HEXIMA LIMITED

ASX ANNOUNCEMENT

29 April 2022

Quarterly Activities Report and Appendix 4C

Important additions to the team
Pezadeftide's novel MoA presented at American Academy of Dermatology
Cash at bank plus R&D Tax Rebate receivable of $10.9 million at quarter end
Expected announcement of results of phase II clinical trial in Q2 2022

MELBOURNE, AUSTRALIA (29 April 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 March 2022. Quarterly activities are set out in the attached NailMail, Hexima's quarterly communication to shareholders.

A highly anticipated event expected in Q2 2022 is the release of results for Hexima's phase II clinical trial of pezadeftide for the treatment of onychomycosis.

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

Q1 2022

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

- Appointed Mr Philip Rose as Chief Commercial Officer and strengthened the manufacturing team with the appointment of Mr Om Srivastava as Vice President Tech Ops. Both roles are based in the US;
- Participated in the Edison Open House Global Healthcare 2022;
- Presentation of pezadeftide's Mechanism of Action at AAD Conference in Boston, MA;
- Ongoing preparations for the initiation of the phase I Maximal Use clinical trial (MUsT HXP124-ONY-003) to be conducted in the US.This study is expected to start in mid 2022;
- Continued steady progress towards completion of the phase II study (HXP124-ONY-002) and results announcement on schedule for Q2 2022.

The initiation of the Company's first US clinical trial (HXP124-ONY-003) remains on track for mid 2022. In advance of that trial Hexima expects to file its IND application with the FDA in the second quarter of 2022. The Company's overall timetable of development activities remains on track, importantly including the release of its phase II clinical trial results in Q2 2022 and the subsequent initiation of phase III.

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INVESTOR ENGAGEMENT

During the quarter Hexima attended a number of investor focused events. This is a carefully developed strategy to enhance engagement with domestic and international investors as it progresses towards the release of phase II clinical trial results in Q2 2022.

In January, the Company participated in Edison Open House Global Healthcare 2022.The Open House is hosted at https://www.edisongroup.com/ where Hexima's CEO, Michael Aldridge presented to international investors. A copy of the presentation and Edison's research report is available on Hexima's website.

The benefit of the Edison platform is the ability to track engagement with international investors in real time. During the Open House we enjoyed 10,943 video views of our presentation with the largest segment (27.8%) being North American investors.

Don't forget to visit our new website www.hexima.com.au to learn more about pezadeftide and onychomycosis

MUsT PHASE I CLINICAL PHARMACOLOGY TRIAL (HXP124-ONY-003)

This single centre study is designed as an open label study to evaluate the pharmacokinetics and safety of pezadeftide when applied in a maximal use setting to the toenails of patients with severe onychomycosis. The study plan is to enroll approximately 20 patients and treat all 10 toe nails daily for 4 weeks.

An important goal of the study is to show minimal or no absorption of pezadeftide into the patient's bloodstream when applied under maximal use conditions. Such an outcome could facilitate Hexima's progress to pivotal phase III studies, and may also enable Hexima to secure a waiver for certain clinical and non-clinical toxicology studies which FDA might otherwise have required. As such the MUsT is an important study. The final protocol will be included in our Investigational New Drug application (IND) we plan to file in Q2 2022 which will allow us to initiate the study in mid-2022.

PHASE II CLINICAL TRIAL (HXP124-ONY-002)

