

#### Dear Shareholder,

We are very pleased to be providing this Investor Update, which details the activities of recent months and plans for the clinical development of Photosoft<sup>TM</sup> a next generation Photo Dynamic Therapy (PDT) for the treatment of a number of cancers.

During 2017, the focus of Invion was to identify and pursue opportunities to reshape and enhance the Company's pipeline and business growth.

At the AGM held 30 November 2017, the Shareholders of Invion approved a strategic transaction with The Cho Group, which has provided Invion a licence to develop and commercialise Photosoft<sup>TM</sup> for the treatment of cancers.

Invion is now leading the global clinical development of Photosoft<sup>TM</sup>, and retains the commercialisation and distribution rights to Photosoft<sup>TM</sup> in Australia and New Zealand.

The development of Photosoft™ is funded via an R&D agreement with The Cho Group, which sees The Cho Group providing non-dilutive funding to the company covering all development costs to meet preagreed development milestones.

Since the AGM, MD & CEO, Dr Greg Collier, and the team have been working hard on the manufacturing and development plans for Photosoft<sup>TM</sup>, and we are now progressing research on a number of fronts. Invion has added some experienced biotechnology senior management to the team as operations have expanded.

We look forward to building on the data and research findings from the initial trial in prostate cancer, conducted in 2017 by Dr Donald Murphy and other experience with Photosoft<sup>TM</sup>.

A proteomics analysis of protein samples found in the urine of the patients in the Murphy study found various immune-related biomarkers were upregulated, with high statistical significance (p<0.001).

Management and the Board remains committed to finding a way to advance Invion's current respiratory assets - nadolol and zafirlukast – and discussions with potential commercial partners for these assets remain a key focus

I hope you find this newsletter and update informative. We look forward to continued communications as we progress Invion's assets.

Yours faithfully,

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Thian Chew Chairman

# INVION

## INVESTOR UPDATE APRIL 2018

INVION LIMITED ASX: IVX

SHARES ON ISSUE: 5.45B

MARKET CAP: \$152M

#### **TOP SHAREHOLDERS**

Rank	Name	%IC
1	UNLIMITED INNOVATION GROUP	51.61
2	POLAR VENTURES LIMITED	10.00
3	MR HONSUE CHO	5.20
4	RMWC PTY LTD	1.83
5	CITICORP NOMINEES	1.58
6	ACSLNC PTY LTD	1.10
7	HSBC CUSTODY NOMINEES	0.99
8	BNP PARIBAS NOMINEES	0.96
9	MR E WONG & MRS Q NGUYEN	0.69
10	J P MORGAN NOMINEES	0.53



#### **INVION BUSINESS AND DEVELOPMENT PLAN**

Exclusive Distribution and Licence
Agreement: Invion has been appointed exclusive distributor and licensee in Australia and New Zealand of Photosoft<sup>TM</sup> for the treatment of cancers. The appointment has been made by The Cho Group, a Hong Kong based group that funded and successfully commercialised a number of unique and advanced technologies.

R&D Services Agreement: Invion will conduct clinical development of Photosoft™ globally, initially targeting prostate cancer in Australian-run clinical trials. The Cho Group will provide non-dilutive funding for the clinical trials. The clinical development program is being designed and managed by a joint steering committee between the two companies.

#### **INVION BOARD OF DIRECTORS:**

MR THIAN CHEW, (CHAIRMAN), DR GREG COLLIER (MD & CEO), DR MITCHELL GLASS, DR JAMES CAMPBELL

**COMPANY SECRETARY:** MELANIE FARRIS

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#### Operational Update

Work is underway at Invion on necessary arrangements for manufacturing and developing Photosoft<sup>TM</sup> in Australia. Photosoft<sup>TM</sup> manufacturing will be implemented in Australia, test batches will be made and all the appropriate laboratory and animal testing will be completed to meet the stringent regulatory requirements of the Australian and international regulators, including the TGA and FDA.

The aim is to develop several formulations of Photosoft<sup>TM</sup> - e.g. creams, oral and IV - so that Invion will be ready to explore Photosoft<sup>TM</sup>'s potential benefits in various cancer types in the clinical trials that will follow.

The major technical steps include:

- Selection and qualification of a suitable Contract Manufacturing Organisation (CMO)
- Transfer of the manufacturing technology to the CMO
- Manufacture of the Active Pharmaceutical Ingredient (API) for use in pre-clinical testing
- Formal pre-clinical studies to the regulatory standards by an approved provider
- Formulation studies to develop various Photosoft<sup>TM</sup> products
- Packaging design
- Manufacture of final formulated product for use in human studies
- Stability studies to ensure the shelf-life of the Australian-made product

Invion will work with expert approved technical partners to ensure that the manufacturing and laboratory and animal testing of Photosoft<sup>TM</sup> proceeds at optimum pace while meeting all the necessary standards. Overseeing this work will be the experienced Invion operational team comprising Craig Newton (Chief Operating Officer), Louise White from SeerPharma (Quality and Manufacturing Advisor) and Xenia Sango (Regulatory and Clinical Advisor).

Photodynamic Therapy has potential application in a wide range of cancers including skin cancers and solid tumours. Of these, non-melanoma skin cancers, prostate cancer and ovarian cancer hold promise based on the need for new treatment options and/or the experience to date with PDT.

