**ASX & Media Release**

# Patrys CEO Interviews with Bioshares CEO Transcript & Boardroom Radio

**Melbourne, Australia; 22 June, 2011:** Patrys Limited (ASX: PAB; Company), a clinical stage biopharmaceutical company focused on the development of novel treatments for cancer, has today released interviews with Bioshares and Boardroom Radio.

The interviews with CEO Dr Marie Roskrow provide an update on the status of Patrys' development program for its large portfolio of anticancer compounds and the clinical program for its lead clinical stage products.

Bioshares is Australia's leading biotech stock report, delivering independent investment research to investors on Australian biotech, pharmaceutical and healthcare companies. The report is also available on www.bioshares.com.au

***To listen*** to the Boardroom Radio interview, copy the following details into your web browser: brr.com.au/event/**81694**.

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**About Patrys Limited:**
Based in Melbourne, Australia, Patrys (ASX: PAB) is focused on the development of natural human antibodies as therapies for cancer. Patrys has a deep pipeline of anti-cancer natural human antibodies that enable both internal development and partnering opportunities. More information can be found at www.patrys.com.

**About PAT-SM6:**
The natural human antibody PAT-SM6 has been shown to have potent anti-cancer properties in a large number of laboratory and animal studies. More specifically, Patrys has now screened PAT-SM6 against more than 200 tumours from individual patients with various cancers, and the product binds to over 90% of the tumours screened regardless of cancer type or patient age, gender or disease stage. With respect to melanoma, PAT-SM6 has shown particularly strong promise. Patrys has filed patent applications to cover the PAT-SM6 antibody molecule, disease target, and the mechanism of action. In October 2010, Patrys initiated a human clinical trial to evaluate PAT-SM6 as a therapy for melanoma. To date, the first group of patients has been treated and Patrys received approval to progress the clinical trial. The clinical trial is taking place at the Royal Adelaide Hospital (RAH) Cancer Centre and associated Pain and Anaesthesia Research Clinic.

# INVESTOR BRIEFING

**22 June, 2011**

## With Dr. Marie Roskrow, CEO, Patrys Ltd

**Background**

**Patrys is a world leader in the area of developing natural human antibodies to treat a range of diseases. Its first anticancer drug candidate, PAT-SM6, is undergoing a Phase I clinical trial assessing the drug's safety in patients with melanoma. In addition, Patrys has isolated more than 200 further antibodies potentially capable of fighting disease. The company is seeking to bring its second drug candidate, PAT-LM1, into the clinic in 2012.**

# Topic: Patrys Clinical Program Update

**The CEO Transcript: Can you please summarise the basic concept that underpins the Patrys technology which uses natural human antibodies, and why this might be an effective way of treating cancer?**

**Marie Roskrow:** The Patrys technology is based on identifying the best natural human antibodies. How this works it that basically we extract antibodies from patients, grow them in the lab (or larger production facility), find out which are the best fighters against diseased cells and then infuse those back into patients.

The reason for this approach is that there are a huge number of cell divisions constantly occurring in our bodies, and sometimes the division goes wrong and pre-cancerous cells are made. This happens quite frequently in everyone but it doesn't mean everyone goes on to get cancer, because the immune system is so good at correcting these mistakes.

Those pre-cancerous cells look different to normal cells, which allows the immune system to recognise and attack them. It does this by producing, first of all, an IgM antibody. That IgM antibody recognises a target on the surface of the pre-cancerous cell and uses that to lock on and wipe it out.

If these antibodies that are formed naturally are so effective in our bodies, then it makes sense to extract the antibodies and screen them to establish which are the best at destroying cancer cells.

It is these antibodies that are infused in large quantities back into a patient with cancer, and they are naturally customised to find the tumour and destroy it.

**The CEO Transcript: Is this a radical and new approach to treating cancer?**

**Marie Roskrow:** People have considered this approach for a long time because the idea of harnessing the body's defences is based on simple biological concepts. There's no especially fancy engineering or technology underlying this and that's why it is so attractive.

The challenge researchers have had in the past is extracting and identifying the key antibodies because of the sheer population, many hundreds of thousands, which are floating around in a patient's body.

The important differentiator that Patrys possess is that we have a platform whereby we can screen those antibodies to make sure there is absolute specificity. Historically, that was very difficult to achieve. And even if you got beyond that, there was always the concern that IgM antibodies – a subgroup making up 99.9 per cent of the antibodies that come through our screening – are technically very difficult to manufacture at commercial scale.

