JOSEPH GUNNAR & CO., LLC

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Initiating Coverage

Healthcare

Immuron Limited (IMRN - $6.07 - Buy)

Emerging Biologics in Fatty-Liver and Infectious Disease Management

Key Points

Technology Platform. Immuron's platform technology is based on producing antigen targeted, hyper-immune bovine colostrum powder (BCP) suitable for pharmaceutical use.

Product Pipeline – NASH. IMM-124E because of its mechanism of action (MOA), multifactorial pathway type of treatment and safety profile, has a chance to become one of the major therapeutics used in combination with other drugs. IMM-124E is currently in Phase 2 clinical trial in the US, Australia and Israel for the treatment of nonalcoholic steatohepatitis (NASH).

Market Opportunity – NASH. NASH is a disease of the liver caused by chronic inflammation and a buildup of fat in the liver, and is a manifestation of NAFLD (nonalcoholic fatty-liver disease). Estimates place NASH prevalence at approximately 24 million people in the US, or approximately 7% of the population, with similar prevalence in other major developed markets.

Business Model - IMM124. Immuron has a strategy in place for the IMM-124E and would like to partner the drug. Immuron expects to have the results of MOA study they are doing in NASH with Dr. Arun Sanyal at Duke University from August through October. The Company will likely target a worldwide development and commercialization partnership.

Product Pipeline - *C. difficile* infection (CDI). IMM-529 which was developed in collaboration with C. *difficile* researcher Dr. Dena Lyras and her team at Monash University, targets the virulent Toxin B, the spores and the vegetative cells. The Company initiated Phase 1/2 clinical trial in Israel in the second quarter of 2017.

Market Opportunity – C. difficile infection (CDI). Clostridium *difficile,* or C. *difficile,* is a gram-positive, toxin-producing, spore-forming bacterium that generally causes severe and persistent diarrhea in infected individuals.. It is a common cause of hospital acquired infection in the United States with an estimated 450,000 acute infections per year. CDI is responsible for the death of approximately 29,000 Americans each year.

Business Model. The IMM-529E. is a simple value proposition. It neutralizes the disease but does not touch the rest of the microbiome.

Management Team. Immuron management and development team has experience in designing and developing therapeutics, building a stable manufacturing supply chain and bringing products to the market.

Summary

Our 12-month price target is based on a forecast enterprise value of USD 50 million, or $15 per share, uses 130 million shares (3.3 million ADS) outstanding at the end of fiscal 2017. The discounted cash flow analysis for the company's two lead clinical assets for fat liver disease and CDI utilizes a 15% discount rate and a 3% terminal growth rate.

Immuron is well positioned to address unmet medical needs in large opportunity markets. The company has two clinical assets, four phase II clinical trials in process. Licensing deals and M&A provide valuation support.

Rating, Price and Target	
Symbol	IMRN
Rating	Buy
Price	$6.07
Price Target	$15.00

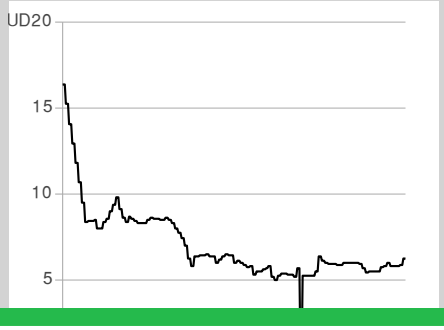
Market Data	
Market Cap (M)	$19.50
Shares Outstanding (M)	3.30
Average Daily Volume (000s)	10.00
Net Cash/Debt ($M)	$4.00
Dividend Yield	0.0%

FYE Jun	2017A	2018E	2019E
EPS	(6.40)	(3.60)	(3.70)
Revenue (M) (AUD)	1.4	1.3	0.5

Semi-Anually EPS	H1	H2
2017A	-	-
2018E	(1.90)	(1.70)
2019E	-	-

Semi-Anually Revenue (M)	H1	H2
2017A	-	-
2018E	0.8	0.5
2019E	-	-

Volume and Closing Price for IMRN



Overview

Immuron is a clinical-stage biopharmaceutical company with a platform focused on the development and commercialization of a novel class of immunomodulator polyclonal antibodies, which are blood proteins that are produced by the immune system that can be specifically targeted to change the activity of the immune system.

Immuron's oral polyclonal antibodies offer targeted delivery within the gastrointestinal (GI) track but do not cross into the bloodstream. The Company's two lead immunomodulatory product candidates, IMM-124E and IMM-529, could improve on the existing treatment paradigms for NASH (Non Alcoholic Steatohepatitis) and for Clostridium difficile (C. difficile), respectively.

The safety profile of Immuron's compounds, which has a Generally Regarded as Safe (GRAS) FDA designation, enables the Company to commercialize the platform-derived products through a range of regulatory pathways, including prescription (Rx), medical foods, over-the-counter (OTC) medicines and dietary supplements.

The Company also markets an OTC product, Travelan, as a preventative to Traveler's Diarrhea.

As of June 30, 2017 and June 30, 2016, Immuron's accumulated deficit was AUD$50 million and AUD$43 million, respectively

Investment Highlights

Immuron's lead assets target two prevalent diseases with major unmet need: NASH and C. *difficile.*

Technology Platform. Immuron's platform technology is based on producing antigen targeted, hyper-immune bovine colostrum powder (BCP) suitable for pharmaceutical use. Cows, prior to calving, are immunized with vaccines to ensure immunogenicity and after calving, the first milk is harvested and polyclonal antibodies are collected. This process ensures that the colostrum contains a high concentration of antibodies and high concentrations of Immunoglobulin G1.

The underlying nature of Immuron's platform technology enables the development of medicines across a large range of diseases, including infectious diseases and immune mediated disorders. The dairy origins of Immuron's antibodies classifies the technology is safe (GRAS by FDA) and enables the Company to commercialize the platform through most regulatory pathways, including prescription (Rx), medical foods, over-the-counter medicines, and dietary supplements.

Product Pipeline – NASH. The mechanism of action for IMM-124E is unique and acts on multiple pathways to reduce inflammation in the liver by targeting the gut innate immune system to upregulate regulatory T cell (Treg) populations and by neutralizing intestinal bacterial-Lipopolysaccharide (LPS), thereby decreasing the translocation of these toxins into the liver, and thus reducing pro-inflammatory burden in the gut and in the liver. IMM-124E because of its mechanism of action, multifactorial pathway type of treatment and because of its safety profile, has a chance to become one of the major therapeutics used in combination with other drugs.

Clinical Status of IMM-124E. IMM-124E is currently in Phase 2 clinical trial in the United States, Australia and Israel for the treatment of nonalcoholic steatohepatitis (NASH). In addition to NASH, IMM-124E is also in two NIH-sponsored Phase 2 clinical trials for the treatment of ASH, in collaboration with Dr. Arun Sanyal at the University of Virginia, and in Pediatric NASH, in collaboration with Dr. Miriam Vos at Emory University.

Market Opportunity – NASH. NASH is a disease of the liver caused by chronic inflammation and a buildup of fat in the liver, and is a manifestation of NAFLD (nonalcoholic fatty-liver disease). The presentation of NASH resembles alcoholic liver disease but occurs in people who drink little or no alcohol. Current estimates place NASH prevalence at approximately 24 million people in the United States, or approximately 7 percent of the population, with similar prevalence in other major developed markets. There are currently no approved therapies for the treatment of NASH, making this disease one of the largest unmet medical needs in the world today, and a key therapeutic area (TA) targeted by large pharmas.

Market Opportunity Pediatric NASH. Pediatric NASH is also a large opportunity with an estimated 2 to 3 percent of the kids afflicted with NASH. There is nothing in the market that is FDA approved. Because IMM-124E is considered safe, it is the ideal therapy for this demographic. This candidate drug has no side effect profile and stays within the gut. It clears the intestinal bacterial-Lipopolysaccharide (LPS) and the Company

is hopeful that it can impact the disease. The FDA has indicated that it would like to extend the 3 month study and add more patients. Immuron currently has 7 patients enrolled.

Market Opportunity – ASH. IMM-124E has the ideal safety profile for ASH patients. The target patient population is very sick. The efficacy of IMM-124E in ASH is unknown. Currently this opportunity is a black box for Immuron.

Business Model - IMM124. Immuron has a strategy in place for the IMM-124E and would like to partner the drug. The Company has not had any formal business discussions, as they are waiting for the right time. Immuron expects to have the results of the mechanism of action study they are doing in NASH with Dr. Arun Sanyal at Duke University from August through October. This salvo of data could be a significant catalyst in discussions with partners. The Company will likely target a worldwide development and commercialization partnership.

Product Pipeline - C. difficile infection (CDI). IMM-529 which was developed in collaboration with C. *difficile* researcher Dr. Dena Lyras and her team at Monash University, targets the virulent Toxin B, the spores and the vegetative cells. It is a three pronged approach that is unique and which has yielded exceptional results in the pre-clinical studies including prevention of primary disease; treatment of primary disease and suppression of recurrence. The Company believes that to date, it is the only investigational drug that has showed therapeutic benefits in all three phases of the disease.

Clinical Status of IMM-529. Immuron successfully completed the pre-clinical program in January 2016 and are currently preparing clinical supplies to support Phase 1/2 clinical trials, which will enroll as many as 60 patients. The Company initiated Phase 1/2 clinical trial in Israel in the second quarter of 2017. As the clinical trial will be conducted outside of the United States, specifically, in Israel, the Company is not required to apply for an IND.

Market Opportunity – C. difficile infection (CDI). Clostridium *difficile,* or C. *difficile,* is a gram-positive, toxin-producing, spore-forming bacterium that generally causes severe and persistent diarrhea in infected individuals. It can also lead to more severe outcomes, including death. C. *difficile* infection (CDI) is most often associated with the prior use of antibiotics. The U.S. Centers for Disease Control (CDC) has identified CDI as an antibiotic-resistant bacterial threat in the United States. It is a common cause of hospital acquired infection in the United States and has overtaken methicillin-resistant Staphylococcus aureus in prevalence with an estimated 450,000 acute infections per year, and nearly 100,000 cases of first recurrences. CDI is responsible for the death of approximately 29,000 Americans each year.

Business Model. The IMM-529E is a simple value proposition. It neutralizes the disease but does not touch the rest of the microbiome. Immuron is providing the market with what it needs – to eradicate C diff. IMM-529E binds to the toxin B, binds to the spores, binds to the cells – to clear those out of the body. Microbiome stays intact and has a chance to fight C diff on its own which it does naturally. It is the Holy Grail.

Immuron has partnered with Dr. Dena Lyra, one of the leading experts in C. diff. The Company is currently conducting Phase 1 and 2 trails with 60 patients at Hadassah University in Israel.

Strategy is to get as much data as possible and go to the FDA and do a pivotal study, The Company believes that if the data they are going to get is as good as what they have seen in pre-clinical studies, IMM-529 could become the standard of care.

Immuron will likely retain IMM-529 for the treatment of C diff infection. CDI is an orphan disease and there is a lot of value in keeping this asset. From the Company's perspective, C diff treatment platform alone could validate the whole company.

OTC Asset – Travelan. Travelan is the only product currently on the market designated by TGA and Health Canada for the prevention of Traveler's Diarrhea (TD). Travelan uses hyperimmune BCP from cows vaccinated against various strains of ETEC to protect against TD and to reduce the risk of TD, along with the symptoms of minor gastrointestinal disorders. Sales in fiscal year2016 were AUD$1.0M. Travelan is now marketed in four countries: Australia, U.S.A, China and Canada.

Other Development Programs. In addition to the IMM-124E and IMM-529 programs, Immuron also has two research collaborations ongoing with the U.S. Department of Defense including one with the U.S. Army and a second collaboration with the U.S. Navy, for the study of shigella, campylobacter and Enterotoxigenic Escherichia coli (ETEC) vaccines. Except for clinical supplies, these collaborations involves little R&D investment from Immuron, but has the potential for meaningful upside.

Management Team. Immuron management and development team has experience in designing and developing therapeutics, building a stable manufacturing supply chain and bringing products to the market (in partnerships or organically), gained across both large pharmas (e.g., Pfizer) and emerging biotechnology companies. The Advisory Board has experts in their field including Dr. Arun Sanyal in NASH and Professor Dena Lyras in C. *difficile.*

Market Protection. In the United States, for premarket approval purposes, the FDA regulates Immuron products as biologics under the FDC Act and related regulations. The Company believes that any of their product candidates approved under a Biologics License Application (BLA) should qualify for a 12-year period of exclusivity against biosimilar competition currently permitted by the Biologics Price Competition and Innovation Act (BPCIA).

