# ASX Announcement

**27 April 2021**

# Quarterly Activities Report and Appendix 4C

***First meeting of Hexima's Scientific Advisory Board***

***Expansion of Phase IIb clinical trial sites***

***Successful R&D webinar***

***Cash on hand as of 31 March 2021 $5.88 million***

***Funding sufficient to complete Phase IIb clinical trial***

MELBOURNE, AUSTRALIA (27 April 2021): Hexima Limited (ASX:HXL) a clinical stage biotechnology company developing HXP124, a new prescription treatment for onychomycosis, today files its Appendix 4C and quarterly activities report for the quarter ended 31 March 2021. Quarterly activities are set out in the attached NailMail, Hexima's quarterly communication to shareholders.

**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, 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 HXP124 for the treatment of onychomycosis. Hexima holds granted, long-life patents protecting HXP124 in major markets globally. For additional information about Hexima please visit www.hexima.com.au. You can also find us on Twitter and LinkedIn.

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

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www.hexima.com.au

Q1 2021

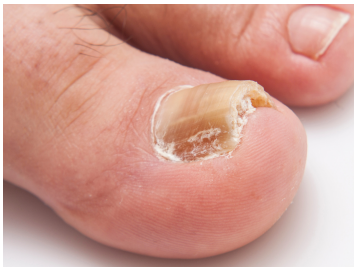
# NailMail

Investor News

**NailMail is Hexima's regular quarterly newsletter to shareholders, investors and interested parties. If you have any questions or comments you may wish to review our website at www.hexima.com.au.**

## About Onychomycosis

Onychomycosis is a common fungal infection of the nail plate and nail bed. Prevalence of onychomycosis has been estimated at approximately 10% (Japan) and 13.8% (USA) [1]. Onychomycosis is an infectious disease 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 because 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]

## 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, 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 HXP124 for the treatment of onychomycosis. Hexima holds granted, long-life patents protecting HXP124 in major markets globally.


**Hexima Limited**

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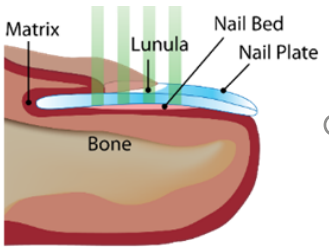


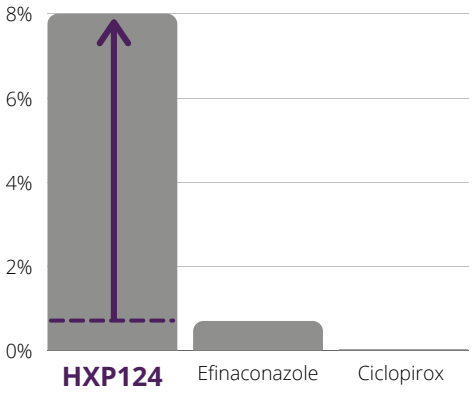

# THE SCIENCE BEHIND HXP124

Onychomycosis is caused by fungal pathogens invading under the nail plate and infecting the nail bed. The nail plate presents a major barrier to topical products being able to reach the fungus.

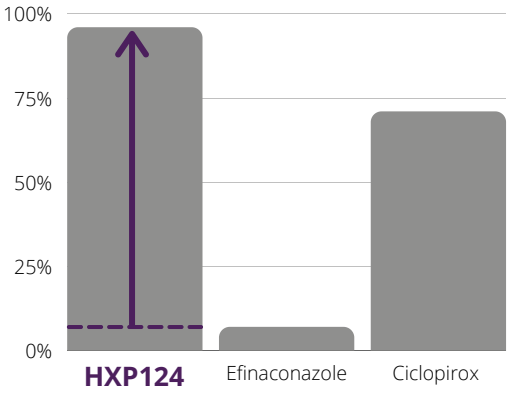
HXP124 is a novel antifungal molecule that is better able to penetrate the nail plate and rapidly kills the fungal pathogens that cause onychomycosis.

