7 November 2014

VIRAX HOLDINGS LIMITED

ABN: 56 006 569 106

A: 108 Outram Street
West Perth, WA 6005

T: +61 (8) 9486 2333
F: +61 (8) 9355 4580

**By E-lodgement**
The ASX Market Announcements Platform
ASX Limited

**VIRAX SHAREHOLDER NEWSLETTER**

**7 November 2014, Melbourne, Australia:** Australian oncology technology company Virax Holdings Limited (ASX: VHL) provides the following market update via a shareholder newsletter.

For further information contact:

Mr Rudi Michelson

**Monsoon Communications**

Ph: +61 (0) 3 9620 3333

Dr Robert Crombie

**Managing Director**

Ph: +61 (0) 439 361 331

***About Virax***

Virax is a clinical stage oncology company currently engaged in the development of novel products for the treatment of cancer. It holds an exclusive worldwide license to the novel cancer compound GGTI-2418 for the treatment of multiple myeloma, breast and pancreatic cancer.

GGTI-2418 is expected to enter Phase 1b/2 clinical trials in breast cancer and multiple myeloma in early 2015.

In addition, the company has granted a license to major French biotechnology company Transgene for access to its Co-X-Gene™ technology for use in two of Transgene's immunotherapeutic products. These are TG4001 – a treatment for pathologies relating to human papilloma virus (HPV) infection that can lead to oropharyngeal (head and neck) cancer and TG4010 – a treatment for non-small cell lung cancer (NSCLC).

**INVESTOR NEWSLETTER**
EDITION 02
NOVEMBER 2014

# virax

Virax is developing a pipeline of novel oncology products to treat a range of cancers

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| ASX code | VHL |
| Share price | $0.008 |
| Market cap | $7.6m |
| 52 week range | $0.005-$0.02 |
| Cash (31/10/14) | $3.8m |

Dear Shareholders,

This is a landmark period for your company, as we begin to establish a new identity as Prescient Therapeutics and move to acquire a second major oncology technology this year.

Shareholders will be asked to vote on the proposed rebranding as well as the acquisition of oncology company AKTivate Therapeutics and its lead asset TCN-P (Triciribine Phosphate Monohydrate) at an Annual General Meeting to be held in Melbourne on 28 November.

On approval, the name change will be effective immediately. We believe a new identity is critical to more accurately reflect the new product pipeline which is now poised to feature two first in class oncology compounds.

With shareholder support, we will aggressively pursue development of the newest asset TCN-P in tandem with our existing lead oncology candidate GGTI-2418.

This means we will have two novel compounds in simultaneous clinical development under two separate Investigational New Drug (IND) applications.

It also means we will have five clinical trials in progress – two of which are funded by US government authorities.

Very few ASX-listed biotech companies exhibit this diversity and quality project pipeline and subsequent clinical and commercial opportunity.

## WHY TCN-P?

Like our other lead oncology asset GGTI-2418, TCN-P brings an exceptional portfolio of pre-clinical and clinical data underpinning its promise as a novel cancer therapeutic.

It is synergistic with GGTI-2418 but targets different tumour survival pathways.

A Phase 2 breast cancer trial of TCN-P is now recruiting and a Phase 1b ovarian cancer trial is also underway. A further Phase 1 leukaemia trial is on track to begin early next year.

Shareholders should also note the TCN-P program is largely de-risked: the US Food and Drug Administration (FDA),the regulatory body that overseas clinical trials in the United States has supported the program through an IND (Investigational New Drug). Furthermore the drug has already been made to the exacting standards of GMP (Good Manufacturing Practice) required for administration to humans. Thus many of the major manufacturing issues and heavy drug costs facing most biotechs have been circumvented.

Like GGTI-2418, this technology emanates from prestigious US research centres.

We have negotiated very favourable payment terms for TCN-P assets with a structured payment heavily weighted towards clinical success if the drug performs as we expect.

