We prove.
You improve
## Content

<table>
<thead>
<tr>
<th>I. Founder and Scientific Officer</th>
<th>02</th>
</tr>
</thead>
<tbody>
<tr>
<td>II. Company Profile</td>
<td>04</td>
</tr>
<tr>
<td>III. Vaccine Department</td>
<td>06</td>
</tr>
<tr>
<td>IV. Our Future Facility</td>
<td>08</td>
</tr>
<tr>
<td>V. Assay Development</td>
<td>10</td>
</tr>
<tr>
<td>VI. Quality</td>
<td>14</td>
</tr>
<tr>
<td>VII. Project Management</td>
<td>18</td>
</tr>
<tr>
<td>VIII. Worldwide Business</td>
<td>19</td>
</tr>
<tr>
<td>IX. VisMederi Group</td>
<td>20</td>
</tr>
<tr>
<td>X. Research Projects</td>
<td>22</td>
</tr>
<tr>
<td>XI. Synergies Partnerships</td>
<td>24</td>
</tr>
<tr>
<td>XII. Economic and Financial Indicators</td>
<td>26</td>
</tr>
<tr>
<td>XIII. Scientific Publication</td>
<td>28</td>
</tr>
</tbody>
</table>
VisMederi provides its clients with comprehensive clinical trial and research project support, from concept to completion, in compliance with the most stringent quality standards.

Page 14

VisMederi offers its clients a large portfolio of qualified and serological assays for pre-clinical and clinical activities.

Page 10

Emanuele Montomoli is the founder and CSO of VisMederi Srl

VisMederi Srl, the innovative Sienese Company established in June 2009 by the Department of Molecular Medicine of the University of Siena. Within a few years, the Company has integrated in the field of Life Sciences and Public Health, gaining the role of a highly qualified and reliable partner at an international level.

Emanuele Montomoli
Founder and Chief Scientific Officer of VisMederi
VisMederi is a globally competent, well-resourced Research and Service Company that assists corporations and the pharmaceutical industry in enhancing public health through the development and optimization of safer and more efficient drugs and vaccines.

VisMederi’s headquarters are located in Siena, Italy, a city with a research tradition extending back to the early 20th century, a center of international excellence in the field of vaccines and Life Sciences, and home to one of the most prestigious universities in Italy. VisMederi conducts and perfects serological tests to evaluate the immunogenicity of vaccines, creates and validates bioanalytical methods and experimental protocols for the release of therapeutic molecules and vaccines in development phases, and performs quality control at the intermediate stages of vaccine production thanks to the considerable scientific expertise and experience of its management and staff.

WHY VisMederi?

01. Competence, skills and expertise

02. Quality

03. Reliability

04. Flexibility, dynamism and speed
VisMederi Laboratories

Strada del Petriccio e Belriguardo 35
53100 Siena – Italy

VisMederi Headquarter

Via Franco Ferrini 53
Loc. Tognazza
53035 Monteriggioni
Siena - Italy
Vismederi constantly undergoes a validation process in accordance with EMA, FDA and PMDA international guidelines, in order to demonstrate the validity, the trustworthiness and robustness of its tests.

All of VisMederi activities are carried out in compliance with the European system of certification:

- UNI EN ISO 9001:2015
- UNI CEI EN ISO/IEC 17025:2005
- UNI EN ISO 15189:2013
- GCLP
- ISO/IEC 27001:2013

Vaccine Department

<table>
<thead>
<tr>
<th>14</th>
<th>Laboratories (1.200 mq)</th>
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</thead>
<tbody>
<tr>
<td>5</td>
<td>Biosafety Level 2</td>
</tr>
<tr>
<td>4</td>
<td>Biosafety Level 2 +</td>
</tr>
<tr>
<td>3</td>
<td>Biosafety Level 3</td>
</tr>
<tr>
<td>2</td>
<td>Cell Culture</td>
</tr>
</tbody>
</table>

**Biological risk category**

- **5** Laboratories
- **4** Laboratories
- **3** Laboratories
- **2** Facilities
Logistic and Samples Storage (1.500 m²)

-20°C  -80°C  LIQUID NITROGEN
Embarking on a new chapter in innovation and scientific excellence, VisMederi proudly announces the construction of a cutting-edge lab facility set to open by the end of 2023. This state-of-the-art structure will spread across an impressive 4000 square meters, fully equipped to propel us into the forefront of biomedical research.
Designed with meticulous attention to detail, our future facility features:

4 Biosafety Level 2 Laboratories
Committed to the highest safety standards, these labs will be the crucible for groundbreaking research.

