

MIAS

by ATHESYS[®]

Modular Immune Adsorber System An approach for treating severe sepsis

Executive Summary

What MIAS does

Many studies have identified severe sepsis (blood poisoning) as one of the great medical challenges of our time. Worldwide, about 1 million treatments are administered annually, with 80,000 patients being treated in Germany alone. The mortality rate associated with subject affliction is alarmingly high.

After several years of basic research, a new therapeutical treatment called *Modular Immune Adsorber System (MIAS)* has been developed. In the pilot study, treatment was given to patients suffering from severe sepsis. Medical state stabilized considerably. This indicates that in Germany alone, over 25,000 lives could be saved every year.

The new method has already been used with great success and has won a number of international awards (Abel-Rowntree Turner Award, Roger Bone Award). Amongst specialists, MIAS is considered a pioneering and exemplary development in Scientific Journals (Shock, Vol. 28, No 4, pp. 418-425, 2007).

How MIAS works

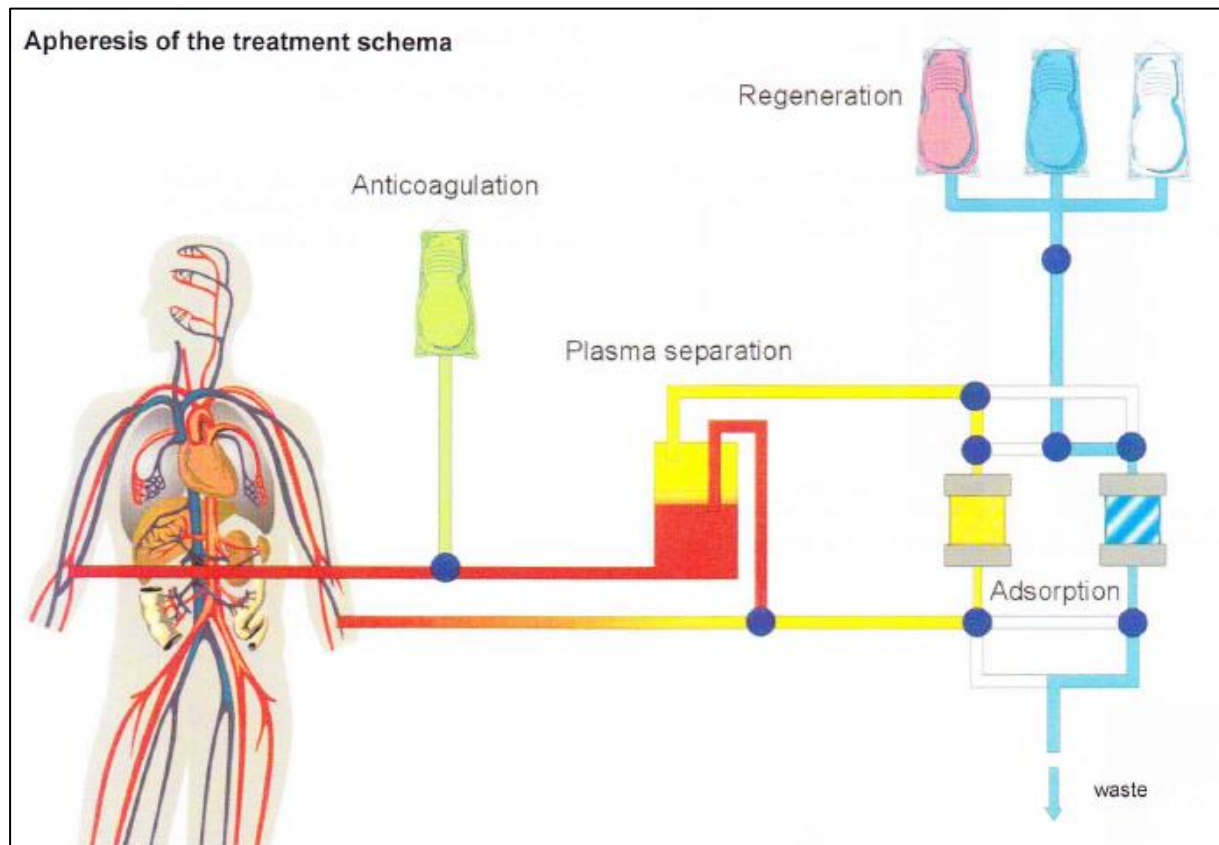
Despite the use of antibiotics and intensive-care medicine in modern therapy, the mortality rate for sepsis is still alarmingly high and a major motivating factor behind the intensive international research to find new methods for treatment.