Under the terms of the transaction agreement, Virax will take responsibility for all future clinical development.

We look forward with great optimism to unlocking this compound's true potential. By harnessing the capability of both of these exciting and novel assets, we expect to deliver a multi-pronged attack on cancer, particularly those cancers with an unmet medical need.

## GGTI-2418 UPDATE

Longstanding shareholders would be aware this latest strategic acquisition follows on from the takeover earlier this year of Pathway Oncology and the drug candidate GGTI-2418.

As discussed, this is an equally promising oncology asset that is expected to progress to Phase 1b/2a clinical trials in breast cancer patients in Q1 2015. It will also be trialled as a new treatment for multiple myeloma next year.

## NEW APPOINTMENTS

Shareholders would be aware I was appointed to the Managing Director role in June this year.

In addition, the company has recently made several other key strategic appointments that we regard as pivotal to driving our oncology programs.

Overseeing development will be eminent US oncology expert Professor Joe Sparano, who has agreed to take position on our Scientific Advisory Board (SAB). He is internationally regarded for his work on developing novel therapeutic approaches for breast cancer, lymphoma and other cancers. (More about his credentials appears later in this newsletter).

That we have been able to attract an expert of this calibre is further validation of the inherent clinical and commercial opportunity.

He will be joined on the SAB by well-known international multiple myeloma authority Australian Professor Joshua Douglas.

ABOVE: Dr Rob Crombie, Managing Director

These strategic appointments ensure a high-class team to position your company for success.

We now have highly qualified, world leading breast and multiple myeloma authorities on board. I bring an extensive scientific and commercialisation background.

Together we are determined to progress our novel technologies for optimal scientific and commercial success.

## RELOCATION

In another development, the company will also relocate its headquarters from Perth, Western Australia, to Melbourne. We also regard this as an important step forward. Infrastructure services, contractors and peer companies are largely concentrated in the Eastern states. It makes both commercial and logistic sense for us to progress our clinical and commercial programs from these centralised headquarters.

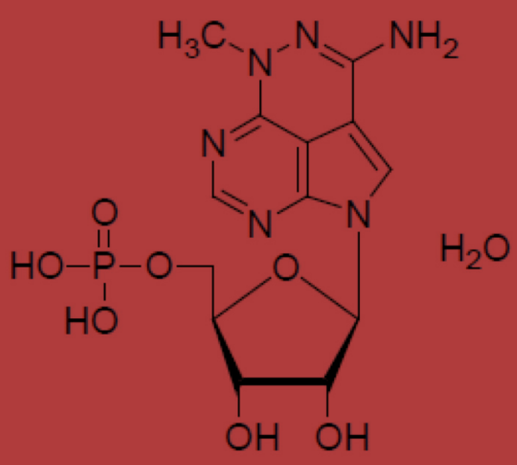
## FINALLY

We thank you for your ongoing support and look forward to updating you, our shareholders, of progress. It has been an eventful year to date as we move to acquire the assets and human resources necessary to reposition and transform this company.

A name change may be just the beginning, as we aim to make Prescient Therapeutics a leader in the development of next generation cancer treatments. Your continued support is greatly appreciated.

Sincerely,

Dr Rob Crombie




# THE AKTIVATE THERAPEUTICS ACQUISITION

As discussed earlier in this newsletter, the acquisition of AKTivate Therapeutics and its novel cancer technology TCN-P promises to further position Virax as a specialty oncology company with two highly promising cancer assets in mid stage development.

Shareholders will be asked to vote on this exceptional opportunity at our Annual General Meeting to be held in Melbourne on 28 November.

We regard TCN-P as a highly encouraging, blue chip asset. Our plan is to aggressively pursue its development in tandem with our other lead cancer drug candidate GGTI-2418.

In essence this means Virax will be progressing five clinical trials under two Investigational New Drug applications over the next 12 months.