Of course, as I'll detail later, we've addressed both those historical hurdles in two ways. Firstly, by ensuring that all the antibodies that made it through our screening did no 'collateral damage' to normal cells, and secondly by refining the production process and securing partnerships with highly expert manufacturers to bring our process to commercial scale.

**The CEO Transcript: Patrys is currently conducting a Phase I trial at Royal Adelaide hospital in treating melanoma. Can you describe the structure of that trial and the progress to date?**

**Marie Roskrow:** The trial involves a single dose of PAT-SM6 based on the typical "three plus three" trial structure used in cancer clinical trials. We have three patients in each cohort and in the first and current part of the study we have three different dosing groups. We have started at a very low dose of 0.15 mg/kg, which will double in the next group to 0.3 mg/kg and again double to 0.6 mg/kg. Between each cohort we have to wait a month while the Data Safety Monitoring Board reviews the safety data.

**The CEO Transcript: Can you describe the state of disease those patients had progressed to prior to entering the trial?**

**Marie Roskrow:** These patients have a type of melanoma called "In-transit Melanoma," which is a form of cutaneous melanoma confined to the skin. The problem with this type of melanoma is that it's recurrent. Patients have the melanomas surgically excised; they can have radiation therapy or topical treatment or limb infusion, yet almost always the cancer returns.

The issue is that these recurring in-transit melanomas eventually do transform, becoming aggressive metastatic melanomas.

Patients can live with these types of melanoma for many, many years. What's been attractive about treating this particular indication is twofold. Firstly, the patient is relatively healthy because this is not end-stage metastatic melanoma. The second advantage is that we can perform biopsies on the tumours. We biopsy the tumour before the treatment, then give the antibody intravenously over 60 to 90 minutes – a relatively short infusion. It's done

as an outpatient procedure. A few days later the patient returns and the tumour is rebiopsied.

The PAT-SM6 melanoma clinical trial aims to only establish safety and we've commenced dosing at extremely low doses. Once the initial nine patients have been treated, we will determine if all of that safety data looks good. We estimate that will occur in late August depending on how quickly we can recruit patients. If the data looks good, we will expand the trial.

Our ultimate plan is to add more groups of three patients as a continuum from the current trial and establish the dose levels required to see activity within the tumour. I'm not talking about patients' tumours melting away on the surface of their skin; that's completely unreasonable to expect. But what we might expect is detection of the antibody's presence when we view the tumours, pre and post treatment. We may see some evidence of apoptosis (cancer cell death). That's a long shot in this trial, but certainly one of the reasons we're undertaking the biopsies.

**The CEO Transcript: What will be the structure of that second part of the Phase I trial with PAT-SM6?**

**Marie Roskrow:** The second part of the trial will be a continuation of the current trial, and we don't expect a break in the study. That's the way the protocol is designed. We'll add probably another 15-18 patients on top of the nine, which constitute the first phase of the study. Typically a trial of that size would take 12-18 months to complete the trial extension. But of course it will depend on other factors such as the speed of recruitment which is outside our control.

**The CEO Transcript: In terms of pre-clinical data on PAT-SM6, what sort of evidence was there that this drug candidate might actually be effective in treating solid cancers such as melanoma?**

**Marie Roskrow:** Part of the screening process is that we screened the antibodies against a whole bank of both normal cells and tumour cells from patients using the techniques of immunohistochemistry and flow cytometry.

We began with 40,000 antibodies and each screening level was done on tumour cells and on normal cells. This was done to establish specificity. Any antibody that was attaching to normal cells as well as their cancerous counterparts was discarded.

And we completed screening with 200 antibodies that were entirely tumour-specific. So, PAT-SM6 has been shown by both flow cytometry and extensive immunohistochemistry to be very selective for a variety of solid tumours and also liquid tumours. We hope to publish this data formally.

We have people in Würzburg, Germany, working on multiple myeloma and other haematological cancers. It looks potentially interesting from that perspective. We've used PAT-SM6 successfully in xenograft models; some that were done at the university a few years ago and we have ongoing studies in Australia through vivoPharm, our contract partner. Considering all this information, we can confidently say that PAT-SM6 is highly specific for a variety of cancers, and that's the basis on which we'll proceed.