The new MIAS approach is based on the perception that the body's own mediators play a vital role in the pathological process of the development of sepsis. A medical evaluation has been carried out by the Medical University of Vienna (AKH). Charité Berlin and the University of Tübingen, partners of high scientific reputation, are also participating .

Using specific immune adsorption in an extracorporeal circuit, Interleukin-6 (IL-6), complement factor C5a and Lipopolysaccharide (LPS) were removed from the blood plasma of patients suffering from severe sepsis both with and without immune paralysis. In the pilot study the mortality rate of patients treated with MIAS improved significantly.

MIAS is modelled on dialysis

Treatment with MIAS corresponds to the principle and procedure used in *dialysis*. Outside the body, the patient's blood is cleansed of toxic substances by filtering, and subsequently pumped back into the body again. In the filters, substances that are relevant to sepsis are combined with antibodies.



Market Volume and Potential

With costs totaling EUR 1,700 million, severe sepsis in Germany alone is a major cost factor in intensive care units. The number of patients will continue to increase. Progress in dealing with sepsis has mainly been achieved by improving diagnostics and thus detecting sepsis at an earlier stage. Costs could be cut significantly, creating a win-win-situation for patients, the society, for hospitals using the new product, for the health insurers footing the bill as well as for manufacturers and investors.

| Market Volume & Potential | |
|--|-----------------------------|
| Most frequent causes of death in Germany in 2002 (ICD-10) * | |
| Chronic ischemic heart disease | 94,166 |
| Myocardial infarction | 64,218 |
| Sepsis* | 60,000 |
| Heart failure | 56,955 |
| Stroke | 39,433 |
| Tumors (lung) | 39,105 |
| Tumors (colon) | 20,363 |
| * International Classification of Diseases | |
| Market volume: | Patients with severe sepsis |
| DE | 80,000 |
| EU | 240,000 |
| USA | 240,000 |
| Worldwide | 1,000,000 patients |
| Documented in medical journals, Google | |

Customers and Distribution

Customers for MIAS and for this new product are mainly hospitals specializing in the treatment of severe sepsis. This target group in Germany alone is about 300 hospitals and approximately 80,000 cases per year. Worldwide the annual potential is around one million cases.

The production facilities needed to be built are planned to provide a capacity for 3,000 treatment units (TU) to be expanded up to 10,000 units. Break-even should be reached with approximately 1,000 units per year. It is anticipated that the production capacity will be utilized completely, covering up to 12 % of Germany's requirements.

Deliveries will be made to hospitals. Additionally, contracts with established distributors could be negotiated in order to use their sales structure in the field of intensive medical care.

MIAS is a Class III medical device and not a drug. Therefore, the regulatory requirements are comparatively easy to meet. The costs for clinical studies are also substantially lower as required for pharmaceuticals. With its capacity to save lives, MIAS will quickly become widely accepted and requested.

Economic benefits of MIAS

With patents and edge in research, Athesys AG owns a product that is leading in this market. With its capacity to save lives, one can anticipate that MIAS will rapidly become accepted as the dominant treatment method.