Your company will have one of the most advanced clinical programs on the ASX and we would expect a re-rating of our market capitalisation based on the pronounced valuation discount compared to other ASX listed biotech companies in Phase 2 development.

## LOW RISK ACQUISITION

The Board regards the AKTivate takeover and acquisition of TCN-P as extremely low risk with great potential upside.

This is because two mid stage trials in breast and ovarian cancer are already funded through US Government grants from The National Cancer Institute and the US Department of Defense In addition, principal investigators have been appointed at key US hospitals and trial protocols have been approved. The asset is also secured by a robust intellectual property portfolio.

## THE AGREEMENT

Terms of the agreement are very attractive. Virax will pay an upfront payment of US$300,000 as well as 134 million shares upfront. A further 100 million shares will be paid on clinical success in any one of three indications – breast or ovarian cancer or leukaemia.

In essence, this means the majority consideration is linked to the achievement of clinical and commercial milestones to drive the value of Virax. We are confident of expeditiously targeting and meeting these milestones, with our first class scientific team determined to exploit the opportunity.

## HOW IT WORKS

TCN-P or triciribine phosphate monohydrate is a small molecule that blocks or inhibits a growth protein inside cancer cells called AKT (also known as Protein Kinase B).

AKT plays an important role in cancer cell division and is overexpressed in a number of malignancies, including breast, ovarian and pancreatic cancers, as well as leukaemia.

This protein is associated with a poor outlook, resistance to chemotherapy and shortened survival time in patients.

TCN-P is the first small molecule AKT inhibitor to be evaluated in clinical trial and all studies to date suggest it has strong potential to disrupt tumor survival. It may be used as a monotherapy, or as an adjunctive treatment with existing therapies.

## NEXT STAGE OF DEVELOPMENT

As discussed, this acquisition comes with the drug already in human clinical trials and the AKT drug target is an emerging area of intense interest by global pharmaceutical companies.

Virax is determined to progress three near term trials of the compound in breast and ovarian cancer as well as leukaemia as expeditiously as is possible.

Trial details are as follows:

- **Breast Cancer:**
  TCN-P is currently being trialled in a Phase 1b/2 breast cancer study at the prestigious Albert Einstein College of Medicine in New York. Fifteen patients have been treated to date, with headline data from the trial expected to be available Q3 2015.
- **Ovarian Cancer:**
  Recruitment for a Phase 1b trial of TCN-P in ovarian cancer patients will commence shortly at the Moffitt Cancer Center in Florida. Virax will target Phase 2 development 2016/17.
- **Leukaemia:**
  A third Phase 1b clinical study in leukaemia patients is expected to begin early next year at the Moffitt Cancer Center in Florida. Up to 16 patients will be enrolled with TCN-P to be evaluated in a dose-escalating study. TCN-P will be examined in combination with current standard of care cytarabine.

## ANNUAL GENERAL MEETING

To be held at 11am (EST)
Friday 28 November 2014
Institute of Chartered Accountants,
Level 3 Bourke Place,
600 Bourke Street
Melbourne VIC 3000


For full interview,
please visit link:
**www.virax.com.au**

# MANAGING DIRECTOR DR ROB CROMBIE DISCUSSES THE AKTIVATE THERAPEUTICS ACQUISITION

Q: What will this acquisition mean for investors?

"I think it is transformational. It brings a second program into the company. We have now two mid-stage clinical programs running with two separate INDs with the US FDA and five clinical indications. So five clinical trials in different indications. It gives us what I say are multiple shots on goal. We have got several programs running and if one of the programs should fail then we have back-ups to that. And these are programs that are with some of the best clinical centres in the United States. So, it is exciting times."

Q: The centrepiece of this acquisition is of course the novel cancer compound TCN-P. What is this and how does it work?

