

# ASSEMBLASE Pty Ltd BUSINESS PLAN

OCTOBER 2019







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# **Executive Summary**

Assemblase is a highly adaptable product that can be used across any biochemical reaction where rate limiting barriers are creating vast inefficiencies in yield. Currently, Assemblase Pty Ltd is using Paclitaxel manufacturing as a case study to showcase how Assemblase can enter and dominate the cancer drug development market. There are plans to expand into different industries such as high value therapeutics, food industry and consumer good production optimising profit.

#### **Business**

Assemblase is an Australian business forged by deep foundations in science, pioneering innovation. The trade secret Assemblase scaffold provides the necessary platform to increase reaction yields and decrease reaction times. Resulting in vast improvements to any biochemical reaction. The highly experienced team has produced a superior solution that differs from competitors due to its novel process making Assemblase highly versatile, robust and cost-effective.

#### Market

Assemblase will enter the market through Paclitaxel biochemical manufacturing with the domestic market valued at \$11 million and global market valued at \$200 million. Assemblase will then expand into a variety of enzyme biochemical manufacturing processes such as high value therapeutics, industrial and textiles. This market is predicted to reach \$6.4M by 2020. Through providing a highly personalised good that incorporates novel science Assemblase will retain competitive advantage over its domestic peers ProSci, Deltagen, Enzyme Solutions and its international counterpart Novozymes.







#### **Finances**

Assemblase is set to penetrate the \$200 million Paclitaxel market gaining \$1,780,359 of revenue each year. The F2 classification of Paclitaxel ensures all manufacturers include Assemblase in their production process. Further expansion through the enzyme market will result in significant increases in revenue. Notable costs for Assemblase Pty Ltd are Research and Development valuing \$204,000 each year. This will increase by 10% starting in 2022, in a bid to maintain competitive advantage allowing Assemblase to provide a novel solution that is different from peers in the area. Assemblase will be looking to undergo 3 rounds of funding; Pre-seed, Seed A, and Seed B raising \$100,000, \$2,000,000 and \$10,000,000 respectively.

#### **Future**

Assemblase Pty Ltd's future strategy is rooted in innovation, ethical scientific practice, social responsibility and education. Assemblase Pty Ltd will undergo a soft market entrance strategy into the Australian market. Initially, improving the manufacturing process of cancer pharmaceutical 'Paclitaxel' over 10 months. Upon protocol optimisation, the Assemblase scaffold will expand to be included and marketed to other biochemical reactions in high value therapeutics, consumer goods and industrials. Upon successful integration into the Australian market over a 22-month period Assemblase will expand into the Asia Pacific area, Europe and America. This will occur through acquisition of international companies as well as, special purpose vehicles (SPV) mitigating cultural fit issues and entrance barriers.







# The Business

# **Business Structure**

Company Name	Assemblase Pty Ltd
ABN	Pending
Founding Date	February 2019
Company Address	E26 School of Biological, Earth and Environmental
	Sciences (BEES), UNSW NSW 2052
Contact Information	Unsw.igem@gmail.com
CEO	Edward Johnson

# Registrations

ABN	Pending
TFN	Pending
Web license	Pending
Scientific License	Pending
Patents	Pending

# **Legal Structure**

Assemblase has a Proprietary Limited legal structure this allows for the initial founders to retain ownership whilst easily bringing in outside funding parties.







## **Organisation Structure**

Edward Johnson Chief Executive Officer

Chief Operations Kevin Huynh Chief Laboratory Quoc Phuong Tran

Finance Edward Johnson

DNA Expression Team Melissa Tran Protein Expression Team Nicole Fenton

Analytics Sebastian Porter Zadro

> Publication Justine Salazaar

Laboratory Adviser David Downes

#### **Edward Johnson**



Chief Executive Officer

Edward has a wealth of experience in corporate advisory having worked with investment bank Allen partners where he has worked on a range of asset manager strategies, as well as on research and business plans for an ASX listed medical imaging company. Prior to Allen Partners, Edward was consulting at start up 'Sonder' producing a unique multi-platform marketing strategy.

Currently, Edward is working towards a Dual Bachelor's Degree of Commerce and Advanced Science at the University of New South Wales. Additionally, Edward has studied behavioural and corporate finance at the internationally renowned Ludwig Maximillian University, Munich.

**Quoc Phuong Tran**Chief Laboratory

Quoc Phuong Tran is a highly developed researcher having been involved in multiple research projects within biology and Chemistry. Quoc has provided insight into the origins of life chemistry through his previous work with Prof. Pall Thordarson and more recently Dr. Albert Fahrenbach. Recognized for his efforts, he has been included as







a co-author on a paper soon to be submitted for publication in the Fahrenbach group. This experience has led to the procurement of core scientific skills including analytical techniques, most notably, High-Performance Liquid Chromatography (HPLC), Liquid Chromatography-Mass Spectrometry (LCMS), and Nuclear Magnetic Resonance (NMR) spectroscopy. Outside of research, he has developed design skills through the production of a ground-breaking video game which deals with pressing issues in science.

