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# Ai Mediq S.A.

## Company overview

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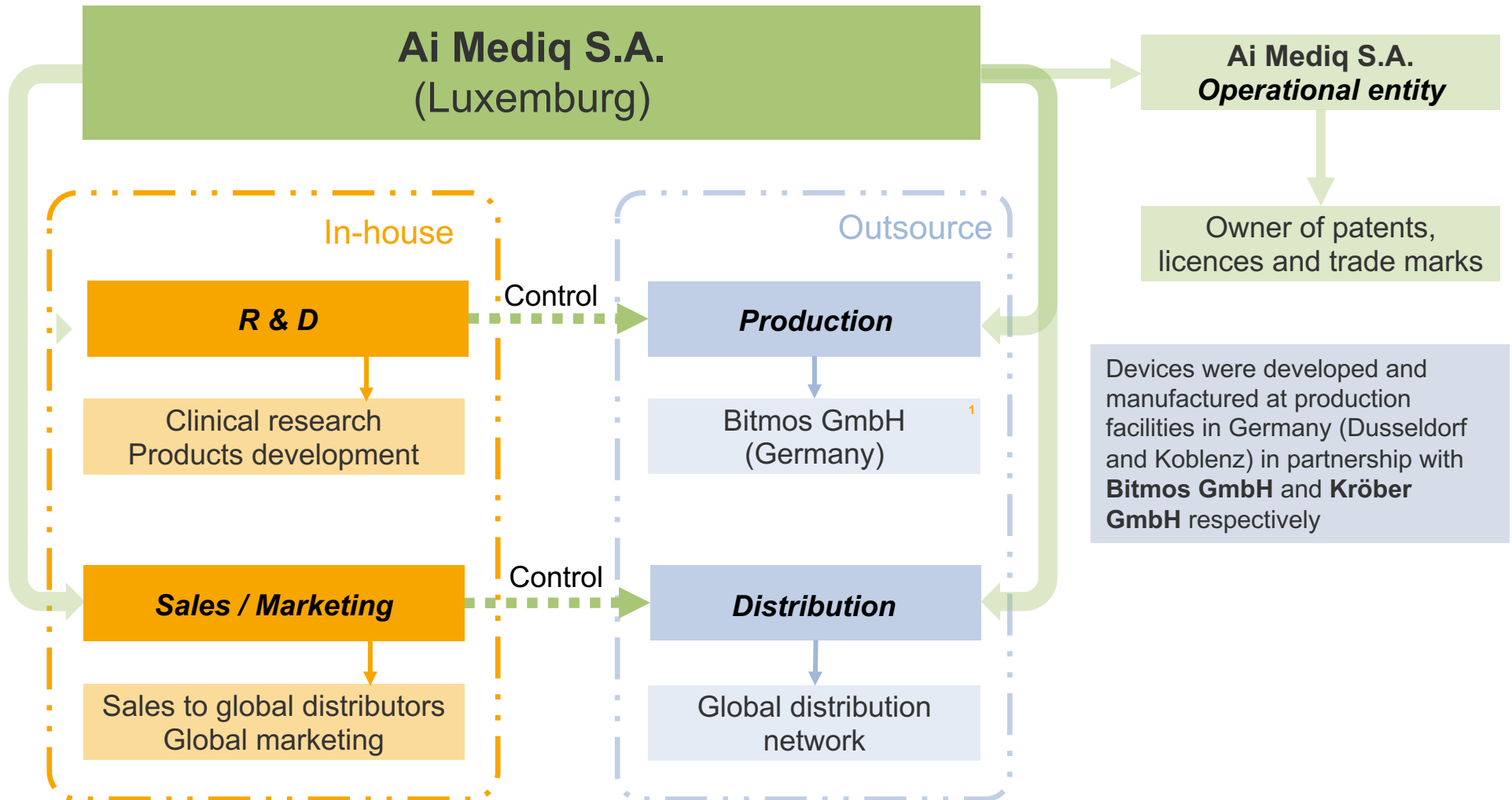
# About the Company



- Ai Mediq S.A. is a **BioMedical Technology company**, headquarters in Luxembourg.
- The company is focusing on **development** of therapeutic solutions based on individual cell protection mechanisms management following the concept of personalized medicine.
- Company's **core research direction** is **hypoxia** (related to highly metabolically active tissues – heart, brain etc.) and its effects on human body under different conditions.
- In 2014 Ai Mediq® has developed the first in the world medical device that can provide Interval Hypoxic Hyperoxic Treatments (IHHT®) with immediate biological feedback SRT® (Self-Regulated Treatment) technology - **ReOxy**.
- In 2016, the Company successfully completed CE marking process of the ReOxy device as the new type of medical device.
- Overall investment into research, development and industrial production establishment amounts to €5 m.
- ReOxy approved by TUV Rheinland for professional use by healthcare facilities in treatment of cardiac patients.
- The **current business model** of the Company is **sales of ReOxy devices** via regionally exclusive distributors.

