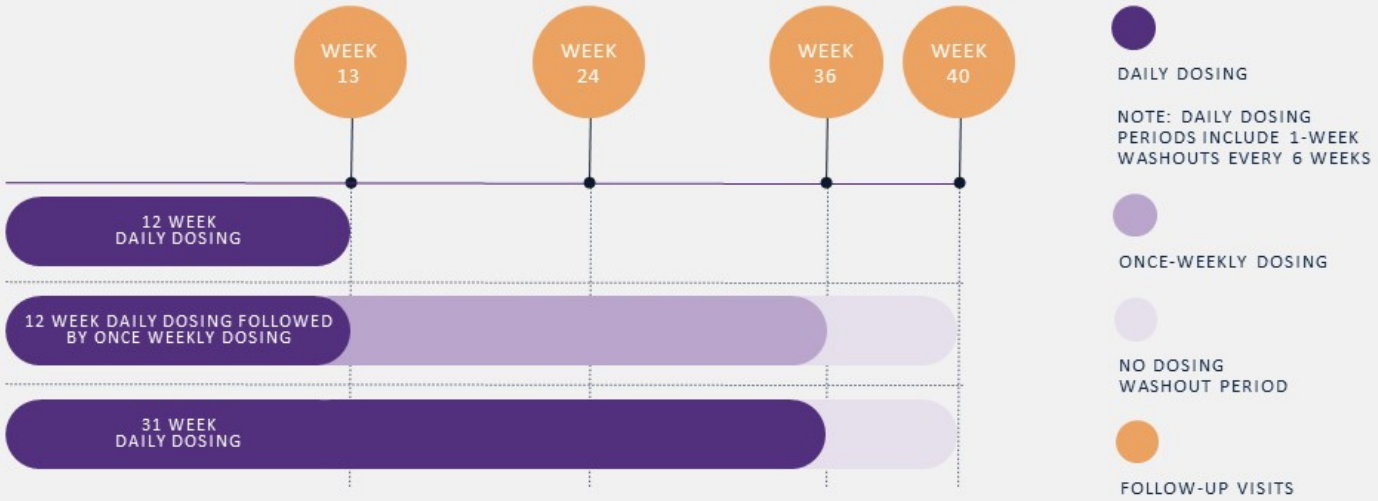
- No spill / difficult to misplace
- Easy to open / child resistant
- Reinforces FDA use directions
- Connects by QR code to mobile app

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.

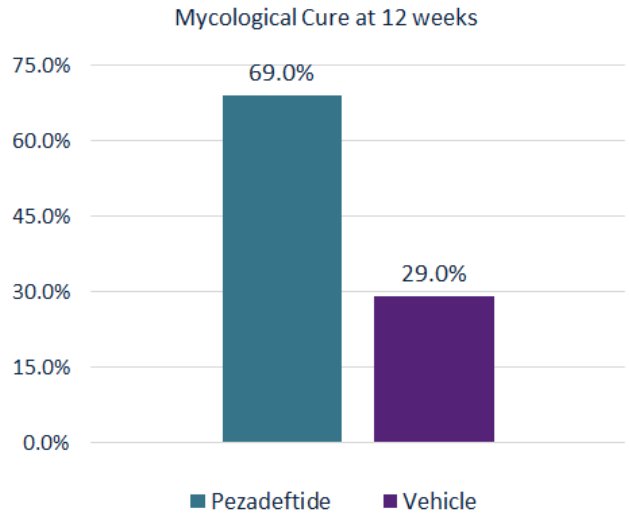
Beyond that, Hexima continues to add further intellectual property protection to this patent estate which covers important innovations we have made in our R&D program.

Presentation at American Podiatric Medical Association Conference

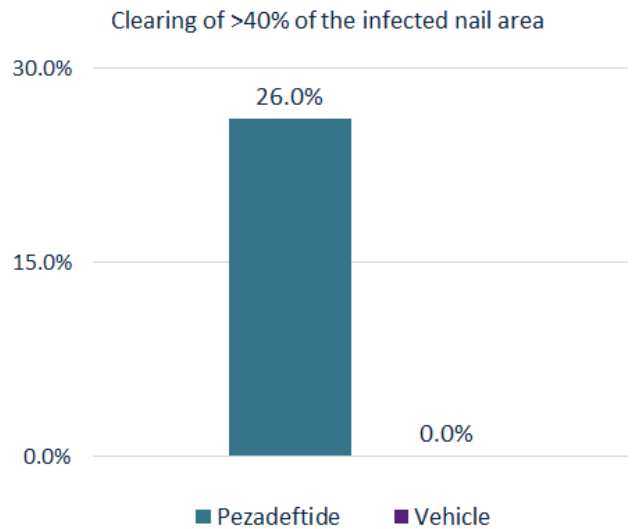
Hexima presented clinical data from its phase I/IIa clinical trial of pezadeftide for the treatment of onychomycosis at the annual meeting of the American Podiatric Medical Association (APMA) in Aurora, Colorado in July 2021.

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

Expected and Actual Use of Funds			
Categories	**Expected Use of Funds [1, 2] $000's**	**Actual Use of Funds 1 October 2020 to 30 Sep 2021 $000's**	**% of total**
Phase IIb clinical trial	3,400	3,130	92
Scale-up of HXP124 manufacture and production of material for toxicology studies	1,200	1,986	165
Formulation, stability and chemistry, manufacture and controls	700	595	85
Toxicology studies	2,000	598	30
Market research	100	68	68
Costs of the offer	700	703	100
Working capital	2,300	2,752	120
Totals	**10,400**	**9,832**	**95**

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 September 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	110	110
1.2	Payments for		
	(a) research and development	(1,704)	(1,704)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(540)	(540)
	(f) administration and corporate costs	(285)	(285)
1.3	Dividends received (see note 3)		
1.4	Interest received		
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives		
1.8	Other – GST Refund	151	151
	Other – Reimbursement of LT receivable		
1.9	**Net cash from / (used in) operating activities**	**(2,268)**	**(2,268)**

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 (3 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)		
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		
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)		
3.10	**Net cash from / (used in) financing activities**	**-**	**-**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,442	3,442
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,268)	(2,268)
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 (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)		
4.5	Effect of movement in exchange rates on cash held	43	43
4.6	**Cash and cash equivalents at end of period**	**1,197**	**1,197**

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	1,196	3,421
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)**	**1,197**	**3,422**

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	4
7.4	**Total financing facilities**	300	4

7.5	**Unused financing facilities available at quarter end**	296

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)	(2,268)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,197
8.3	Unused finance facilities available at quarter end (item 7.5)	296
8.4	Total available funding (item 8.2 + item 8.3)	(775)
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.3

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: Hexima expects it will continue to have the current level of net operating cashflows at least for the next quarter.

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: Hexima is taking steps to raise further capital to funds its operations. Hexima intends to undertake a capital raising transaction during the second fiscal quarter and the company's board of directors currently expects those plans will be successful.

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:	Hexima expects to be able to continue its operations and to meet its business objectives on the basis of its capital raising plans summarised in 8.6.2.

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: .....

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.