APP Securities Company Research

24 July 2017

Noxopharm Ltd

Pharmaceuticals

NOX A$0.32 **TARGET PRICE** A$1.00

SPECULATIVE BUY

Noxopharm ltd. is a biopharmaceutical company, which engages in drug development operating in the healthcare sector. It intends to focus on two areas of drug technology. The company was founded by Graham Kelly on October 27, 2015 and is headquartered in Turramurra, Australia.

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NOX66 – The only drug being trialled with the ability to reverse cancer resistance mechanisms

NOX has created NOX66 as a new dosage form of idronoxil, a first-in-class sensitiser of both chemotherapy and radiotherapy in cancer cells, through blocking their ability to repair the damage caused by drugs and radiation.

The main attraction of NOX is that NOX66 is the only drug being trialled with the ability to reverse cancer resistance mechanisms in both chemotherapy and radiotherapy.

NOX will be initiating a total of 6 proof-of-principle clinical trials during calendar year 2017, recruiting a total of 120 patients. 1 of the proposed 6 clinical studies is focused on chemotherapy alone, another 4 on radiotherapy alone, and the sixth study on combined chemotherapy and radiotherapy.

The first Phase 1b clinical study (chemotherapy alone) is currently underway with the first cohort of 8 patients recruited. All 8 patients have successfully passed a safety 3-week run-in study of NOX66 alone, and currently are being treated with NOX66 + chemotherapy (carboplatin). The second and final cohort of 8 patients currently are being recruited.

All 16 patients are being given NOX66 plus 3 months of low-dose carboplatin, followed if necessary by 3 months of standard-dose carboplatin.

The 3 NOX66 + radiotherapy studies are expected to start within the next 4-6 weeks. Radiotherapy studies are much shorter (3 months) than chemotherapy studies (7 months).

We expect preliminary clinical data to be available before the end of the year.

The Company also is developing a small pipeline of non-oncology drugs, based around a proprietary drug delivery platform responsible for delivering NOX66 across the blood-brain barrier to reach the brain. These drugs are targeting neurodegenerative diseases associated with traumatic brain injury and Alzheimer's Disease etc.

NOX's capital position is estimated to be AU$2.52m at the end of FY17. However, with the growing confidence in the safety and efficacy of NOX66, NOX believes clinical trials can be shortened to completion in 4 years, and with it, the need to bring forward the raising of additional capital.

Valuation

Successful trials, as outlined within this report, will substantiate a value well in excess of $1.00/sh based on the size of the potential market.

We are retaining our 12-month price target of $1.00/sh and retaining our SPECULATIVE BUY recommendation.

Company Data

Number of shares	85.2M
Market capitalisation	$27.3M
Free Float (%)	50.4026%
12 month high/low	$0.675/$0.135
Average Daily Turnover ($m)	0.0
% S&P/ASX 200	N/A
DDM Ranking	N/A
Industry Group	Pharmaceuticals

Data Source: FactSet, APP Securities

Share Price Performance

Source: APP Securities, Company Reports.

APP Securities contributes all company estimates to Bloomberg, Thomson Reuters, FactSet and Capital IQ.
Note: Numbers displayed are a sub-set.

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COMPANY OVERVIEW

Noxopharm (NOX) has positioned itself as the company most likely to make current standard cancer therapies work the way we would like them to work – effectively and safely. This claim is built around the experimental anti-cancer drug, idronoxil, and a new way of using it in a product called NOX66.

Chemotherapy and radiotherapy remain the backbone of cancer therapy. The ways we use these therapies have changed little over the last 50 years. Certainly, the survival prospects of some cancers have improved greatly over that time, but the survival prospects of many others such as cancer of the pancreas, lung, liver, stomach, head and neck, cervix, kidney and brain have changed little over 50 years.

For many forms of cancer, chemotherapy and radiotherapy clearly are under-performing. The aim of NOX is to use NOX66 to make standard therapies perform the way that doctors and patients would like to see them work.

In Australia, 1 in 2 men and 1 in 3 women will be diagnosed with a potentially lethal cancer before the age of 85 and 40% of these patients will die from that cancer within 5 years of diagnosis. Overwhelmingly those deaths stem from the problem of resistance mechanisms, with the cancer either failing to respond to treatment from the start, or responding initially but then becoming resistant. Once resistant to all forms of therapy, and once a cancer spreads from its original site, cancer is invariably fatal.

With 1 in 4 of us likely to die from cancer, finding a way to make current therapies work better is one of the most urgent needs we face as a community.

It also is a major investment opportunity.

