



## Non-Confidential Executive Summary

### Elsius Biomedical Inc.

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#### Business Summary:

- Company's purpose/mission.

Elsius wants to bring to the market an ECMO (ExtraCorporeal Membrane Oxygenator) system that is better than what is actually the standard of care, is transportable for emergency use, allows better patient outcomes and requires less time in the hospital thus significantly cutting costs.

- Company's overall strategy and objectives.

The company has validated the technology in pre-clinical lab testing (up to tests with human blood), animal tests settings and the technology received \$16M USD in government funds, those funds were tied to performance milestones. The system is ready for human clinical trials and certification by the relevant authorities. It will perform first in men in Europe (Germany) and get CE mark approval through TUV. Concurrently will get FDA approval through a 510K process. At that point, it is likely it will become the target for an acquisition (this is the current model in the medical devices industry), if this doesn't materialize, it will pursue organic growth and expand the line of product aggressively.

#### Customer Problem:

- Problems the Elsius system solves.

The two main issues in ECMO are portability/flexibility and negative impact on blood.

The first makes the technology impractical for use outside the Intensive Care Unit (ICU), while the second forces doctors to medicate patients heavily, in particular using heavy doses of blood thinners, that have severe side effects. In addition, it forces them to use extremely expensive drugs.

- Why customers will pay for Elsius' system.

Elsius' product is portable, so it can be used in a wider number of applications, especially in emergency situations. It also allows doctors to reduce the use of blood thinners significantly. This allows better outcomes for patients, allowing them to stay less in the ICU and in the hospital in general. This will significantly abate ECMO providers costs, since the main costs driver for ECMO is the cost of the personnel monitoring patients 24/7, the cost of drugs and the ICU ward operating costs.

#### Product/Services:

- Elsius system main features and benefits.

There are three distinct benefits over the current competition. First, the blood pump and the oxygenator are integrated into a single compact unit, unlike the competition that has the two units separated. Second, the whole system has been developed with ECMO in mind from the beginning and it's not an adaptation of extracorporeal circulation technology used in cardiac surgery, meaning that blood flows, gas exchanges and biocompatibility are vastly optimized for ECMO specific applications. Third, all the blood contacting surfaces in our device are treated with a proprietary coating that makes them more similar to the inside of the human blood vessels. This reduces significantly the three main adverse effects on blood, which are: Hemolysis (or a measure of the damage done to blood cells), inflammatory response and coagulation, effectively reducing the need for blood thinners.

- Intellectual property position.

The company has a full global license of three relevant patents related to the device and the biocompatible coating. It has also trade secrets on the composition of the chemicals used for the coating and the method used to apply them, in addition to specialized knowledge on how to manufacture the device (like the oxygenator fiber weaving patterns and machinery, for example)

- Environmental and regulatory issues.

The device is a Class II so it will need regulatory approvals to be sold. We are planning on concurrently applying for the European CE mark and the FDA approval. In Europe it will require between 15 and 20 patients and about three months to get CE mark and in the US no patients (but maybe clinical data from Europe will help) and 90 days through the 510K process (the predicate device is the corX from Cardiovention, a company that went bankrupt in 2003).

#### Target Market:

- Current and addressable market(s).

ECMO was developed about 25 years ago as a support therapy for premature babies, which is a very limited market with very little upside potential. About ten years ago, during the big flu pandemics (SARS, avian and swine flu), doctors started experimenting with ECMO on adult patients with promising results; from there, given the success of ECMO in treating a host of cardiovascular and

