

HEXIMA LIMITED

ASX ANNOUNCEMENT



21 July 2022

QUARTERLY ACTIVITIES REPORT

Second Calendar Quarter 2022

MELBOURNE, AUSTRALIA (21 July 2022): Hexima Limited (ASX:HXL) a clinical stage biotechnology company today releases its Appendix 4C and Use of Funds Statement and sets out below its quarterly activities report for the quarter ended 30 June 2022.

During the quarter under review Hexima:

- Filed an Investigational New Drug Application (IND #142947) with FDA to initiate a Phase I clinical trial in the US evaluate the safety of pezadeftide in a maximal use setting. This IND is now open.
- Completed preparations for the initiation of the phase I US safety study.
- Initiated a 9-month chronic dermal toxicology program of pezadeftide.

On 24 June 2022 Hexima announced that *“based on its preliminary review, the results of its phase II clinical study of pezadeftide for the treatment of onychomycosis (HXP124-ONY-002) are inconclusive and will require further detailed investigation and evaluation. The results seen in this study do not appear to correlate with results observed in its prior phase I study (HXP124-ONY-001) and do not support moving directly into a phase III program. Hexima intends to conduct a detailed review of the complete clinical trial data set and study conduct and expects to report its findings when complete.”*

Following that further detailed review Hexima announced on 11 July 2022 that the study *“data provide evidence of modest activity of pezadeftide in the treatment of onychomycosis, an observation generally supported by a post hoc and blinded review of the clinical appearance of the treated nails conducted by an independent clinician, a member of Hexima’s Scientific Advisory Board. However, after careful consideration Hexima does not believe the data support the Company’s goal of developing a safe, more effective and convenient topical therapy with a shorter course of treatment.”*

“Accordingly, Hexima intends to wind down its development program of pezadeftide for the treatment of onychomycosis in an orderly fashion and will make no further significant investment.”

And continued- *“Hexima has initiated a process of exploring strategic options for the Company seeking to secure value for Hexima’s intellectual property and residual cash resources. These discussions are very preliminary and the contemplated transaction or transactions may or may not occur. The Board is unable to provide further information at this stage”*

This announcement is authorised for release to ASX by Michael Aldridge, Managing Director & CEO

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Expected and Actual Use of Funds			
Categories	Expected Use of Funds ^[1] \$000's	Actual Use of Funds 1 October 2020 to 30 Jun 2022 \$000's	% of total
Phase IIb clinical trial ^[2]	3,400	5,609	165
Scale-up of HXP124 manufacture and production of material for toxicology studies ^[3]	1,200	3,681	307
Formulation, stability and chemistry, manufacture and controls ^[4]	700	1,611	230
Toxicology studies ^[5]	2,000	1,839	92
Market research	100	68	68
Costs of the offer	700	703	100
Working capital	2,300	5,402	235
Totals	10,400	18,913	182

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 were 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.

3. Costs of the scale-up of HXP124 manufacture were approximately 75% higher than expected due to completion of two additional manufacturing runs 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 30% 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 was rescheduled.

Appendix 4C

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

Name of entity

Hexima Limited

ABN

64 079 319 314

Quarter ended ("current quarter")

30 June 2022

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	113	441
1.2 Payments for		
(a) research and development	(2,934)	(10,435)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	(563)	(2,045)
(f) administration and corporate costs	(453)	(1,924)
1.3 Dividends received (see note 3)		
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid	(1)	(2)
1.7 Government grants and tax incentives	22	3,683
1.8 Other – GST Refund	81	513
1.9 Net cash from / (used in) operating activities	(3,734)	(9,768)

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)		11,000
3.2 Proceeds from issue of convertible debt securities		
3.3 Proceeds from exercise of options		66
3.4 Transaction costs related to issues of equity securities or convertible debt securities		(699)
3.5 Proceeds from borrowings		
3.6 Repayment of borrowings	(6)	(24)
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	(6)	10,343
4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	7,622	3,422
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(3,734)	(9,768)
4.3 Net cash from / (used in) investing activities (item 2.6 above)		

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

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)	(6)	10,343
4.5	Effect of movement in exchange rates on cash held	75	(40)
4.6	Cash and cash equivalents at end of period	3,957	3,957

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	3,956	7,621
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)	3,957	7,622

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	
<i>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.</i>		

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

7. Financing facilities <i>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.</i>	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	4,286	0
7.3 Other – NAB Credit card facility	300	7
Other – Bank of America credit card facility	145	5
7.4 Total financing facilities	4,731	12
7.5 Unused financing facilities available at quarter end		4,719
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)	(3,734)
8.2 Cash and cash equivalents at quarter end (item 4.6)	3,957
8.3 Unused finance facilities available at quarter end (item 7.5)	4,719
8.4 Total available funding (item 8.2 + item 8.3)	8,676
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.3
<i>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.</i>	
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: 21 July 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.