The search for ways to make cancer cells more sensitive to chemotherapy and radiotherapy has been a high priority in medical research for many years, unfortunately with very little to show for it.

NOX believes that it is poised to succeed where others have failed. If it is successful, then we would expect NOX66 to become a major new drug, likely being used in most patients with life-threatening cancers undergoing chemotherapy or radiotherapy.

If NOX66 delivers on its promise, the rewards for both patients and investors could be extraordinary.

IDRONOXIL/NOX66

Idronoxil is the active drug. NOX66 is the final dosage form containing idronoxil.

20 years ago, experimental drug, idronoxil, was being hailed as one of the best prospects to increase the effectiveness of chemotherapy. But despite its early promise, it faltered and failed at the final step.

NOX resurrected idronoxil (a) because it believes that it still remains the best prospect, with no other drug prospect still coming close in terms of potency and safety, and (b) because it is confident that it has discovered why it failed early on and how finally to make it work.

Chemotherapy drugs and radiotherapy work by inflicting damage on the cancer cell, particularly the cancer cell's DNA. DNA is the brain of a cell, so if the damage is sufficiently severe, the cell will die. The problem is that cancer cells supercharge their DNA repair mechanisms to the point where it becomes impossible to inflict enough damage to kill the cell. The more treatment a cancer patient receives, the more supercharged the cancer becomes. Eventually it becomes impossible to inflict enough damage and the cancer becomes untreatable.

Idronoxil works by blocking the cancer cell's repair mechanisms. Unable to repair the damage inflicted by even low doses of chemotherapy or radiotherapy, the cancer cell dies.

Importantly, idronoxil only targets cancer cells, so healthy cells are spared. There are no known safety issues associated with idronoxil in humans.

NOX believes that the way idronoxil was given to patients in the past (by mouth or by intravenous injection) led to it being almost totally inactivated by the body. They then came up with a way to stop the body inactivating the drug. It is a technology called LIPROSE that puts a protective shield around idronoxil and allows it to reach its target cancer cells with its anti-cancer potency preserved.

ONCOLOGY

NOX will be initiating a total of 6 proof-of-principle clinical trials during calendar 2017 which primarily is looking at the ability of NOX66 to provide meaningful responses (tumour shrinkage) to chemotherapy or radiotherapy. These 6 studies will recruit a combine total of 120 patients.

The purpose of these 6 clinical studies is:

- To confirm the safety of NOX66;
- To determine the most clinically effective way to use NOX66; and
- To guide the design of a final (next step) registration study.

The trial program is designed to run through until approximately 3Q FY18 with trials finishing at various times before then, with each progressively complete from Feb 2018.

1 clinical study involves chemotherapy along, 4 involve radiotherapy alone, and the sixth involves a combination of chemotherapy and radiotherapy.

Initial Clinical Study

The first trial is testing NOX66 with chemotherapy. The chemotherapy drug is carboplatin, one of the most widely used and most potent chemotherapy drugs.

This is an important study because it is the first opportunity to test the safety of NOX66 in humans. Even though idronoxil had been given to over 400 patients in other studies without any toxicity being found, the current study is the first time that idronoxil was being given in a way that NOX believes would allow it to work. That meant needing to re-test its safety.

The study commenced in April at three hospitals in Tbilisi, Georgia with 16 patients (2 cohorts each of 8 patients), and potentially a further 20 patients in the phase 2a arm. The patients have late-stage cancers (breast, lung, prostate, ovarian, head & neck) and have failed to respond to all standard forms of chemotherapy.

Patients start with a 3-week Phase 1a arm of NOX66 alone. Providing there are no safety issues, then they progress on to the Phase 1b arm of NOX66 in combination with carboplatin.

The Phase 1b arm comprises 3 months of low-dose carboplatin, followed if necessary by 3 months of standard-dose carboplatin.

At 5th of June, all patients in the first cohort have completed the 3 week 1a arm, concluding that NOX66 did not cause any untoward side-effects, in line with expectations. Subsequently, the patients have begun phase 1b arm of the trial.

The Company proposes to present the early data received at those points at clinical conferences commencing in September 2017.

NOX66 is being assessed for its ability to overturn the drug-resistance mechanisms developed by cancer cells that enable them to resist all chemotherapy drugs including carboplatin.

The 4 hypotheses being tested are that:

- NOX66 alone will be well tolerated;
- NOX66 will not exacerbate carboplatin toxicity;
- NOX66 will reverse resistance to carboplatin, providing meaningful tumour responses where none would be expected; and
- NOX66 will restore carboplatin effectiveness to the point where its dosage can be reduced to a well-tolerated level.