#### Non-Melanoma skin cancers

Every year, tens of thousands of Australians have cancerous or precancerous skin lesions (actinic keratoses, basal cell carcinomas and others) removed surgically or burnt off using cryotherapy. PDT offers an alternative particularly where there are a number of adjacent lesions in which case PDT "field" therapy can be applied to address all the lesions and with minimal scarring. In Australia and other markets, PDT using previous generation photosensitisers is an established but not widely used option in this indication. This is due in part to the pain associated with these previous products. Improved photosensitiser technology has the potential to open up this large potential market.

#### Prostate cancer

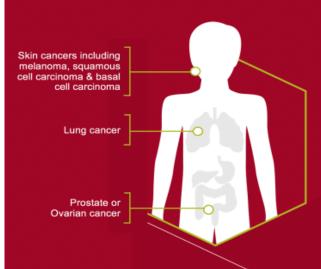
Prostate cancer is the most common cancer in men with 20,000 diagnosed per year in Australia and over 3,000 deaths. In November 2017, a new photosensitiser, Tookad®, was approved for use in Europe for lowrisk prostate cancer. Clinical studies showed that Tookad® cleared signs of cancer in many patients and also delayed progression to higher risk prostate cancer. This sets the scene for the new generation of PDT such as Photosoft™ to enter the mainstream of cancer therapy.

#### Ovarian cancer

Every year in Australia over 1,300 women are diagnosed with ovarian cancer. Despite treatments such as surgery, chemotherapy and radiation therapy, over 900 of those women will die from their cancer. Photodynamic therapy may provide an option which targets the cancer cells with lower sideeffects and can be added to the suite of therapies available. Our collaboration with the Hudson Institute at Monash University is initially focussed on ovarian cancer.

### RESEARCH ALLIANCE WITH HUDSON INSTITUTE OF MEDICAL RESEARCH

- Hudson Institute, affiliated with Monash
  Health, Monash University and a partner
  of the Monash Health Translation Precinct,
  is a leading Australian biomedical
  research institute recognised
  internationally for delivering better health
  through research into cancer and
  inflammation
- The alliance is aimed at advancing Invion's licenced cancer treatment technology, Photosoft<sup>TM</sup>
- Hudson Institute will provide research and clinical expertise on a series of projects in collaboration with Invion
- Projects will target a range of common and difficult to treat cancers, starting with ovarian cancer
- The agreement provides a framework for Invion and Hudson Institute to collaborate on a range of research and development projects for the Photosoft<sup>TM</sup> technology for the treatment of a range of cancers
- Under the Alliance Agreement, Hudson
  Institute will provide the research facilities
  and expertise required to undertake
  individual Invion-sponsored research
  projects. Hudson Institute will be
  responsible for all legislative and
  professional standards compliance
  requirements, in accordance with global
  best practice
- Initial projects will focus on ovarian cancer, and it is envisioned that projects will quickly expand into other cancer indications



#### **TEAM PROFILES**

#### Craig Newton - Chief Operating Officer

Craig Newton has over 30 year's experience in senior business and operational roles in the Medical Device, Pharmaceutical and Biotech sectors, among both large companies and small start-ups, with activity in Australasia, Asia and Europe.

His experience encompasses marketing, operations and project management across diverse therapeutic areas, including oncology, haematology, cell therapies, fertility and cardiovascular disease. Craig has worked at CSL, Serono UK, Bio Nova International, AVAX Australia and Cryptome Pharmaceuticals, in Chief Operating Officer, Sales and Marketing Director and Business Unit Manager roles.

#### Louise White – Manufacturing and QA

Louise is a Partner & Senior Consultant at SeerPharma – an Asia-Pacific QA and compliance consultancy - and has over 35 years experience in the pharmaceutical industry. This includes 13 year's experience at CSL Limited and over 22 years in SeerPharma. At CSL, Louise held roles in Virology R & D, Bacterial Vaccines Production, Quality Control and Production Planning. As a partner with SeerPharma, Louise has worked with many biopharmaceutical organisations to design and implement Quality Management Systems to a variety of standards including: TGA, ISO, FDA and European cGMP standards. She has also worked on many major validation projects at multinational companies for both sterile and non-sterile products.

#### Xenia Sango – Regulatory and Clinical Advisor

Xenia Sango is a highly experienced healthcare executive and independent consultant with over 30 years' global experience in senior clinical, regulatory and international commercialisation roles.

This includes 23 years at CSL in senior positions including Senior Director, Influenza Global Commercial Operations, Director of International Registrations, and Head of Regulatory Affairs. Xenia's achievements include leading the establishment of CSL's global regulatory function, launching CSL's flu vaccine in the USA and Europe, and establishment of subsidiaries in the USA and Germany. As Business Development Manager Research at Epworth HealthCare, Xenia augmented the research business, managed the Clinical Research Unit including the establishment of Phase Ib capability.

#### WHAT IS PHOTODYNAMIC THERAPY

Invion is developing Photosoft™ as a next generation Photo Dynamic Therapy (PDT).

PDT uses non-toxic photosensitisers and visible light in combination with oxygen to produce cytotoxic-reactive oxygen that kills malignant cells, shuts down tumours and stimulates the immune system. In contrast to surgery, or radiotherapy and chemotherapy which are mostly immunosuppressive, PDT causes acute inflammation, expression of heat-shock proteins, and invasion and infiltration of a tumour by leukocytes.

As a next-generation PDT, Photosoft<sup>TM</sup> is targeted to address the limitations of first generation PDT therapies through better solubility and tissue distribution, as well as stronger absorption that allows deeper penetration of tissues and better tumour specificity.

Photosoft<sup>TM</sup> uses a laser light activation method based on short, pulsating 'near infrared' (NIR) wavelengths.



