9:00 AM, Friday 29 January 2021 AEDT

Hexima Limited (ASX:HXL)
Q4 2020 Quarterly Cashflow and Activity Report Investor Call

Good morning everyone, it is my pleasure to welcome you all to Hexima's quarterly investor call for the fourth quarter of 2020.

My name is Michael Aldridge and I am the CEO at Hexima. I am joined on this call by Nicole van der Weerden our Chief Operating Officer.

Earlier this morning we released to ASX our quarterly reports covering both our cashflow and activities for the three months ended 31 December 2020. And I am very pleased to be with you today to discuss some of the more important milestones and developments we successfully achieved during the quarter.

In addition to that however, as you know this is our first quarter as the newly public and ASX listed Hexima and so I would like to take a few minutes to also discuss Hexima's business and its prospects going forward.

I am genuinely excited by the potential that Hexima enjoys. I think we have a great opportunity to both improve the treatment of a very common and difficult to treat fungal infection but also to deliver significant value for our shareholders.

First however let's discuss the fourth quarter of 2020 and highlight some of the information we set out in our quarterly report.

During the quarter Hexima delivered on two critically important milestones in our HXP124 development program.

First and most importantly, we initiated our phase IIb clinical trial of HXP124. This is a trial which is enrolling patients suffering from onychomycosis (or fungal infections of the toenail) and testing HXP124 as a potential therapy. We are very pleased to have established an infrastructure of ten clinical sites across Australia and New Zealand all now actively recruiting, enrolling and treating patients with onychomycosis. This has been a significant undertaking and we are very encouraged by progress in this trial to date.

In this study, we are testing HXP124 in three different courses of therapy, seeking to optimize the key factors of safety, efficacy and convenience. Results from this trial are expected in the second quarter of 2022 and we anticipate these results will demonstrate our product to be a rapidly acting, very safe and convenient approach to effectively treating what is a very common and difficult to treat disease.

Our second important milestone was successfully completing our public offering and associated listing on ASX. Following this successful public offering and a private placement we completed earlier in the year and together with the receipt of our R&D Tax Incentive rebate of $1.9 million in the quarter, we finished 2020 with $7.6 million in the bank.

Importantly, Hexima now has the runway to complete our ongoing phase IIb clinical trial. Again, it is the positive results from this trial which would both demonstrate the potential of HXP124 as a new and attractive treatment for onychomycosis but would also form the primary basis for progressing into phase III clinical trials in US.

In addition to these two key milestones, I am pleased to report that we continue with scale-up of our manufacturing activities and toxicology studies to support our future clinical plans.

A final comment on the quarter, we recently announced that our business, like many in Australia, was affected by Coronavirus related restrictions. We saw the pace of enrolment of patients into our phase IIb trial had been impacted.

Importantly, this has not affected in any way the integrity of the trial and we have recently implemented measures to accelerate the rate of recruitment into this study. We are pleased with the early feedback on the positive impact these measures have had, and we expect that the clinical trial will report out in the second quarter of 2022.

Immediately ahead of our public offering late last year we put in place the senior management team with the necessary skills and experience to run a dermatology development program and deliver this trial. We remain laser focused on the efficient conduct and delivery of results from this critically important program.

Now I would like to turn to Hexima, its business and our lead product more generally.

Given that we very recently went public we believe it critical that we have an active program of outreach to our shareholders and investors telling the Hexima story.

Hexima's ultimate goal is to deliver on what we call "the promise of HXP124". We wish to deliver a new, patent protected, safe and effective prescription medication for onychomycosis.

However, the management of toenail infections is a very consumer driven market. To be successful a new treatment for this disease will need display important consumer friendly attributes. Therefore, we are also looking to ensure that HXP124 is a very safe topical medication, have a short treatment course (making it convenient for patients), be rapidly acting (so that patients can quickly see that the medication is actually working) and, of course, have a high cure rate.

In our view this market historically has been plagued by substandard products. Patients and their clinicians have often been disappointed by available treatments. Treatment times of a year or more of daily therapy or the occurrence of rare, but serious side effects, are regarded as unacceptable, particularly in the context of their lower cure rates.

The "promise of HXP124" is what we call the "game changer" in this consumer driven market. We believe HXP124 can address the three main components of consumer preference namely:- safety, efficacy & just as importantly convenience.

Our confidence in this is based on Hexima's phase I clinical trial. In this trial we demonstrated HXP124 to be:

- a safe and topically applied medication;
- with a very short course of therapy (we tested just 6 weeks); and
- rapid clearance of infection and very promising efficacy

The study reported at the 12-week follow-up visit,

- the mycological cure rate was 52% (meaning that laboratory tests could no longer detect any fungal infection in more than half of HXP124 patients), and
- clinical efficacy (which we define as <10% of the nail area infected) was 19.5% (meaning that healthy clear nail was starting to grow out, again at 12 weeks after just 6 weeks of daily treatment).

Those results give us great confidence going forward.

We are now in the middle of a phase IIb clinical trial. The results of this trial are intended to validate the potential to deliver on that promise.

Given how common this disease is, the size of this market (which has been reported globally at $3.7 billion) and the short comings of existing approved products the value implications for Hexima of a successful phase II clinical trial should be significant.

As you may know I was previously the CEO of an ASX listed company called Peplin. Over my 5-year tenure at Peplin we very successfully developed a topical product to treat actinic keratosis, called Picato. Actinic keratoses are common pre-cancerous skin lesions on sun exposed face and arms and are particularly common in Australia.

An important reason for me joining Hexima was the dramatic similarities I saw between Hexima and Peplin. Peplin was also founded on some very strong Australian science and was also developing a topical product to be used by dermatologist globally to treat a very common disease where existing products had clear shortcomings. The similarities were striking to me.

You may recall that Peplin completed the development of Picato and then was acquired by LEO Pharma from Denmark for close to $300 million in cash.

I am proud to have gone on to have a number of further successes in my career with other biotechnology companies, but I am particularly proud of that achievement at Peplin. Not only

for the successful development of a new and better way to treat actinic keratosis but also that we successfully delivered significant value to Peplin's shareholders.

I am pleased to have reassembled many of the people from Peplin (both in Australia and the US) who were instrumental in Peplin's success. They are now part of the great team at Hexima. We are all uniquely enrolled in the goal of delivering that outcome for Hexima.

Thank you for joining us in this journey, I am genuinely excited by the potential for this company and pleased to be leading this truly exciting effort.

I would now be happy to discuss any questions you may have.