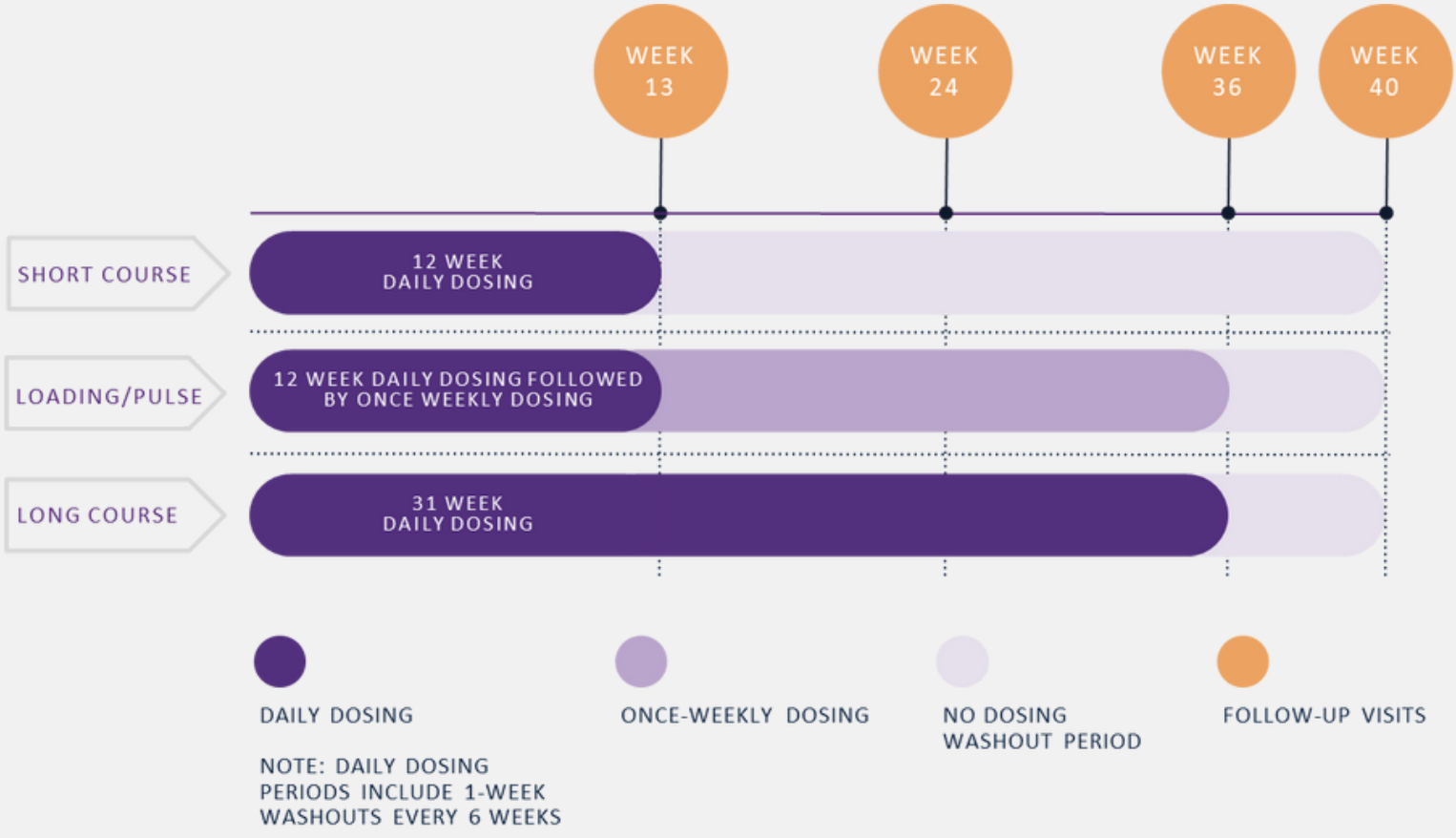
The most important and near term event in Hexima's development program is the planned announcement of phase II clinical trial results in Q2 2022.

This phase II trial is a multi-centre, randomized, double-blind, vehicle-controlled study to investigate the efficacy, safety, and tolerability of pezadeftide in patients with mild to moderate onychomycosis.

Hexima is comparing three separate treatment regimens (as set out in the schematic below). Each treatment regimen has an active (formulation containing drug) and a vehicle (formulation with no drug) arm. Both the patient and the clinician are blinded as to which subjects are on active or vehicle.

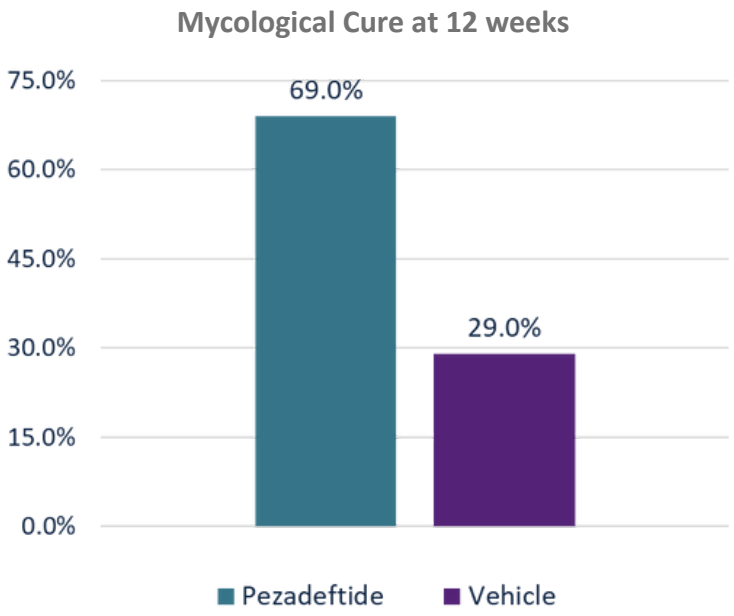
As of the end of April 2022 all patients are in the process of completing final follow-up visits and the Company will now collect final data, clean the database and submit critical queries to clinical sites, ensuring completeness prior to database lock and breaking the blind. Hexima will then analyse the data by treatment group and key efficacy and safety parameters prior to presenting the results.