Platform with a long runway. IMM-124E and IMM-529 are the first two drug candidate salvos. Immuron is currently collaborating with the U.S. Department of Defense for the research of Shigella, Campylobacter and ETEC vaccines.

Shigella kills a million people a year. It is not just a military applications of those studies. Immuron could have a vaccine for those diseases that kill a lot of people completely paid for by the U.S. Army or Department of Defense. The Company could get ready for commercial launch over the next few years at near zero cost to investors.

Summary. In sum, the Company is developing a potent anti-infective anti-inflammatory platform. In terms of the platform, Immuron can create anti bodies against any components of a bacteria even a virus. The Company believes that can create anti bodies against any targets, test them and have them ready for clinical studies in less than a year.

Valuation

Our 12-month price target is based on a forecast enterprise value of USD 50 million, or $15 per share, using 130 million shares (3.3 million ADS) outstanding at the end of fiscal 2017. The discounted cash flow analysis for the company's two lead clinical assets for fat liver disease and CDI utilizes a 15% discount rate and a 3% terminal growth rate.

Immuron is well positioned to address unmet medical need in large opportunity markets. The company has two clinical assets, four phase II clinical trials in process. Licensing deals and M&A provide valuation support.

Risks

Operating Losses. Immuron has incurred losses in every period since they began operations in 1994 and reported net losses of AUD $6.8 million, $5.6 million, AUD $2.7 million and AUD $2.5 million during the fiscal years ended June 30, 2017, 2016, 2015 and 2014, respectively. For the six-month periods ended December 31, 2016 and 2015, the reported net losses were AUD $3.4 million and AUD $3.1 million, respectively. As of June 30, 2017 and June 30, 2016, accumulated deficit was AUD $49.5 million and AUD $42.8 million, respectively.

Commercializing Company owned IP. Ability to generate significant revenue from prescription products and achieve profitability depends on the ability to, alone or with strategic collaboration partners, successfully complete the development of and obtain the regulatory approvals for prescription product candidates. The Company is actively pursuing potential partner collaboration.

Development Stage Company. Immuron is a development stage company with pharmaceutical products designed to treat a range of anti-inflammatory and anti-infectives. Other than Travelan product, the Company has not sufficiently advanced the development of any of the products, including current lead product candidate, IMM-124E, to market or generate revenues from their commercial application.

Uncertainties Related to Research and Clinical Trials. The Company's research programs are based on scientific hypotheses and experimental approaches that may not lead to desired results. In addition, the timeframe for obtaining proof of principle and other results may be considerably longer than originally anticipated. In order to obtain approvals to market a new drug product, Immuron or potential partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, they will have to conduct extensive preclinical testing and clinical trials. Clinical trials may not demonstrate statistically sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates employing the technology.

Reliance on third parties to conduct trials. Immuron does not have the ability to conduct all aspects of preclinical testing or clinical trials. The Company is dependent on third parties to conduct the clinical trials for IMM-124E and IMM-529, and preclinical studies for other product candidates, and therefore the timing of the initiation and completion of these trials and studies may occur at times substantially different from expectations.

The Company also relies on research institutions to conduct our clinical trials. Reliance upon research institutions, including public and private hospitals and clinics, provides the Company with less control over the timing and cost of clinical trials.

Access to Intellectual Property Rights. The product candidates may require specific formulations to work effectively and efficiently and rights to such formulations may be held by others. Immuron may be unable to acquire or in-license third-party intellectual property rights on terms that are acceptable.

Development of current or future pharmaceutical products. Immuron cannot predict if or when the development of IMM-124E, IMM-529 or any future pharmaceutical product will be completed or commercialized. The Company may not be able to progress with the development of current or any future pharmaceutical product candidates to a stage that will attract a collaborative partner.

Acceptance in the medical community. Even if Immuron obtains approval for a product candidate, they may not generate or sustain revenue from sales of the product if the product cannot be sold at a competitive cost or if it fails to achieve market acceptance in the medical community.

Competition. There are multiple companies working in the field of fatty-liver diseases and C. *difficile* therapeutics, including Intercept, Gilead, Genfit, Tobira, Galmed are all developing therapeutics for fatty-liver diseases and Seres, Synthetic Biotechnology and Assembly Biotechnology for C. *difficile.*

Limitations to Commercial Profile. Treatment with product candidates may produce undesirable side effects or adverse reactions or events. If any such adverse events occur, the clinical trials could be suspended or discontinued.

Reliance on Sole Manufacturer. The lead compound, IMM-124E, is manufactured by Synlait based in New Zealand. This manufacturer enables large scale manufacture of colostrum to provide drug substance for the current and prospective trials in fatty-liver and c. *difficile* patients. Immuron also relies on a sole manufacturer Catalent Australia, to encapsulate all of our marketed and investigational drug products.

Limits on Reimbursement. Immuron's ability to commercially exploit the products successfully will depend in part on the extent to which reimbursement for the cost of products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations.

Orphan Drug Exclusivity. Of Immuron current product candidates, the only one designed for treatment of an indication that would likely qualify for rare disease status is IMM-529 for the treatment of recurrent C. *difficile.*

An orphan drug designation entitles the product to a period of marketing exclusivity. The applicable period is seven years in the United States and ten years in the European Union. Orphan drug exclusivity may be lost if the FDA or European Medicines Agency (EMA) determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

For additional risk considerations, please refer to the company's SEC filings.

Financial Results

Operating revenues increased in the fiscal year 2017 in comparison to fiscal year 2016. Overall growth can be attributed to the maturing U.S. sales channel. Revenues are primarily from the flagship product Travelan which are sold in the U.S. through customers such as PassportHealth and Medique. The Company does not have any formal agreements with PassportHealth for the sale of Travelan. There was also an increase in sales in the Canada market. Immuron also opened new distribution channels into the Chinese market.

The Company also initiated programs to reengage the Australian customer and expects revenues from Travelan product to increase in this market.

Figure 1. Immuron Limited – Overview of Business

	For the Year ended June 30,		
	2015 AUD$	**2016 AUD$**	**2017 AUD$**
Statement of Operations:			
Total Operating Revenue	$ 1,002,380	$ 1,001,077	$ 1,396,197
Total Gross Profit Less Direct Selling Costs	493,079	430,894	515,523
Total operating expenses	(4,775,920)	(9,038,676)	(8,934,050)
Loss Before Income Tax	(2,691,820)	(5,599,004)	(6,804,154)
Balance Sheet Data:			
Total assets	$ 6,018,412	$ 8,827,484	$ 8,286,491
Total current liabilities	1,207,810	3,886,921	1,711,565
Total liabilities	1,207,810	3,886,921	1,711,565
Total stockholders' equity	4,810,602	4,940,563	6,574,926

Sources; Company reports and Joseph Gunnar

R&D expenditure increase was predominantly due to the increased expenditures of Phase 2 NASH clinical trial as the program recruitment accelerated and more patients entered the trial.

Immuron's strong mature relationships with its key manufacturing partners for the Company's flagship consumer product Travelan, has enabled the Company to improve gross profit percentage to 76 percent in fiscal 2017 from 70 percent in fiscal 2016. These strong manufacturing partnerships have given rise to greater efficiencies in the manufacturing processes which not only resulted in the improvement in Gross Profit ratio but also an overall increase in Gross Profit.

Sales and Marketing Costs increased in fiscal year 2017 compared fiscal year 2016 due to increased marketing activities in oversea markets. Freight Costs, despite the increased number of sales, remained constant due to more established logistical channels for shipping Travelan from Australia to the overseas countries.

Consulting, Employee and Director expense decreased in fiscal 2017 when compared to fiscal 2016 as the company issued options to directors during fiscal 2016 resulting in a higher expense. Director fees and staff salaries have remained constant.

Corporate Administration expenses were flat in fiscal 2017 as compared to fiscal 2016 despite the general increase in the size of the business. The cost of services required to initiate the NASDAQ listing including legal, accounting and audit costs were not present during the 2017 fiscal year.

Finance Costs incurred by Immuron in fiscal 2017 are attributable to the finance costs associated with the SBI Investment Fund Convertible Loan Facility which the Company executed in February 2016. This facility provided Immuron with the short to medium-term cash flow requirements it needed to ensure the Company's momentum surrounding its pipeline research programs was not diminished.

Impairment of inventory incurred in fiscal 2017 related to the writing down of Colostrum from inventory balance as it reached expiry date.

Marketing and Promotion expenses increased in fiscal 2017 as compared to fiscal 2016 as the Company increased its promotional efforts of its existing flagship consumer product Travelan. The increase was associated with the product's launch in the US and China consumer markets. The higher Marketing and Promotional costs incurred during the fiscal 2017 in comparison to the fiscal 2016, can also be attributed to increase in investor relations and public relations profiles ahead of the NASDAQ listing.

Research and Development expense increased in fiscal 2017 from fiscal 2016 primarily due to the increase in the Phase 2 NASH clinical trial, together with the advancement of its other early pipeline products.

During fiscal year 2017, Immuron brought the management of its Phase 2 NASH clinical trial program in-house, removing the need for some of the external outsourced management while also providing Immuron with greater control over the program.

The ramp of the trial from development to patient recruitment and testing, caused an expected increase in the overall research and development expenditures.

Additional costs were incurred through the establishment of additional clinical trial sites to lift the clinical trial recruitment rates.

Travel and Entertainment expense decreased for fiscal 2017 from fiscal 2016, as the Company's management reduced its frequency of travel with more time spent on projects to be delivered locally.

Total comprehensive loss for fiscal 2017 was AUD$6.8 million as compared to a loss of AUD$5.6 million for fiscal 2016.

Figure 2. Immuron Limited – Balance Sheet Summary

	Consolidated Statement of Financial Position As at		
	30 Jun 2015 AUD$	**30 Jun 2016 AUD$**	**30 Jun 2017 AUD$**
Assets			
Cash and cash equivalents	$3,116,074	$2,290,639	$3,994,924
Trade and other receivables	1,691,629	4,387,772	1,768,237
Total current assets	5,998,898	8,809,421	8,267,654
Property, pland and equipment	19,514	18,063	18,837
Total Assets	$6,018,412	$8,827,484	$8,286,491
Total current liabilities	1,207,810	3,886,921	1,711,565
Total liabilities	1,207,810	3,886,921	1,711,565
Total stockholders' equity	$4,810,602	$4,940,563	$6,574,926

Sources: Company Reports and Joseph Gunnar estimates

Liquidity and Capital Resources

Immuron has incurred cumulative losses and negative cash flows from operations since the Company's inception in 1994, and as of June 30, 2017 the Company had accumulated losses of AUD$49.5 million.

As of June 30, 2017, Immuron had cash and cash equivalents of AUD$3.99 million. The Company also reported a total of AUD$1.7 million in receivables.

Figure 3. Immuron Limited – Cash Flow Results

	Consolidated Statement of Cash Flows For the Year Ended 30 June			
	2014 AUD$	**2015 AUD$**	**2017 AUD$**	**2017 AUD$**
Net Cash Flows Used In Operating Activities	(2,650,577)	(3,020,933)	(5,158,336)	(7,031,088)
Net Cash Flows Used In Investing Activities	(15,901)	(3,168)	(2,441)	(5,696)
Net Cash Flows Provided By Financing Activities	7,361,555	(1,614)	4,335,342	8,701,052
Cash and Cash Equivalents at the End of the Year	$ 6,141,789	$ 3,116,074	$ 2,290,639	$ 3,994,924

Sources: Company Reports and Joseph Gunnar

Operating activities. For the twelve months ended June 30, 2017 and 2016, net cash used in operating activities increased to AUD$7.03 million from AUD$5.16 million respectively. The use of net cash in all periods resulted from ordinary business operations.

Cash flows from operating activities for the year ended 2017 and 2016 also included inflows of AUD$1.62 million and AUD$1.47 million, respectively in relation to refunds received through the Australian Federal Government's Research and Development Income Tax Incentive program for eligible expenditure.

Investing activities. Net cash used in investing activities in fiscal 2017 and 2016 was AUD$5.69 million and AUD$2.44 million, which is primarily related to purchases of office equipment.

Financing activities. For the twelve months ended June 30, 2017, net cash provided by financing activities was AUD$8.7 million, which comprised of proceeds from issue of securities and exercise of options of AUD$12.52 million, and other borrowings of AUD$0.5 million less repayments of AUD$2.19 million related to these borrowings.

