EnGeneIC Limited

Intersection of Precision Oncology and Immune-Oncology.

SUMMARY

Founded: **2001**

Headquarters: **Sydney**

Industry: **Biotech**

Focus: **Cancer Treatment**

Investment Highlights

- 419 patents in 17 families granted globally
- Patent life exceeds 2040 eliminating competition
- Unparalleled safety profile with over **126** end stage patients administered with **1,300** doses of therapy
- High value licencing and partnership model
- Multi-billion dollar exit potential
- Strong management team with prominent board advisors

Capital Raise

Pre-IPO round raising $36.5M at pre-money valuation of $181M. Q4 19/ Q1 2020

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Overview

EnGeneIC is a clinical stage biopharmaceutical company focused on developing a proprietary nanocell platform for the targeted delivery of chemotherapeutics and functional nucleic acids in cancer while stimulating the innate and adaptive immune system.

Following the successful completion and outstanding results obtained in phase 1 trials the company has initiated phase 2A clinical trials for the treatment of brain, lung and pancreatic cancer. Preliminary phase 1 clinical evidence is already indicating that EnGeneIC's treatment demonstrates a substantial improvement over current available therapies and thus if initial phase 2A results are consistent it is expected that EnGeneIC's treatment will be granted 'break through status' to expedite the development and review of the treatment by regulating bodies and fast track the time to commercial use.

With over USD$80M invested into the technology accompanied by years of research and development, EnGeneIC is now at a critical inflection point and presents to investors a unique opportunity to fund the final stages of a revolutionary cancer treatment and capitalize on the significant liquidity events possible in the next two years following successful trial results.

To date all pre-clinical and clinical data (from trials) has been published in peer-reviewed high impact journals such as Cancer Cell, Nature Biotechnology and Lancet Oncology.

The Treatment

EnGeneIC's revolutionary cancer treatment can be explained in three core components:

1. EnGeneIC discovered a bacterially derived, non-living nanocell now termed EDV (EnGeneIC Dream Vector) that can be packaged with a large range of molecular payloads and specifically targeted towards cancer cells using bispecific antibodies that have specificity to proteins found on the surface of the cancer cell. This EDV is an ideal vehicle to deliver a range of different payloads to targeted areas of the body. Furthermore, the extremely stable membrane ensures the payload is fully retained within the nanocell, enabling an unparalleled safety profile.

2. EnGeneIC is able to package super-cytotoxic drugs and siRNA/miRNA's in very high concentrations inside the EDV, without any leakage, and deliver them directly into the cancer cell without effecting healthy cells within the body. This first in class cyto-immunotherapy allows for EnGeneIC's treatment to be far more potent yet far less toxic than other cancer treatments on the market today whilst offering a potential new means for treating drug-resistant cancers. The drug and the antibody can be changed for the type of cancer one wants to treat opening the door for personalized cancer treatments. **To date over 126 end stage patients have been administered with over 1,300 doses of therapy.**

3. Once the tumor killing payload has been delivered EnGeneIC's groundbreaking cancer therapy then stimulates the innate and adaptive immune system to augment anti-tumor efficacy; ultimately training a person's immune system to independently kill cancer cells throughout the entire body.

The production is highly scalable resulting in an extremely low cost of goods to enable affordable access to cancer treatments in markets such as Asia for the first time in history. The treatment can be freeze dried with no loss of activity to accommodate streamlined shipping and distribution.

EDV technology is the only technology reported so far that achieves;

- Direct tumor cell killing
- Does not harm normal cells
- Stimulates the innate immune system and the adaptive immune system to dramatically augment anti-tumor efficacy

Timeline

Innovative mechanism of action combines precision therapy with immunotherapy redefining cancer treatment	
Customized Targeted Payload:	The nanocell platform first creates an immunogenic tumor microenvironment via the delivery of cytotoxic agents (drugs or siRNA/miRNAs) directly to the tumor cells where the payload is released intracellularly.
Innate Immune System Activation:	Dying tumor cells and uptake of the nanocell platform by phagocytic cells of the immune system in the liver, spleen and lymph nodes then stimulate the innate immune system towards an antitumor phenotype, by activating M1 macrophages, anti-tumor NK cells and facilitating dendritic cell activation and maturation.
Adaptive Immune System Response:	Lastly, the body produces an adaptive response in which tumor specific cytotoxic CD8+ T-cells increase, Treg cells in the tumor decrease, activation of dendritic cells and iNKT cells

