

INNATE IMMUNOTHERAPEUTICS LIMITED (IIL)

TAKING THE PAIN OUT OF MULTIPLE SCLEROSIS - INITIATION OF COVERAGE

DIRECTORS & MANAGEMENT

Michael Quinn	Non-Executive Chairman
Simon Wilkinson	Managing Director & CEO
Christopher Collins	Non-Executive Director
Elizabeth Hopkins	Non-Executive Director
Dr Robert Peach	Non-Executive Director
Andrew Sneddon	Non-Executive Director
Dr Gill Webster	CSO
Jeff Carter	CFO
Andrew Cooke	Company Secretary

MARKET DATA

ASX Code:	IIL
Current Price (20/05/16):	\$0.30
52 Week Share Price Range:	\$0.12 - \$0.34
Market Capitalisation:	\$58.9 million

CAPITAL STRUCTURE (as at 06/05/16)

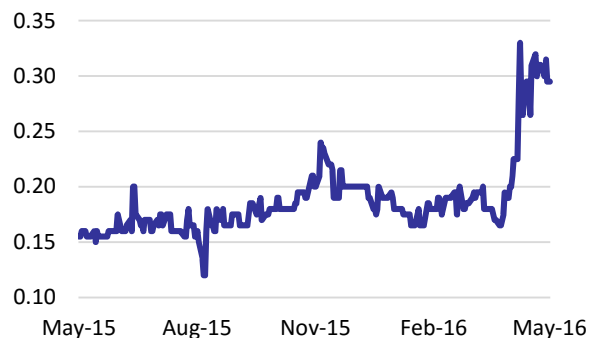
Shares on Issue:	196.4 million
Unquoted Securities (options)	20.5 million
Loyalty Rights*	33.0 million

*Expiring December 2016

MAJOR SHAREHOLDERS (as at 30/04/16)

Collins Family	22.5%
Australian Ethical	9.8%
Top 20	53.8%

SHARE PRICE CHART



SENIOR ANALYST

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 May 2016



Innate Immunotherapeutics Limited (ASX: IIL) is a clinical stage medical biotechnology company that has designed and developed a proprietary drug – MIS416 - that targets the human innate immune system using a unique immunomodulatory microparticle technology.

This bacteria-derived biologic is currently being trialled as a treatment for Secondary Progressive Multiple Sclerosis (SPMS). MIS416 has also been found to have beneficial application in the treatment of certain cancers, infections and other diseases.

Previous clinical trials support the efficacy of the drug in alleviating the symptoms of SPMS with the current 93 patient Phase 2B trial due for completion in April 2017.

Reporting of the current clinical trial results is expected in Q3 2017, which the Company believes will catalyse the ongoing interest from major pharmaceutical companies toward concluding a probable trade sale or exclusive licencing and distribution agreement for MIS416.

Competition to secure this important technological breakthrough is expected to be robust with a transaction multiple likely to reflect the already considerable interest.

EXECUTIVE SUMMARY

*Leading medical
biotechnology company*

Innate Immunotherapeutics Limited (ASX: IIL) is a leading Australian medical biotechnology company that has designed and developed a proprietary drug – MIS416 - that targets the human innate immune system.

Using a unique immunomodulatory microparticle technology, the Company has developed a bacteria-sourced treatment for Secondary Progressive Multiple Sclerosis (SPMS), an advanced and highly disabling form of the neuro-degenerative disease, multiple sclerosis.

Innate Immunotherapeutics has previously conducted successful Phase 1 and 2A trials along with an ongoing Compassionate Usage program in New Zealand that has provided a unique and early insight into the efficacy of **Innate's** drug treatment.

*12-month Phase 2B trial
currently underway*

The Company has recently finalised patient enrolment into a 12-month Phase 2B Randomised, Double-Blind, Placebo-Controlled trial of the efficacy and safety of MIS416 in the treatment of SPMS. A total of 93 patients have been recruited from seven sites across Australia and New Zealand with the trial participants receiving a weekly measured dose of MIS416 intravenously.

*100% safety record to
date*

The Phase 2B clinical trial will determine whether MIS416 is safe, tolerable, and improves a range of signs and symptoms associated with SPMS. Such results have already been observed through the earlier trials and anecdotal reports received from patients, clinicians and caregivers. Observed improvements in SPMS sufferers have been documented in cognition, mobility, strength and a reduction in pain and fatigue.

A report on the efficacy of the Phase 2B trial will be published in mid-2017.

Innate is confident the results of this trial will confirm the success and suitability of MIS416 in the safe treatment of SPMS and diminution in symptoms associated with advanced multiple sclerosis. The previous goal for treatment in these patients was to slow the rate of disease progression however MIS416 appears to be achieving a much more beneficial treatment effect.

*No currently approved
drugs for treatment of
SPMS*

With no currently approved drugs for the effective ongoing treatment of SPMS, the Company expects that immediately following the publication of the trial report (July 2017) there will be a significant level of market competition to acquire or licence MIS416 ahead of a Phase 3 trial.

Innate has signalled its preferred approach would be an outright sale of the whole company to a Big Pharma corporate. These parties recognise the significant opportunities presented in the US\$4 billion SPMS treatment space as well as the potential for an immune modulating drug like MIS416 to treat other neurological conditions such as refractory epilepsy and CNS trauma, as well as certain cancers that are prime targets for immuno-oncology treatment approaches.

During the waiting period for the trial's completion and results to be published, **Innate** is also developing a manufacturing scale-up plan for the commercial production of the MIS416 drug which it intends to include as part of the eventual sale or licencing package.

*Current prices unlikely
to be revisited*

Whilst the importance of awaiting success from the Phase 2B trial results cannot be overstated, there is a significant opportunity now to participate in high-value upside with current prices unlikely to be revisited.