"TCN-P is a small molecule and it targets a pathway called AKT. AKT pathway is actually like a master-switch for cancer. It is actually the pathway that is most commonly altered in cancer. It is a fundamental pathway and it is a pathway that large pharma have been interested in for some time, so we are keen to develop a drug in this area. In a non-technical way, AKT is basically controlling the cells and the way cells grow. Cancer is about when a cell goes out of control, so AKT comes in and it blocks that out-of-control growth of the cancer cell and it brings it back into control and kills the cell."

Q: It (TCN-P) is showing great promise in a range of cancers, including some very prominent cancers.

"There is a lot of work in patients that has already been done with TCN-P. It has been in 100 patients already. So, we know the way this drug acts. We know the mechanism of action and we know it is relatively safe in patients."

Q: And there is a desperate need for new therapies to work alongside existing therapies?

"What is fundamentally the problem at the moment is that cancer becomes resistant to frontline therapies. A large proportion of patients are left with no other therapy and no other therapy choices. Our drug has been shown in pre-clinical studies to actually break that resistance to the chemo drug. And so, it works in synergy with front-line therapies and we are excited about the prospects."

Q: This is predominantly a scrip deal. Can you outline the terms and benefits of the acquisition?

"The way we have structured this deal is similar to the way we structured the Pathway Oncology deal. This deal involves 234 million shares of scrip. It is broken down into an upfront payment of scrip of 134 million, and a further 100 million on the back of clinical success.

What is important about that, is it means we are not giving away a large amount of scrip without seeing some benefit in the clinic of the product. And I think that is very important. It means that our shareholders know that this is a success-driven deal, and so I think the other aspect of course, is that because it is predominantly scrip, it means we are maintaining the cash we have raised for clinical development programs."

Q: Why do you say the AKTivate acquisition is largely de-risked?

"Firstly, these are clinical products, so we are not going through the research process. We are actually skipping all the research and I think that is where a lot of companies spend an awful lot of time in the lab, at the bench trying to develop drugs. We have fast-forwarded, fast-tracked that process into the clinic. We are buying these programs that are clinical programs. Not only that, these have active INDs. These drugs are being administered to patients as we speak. The breast cancer trial is recruiting at the Montefiore Centre in New York and we have started, a matter of days ago, the ovarian trial at the Lee Moffitt in Florida.

"Also, these programs are funded by Government grants. These Government grants are from the National Cancer Institute in America and also the US Department of Defense.

"So, from a financial perspective, these are fully funded programs. If we wanted to expand on recruitment we have the option of accelerating development."

Q: What are the next big inflection points for investors?

"We see this as a transformational deal. This changes the company fundamentally. Investors will start to see the programs taking shape over the next few months. I have been in the job for three months and in that short three months we have changed the company quite radically. I see this as a fast-track to develop these drugs in the clinic. Of course, the ultimate major inflection point is seeing that these drugs work in patients.

Q: So, investors should start seeing some key milestones being hit and value created in the next 18 months to 2 years?

"Absolutely. Our plan here with these drugs is to develop them over the next couple of years and then line them up for big pharma licensing. That is an area I am quite comfortable with."

Q: So you would license before Phase 3?

"We are quite realistic. Phase 3's require large amounts of cash. Remember these are adjunct therapies, they are 'add ons' to the frontline therapies, and frontline therapies are the therapies that the pharma companies are developing. I think no doubt, if we show as we expect that our drugs work in combination, then we will have large pharma interest."

Q: What is the company's cash position?

"We are about $3.5 million at the moment. It does mean that we are going to have to go to the market to raise more money at the start of next year, so we are looking at about a March time-frame."

Q: Final message for investors?

"I think now is the time to come on board. It is an exciting company and it is unique in the ASX-listed marketplace. There is no other company that has the pipeline of products that we have and the direction of treating cancer that we have.

"We are at the cutting edge of novel, first in class therapies that are combination therapies to treat a range of unmet medical needs in cancer."