Program	Phase 1 Completed	Phase 2A	Comments
First-in-Man (Several Cancers) (Melbourne)	→		Determined maximal tolerated dose. Demonstrated safety with minimal to no toxic side effects. Despite patients being end-stage, 10 out of 22 patients achieved stable disease after 1st treatment cycle and showed increased overall survival. One lung cancer patient survived an additional two years.
End-stage Mesothelioma Trial (Sydney)	→		First trial in the world delivering microRNA into thoracic cancer. Showed safety with minimal to no toxic side effects. 69% patients derived clinical benefit. Median overall survival reached 41 weeks instead of historical 6 to 8 weeks. One patient achieved near complete remission.
Child Platform Trial (end-stage neurological tumors) (Sydney)	→		Showed safety with minimal to no toxic side effects. Two of the 8 children with DIPG achieved stable disease and survived over 100 weeks.
Recurrent Glioblastoma Trial (Melbourne)	→		14 patient study. Median overall survival of 10 months, compared to 4 months with standard of care; 3 patients survived > 2 years
Recurrent Glioblastoma (USA)	→		One patient achieved highly significant tumor reduction and is alive after 2 years. Story reported by CBS TV report (USA)
Compassionate Case Study (end-stage pancreatic tumor) (Sydney)	→		A dramatic anti-tumor efficacy response was observed with prolonged overall survival and no toxicity. The patient received 45 repeat doses.
Designer Platform (Several Cancers) (Melbourne)		⇢	Phase I completed. Showed safety. One bladder cancer patient achieved complete elimination of the tumor in the bladder. Expansion Phase (10 more patients) to commence Q3, 2019
Pancreatic Cancer patients (Melbourne & Sydney)		⇢	Commenced March 2019. Two more sites likely to commence, Q3, 2019
Non-Small Cell Lung Cancer & Mesothelioma patients (Sydney and Perth)		⇢	Expect commencement Q3, 2019 based on timing of funding
Glioblastoma (brain cancer) patients (USA)		⇢	Expect trial to commence Q1, 2020 based on timing of funding

The Results

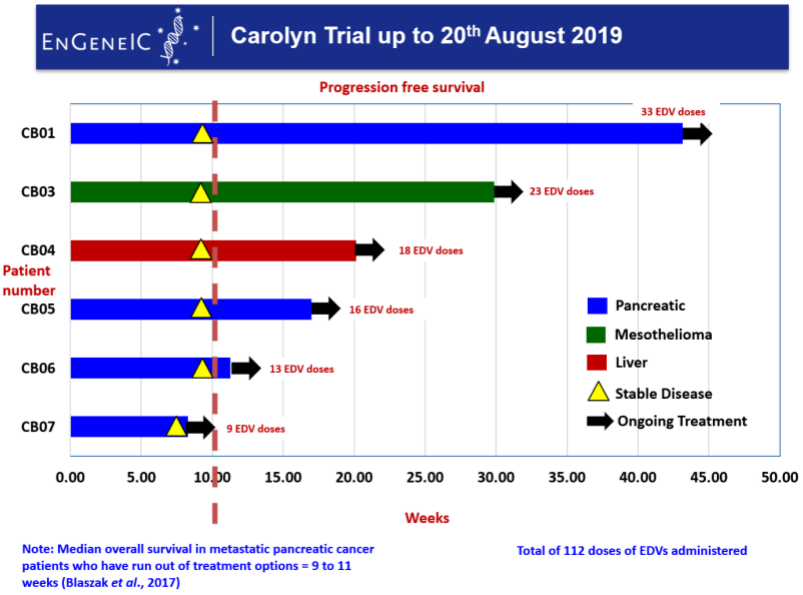
Described below are some of the results obtained from the Phase 1 clinical trials as listed above.

End-stage Glioblastoma (fatal form of brain cancer) patient

- In the Phase I trial at two major hospitals in USA, one male patient (Lenox Hill Hospital, New York) with recurrent glioblastoma had partial dysfunction of lower limbs due to tumor impinging on critical leg movement functions.
- After 1st cycle of the nanocell platform with 7 doses, patient's MRI scan showed over 50% reduction in tumor size and patient's movement functions returned.
- Immune profile also showed increase in professional tumor antigen presenting cells and CD8+ anti-tumor T cells. This story was televised by CBS TV (USA). In 2017, US FDA granted EnGeneIC "Orphan Drug Status" for the EDV-therapeutic for treatment of glioblastoma.