KEY POINTS

- Innate Immunotherapeutics (ASX: IIL) has designed and developed a drug for use in treating advanced Multiple Sclerosis:** Medical biotechnology company IIL has manufactured a unique proprietary technology that utilises a patient's own immune system to combat the deleterious effects of neuro-degenerative such as Secondary Progressive Multiple Sclerosis (SPMS).
- Currently conducting a Phase 2B drug trial:** The Company is undertaking a randomized, double-blind placebo Phase 2B trial with a 93 patient group to determine the efficacy of the MIS416 drug in treating SPMS. The trial is due for completion in April 2017.
- Early results show positive improvement:** Through previous Phase 1 and 2A trials and IIL's New Zealand-based compassionate use program - now in its 8th year – patient reported responses to treatment have been overwhelmingly positive with no significant safety concerns.
- Other treatment capabilities:** The MIS416 drug developed by IIL has shown positive efficacy results in animal disease models of cancer, infection and certain neuro-inflammatory conditions.
- SPMS treatment options are extremely limited:** Currently there are no approved drugs for the safe and effective ongoing treatment of SPMS.
- Big Pharma closely monitoring trial outcome:** Completion of the Phase 2B trial and accompanying report is expected to accelerate corporate transaction interest in IIL from Big Pharma via either a trade sale or licensing agreement for MIS416. The market for SPMS treatment is estimated at more than US\$4 billion.

INVESTMENT PROPOSITION

Within the next twelve months, **Innate Immunotherapeutics** is due to complete a significant efficacy trial of MIS416 in patients with the currently untreatable secondary progressive form of multiple sclerosis.

With no current approved disease modifying therapies or treatment for SPMS, Innate is in a commanding position to secure meaningful market share.

There is already significant Big Pharma interest in the trial outcome with the Company having held high-level discussions already with several manufacturers of drugs for early stage MS and other pharmaceutical companies who are interested in the potential for MIS416 to be used in other neuro-inflammatory conditions.

The Company is confident a successful study outcome will drive an outright sale or substantial out-licensing transaction within the next 15-18 months. Competitive tension amongst likely bidders should ensure integrity of the process and ensure a healthy premium is secured for Innate shareholders.

Subject to successful Phase 2B trials, Gordon Capital has determined a relative valuation range from potential market share, recent transactions and historic multiples for **Innate Immunotherapeutics** of A\$1.22 to A\$2.43.

Gordon Capital relative valuation range for IIL from A\$1.22 to A\$2.43

BUSINESS OVERVIEW

Since 2008, **Innate Immunotherapeutics** has been developing its proprietary immune modulating drug technology with an initial focus on the Secondary Progressive form of Multiple Sclerosis (SPMS).

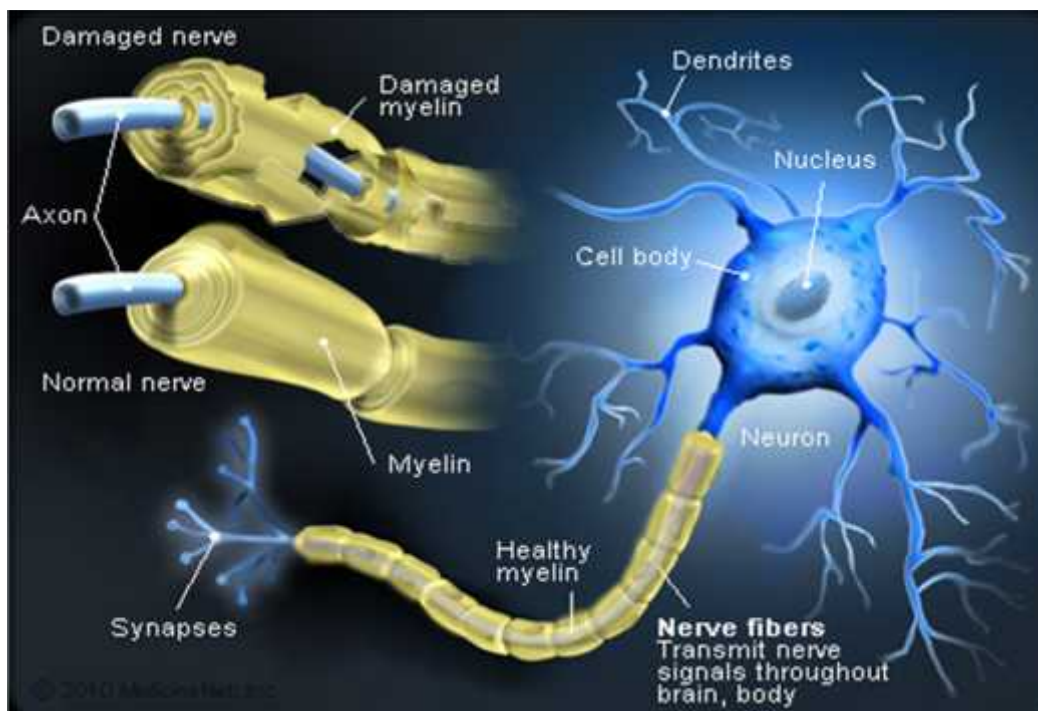
Multiple Sclerosis

Multiple Sclerosis (MS) is a progressively degenerative disease of the body's immune system where the protective myelin sheath surrounding nerve fibres in the brain is damaged which in turn leads to a wide range of health complications and loss of neurologic function.

These fibres inside the central nervous system (CNS) are damaged by a likely combination of both neuro-degenerative and autoimmune processes and trigger inflammatory processes that can cause further damage and cause myelin to disappear.

As a result, electrical impulses that travel along the nerves slow down as the nerves themselves are damaged with some of them stripped of their myelin covering (become demyelinated).

FIGURE 1. **WHAT IS MS?**



Source: MedicineNet

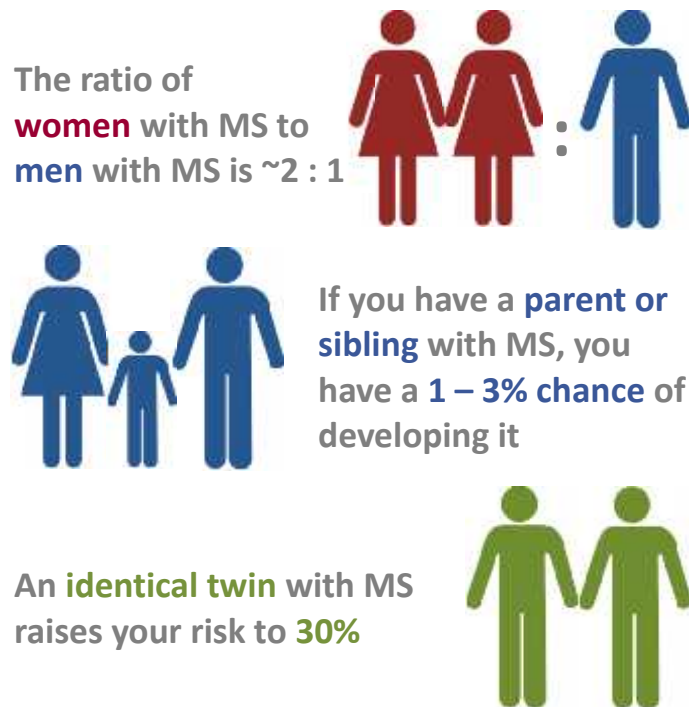
MS affects more women than men

MS affects more than 2.3 million people worldwide

The cause of MS remains unknown, though it is generally believed to be a combination of genetic, immunological and environmental factors. Most people with MS are diagnosed between the ages of 20 and 50, with at least two to three times more women than men being diagnosed with the disease.

