AUSTRALIAN
RESEARCH
INDEPENDENT INVESTMENT RESEARCH

Noxopharm Limited

(ASX: NOX)

Update - May 2017

INDEPENDENT
INVESTMENT RESEARCH

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INDEPENDENT INVESTMENT RESEARCH

Noxopharm Limited (ASX: NOX)

Update - May 2017

Investment Profile	
Share price ($) as at 24 May 2017	0.39
Issued capital:	
Ordinary shares (M)*	85.2
Performance Shares (M)	0.0
Options (M)	22.6
Fully Diluted (M)	107.8
Market capitalisation ($M)	33.2
12-month Low/high ($)	0.13/0.89

*Includes shares held in escrow

Board and Management

Peter Marks: Non-Executive Chairman
Dr. Graham Kelly: Managing Director & CEO
Dr. Ian Dixon: Non-Executive Director

Major Shareholders	%
Graham & Prue Kelly Family Trust	36.9
David Hannon	8.8
Anglo Menda Pty Ltd	6.0
Suburban Holding Pty Limited	3.1
Robert Birch	2.2

Share Price

CLINICAL TRIAL PROGRAM COMMENCES

Clinical Trial Program Commences: The company has commenced a comprehensive clinical trial program that will see the initiation of 7 clinical trials throughout 2017. The first clinical trial is underway which focuses on using NOX66 in conjunction with chemotherapy on patients with late-stage cancers. The remaining six trials will be testing NOX66 with radiotherapy and one study will treat patients with NOX66 and both chemotherapy and radiotherapy. In addition to the standard objective of testing the safety of NOX66, the primary objective of the trials is to determine the ability of NOX66 to provide meaningful responses (partial or full tumour shrinkage) in patients with late-stage cancer.

Idronoxil-C: The company has determined through laboratory testing, that the behaviour of idronoxil in the body when delivered using the NOX66 formulation is vastly different than when idronoxil is delivered in other forms. The company has termed the form of idronoxil after being administered using the NOX66 formulation as "Idronoxil-C." In March, the company announced it had been awarded a $50,000 grant by the Federal Government for a research project being conducted by Monash University. The objective of the research program is two-fold: (1) make a synthetic version of Idronoxil-C; and (2) develop delivery formulations of Idronoxil-C beyond that of NOX66 for specific cancer indications. The company has lodged a PCT patent application to begin the process of securing a patent for Idronoxil-C.

Abscopal Response Presents Significant Opportunity: Abscopal response refers to the rare event encountered in cancer patients undergoing radiotherapy, whereby following exposure of radiotherapy to a limited number of tumours all tumours disappear, effectively curing the patient of cancer. The abscopal response has only occurred in a select few patients to date and the conditions required to create such a response are not yet known. After the CEO experienced an abscopal response following the combination of radiotherapy treatment and NOX66, the company believes the drug has a mechanism to promote an abscopal response to radiotherapy. The company will be using the clinical trials to determine the ability of NOX66 to shrink both the tumours directly exposed to radiotherapy and the non-exposed tumours. While the ability to sensitise cancers to radiation would be a significant breakthrough, the ability to create an abscopal response on a regular basis would be a game changer in the treatment of cancer.

Delivering Idronoxil to the Brain: The company has entered into a research program with the University of Hong Kong looking at the use of NOX66 to treat brain cancer. The collaboration comes after the recent breakthrough in the laboratory confirming that Idronoxil-C crosses the blood-brain barrier and enters the brain at high levels. The program seeks to confirm NOX66 can sensitise brain cancer cells to the chemotherapy drug, Temozolomide, or to radiotherapy. The ultimate goal is to demonstrate the use of NOX66 in combination with chemotherapy or radiotherapy will deliver meaningful response rates in both adult and paediatric brain cancers.

Capital Position: After raising $6m for the IPO, the company has $3.6m remaining which is expected to be sufficient to cover the expenses of the clinical trial program. If meaningful clinical responses result from the clinical trials, the company will need to raise additional capital to undertake further trials and progress the development of the drug. Given the potential market opportunity for NOX66, we do not envisage the company having any difficulty in raising further capital, however this will likely result in existing shareholder positions being diluted.

Investment Case: Given the early stage of development of NOX66, an investment in the company is highly speculative. However, the company has taken significant steps in the development of NOX66 since we initiated coverage on the company in November 2016. One of the most the most significant being the inadvertent creation of Idronoxil-C, which through the NOX66 formulation provides idronoxil in an active form to the cancer cells for a prolonged period of time. The company is currently undertaking research to synthesise Idronoxil-C so it can be targeted for specific use in different cancers. If results from the clinical trials show that the use of NOX66 in combination of chemotherapy and radiotherapy treatments sensitises the cancer cells to these treatments, the market opportunity for NOX66 is significant. We would expect a meaningful response from the clinical trails to be a catalyst for the share price.