The main purpose of the study is to test the safety and clinical benefit of using NOX66 in conjunction with carboplatin therapy in patients with late-stage solid cancers.

The rationale is that NOX66 will enable drug-resistant cancers to respond to carboplatin in a meaningful and well tolerated way. The patients will have exhausted all standard treatment options so that any further response to carboplatin normally would not be anticipated.

The patients will be drawn from the following cancer types: breast, lung, ovary, prostate, head & neck. More importantly, NOX is anticipating that a meaningful response will be achievable using a lower than normal dosage of carboplatin.

The study has an adaptive design meaning that in the event of significant tumour responses after either the low or standard carboplatin dose, the study can be expanded immediately into a Phase 2a arm through the recruitment of a further 20 patients. The study is being conducted in Georgia because of the anticipated speed of patient recruitment, backed up by a high standard of health care and FDA-audited clinical trial sites.

Next 3 clinical studies

The next 3 clinical studies to start all involve radiotherapy and all are in patients with late-stage prostate cancer. The Company has identified metastatic, castrate-resistant prostate cancer as the preferred clinical target for an initial marketing approval, with NOX66 being us as a radio-sensitiser We anticipate that these studies will start treating patients by the end of August 2017.

The men in these 3 studies will have metastatic, castrate-resistant prostate cancer that has no further treatment options. This means that their cancer will have spread to various sites around the body, will have stopped responding to hormone therapy, and will have failed chemotherapy.

These men will be eligible for palliative radiotherapy, meaning low-dose radiation designed to relieve symptoms such as pain by shrinking 1 or 2 larger lesions on a temporary basis.

NOX is using NOX66 in combination with radiotherapy with the aim of converting a temporary partial shrinkage into a long-lasting complete shrinkage.

The Company is testing NOX66 with 3 different forms of radiotherapy now being used to treat late-state prostate cancer:

- The first is standard external beam radiotherapy, the most common form of radiotherapy where patients lie under a beam of radiation.
- The second is stereotactic body radiotherapy, a computerised delivery method that delivers external beam radiation in a more focused way designed to limit damage to healthy tissues. This form of radiotherapy is more expensive and more restricted.
- The third is a new, experimental form of radiotherapy known as brachytherapy, where a radioactive material is injected intravenously and seeks out prostate cancer cells, delivering a low dose of radiation directly to the cancer tissue.

The first 2 studies should be relatively short. Patients receive NOX66 and radiation to 1-2 lesions over up to 2 weeks, and then scanned 3 months later. In the third study, the radioactive drug is injected each month for up to 6 months, with scanning every month.

Should any of these studies deliver a positive outcome, then NOX would be well-placed to offer something meaningful to a significant number of men worldwide with prostate cancer where currently no treatment options exist. Late-stage prostate cancer represents a large market of significant unmet medical need.

The global prostate cancer therapeutics market size was valued at USD 7.9 billion in 2016 and is expected to grow at a CAGR of 4.8% over the forecast period 2014-2025. As per data published by the World Cancer Research Fund International, more than 1.1 million cases of prostate cancer were reported in 2012, which accounts for around 8% percent of the total tumour cases. [Source: Grand View Research http://www.grandviewresearch.com/Filters?search=prostate+cancer]

5th and 6th studies

These 2 studies will involve patients with late-stage solid (non-blood) cancers and where there are multiple cancers able to be treated with radiotherapy. The Company anticipates these patients will mainly have cancer of the lung, breast, large bowel and ovary (prostate cancer excluded).

Like the 3 prostate cancer studies above, a palliative (low dose of radiation) will be delivered to 1-2 cancer lesions only, with many more lesions not being exposed to radiation. The aim is (as with the 3 prostate cancer studies) to see what effect NOX66 treatment has on the response of the 1-2 tumours exposed to radiation, as well as the response of the remaining non-exposed tumours.

The only difference between the two studies is that the 5th study will involve NOX66 + radiotherapy only, and the sixth study will involve NOX66 + radiotherapy + chemotherapy.

We understand that these 2 studies are expected to commence in September/October 2017.

Compassionate Use Program

The Company also is making NOX66 available on a limited compassionate use basis to patients that have exhausted all standard treatment options. Compassionate use relates to the supply of an experimental drug to a patient who has a life-threatening disease and has no further treatment options.

It is highly unusual for experimental drugs to be made available on a compassionate use basis so early in their development program, and speaks to the confidence that the Company must have in their product both in terms of its safety and its efficacy.