Currently, Quoc is working towards a Bachelor's Degree of Advanced Science at the University of New South Wales.



Kevin Huynh

Chief Operations

Kevin is an experienced entrepreneur - from founding and developing his own start-ups, to working in Inc 5000 companies. His background in Information Systems allows him to work effectively in lean and agile work environments. His skills in commerce compliment his background

in Biotechnology allowing Kevin to play an integral part at Assemblase Pty Ltd.

Currently, Kevin is working towards a Dual Bachelor's Degree of Commerce and Advanced Science at the University of New South Wales.

#### Sebastian Porter Zadro

**Analytics** 

Sebastian is an experienced programmer and bioinformation working directly with Professor Paul Curmi. Sebastian has developed skills in organisation and teamwork through his involvement as vice president of

Basketball society. Additionally, his passionate nature has seen him coach multiple basketball skills utilising initiative and leadership skills to develop others.

Currently, Sebastian is working towards a Dual Bachelor's Degree of Commerce and Advanced Science at the University of New South Wales.









**Justine Salazar** 

**Publications** 

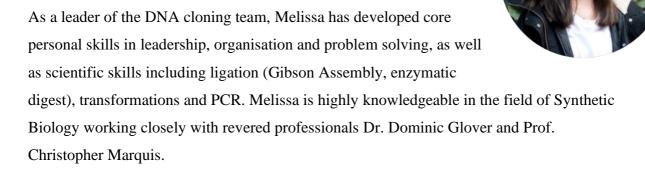
Justine is highly skilled in organisation and administration due to extensive experience as an Events Coordinator at the Biotechnology and Biomolecular Sciences Society. Justine is a keen-learner, eager to build on her academic foundations in Biotechnology and her interests in Software Design. Her hunger for knowledge and determination has contributed to

her most recent accomplishment of delivering successful events such as the Careers Night for the Biotech Society and the Synthetic Biology Symposium for the UNSW iGEM team. Having worked as a Student Ambassador for Science at UNSW, Justine has grown into a conscientious team-player, who can take initiative and perform tasks reliably.

Currently, Justine is working towards a Bachelor Degree of Biotechnology at the University of New South Wales.

Melissa Tran

DNA Expression Team



Melissa has extensive mentorship skills through her role as a one-on-one and class tutor in HSC Biology and Mathematics. She has further developed her organisational skills, holding a former position in the Fundraising and Formal Committee. Additionally, Melissa has highly developed communication and presentation skills having lead talks at the Biotechnology and Biomolecular Sciences Careers Night.







Currently, Melissa is working towards a Bachelor's degree in Advanced Science, with a dual major in Molecular Cell Biology and Psychology at the University of New South Wales.



**Nicole Fenton** 

Protein Expression Team

Nicole has highly developed communication and presentation skills having lead talks at illustrious UNSW Synthetic Biology Symposium on the topic of sustainability and Cancer therapeutics.

Nicole is also a current member of the 2019 UNSW iGEM team where she works in the laboratory to plan, perform and troubleshoot experiments. Additionally, Nicole is well versed in working in a team due to her experience as a senior gymnastic coach. This role has seen her lead and organise group tasks to ensure smooth business operations.

Currently Nicole is working towards a Bachelor's Degree of Advanced Science at the University of New South Wales.

**David Downes**Laboratory Adviser

David Downes has extensive teamwork and leadership skill holding a formative position on the Medical Science Students Society and Biotechnology and Biomolecular Sciences Society subcommittee. He has developed organisational skill with his position as Events Officer in the external organisation

Youth Neuro Australia. Prior to starting his degree, David has spent time gaining extensive experience in the Victor Chang Cardiac Research Institute, the Westmead Children's Hospital, and the Randwick Sydney Children's Hospital. David's commitment to education saw him selected to take part in a Summer Internship at the highly coveted Cardiothoracic Surgical Skills hosted at Stanford University. Building on skills and experience gained through these opportunities, David now acts as a Laboratory member in the UNSW iGEM team.

Currently David is working towards a Bachelor's Degree of Medical Science at the University of New South Wales.







#### Location

Assemblase Pty Ltd is based out of Sydney at the University of New South Wales.

Assemblase Pty Ltd is planning on relocating to the science district in Sydney which is based in Macquarie park. Movement to this area will reduce delivery costs and provide the facilities that could allow for expansion.

#### **Products & Services**

The Assemblase scaffold is a self-assembling protein scaffold that allows enzymes to be colocalised. This increases the rate of reaction as intermediates in the multi-step reaction pathway has a higher probability of binding to the next enzyme. Substrate channelling occurs, effectively streamlining the biochemical reaction process by reducing reaction time. The Assemblase scaffold is thermally stable and not affected by differing pH, being adapted from Archaea which habitat extreme conditions. Currently, up to 2 different enzymes can be applied to the scaffold in a 2:4 ratio, alleviating diffusion related limitations. Furthermore, the scaffold can attach any enzyme making the scaffold vastly adaptable.