**The CEO Transcript: How important is the success of this first trial in terms of validating the whole Patrys platform?**

**Marie Roskrow:** It's very important. As I've tried to emphasise to our investors in the last two weeks, this is a pure safety study at extremely low doses and we don't expect to see any anti-tumour responses. The trial is not designed to show that. It's designed to give us the formation of the safety base which is critical. Only if safety is established will we continue to the next phase.

So that's the importance of the trial. As this is the first trial in melanoma with intravenous IgMs we have to be very cautious.

**The CEO Transcript: Can you describe some of the previous success you've had with another drug candidate, PAT-SC1, in a gastric cancer trial?**

**Marie Roskrow**: PAT-SC1 was the first antibody that was produced and characterised in Würzburg where the technology originated. At the time they thought, as they did until very recently, that PAT-SC1 was a purely gastric antibody.

They treated 51 patients with gastric cancer – which was actually a lot – at their university between 1997 and 2000. The patients were all going to have a gastrectomy, so they were early to middle stage patients. They hadn't presented too late to be eligible for surgery. They received one injection of PAT-SC1, which was 20 milligrams (equivalent to around 0.3 mg/kg), again a very small dose. Then they proceeded with the gastrectomy and there was no additional treatment.

It was a very simply designed study. The patients were followed up, and we have data up until three years afterwards. We looked at historic control patients who had not received PAT-SC1 and it it could be seen from the survival graphs that patients who received one shot of PAT-SC1 had a 90% greater chance of being alive at three years after surgery compared to the historical patients that didn't receive the antibody treatment.

The trial design was not as robust as it would be today, however the fundamental message, very clearly, was the difference in survival. And in this sort of indication that's significant.

**The CEO Transcript: Are there plans to move PAT-SCI and PAT-LM1 into the clinic in coming months?**

**Marie Roskrow:** We've got PAT-SM6 in the clinic and we're also going to be expanding those clinical trials. Next year we're working towards doing a Phase I/II solid tumour multi-dose study with PAT-SM6, which will run in parallel to the ongoing single dose melanoma study, as I've just described.

The next antibody into the clinic will be PAT-LM1, which we're preparing for at the moment. We're in the early stages of manufacturing scale-up, so that takes time to become confident that the process is running well and we can actually produce large quantities of PAT-LM1.

We will go straight to the Phase I/II multi-dose all-comers study. So we will have two of those running, plus the (current) melanoma study, which for us is sufficient.

For PAT-SC1, our plan will be to seek to out-licence next year. We've looked back now at the PAT-SC1 package and there are again some relatively simple things that we can do to improve that package, both from a pre-clinical perspective and from an intellectual property perspective.

**The CEO Transcript: Can you explain why with the PAT-LM1 trial you can move straight into a Phase I/II study rather than a single dose escalation safety study, similar to what the company is currently conducting with PAT-SM6?**

**Marie Roskrow:** We decided to pursue this route because at the time we only had sufficient quantities of the compound to do a single dose study which not many companies do. We made the decision to get into the clinic and start generating data, rather than waiting to build up large quantities of PAT-SM6 first.

Because it is a world-first trial of infused IgM in this type of patient, we resolved to begin at a low dosage. Most antibody and oncology drug developers, if they've got good toxicology work and they've got good pre-clinical work, go straight to a Phase I/II all-comers study.

We've been through that process with PAT-SM6 in a single dose. As PAT-LM1, though different, is still functionally an IgM then we see no reason to do a single dose study.

**The CEO Transcript: With PAT-LM1, what type of indications would you initially be looking at?**

**Marie Roskrow:** It's too early to be specific. We've got good xenograft data in three or four different solid tumours and we're doing a little bit more work around that. But they will be common solid tumours with big market potential.

**The CEO Transcript: Is there another potential way that these naturally occurring antibodies could be used?**

**Marie Roskrow:** Anybody that develops antibodies these days, either IgMs or IgGs, are not looking just for therapeutics – they're looking for other angles too. Diagnostics, for example, is a very important part of antibody development, certainly when you look at what some of the antibody developers are doing. They want the therapeutic market but if possible they also want to be able to use that same antibody, perhaps in a modified form, for diagnostics.

With PAT-SM6 that's something that we're doing some pre-clinical work on now, looking at labelling the antibody and undertaking animal studies. Then we will proceed to a human study looking at imaging in a PET-CT scanner to look at where the disease is localised.

The area of diagnostics is not our core business at Patrys, but we recognise the importance of thinking commercially about enhancing the value of our product portfolio, especially when it is possible to capture significant potential value with early stage studies that require relatively modest investment.

