



**VIVALIS AND KAKETSUKEN SIGN TWO COMMERCIAL LICENSE AGREEMENTS TO USE THE EBx<sup>®</sup> PLATFORM FOR THE PRODUCTION OF HUMAN AND VETERINARY VIRAL VACCINES.**

**Nantes (France) & Kumamoto (Japan) - December 17<sup>th</sup>, 2008** – VIVALIS (NYSE Euronext: VLS) and THE CHEMO-SERO-THERAPEUTIC RESEARCH INSTITUTE (KAKETSUKEN) announced today the signature of two commercial licenses to use the Vivalis proprietary EB66<sup>®</sup> cell line, for the production of several veterinary and human vaccines, including Vaccinia virus-based recombinant human vaccines, inactivated and live viral human vaccines.

Vivalis technology offers the possibility to replace the egg-based production process and overcomes many related manufacturing concerns, such as harvesting primary cells from thousands and thousands of chicken embryos or risks of introduction of contaminants. The EB66<sup>®</sup> cell line, derived from duck embryonic stem cells, presents unique industrial and regulatory characteristics: (i) EB66<sup>®</sup> cells display long term genetic stability and immortality; (ii) they can grow in suspension up to high cell densities in serum free medium; (iii) they can be scaled up for growth in large bioreactors for industrial productions; (iv) a biological master file (BMF) describing the history and sanitary status of the cell line is filed at the US Food and Drug Administration (FDA). Vivalis has already demonstrated efficient poxvirus production in 100L stirred tank bioreactor, allowing the production in a single run of 50 000 to 100 000 purified doses of vaccines.

The two licenses trigger up front payment, milestones payments and royalties on net sales. Terms of the agreement were not disclosed.

*"Vivalis is very pleased to enter into this commercial agreement with Kaketsuken, and to pursue the successful R&D collaboration that the two teams have established over the last couple of years. This agreement with Kaketsuken, which is a leading company in the fields both human and animal vaccines in Japan, constitutes an additional and significant industrial endorsement of Vivalis EB66<sup>®</sup> technology, and the large panel of vaccines (recombinant and non-recombinant, live and inactivated human vaccines) included in the agreement further illustrates the broad fields of application of the technology, a unique feature of EB66<sup>®</sup> cell line.*

*With these 2 new commercial licenses, Vivalis has outperformed its 2008 targets with 7 licenses signed in 2008, 4 of them commercial. With a portfolio of 21 licenses (9 research licenses and 12 commercial licenses), the EB66<sup>®</sup> cell line is reinforcing its position as a new standard cell substrate for the manufacturing of biological products. This new agreement confirms the revenue momentum that Vivalis has recorded since Q2 2008."*, said Franck Grimaud, Vivalis CEO.

Dr. Hiroshi Mizokami, PhD, Kaketsuken's Executive Managing Director, stated *"Kaketsuken expects the potential of Vivalis EBx<sup>®</sup> cell technology to effectively and efficiently replicate various human and veterinary viruses"*.

## About recombinant vaccinia vaccines

The use of vaccinia virus as a smallpox vaccine led to the worldwide eradication of smallpox. In the 80's the demonstration that recombinant poxviruses mainly vaccinia virus expressing foreign antigen could be used as live vaccine *in vivo* has opened a new era in vaccine development. Today poxviruses, such as vaccinia viruses (MVA, Lister strains etc...) and avipoxviruses, two distinct poxvirus family members, were demonstrated to be extremely safe and useful recombinant vaccines for both animal and human health. Recombinant avipoxvirus based-vaccines for Animals are already marketed. In Human health, more than 20 different recombinant vaccinia based vaccines are currently under clinical evaluation, two of them being in phase III clinical trials.

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**Next financial press release:  
January 27, 2009, after NYSE Euronext market closing: 2008 annual revenues**

## **About Vivalis ([www.vivalis.com](http://www.vivalis.com))**

VIVALIS (NYSE- Euronext: VLS) is a biopharmaceutical company that provides innovative cell-based solutions to the pharmaceutical industry for the manufacture of vaccines and proteins, and develops drugs for the prevention and treatment of viral diseases. VIVALIS's expertise and intellectual property are exploited in three main areas:

1. The development and manufacturing of vaccines. VIVALIS offers research and commercial licenses for its EB66® cell line, derived from duck embryonic stem cells, to pharmaceutical and biotechnology companies for the production of viral vaccines. Vivalis receives up front, milestones, and royalties on its licensees net sales.
2. The development of production systems for recombinant proteins and monoclonal antibodies. VIVALIS licenses its EB66® cell line for the production of recombinant proteins to biotechnology and pharmaceutical companies. Vivalis receives up front, milestones, and royalties on its licensees net sales.
3. The construction of a portfolio of proprietary products in the area of vaccines and anti-viral molecules (hepatitis C).

Based in Nantes (France), VIVALIS was founded in 1999 by the Grimaud group (1,450 employees), the second largest group worldwide in animal genetic selection. VIVALIS has established numerous partnerships with world leaders in this sector. VIVALIS is a member of the French ATLANTIC BIOTHERAPIES bio-cluster.

VIVALIS  
Compartment C d'Euronext Paris - FR0004056851  
Reuters : VLS.PA – Bloomberg : VLS FP  
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For further information please contact:

**VIVALIS**  
Franck Grimaud,  
CEO  
Phone: +33 (0) 228 07 37 10  
[investors@vivalis.com](mailto:investors@vivalis.com)

Newcap Financial Communication Agency  
Steve Grobet / Emmanuel Huynh  
Phone: +33 (0) 1 44 71 94 91  
[vivalis@newcap.fr](mailto:vivalis@newcap.fr)

**About KAKETSUKEN** ([www.kaketsuken.or.jp](http://www.kaketsuken.or.jp))

KAKETSUKEN is a Juridical Foundation which researches, develops, manufactures and supplies biological products such as vaccines for humans and animals, and blood plasma derivatives. Based in Kumamoto, Japan, the foundation has pursued the preventive medicine fields of microbiology, immunology and serology, towards the improvement of health and hygiene, and is a leading company in the fields of human vaccines, animal vaccines, and blood plasma derivatives respectively in Japan. In the field of human vaccines, Kaketsuken is currently manufacturing more than 10 kinds of vaccines for humans, such as Influenza vaccine, DTaP vaccine, recombinant Hepatitis B vaccine and Hepatitis A vaccine. Kaketsuken is also developing a therapeutic monoclonal antibody for HIV, a cell-cultured Japanese encephalitis vaccine and Influenza vaccine.

For further information please contact:

**KAKETSUKEN**

Corporate Administration Division

Kazuhiro Hamaji

Tel : +81 96 344 1211

[hamaji@kaketsuken.or.jp](mailto:hamaji@kaketsuken.or.jp)