



## **Vivaldi Biosciences Inc. Announces Issuance of US Patent for Influenza Vaccines**

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New York, NY – Vivaldi Biosciences Inc. (Vivaldi), a biotechnology company focused on development of vaccines for influenza, today announced that the United States Patent and Trademark Office has issued US Patent 7,588,768 covering live attenuated influenza vaccines (LAIVs) with modifications to the viral NS1 gene, and methods for producing the vaccines in cell culture systems. This proprietary technology is applicable to rapid development and production of LAIVs against virtually all seasonal and pandemic influenza strains, including novel (swine-origin) H1N1. Vivaldi has exclusive rights to the patented technology and has LAIV candidates in development.

Live attenuated vaccines replicate safely in the recipient without causing disease, providing longer lasting immunity and greater protection than vaccines based on inactivated virus. Vivaldi's LAIV candidates represent the first prospectively designed live virus vaccines. Distinct from live influenza vaccines developed by isolation of temperature-sensitive strains, Vivaldi uses advanced reverse genetics methods to delete a portion of the gene for nonstructural protein 1 (NS1), a virulence factor of the influenza virus. Each LAIV candidate has a single, defined modification that is genetically stable. Vivaldi's LAIVs are expected to produce a potent, durable immune response, with potential for cross-protection against a range of circulating influenza strains.

Vivaldi's LAIVs have a unique mode of action. They stimulate production of interferon, which acts as a natural adjuvant, boosting both antibody and cell-based immunity. Vivaldi's LAIVs thus will be "self-adjuvanted", eliminating the safety and regulatory risks of novel adjuvants, which are integral to many influenza vaccine technologies in development. Vivaldi's LAIVs are being developed as a single-dose nasal spray. Nasal administration is convenient and pain-free, and well-suited for mass immunization. Moreover, LAIVs administered intranasally elicit production of antibodies in the nasal passages, creating a first line of defense at the natural point of entry of circulating influenza viruses.

The recently issued patent is assigned to the Mount Sinai School of Medicine (MSSM) and licensed exclusively to Vivaldi. The patent is part of an intellectual property portfolio from MSSM that includes more than 25 issued patents and numerous patent applications, to which Vivaldi has exclusive rights in the US and major international markets. The licensed MSSM patents cover four major patent families including compositions and methods of production for NS1-modified influenza vaccines, cell-substrate production methods, and assays for discovery of small-molecule inhibitors of NS1 with potential as antiviral drugs.

“We are confident that Vivaldi’s extensive patent estate, combined with its exclusive rights to the use of reverse genetics and plasmid rescue technologies for vaccines with modifications of NS1, will provide our products with long-term market exclusivity,” said Douglass B. Given, MD, PhD, President and CEO of Vivaldi. “This patent is an important component of Vivaldi’s formidable intellectual property portfolio covering specific vaccine candidates and manufacturing techniques licensed from Mount Sinai School of Medicine in New York.”

#### About Vivaldi Biosciences

Vivaldi Biosciences, located in New York City, is developing live attenuated influenza vaccines (LAIVs) by altering the gene for NS1. Unaltered, NS1 allows the influenza virus to evade the host’s defensive interferon response and cause disease. In preclinical studies, Vivaldi’s vaccines induce potent and protective antibody and cellular immune responses to influenza virus, with the potential to provide long-lasting immunity and cross-protection to mismatched influenza strains with a single low-dose immunization via nasal spray. Vivaldi’s initial focus is the development of a seasonal influenza vaccine that provides improved protection for adults age 50 and over. Older adults are among the most vulnerable to influenza and its complications, however, the currently approved and marketed influenza vaccines are either less effective or not approved for this age group. Vivaldi plans to file an Investigational New Drug application and begin clinical trials of its lead LAIV in 2010. Additional information about Vivaldi can be found at [www.vivaldibiosciences.com](http://www.vivaldibiosciences.com).

#### Forward-Looking Statements

To the extent any statements made in this release contain information that is not historical, these statements are essentially forward-looking and are subject to risks and uncertainties, including the difficulty of predicting FDA approvals, acceptance and demand for new vaccines and other pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials, availability of additional intellectual property rights, availability of future financing sources, the regulatory environment and other risks the Company may identify from time to time in the future.

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