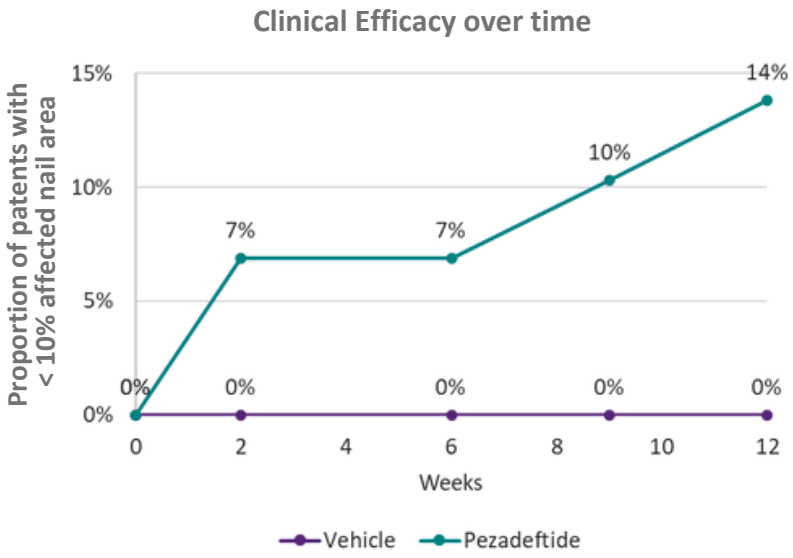
This study is central to Hexima's development program because it is intended to provide critical information on the safety and efficacy of topical 2% pezadeftide in treating onychomycosis and to provide data to determine which treatment approach is the safest, most effective and convenient for patients.



PHASE II CLINICAL TRIAL (HXP124-ONY-002) - RESULTS EXPECTED Q2 2022

In the phase I clinical trial (HXP124-ONY-001) the Company observed mycological cure rates of greater than 50% and early evidence of visual improvement of the nail and clearance of the fungal infection (after just 6 weeks of daily treatment and 12 weeks follow-up). Both these measures showed a clear differential from vehicle.





In contrast, this phase II study design allowed the Company to treat nails for longer periods of time (up to 36 weeks) and follow-up all patients out to 40 weeks. As compared to the phase I study, the success of the phase II study would be defined by:

- comparable or better mycological cure rates; coupled with
- stronger evidence of clinical cure, particularly as the nails have a longer time to grow out healthy and clear.

Finally and ideally, evidence of differential activity between the three different treatment regimens will help inform our phase III strategy.

We would regard such results as valuable support for our goal of seeking approval from FDA to advance into phase III clinical trials.

From a value perspective, positive results would significantly de-risk the potential for pezadeftide to ultimately represent a new and clinically differentiated, safe and more effective topical product for onychomycosis with a potentially shorter course of therapy.

PRESENTATION OF PEZADEFTIDE'S MECHANISM OF ACTION AT AMERICAN ASSOCIATION OF DERMATOLOGY (AAD) CONFERENCE IN BOSTON, MA

Hexima presented a poster at AAD's annual conference in Boston, MA in March 2022, this demonstrating pezadeftide's novel and powerful fungicidal mechanism of action.

Pezadeftide is a broad spectrum and powerful anti-fungal agent. Its unique ability to rapidly penetrate the human nail and attack and kill the fungal infection under the nail makes it an ideal candidate for the treatment of onychomycosis.

In addition, pezadeftide's mechanism of action is novel. This means that Hexima is the first in the world to characterize the fungicidal activity of this new class of compounds. This novelty is valuable because pezadeftide's fungicidal activity includes some fungal species which are either resistant to, or difficult to kill with existing drugs.

Presenting this data to dermatologists at AAD is important because dermatologists are the specialists conducting much of the research in onychomycosis and are the clinicians to whom more challenging cases are often referred.