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respiratory issues, physicians started using ECMO more and more widely, from COPD to post cardiac surgery, to emergency situations (drownings, fumes inhalations, heart attacks, etc.), a trend that is in accelerated expansion as of today. The market at the moment is about \$1.5B USD worldwide, divided roughly equally between Europe, the US and the rest of the world, it's in constant strong growth due to the expansion of ECMO able wards and ECMO trained personnel, new indications and an aging population. It is being pushed aggressively in the emergency market with the long-term aim of making ECMO a standard of care for first responders. This will push the market to about \$7B USD in 5 years and \$20B USD in about 10 years. Those projections seem to be validated lately by the infusion of capital that is starting to be invested in ECMO companies and technologies. A-Lung, a competitor with an inferior product that addresses a niche of the ecmo market (ECCOR) just raised \$66M USD, Fresenius, the biggest dialysis company in the world, just bought an ECMO company (Medos AG) and Livanova just acquired for \$250M USD TandemLife. The market is dominated by a German company (Maquet) which has a stagnant product and apparently no intention on upgrading it, creating an optimal environment for a company with a better product.

#### **Customers:**

- Customer base.

Doctors that will prescribe ECMO are Intensivists, Cardiac Surgeons, Pneumologists, ER doctors, Interventional Cardiologists, Transplant Doctors, Pediatric Surgeons and Resuscitationalists. Perfusionists will be the operators of the system, hospitals and health authorities will be the ones paying for the system (except in jurisdictions like China, where the patient will most likely pay directly).

#### **Sales/Marketing Strategy:**

- Market strategy.

The product is already reimbursed worldwide (with DRG and CPT codes assigned) so we will address those wards where ECMO is already used and that are internationally recognized, at first, while participating in pivotal studies, if possible, for new fields like emergency medicine.

- Market share capture strategy.

We will demonstrate in reference ECMO centers that our device is not only better than the competition but has the critical advantage of enabling doctors to reduce the use of blood thinners in patients, obtaining better outcomes, reducing the time in the hospital thus allowing more capacity and enabling doctors to treat patients earlier. This will reduce significantly ECMO costs for hospitals.

- Market percentage.

About 1% after two years and up to 7 % at 5 years

- Channels of distribution.

Through distributors in Europe, at the beginning using existing contacts of the management team and direct in the US at the start in reference "champion" centers, followed by strategic partnerships with sales networks in a second time, probably GPOs, IDNs and RPCs, like Premier and/or Vizient.

#### **Business Model:**

- Revenue generation.

The product is comprised of two parts, a disposable part, called cartridge and a fixed part, called controller or console. Each ECMO patient uses on average between 2 and 7 disposable cartridges, those are sold for about \$15K USD to hospitals and provide a significant margin over COGS (Cost of Goods Sold). Disposable ancillary products, like cannulae and tubing packs, in a second phase will add to the recurring revenue. Hospitals that like and use the product will be required to keep stock and replenish them regularly, the same is also valid for ambulances and emergency vehicles.

- Burn rate.

Right now, we have about a \$50K USD per year burn rate, it will jump to about \$100K USD per month for the next two years in the pre revenue phase and then it will be offset by revenues with a breakeven that is projected in year three.

#### **Competitors:**

- Competition breakdown.

The main competitor is Maquet of Germany with about 85% of the market, followed by some legacy players like Medtronic, Livanova and Terumo, with small percentages. There is also a cohort of new companies trying to gain market share and/or trying to develop new products with negligible market share positions (Hemovent, A-Lung, TandemLife). Interestingly Fresenius, the biggest dialysis company in the world, has just acquired an ECMO company (XENIOS-MEDOS). In last minute news, Livanova just acquired TandemLife, additionally consolidating the market, which now has very few independent players left (we are the one with the best product by far).

#### **Corporate Advisors (if any):**

Dr. Ken Parhar (Calgary)  
Dr. Joe Bellezzo (San Diego)  
Dr. Brian Grunau (Vancouver)  
Prof Fabiana Rossi (Milan-IT)  
Prof Paolo Biglioli (retired, Italy)  
Prof Hans Wendel (Germany)  
Dr. Mark Gartner (Pittsburgh)  
Dr Patrick Cahalan (Florida)  
Dr. Ahn Nguyen (Chicago)

#### **Capital spent:**

~\$16M USD government grants for R&D  
\$1.5M private capital

#### **Capital Seeking :**

\$5M USD

#### **Use(s) of funding:**

Design freeze  
ISO certification  
Clinical validation (EU)  
FDA approval (510K)  
Manufacturing  
Marketing and Sales

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- Competitive analysis.