5 Biosafety Level 2+ Laboratories
Furnished with advanced technology, these spaces allow our scientists to explore further and deeper into life sciences.

2 Cell Culture Facilities
Tailored to foster the delicate art of cell cultivation, offering the perfect environment for pivotal experiments.

2000 Square meters for Logistic and Sample Management
An extensive area, dedicated solely to ensuring the seamless workflow and safeguarding vital samples.

With this new facility, VisMederi continues to lead the industry, transforming vision into reality.
VisMederi offers its clients a large portfolio of serological qualified assays for pre-clinical and clinical activities.

The tests conducted within VisMederi’s facilities are routinely validated and standardized in order to assure high-quality protocols applicable in both clinical trial and research settings. All laboratory experiments are conducted in BSL2, BSL+, and BSL3 environments. Traditional assays for the evaluation of virus vaccine immunogenicity characterize VisMederi’s daily research, but in order to respond effectively to the needs of current and potential partners, the company is continually optimizing and validating serological assays, with an emphasis on innovative platforms. Assays Development at VisMederi is responsible for the design, optimization, and standardization of bioanalytical microbiological, serological, and viral assays and tests related to vaccine immunogenicity evaluation and epidemiological screening.
**SARS-COV2 ASSAY**

- Enzyme-Linked Immunosorbent Assay (ELISA) for IgG, IgM and IgA in serum/plasma samples
- ELISA - Avidity
- Elecsys Cobas (ROCHE) for S and N quantitation
- S-IgA quantitation in mucosal samples
- Neutralization CPE
- Viral Escape Assay
- Neutralization PRNT
- Pseudotypes MN Lentiviral
- Pseudotypes MN VSV
- Analyses of cellular response using cytofluorometry (Intracellular staining – FACS)
- ELISpot
# Assay Development

## NEW EMERGING VIRUSES ASSAYS

<table>
<thead>
<tr>
<th>Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow Fever (17D) PRNT</td>
</tr>
<tr>
<td>Yellow Fever HAI</td>
</tr>
<tr>
<td>Dengue (MN &amp; PRNT)</td>
</tr>
<tr>
<td>Zika (MN &amp; PRNT)</td>
</tr>
<tr>
<td>Mokeypox (MN &amp; ELISA)</td>
</tr>
<tr>
<td>Vaccinia virus (MN &amp; ELISA)</td>
</tr>
<tr>
<td>West Nile (PRNT &amp; MN)</td>
</tr>
<tr>
<td>Lassa Virus (PP &amp; MN)</td>
</tr>
<tr>
<td>Ebola Virus (PP &amp; MN)</td>
</tr>
<tr>
<td>Marburg Virus (PP &amp; MN)</td>
</tr>
<tr>
<td>Rift Valley Virus (PP &amp; MN)</td>
</tr>
</tbody>
</table>
## INFLUENZA & RSV ASSAYS

<table>
<thead>
<tr>
<th>Assay Type</th>
<th>Description</th>
<th>Platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAI</td>
<td>Haemagglutination inhibition assay - FLU</td>
<td></td>
</tr>
<tr>
<td>SRH</td>
<td>Single Radial Haemolysis assay - FLU</td>
<td></td>
</tr>
<tr>
<td>MN</td>
<td>Micro-Neutralization assay – FLU &amp; RSV</td>
<td></td>
</tr>
<tr>
<td>ELISA</td>
<td>IgG/IgM/IgA (HA1, HA &amp; NP) – FLU &amp; RSV</td>
<td></td>
</tr>
<tr>
<td>ELLA</td>
<td>(Anti-Neuraminidasi Ab)</td>
<td></td>
</tr>
<tr>
<td>Lenti-Viral</td>
<td>Pseudotyps</td>
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<tr>
<td>ELISpot</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICS</td>
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</tbody>
</table>

## BACTERIAL ASSAY

<table>
<thead>
<tr>
<th>Assay Type</th>
<th>Description</th>
<th>Platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBA</td>
<td>Serum Bactericidal Assay – SBA &amp; L-SBA</td>
<td></td>
</tr>
<tr>
<td>OPA</td>
<td>OPA Assay</td>
<td></td>
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</table>

## OTHER ASSAYS AND PLATFORMS

<table>
<thead>
<tr>
<th>Assay Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real Time PCR</td>
<td></td>
</tr>
<tr>
<td>LAL Test</td>
<td>(Limulus Amoebocyte Lysate) for endotoxine determination</td>
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<tr>
<td>CYTOF</td>
<td></td>
</tr>
<tr>
<td>Luminex Multiplex Assay</td>
<td></td>
</tr>
<tr>
<td>Mesoscale Platform</td>
<td></td>
</tr>
</tbody>
</table>
Quality

VisMederi has made Quality one of its hallmarks highly recognized and appreciated by national and international customers.