Data from compassionate use programs are not owned by the Company owning the drug. There is nothing to stop the patients and their treating doctors from speaking about their experience, but privacy laws mean that the Company cannot comment.

The Company has not disclosed how many patients are involved in this program, but we understand it is a small number. The Company also has indicated that it is converting this informal arrangement into a formal Phase 2 arrangement where NOX66 will be used in patients with rare cancers in combination with the standard forms of therapy applicable to each rare cancer type.

The Company has indicated that the potential benefits of this approach are:

- an opportunity to gain more experience with the drug across different cancer types; and
- the ability gather data (otherwise too difficult to obtain given the rarity of the cancers) that would be available for use in future regulatory submissions.

CORPORATE STRATEGY

The clinical trial program is forecasted to be completed in 4 years, enabling NOX to generate commercial return within 5 years (2022). A 4-year program contrasts significantly with the 8-plus years normally required to bring an anti-cancer drug from the time of treatment of Phase 1 patient through to marketing approval. This shortened timetable is the consequence of the Company's confidence in the safety and efficacy of NOX66.

Generally, drug development involves 3 discrete, consecutive phases:

- Phase 1 (safety; understanding behaviour of drug in the body);
- Phase 2 (indicative evidence of efficacy; provide guidance on design of the final clinical trial); and
- Phase 3 (final clinical trial; data submitted for marketing approval).

NOX has adopted a strategy that condenses these phases into a 2-step program, with current clinical activities (Step 1) designed to provide combined Phase 1 and Phase 2 evidence.

Creating the following key milestones:

- End of Q4 2017 (Calendar): Preliminary clinical data to provide guidance on the preferred clinical indication;
- End of Q1 2018: Confirm preferred clinical indication; and
- End of Q2 2018: Complete planning of study in agreement with regulators in key territories; advanced recruitment of sites and investigators.

A registration study is the final study that is conducted in collaboration with the regulatory agency in a country (FDA in the case of the US; TGA in Australia, EMA in Europe). A study design is agreed upon, with certain outcomes set. In the case of cancer drug studies, such outcomes are the number of patients still alive at the end of the study (overall survival) or the number of patients whose cancer has failed to get worse (progression-free survival).

That would put NOX66 in line to receive marketing approval and be generating revenue by 2022.

NON-ONCOLOGY

Studies of NOX66 in animals has shown that NOX66 leads to high levels of idronoxil reaching the brain, comparable to levels in the rest of the body.

The significance of this lies in the fact that only about 2% of all drugs consumed by humans are able to cross the blood-brain barrier, a highly selective filter in the blood vessels in the brain that serves to protect this vital organ from unwanted chemicals.

Though the findings are in animals and yet to be confirmed in humans, rats have proven to be a reliable predictor of the ability of drugs to cross the human blood-brain barrier.

This finding has opened the door for NOX to look at using NOX66 in the treatment of brain cancers, and we understand the Company is undertaking pre-clinical studies to that end.

However, it also has opened a very significant door to use the same NOX66 delivery mechanism to deliver drugs other than idronoxil into the brain to treat non-cancer conditions of the brain such as neurodegenerative diseases. The blood-brain barrier has proved a major stumbling block over the years in making any significant progress in the treatment of diseases such as Alzheimer's, Parkinson's, Huntington's, multiple sclerosis and motor neurone disease (ALS), or to aid in the recovery of the brain from traumatic injury such as stroke or concussion.

NOX has already announced a collaboration with the University of New South Wales (UNSW) to use their proprietary drug delivery technology platform to deliver a NOX drug into the brain to limit the damage that occurs in the brain following stroke.

The Company appears to be keeping this drug program under wraps, we understand because of their need to file patents over what could be a significant opportunity in light of the lack of effective treatments of a condition known as excitotoxicity which underpins many brain diseases.

NOX CAPITAL POSITION

The capital position for NOX at the end of 3QFY17 was A$3.64m, and is estimated to be $2.5m at the end of FY17, with an underlying burn rate of $300,000/month.

Prior to the revised timetable of the shortened clinical trial program, the $6m raised in 2016 at the IPO was done on the basis of running 2 Phase 1 studies through to completion in 2018, with a follow-up capital raising at that time to allow the Company to embark on a Phase 2 program.

However, the Company's growing confidence in the safety and efficacy of NOX66 has led the Board to determine that the potential to put the Company on a commercial footing within 5 years more than justifies the expanded clinical trial program and, with it, the need to bring forward the raising of additional capital.

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