MS affects more than 2.3 million people worldwide and is associated with a reduced life expectancy of between 5 and 15 years

FIGURE 2. MS RISK FACTORS



Source: Healthline.com

According to the National MS Society (US) multiple sclerosis is not a “reportable” disease. This means government does not require clinicians and physicians to report when a diagnosis for MS is made and as a result there is no simple accounting for the exact number of people with MS.

MS incidence highest in Northern European Caucasians

Incidence of MS has been documented across the world and is highest in North America and Europe and lowest in sub-Saharan Africa and East Asia. In some populations it is virtually non-existent including the Inuits, New Zealand Maori and Australian Aborigines. The incidence of MS is also higher in colder climates.

FIGURE 3. GLOBAL DISTRIBUTION OF MS



Source: MultipleSclerosis.net

Multiple Sclerosis is an expensive disease to manage with the Multiple Sclerosis Society of America estimating direct and indirect health care costs range from US\$8,528 to US\$54,244 per patient per year in the United States. MS ranks second only to congestive heart failure in terms of cost compared with other chronic diseases.

Lifetime financial costs of MS estimated at US\$1.2 million

The lifetime financial cost of MS, including both direct medical expenses and indirect costs associated with loss of income and other expenses, has been estimated at US\$1.2 million per person with the disease.

There are two main forms of MS:

Two types of MS

-)] **Relapsing Remitting MS (RRMS)** – generally affects younger people
-)] **Secondary Progressive MS (SPMS)** – skews towards older persons

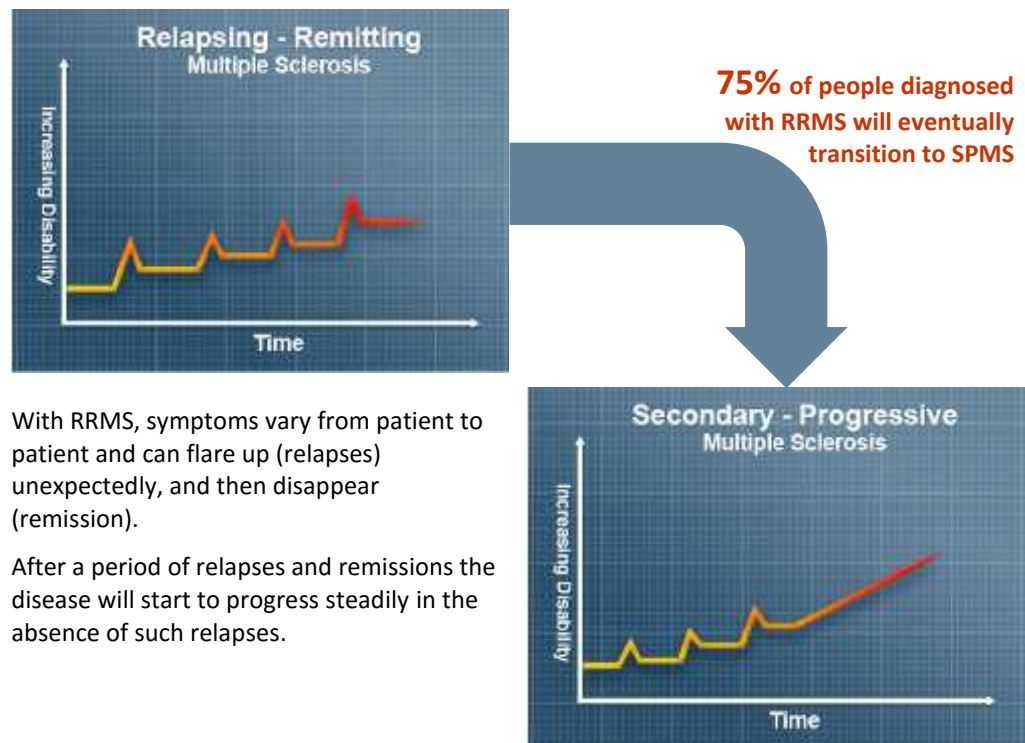
Diagnosis of MS is mainly through an MRI (magnetic resource imaging) scan with acute inflammatory demyelination of the nerves showing up as lesions.

Within 20 years of initial diagnosis, 75% of people with RRMS go on to develop SPMS which significantly impacts their cognitive function, mobility and overall quality of life. Despite the high number (currently 13) of approved drugs available for the treatment of RRMS none of these drugs have been found to be effective in the treatment of SPMS.

Currently no approved drugs or effective ongoing treatment of SPMS

There are currently no approved drugs or safe and effective ongoing treatment for SPMS.

FIGURE 4. **RRMS vs SPMS**



With RRMS, symptoms vary from patient to patient and can flare up (relapses) unexpectedly, and then disappear (remission).

After a period of relapses and remissions the disease will start to progress steadily in the absence of such relapses.

Source: MedicineNet

FIGURE 5. **EARLY SIGNS OF MS**



Source: MultipleSclerosis.net

MIS416

Innate has been developing a bacterial biologic microparticle (right) – MIS416 – which can uniquely target both the regulatory and defensive functions of the innate immune system (myeloid cells) and has been found to be effective in the treatment and management of SPMS symptoms.



Source: Innate Immunotherapeutics

Long term treatment for SPMS with MIS416 has shown no significant dose intolerance or cumulative toxicity in treated patients to date.