Assemblase will foster an elite service that will allow users to increase the rate of reaction of their biochemical processes. This will prove to advance industry significantly, removing inefficiencies and increasing production of units. Users will either provide Assemblase Pty Ltd with the desired enzymes that they require for their reaction or alternatively, the description of enzymes which will then be sourced. These enzymes will be attached to the scaffold using a tag and catcher system. The scaffold will then be sent back to the customer and will be able to be added to the required reaction. The user will be then sent the required scaffold dependent on how regularly they will require the scaffold and how often the customer is running the reaction.

Additionally, Assemblase Pty Ltd will provide a consulting service which will provide business' with industry expert advice on their redox reactions. This service will allow business to gain an outside perspective that will ensure that the optimal protocols are in place to improve reaction efficiency and meet regulation requirements.







#### **Approval of Science**

Based off modelling data as well as, a paper by Dominic Glover et al "Enhanced Enzyme Activity through Scaffolding on Customizable Self-Assembling Protein Filaments" the science behind Assemblase is sound. For further information please contact UNSW.iGEM@gmail.com.

#### **Methods of Action**

The Assemblase team will utilise trade secret information to express the enzyme that clients desire. Using colony transformation, PCR, and protein synthesis the enzyme will be grown, cultivated and isolated. This will occur for each subunit of the Assemblase structure which will be stored separately. The end product will then be distributed to customers who can then add the different elements of the scaffold to their biochemical reaction. The protein scaffold will self-assemble within the reaction mix increasing the reaction rate.

#### **Proof of Scalability & Safety**

The optimal growth conditions and protocols for Assemblase is still undergoing optimization however, based on mathematical modelling the scaffold has the potential to rapidly and safely increase reaction yield.

Upon the set-up of a commercialisation process, a third party will be used to help distribute Assemblase. Due to the relatively simple production process of the Assemblase scaffold, the production line can be easily scaled up to meet industry need.

As Assemblase is not a component of living bacteria there are currently no safety regulations or requirements that could limit the use of Assemblase. Due to the nature of the product there is no perceivable issues that could arise with the use of Assemblase. Further testing to show that Assemblase can be adapted to multiple production process outside of Taxol production will demonstrate the adaptability to other product lines culminating in higher investment potential

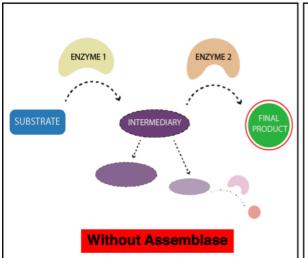






### **Proposition of Value**

Currently there is no commercially available protein scaffold this is due to the novel nature of this science. Additionally, there are attempts to improve multi-step reaction inefficiencies however, this appears to be limited in a commercial setting. Assemblase could therefore provide a novel solution to solve this well-documented problem.



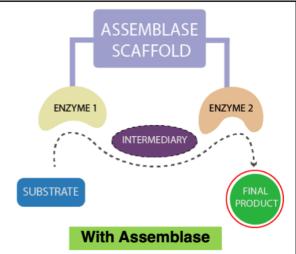


Figure 1 - How Assemblase Works

Assemblase Pty Ltd.'s goal is to improve the manufacturing of multi-step enzymatic reactions. Through applying the Assemblase scaffold to enzymes, enzymes will be kept in close proximity, increasing the probability that the product of one enzyme will enter as the substrate for the next in a multi enzyme reaction. This reduces the loss of intermediaries through diffusion, increasing reaction rate. Paclitaxel is being used a case study due to its renown nature. Additionally, we can apply Assemblase to two different pathways within Paclitaxel manufacturing. This in conjunction with the application of FRET3, acts as a proof of science, demonstrating Assemblase is in fact adaptable and multi-modular.

#### **Patents**

Assemblase Pty Ltd. currently does not have any patents published however, is planning on selling its good as a trade secret. Through alterations of the Spy and Snoop catcher systems, our good is free to be sold without restrictions from patents. Assemblase will acquire patents to further gain monetary compensation outside Australia upon a successful domestic launch strategy this is outlined in business milestones.







#### **Business Model**

Assemblase will be sold as a good as well as, a service. Customers will provide the sequence of their enzyme or will provide the Assemblase team with what enzyme they are looking to use. Assemblase Pty Ltd will then adapt the desired enzyme to the scaffold charging the client a service fee as well as the good. Currently, research is conducted into the recovery methods of the Assemblase scaffold, however, based off current stability predictions the product will need to be replaced monthly. Assemblase will also license its products upon successfully attaining patents throughout different jurisdictions.

Investors will be expected to provide future funds based on revenue targets which will negotiated upon investment. Additionally, royalties and repayment structures will be according to equity tranches depending on each round of capital raising outlined in the finances section.

### **Minimum Viable Product (MVP)**

The minimum viable product for the Assemblase scaffold is a protein scaffold that could increase reaction rate by a minimum amount of 10% this would ensure that consumer need is met. Assemblase must be able to self-assemble and be stable and unreactive with undesired elements of customer reaction process. Additionally, the Assemblase scaffold must not alter or create any by-products that could hinder or to a reasonable level inconvenience current production method.

