



Executive Summary

Business – Stem Sel[®] Srl is an academic spinoff company participated by AlmaCube Srl, the incubator of the University of Bologna and Unindustria. It is based on the development, engineering, manufacturing, and commercialization at relatively “low scale” of the instrument **Celector[®]** (and related disposables), currently at a prototype phase. This product is based on an innovative and patented technology for the **tag-less separation and selection of living cells**, in particular **human stem cells** from adult tissues, such as “discarded” tissue (e.g. placenta, umbilical cord blood or lipoaspirate). Celector[®] will be sold for a totally **non-invasive** characterization, quality control, and selection of stem cells for cell therapy applications in **Regenerative Medicine**.

Stem Sel[®] Srl cooperates with opinion leaders in cell preservation and manipulation, such as the worldwide excellence Rizzoli Orthopaedic Institute (IOR), Bologna, Italy. The opinion leaders that collaborate with Stem Sel contribute to finalization of the Celector[®] development towards most mature applications of cell therapy. These applications have been chosen among those capable to give an answer to most emerging needs in the field of cell therapy. The opinion leaders have already expressed a very positive judgment on the key role of Celector[®], which they consider as a revolutionary technology when compared to current competitors/analogues. The Spinner Program of the Emilia-Romagna Region supported the business idea and early business planning of Stem Sel. Stem Sel won the StartCup 2013 Edition 2012, the business plan competition between high-tech business projects of the Emilia-Romagna Region. Stem Sel led first among 52 projects selected by a panel of expert entrepreneurs and investors. Stem Sel was awarded with the UK Trade Investment's UK-IT Entrepreneur Award 2012, and it also entered the European phase of the Intel Business Challenge 2012.

Market – It has been esteemed by online sources that in 2014 the market of technologies and equipment for cell therapy will reach 400 M\$ in US, and 1000M\$ worldwide. By the end 2016 it is expected to rise up to 800 M\$ in US, and 2500 M\$ worldwide. Nevertheless, still few players are present in this market. Potential clients for a first version of Celector[®] are R&D labs of research centers of (a) companies that collect and store stem cells for transplants (cell banks), or of (b) companies producing stem cells-based products for cell therapy (cell and tissue engineering factories). These clients develop new applications based on stem cells, particularly multipotent stem cells such as mesenchymal stem cells (MSCs). MSCs currently are most promising stem cells for clinical applications: about 400 cell factories are sponsoring many of the thousands MSC-based clinical trials in the world.

Competitiveness – Compared to the market benchmark, you can then highlight the following innovative aspects of Celector[®]:

1. **Exclusive application:** the only instrument on the market able to really select multipotent stem cells (e.g. MSCs) without immunomarkers and no stress.
2. **No handling/manipulation:** cells not only are selected without immunolabeling, but also without any contact with the separation device: the cells are simply suspended / diluted in a physiological buffer solution (e.g. phosphate buffer, PBS).
3. **Easy-to-use:** before being introduced into Celector[®] the desired number of cells, it may be only necessary a single, low-field centrifugation step. It is not necessary the immunolabeling process, which usually takes at least 2 hours. Injection of the cells occurs via an automatic injection system easy-to-use.



Celector® also has the following advantages: (1) lower investment for instruments, (2) lower costs of operation and maintenance (3) disposable device of cell fractionation, (4) full preservation of cell viability, (5) lower operation times.

Intellectual property - Celector® is based on a technology patented in Italy (no. IT1371772) and in USA and Canada (no. 8263359 US en. CA2649234). Patents are property of the University of Bologna, with exclusive license issued to Stem Sel® for the entire duration of the patent. Stem Sel® has also a patent pending submitted in August 2014 (VI2414A000314) for the fluidic device that implements the technology already patented, ensuring high productivity and cell recovery, which are basic requirements for the future development of the instrumental version for the clinical use. In August 2015 the patent pending has been extended under PCT (PCT/IB2015/056195).

Product development – Three units of Celector® in "Alpha prototype version" are present to date, with related consumables, to be installed at opinion leaders' labs. This is to identify and develop dedicated protocols to address potential customers. In confidential documentation of Stem Sel®, available after an NDA contract, are shown technical characteristics and the prototyping plan. Results and competitive advantages are also explained in the documentation.