The Company's presence and publications at international dermatology and podiatry conferences continues to generate increasing awareness of pezadeftide 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.

The novel mechanism of action is described on the following page and you can also view the full poster as presented at AAD.

MILESTONES TO LOOK FORWARD TO IN Q2 2022

File IND with FDA

As noted earlier, Hexima anticipates completing and compiling its manufacturing and toxicology information ahead of filing the Investigational New Drug (IND) Application with FDA. This is a pre-requisite to the initiation of a clinical trial program in the US.

Announce results of Phase II clinical trial (HXP124-ONY-002)

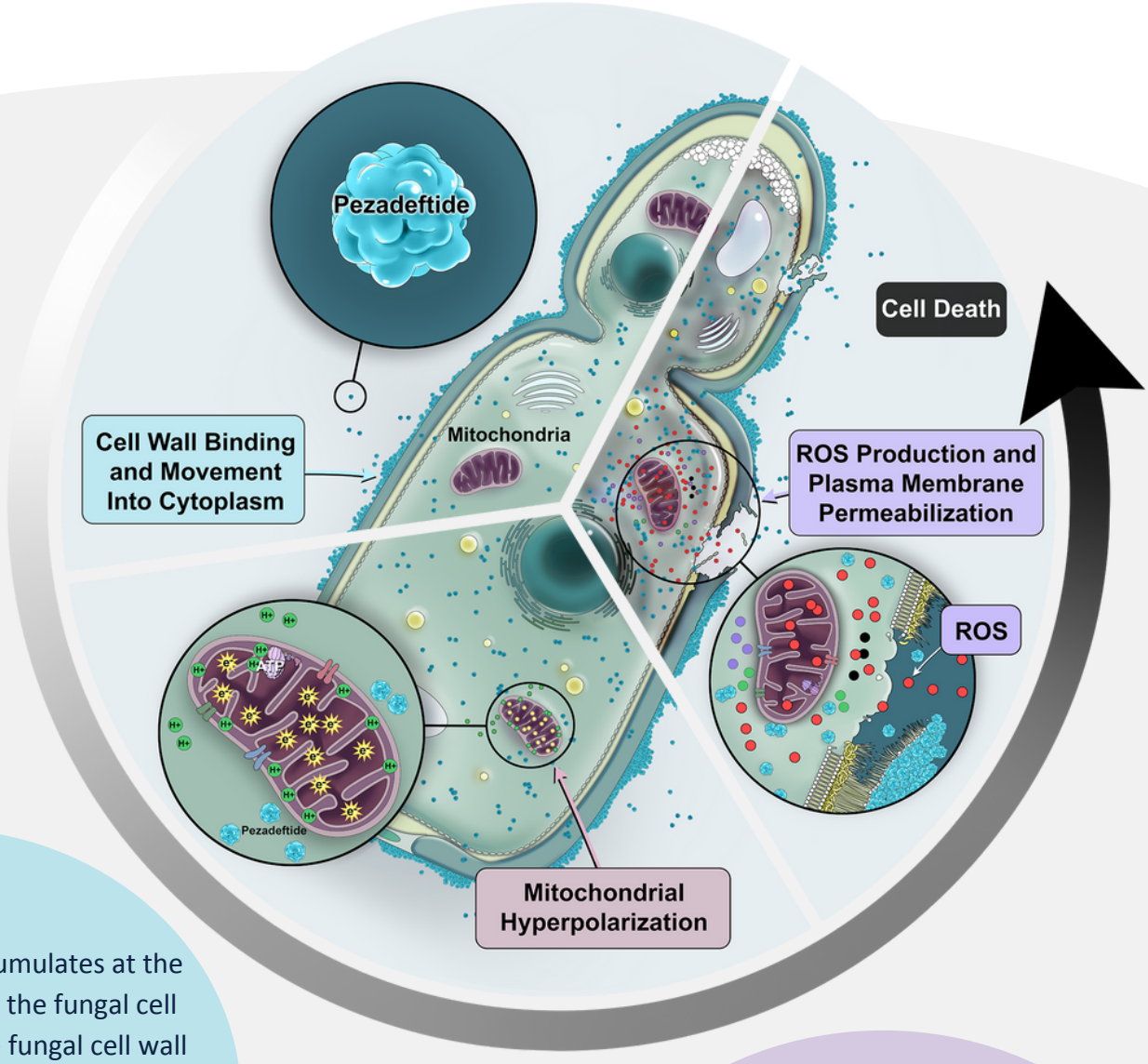
Hexima expects to complete the phase II study and announce results on schedule in Q2 2022.