Primary Target Markets

Immuron's lead assets target prevalent diseases with major unmet need: NASH and C. *difficile.*

Non-alcoholic fatty liver disease (NAFLD), defined as accumulation of excess fat in the liver, is the commonest cause of liver disease in Western countries. In the United States it is estimated to affect between 3% and 40% of individuals (Williams CD, et al. Gastroenterology 2011) and is predicted to become the leading cause of liver transplantation over the next 10 years (Wong RJ, et al. Gastroenterology, 2015).

Weight loss, as part of lifestyle change, is the only recommended intervention, with a loss of >7% total body weight associated with clearance of histological non-alcoholic steatohepatitis (NASH) and a >10% loss associated with an improvement in fibrosis. However, even within trial settings where motivation is usually high, less than 20% achieve >7% weight loss, and so alternative treatments need to be found (Villar-Gomez E, et al. Gastroenterology 2015).

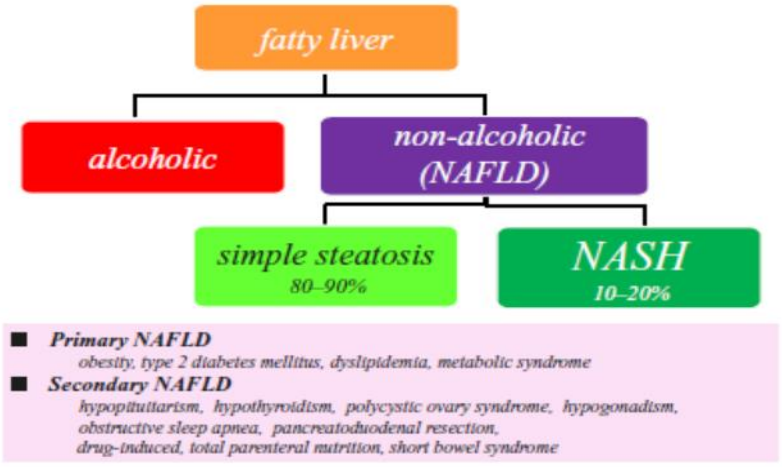
There remains uncertainty as to which patients with NASH need to be treated; cardiovascular and liver-related mortality and morbidity is directly related to fibrosis stage, and so patients with evidence of progressive fibrosis should be identified and prioritized (Ekstedt M, et al. Hepatology 2015).

Indeed, cardiovascular disease is the leading cause of death in NAFLD (Angulo P, et al. Gastroenterology 2015) and so emerging pharmacotherapy should ideally aim to reduce both liver-related and cardiovascular mortality.

Characteristics and diagnosis of NAFLD/NASH

Changes in diet and lifestyle have resulted in a dramatic increase in the prevalence of obesity and metabolic syndrome in Western countries and many Asian countries. This has resulted in a significant increase in the incidence of non-alcoholic fatty liver disease (NAFLD), which is considered to be a hepatic manifestation of metabolic syndrome. NAFLD has become an important public health issue because of its high prevalence. NAFLD consists of two clinical entities: simple steatosis and non-alcoholic steatohepatitis (NASH). Currently, NAFLD is the most common cause of chronic liver disease in these countries.

Figure 4. Classification of Fatty Disorders of Liver



Sources:Chalasani Nu, et al. Hepatology 2012

Nomenclature of NAFLD/NASH

NAFLD is characterized by excessive accumulation of fat, or steatosis, in the liver in individuals with a history of a little or no alcohol consumption. While simple steatosis accounts for 80–90% cases of NAFLD, NASH accounts for the remaining 10–20%. Simple steatosis is mostly a benign non-progressive clinical entity, while NASH can progress to cirrhosis or even hepatocellular carcinoma (HCC). NASH is histologically characterized by hepatic steatosis associated with evidence of liver cell injury and inflammation, steatohepatitis, and varying degrees of fibrosis; these histological features are indistinguishable from those of alcoholic hepatitis. NASH has emerged as a distinct clinicopathological entity (Sanyal AJ, American Gastroenterological Association AGA technical review 2002) and even now, a liver biopsy still remains the gold standard for making a definitive diagnosis.

Traditionally, fatty disorders of the liver have been classified as alcoholic or non-alcoholic. Primary NAFLD/NASH is associated with obesity, diabetes, or dyslipidemia, and the so-called insulin resistance or metabolic syndrome. Secondary NAFLD/NASH is rare and may be associated with many conditions including polycystic ovary syndrome, endocrine diseases and sleep apnea.

Clostridium difficile is responsible for nearly 500,000 infections and resulted in approximately 29,000 deaths in 2011 (Lessa FC, et al. N Engl J Med 2015). A review of the US National Hospital Discharge Surveys reveals an increasing incidence, nearly doubling from 4.5/1000 discharges in 2001 to 8.2/1000 discharges in 2010 (Reveles KR, et al. Am J Infect Control 2014). *C. difficile* infection (CDI) is a leading cause of hospital-acquired infection with an estimated economic burden exceeding $1.5 billion in the United States for 2009 (Zimlichman E, et al. JAMA Intern Med 2013). Further, rates of outpatient diagnoses are increasing.

Pathogenesis

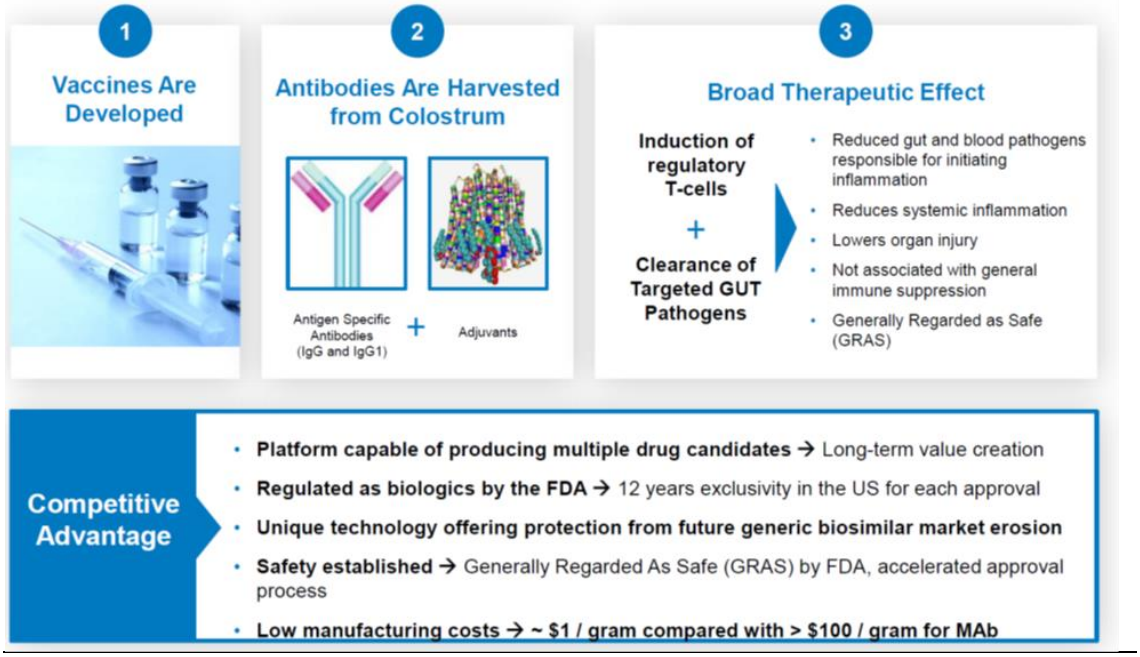
C. difficile is an anaerobic, spore forming, gram- positive organism that is transmitted via the fecal–oral route. The environmentally resistant spores are ingested and activated by bile acids in the small intestine (Song JA, et al. J Bacteriol 2008). Once activated, the bacterium adheres to colonic mucosa. Virulence is mitigated by the production of toxins A and B. These toxins result in a profound inflammatory response, alterations in cellular tight junctions, and apoptosis leading to the clinical symptoms of diarrhea. Animal models reveal that toxin B may be the more potent of the two toxins, with toxin A inducing a more localized effect (Carter GP, et al. MBio 2015).

The underlying host colonic microbiome plays an important role in the pathogenesis of CDI. The association between antibiotic administration and subsequent development of CDI has long been recognized, particularly with clindamycin, cephalosporins, and fluoroquinolones (Leffler DA, et al. N Engl J Med 2015). Alterations in host microbiome from antimicrobial agents may set the stage for *C. difficile* colonization. An increased understanding of the complex underlying pathophysiology of CDI has led to various novel therapeutic modalities.

Platform Technology

Immuron's platform technology is based on producing antigen targeted, hyper-immune bovine colostrum powder (BCP) suitable for pharmaceutical use. Polyclonal antibodies are collected from the first milking of a cow after calving. Prior to calving, cows are immunized with proprietary vaccines to ensure maximum immunogenicity and after calving, the first milk is harvested and purified. This proprietary process ensures that the colostrum contains a high concentration of antibodies and high concentrations of Immunoglobulin G1. The technology is safe (classified as GRAS by the FDA), low cost, and can be applied to a variety of diseases.

Figure 5. Oral Immunoglobulins: Scalable Technology



Sources: Company Reports and Joseph Gunnar

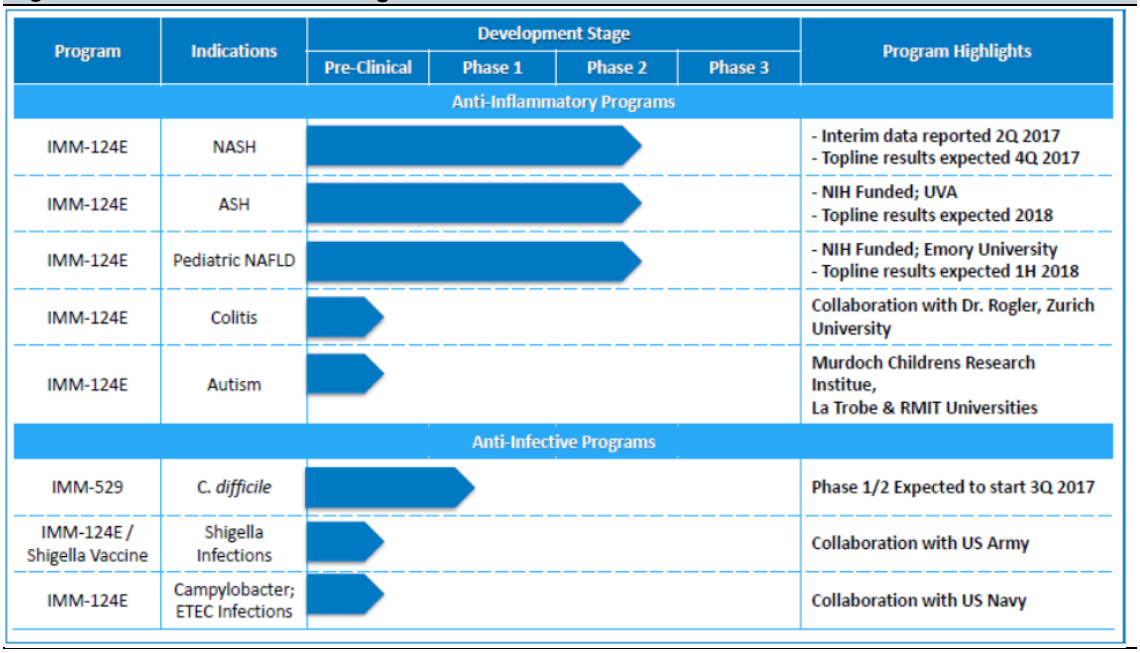
The underlying nature of Immuron's platform technology enables the development of medicines across a large range of diseases, including infectious diseases and immune mediated disorders. The platform can be used to influence the cell-mediated immune system through regulatory T cell populations, or it can directly block viruses or bacteria at mucosal surfaces (such as the GI tract) and neutralize the toxins they produce. Additionally, the dairy origins of Immuron's antibodies enables the Company to commercialize the platform through most regulatory pathways, including prescription (Rx), medical foods, over-the-counter medicines, and dietary supplements. The GRAS status of technology platform allows Immuron to advance the preclinical programs into clinical trials faster relative to other companies due to the platform's proven safety profile.

Pipeline

IMM-124E is currently in an ongoing Phase 2 clinical study for the treatment of NASH. Over 100 patients have been recruited to date out of a target of120. The mechanism of action for IMM-124E is unique and acts on multiple pathways to significantly reduce inflammation in the liver by targeting the gut innate immune system to upregulate regulatory T cell (Treg) populations and by neutralizing intestinal bacterial-LPS, thereby decreasing the translocation of these toxins into the liver, and thus reducing pro-inflammatory burden in the gut and in the liver.