Continuous improvement, data integrity, attention to details and regulatory compliance are driving forces that envelope each internal process and combines together with an intense audit program and with a complete set of procedures to assure full compliance of regulatory standards and ISOs quality requirements.

Certifications and accreditations

The VisMederi Group is recognised worldwide for its excellent certified services. Certifications are considered true quality indicators for customers and represent an effective stimulus for company growth.
VisMederi is UNI EN ISO 9001:2015 certified for its Quality Management System. Quality is defined by the ISO 9001:2015 as the level in which a series of intrinsic characteristics meet the requirements in a process of continual improvement.

VisMederi obtained Accredia’s accreditation as a medical laboratory operating in compliance with UNI EN ISO 15189:2007. The standard specifies requirements concerning the quality and competences in terms of methodologies, scientific, technical and technological, organizational and procedural elements, as well as the specialization of the staff. The management system requirements of ISO 15189 naturally meet the principles of ISO 9001:2008 Quality Management System – Requirements.

EN ISO 27001:2013 is an international standard that provides the requirements of an Information Security Management System – ISMS. The Standard includes people, processes and IT systems by applying a risk-based approach. VisMederi obtained this prestigious certification in 2019 in order to meet the contractual requirements of important customers as well as to improve its skills on data and information security.
People are the most important asset for VisMederi today and for its growth and development tomorrow. The success of VisMederi originates from the human capital investing its own skills and professionalism in this Company: strongly motivated women and men sharing the ideal of the Company, its steady rooting on the territory combined with its international perspective.

Human resources

The workgroup has been increased over the years by highly qualified technical professionals who have recognized VisMederi as a vibrant reality and an opportunity to test and broaden their knowledge. The Business departments collaborate with an Administration Department, a Finance and Management Control Department, a Legal Department, and a Communications Department to coordinate Research activities. Constant with a never-ending growth trend since the beginning of the business, VisMederi has continued to increase its human resources and to stabilize existing jobs, achieving excellence in a perspective of sharing its goals and preserving its values.
The growth of the staff from 2009 to 2023
Our services include scientific, technical, and logistical support for experiment protocol design and evaluation, process monitoring, sample analysis, data elaboration, release of results, and reporting. A team with diverse and complementary expertise allows us to administer projects comprehensively in order to better interpret the requirements and company goals of our clients. VisMederi’s laboratories and research facilities allow for thorough examination of all phases I, II, III, and IV of clinical trial development. In addition, it partners with laboratories, research facilities, and international research centers to develop pre-clinical protocols.

Project Management

VisMederi offers its clients full clinical trial and research project support from concept through completion based on high quality standards.
Worldwide Business
**VISMEDERI HOLDING** is the company that holds a qualified share of the companies that are part of the VisMederi Group. The Group operates in various business areas all related to Research and Innovation in the fields of Public Health, Life Sciences and Biotechnologies and is composed of VisMederi Srl, VisMederi Research Srl, VisMederi Life Sciences Srl, VisMederi Diagnostics, VisMederi Pharma Srl and ETHS Srl – Education and Training for Health Sciences Srl with single shareholder.

www.vismederiholding.com

**VISMEDERI PHARMA** is a pharmaceutical company operating in the field of research, development, production and marketing of pharmaceutical products, vaccines, diagnostics and medical devices.

www.vismederipharma.com
**VISMEDERI RESEARCH** was founded in 2014, and based in Siena, VisMederi Research is VisMederi’s “sister company” that is deputy to performing basic and applied research activities, supporting the development and optimization of new protocols. Among various activities, Vismederi Research handles culturing and storage of various human and animal cell lines; growth and propagation of influenza viruses in the cell and embryonated chicken eggs platforms; production of pseudotyped viral particles along with many assays optimised to be applied in research studies for Influenza and for newly emerging infectious diseases.

www.vismederiresearch.com

**VISMEDERI LIFE SCIENCES** offers professional chemical-physical and microbiological analysis services within the scope of food and environmental self-control procedures through investigation on food, work surfaces, water and soil. It also carries out validation and drafting of HACCP self-control plans, training courses on current regulations, internal and supplier inspections and qualified consultancy.