Initiation of Maximal Use Clinical Trial (HXP124-ONY-003)

Following acceptance by FDA of the IND, the Company anticipates completing study start-up preparations and initiating the Maximal Use clinical trial in mid-2022.

PEZADEFTIDE NOVEL FUNGICIDAL MECHANISM OF ACTION

PEZADEFTIDE HAS A NOVEL FUNGICIDAL MECHANISM OF ACTION THAT CAN BE DESCRIBED IN THREE KEY STEPS.



STEP 1

Initially, pezadeftide accumulates at the cell surface and binds to the fungal cell wall. The structure of the fungal cell wall is unique to fungal cells and likely drives the specificity of pezadeftide for fungal cells over mammalian or bacterial cells. Pezadeftide then moves into the cytoplasm of the cell.

STEP 2

Once inside the cell, pezadeftide hyperpolarises the mitochondrial membrane, increasing the negative charge inside the mitochondrial matrix. Under normal conditions, cells use an electron gradient in their mitochondria to generate energy. When pezadeftide hyperpolarises this membrane, energy generation in the cell rapidly increases, putting the cell into ‘overdrive’.

STEP 3

A by-product of energy generation in the cell is the production of reactive oxygen species (ROS). These ROS are damaging to cellular components, including membranes. Their production increases in response to pezadeftide, resulting in permeabilization of the plasma membrane and cell death.

Expected and Actual Use of Funds			
Categories	**Expected Use of Funds [1] $000's**	**Actual Use of Funds 1 October 2020 to 31 Mar 2022 $000's**	**% of total**
Phase IIb clinical trial[2]	3,400	5,072	149
Scale-up of HXP124 manufacture and production of material for toxicology studies[3]	1,200	3,240	270
Formulation, stability and chemistry, manufacture and controls[4]	700	1,546	221
Toxicology studies[5]	2,000	1,090	55
Market research	100	68	68
Costs of the offer	700	703	100
Working capital	2,300	4,605	200
Totals	**10,400**	**16,324**	**157**

1. Expected Use of Proceeds and Current Cash as set out on page 10 of the Company's Prospectus dated 15 October 2020. Expected Use of Funds is net of the estimated R&D Tax Incentive rebate of 43.5% on eligible activities. For eligible R&D activities, the actual use of funds (when on budget) will therefore be approximately 177% of the expected use of funds.

2. Costs of the phase IIb clinical trial are in line with expectations. Early COVID-19-related delays in recruitment were previously disclosed and have resulted in this expenditure being delayed relative to initial expectations. Hexima remains on track to deliver results from this study in Q2 2022.

3. Costs of the scale-up of HXP124 manufacture were approximately 20% higher than expected due to completion of an additional manufacturing run to produce material for toxicology studies and to further optimise the manufacturing process.

4. Costs of formulation, stability and chemistry, manufacture and controls were approximately 25% higher than expected due to additional costs relating to manufacture of drug product for toxicology studies and formulation optimisation.

5. Spending on toxicology studies has been lower than expected as an anticipated study that was budgeted was not required and another has been rescheduled into 2022.

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 March 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	109	328
1.2	Payments for		
	(a) research and development	(3,637)	(7,501)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(414)	(1,482)
	(f) administration and corporate costs	(496)	(1,471)
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)
1.7	Government grants and tax incentives		3,661
1.8	Other – GST Refund	174	432
	Other – Reimbursement of LT receivable		
1.9	**Net cash from / (used in) operating activities**	**(4,264)**	**(6,034)**

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 (9 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
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	66	66
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(116)	(699)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings	(9)	(18)
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**	**(59)**	**10,349**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	12,119	3,422
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,264)	(6,034)
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 (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(59)	10,349
4.5	Effect of movement in exchange rates on cash held	(174)	(115)
4.6	**Cash and cash equivalents at end of period**	**7,622**	**7,662**

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	7,621	12,118
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)**	**7,622**	**12,119**

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 Hexima can borrow up to 80% of its R&D Tax Incentive receivable	2,929	0
7.3	Other – NAB Credit card facility	300	9
	Other – Bank of America credit card facility	115	0
7.4	**Total financing facilities**	3,344	9
7.5	**Unused financing facilities available at quarter end**		3,335
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)	(4,264)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,622
8.3	Unused finance facilities available at quarter end (item 7.5)	3,335
8.4	Total available funding (item 8.2 + item 8.3)	10,957
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.6

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: 28th April 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.