Pancreatic and All-comers Trial – Interim Promising Data

In the recently commenced pancreatic cancer trial which also has an all comers arm, (shown in Product pipeline above), the interim result is shown in the figure below. We currently have 4 end-stage pancreatic cancer, one liver cancer and one mesothelioma patients and the dramatic result is that all of them have their tumors halted with several tumor spots disappearing. One pancreatic cancer patient is out to 43 weeks which is the same as that which was achieved in the compassionate case pancreatic cancer patient. It is to be noted that end-stage pancreatic cancer patients median survival time is around 10 weeks from when they run out of treatment options. The mesothelioma patient is 86 years old and he too has done remarkably well on the EDV treatment.



Capital Requirements

EnGeneIC is currently issuing a $3M Convertible Note bearing a 20% discount to the upcoming $36.5M pre-IPO round to fast track the commencement of the Phase 2A trials and accommodate patients on waitlists as soon as possible. Over the next two years, EnGeneIC aims to accomplish the following milestones:

- Raise $36.5 million as a pre-IPO round of fund raising.
- Commence three to four Phase 2A clinical trials in serious unmet oncology needs such as;
    - End-stage Pancreatic cancer: Sydney & Melbourne hospitals
    - Non-Small Cell Lung cancer (NSCLC): Perth & Sydney hospitals
    - Mesothelioma: Perth & Sydney hospitals

  - Recurrent glioblastoma: Lenox Hill (New York) & Johns Hopkins (Baltimore) hospitals
  - One other cancer to be identified from results in our All Comers clinical trial
- Continue with our All Comers clinical trial to identify which cancers are responding best to EDV therapeutics.
- Global Intellectual Property (IP) protection.
- Secure one or more licensing deals with major pharmaceutical firm(s)
- cGMP-like manufacturing of EDVs for clinical trials.
- Proceed with IPO strategy on the NASDAQ. IPO as soon as possible, ideally Q1/Q2, 2021.

EnGeneIC has a highly-competent team of senior executives, staff and professional advisers with the skills and experience necessary to achieve the above milestones.

Exit Strategy

An investment in EnGeneIC is well positioned to take advantage of one of three major liquidity events available to the breakthrough biotech firm.

Public listing via IPO

Presently EnGeneIC are targeting an IPO on the NASDAQ as early as Q1/Q2 2021. Comparable IPO's would predict a multi-billion dollar market valuation. EnGeneIC are currently in discussion with JP Morgan as financial council and underwriter for this process.

Company	IPO Date	Market Cap at IPO	Description
BridgeBio Pharma	June 26, 2019	USD$2.05B	Genetic disease therapies
Adaptive Biotechnologies	June 27, 2019	USD$5B	Immunotherarpy

Licensing deal with major pharmaceutical firm

EnGeneIC's focus is to secure one or more licensing deals with major pharmaceutical firm(s) at the earliest indication of success in the phase 2A trials since this brings in substantial revenue (usually in hundreds of millions of dollars in upfront and early milestone payments). Discussions are already underway with some of the world's biggest pharmaceutical firms who have initiated due diligence on the technology in preparation for success in these clinical trials. Below are some recent licensing deals with other pre-clinical biotech companies at similar valuations to EnGeneIC:

Licensor & Licencsee	Business	Market Cap at time of deal	Total deal value (ex royalites)	Upfront payment to biotech	Milestone Payments	Royalties Paid
Mersus NV & Incyte	Antibody Platform	$220M	$2.9B	$120M + $80M in equity	$350M per program for 8 programs	Yes
Five Prime Therapeutics & Bristol Myers	Antibody Platform	$198M	$1.7B	$40M + $20M in equity	$1.39B	Yes
Zymeworks & J&J	Protein Therapeutics	$342M	$1.45B	$50M	$282M in development mile-stones & $1.12B in commercial	Yes

Acquisition

Recent acquisitions of biotech firms by pharmaceutical firms include Spark and Peloton Therapeutics. Both firms were at the conclusion of their Phase 2 trials and preparing for an IPO before they were acquired.

Company	Acquisition Announcement	Price	Acquired by	Description
Spark therapeutics	February 25, 2019	USD$4.8B	Roche	Spark Therapeutics is focused on the development of gene therapy.
Peloton Therapeutics	May 21, 2019	USD$2.3B	Merck	Peloton Therapeutics is a biotech company involved in discovering and developing novel drugs for cancer treatments.