Today the VisMederi Life Sciences laboratory is able to carry out tests for the detection of Coronavirus on different types of surfaces and in any structure, detecting the presence of SARS COV-2 virus RNA using a Real Time PCR technique.

www.vismederilifesciences.com

**VISMEDERI DIAGNOSTICS** is a private health care facility located in Siena, Italy. The diagnostic section laboratory is responsible for performing clinical tests for the prevention, diagnosis, and monitoring of diseases and infections.

Our goal at Vismederi Diagnostics is to provide citizens and businesses with fast and efficient testing services, using state-of-the-art equipment and specialized personnel. We are accredited and licensed by the Tuscany Region, ensuring that our services meet all necessary standards and regulations.

www.vismederidiagnostics.com

The **FONDAZIONE VISMEDERI** is a non-profit organization which exclusively works in the field of social solidarity, training and scientific research of particular social interest. It aims at improving the global health conditions of humanity by supporting and promoting the knowledge, development and production of new vaccines, especially against neglected diseases, accelerating their introduction for the benefit of the poorest populations and countries.

The VisMederi Foundation promotes and encourages, also through the establishment of Research Centres, initiatives aimed at deepening and disseminating knowledge of these disciplines for the purposes of scientific, social, economic and cultural progress.

www.fondazionevismederi.org
Research Projects

01 PEDVAC-iNTS

The PEDVAC-iNTS project, funded for 4 years by the European Union, within the EDCTP2 - European & Developing Countries Clinical Trial Partnership 2 program, involves international experts from 7 institutions including academies, research institutes, small and medium-sized enterprises (SMEs) and non-profit organizations from Europe and Africa. The research team, coordinated by the Sclavo Vaccines Association of Siena together with the University of Siena, will conduct a phase I / II paediatric study in Ghana, a country where the disease is endemic. The project also aims at strengthening international collaboration, including partners from African countries, to improve disease awareness in resource-limited endemic countries where the disease represents a significant public health burden.

02 FLUuniversal

Influenza has been a major global problem for centuries. Although vaccination can reduce a flu epidemic's health and economic consequences, current vaccines are far from perfect. Many research teams have been working worldwide to create an effective universal flu vaccine, spending hundreds of millions on research and development. Yet, until now, no breakthrough has been achieved. The FLUniversal consortium believes that FLUniversal is not "yet another costly universal influenza project" but a real opportunity to create a genuine universal flu vaccine which will set the new gold standard for rapid and cost-efficient vaccine development. FLUniversal builds on a vaccine technology that already has surmounted key hurdles of novel vaccines (demonstration of safety and robust immunogenicity in humans and manufacturability) and combines these advances with an immunisation strategy proven to drive the immune response to features of influenza viruses that are widely, if not universally, displayed. The FLUniversal consortium aims to develop DeltaFLU as Universal Flu Vaccine that protects against all influenza virus strains.
Inno4Vac

Vaccines are a huge public health achievement, saving an estimated 2.5 million lives every year and protecting millions more from illness and disability. However, developing new vaccines is extremely time consuming, costly and risky; on average it takes over 10 years and costs more than EUR 800 million to bring a vaccine to the market. However, in recent years, researchers in academia and biotech companies have made huge strides in fields such as immunology, big data and artificial intelligence. These advances could potentially speed up the development of new vaccines and make the whole process more efficient.

The aim of Inno4Vac is to harness these advances and incorporate them into the vaccine industry. The project brings together experts in clinical research, immunology, microbiology, systems biology, mathematical models, and regulatory issues.

This diverse team will focus on four key areas. Two areas focus on in silico (i.e., computer-based) tools. The first area uses artificial intelligence, big data analysis and computational modelling to build an open access, cloud-based platform to develop vaccines and assess their efficacy in silico. The second in silico area focuses on developing a modular computational platform to model the manufacture and stability testing of vaccines.