In addition to NASH, IMM-124E is also in two NIH-sponsored Phase 2 clinical trials for the treatment of ASH**,** in collaboration with Dr. Aron Sanyal at the University of Virginia, and in Pediatric NASH**,** in collaboration with Dr. Miriam Vos at Emory University.

Figure 6. Immuron's Clinical Programs



Program	Indications	Development Stage				Program Highlights
		Pre-Clinical	Phase 1	Phase 2	Phase 3	
Anti-Inflammatory Programs						
IMM-124E	NASH					- Interim data reported 2Q 2017 - Topline results expected 4Q 2017
IMM-124E	ASH					- NIH Funded; UVA - Topline results expected 2018
IMM-124E	Pediatric NAFLD					- NIH Funded; Emory University - Topline results expected 1H 2018
IMM-124E	Colitis					Collaboration with Dr. Rogler, Zurich University
IMM-124E	Autism					Murdoch Childrens Research Institue, La Trobe & RMIT Universities
Anti-Infective Programs						
IMM-529	C. *difficile*					Phase 1/2 Expected to start 3Q 2017
IMM-124E / Shigella Vaccine	Shigella Infections					Collaboration with US Army
IMM-124E	Campylobacter; ETEC Infections					Collaboration with US Navy

Sources: Company Reports and Joseph Gunnar

IMM-529 has successfully completed its pre-clinical program in **CDI** and the company has begun Phase 1/2 trials in Israel in the second quarter of 2017. IMM-529 which was developed in collaboration with C. *difficile* researcher Dr. Dena Lyras and her team at Monash University, targets the virulent Toxin B, the spores and the vegetative cells. It is a three pronged approach that is unique and which has yielded positive results in the pre-clinical studies including Prevention of primary disease, Treatment of primary disease and Suppression of recurrence.

In addition to these programs, Immuron also has research collaborations with the U.S. Department of Defense including with the U.S. Navy and with the U.S. Army, for the study of shigella, campylobacter and Enterotoxigenic Escherichia coli (ETEC) vaccines**.** ETEC is a type of E-coli and is one of the leading bacterial causes of diarrhea in the developing world, as well as the most common cause of travelers' diarrhea.

Immuron also started a pre-clinical program in IBD**,** in collaboration with IBD KOL, Professor Gerhard Rogler, MD, PhD. and the University of Zurich, Switzerland.

Marketed Asset

Travelan: Travelan is a product currently on the market designated by TGA and Health Canada for the prevention of Traveler's Diarrhea (TD). Travelan uses hyperimmune BCP from cows vaccinated against various strains of ETEC to protect against TD and to reduce the risk of TD, along with the symptoms of minor gastrointestinal disorders. Two independent, double-blinded, placebo-controlled clinical trials in Europe in 90 healthy volunteers showed protection of up to 90% against infection with the type of E. coli that causes TD, along with indicating a significant reduction in abdominal cramps and stomach pain. There were no reported side effects in the clinical trials. Importantly, because Travelan is not an antibiotic, it does not have the side-effect profile of antibiotics and also does not contribute to the worldwide concerns about bacterial drug resistance. Sales in fiscal year 2017 were AUD$1.4 million. Travelan is now marketed in four countries: Australia, U.S.A, China and Canada.

Strategy

Immuron's goal is to become a key biopharmaceutical company developing and commercializing therapeutics to address increased unmet medical needs in inflammation-mediated diseases and anti-infectious diseases. This includes advancing the two lead oral polyclonal antibodies, IMM-124E and IMM-529.

Elements of the strategy include leveraging the technology platform and collaborations to expand the differentiated polyclonal-based product pipeline across multiple indications including ASH, Pediatric NASH and various novel anti-infective programs with the DoD (U.S. Army and U.S. Navy).

The company plans to partner the fatty-liver programs at the right time and with the right commercial/ development partner(s) for NASH, ASH and pediatric NASH.

Immuron expects to continue investing in and growing Travelan Worldwide including in the U.S., Australia, Canada and China, and in new markets.

Further investing in mechanism of action studies expands understanding of the unique MOA across targeted diseases and conditions, and potentially identify new opportunities for investment.

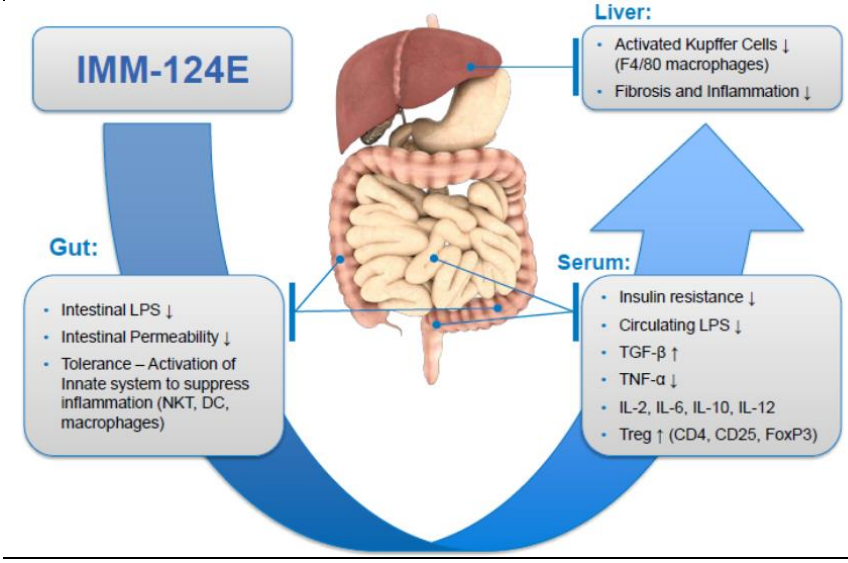
Immuron continues to protect and leverage its intellectual property portfolio and patents. The company has 13 issued patents and 23 pending patent applications worldwide. Immuron has been issued patents in the U.S., Australia, Canada, India, Japan and New Zealand.

The company continued to make progress on IMM-124E and reported top line results of a phase 1/2a clinical trial (N=10). The thirty day treatment endpoint was met and no safety issues were reported.

IMM-124E – Value Proposition

Multi-Factorial I Broad Anti-Inflammatory Upstream Effect – Consensus medical opinion is that NASH is a multi-factorial disease, and that targeting only one or two pathways is likely to only have a marginal effect on the disease. IMM- 124E offers hope for long-lasting effects because of its broad upstream anti-inflammatory effects which induces the release of regulatory T-cells and anti-inflammatory cytokines while decreasing levels of pro-inflammatory cytokines.

Figure 7. IMM-124E Attractive Profile for Use in Combination Therapy



Sources: Company Reports and Joseph Gunnar

Attractive Profile for Chronic Use - Because of its tolerable safety profile, which is derived from a GRAS (Generally Regarded as Safe) platform, data could support the use of IMM-124E as a chronic / long-term treatment, providing a unique advantage over other NASH therapies as some have already shown side effect profile (e.g., increased cholesterol).

Potential for Use as Backbone Agent for both Early and Severe Disease - While other more toxic agents in development are likely to be confined to severe populations, we believe that IMM-124E could be used in NASH patients, including for those with mild fibrosis and potentially in NAFLD patients as well, to reduce their elevated inflammation state.

Potential for Use in Combination Therapy - Because of its delivery method and GRAS profile, it is likely that IMM-124E can not only be used as monotherapy, but also in combination with other NASH agents, if these are approved, and if physicians feel that this is warranted for their patients.

Figure 8. IMM-124E in NASH (Non-Alcoholic Fatty Liver)

- **Targeted antibodies mediate broad anti-inflammatory mechanism of action**
  - Upstream Effect: **LPS-TLR4 pathway**
  - Downstream: **Anti-inflammatory through both innate and adaptive immune systems** (e.g., the induction of regulatory T-cells to control and inhibit excess inflammation)
- Strong **anti-fibrotic effect** demonstrated with CCl4 model
- **Unique competitive profile due to safety/MOA:**
  - Addresses **multi-factorial** nature of NASH
  - Potential for **combination use**
  - Safety profile supporting of **long-term chronic use**
  - Potential to **expand to mild/moderate** populations
- **Market exclusivity** (biologics; High barriers to generic biosimilar entry)

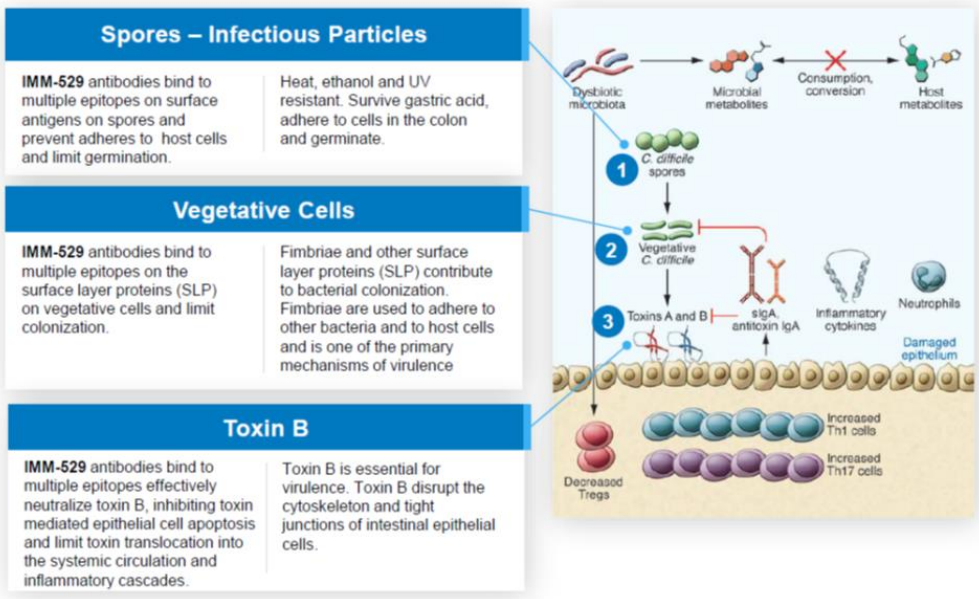
Sources: Company Reports and Joseph Gunnar

Immuron also commenced in 3Q17 phase 1/2, randomized, double blind, placebo-controlled clinical study of IMM-529 for the treatment of CDI. Topline results expected from phase 1/2 study in CDI in 2018.

IMM-529 – Value Proposition

Triple Mechanism of Action - IMM-529 not only targets the Toxin B, but it also contains antibodies to the spores and the vegetative cells.

Figure 9. IMM-529E Targets Primary Disease and Recurrence



Sources: Company Reports and Joseph Gunnar

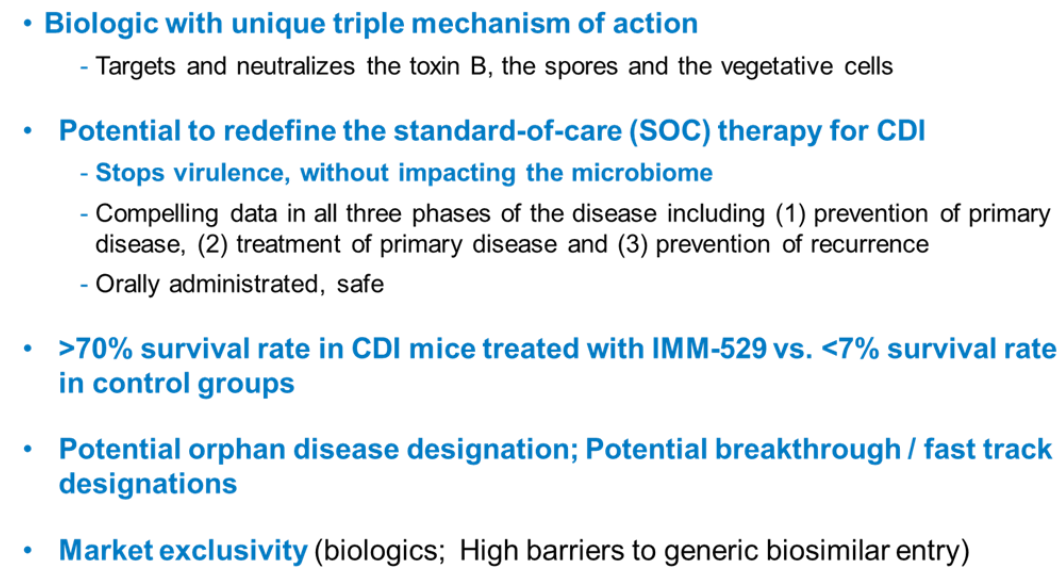
Effective vs Virulent Strains - IMM-529 has been shown to be effective vs both the normal strains as well as the virulent strains of CDI, providing a strong Proof-of-Concept (POC) model that IMM-529 can be a front line agent in the battle against difficult to treat strains.