# About Company

## Ai Mediq Group Structure



ReOxy is a new medical device providing a treatment method which uses reduced oxygen gas mixtures, that leads to more efficient transport and utilization of O<sub>2</sub> in body tissues



# Business Idea

## Background

- **Ai Mediq S.A.** was established with the aim to **commercialize the idea of application** of positive effects of short-term episodes of hypoxia in different areas of medicine
- The therapeutical potential of dosed hypoxia was evaluated during multiple clinical trials
- The most recent clinical trial have demonstrated the evidence of dosed hypoxia efficacy in cardiac patients including elderly individuals

### Problems/Needs

- There were **no known means** to create state of controlled hypoxia in human body **that would be safe** for various patient and age groups while being capable of launching intra-cellular adaptation mechanisms.
- There was **no mechanism** to reach the treatment effect of hypoxia dose and algorithm to calculate such a dose.

### Ai Mediq is the first in the world to develop

- **Way to dose a hypoxic load** based on response of human body to inhalation of gaseous mixture with reduced oxygen
- **Algorithm** for calculation of **individual therapeutic dose**
- **New device** to facilitate the interval hypoxic therapy method involving the biological feed-back with **automatic calculation** of individual treatment hypoxia dose

**ReOxy® is the only device for Hypoxic Treatment that is approved as a medical device for professional use by healthcare facilities in treatment of cardiac patients**

**Ai Mediq is a global pioneer in implementation of non-pharmacological hypoxia-management treatment method in different spheres of medicine**

### Current application - Cardiac Rehabilitation

*(ReOxy intended use – improvement of tolerance to physical load in Coronary Artery Disease patient)*

**Cardiac Rehabilitation (CR)** programs **reduce mortality**, morbidity, unplanned hospital admissions, quality of life. CR programs are currently recommended for all individuals with CVD, with Class I recommendation in international guidelines.

The pool of patients eligible for CR is thus steadily increasing, but ...

**CR market unmet needs: only about 30 % percent of eligible patients participate in CR programs**

**ReOxy treatment solutions**

Challenge 1

The key component of CR is physical exercise, but the enrollment rates suffer due to presence of contraindications and limitations (obesity, orthopedic problems, severe concomitant diseases, elderly patients).

Solution 1

ReOxy treatment has been shown to be as effective as physical exercise without performing the physical exercises *per se* and thus without such limitations.

Challenge 2

Despite the demonstrated cost-effectiveness of existing CR programs, participation and compliance rates of European patients are low due to geographical distance and transport issues, local shortages in resources, incomplete insurance coverage.

Solution 2

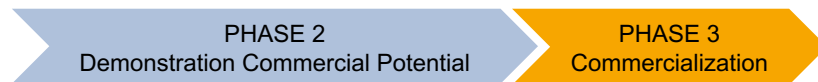
Development of a portable device for CR in environmental context of patient's home.

### ■ Project 1 Commercialization of current ReOxy device



The new approach in **cardiac rehabilitation** using innovative personalised therapeutic method effective in patients with limited physical exercise ability

### ■ Later Stage – TRL 7- 8



Demonstration of economic value of new method in Rehabilitation as part of Reimbursement Strategy (EU)

- Providing proof of performance of ReOxy treatment in Rehabilitation Programme
- Performing of a health technology assessment and cost-effectiveness analysis
- Finalising of regulatory proceedings for extension of CE-marking for application of the ReOxy device in Rehab Pr

### ■ KOLs

- Prof. R. Pedretti, Prof. M Volterrani, Italy
- Prof. J Niebauer, M.Burtcher, Austria
- Prof. S Stoerk, Germany/ Prof. J Cleland, UK

### ■ Project 2 Development of new portable IHHT device for home use

An innovative non-invasive home-used medical device for improving physical capacity without exercise training in cardiac patients through repeated hypoxia-based intervention

### ■ Early Stage – TRL 5 - 6



Development of home-based version of ReOxy to provide a self-help program for patients who may not be able to repeatedly attend a hospital-based program in a convenient way. **New innovation technology** of gas separation.

Development of New business model for **New market (Homecare Market)**

Regulatory proceedings for obtaining of CE-marking for application of the ReOxy device in Rehab Programme

## Planning Research Projects: Hypoxic Preconditioning

### Extension of Intended Use for ReOxy: Hypoxic Preconditioning in the preoperative preparation of cardiac patients/ pre-acclimatization of cardiac patients

#### Phase 1 Activities (COMPLETED) - Feasibility of concept/ Risk assessment

- Pilot clinical trial to provide proof of performance of a new method of cardioprotection – Hypoxic Preconditioning

#### Results of clinical trial\*

- Statistically significant decreased mean level of Troponin I in the IHHT group on the day after surgery. Values of lactate are significantly different after surgery
- Trend of decrease in the number of paroxysmal atrial fibrillation in the perioperative period in the IHHT group compared with the control group; 2 cases of ventricular fibrillation (5%) were seen in the control group only.