The Company has been issued patents covering the use of MIS416 to treat all forms of multiple sclerosis in all major markets, being primarily North America, Western Europe and Australasia. This market has been estimated to be worth more than US\$4 billion annually. Innate is targeting this market specifically for the potential commercialisation opportunity of its MIS416 drug.

Global market patents in place

SPMS market estimated to be worth more than US\$4 billion

FIGURE 6. **MARKET OPPORTUNITY** (MIS416)

	Relapsing Remitting MS	Secondary Progressive MS
Sufferers worldwide:	60%	30%
Number of approved disease modifying drugs:	13	0
Estimated annual market revenues (2015)*:	US\$20.5 BILLION	-
Estimated potential annual market revenues:	IIL TARGET MARKET	
	US\$4 BILLION	

RRMS and SPMS comprise 90% of the MS market. The remaining 10% comprises two rarer forms of progressive multiple sclerosis

*Source: Leerink Partners Estimates, Company Reports & SEC Filings

In addition to its treatment efficacy for SPMS, the current Phase 2B trial could also demonstrate a proof of concept platform for the use of MIS416 in treating other diseases with a neuro-inflammatory component.

Previous Trials – Phases 1B/2A

Previous trials successful and safe

A Phase 1B trial in patients with either Primary Progressive or Secondary Progressive MS was completed in October 2011. A follow-on Phase 2A study in patients with SPMS was completed in July 2012.

FIGURE 7. **TRIAL SUMMARY** (MIS416)

	Phase 1B	Phase 2A
Participants	19	15 enrolled, 11 completed
Duration	Weekly dosing for 4 weeks	Weekly dosing for 12 weeks
Style	Open Label, dose-escalation	Open Label, dose-confirmation
Completed	October 2011	July 2012

Source: Innate Immunotherapeutics

Results from both studies met or exceeded expectations providing the impetus for the current Phase 2B trial underway in Australia and New Zealand. The early NZ-based trials received significant funding support for the National MS Society of the United States (US\$550k) and the NZ Government (NZ\$600k). In a show of confidence the NMSS has taken an equity position in the Company and is currently its 8th largest shareholder.

Compassionate Use

Compassionate use program provides likely Phase 2B trial data signatures

For the past 8 years, SPMS patients in New Zealand have been receiving treatment for SPMS with MIS416 under a Compassionate Use program. This has been possible as use of an unapproved experimental medicine is permitted under NZ drug laws. This program has provided substantial anecdotal data on the longer-term benefits of MIS416 drug treatment and the likely results from the current Phase 2B trial.

While the original patient has received in excess of 175 doses of MIS416, an average of 70 doses have been administered to 27 patients over an average treatment period of 26 months.

- J 20 of the 27 patients with SPMS self-reported significant and sustained improvement in a range of their MS related signs and symptoms
- J Patient reports have included improved mobility, eye sight, bladder & bowel control, cognition, strength, and significant reduction of fatigue
- J Reported improvements have been sustained for a minimum of 12 months or longer
- J Long term treatment with MIS416 has shown no significant dose intolerance or cumulative toxicity treated patients
- J Most common side effects – transient self-limiting headache, fever, chills, muscle pain and weakness

Current Trial – Phase 2B

Recruitment for the Phase 2B trial was completed in April 2016. A total of 93 patients have enrolled in the trial which lasts 12 months.

FIGURE 8. PHASE 2B TRIAL OUTLINE

STUDY DESIGN	
Phase	2B
Design	Randomised, double-blind, placebo-controlled study of the efficacy and safety of MIS416 in the treatment of subjects with SPMS
Sites	5 x Australia and 2 x New Zealand
Number	93 subjects with SPMS randomised 2:1 to MIS416 or saline placebo
Doses	Weekly intravenous infusion of MIS416 or saline over 13 cycles of 4 doses per cycle (52 weeks in total)

KEY OBJECTIVES	
]	To determine the efficacy of MIS416, relative to placebo, as assessed by various measures of neuromuscular function, disability and health status and to determine the safety and tolerability of once weekly intravenous treatment
]	To explore the effect of MIS416 on disease activity and neurodegeneration by measuring a wide range of blood markers, imaging markers and patient reported outcomes
]	Study is exploratory by design in order to inform the choice of endpoint(s) for Phase 3
]	No adjustments have been made for multiplicity of outcomes, success will be judged on consistency of outcomes rather than statistical testing

STATUS	
]	First patient enrolled in October 2014
]	Last patient enrolled in April 2016
]	No interim analysis
]	Clinical study report Q3 2017

Source: Innate Immunotherapeutics

Clinical Assessment – Endpoints & Patient-Reported Outcomes

The efficacy of MIS416 in treated patients compared to the placebo group will be determined using performance measures related to neuromuscular functions as well as patient reported outcomes related to disability and health status. All efficacy assessments are carried out under clinical supervision at specified intervals and specifically include:

PRIMARY ENDPOINTS

Neuromuscular Function (baseline & 3 monthly)

-) MS Function Composite comprising the; timed 25 Foot Walk, 9 Hole Peg Test, and Paced Auditory Serial Addition Test
-) Symbol Digit Modalities Test
-) Sloan Low-Contrast Letter Visual Acuity
-) Jebsen Hand Function Test [standardised and objective evaluation of fine and gross motor hand function using simulated activities of daily living]
-) Grip, tip and key pinch strength
-) 6-Minute Walk Test

SECONDARY ENDPOINTS

Disability & Health Status (baseline & 3 monthly)

-) Expanded Disability Status Scale
-) Patient Reported Outcomes (PROs) including:
 - Z SF-36 and its components
 - Z MS Impact Scale
 - Z Neurological Fatigue Index for MS
 - Z Brief Pain Inventory

Cranial MRI (performed at Baseline, 3 mths and End of Study Visit)

-) Whole Brain Atrophy (WBA)
-) Magnetisation Transfer Ratio (MTR)

Data collected from these performance-related outcomes, patient reported outcomes, and MRI will be examined in accordance with a preapproved Statistical Analysis Plan. No single measure has been declared as primary endpoint but rather success will be determined by the degree to which the overall performance of the MIS416 treated group compares to the untreated placebo group.

As the current trial is not a pivotal/approval trial, the exploratory study design incorporating multiple endpoints, is appropriate in the context of the complex range of symptoms experienced by patients with SPMS. The trial results are expected to be published within six months of completion of the trial in April 2017.

