HEXIMA LIMITED

ASX ANNOUNCEMENT

31 January 2022

Quarterly Activities Report and Appendix 4C

Completion of $11 million financing
Important additions to the team
cGMP manufacturing run complete
Cash at bank plus R&D Tax Rebate receivable of $14.3 million at year end

MELBOURNE, AUSTRALIA (31 January 2022): 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 31 December 2021. Quarterly activities are set out in the attached NailMail, Hexima's quarterly communication to shareholders.

Hexima has now completed large scale cGMP manufacturing of pezadeftide at its European CMO. This is an important milestone. It marks the completion of a multi-year program of transferring and scaling-up the manufacturing technology for pezadeftide from the original pilot-scale site in Australia to a commercial scale CMO in Europe.

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.

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 a 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 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 pezadeftide 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

Q4 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

- Finished the calendar year well capitalised with $14.3 million in cash at bank and R&D tax rebate receivable;
- Completed a successful $11 million placement and SPP at A$0.32 per share to fund preparations for phase III clinical trials. Funding was well supported by multiple new institutional investors and existing shareholders;
- Appointed Dr Nancy Sacco as Chief Development Officer to lead development efforts into our US phase III development program, and Mr Philip Rose as Chief Commercial Officer;
- Successfully completed cGMP manufacturing of pezadeftide, a key component of our IND to be filed with FDA;
- Enhanced the Scientific Advisory Board with the appointment of Dr Shari Lipner;
- Presented at AusBiotech Invest, the preeminent opportunity for Australian biotech companies to present to a network of international partners and investors;
- Submitted a poster which was accepted for publication at American Academy of Dermatology, the poster will be presented at the AAD in Boston on 25 March 2022.

Hexima expects to file an IND with FDA in the first quarter of 2022. The initiation of our first US clinical trial under that IND remains on track for mid 2022, and the Company's overall timetable of development activities including the release of its phase IIb data in Q2 2022 and the subsequent initiation of phase III remains on track.

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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 Q4 2021

The final calendar quarter of 2021 reflects a period of important progress towards Hexima's goal of delivering a new safe and effective topical treatment for onychomycosis with a more convenient shorter course of therapy, and the Company remains poised to deliver continued progress in the first quarter of 2022 and beyond.

Financing

All final approvals for the $11 million placement and SPP were completed at the Company's AGM held in December. A $10 million institutional placement was successfully completed with an associated SPP to shareholders raising a further $1 million, all at $0.32 per share.

Proceeds from the financing will be used to accelerate Hexima's business plans, particularly into the US and other international markets by:

- completing the preparation and submission of an Investigational New Drug (IND) Application to FDA and conduct a clinical safety study in the US;
- finalising all development including: clinical, manufacturing, toxicology and CompliancePak packaging unit and mobile app necessary prior to initiating a phase III clinical trial program;
- securing executives and expertise with the necessary experience to conduct late-stage product development in the US market;
- evaluating the option for Hexima to raise capital in the future on attractive terms with US and international investors; and
- exploring the potential for pezadeftide or one of its related defensin class peptides to be an attractive follow-on product candidate to treat localized fungal infections (in addition to onychomycosis).

Wilsons Corporate Finance Limited and Canaccord Genuity (Australia) Limited acted as joint lead managers and bookrunners for the placement.

Hexima finished the year well capitalised with $14.3 million in cash at bank and R&D tax rebate receivable.

Advancing the Development Program

Important steps in advancing pezadeftide to market were achieved.

The Company has now completed large scale cGMP manufacturing of pezadeftide at its European CMO. This is an important milestone. It marks the completion of a multi-year program of transferring and scaling-up the manufacturing technology for pezadeftide from the original pilot-scale site in Australia to a commercial scale CMO in Europe.

Preparation of Hexima's IND filing with FDA is almost complete and the Company expects to file its IND in Q1 2022. This filing is in anticipation of a small, single centre safety study (ONY-003) that will be conducted in the US to understand the pharmacokinetic properties of pezadeftide when applied to more compromised fungal infected nails in a maximal use setting.

The phase IIb clinical trial (ONY-002) at centres in Australia and New Zealand continues to progress well. COVID-19 travel restrictions have not had a material impact and as previously announced the Company expects to report results in Q2 2022.

Building the Team

Dr Nancy Sacco, Chief Development Officer

In December 2021, Dr Nancy Sacco was appointed as Chief Development Officer - a critical role that will be central to the successful development and delivery of Hexima' s first product.

Dr Sacco brings over 20 years of strong leadership experience in the pharmaceutical industry, driving business objectives, including non-clinical discovery, late-stage clinical development, registration, and approval of a range of important pharmaceutical products. Dr Sacco holds a PhD from West Virginia University School of Medicine.

Prior to this appointment, Dr Sacco held Vice President and Head of Clinical Development roles at Xentria, Inc. and AnaptysBio, Inc., overseeing programs with monoclonal antibodies for rare and dermatologic diseases.

In addition, Dr Sacco held executive leadership positions at Revance Therapeutics, Inc. and Avexis, Inc (now Novartis), overseeing clinical operations including the initiation and completion of pivotal studies evaluating safety and efficacy of innovative products (proprietary neurotoxin Daxibotulinum and AVV9 gene therapy ZolgenSMA, respectively).