COMPANY UPDATE

- Since we initiated coverage on NOX in November 2016, there have been a number of developments with the company's formulation of idronoxil as NOX66 for the treatment of late-stage cancer. The major developments are detailed below.
- The company commenced the clinical trial program during the 1Q'CY17, with the first of seven clinical trials in the program commencing. All clinical trials are expected to commence in 2017.
- The company has moved into new premises as a result of the expanded infrastructure needs of the business. The company has also employed additional personnel to ensure there is sufficient personnel to complete the clinical trial program. This resulted in the administrative and corporate costs increase by 127.6% in the March quarter from the previous quarter.
- The company has taken steps to scale up production of NOX66 to meet its growing clinical trial needs as well as an anticipated potential provision for future programs. This has involved investing in its own interim small-scale manufacturing plant with a capacity of >100,000 doses per day.
- 4.2m shares were released form escrow in April 2017, taking the free-float shares on issue to 38.3m. 46.9m shares remain in escrow (55% of shares on issue) until 9 August 2018.
- The company had $3.6m cash on hand at 31 March 2017. The company expects this to be enough capital to complete the clinical trial program. If meaningful results are realised from the clinical trials then the company will be required to raise additional capital to further develop NOX66 and other drugs in the pipeline.

Idronoxil-C

- Laboratory testing has shown that following the administer of idronoxil using the NOX66 formulation there was some significant improvements to the behaviour of the idronoxil in the body. Not only was Phase 2 metabolism largely avoided, there was a sustained presence of idronoxil around the cancer cells. The longer the presence of the drug the more effective it is. The company has termed the form of idronoxil administered through the NOX66 formula as "Idronoxil-C".
- The company was awarded a Federal Government grant to fund a research project being conducted by Monash University. The objective of the research program is two-fold: (1) make a synthetic version of Idronoxil-C; and (2) develop delivery formulations of Idronoxil-C beyond that of NOX66 for specific cancer indications.
- The company has lodged a PCT patent application to begin the process of securing a patent for Idronoxil-C. The company will be seeking to obtain patents in as many countries as possible. Securing a patent will be a significant milestone for the company.

Delivering Idronoxil to the Brain

- The company has entered into a research program with the University of Hong Kong looking at the use of NOX66 to treat brain cancer. This comes after the breakthrough in the laboratory where idronoxil in the form of NOX66 crossed the blood-brain barrier of animals, entering the brain at high levels, unlike the regular form of idronoxil which does not.
- Confident that they can get idronoxil into the brain, the company now is looking to see whether the best way to use the drug for brain cancer is in combination with chemotherapy or radiotherapy. Radiotherapy is the front-line therapy for brain cancer, but the sensitivity of brain tissue to radiation means that only low doses can be used, generally only once. Temozolomide (TMZ) is the only chemotherapy drug that can cross the blood-brain barrier and while it is the only chemotherapy approved for the treatment of brain cancer, it is a poorly-acting drug with only one in five (20%) patients with brain cancer responding to treatment with this drug, and then only with a survival advantage of a matter of weeks

- The company is conducting laboratory research with a variety of collaborators including the University of Hong Kong and the Olivia Newton John Cancer Research Institute comparing the ability of NOX66 to act as a sensitiser of radiotherapy or TMZ for adult brain cancers, paediatric brain cancers such as DIPG, and secondary brain cancers such as lung and breast cancer and melanoma.

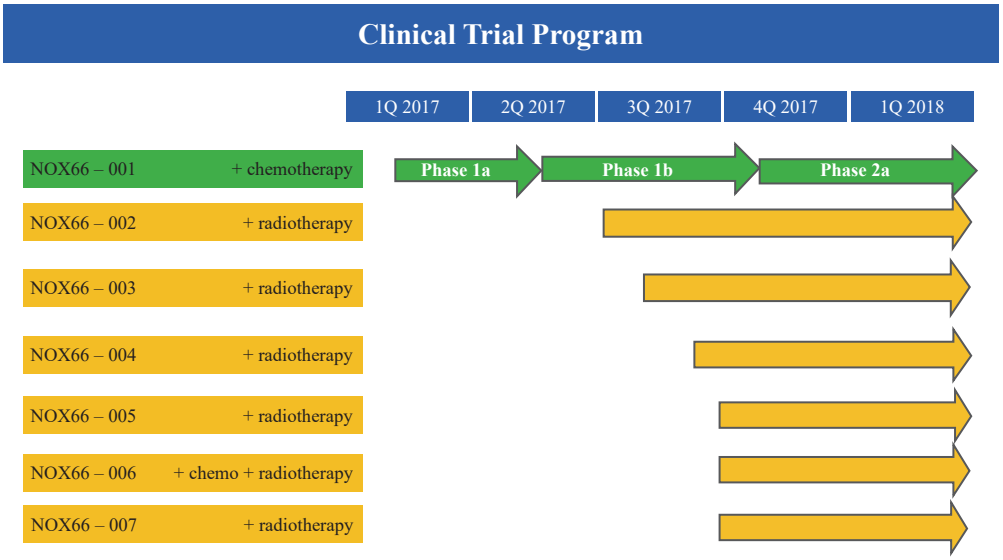
Non-Oncology Treatments

- The company has been very active with expanding the pipeline of potential drugs announcing the research into the first of its non-oncology drugs using its drug delivery platform.
- The company has entered into a research agreement with the University of New South Wales (UNSW) to develop a treatment to prevent the after-effects of brain and spinal cord injury. The drug would be delivered following an acute brain or spinal cord injury to limit further damage with the objective of improving the recovery prospects. There is the potential to expand the treatment to a wide range of neurodegenerative diseases.