The other two areas focus on lab-based tools. The first will develop new and improved models of certain diseases such as flu that can be used to study vaccine efficacy early in the development process. The other aims at delivering models based on human cells that offer a more reliable view of the level of immune protection a vaccine could offer.

Throughout the project, the partners will develop strategies and roadmaps to ensure that their models meet the needs of medicine regulators and integrate them into vaccine development processes. Ultimately, the models developed by the project should help to make vaccine development both faster and more efficient.

Reference Lab for CEPI: Vismederi has been selected as reference laboratory for CEPI

CEPI establishes a global network of laboratories to centralise assessment of COVID-19 vaccine candidates. Five laboratories initially selected to work together as part of a centralised network to reliably assess and compare immunological responses generated by COVID-19 vaccine candidates. CEPI’s mission is to promote and strengthen public-private collaboration in order to develop, manufacture and stockpile vaccines necessary to respond to emerging infectious diseases and to support vaccine research and development in connection with public health emergencies. In pursuit of this mission CEPI manages a portfolio of vaccines at various stages of development, targeting pathogens selected from the WHO Blueprint list of priority diseases. CEPI also engages in promoting vaccine development more widely for the benefit of global health initiatives.

INDIGO

Despite the availability of flu vaccines for several decades, influenza is still an important disease in both developing and developed countries with annual 500,000 casualties and many more diseased people. Vaccination is the most cost-effective way to control this disease. The aim of the INDIGO is to deliver 1) an affordable seasonal flu vaccine with high efficacy at low cost and possible exploitation within a few years after completion of the project and 2) a further improved flu vaccine concept dealing with technological shortcomings and challenges of wide-spread use.
The synergy with the University of Siena has continued both within the framework of European projects and with the Molecular Epidemiology Research Laboratory directed by Prof. Emanuele Montomoli. Intense collaboration has continued with the Toscana Life Sciences incubator in Siena.

UNIVERSITY OF SIENA

Collaborating to various research projects, the University of Siena is for VisMederi also an important think tank, in the form of PhD studies in business. The Company contributed to a PhD in Life Sciences funding supporting the project. Several researchers have carried out their PhD in VisMederi, helping to enrich the knowledge and skills of the Company. VisMederi has also contributed to various initiatives promoted by the University, from scientific dissemination activities to activities supporting active job search and introduction of high school students to the world of Sciences and Research. VisMederi is also part of the Institute for Global Health that is the natural evolution of the University of Siena’s tradition in science, infectious diseases, its prevention and treatment, vaccines and public health. The IFGH offers internationally recognized programs delivered by global academic and industry leaders in selected areas of global health, equipping program participants with the practical and professional expertise they need to lead the next generation of scientists, researchers, and health practitioners across the globe.
University of Milan

The partnership with the University of Milan started between the first and the second Italian wave of SARS-CoV-2 in 2020. Initially the collaboration was based on the development of new generation of purified proteins synthesized through the Leishmania tarentolae platform. Subsequently the collaboration was strengthened through the development of a new potential mucosal vaccine that uses the Leishmania platform as a carrier for the immunological response. To date, the collaboration continues with several scientific publications in the field of infectious diseases prevention.

FONDAZIONE TOSCANA LIFE SCIENCES

VisMederi has set up its own laboratories in the Bioincubator and has collaborated in science projects promoted by the TLS Foundation with the aim to introduce people to the world of research, science, innovation and business culture.
## Economic and Financial Indicators