Expenses of hospitals and health insurance companies:

For survivors to date

Treatment with MIAS

| | | |
|------------------|-------------|----------------------------|
| Duration of stay | 18.4 days | 5.0 days |
| Cost per day | 1,162 Euro | 1,162 Euro |
| --- | | 10,000 Euro / cost of MIAS |
| total cost | 21,380 Euro | 15,810 Euro |

Savings for health insurers EUR 5,570

Savings for hospitals EUR 15,570

SWOT Analysis

Strengths

Weaknesses

| | |
|--|--|
| <p>MIAS has been clinically tested and has won international awards. Production has been carried out manually yet. Patent protection in numerous countries. Charité Berlin is a partner with a high reputation.</p> <p>Treatment has no negative side-effects. Up to 25,000 lives could be saved every year in Germany alone. Application cuts costs significantly, creating a win-win-situation for the hospitals using the product, for health insurers footing the bill, and for manufacturers and the society as well.</p> <p>No drug approval necessary.</p> | <p>It will take about 10 calendar quarters before sales can start.</p> <p>Initially the key figures pose a risk.</p> <p>Only a small study has been conducted so far.</p> |
| <p>High market potential.</p> <p>Existing therapies failed.</p> <p>Cost of sepsis treatment is very high.</p> <p>Apheresis is a well known treatment.</p> | <p>Better success through other therapies.</p> <p>Delay in achieving the CE mark.</p> <p>Health insurers and paying agencies are putting pressure on costs.</p> |

Opportunities

Threats

Information to Investors

Athesys AG (a corporation with a registered stock capital of EUR 50,000 and based in Germany) will be producing and manufacturing MIAS. This product has already been used in a pilot study with great success, has won international awards and is considered a pioneering and very promising treating method with registered patents.

To-date, EUR 25 million has been invested in the project. In order to conduct additional clinical studies, support development of pharmaceutical and industrial production and finance market launch an approx. additional EUR 20 million investment is required by Athesys AG.

New investors and joint-venture-partners will benefit from great savings compared to existing methods of treating severe sepsis thanks to a lower mortality rate.

In view of the substantial economic impact, insurance companies as well as the pharmaceutical industry will show interest in lucrative purchase of or participation in Athesys AG.

Equity capital and foreign investment

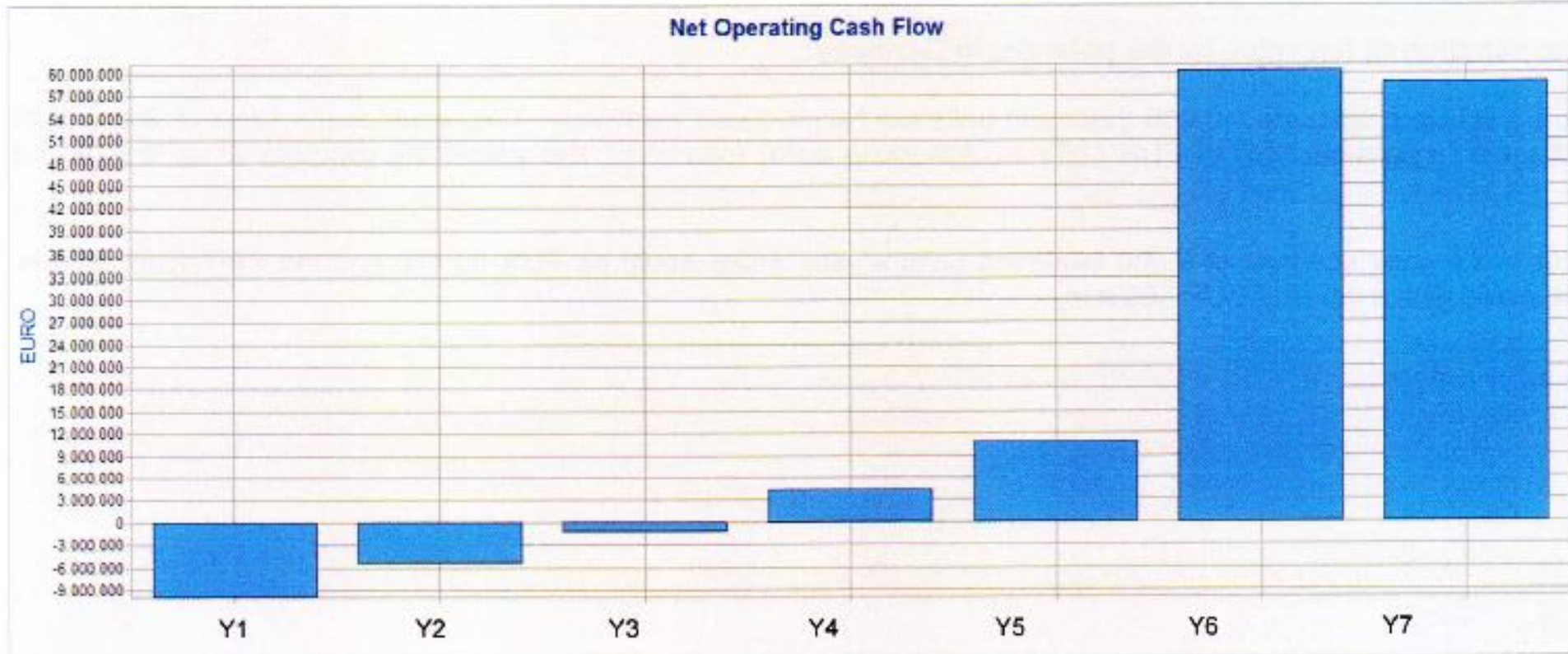
60 percent of Athesys AG are owned by the initiators. The additional capital is to be provided as equity or payment in-kind from additional partners who will receive, for their investments, the equivalent of 40 percent of the shares in Athesys AG.