The results – after being fully anonymised and de-identified - will also form part of the Multiple Sclerosis Outcome Assessments Consortium (MSOAC) patient Database generated by the Critical Path Institute in Arizona (USA) as part of their Online Data Repository (CODR). As at April 2016 the database holds more than 15,000 individual patient records available for critical analysis and evaluation. Innate was invited to join the MSOAC consortium at the beginning of 2015. Data from the Innate trial will be a valuable addition to the Consortium's database as previous SPMS trials have not been designed to specifically capture a range of functional improvements in patients.

Clinical trial results will also form part of global MS patient database

Sale or Licence - Big Pharma Expected To Step Up

Proof of Concept platform enhances saleability

Success in the Phase 2B trial will generate significant commercial opportunities for the Company, not only validating MIS416 as an effective treatment for SPMS but also providing a Proof of Concept for the use of this unique immune modulating microparticle platform in other neurology diseases and disorders.

BUSINESS DRIVERS & GROWTH PROFILE

Value transformative technology

Innate Immunotherapeutics' development pathway for its MIS416 drug is approaching a critical milestone. A successful documented efficacy outcome from the Phase 2B trial in Secondary Progressive Multiple Sclerosis will be transformative for the Company.

Widespread interest from Big Pharma in trial outcome

There is already widespread interest among major pharmaceutical companies in the outcome of the trial and of the potential for MIS416 in treating advanced MS sufferers. Also for its derivative platform use in treating a number of other significant and debilitating medical conditions.

The Company has a high degree of confidence in the safety and efficacy of its drug and of its pecuniary value to Big Pharma.

Transaction value at significant multiple to current market capitalisation

Innate has signalled its preference for a post-Phase 2B competitive bidding process resulting in the outright sale of the Company and its associated technology. A staged exit could also be the result of such a process if the combination of upfront, milestone, and loyalty payments were in significant excess to proceeds from an outright sale. For shareholders, all these options would create significant value.


Recognising the uniqueness of the drug treatment and its capacity to capture whole of market share we expect any acquisition process to begin at a significant multiple to the Company's current market capitalisation.

FIGURE 9. **CLINICAL RESEARCH PHASE STUDIES**

	PHASE 1	PHASE 2	PHASE 3
Patients	20 to 100 healthy volunteers or people with the disease/condition.	Up to several hundred people with the disease/condition.	300 to 3,000 volunteers who have the disease or condition
Length of Study	Several months	Several months to 2 years	1 to 4 years
Purpose	Safety and dosage	Efficacy and side effects	Efficacy and monitoring of adverse reactions
% of Drugs that move to next Phase	70%	33%	25-30%

Source: US Federal Drug Administration (FDA)

FIGURE 10. **FDA DRUG REVIEW PROCESS**

BASE	Drug Developed	
STAGE 1	Animals Tested	PRE-CLINICAL
STAGE 2	Investigational New Drug (IND) Application to FDA	
STAGE 3	Phase 1 Trial	
STAGE 4	Phase 2 Trial 	CLINICAL
	<i>AT END OF PHASE 2, FDA & DRUG SPONSOR DISCUSS SCALE & SCOPE OF PHASE 3</i>	
STAGE 5	Phase 3 Trial	
STAGE 6	Review of IND	
STAGE 7	New Drug Application (NDA) to FDA	
STAGE 8	Application Review	FDA REVIEW
STAGE 9		
STAGE 10	Drug Labelling	
STAGE 11	Manufacturing Facility Inspection	
STAGE 12	FDA Approval	

Source: US Federal Drug Administration (FDA)

FDA Expedited Programs for Serious Conditions

The usual process to securing new drug approval is for clinical safety and efficacy to be clearly demonstrated and thoroughly documented in the above described stage-gated fashion. In some instances it is possible to pursue an expedited approval process where an unmet need in a serious medical condition can be demonstrate. The FDA has previously indicated that SPMS is such a condition and that a drug to treat SPMS could be assessed using one or more the Agency's expedited approval programs. Such programs include "Fast Track" and "Accelerated Approval".

Accelerated approvals

Fast Track

Under fast track provisions the FDA's review time of drugs that treat serious or life-threatening diseases and those that have the potential to meet an unmet medical need is materially reduced. Drug manufacturers and sponsors are able to submit clinical trial results relevant to an application as data becomes available rather than having to wait until all information is at hand. MIS416 appears to warrant Fast Track designation and current interactions between the Company and FDA should determine this issue before the end of 2016.

Accelerated Approval

Under accelerated approval provisions, drug approval can be obtained prior to the normal Phase 3 efficacy measures. In such circumstances surrogate or intermediate clinical endpoints are used to evaluate effectiveness. These can include clinical observations and/or patient reported outcomes that appear likely to predict the clinical benefit of a drug.

Surrogate endpoints

With accelerated approval, using surrogate or intermediate clinical endpoints, a drug company will still need to conduct subsequent studies to confirm efficacy of the drug as originally designed through further study. These are known as Phase 4 confirmatory trials.

MIS416 could be a candidate for accelerated approval if the current Phase 2B trial continues to demonstrate the safety of MIS416 and also demonstrates clear efficacy based on endpoint(s) accepted by the Agency as being predictive of clinical benefit.

Enhanced Formulation

MIS416 is administered as a small intravenous injection into the patient's bloodstream with clinical trial efficacy and safety results to date reflecting the effectiveness of this dosage method.

The Company is also considering the potential for an oral formulation of MIS416 as part of a longer-term patient care management program where oral dosing may be sufficient to maintain the benefits reported by patients during the initial six months of treatment.

Any such development toward safe and effective oral delivery of MIS416 would greatly enhance the value and marketability of the drug and help secure its position as the patient preferred standard for SPMS treatment if or when another drugs enter the SPMS market.