FRET systems can be used to demonstrate that substrate channelling via the Assemblase scaffold is occurring through showing a visual colour change. This has been used to validate the process.

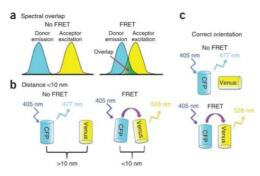


Figure 2 - How FRET Works5







Native Page gel can be used to visualise that the arms of Assemblase have been created successfully. The gel also demonstrates that the enzymes have been successfully attached to the different arms of the Assemblase structure.

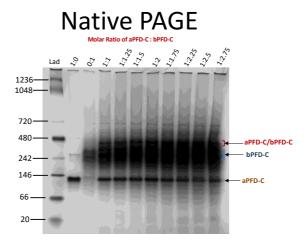


Figure 3 - Native Page Gel Showing Successful Assembly of Hexameric Structure

Further analysis of product formation will demonstrate that the Assemblase process has been effective. This can be through assays, such as Nuclear Magnetic Resonance (NMR) for a specific reaction product or substrate.

# **SWOT Analysis**

 Self-Assembling • Ease of use methods needed Extensive industry Third party will be Adaptable needed for scale up Thermostable Drug production Versatile pH Natural Environmentally friendly **OPPORTUNITIES THREATS STRENGTHS WEAKNESSES** 







# **Risk Assessment**

	Risk & Likeliness (1-10)	How to avoid the risk?
External factors	6	
Economic factors	3	The current economic environment for Assemblase is quite troublesome, however, synthetic biology companies have negligible correlation with the market and are therefore exempt from market volatility. Currency hedging strategies can be used to mitigate future economic issues upon expansion into different countries.
Political factors	6	Through keeping up to date with the legal environment, risks pertaining to changing government policy are mitigated
Social factors	8	A strong marketing campaign as well as an education strategy will ensure the public are well versed in synthetic biology and adopt goods made using Assemblase.
Technological factors	3	In order to ensure Assemblase incorporates the most efficient technology, funding and revenue streams are necessary. This can be accomplished through gaining financing partners.
Development of the industry	9	As Assemblase is novel in nature this concern is quite pressing, however, through strong market presence Assemblase will be the established provider of protein scaffolds
The market & customers	8	Through diversifying Assemblase's product reach, new markets will be reached reducing risk
Competition	8	Through using trade secret production methods and patents a competitive edge will be maintained
Internal factors:	4	
Organization & human resources	1	The legal status of Assemblase ensures all members have a vested interest in the success of the company
Production	4	Developing optimal protocols that enable fast and reliable production process
Finances	7	Through developing a strong network of long-term investors financial health will be maintained







# **Market Analysis**

### **Market Segmentation**

#### **The Cancer Market**

Currently, cancer affects 431,7045 people with 1 in 2 people will be diagnosed with cancer before 856. This costs Australia \$6.3 billion every year with the Australian government paying \$4.5 billion via the public health system 'Medicare' and Pharmaceutical Healthcare System (PBS). This accounts for 4% of the government budget. These costs include Medicare and pharmaceutical claims, inpatient hospital episodes and emergency department presentations, treatments and future monitoring. Furthermore, the second most expensive cancer was breast cancer (\$0.8billion)8 after colorectal cancer (\$1.1billion). There are 19,5359 people being diagnosed with breast cancer each year. Of the 19,535 people diagnosed 3,185 people will lose their fight with breast cancer each year.

#### **Paclitaxel Market**

Paclitaxel is a commonly used treatment for breast cancer promoting the formation of

microtubules which inhibit cell division leading to apoptosis.

It was the first blockbuster drug, (>\$1Billion sales)10 and currently the Paclitaxel market is valued at \$200,000,00011 globally and \$11,000,000012 in Australia. The widely inefficient manufacturing process has led to treatment costs equal to \$80013 per month in America. In Australia Paclitaxel cost the Pharmeutical Benefits Scheme \$24.8312,

however, a reduction in price by \$1 would amount to PBS

NΗ

Figure 4 - Paclitaxel Molecule

paying \$500,000 less for Paclitaxel manufacturing. Paclitaxel is classified as an F2 drug, meaning every manufacturer is subject to continuous disclosure. If one of the 6 manufacturers change their production all 5 others will have to adapt as to not be outpriced by the market. Paclitaxel is also the precursor for many other chemotherapy drugs such as Abraxane, Taxoprexin, Opaxio. Additionally, Assemblase could undergo expansion into the NAB Paclitaxel Total Addressable Market of \$25M<sub>13</sub>. Using the Assemblase scaffold, Paclitaxel has been predicted to produced 6 times more efficiently and significantly more sustainably than current production methods.