Athesys AG is quite confident to attract strong market awareness and high profitability rapidly after product launch of MIAS.

Comparable markets reveal that big companies are looking for promising start-ups and are buying emerging companies at good multiples.

Prospects

With regard to Germany, long-term plan is to achieve a market share of >12% with the sale of 10,000 treatment units per year, and to increase sales considerably reflecting cautious budget figures. Initial sale of 3,000 treatment units gives an EBIT of 8 to 10 million Euro.



Athesys AG

| | | |
|--|---|--|
| Company: | Limited company with shares, in Germany Capital Euro 50,000.- Partet in 50.000 Shares | |
| Licensor | Aphera AG | |
| Extent of the license | Licence for production and distribution of the Sepsisadsorbers „MIAS“ within the european economic region as well as in the MENA Region, right for worldwide production | |
| Key persons | Dr. Peter Kruschke Dr. Andreas Hild | Co-inventor Initiator |
| Capital requirement | 20.000.000,-- Euro | |
| Industrial partners | Rational GmbH: Ovalehn: Medicap clinic GmbH: | Verfahrenstechnik Eierproduzent Apheresegerät |
| Involved hospitals | Charité, Berlin 1. Study Universität Tübingen | Prof. Dr. Petra Reinke Prof. Dr. Karin Klingel, Molecular Pathology |
| Review of the implementationplan | TPA Horwath Vienna in co-operation with Allg. Krankenhaus, Wien (AKH) | |
| Distribution | own distribution or thrugh proffessionals like Assid Bonz or others | |
| Regulatory | medical device class III | |
| Time to first sale | 10 quarters from capital injection | |
| Breakeven | 960 sold units / year | |
| Revenue target immediat In the following year | 3,000 units or Euro 22,5 Mio. In year 3 – 4 10,000 units with >Euro 70 Mio. (year 4-5) | |

Athesys AG - Management Team & Contact

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Further Reference

This executive summary is based on documents compiled by Athesys AG (Johann-Strauss-Strasse 6, D-71065 Sindelfingen, Baden-Württemberg, Germany).

A comprehensive medical evaluation has been conducted by Medical University of Vienna, Austria (AKH). The regulatory, organizational and financial evaluation has been accomplished by TPA Horwath European & Technology Consultants, Vienna.

Charité Berlin and the University of Tübingen are participating and partners with high scientific reputation.

Medical evaluation and financial data were updated in 2012 and 2013.