### 2018/2023

<table>
<thead>
<tr>
<th>INDEX</th>
<th>2023 - Q2</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Sales</td>
<td>11,173,692</td>
<td>23,075,541</td>
<td>14,439,095</td>
<td>5,982,693</td>
<td>3,662,079</td>
</tr>
<tr>
<td>EBITDA / Net Sales</td>
<td>57,95%</td>
<td>57,79%</td>
<td>40,56%</td>
<td>14,13%</td>
<td>13,13%</td>
</tr>
<tr>
<td>EBIT</td>
<td>6,196,700</td>
<td>12,924,570</td>
<td>5,620,275</td>
<td>845,653</td>
<td>370,517</td>
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<tr>
<td>EBITDA</td>
<td>6,474,751</td>
<td>13,334,852</td>
<td>5,856,681</td>
<td>385,653</td>
<td>481,008</td>
</tr>
<tr>
<td>ROE</td>
<td>95,76%</td>
<td>86,21%</td>
<td>89,88%</td>
<td>37,06%</td>
<td>24,29%</td>
</tr>
<tr>
<td>ROI</td>
<td>40,80%</td>
<td>52,64%</td>
<td>39,78%</td>
<td>10,82%</td>
<td>11,09%</td>
</tr>
<tr>
<td>ROS</td>
<td>55,46%</td>
<td>56,01%</td>
<td>39,82%</td>
<td>11,42%</td>
<td>10,12%</td>
</tr>
<tr>
<td>ROA</td>
<td>108,04%</td>
<td>108,40%</td>
<td>83,73%</td>
<td>16,53%</td>
<td>13,95%</td>
</tr>
<tr>
<td>ROCE</td>
<td>47,08%</td>
<td>79,13%</td>
<td>64,14%</td>
<td>24,73%</td>
<td>14,50%</td>
</tr>
<tr>
<td>Capitalization rate</td>
<td>0,66</td>
<td>0,60</td>
<td>0,46</td>
<td>0,39</td>
<td>0,59</td>
</tr>
<tr>
<td>Operating Profit Margin</td>
<td>55,46%</td>
<td>56,01%</td>
<td>38,92%</td>
<td>11,42%</td>
<td>10,12%</td>
</tr>
<tr>
<td>Normal (OPM)</td>
<td>56,81%</td>
<td>39,54%</td>
<td>28,01%</td>
<td>9,11%</td>
<td>7,77%</td>
</tr>
<tr>
<td>Net Profit Margin (NPM)</td>
<td>34,19%</td>
<td>40,34%</td>
<td>53,84%</td>
<td>60,78%</td>
<td>40,65%</td>
</tr>
<tr>
<td>Debt Ratio</td>
<td>0,52</td>
<td>0,67</td>
<td>1,19</td>
<td>1,55</td>
<td>0,68</td>
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<tr>
<td>Debt to Equity</td>
<td>1,52</td>
<td>1,68</td>
<td>2,17</td>
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<td>1,68</td>
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<td>Leverage</td>
<td>2,92</td>
<td>2,48</td>
<td>1,82</td>
<td>1,65</td>
<td>2,46</td>
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<td>Total Solvency Ratio</td>
<td>8,90</td>
<td>2,78</td>
<td>2,06</td>
<td>1,33</td>
<td>4,25</td>
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<tr>
<td>Current Ratio</td>
<td>8,79</td>
<td>2,74</td>
<td>1,98</td>
<td>1,26</td>
<td>3,80</td>
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<tr>
<td>Acid Test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Economic and Financial Indicators

#### ROE
2023-Q2
- 2022: 86.21%
- 2021: 89.88%
- 2020: 37.06%
- 2019: 24.29%
- 2022-Q2: 95.76%

#### ROI
2023-Q2
- 2022: 52.64%
- 2021: 39.78%
- 2020: 10.82%
- 2019: 11.09%
- 2022-Q2: 40.8%

#### ROS
2023-Q2
- 2022: 52.64%
- 2021: 39.82%
- 2020: 11.42%
- 2019: 10.12%
- 2022-Q2: 55.46%

### Operating Profit Margin Normal (OPM)

<table>
<thead>
<tr>
<th>Year</th>
<th>OPM</th>
</tr>
</thead>
<tbody>
<tr>
<td>2023-Q2</td>
<td>55.46%</td>
</tr>
<tr>
<td>2022</td>
<td>56.01%</td>
</tr>
<tr>
<td>2021</td>
<td>38.92%</td>
</tr>
<tr>
<td>2020</td>
<td>11.42%</td>
</tr>
<tr>
<td>2019</td>
<td>10.12%</td>
</tr>
</tbody>
</table>

#### Key Financials

**2023-Q2**
- Net Sales: 11,173,692
- EBIT: 6,196,700
- EBITDA: 6,474,751

**2019**
- Net Sales: 3,662,079
- EBIT: 370,517
- EBITDA: 481,008
Rectal Administration of Leishmania Cells Elicits a Specific, Th1-Associated IgG2a Response in Mice: New Perspectives for Mucosal Vaccination against Leishmaniasis, after the Repurposing of a Study on an Anti-Viral Vaccine Candidate.

Brand-specific estimates of influenza vaccine effectiveness for the 2021-2022 season in Europe: results from the DRIVE multi-stakeholder study platform.

Memory-like innate response to booster vaccination with MF-59 adjuvanted influenza vaccine in children.

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