Effective in All phases of the Disease - IMM-529 has shown that it can be an effective agent in all phases of the disease including prevention of infection, treatment of primary disease and recurrence. This represents a much larger potential use than current drug development programs which primarily target recurrence.

Oral Therapy - IMM-529 is an oral therapy lessening costs on the healthcare system overall.

Not an Antibiotic - IMM-529 is not an antibiotic, and hence is only targeted at C. difficile, Toxin B, spores and vegetative cells. It therefore does not negatively impact the rest of the flora and allows the flora to return to normal, while fighting the primary infection / recurrence.

Figure 10. IMM-529E Clostridium *difficile* Infection (CDI)



Sources: Company Reports and Joseph Gunnar

Elements of overall strategy include leveraging the technology platform and collaborations to **expand** the differentiated polyclonal-based product pipeline across multiple indications including ASH, Pediatric NASH and various novel anti-infective programs with the DoD (U.S. Army and U.S. Navy).

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Operational Highlights

Fatty Liver Product Portfolio

Programs in Clinical Development - NASH, ASH and Pediatric NAFLD
The lead Principle Investigator for the Immuron non-alcoholic steatohepatitis (NASH) clinical study, Dr. Arun Sanyal, is the former President of AASLD (American Association for the Study of Liver Diseases) and current Chair of the Liver Study Section at the National Institute of Health (NIH).

NASH is a severe form of non-alcoholic fatty liver disease (NAFLD). It is estimated to affect about 16 million people annually in the United States. The lead Principal Investigator for the Immuron non-alcoholic steatohepatitis (NASH) clinical study is Dr. Arun Sanyal, the current Chair of the Liver Study Section at the National Institute of Health (NIH).

The study achieved its recruitment goal of at least 120 patients this year and successfully enrolled 133 patients with biopsy proven NASH. The primary endpoint is changes in liver fat content confirmed by MRI and secondary endpoints being changes in ALT (liver enzymes). The top-line results for the study are expected to be reported by Q4 2017.

Health authorities estimate pediatric NAFLD affects five- to ten- percent of the US pediatric population. Immuron's Phase I/II clinical trial with Emory University is targeted at addressing this opportunity.

The lead Principal Investigator for Immuron Pediatric NAFLD study is Dr. Miriam Vos of Emory University. Immuron NIH funded Phase II double blind, placebo control, randomized clinical study of IMM-124E enrolled the first patient into the study in February this year and has so far randomized over 10 percent of the targeted 40 patients into the study. The primary endpoint is changes in ALT (liver enzymes) following 3 months of treatment with top-line results expected in Q4 2018.

Dr. Arun Sanyal is also the lead Principal Investigator of the Immuron alcoholic steatohepatitis (ASH) clinical study which is also funded by the NIH. Over half of the targeted 66 patients have been randomized into the study. The primary endpoint is changes in ALT (liver enzymes) with top-line results are expected in Q1 2019.

Figure 11. Immuron Limited – Operational Milestones

- Fatty liver trials are on track and top-line results expected Q4 2017 for NASH, Q4 2018 for Pediatric NAFLD and Q1 2019 for ASH
- NASDAQ Listing raises US$6 million
- NASH Phase II Study achieves major milestones and receives new US stimulus
- Paediatric NAFALD Phase II trial recruits first patient
- Clostridium *difficile* infection trial clinical drug manufactured, ethics and regulatory approvals and site initiated
- Travelan marketing strategy drives sales growth
- US Department of Defence Research Collaboration expands
- IMM-124E progresses to next study phase in acute colitis model

Sources: Company Reports and Joseph Gunnar

Milestones - NASH Clinical Trial

Immuron reported the results of the planned interim analysis in July this year. The primary objective of the interim analysis was to evaluate the safety of IMM-124E. The interim analysis was conducted by an Independent Committee and was not powered for efficacy due to the limited sample size.

The report submitted to Immuron by the Committee confirmed that there were no safety concerns or adverse events for both treatment groups. The efficacy signals on liver enzymes (ALT and AST), which demonstrated a dose related reduction in both treatment doses at 24 weeks, was not statistically different than placebo.

Immuron also made progress on IMM-124E research in NASH with two new studies at Duke University and Sanyal Biotechnology. The studies could augment the evidence of IMM-124E's unique mechanism of action (MOA) and expected effect on NASH. The studies will attempt to generate comparable results in the two leading NASH mouse models which mimic the full clinical spectrum of human NASH, from simple steatosis to substantial fibrosis and cirrhosis.

The studies are ongoing and are expected to be completed by Q4 2017.

Clostridium Difficile Infection (CDI) Trial Drug Completes Manufacturing Phase

Immuron is pursuing the biopharmaceutical research and development for an effective and safe non-antibiotic treatment of CDI. This indication is estimated to account for more than 450,000 patients and over 29,000 deaths per year in the United States.

The IMM-529 drug product for the study has been manufactured and is a first-in class oral immunotherapeutic targeting the treatment of Clostridium difficile infection. IMM-529 has been shown in pre-clinical tests to be an effective treatment in all phases of the disease and success in this trial could support the continued clinical development of the IMM-529 drug product.

The Company received approval from the Israeli Ministry of Health (MoH) and the Hadassah Medical Center Ethics Committee in August of this year to perform Immuron's IMM-529 clinical study. The first of 60 patients is scheduled to be randomized by end of September 2017. The Phase I/II randomized, double-blind, placebo-control clinical study is designed to evaluate the safety and preliminary efficacy of Immuron's IMM-529 drug product for the treatment of CDI.

The primary objective of the study is to assess IMM-529's patient safety and tolerability, while secondary endpoints will evaluate the preliminary efficacy of the product evaluated by duration and severity of symptoms, and the rate of recurrence. Top-line results are anticipated in the fourth quarter of 2018.

Competition

Immuron competitors, are numerous and include, major pharmaceutical companies such as Gilead; biotechnology firms such as Intercept with its product obeticholic acid, Genfit with its product Elafibrinor, Tobira with its product Cenicriviroc, Seres with its product SER-109 and Synthetic Biologics with its product ribaxamase; universities and other research institutions. Many of the competitors have more financial resources and experience in pre-clinical testing and human clinical trials of new or improved drugs, as well as in obtaining FDA, EMA, TGA and other regulatory approvals.

Manufacturing Process

Effective June 28, 2013, Immuron entered into a Development and Supply Agreement with Synlait Milk, a New Zealand company which specializes in the processing of infant formula and special milk powders with expertise in on-farm manipulation of milk (including colostrum), processing technologies, product development and marketing.

The lead compound, IMM-124E, is obtained from Synlait. Immuron’s active ingredient is manufactured under full cGMP conditions in an Australian TGA-licensed facility. Many of the active ingredients are the same as those of normal cow's milk. However, the main differentiation between milk and Immuron’s active ingredient constituents is the presence of antibodies in the order of 35-45% by weight of dry colostrum powder. The main classes of immunoglobulins found in the active ingredient are IgG with smaller amounts of IgM and IgA. The major class of immunoglobulin found in bovine colostrum is IgG1 making up between 65% and 90% of total immunoglobulins, in contrast to milk which comprises predominantly IgA.

The Development Agreement expires on July 21, 2018 unless extended or earlier terminated by the parties.in accordance with the Development Agreement.

Nonalcoholic Fatty Liver Disease: Overview of Therapies

NAFLD parallels the obesity epidemic within the United States and is the most common hepatic disease in the western hemisphere (Peery, *et al*. Gastroenterology 2012)). By 2030, non-alcoholic steatohepatitis (NASH) is predicted to become the most common reason for liver transplantation in the US (Zezos, *et al*. World J Gastrol 2014)). With an explosion of novel therapies for hepatitis C virus and a relative paucity of treatment options for the spectrum of fatty liver disease, much attention has turned toward development of NASH disease modifying agents.

History

First introduced in 1980, NAFLD is a relatively new concept (Ludwig, *et al*. Mayo Clinic Proc 1980). It is divided into non-alcoholic fatty liver (NAFL) and non- alcoholic steatohepatitis (NASH) based on histologic findings. NAFL has largely been considered benign, but recent cohort studies show a high risk for progression to NASH in up to 44% on serial biopsies at 5 years (McPherson, *et al*. J Hepatol 2015). NASH causes progressive fibrosis that can lead to cirrhosis and hepatocellular cancer (HCC).

Patients with NAFL can be divided into primary (traditional obesity, insulin resistance and metabolic syndrome) and secondary causes (Wilson’s disease, parenteral nutrition, medications), with primary causes being far more common (Angelo, *et a*l. N Engl Med 2002)). Patients with NASH may take a few years or decades to develop cirrhosis, and many die of alternative causes before progressing. Rate of progression

do not correlate with body mass index (BMI) or hyperlipidemia (Powell, *et al*. Hepatology 1990). Instead, risk factors for more aggressive disease include the presence of diabetes, Hispanic ethnicity, and microvesicular steatosis on biopsy (Ong, *et a*l. Clin Liv Dis 2007). Left alone, NASH results in progressive fibrosis and is an under-recognized cause of cryptogenic cirrhosis (Adler, *et a*l. Am J Med 1979). Cirrhosis of any kind is a risk factor for HCC, and cirrhosis from NASH is no exception. Following the trend of obesity and metabolic syndrome, HCC is the fastest growing cancer type in the US (Bugianesi, *et al*. Gastroenterology 2002).

Epidemiology

NAFLD is associated with visceral obesity and diabetes. It has mirrored the epidemiologic course of obesity in the US and is detected in 73–90% of obese individuals on biopsy (Quereshi, *et al*. Clin Obes 2016). About one--third of the US population are estimated to have NAFL. By most estimates, NASH comprises about 15% of all NAFLD and 3–5% of the American population. Hospitalizations for NAFLD have increased by 97% since the year (Vernon, *et al*. Aliment Pharmocol 2011).

Pathophysiology

The pathophysiology of NAFLD is complex and includes numerous genetic, dietary, metabolic and hormonal factors. Although most experts theorize a two-hit model to explain the progression from NAFL to NASH, new insight suggests a multiple hit hypothesis (Tilg, *et al*. Hepatology 2010) The first hit refers to insulin resistance, resulting in increased fat accumulation within the hepatocyte (steatosis). With the background of increased liver fat, hepatocytes are vulnerable to multiple pathophysiologic processes resulting in lipid oxidation, including impaired hepatocyte apoptosis and cytokine activity (Day, et al. Gastroenterology 1998).

A genetic basis for the first hit has been proposed, citing abnormalities in lipid transporters and hormonal regulators, like leptin and adiponectin, in certain populations (Fabrini, *et al*. Hepatology 2010). Dietary carbohydrate intake, insulin resistance, metabolic syndrome, and certain medications all inhibit the reduction of reactive oxygen species (ROS) and represent potential hits in a susceptible individual (Rolo,*et al.* Free Radic Med 2012).

Insulin resistance predicts fibrosis independent of ethnicity, but although the prevalence of diabetes is highest among African Americans, the burden of NASH most disproportionately affects the Hispanic population. This line of evidence suggests that insulin resistance is not the only variable involved (Sheth, *et al*. Ann Intern Med 1997). Identification of various factors conferring increased risk of the development of NASH has offered potential targets for treatment.

Diagnosis

The diagnosis of NAFLD has three requirements: demonstration of hepatic steatosis by imaging or biopsy; exclusion of significant alcohol consumption, >30 g/day for men and >20 g/day for women within the past years; exclusion of other causes of hepatic steatosis (Lindon, *et al.* Dig Dis Sci 2012).

In most patients undergoing evaluation, radiologic and laboratory findings are sufficient to make the diagnosis of NAFLD; however, liver biopsy is the gold standard for diagnosis of NASH.

NAFLD activity score (NAS)

The NAS is a validated scoring system used to grade disease severity in patients with NAFLD (source 31). The NAS is the sum of the biopsy's individual scores for steatosis (0 to 3), lobular inflammation (0 to 3), hepatocellular ballooning (0 to 2), and fibrosis (0 to 4). An NAS of 1 or 2 corresponds to NAFL, 3 or 4 corresponds to borderline NASH, and >5 corresponds to NASH.