**The CEO Transcript: So somebody who has been diagnosed with solid tumours could potentially be imaged before surgery so the surgeon could visualise the tumours?**

**Marie Roskrow:** Yes, potentially.

**The CEO Transcript: And also to gauge how effective treatment has been?**

**Marie Roskrow:** Exactly. If we're treating a patient, for example, with PAT-SM6, and they've got lung cancer, you could use the same antibody as an imaging agent to see the response to your treatment. Because if it's the same antibody, you can hypothesise (that) obviously it's gone to the tumour and had an anti-therapeutic effect. And you could characterise and observe that using the same diagnostics. So it's another angle for potential usefulness.

**The CEO Transcript: Can you provide an update on the manufacturing progress for your antibody drug candidates?**

**Marie Roskrow:** Patrys has spent several years and made a significant investment into establishing manufacturing capabilities because IgM antibodies have traditionally been challenging to produce on a large scale. Getting the manufacturing right has taken longer than expected and as a result has put us behind our original timelines. However, in the last 12 -18 months we've really made progress to the point where we can now produce high quantities of, for example, PAT-SM6.

We've also now moved our system to Laureate (USA) to do our production. They recently did a 250 litre run, which is modest compared to antibody producers. But it's a significant scale-up of the system, and we managed to produce very high quality PAT-SM6 in much larger gram amounts than we actually expected.

PAT-LM1 is now in the first stage of that scale-up manufacturing. Obviously every antibody is different but so far things are going well. Each of our antibodies now that we produce we will be using the same PER.C6 cell lines and we will fundamentally use the same manufacturing system, although we may have to tweak it slightly for different antibodies.

**The CEO Transcript: With all of your antibody drug candidates being naturally occurring in the body, is there an argument that they should have a reasonably good safety profile?**

**Marie Roskrow:** Yes, that's one of the great things about our technology, and is at the core of our screening. We've screened out all the antibodies that bind to any normal tissues whatsoever. So it's a very fundamental difference between the Patrys products and other chemotherapeutics out there including other antibodies. The problem with the drugs on the market for oncology is that the vast majority have significant side effects. Because of our screening we anticipate that we're not going to see such significant side effects. Obviously that will be borne out in the clinical studies. But that was the underlying rationale for how we designed the screening process. So we believe that may be a significant advantage.

**The CEO Transcript: How would you describe the interest in the field of naturally occurring cancer antibodies and is the interest growing?**

**Marie Roskrow:** There are significantly more players coming into this space than there were when Patrys started several years ago; there was virtually nobody in this space then. But now there are half a dozen companies that have things in early stage clinical trials using IgM antibodies and not just in cancer.

People are using them in infectious diseases and other diseases that naturally induce an IgM response. There's growing interest, but there's skepticism still too. People that are interested in antibodies, generally speaking, they're used to IgGs (rather than IgMs) and it

can be quite difficult to convince people otherwise. But at the end of the day the proof will be in the clinical data.

**The CEO Transcript: What level of interest are you seeing from potential partners or licensees?**

**Marie Roskrow:** At the moment we're not actively talking to partners. With PAT-SM6 and PAT-LM1, we're going to proceed through to the end of Phase I/II, subject to financing. And once we get to that point I think we'll have a much clearer picture as to whether either or both of those antibodies are worth pursuing. It is at this stage that we will then consider partnering those drugs. We'll start serious discussions next year to partner PAT-SC1.

**The CEO Transcript: In terms of your current funding, do you have sufficient funds to complete the first stage of the PAT-SM6 trial, and is that sufficient to expand that study into a further 15 to 18 patients?**

**Marie Roskrow:** At the end of March we had $7.5M in the bank. That's sufficient to fund the company through to February/March of next year and will allow us to complete the current PAT-SM6 trial. It will also allow us to commence the extension phase of that study and to add in clinical sensors. We've got enough money to complete many pre-clinical programs that are ongoing, the data of which will feed into the design of the future clinical studies.

Any additional financings would be directed toward a Phase I/II (trial) for PAT-SM6 and the Phase I/II (trial) for PAT-LM1 next year. Additional funding would also be used for an imaging study which is relatively cheap, and for some manufacturing and toxicology work. While significant investment will be required to the end of December 2012, we potentially have two drugs that are ready for out-licensing at a Phase II level, which is obviously a significant step up in terms of their value. And PAT-SC1, if we can license that, will offset some of the required cash.

**The CEO Transcript: Thank-you very much for your time.**

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