FINANCIAL RISK MANAGEMENTS

Risk Management

26 August 2020 .

Rate the probability that the risk will be realized in the negative, with 1 being extremely unlikely and 10 being almost definite.

Rate the impact that the negative outcome of the risk will have on the company, with 1 being survivable and 10 being death to the company.

The higher the number is, the higher the significance of the risk is.

Identify the Risks		Risk Analysis & Evaluation			Risk Management
	Risks	(a) Possibility scale of 1 to 10	(b) Impact scale of 1 to 10	(c) Order of Significance (a) x (b)	
Covid-19					
1	Covid-19	5	2	10	Following and implementing government health regulations and guidelines, minimising office staff numbers. Implementing work from home practices, hygiene practices. Maintaining social distancing.
Going Concern					
2	Going concern - Risk that the company will become insolvent	1	2	2	As at June 30, 2020 the cash balance was A$ 3,250,468. On 24 July 2020, the company completed a capital raising comprising 1,066,668 American Depositary Shares (ADS) at US$18.75 per security. The gross proceeds to the company were US$18,379,623.
3	Risk the company will not be able to raise capital	1	2	2	Company duel listed and can raise on ASX and/or NASDAQ. On 24 July 2020, the company completed a capital raising comprising 1,066,668 American Depositary Shares (ADS) at US$18.75 per security. The gross proceeds to the company were US$18,379,623.
Human Capital					
4	Inability to find suitably experienced replacement CEO	1	3	3	The company has successfully recruited experienced-CEOs from both Biotechnology and big pharma backgrounds in the past and there is no reason why this would change in the future..

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5	Staff Loss of key personnel and staff turnover	2	3	6	Position SOPs clearly defined according to skill. Retain employees through job satisfaction. Ability for other people within team to either (1) handle the workload, (2) manage external consultants to handle some of the initiatives, (3) have temporary talent pool on standby.
Technology/Industry Risks – Platform Issues					
6	Safety issues with on-market therapeutics	1	4	4	Our technology plate form is based on bovine colostrum which is a milk derivative which is consumed in great amounts worldwide and is Generally Regarded As Safe. Given the appropriate safety profile of our products which risk is minimal.

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7	IMM-124E Phase III Travellers Diarrhoea results failure	2	5	10	IMM-124E has an established market in Australia, Canada and the USA with a strong and loyal following. It has been extensively evaluated by our Research Collaborators in the US Department of Defense in various preclinical settings and has generated robust data to suggest a very low probability of failure. We are planning to initiate 2 phase II clinical trials with second new drug candidate that is being developed with the Naval Medical Research Centre this reduces the reliance on just one clinical indication with one drug candidate.
8	A product development program failing	3	6	18	The company has several programs in the development pipeline beside the planned Phase II clinical studies in Travellers Diarrhoea and CDI. These projects will move into the clinic as the preclinical studies are completed.
Technology/Industry Risks – Platform Issues					
9	IT security & backup	3	5	15	Systems are well controlled by IT partner. Documented system for regular backup required for all employees. Periodic revisions of the passwords take place for all company email addresses.

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10	Clinical Trial safety failure or reportable event	1	3	3	Given the safety profile of clinical assets, major AEs are unlikely.
Intellectual Property					
11	Failure to attain, or delay in attaining, patents for trials	5	6	30	Beside patents, our clinical assets will be protected by exclusivity provisions in our major markets including (1) US, with 12 years of market exclusivity for biologics and (2) EU, with 10 years of market exclusivity for new products.
12	Infringement of third-party IP	2	5	10	Given that our clinical assets are biologics and therefore complex to develop, launch and market, we believe that we have other protection beyond our current IP positions
13	New technology produced other competing company	4	5	20	The competitive environment in Travellers Diarrhoea and C-Difficile and other anti-infectives is complex and evolving with not to many players operating in this space. At this time, we do not anticipate that any single assets will dominate our markets (e.g, not HCV like), which means that there will be room for a number of therapies including those of Immuron's.
Production *(Travelan and Protectyn)*					
14	Vaccine production problematic	2	3	6	Our current vaccine manufacturing process has been in commercial scale operations since 2004 with no vaccine production issues reported to date. CSIRO have developed a new liquid fermentation production process as a backup to the existing method of manufacture.
15	Product stability failure	1	7	7	Currently there is no reason to be concerned about stability. The company has expanded product shelf life from 3 years to 10.8 years
16	Herd failure	2	7	14	Company has sufficient colostrum powder reserves allowing sufficient time to review and plan for alternatives should main colostrum supplier Synlait go offline.
17	Loss of major supplier - Synlait	2	5	10	Secondary suppliers have been identified but no plans are in currently in place to certify these manufacturers given cost. Company has sufficient colostrum powder reserves which would mitigate the time lost in identifying a new manufacturer.

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Commercialisation					
18	Failure to partner and/or licence technology/products	4	6	24	The company is continuing the process of identifying and targeting potential partners for its clinical assets. we do however, enjoy a strong non-dilutive partnership with the US Department of Defense.
19	Competitor product release (Travelan)	4	5	20	While we do not anticipate another product being released into the market place. Should a new competitor launch into the market it would obviously have impact on Travelan.
20	Competitor product release (C-Diff)	4	6	24	Immuron's technology platform is unique. Our CDI clinical asset is the only compound in development which targets the3 infectious stages of the disease, spores, vegetative cells and toxin B.
21	Non-granting of regulatory approval in US/EU for Travelan	3	7	21	The product is sold as a dietary supplement in the USA, The risk on non-approval is not relevant at this stage. Given the technology platform's safety profile.
22	C-Difficle program failures	2	6	12	At this stage, the risk of failure is extremely low, especially given the past results in the preclinical development program.
Pipeline Risk					
23	Ability to progress including experimental, clinical, partnering and IP risk	3	7	21	We do not know of any risk, beyond normal development risk faced by other biotech companies that could impact our company
Regulatory Risk					
24	Non-Compliance with ATO	2	2	4	The company has engaged experienced consultants which audit compliance to meet ATO guidelines.
25	Non-Compliance with ASIC & ASX /NASDAQ	2	7	14	The company has engaged experienced consultants and lawyers which audit compliance to meet ASIC & ASX /NASDAQ guidelines.
26	Non-Compliance with Health Department(s) regulations	2	8	16	The company has employed experienced personnel with extensive experience in the regulatory requirements and also engaged experienced consultants which audit compliance to meet the relevant regulatory guidelines.