Figure 12. NAS Scoring System

Steatosis	**S score**
<5%	0
5-33%	1
34-66%	2
>66%	3
Lobular inflammation	**L score**
None	0
<2 foci/200 x	1
2-4 foci/200 x	2
>4 foci/200 x	3
Hepatocyte balloning	**B score**
None	0
Few balloned cells	1
Many balloned cells	2
NAS components: Grade= Total score:S+L+B. Range, 0-8	

Sources: Kleiner, *et al*.Hepatology 2005

Clinical trials/new pharmaceuticals

With few efficacious pharmacologic treatments for NAFLD and NASH, attention has turned to the development of agents with novel mechanisms of action. Targets of these pharmacologic treatments include improving lipid metabolism and insulin sensitivity in hepatocytes, decreasing hepatocyte death by inhibiting apoptosis, and decreasing inflammatory responses to injury. Most trials use the primary endpoint of improvement in liver histology but secondary endpoints, including improvement in transaminases, inflammatory markers and markers of fibrosis, are of interest as well.

Figure 13. Summary of Preclinical Agents

Drug	Mechanism of action	Primary end point	Results
Elafibranor (GFT505)	Dual peroxisome proliferator acivated receptor (PPAR) = play role in hepatocyte fatty acid metabolism, modulating inflammatory responses	NASH reversal without worsening of fibrosis	Post-hoc analysis using a more stringtent response criteria demonstrated a response rate of 19% versus 12% when compared to a placebo (p=0.045)
Obeticholic acid (OCA)	Potent activator of farnesoid X receptor and promotes insulin sensitivity and decreased hepatic gluconeogenesis and circulating triglycerides	Improvemnet in NASH score by >2 points without worsening of fibrosis - evaluated by post-treatment biopsy	Improvement in NASH score by >2 points occurred in 45% of patients taking OCA vs. 21% in the placebo group
Emricasan	Irreversible pan-caspase inhibitor avid in hepatocytes preventing apoptosis of steatotic hepatocytes, resulting in decrease fibrotic properties	Phase 2 clinical trial - evaluate the effect of emricasan subjects with NAFLD and elevated ALT	Mean absolute reduction in ALT from baseline at 28 days - 25.8 vs. 9.4 (p=<0.05)
Aramchol	Novel synthetic lipid molecule that acts on inhibition of the stearoyl-coenzyme A desaturase 1 activity, thereby decreasing the synthesis and increases the beta-oxidation of fatty acid	Difference in liver fat content, measured by magnetic resonance spectroscopy	High-dose aramchol demonstrated a significant reduction of 12.57% vs. 6.39% increase in placebo group (p=0.02)
Cenicriviroc	Antagonist of CCR2/CCR5, which are implicated in liver inflammation and fibrosis, resulting in anti-fibrotic properties	Drop in NAS >2 with no concurrent worsening of fibrosis stage	To be determined
GR-MD-02	Complex carbohydrate that binds to galectin-3 protein, resulting in anti-fibrotic properties	Not yet released	Not yet released

Sources: Ratziu, *et al*.Gastroenterology 2016

Elafibranor

Elafibranor (GFT505) is a novel dual peroxisome proliferator- activated receptor (PPAR) alpha/delta agonist, similar to the thiazolidinediones, which are PPAR gamma agonists. They play a major role in fatty acid transport, beta-oxidation, modulating gluconeogenesis and inflammatory responses (Chinetti, *et al.* J Clin Invest 2006)

In murine models, treatment with elafibranor resulted in improvement in liver dysfunction markers, decreased hepatic lipid accumulation and inhibited pro-inflammatory and pro-fibrotic gene expression. Mice also exhibited a decrease in the progression.

In a published Phase III randomized controlled trial, Ratziu *et al* (Perez, *et al.* J Lipid Res 2012) compared elafibranor (80 mg and 120 mg) to a placebo administered over 1 year in patients with non- cirrhotic NASH. The primary endpoint of resolution of NASH without worsening of fibrosis on post-treatment biopsy was not significant compared to the placebo.

Obeticholic acid (OCA)

OCA is a synthetic variant of the natural bile acid chenodeoxycholic acid, and is a potent activator of the farnesoid X nuclear receptor. It promotes insulin sensitivity and decreases hepatic gluconeogenesis and circulating triglycerides. Mudaliar *et al* (Gastroenterology 2012) demonstrated that administration of OCA in patients with diabetes and NAFLD increased insulin sensitivity and reduced steatosis and lobular inflammation after only 6 weeks of therapy.

OCA is in Phase III trials and could likely be the first next-generation drug approved for NASH. It is also under study for the treatment of primary biliary cirrhosis and has been shown to improve liver associated enzymes in that case population (Mosotii, *et al.* Gastroenterology 2012).

Emricasan

Emricasan is an irreversible pan-caspase inhibitor that is orally active and retained in the liver (Veno, *et al.* J Pharmacol 2007). Caspases play an important role in apoptosis and it has been demonstrated that steatotic hepatocytes undergo apoptosis (Angelo, *et al.* Gastroenterology 2003). Preclinical models showed that treatment with emricasan in mice with high-fat diets resulted in decreases in AST/ALT levels, NAS histological score and inflammatory markers.

Further trials with histologic endpoints are warranted, particularly using emricasan as adjunctive therapy to metabolically active agents in patients with NASH and fibrosis.

Aramchol

Aramchol is a novel synthetic lipid molecule obtained by conjugating cholic acid and arachidic acid that has been shown reduce hepatic fat content in animals with a high- fat diet.

Safadi *et al*. (Clin Gastro 2014) performed a randomized, double-blinded, placebo- controlled clinical trial of patients with biopsy-proven NAFLD, examining change in liver fat content with low (100 mg) or high (300 mg) dose aramchol administered over 12 weeks. A dose response relationship was observed with the higher dose aramchol arm; specifically, a significant decrease was found in liver fat content, as evaluated by MRS (p = 0.02). No other secondary endpoints in this study were statistically significant. Trials with a longer duration of treatment may be needed to clarify potential effects of this agent.

Cenicriviroc (CVC)

CVC is a novel, oral antagonist of the dual C-C chemokine receptor types 2 and 5 (CCR2/CCR5). CCR2/CCR5 are implicated in liver inflammation and fibrosis, and are thought to aid in the treatment of NASH by decreasing recruitment, migration and infiltration of pro-inflammatory monocytes to the site of liver injury induced by activated Kupffer cells, mainly via antagonism and resulting in anti-fibrotic properties (Miura, *et al*. Am J Physiol 2012).

Phase I human data showed improvement in serological tests indicative of liver fibrosis and improvement in liver stiffness on FibroScan, with a favorable safety profile (Harrison, *et al*. Hepatology 2014).

Targeting the gut microbiome

Immuron IMM-124e is an IgG-rich extract of bovine colostrum from cows immunized against lipopolysaccharide (LPS), and is believed to reduce exposure of the liver to gut-derived bacterial products and LPS (Adar, *et al*. Clin Exp Immunol 2012). In Phase I studies and pre-clinical data, IMM-124 was found to improve liver enzymes, insulin resistance (OGTT and HgbA1c), and dyslipidaemia (LDL) (Mizrahi, *et a*l. J Inflamm Res 2012). A Phase II RDBPCT is currently evaluating the effects of 24 weeks of IMM-124e in patients with biopsy-proven NASH (NCT02316717).

Figure 14. Drugs with Proven Benefit in NAFLD

Class	Drug	Latest phase in development in NAFLD	Pre-clinical data	Clinical data
Incretin based therapy	Liraglutide	Proof of concept phase IIb trial completed	Improved steatosis, ALT, and insulin sensitivity	Histology: NASH resolution Nonhistological: weight loss, improved diabetic control
	Exenatide	Proof of concept phase IIb trial completed in patients with NASH and diabetes	Improved steatosis	Results from phase IIb trial not published
	Sitagliptin	Phase IIa trial in NAFLD completed. Approved for use in type 2 diabetes	Improved steatosis and insulin sensitivity	Histology: improved hepatocyte ballooning and reduction in NAS scores
SGLT-2 inhibitor	Canagliflozin; Iprogliflozin; Luseogliflozin	Rodent studies completed	Improved steatosis and fibrosis	Nonhistological: weight loss and improved ALT
PPAR agonists	Pioglitazone	Phase IIb trial completed. Aproved for use in type 2 diabetes	Improved inflammation and fibrosis	Histology: improved hepatic steatosis, inflammation, ballooning and fibrosis
	Elafibranor	Phase IIb trial in NASH completed	Improved steatosis and fibrosis	Histology: NASH resolution in those with NAS>4
	Saroglitazar	Phase IIa trial in NASH and diabetes completed	Reduced steatosis, NASH and fibrosis	Nonhistological: improved ALT
	MSDC-0602	Phase IIb	Reduced transaminases	Nonhistological: improved HBA1c
FXR-bile acid axis	Obeticholic acid	Phase IIb trial in NAFLD completed in US	Improved steatosis	Histology: Improved NAS scores
	GS-9674	Phase IIa recruiting	Reduce hepatic steatosis and fibrosis in NASH	-
	INT-767	Phase I trial anticipated		-
	Volixibat	Phase IIa trial in NASH recruiting	Improved NAFLD scores in mice	-
	Sevelamer	Animal studies only	Reduced steatosis	-
Hormone signalling	BMS-986036	Phase IIa trial evaluating MRS in NASH	Improved insulin sensitivity	-
	NGM-282	Phase IIa trial in NASH recruiting	Reduction of hepatic fat	-
De novo lipogenesis	Aramchol	Phase IIa complete	Reduced de novo lipogenesis	Nonhistological: redcution in liver fat content
	NDI-010796	Phase I trial completed	Increased fatty acid oxidation	Nonhistological: reduced de novo lipogenesis in adults
	MGL-3196	Phase 1 completed	Reduced hepatic steatosis	Redcution in LDL cholesterol
Antioxidant	Vitamin E	Phase IIb trials completed	Reduced steatohepatitis and fibrosis	Histology: reduced steatosis and improved NAS scores
	Cysteamine	Phase IIb trial in children with NAFLD completed		Results of proof of concept phase IIb trial not published
Targeting apoptosis	Emricasan	Phase IIb in NASH and NASH cirhosis recruiting	Improved NAS scored and fibrosis	Nonhistological: reduced ALT and markers of apoptosis
	Selonsertib	Phase IIb trial in NASH and fibrosis and cirrhosis	Reduced hepatic fibrosis, steatosis in mice	Histology: improved fibrosis in phase IIb trial
Anti-inflammatory	Cenicriviroc	Phase IIb trial completed.	-	Histology: did not meet primary endpoint of 2 point NAS reduction
	BTT1023	Phase IIa trial in NAFLD open	Animal data: reduced fibrosis (mice)	-
Gut microbiome	IMM-124e (IgG-rich extract of bovine colostrum)	Phase IIa trial in NASH ongoing	Improved ALT and glucose tolerance	-
Anti-fibrotic	Simtuzumab	Phase IIb trial terminated	Reduced collagen cross linking in fibrosis models only	Results of phase IIb trial in NASH not published
	GR-MD-02	Phase IIa trial completed	Reduced hyaluronic acid in mice	Results of phase IIa trial not published
Dual therapies	Vitamin E+ Vitamin C	Proof of concept phase IIb trial completed	-	Histology: improved fibrosis
	Vitamin E+UDCA		-	Histology: no improvemnet in fibrosis
	Selonsertib+Simtuzumab	Prrof of concept phase IIa trial completed	-	Histology: improved fibrosis
	Selonsertib+GS-9674	Phase IIa recruiting	-	-

Sources: Center for Liver Research, University of Birmingham, UK

Conclusions

The disease spectrum of NALFD encompasses a wide range of patients, and it will continue to represent a public health burden of epidemic proportion.

Unfortunately, the current therapies have limited efficacy, although sustained weight loss can alter the natural history of disease.

A pipeline of novel therapeutic agents is in development and we expect increasing options for clinicians to treat this patient population in the coming years. Future pharmacologic strategies for NASH treatment will be multi-pronged and target metabolic pathways including insulin sensitivity, fatty acid synthesis and oxidation, and various mechanisms of decreasing inflammation.

The horizon is bright for Immuron whose platform technology has a favorable profile to treat NASH.

Therapies for *Clostridium difficile* Infection

Clostridium difficile infection (CDI) is the leading cause of infectious diarrhea in hospitalized patients and the primary cause of death due to gastroenteritis in the USA (Lessa, *et a*l. N Engl J Med 2015). Infection occurs when an altered gut microbiota allows *C. difficile* spores to germinate into toxin secreting vegetative cells.