#### **Enzyme Market**

Assemblase could be adopted to a wide variety of enzymes in therapeutics, industrials, consumer goods, etc increasing biochemical manufacturing production. This market is valued to \$6.4 billion15 by 2020, consecutively growing 7% since 2014. An enzyme is a substance produced by a living organism which acts as a catalyst to bring about a specific biochemical reaction16. Currently there are attempts to improve multi-step enzymes reaction however this appears to be limited in a commercial setting. Through applying Assemblase, the first commercially available protein scaffold, a removal of inefficiencies will occur. The table below shows some common enzymes demonstrating the wide use in industry and hence the scope of application of Assemblase.

Industry	Enzyme	Use
Baking	Xylanase	Dough conditioning
Diary	Acid proteinase	Milk coagulation
Brewing	Pullulanase	Starch saccharification
Industrials	Lipase	Polycondensation, ring-opening polymerization of lactones, carbonates
Detergent	Lipase	Fat stain elimination
Cosmetics	laccase	Hair dye
Waste Management	Amyloglucosidase	Starch hydrolysis for bioremediation

Example of Commonly Used Enzymes17

### **Stakeholder Analysis**

Through the provision of a transparent good and service to the Paclitaxel market the price of manufacturing Paclitaxel will be reduced. This cost saving due to the oligopolistic manufacturing marketing including Pfizer Australia Pty Ltd (Anzatax, Juno Pharmaceuticals Pty Ltd (Paclitaxel ACT), Accord Healthcare Pty Ltd (Paclitaxel Accord), Sandoz Pty Ltd (Paclitaxel Ebewe), Fresenius Kabi Australia Pty Limited (Paclitaxel Kabi) and Teva Pharma Australia Pty Limited (Paclitaxin) will be dynamically incorporated into pricing. This will result in reduced cost pressure for the Public Benefits Scheme which is part of the Federal







Government. Due to transparency and the competitive market, the savings from a production process with Assemblase will translate into competitive prices offered to the PBS as companies will be outpriced if they do not adapt. This reduction in price pressure on the PBS scheme will allow the government to undergo budget consolidation whereby, it can redistribute the savings to other pharmaceuticals on the PBS scheme.

Additionally, in countries that don't provide a public benefit scheme insurance companies will benefit from reduction in price pressure. This will reduce financial outgoings for these companies.

Through the expansion of Assemblase's good and service into industry there will be a myriad of stakeholders that will be involved including distributors, manufacturers, producers and consumers, all experiencing an increase in sustainability and efficiency in their product lines.

Main Stakeholders	Description
Australian Paclitaxel Manufacturer	Pfizer Australia Pty Ltd (anzatax)
Australian Paclitaxel Manufacturer	Juno Pharmaceuticals Pty Ltd (paclitaxel
	ACT)
Australian Paclitaxel Manufacturer	Accord Healthcare Pty Ltd (paclitaxel
	accord)
Australian Paclitaxel Manufacturer	Sandoz Pty Ltd (paclitaxel ebewe)
Australian Paclitaxel Manufacturer	Fresenius Kabi Australia Pty Limited
	(paclitaxel Kabi)
Australian Paclitaxel Manufacturer	Teva Pharma Australia Pty Limited
	(paclitaxin)
Australian Government	Public Benefits Scheme
International Insurance agencies	Insurance Companies

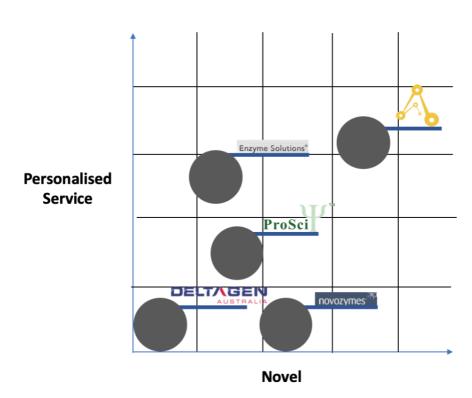




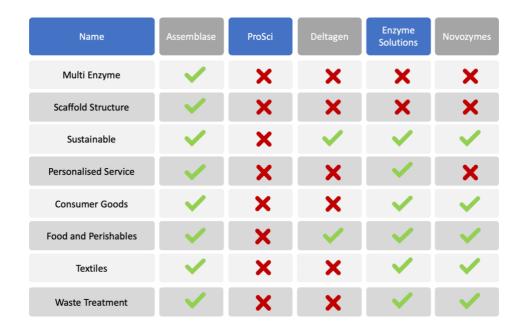


# **Competitors**

Assemblase Pty Ltd is the only company in Australia, as well as globally, that offers a commercially available protein scaffold. The Assemblase scaffold allows multiple enzymes to be attached, maintaining a competitive advantage over competition.



Assemblase Pty Ltd offers a personalised and novel service being the only company that offers protein scaffolding. The personalised service ensures customer satisfaction crucial in the enzyme market.









