Elsius Inc.

Elsius, Inc. is seeking equity funding of 5 million US dollars to bring an ECMO (Extra Corporeal Membrane Oxygenator) system to the market, set up production for worldwide distribution and hire key personnel to execute the business plan. The funding can be executed in different installments to enable the company to start operations with as little as 500,000 dollars raised and have the possibility of bringing a product to market and become the target of an acquisition with as little as 1.5 million (which will stretch the timeline and force the company into outsourcing production). Given the management success in raising raise tens of millions of dollars throughout their careers in government funds in the US, Canada and Europe we are confident that any investor money will be leveraged with government non-dilutive funding. ROI is projected to be 15 to 30 times capital at two to five years from date of investment. It has to be noted that lately there is renewed interest from investors in this technology, evidenced by the fact three companies just raised substantial capital for ECMO systems: Haemovent (6 million Euro), A-Lung (12 million USD) and TandemLife (undisclosed amount, unofficially 16 million USD) all of those companies' products are inferior to Elsius'.

Business summary

Elsius will produce and commercialize worldwide an ECMO system that addresses the shortcomings of current clinical systems that are not optimal for patient recovery and cost containment, ultimately resulting in a higher number of lives saved, shorter hospitalization times and finally lower costs to healthcare systems worldwide. The Elsius system is based on a compact, integrated device design that leverages a proprietary biocompatible coating (EBS) specifically developed for ECLS (Extra Corporeal Life Support) applications, that in particular reduces the inflammatory response associated with the procedure and reduces the need for systemic blood thinners[1]. ECMO is a very complex lifesaving technology that provides circulatory and respiratory support to very sick patients experiencing some kind of circulatory or respiratory failures due to a range of clinical conditions including premature birth, congenital defects, influenza complications (increasingly), COPD, ARDS, severe trauma from battlefields or serious accidents. It can also be used to keep donor's organs perfused after death or recondition and preserve them for transplants purposes (a growing concern for transplant doctors).

Present status

The product has been developed for the better part of ten years to pre-certification status thanks to approximately 16 million dollar of mixed public and private funds and will be ready for market in about a year. The company has been incorporated in Alberta (Canada) under the name Elsius Biomedical Inc. and the core management team has been assembled.

Competitive advantage

The Elsius system has three distinct advantages compared to current market leaders:

- The system is integrated into a single unit (while pump and oxygenator are separated in competing systems.
- The blood pump and blood oxygenator are designed specifically for ECMO applications instead of being an adaptation of Extra corporeal circulation devices form Cardiac Surgery.
- The EBS coating is the most advanced by far on the market and reduces significantly hemolysis (a measure of blood cells damage), inflammatory response and coagulation (blood clotting)

[1] Johnson, G., Curry, B., Cahalan, L., Prater, R., Biggerstaff, J., Hussain, A., ... & Cahalan, P. (2013). Effects of surface-bound and intravenously administered heparin on cell-surface interactions: inflammation and coagulation. *Perfusion*, *28*(3), 263-271.

IP (Intellectual Property)

Elsius owns or has licensed to it, all the relevant patents for the system and is actively pursuing any additional possible IP stemming from the last phases of the development. Currently we are involved in a grant for a magnetically levitating pump with the MIT (Massachusetts Institute of Technology) as partner.

Five years' development

Elsius will finalize the last details of the product (design freeze for mass production) and get the necessary clinical certifications within the first two years of operations. European CE marking will be pursued first (with clinical trials in Germany, Spain and Italy and certification by TUV Germany) followed by FDA approval via a 510K process utilizing clinical data gathered in Europe. Successful completion of FDA and CE certification should significantly streamline other regulatory certifications such as those from Canada Health, Japanese, Brazilian and Chinese health ministries. The company will commence worldwide product commercialization from year three at the latest and expects to generate sufficient revenue to achieve breakeven the same year. A worldwide sales network comprised of direct sales and distributorships will assure sales growth.