Pathogenesis

C. difficile is an anaerobic, spore forming, gram- positive organism that is transmitted via the fecal–oral route. The environmentally resistant spores are ingested and activated by bile acids in the small intestine (Song, *et al.* J. Bacteriol 2008). Once activated, the bacterium adheres to colonic mucosa. Virulence is mitigated by the production of toxins A and B. These toxins result in a profound inflammatory response, alterations in cellular tight junctions, and apoptosis leading to the clinical symptoms of diarrhea.

Animal models reveal that toxin B may be the more potent of the two toxins, with toxin A inducing a more localized effect (Carter, *et al.* MBio 2015). A recently described binary toxin remains of uncertain clinical significance, but appears to result in actin depolymerization and microtubule protrusions, which may aid in bacterial adherence (Gerding, *et al.* Gut Microbes 2014).

The underlying host colonic microbiome plays an important role in the pathogenesis of CDI. The association between antibiotic administration and subsequent development of CDI has long been recognized, particularly with clindamycin, cephalosporins, and fluoroquinolones (Laffler, *et al*. N Engl J Med 2015). Alterations in host microbiome from antimicrobial agents may set the stage for *C. difficile* colonization. This may be more complex than merely providing a space for the bacteria to flourish.

The increased understanding of the complex underlying pathophysiology of CDI has led to various novel therapeutic modalities.

Disease Severity

CDI encompasses a spectrum of disease severity. It is important to be precise in defining the manifestations of CDI so as to properly risk stratify patients, provide appropriate level of treatment, and to ensure similar groups are compared when evaluating new therapies and outcomes. The guide- lines published by the American College of Gastroenterology (ACG) separates CDI into mild, moderate, severe, severe-complicated, or recurrent manifestations.

Figure 15. Severity of *Clostridium difficile* Infection

Mild to moderate	Diarrhea along with signs not meeting severe criteria
Severe	Serum albumin < 3g/dl and either WBC≥15000 cells/µl or abdominal tenderness
Severe and complicated	Hypotension, toxic megacolon, fever >38.5, altered mental state, WBC≥35000 or <2000, end-organ function failure (renal failure, respiratory failure)
Recurrent CDI	Recurrence within 8 weeks of completeing therapy

CDI, Clostridium difficile infection; WBC, white blood cell

Sources: American College of Gastroenterology

Mild disease is CDI with diarrhea being the only symptom. Moderate disease is CDI with diarrhea and additional signs and symptoms that do not meet the following criteria for severe disease. Severe disease is defined as CDI presenting with hypoalbuminemia (<3 g/dl) and either a white blood cell count (WBC) at least 15,000 cells/µl or abdominal tenderness. Severe-complicated disease is defined as any of the following as a consequence of CDI: admission to the ICU attributed to CDI, hypotension (with or without vasopressors), fever at least 38.5°C, ileus or significant abdominal distention, alterations in mental status, WBC at least 35,000 cells/µl, serum lactate more than 2.2 mmol/l, and signs of end-organ dysfunction. Finally, recurrent disease is defined as a recurrence of CDI within 8 weeks of completing therapy (Brandt, *et al.* J Gastroentrol 2013).

Antibiotics in development to treat Clostridium difficile infection

Oral vancomycin and metronidazole have been preferred treatment choices for CDI historically; however declining efficacy of metronidazole will likely limit its use in the future (Zar, *et al*. Clin Infect Dis 2012). Fidaxomicin was approved by the US Food and Drug Administration in 2011 for the treatment of CDI in adults. Phase III clinical trials demonstrated similar clinical cure rates as vancomycin and decreased risk of recurrent CDI (Louie, *et al*. N Engl J Med 2011). With increased incidence and few treatment options, drug development for antibiotics used to treat CDI is needed. Ideal properties for effective CDI antibiotics include nonabsorbable agents that achieve high colonic concentrations (site of infection for CDI), potent activity against *C. difficile* against all circulating strains, and narrow spectrum activity against host gut microflora. Unproven clinical significance but still beneficial pharmacologic properties would include effect on *C. difficile* toxins and disruption of the spore-germination cycle.

The key points are as follows. Several new antimicrobials with in-vitro activity against C. difficile are currently in Phase I–III studies with published results. The majority of these antibiotics target Gram-positive aerobes and anaerobes and thus are narrow spectrum compared with vancomycin and metronidazole. In-vitro studies have also demonstrated antitoxin or effect on C. difficile spores although the clinical significance of these findings is yet to be determined.

Figure 16. New Antibiotics Directed Against *C. difficile* Infection

								Phase II results vs. vancomycin	
Drug	Description	MOA	Antitoxin effect	Antispore effect	Nonabsorbable	Potent C. diff activity	Effect on host microbioata	Clinical cure	Sustained response
Surotomycin	Lipopeptide	Cell membrane depolarizing agent	No	No	Yes	Yes	Gram+ aerobe and anaerobes	Similar	Similar
Ridinilazole	Unknown	Prevents cell division	Yes	No	Yes	Yes	Clostridia only	Similar	Higher
Ramoplanin	Glycolipodepsipeptide	Dsirupts cell wall synthesis	No	Yes	Yes	Yes	Gram+ aerobe and anaerobes	Similar	Similar
Cadazolid	Oxazolidinone	Protein synthesis inhibitor	Yes	Yes	Yes	Yes	Gram+ aerobe and anaerobes	Similar	Higher
LFF571	Cyclic lipopeptide	Protein synthesis inhibitor	Yes	Yes	Yes	Yes	Gram+ aerobe and anaerobes	Higher	Similar
CRS3123	Diaryldiamine synthetic inhibitor	Protein synthesis inhibitor	Yes	Yes	Unknown	Yes	Gram+ aerobe and anaerobes	Pending	Pending

Sources: Gary, *et al*. Houston College of Pharmacy, TX.

Bovine antibodies targeting primary and recurrent *C. difficile* disease are an antibiotic alternative

Immuron has developed colostrum-derived antibodies for the prevention and treatment of CDI. Pregnant cows were immunized to generate hyperimmune bovine colostrum (HBC) containing antibodies that target essential *C. difficile* virulence components, specifically, spores, vegetative cells and toxin B (TcdB).

Mouse infection and relapse models were used to compare the capacity of HBC to prevent or treat primary CDI as well as prevent recurrence.

Administration of TcdB-specific colostrum alone, or in combination with spore or vegetative cell-targeted colostrum, prevents and treats *C*. *difficile* disease in mice and reduces disease recurrence by 67%. *C. difficile*-specific colostrum could be re-considered as an immunotherapeutic for the prevention or treatment of primary or recurrent CDI.

Fecal Microbiota Therapy

Fecal microbiota therapy (FMT) aims at restoring the colonic biodiversity. Although originally described over a half century ago by Eiseman and colleagues (Surgery 1958), it has received considerable attention over the past several years as an effective treatment modality in recurrent CDI.

Post procedure complications are variable in FMT, and involve aspiration from nasoenteral administration of FMT, or colonic perforation from colonoscopy. Further studies are necessary to further define the role of FMT in acute CDI.

Immunologic Therapy

Immunologic and targeted therapy toward the *C. difficile virulence* factors is an attractive therapeutic modality that could potentially limit the need for antibiotics in the treatment of CDI. One avenue explored in the past was the addition of intravenous immune globulin (IVIG), which may contain neutralizing antibodies toward toxins. As recently reviewed elsewhere, the data for IVIG in CDI are largely based on case reports and retrospective reviews, compiling a heterogeneous population with a variety of dosing regimens Shah, *et al*. Am J Heal Pharm 2015) Currently the ACG recommendations for the management of CDI state that IVIG does not have a role as sole therapy in the treatment of recurrent CDI.

Surgical

Despite a myriad of therapeutic approaches detailed above, CDI could ultimately progress to surgical management. Absolute indications for surgical intervention include perforation and abdominal compartment syndrome, although these are not typical. Traditional surgical approach for CDI is a laparotomy with total abdominal colectomy and end ileostomy. This procedure carries a high morbidity and mortality, partly related to the comorbidities of the patient population. In a retrospective series of patients managed surgically for fulminant CDI in hospital mortality was found to be 41% after intervention, with a mean survival time after CDI of 18.1 months (Dallas, et al. Am J Surg 2014).

Conclusion

C. difficile remains a disease of high prevalence, cost, recurrence, and associated mortality. Treatment remains multimodal aimed at prevention, resuscitation, and appropriate use of antimicrobial agents.

Immuron has developed Colostrum-derived antibodies from Immuron may offer a new option to treat patients with CDI.

With further understanding of the pathogenesis and shortcomings of current therapies, the future of management of CDI may include a multimodal approach focusing on microbiota and immunologic therapies that could result in improved cure with reduced recurrence.

Summary

Company Overview. Immuron is a clinical stage biotech, a Biologics company targeting high value inflammation and infectious diseases. We believe the company is developing transformative therapies that have the potential to be the standard of care in NASH and C. difficile. Immuron's oral immunotherapy technology platform also has the potential to expand the product pipeline and enter into new indications.

Management. Immuron's senior management team – Jerry Kanellos, CEO and Dan Peres, CMO - has a proven track record and is spearheading the execution. The Company has thus far executed to plan with accelerated development of the right trials

Ecosystem. Immuron is working with KOLs and leading institutions – Duke and Sanyal Biotech - in the inflammatory and infectious disease space that provide guidance and credibility to the development programs.

Figure 17. Immuron Limited – Investment Highlights

- Positioned to address unmet medical need in large opportunity markets
- Two clinical assets, 4 phase 2 clinical trials in process
- Strong R&D pipeline
- Licensing deals and M&A provide valuation support
- Foundational technology platform – with one registered asset generating revenue
- Listed on NASDAQ in 2Q 2017
- Experienced Management Team with support from KOLs and institutions

Sources: Company Reports and Joseph Gunnar

Primary Opportunity. For background, NASH is the disease form of fatty liver. It consists of accumulation of fat in the liver, inflammation and in severe cases scaring which may in turn lead to end stage fibrosis - Cirrhosis. The disease is associated with metabolic- immunological- and healing- imbalance.

NASH is a Multi Factorial disease requiring multi-faceted treatment and/or combination therapy. The size of the market opportunity is estimated that 30 percent of the entire population has fatty Liver, with 5 percent having NASH. Currently, there are no approved therapies for NASH.

Operational Milestones. Immuron is making progress on driving multiple ongoing therapeutic programs to late-stage clinical development with multiple milestones anticipated over the next 6-18 months. The company's assets and opportunities are focused on its leading two clinical stage compounds. The lead inflammatory program has reported interim data in Q3 with topline results expected before year end 2017. The lead infectious disease program is to commence Phase I/II study in Q3.

Lead Candidate. IMM-124E is a novel solution. On safety, no safety signal in preclinical, Phase I or Phase II to date. The MOA is multifaceted, down and upstream immunological effects, targeting both the innate and the adaptive immune systems. IMM-124E is an ideal candidate for combination therapy with any drug.

Competition. Competitors are primarily focused on improving existing solutions. The endpoint of this development pathway is better, safer and more efficacious drugs, but essentially more of the same. Recent trials have established Immuron IMM-124E safety profile. The mechanism of action (MOA) is unique and this drug candidate is ideally positioned for combination therapy.

In sum, Immuron is a biotech company with novel oral immunotherapies. The Company's lead programs are expected to achieve multiple key milestones over the forecast horizon. The target population for its drug candidates is a large and growing market with high unmet medical needs.

Management

Jerry Kanellos, PhD
Chief Executive Officer

Dr. Jerry Kanellos (PhD) has been the Chief Operating and Scientific Officer since July 2015. Dr. Jerry Kanellos has over twenty five years' experience in the pharmaceutical and biotechnology industry. From 2008 until 2012, Dr. Kanellos was the Chief Operating Officer of TransBio Limited where he was responsible for the strategic identification, development and maintenance of commercial partnerships globally, along with development, management and maintenance responsibility for the intellectual property portfolio, research and development and technology transfer. Prior to this, Dr. Kanellos worked for five years as a consultant to the biotechnology industry. Dr. Kanellos holds a PhD in Medicine from the University of Melbourne.

Dan Peres, MD
Chief Medical Officer

Dr. Dan Peres (MD) has served in various clinical and medical managerial roles in pharmaceutical and medical device companies such as Exalenz Bioscience, CarboFix Orthopedics, NMB Medical Applications, and NovoNordisk Israel. Dr. Peres began his career as a physician and medical director in the Israel army. Dr. Peres' expertise lies with medical strategy, research and development, and the management of clinical studies and other laboratory processors. He has extensive knowledge of the leading International Centers for Liver Disease and established relationships with key opinion leaders, including those currently participating in Immuron's NASH and ASH trials. Dr. Peres has been a certified physician since 2002 when he graduated from the Sackler School of Medicine at Tel-Aviv University.