Engineering, industrialization, and industrial production of the ready-to-market Celector® will be largely outsourced. The technical solutions will be chosen based on the certification for biomedical equipment, even if the use of Celector® does not necessarily require this certification. This will however allow transferring the same solutions to the variants of Celector® for applications where it is in fact required its use as a medical device, for which this certification will be strictly necessary.

Team - Stem Sel® is currently made by founding members, by AlmaCube Srl incubator, and by private investors shareholders.

The Stem Sel® founders are academic researchers with previous business experience, with years of collaboration in academic research in the technology and instrumental methods in the chemical-bioanalytical field: **Barbara Roda** (CTO), associate Professor of Bioanalytical Chemistry; **Pierluigi Reschiglian** (CEO), full Professor of Bioanalytical Chemistry; **Andrea Zattoni** (CFO), associate Professor in Bioanalytical Chemistry; **Kristel Martinelli**, PhD student in Chemistry.

AlmaCube Srl is one of the two Italian academic incubators, and also a private company for profit. It is participated by University of Bologna and Unindustria Bologna.

Highly trained advisors have joined the Stem Sel® team, giving their experience in the management and operational aspects: Eng. **Luca Sereni** and Eng. **Francesco Bianchini**. Recently, Stem Sel® has started a collaboration with Dr. **Maria Luisa Nolli**, Biologist and the former CEO of biotech company and cell factory Areta International Srl, the current CEO of NCNBio Srl, and member of the directive board of Assobiotech Italy and AFI. To support the technical and scientific activities, Stem Sel® has also set up collaborations with **Marco Vaglivello**, Mechanical Eng. (Product Manager), **Silvia Zia**, PhD in Biosciences (R&D Scientist), **Ilaria Vigliotta**, MSc in Medical Biotechnology (Product Specialist), **Martina Rossi**, PhD in Biotechnology (R&D Scientist), and Fabio Gnudi, El. Eng. (SW&HW Developer).



Eco-fin plan

Achieved funds: a total of about 1M €, distributed as follow:

- Financing of debt capital through a loan guaranteed by the UNINDUSTRIA Bologna, issued by CARISBO (20k €) to address another debt capital of 20k € issue by CARISBO. The second loan was in July 2014, with an amortization plan of 4 years with monthly rates, while the UNINDUSTRIA fund has a 36 months plan and is available from January 2015.
- Financing of debt capital through a bank loan, which is guaranteed by the National Guarantee Fund to support The "Innovative StartUp" fund, issued by CARISBO, Bologna, Italy. Gross financing of 190k € in cash from July 2015 with an amortization plan of 8 years with monthly rates.
- Funding POR "Innovative Start-Up" project already granted by the Region of Emilia Romagna. By July 2016 Stem Sel® will support internal R&D, prototyping and engineering steps with industrial partners for an amount of 190k €, that will be partly (115 k€) reimbursed by the region ER in the final balance by late 2017.
- Two-run VC funding from Investors members and Investors Fund, to support R&D, prototyping, engineering, industrialization, certification and production of Celector® till time-to-market. With the last rate in June 2016, these funding will reach 600k €.

Requested funds:

- Phase 2 of the European Project H2020-SMEINST-1-2014, with a budget request of 1.5 M€. Application will be presented on April 2016.
- An amount of 1.5 M€ is expected to follow the business development over the ready-to-market phase, for the (1) amplification of Celector® 1 market, and (2) develop later versions for diagnostics and clinics. This investment will be sought between VCs and/or industrial partners.
- The relevant turnover is figured out as follow:

Years	Instrumentation		Disposables		Service and training		Total
	Quantity	Price (€)	Quantity	Price (€)	Quantity	Price (€)	Turnover (€)
1							
2	20	35.000	1400	500	10	3000	1.430.000
3	30	35.000	2000	500	15	3000	2.095.000

Exit strategy - Stem Sel exit strategy preferentially looks for a trade sale of the majority stake of shares to a corporate player operating in the market of cellular technologies (strategic partner) and/or to private equity, corporate VC investors.