\* results delivered during ESC 2017 Congress in Barcelona «Intermittent hypoxic hyperoxic training as a new method of cardioprotection during coronary artery bypass surgery»

#### KOLs:

Prof. Massimo Piepoli, Italy  
 Prof. Hermann Brugger, Italy  
 Prof. J Cleland, UK  
 Prof. Prof. J Niebauer, Austria

#### Phase 2 Activities - Demonstration of the clinical and economic value of the new treatment method

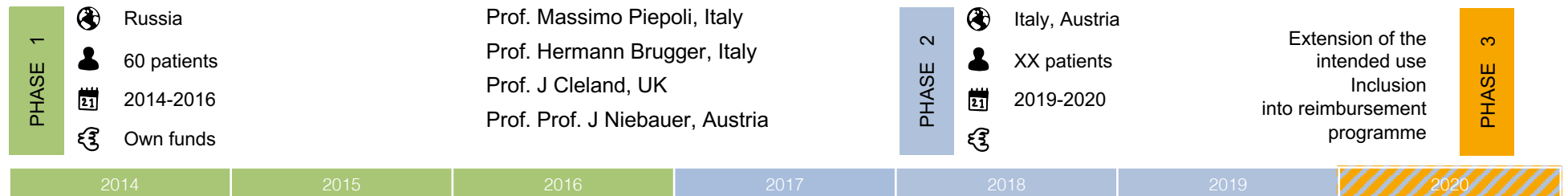
- Clinical trials for large scale validation
- Market access

#### Objectives:

- Provision of proof of performance of ReOxy in patients subjected to major cardiac surgeries on the large scale
- Performing of a health technology assessment and cost-effectiveness analysis to strengthen the business case for the ReOxy treatment in preoperative period
- Finalizing of regulatory proceedings for extension of CE-marking for application of the ReOxy device for preoperative treatment

#### Funding:

- To be determined.
- Local IT / AT grants in coop. w/ EURAC Research (?)





### ReOxy treatment in Rehabilitation after Trauma: Extension of Intended Use for ReOxy with subsequent introduction into reimbursement programme for rehabilitation of trauma patients

#### Preliminary results of experimental and clinical studies

Experimental studies have demonstrated that repeated acute hypoxic sessions have the potential to slow down muscle atrophy and even to stimulate muscle mass accretion when coupled to minimal physical exercise

#### Intermittent hypoxia training in fracture healing

Mol Med Rep 2018 Dec 24.

Xuanwu Hospital, Capital Medical University, Beijing

*The results suggested that IHT and RIPC significantly enhanced fracture healing; however, IHT exhibited superior bone formation and healing effects compared with RIPC.*

Patients with co-morbidities and/or reduced/impaired regenerative processes, namely:

- patients with metabolic disorders (Diabetes Miletus, Obesity), including diabetic foot;
- elderly patients; patients with sarcopenia.

- Horizon 2020 SC1-BHC-07-2019: **Regenerative medicine: from new insights to new applications**
- Proposal Application **Deadline**: 16/04/2019 17:00
- **Project Duration**: Not restricted
- **Project Impact for Ai Mediq**
  - Expansion of market for ReOxy device
  - New staff positions in LUX
  - Strengthening of competence and competitiveness
- Funding rate: 100%
- The Commission considers that proposals requesting a contribution from the EU of between EUR 6 and 8 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

# Intellectual Property

## Unique method and device – Ai Mediq’s registered patents

	No.	Origin / Priority	Description
4 Patents			
	RU2289432 (C1)	RU 2005	Method for increasing of individual non-specific adaptation capabilities using hypoxic-hyperoxic gaseous mixtures
	RU2365384 (C1)	RU 2008	Device for carrying out of complex interval atmospheric diving hypoxic-hyperoxic training
	RU2414250 (C2)	RU 2008	Apparatus for hypoxic and hyperoxic mixtures
	RU2391121 (C1)	RU 2009	Method of non-drug treatment of metabolic syndrome
Pending	PCT/EP2017/060693	PCT/EU 2017	Device and method for improving cognitive and functional abilities by means of hypoxic and hyperoxic gas mixtures
2 Utility Models			
	20 2010 009 330.9	DE 2010	Device for Complex Hypoxic therapy
	20 2012 012 602.4	DE 2012	Apparatus for biologically variable selection of individual courses for interval hypoxia therapy (hypoxic training)
3 Registered Trademarks			
	010659142	OHIM 2012	ReOxy, Nice Class 10, 42, 44
	010659159	OHIM 2012	SRT, Nice Class 10, 42, 44
	010752616	OHIM 2012	IHHT, Nice Class 44.

## Contact information:

Alexey Platonenko  
Chief Executive Officer  
Ai Mediq Group  
19, rue de Bitbourg | L-1273 Luxembourg  
VAT LU24203241  
Business authorisation 10039818 / 1  
Lux: +352 671882215  
UK: +44 7969 608685  
a.platonenko@aimediq.com  
www.aimediq.com

**Ai Mediq S.A.**  
19, Rue de Bitbourg, L-1273,  
Luxembourg  
www.aimediq.com