**RAPID NAIL PENETRATION** + **POWERFUL ANTIFUNGAL ACTIVITY** = **RAPID MYCOLOGICAL CURE* & EARLY CLEAR NAIL GROWTH**

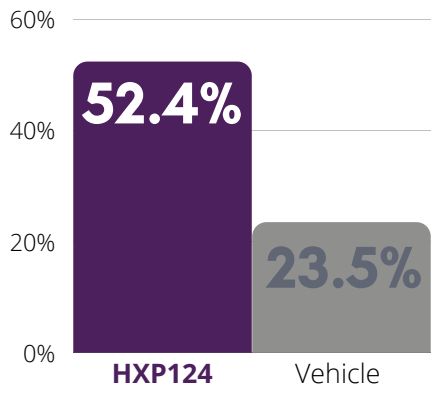
Drug penetrating the nail **within 72 h**[5,6,7]




Fungal cells killed **within 30 mins**[5]




Mycological Cure* measured at 12 weeks after 6-week treatment[8]



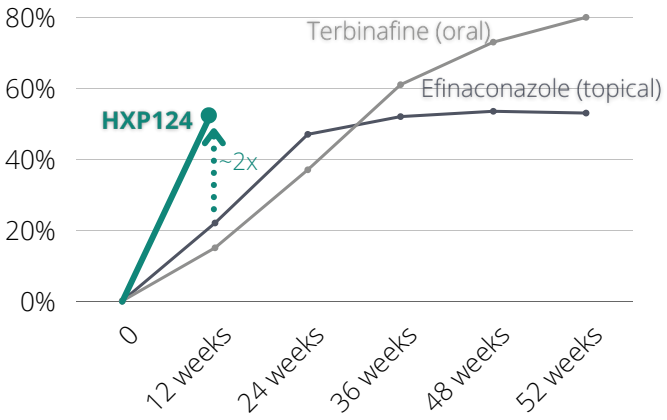

*Mycological Cure = clearance of fungi from the nail as assessed by microscopy and culture

**2x**

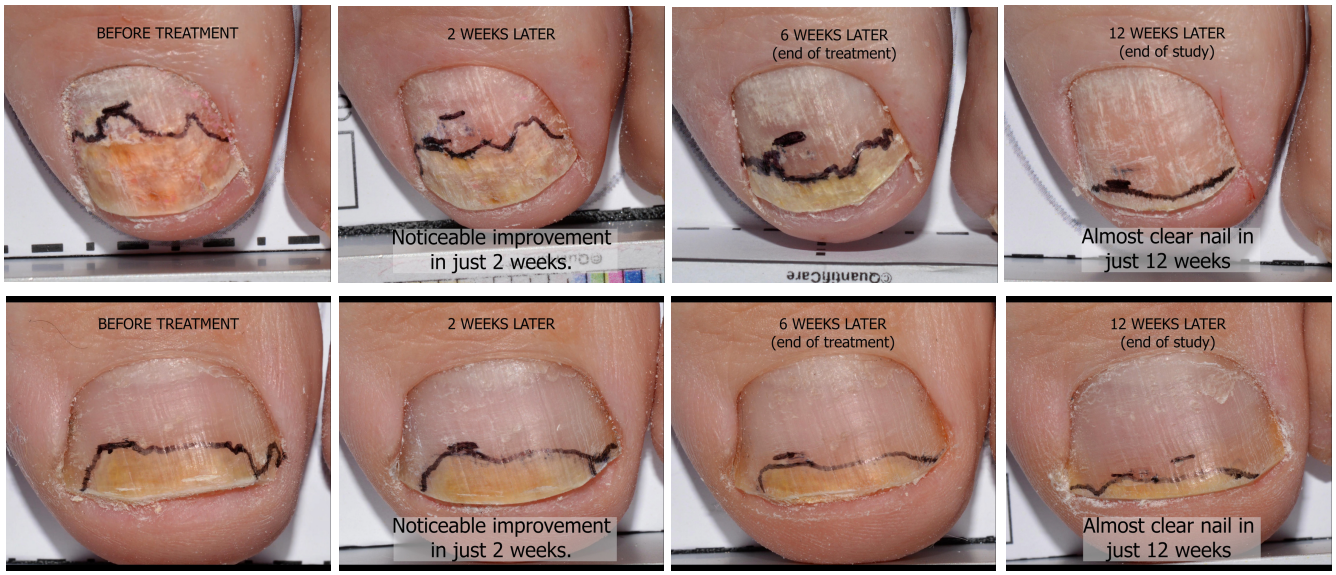
HIGHER MYCOLOGICAL CURE

Following 6 weeks of daily application, HXP124's Mycological Cure* rate measured at 12 weeks was ~2-fold higher than current treatments at the same time point.