*Oral drug
administration for
MIS416 is being
investigated*

SWOT ANALYSIS

STRENGTHS

) The drug works	Previous open label clinical trials and compassionate use observations have shown the drug is effective at mitigating symptoms of SPMS
) Safety	Clinical trials to date have all demonstrated the safety of MIS416 usage
) High Big Pharma interest	Major pharmaceutical companies are closely observing Phase 2B progress and trial outcomes
) Secure IP	Long-dated multi-jurisdictional patents for MIS416 in place in key SPMS markets

WEAKNESSES

) Efficacy must be confirmed	The gold standard to demonstrate drug efficacies are double blinded placebo controlled randomised trials. MIS416 completes such a trial in early 2017
) Satisfaction of clinical endpoints may decide transaction multiples	Transaction multiples and bidding process may be pre-empted on early indication endpoints rather than definitive study results
) Delivery Method	MIS416 is currently administered intravenously. Long-term dosage can contribute to needle fatigue and localised tissue damage and scarring

OPPORTUNITIES

) Commercial optionality	Potential exists for value capitalisation from outright sale or licensing of MIS416
) Other uses for MIS416	Potential exists for MIS416 to be used in treatment and management of other diseases, including co-therapy in some cancers
) Compassionate Use	Compassionate use through each clinical Phase continues to provide early indicators for likely Phase 2B trial outcome
) Fast Track Approval	Potential exists for early fast track designation and subsequent accelerated approval due to seriousness of SPMS and complete absence of effective drugs.
) Oral Medication Delivery	IIL is examining potential for MIS416 to be delivered orally which could substantially 'future proof' the drug

THREATS

) FDA regulatory approval not received	US FDA regulatory approval is critical to the commercial future of MIS416
) Competitor drugs	Concurrent and future development of suitable SPMS drugs could displace potential market share

FUNDING & RISKS

As at March 31 2016, the Company had a cash balance of approximately A\$3.3 million. In coming months the Company has indicated it expects to receive an R&D cash rebate from the Australian government in the order of A\$1.5 million.

In addition to financing the current Phase 2B trial, the Company has recently announced three areas of additional expenditure. These include:

-) a project to make MIS416 ready for manufacturing on a commercial scale
-) accelerated interactions with the FDA to secure an open Investigational New Drug (IND) Application
-) preclinical studies in selected neuro-inflammatory disorders

All these expenditures, if leading to positive outcomes, could be expected to add considerable value when the Company is sold or the SPMS program is partnered.

Based on the current cash burn rate and capital required to complete its spending initiatives Gordon Capital estimates the Company will need to raise between A\$3 to A\$5 million before the end of the current calendar year.

A previous private placement to major shareholders and a small number of high net worth investors in September 2015 raised A\$4 million at 17cps (a 2cps premium to the then prevailing 20 day VWAP). The Company is confident its significant shareholders will support their additional capital program.

Company will need to raise between A\$3 to A\$5 million before the end of the current calendar year

PEER ANALYSIS

Market Opportunity

The major manufacturers of drugs for the earlier relapsing remitting form of MS include:



There are currently 13 FDA-approved disease modifying drugs for treatment of Relapsing Remitting MS:

Self-injected	Avonex Betaseron Copaxone	Extavia Glatopa	Plegridy Rebif
Oral	Aubagio	Gilenya	Tecfidera
Intravenous	Lemtrada	Novantrone	Tysabri

Source: Company Reports, National MS Society (USA)

No current RRMS drugs have been found suitable for treatment of SPMS

As at 2015, these drugs collectively generate around US\$20 billion in annual revenues. Of these RRMS drugs, none have been found to be suitable or effective for treating Secondary Progressive MS.

Early significant cash flow potential

However, there is significant interest from both these pharmaceutical companies with existing RRMS treatment drugs and from companies not currently in the MS treatment space who have nevertheless identified the valuable market opportunities presented by MIS416 in the treatment of SPMS and also in the drugs anti-inflammatory capabilities and ability to treat other diseases, including some cancers.

Deal Metrics

While relevant deal metrics are minimal there have been a small number of noteworthy transactions that provide a value pathway for Innate and the commercialisation potential for MIS416.

Receptos

In August 2015, American biotechnology company Celgene acquired San Diego-based drug company Receptos for US\$7.2 billion. NASDAQ listed Receptos had a drug candidate (Ozanimod) in Phase 3 clinical development for RRMS and ulcerative colitis. At the time of the acquisition Celgene said that if approved, Ozanimod could hit peak annual sales of as much as \$6 billion across the two indications. Following completion of the transaction, one of the founders of Receptos and that company's Chief Scientific Officer, Dr Robert Peach, joined the board of **Innate**.

Receptos founder Dr Robert Peach has joined Board of Innate

Servier

In December 2014, French specialty pharmaceutical company Servier Inc. paid an upfront payment of US\$47 million to GeNeuro SA (a small Swiss university spinout) with an experimental monoclonal antibody called GNBAC1) which earlier in 2014 had completed a small 10 patient open label trial in patients with progressive MS. In return for the payment, Servier obtained an option on ex-U.S. and Japanese rights that's tied to a US\$408 million package of milestones along with a chance to buy an equity stake in the biotech sometime in 2015 (which it subsequently exercised). Using the funds raised, GeNeuro recently announced plans for a Phase 2B 'proof of concept' trial in 260 patients with relapsing remitting MS.

It is important to note that Servier's license is for the non-US territory. In the MS market, approximately 75% of drug sales revenue exclude the US market and so the license is in effect for just 25% of the market.

Biogen

Global American-based biotechnology company Biogen Inc's RRMS drug Tecfidera, launched in the USA in 2013-14, generated sales of US\$3 billion within its first 12 months.

Prior to getting Tecfidera approved by the FDA, Biogen marketed the first of the new generation of RRMS drugs (Tysabri) in a 50/50 partnership with the Irish pharma company Elan. In February 2013, Biogen acquired 100% control of Tysabri after paying Elan US\$3.25 billion and also agreeing to pay Elan contingency payments of between 12 and 25% of global sales. At the time of this transaction the FDA had already issued a 'black box' warning concerning the safety of Tysabri.

Competitor Drug Treatments

Novantrone

According to the National Multiple Sclerosis Society (USA), Novantrone (Mitoxantrone) is currently the only drug approved by the US FDA to treat SPMS.

Mitoxantrone is a generic drug originally approved in December 1987 and developed as a treatment for cancer, this intravenous infused drug has been found to have significant deleterious side effects including greater susceptibility to various types of infections, an increased risk of secondary acute myelogenous leukaemia and elevated cardiotoxicity which limits recommended use of Novantrone to a maximum of 2-3 years and as a result it is rarely used in SPMS therapy.