Name	ProSci18	Deltagen19	Enzyme Solutions20	Novozymes21
About	A leader in its field,	Originally producers of	Enzyme Solutions is	The company's focus is the
	ProSci's priority is to	high-grade enzymes for	involved in sales	research, development and
	provide the highest	the wine and brewing	and distribution of	production of industrial
	quality monoclonal,	industry, over the past	Enzymes for many	enzymes, microorganisms,
	polyclonal, and single	two decades Deltagen	industries including	and biopharmaceutical
	domain antibody	has developed a	Baking, Brewing,	ingredients.
	services in the	position as a key	Cleaning, Dairy,	
	industry.	supplier of food	Ethanol, Fruit Juice	
		flavours, colours and	& Olive Oil	
		processing aids to the	Production, Grain	
		food and beverage	Processing,	
		manufacturers of	Nutraceuticals	
		Australia.	Paper, Protein	
			Processing,	
			Specialty Enzymes,	
			Textiles, Waste	
			Treatment & Wine.	
Founded	1998	1983	1997	1925
Strength	Provide a wide array	Provide both enzyme	Provide a highly	Provide a wide range of
	of services and goods	production as well as	personalise service	enzymes across many
	within therapeutics.	distribution and	with education on	industries leveraging long
		packaging services.	how to use the	standing experience.
			enzyme as well as	
			safety requirements	
			and what enzyme is	
			worthwhile	
Weakness	Quite niche in the	Only provides products	An international	Currently not employing
	therapeutics market,	in food and beverage.	presence and	novel scaffolding methods
	predominately		established market	as well as tailored services
	established in the US.		presence have not	due to the size of their
			been established,	customer base.
			resulting in a narrow	
			product range	
			1	







Competitive Profile Matrix											
		Assemblase		ProSci		Deltagen		Enzyme Solutions		Novozymes	
	Weighting	Score	Weighted	Score	Weighted	Score	Weighted	Score	Weighted	Score	Weighted
Brand Reputation	15%	2	0.31	3	0.46	3	0.46	1	0.15	4	0.62
Marketing	15%	3	0.46	1	0.15	1	0.15	1	0.15	4	0.62
Flexbility	15%	4	0.62	2	0.31	2	0.31	4	0.62	3	0.46
Tailored Service	15%	4	0.62	2	0.31	2	0.31	4	0.62	1	0.15
Product Range	8%	4	0.62	4	0.62	4	0.62	4	0.62	3	0.23
<b>Broad Customer Base</b>	8%	3	0.46	4	0.62	3	0.46	4	0.62	4	0.31
Domestic Reach	15%	4	0.62	2	0.31	2	0.31	3	0.46	4	0.62
International Reach	8%	1	0.15	4	0.62	1	0.15	1	0.15	4	0.31
Total	100%		3.85		3.38		2.77		3.38		3.31

### Value Chain / Supply Chain

Assemblase Pty Ltd will utilise a soft entrance strategy into the Australian market which will ensure that processes are fully optimised before heavily marketing and distributing goods. Through optimising processes whilst working with initial clients, Assemblase Pty Ltd ensures that it mitigates financial losses and any risk associated with the production.

There are six steps involved in the supply chain, allowing the Assemblase scaffold to go from Assemblase Pty Ltd to client and the overall product to go to the end user.

- 1. The initial step involves client sending either a sequence of their enzyme or an enzyme description that can be sourced to be attached to the Assemblase scaffold.
- 2. The components of Assemblase scaffold will then be produced by the Assemblase team
- 3. The different components will then be sent in a biologically compliant storage device by Assemblase Pty Ltd's distributor.
- 4. The user will then add the Assemblase components to their reaction.
- 5. The Assemblase team will provide information aiding the recovery process prior to bead immobilisation.
- 6. The user can then distribute their product to the end user.









1. Preparing the Enzymes



2. Assembling the Scaffold



3. Distributing Assemblase



6. End Product



5. Recovery



4. Addition to Biochemical Reaction

# **Technology Readiness Plan**

Currently, Assemblase is in the Technology Readiness Level 5 with the aim to be at level 9 by year end 2019.

Technology	Definition
Readiness Level	
TRL 1	Basic Research: Initial scientific research has been conducted in cancer
	market and multi-step enzymatic biochemical reactions.
TRL 2	Applied Research: Practical application of Assemblase to Paclitaxel
	manufacturing process has been identified, elevating sustainability and
	alleviating commercial inefficiencies.
TRL 3	Critical Function or Proof of Concept Established: Applied research
	advances and early stage development of Assemblase scaffold structure
	using mathematical modelling.
TRL 4	Lab Testing/Validation of Alpha Prototype Component/Process:
	Design, development and laboratory testing of Assemblase with results
	suggesting MVP is possible.
TRL 5	Laboratory Testing of Integrated/Semi-Integrated System:
	Laboratory data using native page showing Assemblase has been
	formed.
TRL 6	Prototype System Verified: Assemblase demonstration using FRET as a
	validation method.







TRL 7	Integrated Pilot System Demonstrated: Assemblase demonstration in
	small scale Paclitaxel production.
TRL 8	System Incorporated in Commercial Design: Assemblase completed
	and qualified through test and demonstration of Paclitaxel production in
	scaled up bioreactor.
TRL 9	System Proven and Ready for Full Commercial Deployment:
	Assemblase system proven through successful operations in Paclitaxel
	manufacturing, and ready for full commercial deployment.