Mycological Cure* over time[8,9,10]

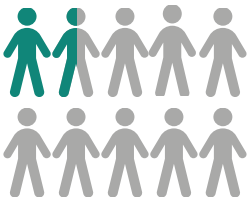



**HXP124 produced rapid clearing of infected nails with just 6 weeks of daily treatment**

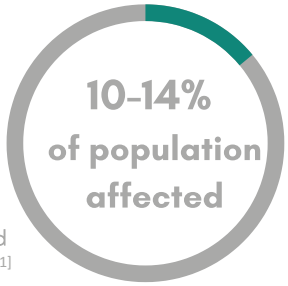



Images from HXP124-ONY-001 clinical trial

# 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.[4]

**3.1M**

Patients treated annually in the US.[11]

"Topical products are preferred by many patients"

Boni Elewski MD,[12]


~70% of scripts in the US are for topical products.[4]

## Onychomycosis has a substantial healthcare burden[2,3]

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

**4 p.a.**

EXPERIENCE PAIN **50%**

ARE IMPACTED WEARING SHOES **51%**

DISTRESSED BY APPEARANCE OF THEIR NAILS **66%**

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.

## 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 during treatment. The clinical and commercial success of topical medications has been constrained by an inability of the antifungal agents to effectively penetrate the human nail and the lack of sufficient antifungal activity when in contact with the target pathogen [13].

## Hexima's Approach

Hexima embraces the significant challenge of new product development for onychomycosis. Hexima has taken a novel approach, building on its many years of groundbreaking research into the evolutionary tools that plants use naturally to fight fungal infections. The result is HXP124; a new and very different 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 approaches.

HXP124 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, HXP124 offers the promise to capture significant value in a large and poorly served market.

# Important developments and milestones in Q1 2021

**First Meeting of Scientific Advisory Board:** We have recruited a group of expert clinical opinion leaders to the Hexima SAB which held its first meeting in February 2021. The SAB members are internationally recognised Dermatologists and Podiatrists based in US, Australia and Japan. They include the lead clinicians from advanced clinical trials conducted for multiple successful therapeutic products developed to treat onychomycosis in international markets. In its inaugural meeting, the SAB discussed the scientific and early clinical data supporting the unique activity of Hexima's lead product, HXP124.

**Expansion of number of Clinical Centres:** During the quarter, we added five more centres to our network of 10 clinics enrolling patients in our phase IIb clinical trial for onychomycosis. In addition, we have put in place a podiatry referral program for recruitment of potential patients from podiatry clinics. This is to ensure that we enrol the number of patients needed to complete this trial in a timely manner. We expect to report results from this clinical trial in Q2 2022.

**R&D Webinar:** On 25 March, we held our first R&D Webinar, an event that was open to all shareholders, investors and interested parties. The webinar presented the body of research which Hexima has conducted on HXP124 and in particular the observations that it rapidly penetrates human nails and it kills fungal cells more quickly and efficiently than other available antifungal therapies.

The rapid nail penetration and powerful antifungal activity of HXP124 by way of a new and rapid fungicidal mode of action is consistent with observations in patients with onychomycosis of dramatic resolution of the fungal infection (mycological cure) and rapid clear nail growth. (See images on page 2).

A recording of the R&D webinar is now available on our website www.hexima.com.au

# Milestones to look forward to in 2021

**American Podiatric Medical Association:** Hexima has been selected to present clinical data from its Phase I/IIa clinical trial of HXP124 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 HXP124'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 [4].