Only currently approved SPMS drug is rarely used with significant side effects

RELATIVE VALUATION

In the absence of a specific recent comparable transaction and assuming successful completion of Phase 3 trials and receiving FDA approval we have made the following assumptions:

- J SPMS Estimated Market Size (2015): **US\$4.0B**
- J SPMS Estimated Market Size (2021) [Yr 3]: **US\$4.4B** (assumes 1.5%pa growth)

Market Share	LOW	HIGH
J IIL MIS416 [Year 3]:	20%	40%
J IIL MIS416 Potential Annual Revenue [Yr 3]:	US\$0.9B	US\$1.76B
(@0.7500 AUDUSD)	A\$1.2B	A\$2.35B

In January 2016, New York University Stern School of Business calculated that - based on financial reporting history - US Drug Companies (Biotech & Pharmaceutical) average EBITDA Operating margin to Sales was ~30%.

Using this multiple we can calculate a possible EBITDA (Year 3) for MIS416 of

- J **LOW** (20% market share): **A\$350 million**
- J **HIGH** (40% market share): **A\$700 million**

Based on historic whole of market transaction multiples of 3-4x EBITDA, Gordon Capital has calculated a theoretical enterprise value range for **Innate Immunotherapeutics** based on market share capture potential of MIS416 of:

LOW	HIGH
A\$1.22	A\$2.43

Gordon Capital enterprise value range for IIL from A\$1.22 to A\$2.43

Ground-breaking drug

OUTLOOK

Innate Immunotherapeutics' strategy is to sell the Company or licence its proprietary drug MIS416 to a Big Pharma immediately following completion of its current Phase 2B trial. The Board of Innate is confident the sustained efficacy from its 'Compassionate Use' program will provide interested Big Pharma with a high degree of confidence regarding the likely outcomes of the Phase 2B trial, ultimately leading to a competitive bidding process to acquire or licence their ground-breaking MIS416 therapeutic drug in the treatment of Secondary Progressive Multiple Sclerosis.

FINANCIALS

FIGURE 11. BALANCE SHEET

INNATE IMMUNOTHERAPEUTICS	1H 2016 Actual A\$'000	FY 2015 Actual A\$'000
Current Assets		
Cash and cash equivalents	2,771	4,089
Trade and other receivables	35	26
Other current assets	227	509
Total Current Assets	3,033	4,624
Non-Current assets		
Property, plant & equipment	150	160
Other non-current assets	-	-
Total Non-Current Assets	150	694
TOTAL ASSETS	3,184	5,319
Current Liabilities		
Trade and other payables	507	453
Provisions	-	-
Loans from related parties	-	-
Interest payable to related parties	-	-
Total Current Liabilities	507	453
Non-Current Liabilities		
Non-financial liability	-	-
Deferred tax liabilities	-	-
Total Non-Current Liabilities	-	-
TOTAL LIABILITIES	507	453
NET ASSETS	2,676	4,866
Equity		
Contributed equity	110,223	110,223
Foreign currency reserve	-1,881	-1,679
Options reserve	1,228	1,081
Accumulated losses	-106,895	-104,760
TOTAL EQUITY	2,676	4,866

Source: Innate Immunotherapeutics

DIRECTORS

Innate Immunotherapeutics has built a strong leadership team with deep industry experience:

Michael A Quinn

BSc, BEc, MBA
Chairman

CEO of Sydney based Innovation Capital. Currently or past director of ResMed (ASX, NYSE), QRxPhrama (ASX), & CAP-XX Limited (LSE).

Andrew Sneddon

BEcon, CA
Independent Director

Former partner of PWC where he led the life sciences practice. Currently Chairman of Elastagen Pty Ltd, MIRteq Pty Ltd, CustomWare Pty Ltd, InterAcct Solutions Pte, TGR BioSciences Pty Ltd and Traditional Therapy Clinics (ASX: TTC)

Elizabeth Hopkins

BSc (Hons) Pharmacology
Independent Director

20 years of experience in successfully commercialising science outcomes. Ten years with Pfizer's European headquarters, including the last two years as Global Project Manager. Currently deputy chair, Christchurch Polytechnic Institute of Technology (CPIT).

Christopher Collins

B.S, MBA
Director

30 years of experience in business management. Collins has helped acquire, manage and make profitable 17 companies representing various industries. Collins was elected to the US House of Representatives in 2012. Collins holds 19% of IIL.

Robert Peach

PhD
Independent Director

Co-founder and CSO Receptos (acquired by Celgene in Aug '15 for US\$7.2b). 30 years of multidisciplinary research expertise in biochemistry and cell biology within the disease areas of immunology, inflammation, and oncology.

Simon Wilkinson

Director & Chief Executive Officer

CEO since 2004. 25 years' experience in finance, banking and business management. He began his civilian career in retail banking after serving as an officer in the Royal New Zealand Navy.

CAPITAL STRUCTURE

As at April 30 2016, **Innate Immunotherapeutics Limited** has **196,442,177** fully paid ordinary shares quoted on the ASX. In addition there are:

Options	20,540,889
Loyalty Rights	33,031,926 (expire December 2016)

The Board of IIL hold a combined total of 35,411,689 shares or 18% of issued capital.