Price will be the same as competitors, as much as possible, but with a better device, the real game changer will be the proprietary coating that allows doctors to reduce blood thinners (up to 90% in our lab tests with human blood) and shorten the time in the ICU, significantly reducing the costs to the hospital, given that personnel and drugs are the two biggest cost drivers in ECMO therapy.

It has to be noted that no competitor has an integrated device on the market (Hemovent is the only one developing one, but is pneumatically driven, so regulatory could be complex) and no one has a biocompatible coating even remotely as performing as ours. Our console/driver (the fixed part) is also extremely portable, ergonomic and easy to use (it was developed with extensive input from practitioners)

**Competitive Advantage:**

- What makes Elsius company different?

We have the R&D already performed, resulting in a significant de-risking in terms of money and time, we have an extremely experienced team both in terms of blood oxygenators and start up experience, we have “been there and done it” before, we have brought oxygenators to market from the design phase, going through all the steps necessary and we understand the unique challenges of the biomedical start up environment, both in terms of regulatory, time and resources. We feel that Elsius has the pieces in place to execute the business plan and bring our product to market successfully, managing to create substantial returns to shareholders and substantial benefits to stakeholders

- Elsius competitive advantage(s).

Experience of the team and a product that is revolutionary in terms of how to better patients’ outcomes. The key advantage is the fact that the Elsius system will NOT require practitioners (doctors and perfusionists, the technicians that actually operate the ECMO machines) to learn new procedures and hospitals to change the way ECMO is currently reimbursed. At the same time, providing better outcomes (saving more lives) and less time in the ICU will translate into substantial benefits for stakeholders, culminating in less costs to hospitals, healthcare systems and society in general.

**Management Team:**

- Background, experience, education, past performance, start-up history, investors, etc.

The CEO has 14 startup companies on his resume in the Aerospace, biomedical (mostly cardiovascular), environmental and IT fields, some are still operating, some were successes, some were not, a lot was learned. All the rest of the team has extensive experience in medical devices and specifically in blood oxygenation. All have start up background where they held senior management positions, in such a heavily regulated field the “been there, done that” quality of the team is essential.

- Why this is the right team for this venture?

For the aforementioned reasons plus the fact that they have previously all worked in team with the CEO during their career, so as a team they are already tested. Some of the team members currently hold positions in other ventures but all of them manifested a willingness to be hired full time when the moment requires. The only position that is not currently covered is VP of Sales and Marketing but we are evaluating already some strong candidates.

We think that we have people to cover all the key aspects of a biomedical startup: management, operations, regulatory/QA, clinical, manufacturing, sales and marketing, financial.

We have also a very strong clinical and scientific advisory board comprised of internationally renowned experts in their relative fields (one cardiac surgeon, one resuscitationalist, one perfusionist, two ER doctors, one ex FDA official, three experts in oxygenation and in biocompatible coatings), we are looking to expand it and are evaluating candidacies.

**Goals:**

- What is your company seeking in terms of funding?

In this stage, we are closing our seed A funding round of \$5 million USD at a pre money evaluation of \$12M USD, this is justified by the fact that the company has invested about \$16M USD in R&D. We feel this could be our only round given the ability and track record of the team (more than \$40M raised) to leverage private money with government money (abundant right now in Canada).

Financials (\$000 CDN)	2018 (projected)	2019 (projected)	2020 (projected)	2021 (projected)	2022 (projected)
Revenues	0	0	\$ 20,237,067	\$ 60,758,016	\$ 119,188,449
Expenditures	\$ 2,480,485	\$ 2,766,075	\$ 11,052,527	\$ 24,177,241	\$ 44,645,789
Net	(\$ 2,480,485)	(\$ 2,766,075)	\$ 9,184 540	\$ 36,580,775	\$ 74,542,660