**Manufacturing:** We are on track to complete scale-up of manufacturing in Q2 2021. In this scale-up process we have resolved the challenges identified and are confident of low-cost manufacturing of HXP124 at commercial scale. We expect to manufacture HXP124 in a topical formulation under GMP conditions to support a US Investigational New Drug (IND) Application with FDA in Q4 2021.

**Toxicology studies:** Our toxicology program remains on track and we plan to complete the necessary toxicology studies prior to filing an IND with FDA in Q4 2021.

**File IND with FDA:** We anticipate compiling our manufacturing and toxicology information and to file an IND with FDA in Q4 2021. This filing is critical to initiating our late stage US development program. We anticipate the first step will be a short safety clinical study in the US prior to proceeding to phase III.

**Notes:**
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. Internal Hexima research; 6. Kaken Pharma and Dow Pharma, Sugiura et al., 2014; 7. UCSF Medical Center, Hui et al., 2006; 8. HXP124 PI/IIa clinical trial, HXP124-ONY-001 (ACTRN12618000131257) 9. Efinaconazole FDA and PMDA reviews; 10. Evans & Sigurgeirsso, BMJ, 1999; 11. ClearView Healthcare Partners proprietary market research, 2019; 12. Infection Inspection, Dermatology World, 2017; 13.Wang et al., Onychomycosis: Diagnosis and Effective Management, 2018;

| Expected and Actual Use of Funds | | | |
|---|---|---|---|
| **Categories** | **Expected Use of Funds [1] $000's** | **Actual Use of Funds 1 October 2020 to 31 March 2021 $000's** | **% of total** |
| Phase IIb clinical trial | 3,400 | 1,129 | 33 |
| Scale-up of HXP124 manufacture and production of material for toxicology studies | 1,200 | 926 | 77 |
| Formulation, stability and chemistry, manufacture and controls | 700 | 437 | 62 |
| Toxicology studies | 2,000 | 0 | 0 |
| Market research | 100 | 56 | 56 |
| Costs of the offer | 700 | 703 | 100 |
| Working capital | 2,300 | 1,472 | 64 |
| **Totals** | **10,400** | **4,723** | **45** |

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

# 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 2021 |

| **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 | 108 | 432 |
| 1.2 | Payments for | | |
| | (a) research and development | (1,428) | (3,755) |
| | (b) product manufacturing and operating costs | | |
| | (c) advertising and marketing | | (3) |
| | (d) leased assets | | |
| | (e) staff costs | (334) | (858) |
| | (f) administration and corporate costs | (234) | (1,168) |
| 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 | (24) | (25) |
| 1.7 | Government grants and tax incentives | | 1,988 |
| 1.8 | Other – GST Refund | 210 | 385 |
| **1.9** | **Net cash from / (used in) operating activities** | **(1,702)** | **(3,003)** |

| | | | |
|---|---|---|---|
| **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 | | |
| | (f) other non-current assets | | |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (9 months) $A'000 |
|---|---|---|---|
| 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 | (15) | (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** | **(15)** | **7,626** |

| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
|---|---|---|---|
| 4.1 | Cash and cash equivalents at beginning of period | 7,577 | 1,357 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (1,702) | (3,004) |
| 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) | (15) | 7,626 |
| 4.5 | Effect of movement in exchange rates on cash held | 20 | (99) |
| **4.6** | **Cash and cash equivalents at end of period** | **5,880** | **5,880** |

| 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 | 5,879 | 7,576 |
| 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)** | **5,880** | **7,577** |

| 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**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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 | 3 |
| 7.4 | **Total financing facilities** | 300 | 3 |

| | | |
|---|---|---|
| 7.5 | **Unused financing facilities available at quarter end** | 297 |

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) | (1,702) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 5,880 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | 297 |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 6,177 |

| | | |
|---|---|---|
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 5 |

NOTE: Item 1.9 does not include the receipt of the annual R&D Tax incentive nor the payment of annual insurance expense. The calculation of item 8.5 has been adjusted to include amortisation of these items 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: ..27 April 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.