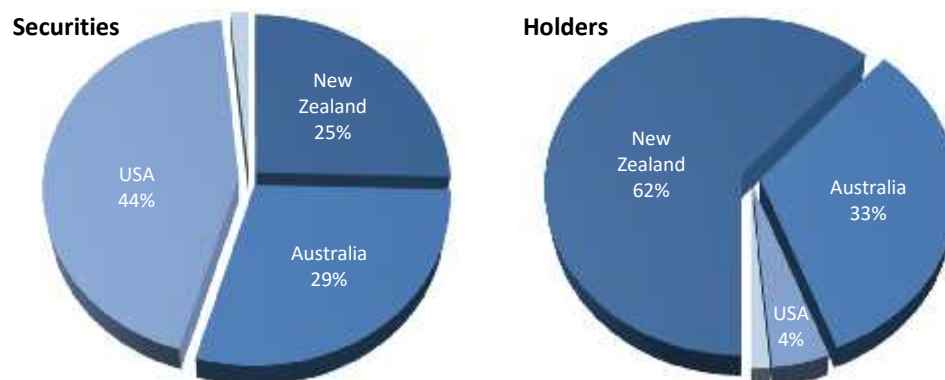
Twenty Largest Ordinary Shareholders	Number of Ordinary Shares Held	Issued Shares %
Christopher Collins	33,899,139	17.26
National Nominees Limited	19,353,904	9.85
Caitlin Collins	5,200,000	2.65
Cameron Collins	5,200,000	2.65
Picton Cove Pty Ltd	4,163,361	2.12
Watkins Family A/C	3,777,500	1.92
Probe International Inc	3,692,689	1.88
Fast Forward LLC	3,500,000	1.78
Ross Arthurs	3,447,371	1.75
Chep li LLC	3,125,319	1.59
Glenn Arthurs	3,035,289	1.55
Mr Neil Ross Brown	2,798,192	1.42
Thomas Massung	2,620,415	1.33
Moore Family Nominee Pty Ltd	2,500,000	1.27
Cubrc Inc	2,080,566	1.21
Citicorp Nominees Pty Limited	1,797,160	0.91
The McMillan Super Fund	1,480,892	0.75
Wiltshire Family A/C	1,361,999	0.69
Thomas McMahon + Ann McMahon	1,221,490	0.62
Richard Taylor	1,200,000	0.61
Top 20	105,455,286	53.81
Balance	90,986,891	46.19
Total Issued Capital	196,442,177	100.00

Source: Innate Immunotherapeutics

Significant Shareholders	
Collins Family	22.5%
Australian Ethical (National Nominees Limited)	9.8%
Probe International Inc	2.6%
Picton Cove Pty Ltd	2.1%
National MS Society (USA) (Fast Forward, LLC)	1.8%

Source: Innate Immunotherapeutics

FIGURE 12. **SHAREHOLDER GEOGRAPHY**



Source: Innate Immunotherapeutics

RECENT EVENTS

03 May 16	Video of Corporate Presentation
18 Apr 16	Investment Presentation
15 Apr 16	Trial Recruitment Complete - Interview with CEO
13 Apr 16	Clinical Trial Fully Enrolled and Strong Interest
30 Nov 15	Half Yearly Report and Accounts
30 Oct 15	Results of Meeting - General Meeting to approve Placement
25 Sep 15	Notice of General Meeting/Proxy Form - Placement
25 Sep 15	Compassionate Use Program Update
21 Sep 15	Placement to Raise Additional Working Capital
17 Sep 15	Trading Halt
02 Sep 15	Dr. Robert Peach Appointed as a Non-Executive Director
28 Aug 15	Results of Meeting - AGM
28 Aug 15	Chairman's Address to Shareholders - AGM
24 Jul 15	Notice of Annual General Meeting/Proxy Form
20 Jul 15	2015 Bioshares Investment Summit Presentation
17 Jul 15	Annual Report to shareholders
19 Jun 15	Full Year Statutory Accounts - Year Ended 31 March 2015
28 May 15	Preliminary Final Report - Year Ended 31 March 2015
20 May 15	Compassionate Use Program Update
04 May 15	Innate Joins MS Outcome Assessment Consortium
09 Apr 15	Presentation 10th Neurotech Investing & Partnering Conference

LINKS & REFERENCES

Clinical Trial - MIS416

<http://www.mstranslate.com.au/treatments/clinical-trials-studies/mis416/>

Disease-modifying therapies for Multiple Sclerosis

<http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Brochure-The-MS-Disease-Modifying-Medications.pdf>

Experimental SPMS Drug From Innate Therapeutics Shows Success in Early Trials

<http://multiplesclerosisnewstoday.com/2015/02/13/experimental-spms-drug-from-innate-immunotherapeutics-shows-success-in-early-trials/>

Immunotherapeutics Limited

<http://www.innateimmuno.com>

MSAA Research Update 2015

http://mymsaa.org/PDFs/MSAA_Research_Update_2015.pdf

Manage MS Relapses

<http://www.rethinkmsrelapses.com/Resources>

MSOAC | Critical Path Institute

<http://c-path.org/programs/msoac/>

Multiple Sclerosis International Federation

<http://www.msif.org/>

National Multiple Sclerosis Society (USA)

<http://www.nationalmssociety.org>

NOVANTRONE® - mitoXANTRONE for injection concentrate

http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/019297s030s031lbl.pdf

Operating and Net Margins (US Companies) - NYU Stern School of Business

http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/margin.html

Safety and Efficacy Study of MIS416 to Treat Secondary Progressive Multiple Sclerosis

<https://clinicaltrials.gov/ct2/show/NCT02228213?term=MIS416&rank=1>

Safety Study of an Immunomodulating Microparticle to Treat Progressive Multiple Sclerosis

<https://clinicaltrials.gov/ct2/show/NCT01191996?term=MIS416&rank=2>

GLOSSARY

Axons – take information from the nerve cell to other nerve cells or a muscle

Biologics - genetically-engineered proteins derived from human genes and designed to inhibit specific components of the immune system that play pivotal roles in fueling inflammation

Central nervous system (CNS) – The part of the nervous system that includes the brain and spinal cord

Dendrites – connect to muscles and organs and bring information

Epidemiology - the study of the causes, patterns and effects of health and disease conditions in defined populations

FDA – Food & Drug Administration (United States)

Immune system – A collection of cells, tissues and molecules that act as the body's defense against disease producing agents (pathogens) such as viruses and bacteria

Magnetic resonance imaging (MRI) – A diagnostic procedure that produces visual images of different body parts without the use of X-rays.

Multiple Sclerosis - disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. Symptoms range from numbness and tingling to blindness and paralysis

Myeloid Cells (Myelin) – sheath that surrounds and protects nerve fibres in the body

Patient-Reported Outcome (PRO) - collation of questionnaire responses directly from patients participating in a clinical trial

Placebo – An inactive, non-drug compound that is designed to look just like a test drug and administered to control group subjects in double-blind clinical trials

Relapsing Remitting Multiple Sclerosis (RRMS) - MS characterised by attacks of worsening neurologic function (relapses) followed by partial or complete recovery periods (remissions), during which no disease progression occurs. Relapsing-Remitting MS may develop into secondary-progressive MS

Secondary Progressive Multiple Sclerosis (SPMS) - MS characterised by slowly worsening neurologic function with no distinct relapses or remissions

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