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Figure 18. Immuron Limited - Income Statement, 2014-2019E

	For the year ended June 30,				For the six months ended		For the year ended June 30,	
	2014 (Restated) AUD$	2015 (Restated) AUD$	2016 (Restated) AUD$	2017 AUD$	31 Dec 2017 AUD$	30 Jun 2018 AUD$	2018 AUD$	2019 AUD$
Revenue								
Operating Revenue	981,051	1,002,380	1,001,077	1,396,197	800,000	500,000	1,300,000	500,000
Total Operating Revenue	**981,051**	**1,002,380**	**1,001,077**	**1,396,197**	**800,000**	**500,000**	**1,300,000**	**500,000**
Cost of Goods Sold	(277,928)	(316,128)	(301,435)	(337,546)	200,000	125,000	325,000	125,000
Gross Profit	**703,123**	**686,252**	**699,642**	**1,058,651**	**600,000**	**375,000**	**975,000**	**375,000**
	72%	68%	70%	76%	75%	75%	75%	75%
Direct Selling Costs								
Sales and Marketing Costs	(79,796)	(76,794)	(133,781)	(407,751)	(225,000)	(300,000)	(525,000)	(600,000)
			-13%	-29%	-28%	-60%	-40%	-120%
Freight Costs	(114,278)	(116,379)	(134,967)	(135,377)	(70,000)	(70,000)	(140,000)	(150,000)
Total Gross Profit less Direct Selling Costs	**509,049**	**493,079**	**430,894**	**515,523**	**305,000**	**5,000**	**310,000**	**-375,000**
Other Income	804,477	1,591,021	3,008,778	1,614,373	600,000	600,000	1,200,000	1,200,000
Expenses								
Amortization	(680,587)	-	-	-	-	-	-	
Consulting, Employee and Director	(555,487)	(728,140)	(2,840,037)	(1,689,521)	(800,000)	(800,000)	(1,600,000)	(2,000,000)
Corporate Administration	(492,465)	(557,422)	(1,320,570)	(1,381,809)	(700,000)	(700,000)	(1,400,000)	(1,500,000)
Depreciation	(3,989)	(3,719)	(3,892)	(4,922)	(2,500)	(2,500)	(5,000)	(6,000)
Finance Costs	(463,685)	-	(341,600)	(24,483)	(15,000)	(15,000)	(30,000)	(30,000)
Impairment of Inventory	(50,204)	(35,340)	(4,176)	(136,494)	(25,000)	(25,000)	(50,000)	(30,000)
Marketing and Promotion	(235,176)	(304,687)	(487,591)	(789,608)	(150,000)	(150,000)	(300,000)	(300,000)
Research and Development	(1,289,675)	(3,018,294)	(3,623,961)	(4,630,674)	(1,500,000)	(1,000,000)	(2,500,000)	(2,000,000)
Travel and Entertainment	(37,327)	(128,318)	(416,849)	(276,539)	(150,000)	(150,000)	(300,000)	(500,000)
Total Expenses	(3,808,595)	(4,775,920)	(9,038,676)	(8,934,050)	(3,342,500)	(2,842,500)	(6,185,000)	(6,366,000)
Loss Before Income Tax	**(2,495,069)**	**(2,691,820)**	**(5,599,004)**	**(6,804,154)**	**(2,437,500)**	**(2,237,500)**	**(4,675,000)**	**(5,541,000)**
Income Tax Expense	-	-	-	-	-	-	-	-
Loss for the Period	**(2,495,069**	**(2,691,820**	**(5,599,004)**	**(6,804,154)**	**(2,437,500)**	**(2,237,500)**	**(4,675,000)**	**(5,541,000)**
Other Comprehensive Loss	-	(12,581	8,846	40,017	-	-	-	-
Total Comprehensive Loss for the Period	**(2,495,069**	**(2,704,401**	**(5,590,158)**	**(6,764,137)**	**(2,437,500)**	**(2,237,500)**	**(4,675,000)**	**(5,541,000)**
Basic/Diluted Loss per Share (cents per share)	5.9	3.6	(7.3)	(6.4)	(1.9)	(1.7)	(3.6)	(3.7)
Weighted-average number of shares outstanding - diluted	41,955,199	74,935,902	76,435,993	103,641,417	130,041,417	130,041,417	130,041,417	150,000,000

Sources: Company Reports and Joseph Gunnar Estimates

Figure 19. Immuron Limited —Valuation Comparables, Prices as of 9/20/17

(In millions, except per share data)

Ticker	Company Name	Stock Price 9/20/2017	% of 52-Week High	% of 52-Week Low	Shares Out.	Market Cap	Enterprise Value	Revenue LTM	Revenue CY+1	EBITDA LTM	EBITDA CY+1	EPS LTM	EPS CY+1
GILD	Gilead Sciences, Inc.	82.64	95.8%	129.6%	1,305.9	107,921.7	113,021.7	28,466.0	25,873.5	17,966.0	16,931.0	9.21	8.76
ICPT	Intercept Pharmaceuticals, I	98.12	56.7%	114.3%	25.1	2,462.8	2,260.9	70.9	134.7	(361.3)	(335.3)	(15.49)	(13.99)
GNFT	Genfit SA	29.78	69.6%	150.4%	31.2	927.9	752.7	7.0	9.4	(35.6)	(55.5)	(1.32)	(1.70)
MCRB	Seres Therapeutics, Inc.	16.09	96.9%	181.8%	40.5	651.8	480.6	22.1	29.9	(92.7)	(84.2)	(2.42)	(2.48)
CNAT	Conatus Pharmaceuticals In	5.67	60.3%	390.1%	30.0	170.1	94.7	17.8	52.1	(25.1)	NA	(0.97)	(0.45)
ASMB	Assembly Biosciences, Inc.	30.49	95.6%	452.3%	17.4	529.4	453.9	3.0	5.5	(50.9)	NA	(2.93)	(3.40)
TTPH	Tetraphase Pharmaceuticals	6.99	70.4%	224.8%	51.1	356.9	238.6	5.0	6.3	(105.0)	(92.0)	(2.82)	(2.52)
AKAO	Achaogen, Inc.	16.18	58.2%	439.7%	42.2	683.3	478.7	35.5	12.5	(68.1)	(80.0)	(3.10)	(3.03)
	Max	98.12	96.9%	452.3%	1,305.9	107,921.7	113,021.7	28,466.0	25,873.5	17,966.0	16,931.0	9.21	8.76
	Median	22.98	70.0%	203.3%	35.8	667.6	479.7	19.9	21.2	(59.5)	(82.1)	(2.62)	(2.50)
	Min	5.67	56.7%	114.3%	17.4	170.1	94.7	3.0	5.5	(361.3)	(335.3)	(15.49)	(13.99)
	Mean	35.74	75.5%	260.4%	192.9	14,213.0	14,722.7	3,578.4	3,265.5	2,153.4	2,714.0	(2.48)	(2.35)
IMRN	**Immuron Limited**	**6.07**	**37.1%**	**135.8%**	**–**	**19.5**	**16.5**	**1.1**	**NA**	**(6.44)**	**NA**	**(0.05)**	**NA**

Ticker	Company Name	LT Growth Rate (%)	Est. 1 Year Growth (%) Revenue	Est. 1 Year Growth (%) EBITDA	TEV/Revenue LTM	TEV/Revenue CY+1	TEV/Revenue CY+2	TEV/EBITDA LTM	TEV/EBITDA CY+1	TEV/EBITDA CY+2	P/E LTM	P/E CY+1	P/E CY+2
GILD	Gilead Sciences, Inc.	(10.1)	(14.9)	(20.1)	3.97x	4.37x	4.92x	6.3x	6.7x	8.2x	9.0x	9.4x	11.0x
ICPT	Intercept Pharmaceuticals, I	NA	439.9	NA	31.88x	16.78x	9.22x	NM	NM	NM	NM	NM	NM
GNFT	Genfit SA	NA	15.9	NA	94.26x	79.85x	84.52x	NM	NM	6.9x	NM	NM	35.8x
MCRB	Seres Therapeutics, Inc.	0.4	37.2	NA	21.77x	16.10x	28.24x	NM	NM	NM	NM	NM	NM
CNAT	Conatus Pharmaceuticals In	NA	6418.2	NA	5.32x	1.82x	2.61x	NM	NA	NA	NM	NM	NM
ASMB	Assembly Biosciences, Inc.	NA	NA	NA	149.12x	81.91x	80.20x	NM	NA	NA	NM	NM	NM
TTPH	Tetraphase Pharmaceuticals	NA	21.9	NA	47.63x	38.04x	45.61x	NM	NM	NM	NM	NM	NM
AKAO	Achaogen, Inc.	NA	(70.1)	NA	13.48x	38.29x	30.05x	NM	NM	NM	NM	NM	NM
	Max	0.4	6418.2	(20.1)	149.12x	81.91x	84.52x	6.3x	6.7x	8.2x	9.0x	9.4x	35.8x
	Median	(4.8)	21.9	(20.1)	26.82x	27.41x	29.15x	6.3x	6.7x	7.6x	9.0x	9.4x	23.4x
	Min	(10.1)	(70.1)	(20.1)	3.97x	1.82x	2.61x	6.3x	6.7x	6.9x	9.0x	9.4x	11.0x
	Mean	(4.8)	978.3	(20.1)	45.93x	34.65x	35.67x	6.3x	6.7x	7.6x	9.0x	9.4x	23.4x
IMRN	**Immuron Limited**	**NA**	**NA**	**NA**	**14.68x**	**NA**	**NA**	**NM**	**NA**	**NA**	**NA**	**NA**	**NA**

Ticker	Company Name	5-Year Historical CAGR (%) Revenue	5-Year Historical CAGR (%) EBITDA	5-Year Historical CAGR (%) EPS	LTM Margins (%) Gross	LTM Margins (%) EBIT	LTM Margins (%) EBITDA	Ratios DSO	Ratios DPO	Ratios DIO	Returns (%) ROA	Returns (%) ROE	Returns (%) ROIC
GILD	Gilead Sciences, Inc.	25.9	33.5	41.1	84.94	58.96	63.11	65.6	92.4	139.2	19.0	62.2	23.9
ICPT	Intercept Pharmaceuticals, I	89.3	NM	NM	99.47	NM	NM	NA	NM	NA	(40.1)	(131.4)	(48.9)
GNFT	Genfit SA	(0.3)	NM	NM	100.00	NM	NM	163.7	NA	NA	(18.1)	(34.0)	(20.3)
MCRB	Seres Therapeutics, Inc.	NA	NA	NA	(296.73)	NM	NM	NA	17.4	NA	(23.7)	(76.3)	(48.5)
CNAT	Conatus Pharmaceuticals In	NA	NA	NA	(82.48)	(141.34)	(140.75)	NA	60.1	NA	(24.0)	(80.6)	(41.4)
ASMB	Assembly Biosciences, Inc.	NA	NM	NM	(131.99)	NM	NM	NA	80.2	NA	(26.6)	(64.5)	(40.6)
TTPH	Tetraphase Pharmaceuticals	NA	NA	NA	NM	NM	NM	206.2	19.0	NA	(41.7)	(73.8)	(46.3)
AKAO	Achaogen, Inc.	NA	NA	NA	(123.03)	(193.44)	(191.64)	50.2	32.1	NA	(24.8)	(92.7)	(32.2)
	Max	89.3	33.5	41.1	100.00	58.96	63.11	206.2	92.4	139.2	19.0	62.2	23.9
	Median	25.9	33.5	41.1	(82.48)	(141.34)	(140.75)	114.6	46.1	139.2	(24.4)	(75.0)	(41.0)
	Min	(0.3)	33.5	41.1	(296.73)	(193.44)	(191.64)	50.2	17.4	139.2	(41.7)	(131.4)	(48.9)
	Mean	38.3	33.5	41.1	(49.98)	(91.94)	(89.76)	121.4	50.2	139.2	(22.5)	(61.4)	(31.8)
IMRN	**Immuron Limited**	**25.5**	**NM**	**NM**	**66.05**	**NM**	**NM**	**251.3**	**NM**	**NM**	**(61.3)**	**(118.2)**	**(76.1)**

Sources: S&P and Joseph Gunnar Estimates

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