#### **Marketing**

Assemblase Pty Ltd will undergo two separate marketing plans which is consistent with the soft launch in Australia. An initial market plan will be constructed based on market analysis, focused on marketing towards Paclitaxel manufacturers. This will allow for process optimisation to occur. The initial method will use direct strategy, going directly to customers.

After Assemblase Pty Ltd has established a presence within Australia, a market strategy composed of both direct and indirect methods will be employed. This will ensure that brand awareness is reached, allowing for expansion into a variety of different market segments. Additionally, an entrance and marketing strategy will be constructed for market integration into international markets.

#### **Packaging**

Assemblase Pty Ltd packaging will be compliant with the requirements of the Office of the Gene Technology Regulator. Upon expansion, packaging will be made to be compliant with the required nation.

#### **Distribution**

Assemblase Pty Ltd will use a third party to distribute the Assemblase scaffold. This distributor will be compliant with the standards set by the Office of the Gene Technology Regulator. The distributor will have offices interstate to ensure domestic expansion is viable. Contracts with international distributors will be used upon international expansion.







# The Finances

#### Revenue



Assemblase Pty Ltd can produce 6x more Paclitaxel, as a result it is assumed Assemblase could gain 20% of the Paclitaxel market due to the F2 classification of the drug. This means that all manufacturers will adopt the Assemblase scaffold as they will risk being outpriced. We have discounted a further 20% of this. Due to transactional noise as well as profit margins, manufacturers will be totalling \$1,780,359 annually. This value is reduced by 10% every year starting in 2022 which is consistent with past pricing providing conservative price estimates. In September 2021 expansion shall occur outside Australia, with the global Paclitaxel market valued at \$200M it is expected

Global Paclitaxel Market that Assemblase Pty Ltd will take up 0.1% of the market.

There will be a yearly increase subject to administration and operational capacity which will reach 1% of the market by 2024.

### **Expenditure**

Assemblase Pty Ltd's major expenditures are research and development. This is to maintain competitive providing a novel

solution that is different from peers in the area. This will total \$204,000 each year increasing by 10% each year from 2022 projected at \$266,205 in 2024. Additionally, cost of goods, legal, travel, and marketing expenses are set to be substantial increasing upon expansion into different markets and product lines.









# Budget

Assemblase Pty Ltd has provide a six, eighteen, and five-year plan to demonstrate funding allocation.

	6 months	12 months	18 months	2 years	5 years
Revenue	0	593,453	1,483,633	2,557,146	120,240,789
Expenses	114,589	428,099	880,607	880,607	108,853,004
Profit	(114,589)	32,909	295,512	656,407	7,026,158

# Six Month Budget

Year	2020	2020	2020	2020	2020	2020
Month	January	February	March	April	May	June
Revenue						
Sales	0	0	0	0	0	0
Total	0	0	0	0	0	0
Six Month Revenue	0					
Expenses						
COGS	0	0	0	0	0	0
Research and Development	16,667	16,667	16,667	16,667	16,667	16,667
Wages	0	0	0	0	0	0
Adminstration	1,667	1,667	1,667	1,667	1,667	1,667
Marketing	0	0	0	0	0	1,667
Distribution	0	0	0	0	0	1,667
Rent	1,667	1,667	1,667	1,667	1,667	1,667
Ultilities	750	750	750	750	750	750
Legal	1,000	1,000	1,000	1,000	1,000	1,000
Interest	0	0	0	0	0	0
Travel	0	0	0	0	0	0
Depreciation	0	0	0	0	0	0
Miscellaneous	500	500	500	500	500	500
Total	0	22,251	22,251	22,251	22,251	25,585
Six Month Expense	114,589	_				
Gross Profit	0	(22,251)	(22,251)	(22,251)	(22,251)	(25,585)
Income Tax	0	0	0	0	0	0
Net Profit	0	(22,251)	(22,251)	(22,251)	(22,251)	(25,585)
Total	(114,589)					







# **Eighteen Month Budget**

Year	2020	2020	2020	2020	2021	2021		
Quarter	1	2	3	4	1	2		
Revenue								
Sales	0	0	148363.28	148363.28	148363.28	148363.28		
Total	0	0	148363.28	148363.28	148363.28	148363.28		
Total Quaterly Revenue	0	0	148363.28	445,090	445,090	445,090		
Expenses								
cogs	0	0	40000	120,000	120,000	120,000		
Research and Development	50001	50001	50001	50001	50001	50001		
Wages	0	0	0	0	0	0		
Adminstration	5001	5001	5001	5001	5001	5001		
Marketing	0	1667	5001	5001	0	0		
Distribution	0	1667	5001	5001	5001	5001		
Rent	5001	5001	5001	5001	5001	5001		
Ultilities	2250	2250	2250	2250	2250	2250		
Legal	3000	3000	3000	3000	4500	4500		
Interest	0	0	0	0	0	0		
Travel	0	0	0	0	3000	3000		
Depreciation	0	0	0	0	0	0		
Miscellaneous	1500	1500	1500	1500	1500	1500		
Total Quarterly Expense	66753	70087	116755	196755	196254	196254		
Gross Profit	(66,753)	(70,087)	31,608	248,335	248,836	248,836		
Income Tax	0	0	12,643	99,334	99,534	99,534		
Net Profit	(66,753)	(70,087)	18,965	149,001	149,302	149,302		
Total	329,729							