Dr Sacco has also held roles of increasing responsibilities at P&G Healthcare (Actonel), Pfizer (Lyrica), Astellas (Myrbetriq and Xtandi) and Takeda (Rozerem and ACTOS).

Phil Rose, Chief Commercial Officer

Subsequent to the quarter end, Phil Rose was appointed as Chief Commercial Officer.

Mr. Rose has 30+ years of leadership experience in the pharmaceutical industry, which includes previous roles as President and CEO of the dermatology focused Obagi Medical Products, Vice President and General Manager of North America for Valeant (now Bausch Healthcare Companies) and Vice President Hospital Sales at Glaxo, Inc. (now GSK). In addition, Phil is a licenced and practicing Pharmacist.

Mr. Rose has served as a commercial consultant to the pharmaceutical industry and prior clients include Alza Corporation (now J&J), Reliant Pharmaceuticals (now GSK), Peplin, Inc. the developer of Picato (now LEO), and Hexima Limited since 2020.

These two key appointments are critical hires for Hexima as it moves towards initiating its phase III clinical trial program later in 2022.

Key elements of their employment contracts are set out below.

Each is eligible to participate in Hexima's ongoing LTI plan and on agreement to increase their time commitment to 100% each will become eligible for the package of U.S. employee benefits which Hexima offers, including health insurance and termination arrangements.

New SAB appoinment

Hexima also added Shari Lipner MD to its Scientific Advisory Board, enhancing its expertise in dermatology. Dr. Lipner is an Associate Professor of Clinical Dermatology, Associate Attending Physician, and Director of the Nail Division at the New York-Presbyterian Hospital/Weill Cornell Medical Center.

Dr. Lipner has authored over 250 peer-reviewed publications, numerous book chapters, lectures nationally and internationally, and is frequently sought out by the media for her expertise. Shari is a retained consultant to the Company.

	Nancy Sacco	**Phil Rose**
Employment "at will"	Effective 1 December 2021	Effective 1 January 2022
Initial time commitment	40% moving to 100% on mutual agreement	50% moving to 100% on mutual agreement
Initial base salary	US$130,000 (based on 40% time commitment)	US$150,000 (based on 50% time commitment)
Target STI	25% of base salary	25% of base salary
Initial grant of LTI options (on move to 100% commitment)	600,000 (900,000)	600,000 (600,000)

MILESTONES TO LOOK FORWARD TO IN 2022

File IND with FDA

As noted earlier, Hexima anticipates completing and filing an IND Application with FDA in Q1 2022. This is a pre-requisite to the initiation of a clinical trial program in the US.

Phase IIB Clinical Trial (ONY-002)

We have recently comprehensively reviewed our clinical trial activities to ensure the integrity of the study and confirm that it remains on track to report results in Q2 2022.

Initiation of Maximal Use Clinical Trial (ONY-003)

Following acceptance by FDA of the IND, the Company anticipates completing preparations and then initiating a maximal use clinical trial which is likely to occur mid-2022.

Presentation at American Academy of Dermatology (AAD) Conference in Boston, MA

Hexima has been invited to present a poster at the AAD annual conference in Boston MA in March 2022. This poster will publish data on pezadeftide's novel and powerful fungicidal mechanism of action. Together with podiatrists, dermatologists are the specialists charged with diagnosing and treating onychomycosis and are the clinicians to whom more challenging cases are often referred. The Company's presence and publications at AAD and APMA medical conferences continue to generate increasing awareness among specialist clinicians and are important initiatives as the Company seeks to develop a new and more attractive treatment option for this common and very difficult to treat disease.

Japan and China Corporate Collaborations

We continue discussion with potential corporate partners for pezadeftide in the Japan and China territories. While difficult to attach a specific timeline, we are encouraged by the quality of engagement we enjoy.

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	31 December 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	109	219
1.2	Payments for		
	(a) research and development	(2,160)	(3,864)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(528)	(1,068)
	(f) administration and corporate costs	(690)	(975)
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)	(1)
1.7	Government grants and tax incentives	3,661	3,661
1.8	Other – GST Refund	107	258
	Other – Reimbursement of LT receivable		
1.9	**Net cash from / (used in) operating activities**	**498**	**(1,770)**

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 (6 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)	11,000	11,000
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	(583)	(583)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings	(9)	(9)
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**	**10,408**	**10,408**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	1,197	3,422
4.2	Net cash from / (used in) operating activities (item 1.9 above)	498	(1,770)
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 (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	10,408	10,408
4.5	Effect of movement in exchange rates on cash held	16	59
4.6	**Cash and cash equivalents at end of period**	**12,119**	**12,119**

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	12,118	1,196
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)**	**12,119**	**1,197**

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	7
7.4	**Total financing facilities**	300	7

7.5	**Unused financing facilities available at quarter end**	293

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)	498
8.2	Cash and cash equivalents at quarter end (item 4.6)	12,119
8.3	Unused finance facilities available at quarter end (item 7.5)	293
8.4	Total available funding (item 8.2 + item 8.3)	12,412
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	5.5

NOTE: Item 1.9 includes 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: 31 January 2022

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.