Okairos is a clinical stage biopharmaceutical company spun off from Merck, Inc. in 2007 and developing genetic vaccines for major chronic infectious diseases, using its novel proprietary technology. The company’s laboratories are located in Rome and Naples, Italy, and its corporate headquarters are in Basel, Switzerland. It currently has 21 employees. Okairos’ technology platform is centered on the development of new, potent adenovirus vectors, derived from strains isolated from chimpanzees and used to encode and deliver specific antigens. These vectors have several major advantages and hold promise in generating effective immune responses where existing vectors have failed. Okairos’ adenovirus vector platform is being used to generate a pipeline of vaccines against a range of infectious diseases for which there is currently no effective vaccine, as well as for cancer.

Okairos’ vision is to become a major global vaccine developer. The company intends to bring its core vaccine candidates through to the completion of Phase II proof-of-concept trials, and will seek partnerships to support Phase III trials and market its vaccines worldwide. Selected vaccine candidates outside of Okairos’ core areas may be out-licensed at an earlier stage of development.

Okairos’ malaria vaccine has completed a Phase I trial, with excellent safety and immunogenicity data. A Phase II trial was completed in 2011, yielding exciting results.

Okairos is developing both a prophylactic and a therapeutic vaccine for HCV.

The prophylactic vaccine was shown to have a strong safety profile and to be highly immunogenic in a Phase I trial in healthy volunteers. A Phase II trial is scheduled in 2011.

The therapeutic vaccine is currently being tested in chronically infected patients in a Phase Ib trial.

Okairos has several other vaccine candidates in its pipeline that include genetic vaccines against Ebola and Marburg viruses, universal influenza and respiratory syncytial virus (RSV).

Build robust pipeline targeting select indications

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<th>Programme</th>
<th>2010</th>
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<tr>
<td>HCV prophylaxis</td>
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<td>Ph 1</td>
<td>Ph 1b</td>
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<td>Ph 2: combo</td>
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Ebola hemorrhagic fever is one of the most lethal viral diseases. Ebola virus causes massive internal bleeding and has a mortality ranging from 50% to 90%. Ebola outbreaks occur regularly in tropical Africa, and the Ebola virus is a high priority target for the development of a preventative vaccine against bioterrorism attack.

The Okairos vaccine is based on the Ebola glycoprotein and showed 100% efficacy after a single shot in non-human primates and clear superiority in head-to-head comparison with competitor’s genetic vaccine. These results pave the way for fast-track development of the Ebola vaccine.

A new class of cancer vaccine will be developed based on Okairos technology. Okairos’ scientists have obtained excellent results from efficacy studies in relevant preclinical models. Over the past two years, Okairos has demonstrated that its vectors can be developed in compliance with the most stringent regulatory requirements, that they possess strong safety profile and that they produce a highly potent immunogenic response in humans.
Malaria is one of the world’s leading causes of death and illness. 300 million new cases of malaria occur each year, resulting in more than a million deaths. The disease is the single greatest infectious killer of children. Malaria has also become a greater problem in the developed world, as large numbers of tourists travel to regions where malaria is endemic. Candidate vaccines are being developed that provide transient protection in humans. However, despite major efforts, no vaccine yet exists with the strong and sustained response needed to provide long-lasting immunity.

Okairos’ malaria vaccine will be composed of vectors encoding for various antigens specific for the various stages of the parasite. The first antigen being tested is TRAP, which is expressed in the liver stage of the parasite and is common to different strains. A completed Phase I trial showed that the vaccine induced a potent CD8 T-cell response. Similar studies, with excellent immunogenicity results are being carried out in Africa on healthy adults and children.

More recently, encouraging results were obtained in a clinical proof-of-concept Phase IIa efficacy study using Okairos’ vaccine in humans. Similar studies are also being carried out with sporozoite-stage and blood-stage antigens. Ultimately this will lead to the identification of the optimal antigen composition that will be tested in Phase IIb field efficacy trials in endemic areas.

The hepatitis C virus (HCV) chronically affects 170 million people worldwide, with three to four million new cases each year, including 30,000 new cases in the U.S. each year. HCV is the leading cause of chronic liver disease in the world and has been correlated with an increased risk of developing primary hepatocellular carcinoma. No vaccine is yet available against HCV. So far, challenges to the development of an effective prophylactic vaccine have included the ability of the virus to escape antibody immunosurveillance and lack of in-depth study of the immune response in HCV-infected individuals.

Okairos’ scientists have shown that the magnitude of an early T-cell response during acute HCV infection correlates with individuals’ ability to spontaneously clear the virus. Okairos vaccine has been tested in a Phase I dose escalation trial in healthy volunteers where it was shown to have a favourable safety profile, and to induce a very strong T-cell response of much greater magnitude than the T-cell response observed in individuals who spontaneously clear the virus. It has also been shown to provide full protection in pre-clinical experiments in which chimpanzees were first vaccinated, and then challenged with the hepatitis C virus. This vaccine is based on the 2000-amino-acid-long non-structural region of HCV.

A Phase II trial of the prophylactic vaccine is scheduled for 3Q 2011. The therapeutic vaccine is currently being tested in chronically infected patients in several Phase Ib trials.
Okairos is led by Riccardo Cortese, MD, PhD

Okairos’ Chief Executive Officer and co-founder, spent many years at Merck, Inc. coordinating efforts that led to the discovery of several novel anti-viral drugs and vaccines which are now on the market, such as ISENTRESS® or at various stages of clinical development. Dr. Cortese was a founder and the first director of the Gene Expression Program at the European Molecular Biology Laboratory (EMBL) in Heidelberg and is a Professor of Molecular Biology at the Medical School of the University of Naples.

He has published in leading scientific journals including Nature, Science and Cell, on a range of topics in immunology, molecular medicine and drug discovery. Supporting Dr. Cortese is a highly experienced management team with leading expertise in vaccine development.

Alfredo Nicosia, PhD, Chief Scientific Officer and co-founder, was Senior Director of the Viral Diseases Vaccine program at IRBM-Merck, and he was previously a scientist at EMBL and at the Sclavo Research Center, Siena, Italy (now Novartis Vaccines). He has contributed to the development of a number of vaccines.

Stefano Colloca, MD, Senior Director of Vector Development and co-founder, Antonella Folgori, PhD, Director of Immunology and co-founder, Elisa Scarselli, MD, Medical Director and Cinzia Traboni, PhD, Regulatory Affairs, bring extensive experience in the development of viral vectors for gene delivery and in molecular virology and immunology. Finally Tom Woiwode, PhD, is the company’s Chief Operating Officer. Tom brings many years of business development, financial and operational as he was previously the co-founder and Chief Business Officer of Amira, Synosia and Flexion and co-founder and Chief Operating Officer of Versant EuroVentures.

The company has raised €23.2 million in Series A and B financing rounds completed in February 2007 and August 2010 respectively, from the following major venture capital funds: BioMedInvest, Boehringer Ingelheim Venture Fund, Life Sciences Partners, Novartis Venture Fund and Versant Ventures. Okairos has also obtained €18 million in grants from the National Institutes of Health in the US, the European Union, the Medical Research Trust and the Bill and Melinda Gates Foundation for the development and early clinical trials of the HCV, malaria vaccines and universal influenza vaccine.

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