# NEW APPOINTMENTS

## DR ROB CROMBIE, MANAGING DIRECTOR

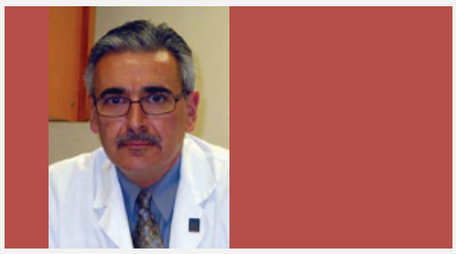
Dr Robert Crombie is an international biotechnology executive with a doctorate in cancer research.

He brings an extensive background in corporate and business development and has held senior management roles at Arana Therapeutics and EvoGenix Limited.

He played a key role in taking Arana Therapeutics from IPO to a $318 million trade sale within five years. He was also pivotal in repositioning EvoGenix Ltd to maximise traction in the fast growing therapeutic antibody market.

Prior to his appointment as Virax managing director, Dr Crombie was a specialist consultant to a variety of start-up companies through his role with the federal government's funding initiative – Commercialisation Australia.

As a strong transaction focused executive he has led negotiations on more than 30 deals between biotechnology and pharmaceutical companies.



## PROFESSOR JOE SPARANO, SCIENTIFIC ADVISORY BOARD

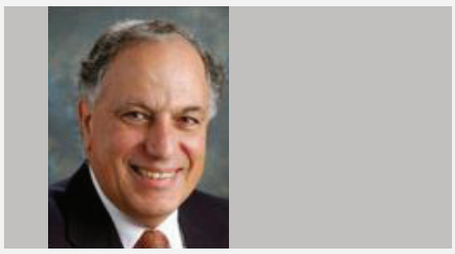
New York based medical oncologist and clinical researcher Professor Joe Sparano is currently professor of medicine and women's health at the Albert Einstein College of Medicine in New York and the associate chairman for clinical research in the Department of Oncology at the Montefiore Medical Center.

He is internationally regarded for his research on developing novel therapeutic approaches for breast cancer, lymphoma and HIV-associated cancers.

He has been involved in the development of numerous Phase I, II, and III NCI sponsored, investigator-initiated and industry sponsored trials, with expertise in breast cancer, lymphoma, HIV-associated cancer, developmental therapeutics as well as development and validation of prognostic and predictive biomarkers.

In addition he serves as Chair of the Eastern Cooperative Oncology Group Breast Cancer Committee, Vice-Chair of the NCI Breast Cancer Correlative Science Committee, and member of the NCI Breast Cancer Steering Committee.

Joe's background and expertise will assist the company as it moves it's breast cancer programs forward for GGTI-2418 as well as the recently announced TCN-P breast cancer program subject to shareholder approval.



## PROFESSOR JOSHUA DOUGLAS, SCIENTIFIC ADVISORY BOARD

Australian based multiple myeloma authority Professor Joshua Douglas has also recently taken up a position on the companies Scientific Advisory Board as of 23rd September.

Among other appointments, he currently heads up Clinical and Laboratory Haematology at the Sydney Cancer Centre and is a former Director of the Institute of Haematology at Royal Prince Alfred Hospital.

He also chairs the Blood Clinical and Scientific Advisory Committee (BCSAC) of the NSW Department of Health and the National ARCBS ethics committee.

Professor Douglas is scientific advisor and member of the International Myeloma Foundation, the Multiple Myeloma Research Foundation, and is secretary of the International Myeloma Society. He serves on the editorial board of numerous journals.

Professor Douglas's background in multiple myeloma will be invaluable to the company as it pushes forward with development of GGTI-2418 in this aggressive form of bone cancer.

virax

Virax Holdings Limited
Level 2, Riverside Quay,
1 Southbank Bvd, Southbank
VIC 3003 Australia

TEL: +61 (0)3 9982 4563
EMAIL: virax@virax.com.au
**www.virax.com.au**