NOX66 CLINICAL TRIAL PROGRAM

- The company has commenced the clinical trial program which will see the initiation of 7 clinical trials in 2017. The first clinical trial has commenced which involves testing NOX66 in conjunction with chemotherapy in patients with a variety of late-stage cancers. All clinical trials are expected to be completed before the end of 2018.
- The clinical trial program will result in the company testing NOX66 in combination with chemotherapy, radiotherapy and a combination of both treatments to determine the best route to market.
- With all clinical trials, in addition to safety, the primary objective will be to determine if the use of NOX66 in combination with chemotherapy and radiotherapy treatments provides a meaningful response (partial or full tumour shrinkage) by patients with late stage cancer.
- In all the trials, patients will take NOX66 daily for the treatment period and for one week post the treatment period.
- As detailed in our Initiation of Coverage report, the inaugural clinical trial will be conducted in phases:
  - **Phase 1a:** patients will initially have a 3 week period of taking just NOX66 to verify the safety of the drug se by the patient.
  - **Phase 1b:** in the event there are no toxicity issues in the patients in Phase 1a, then patients will progress to Phase 1b, where the patients will continue to receive their allocated dosage of NOX66 in combination with carboplatin (a leading chemotherapy drug). The study will be conducted over a 6-month period, in which patients will undergo six cycles of chemotherapy treatment with each cycle lasting 28 days. The first three cycles will involve patients receiving a lower than standard dose of carboplatin, followed by a standard dose for the last three cycles.

    Patients will undergo a CT scan at the beginning of the study and at the end of each of the 3 cycle periods to determine the clinical response of the combined treatment.
  - **Phase 2a:** in the event a meaningful response is detected from phase 1b, an additional 20 patients will be recruited and the combinations of cancer types and carboplatin dosages that show the most meaningful response will be selected to be administered in the new patients.
- The inaugural clinical trial involves 16 patients which are currently at varying stages of phase 1a and phase 1b, meaning that some patients are currently taking NOX66 with low doses of chemotherapy treatment.



Abscopal Response Research

- In addition to conducting research into the ability of NOX66 to sensitise cancer cells to radiation, the company is embarking on research regarding the 'abscopal response' which is a rare occurrence in cancer patients receiving radiotherapy, whereby in the case of multiple tumours, all tumours disappear when only one or two tumours have been targeted by the radiotherapy. The abscopal response effectively refers to the cure of cancer in a patient.
- The company is researching into the cause of the abscopal response in the hope of making it a common occurrence, which would be a significant breakthrough in cancer research and treatment.

INVESTMENT CASE

- An investment in the company is highly speculative given the early stage of the development of NOX66. The results from the clinical initial trials will be significant with respect to the further development of NOX66 and in the event a meaningful response is registered, which route to market is taken.
- In the event the clinical trials are successful, the market opportunity is significant with sales of oncology drugs in excess of $100b and the market continues to grow. Outside of surgery, chemotherapy and radiotherapy are the most common forms of cancer treatment.
- An advantage that NOX66 has is that it is being developed to be used in conjunction with existing treatments and not a drug to be used to cure any one type of cancer. This further opens the potential reach of the drug.
- NOX66 has the potential to significantly improve the response rates to both chemotherapy and radiotherapy ad potentially expand the scope of people that can receive treatment. If the company is able to make a synthetic version of Idronoxil-C, this will further enable the company to develop alternative formulations to target specific types of cancers.
- A meaningful response from the clinical trails will likely result in a re-rating of the stock and will likely be a catalyst for the share price. If meaningful results are obtained from the clinical trial program the company will be seeking to raise additional capital to further progress the development of NOX66. Given the potential market opportunity for NOX66 we do not envisage the company having any problems raising additional capital on the back of positive trials. However, we note that capital raisings will dilute existing shareholder positions.
- While the company has an oncology focus, the company is developing a non-oncology drug pipeline as well, making full use of its technology platform.

CAPITAL STRUCTURE

- At 20 May 2017, the company had 85.2m ordinary shares on issue, 46.9m of which are in escrow until 9 August 2018. We note that the release of shares from escrow will likely have a significant dilutive impact on the shares given the number of free-float shares will more than double upon the release of these shares from escrow.
- The performance shares will be converted to ordinary shares upon the company obtaining a market cap of $50m by 28 February 2021.
- The company has 22.6m unlisted options on issue. All options have an exercise price of $0.30 and an exercise date of 28 February 2021.

Shares & Options on Issue	
Fully paid ordinary shares (Free-float)	38,285,964
Restricted ordinary shares	46,885,465
Options	22,585,716

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