Sales model

The ECMO system is comprised of two components, a state of the art touchscreen electronic controller or console and a disposable pump-oxygenator.
Consoles are currently priced between 50,000 and 135,000 USD and the disposable oxygenator at 15,000 USD, consoles can be leased and/or bought outright while the oxygenators are sold usually in bulk since the hospitals need to have a certain amount of them ready for use in case of emergency patients' spikes.
To gain acceptance for the system, key opinion leaders, perfusionists and hospital administrators will be educated to the benefits of the Elsius system and will serve as ambassadors and authors in the medical literature. Elsius is currently recruiting top professionals in the field for its scientific and medical advisory board.

Target market

The market for ECMO is currently about 50,000 patients a year in Europe and the US plus another 30,000 worldwide. The market is dominated by the German company Maquet (owned by Swedish conglomerate Getinge), however their product is approximately 25 years old and technologically stagnant. Lately there is a strong trend to using ECMO in expanded pathologies partly due to requirements of an aging population, the emergence of pandemics and the increased recognition of ECMO's effectiveness in saving lives. If this new markets materialize like the trends suggest we are looking at a 5 to 8 billion dollar per year Total Available Market (TAM) with projections of 1.5 M cases per year in ten year (a 20 billion per year market). There is also a very strong interest from emergency and first responders in having an ECMO system as standard equipment on emergency vehicles as evidenced by ongoing clinical studies[2].
ECMO devices are sold to hospitals or healthcare systems directly after being approved by the doctors and perfusionists involved in the relevant care, the buying decision is taken after reviewing clinical data, seeing the device in use and listening to opinion makers that have already used it. It has to be noted that the main driver of cost for ECMO (estimated at 200,000 to 600,000 USD per patient[3]), is not the cost of the devices (about 2% to 4%) but that of the personnel (ECMO patients need to be monitored 24/7), which enables ECMO devices to retain an exceptional profit margin.

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[2] Dr. Brian Grunau, St Paul Hospital, Vancouver, BC, Canada https://clinicaltrials.gov/ct2/show/NCT02832752

[3] Mishra, Vinod, et al. "Cost of ECMO, Oslo, Norway." European Journal of Cardio-Thoracic Surgery 37.2 (2010): 339-342.

Financial projections

Existing ECMO market + total available market (TAM)

	Year 1	Year 2	Year 3	Year 4	Year 5
Revenues	0	0	$11,638,404	$43,993,151	$96,657,738
COGS	0	0	$2,661,376	$9,207,425	$19,975,157
Gross margin	0	0	$8,977,028	$34,785,726	$76,682,581
Profit %	0	0	42.54%	58.23%	62.16%
EBITDA	-1,936,200	-1,252,400	$4,950,728.06	$25,619,326.31	$60,079,701.39
Mkt penetration	N/A	N/A	0.81% existing 0.13% TAM	3.08% existing 0.62% TAM	6.9% existing 1.58% TAM
Employees	5	7	12	19	30

Management team

The management team brings more than 70 years of oxygenator development expertise coupled with 50 years of C level management experience, Mr. Biglioli, the CEO and founder, in particular is at his 14th start up company.
All the members on the team have successfully developed, certified and brought to market class III products and are all well known in the cardiac devices and blood oxygenation devices space. Additional resources with previous work experience with management members have been contacted and are eager to join the team at a later date as needed in particular to cover positions in Quality Assurance/Regulatory Affairs, production and business development.

Exit strategy/ROI

Elsius expects to become the target for an acquisition from the moment a certified product with nominal sales is achieved, that should happen as soon as after a year and a half after closing the seed round. Numerous contacts have been already initiated with leading medical devices groups that showed interest in seriously considering an acquisition as soon as the product is certified; currently companies in this field sell for 5 to 10 times revenues. Given the projected revenue stream it could also just continue operations and start distributing dividends to shareholders or possibly go public. Projections show a return on investment between 15 and 30 times capital invested possibly from year 3.

Conclusion

For all the aforementioned reasons Elsius represents a rare opportunity to invest in a company that provides the potential for both an exceptional return on investment and the promise of positively impact the lives of thousands of patients desperate for improved ECLS therapies. What makes Elsius exceptional in the biomedical field is the fact that it has a very complex technology practically developed, a market which is growing with the potential of explosive growth and a management team that has done this before and will take the product to the market and start generating revenue in two years. The two main obstacles that usually impede investment in medical devices companies: time to market and R&D costs, have basically been solved given the amount of government money already invested in technology development and the experience of the management team with very similar products.

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