# Five Year Budget

Year	2020	2021	2022	2023	2024			
Month	December	December	December	December	December			
Revenue								
Sales	148363.28	231,697	250,194	266,860	300,194			
Total	148,363	231,697	3,002,323	3,202,323	3,602,323			
Yearly Total	593,453	2,780,364	3,002,328	3,202,320	3,602,328			
Expenses								
cogs	40,000	160,000	160,000	160,000	160,000			
Research and Development	16,667	16,667	18,334	20,167	22,184			
Wages	0	20,000	30,000	20,000	20,000			
Adminstration	1,667	1,667	2,500	2,500	2,500			
Marketing	1,667	1,667	1,667	1,667	1,667			
Distribution	1,667	1,667	3,334	6,668	13,336			
Rent	1,667	3,333	3,333	3,333	3,333			
Ultilities	750	1,000	1,000	1,000	1,000			
Legal	1,000	1,500	5,000	5,000	5,000			
Interest	0	0	1,667	1,667	1,667			
Travel	0	1,000	1,500	1,500	1,500			
Depreciation	0	5,000	15,000	20,000	20,000			
Miscellaneous	500	1,500	1,500	1,500	1,500			
Total	65,585	215,001	244,835	245,002	253,687			
Yearly Total	1,024,110	2,715,028	2,938,020	2,940,024	3,044,244			
Gross Profit	(430,657)	65,336	64,308	262,296	558,084			
Income Tax	0	26,134	25,723	104,918	223,234			
Net Profit	(430,657)	39,202	38,585	157,378	334,850			







# **Funding Schedule**

Assemblase Pty Ltd requires a large amount of capital for operations. Through funding, capital expenditure on equipment and R&D will be facilitated. The funding schedule will be accompanied with caveats specific to each round ensuring a stable cash flow prior to establishing a network of customers.

			Investment		
Round	Who	Amount	to Date	Tranches	Date
	University, government,				
Pre-Seed	accelerator, family and				
	friends	100,000	100,000	Subordinate	H1 2020
Seed A	Venture Capital Fund	2,000,000	2,100,000	Senior	H2 2020
Seed B	institutional	10,000,000	12,100,000	Senior	H1 2022







# The Future

### **Expansion**

Assemblase Pty Ltd upon successful integration into the Paclitaxel market will aim at expanding into applications with therapeutics as well as other biochemical reactions. This will increase the market share whilst mitigating risks associated with a lack of diversification. Additionally, Assemblase Pty Ltd will aim to expand globally with sales planned within the Asia Pacific region upon successful adoption by the Australian market. Assemblase Pty Ltd plans to acquire scientific companies as a means of expansion within Europe and America using these companies as a special vehicle for sales. This strategy aims to reduce cultural fit problems, as well as issues arising from regulation. These strategies will require an extensive due diligence and market analysis and will only be pursued if there is no strain on domestic business within Australia. The extensive expansion stage will require extensive capital expenditure and will therefore only be realised once business in Australian has been extensively established.

### **Vision Statement**

Assemblase Pty Ltd aims to be a business rooted in sustainable practice working on the frontier of innovation. Assemblase will be advocates for ethical scientific practices. Additionally, Assemblase Pty Ltd will be socially responsible, educating and improving public engagement with synthetic biology.

#### **Business Goals**

Assemblase has established short term and long-term goals that will provide the business with direction. These goals have associated timelines which are outlined in the milestone section.

The short-term goals include; optimising the DNA process, signing initials clients, and establishing Assemblase Pty Ltd to have the necessary team that can provide high class products and services.

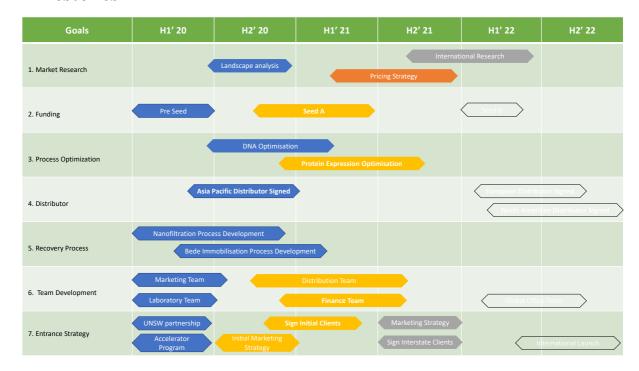






Long term goals include; successfully developing a presence within the Australian marketplace, streamlining the production process, and expanding globally through international distributors.

### **Milestones**





This business plan has been created using the UNSW iGEM team's business plan scaffold. For more information please visit:

https://2019.igem.org/Team:UNSW\_Australia/Collaborations

*In Conjunction with:* 















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