

LIGOCYTE®

PHARMACEUTICALS, INC.

LigoCyte Pharmaceuticals, Inc. is a private, biopharmaceutical company focused on the development of innovative vaccine products based on the company's proprietary virus-like particle platform technology. LigoCyte's lead candidate is a vaccine against norovirus, a ubiquitous and prostrating illness that causes over 70,000 hospitalizations in the U.S. per year and 200,000 deaths in children in the developing world annually. The LigoCyte vaccine has achieved proof-of-principle in a live-virus challenge study in healthy adult volunteers. Designed to study the prevention of norovirus acute gastroenteritis, the Phase I/II clinical trial met all of its primary endpoints, including statistically significant reductions in illness and infection. LigoCyte also has novel rotavirus, respiratory syncytial virus and influenza vaccines in preclinical development that have each achieved proof-of-principle in industry-standard models. Incorporated in 1998, LigoCyte has 39 employees and is located in Bozeman, Montana.

OUR FOCUS

LigoCyte's vaccine development programs focus on unmet gastrointestinal and respiratory targets in commercially attractive markets. The company's core expertise is virus-like particle, or VLP, based vaccines. VLP technology presents vaccine antigens in a highly immunogenic, native form for anti-viral protection without the complexity associated with live viruses. Additionally, LigoCyte's VLP platform technology can be rapidly engineered for applications in infectious disease and oncology, to adapt for antigen drift or to add other vaccine antigens for multivalent, combination products. LigoCyte has also developed dry powder, intranasal delivery vaccine formulations for enhancing mucosal immune responses. These formulations can potentially improve commercial cold-chain distribution options, address stockpile concerns for biodefense applications and do not require needles or trained personnel for delivery, important efficiencies for commercial, biodefense and pandemic applications. To address specific clinical indications, LigoCyte's vaccines may include clinically-proven excipients and adjuvants to maximize efficacy, as well as to help streamline the regulatory process. LigoCyte's norovirus vaccines, for example, include GlaxoSmithKline's MPL® adjuvant under a license and commercial supply agreement with the company.

LigoCyte's strategy is to focus on its research and development strengths, validate its products through mid-stage human clinical trials, and enter into alliances with strategic partners that have the resources and expertise to move the products into the marketplace. The company has raised significant funding from private investors to reach its goals, as well as non-dilutive grant and contract sources through the NIH and DOD. LigoCyte's investment syndicate is led by Forward Ventures, JAFCO Ventures and Novartis Venture Fund. Additional shareholders of LigoCyte include MedImmune Ventures, Fidelity Biosciences, Athenian Venture Partners, MC Life Science Ventures (Mitsubishi International) and GSK.

KEY FACTS

- LigoCyte is a biopharmaceutical company focused on the development of VLP-based vaccines.
- The company's lead norovirus vaccine candidate has shown proof-of-principle in humans, achieving statistically significant reductions in illness and infection in a PI/II challenge study.
- Products in development include:

<u>Program</u>	<u>Stage</u>
Norovirus	Phase I/II
Rotavirus	Development
RSV	Development
Influenza	Development

- LigoCyte's IP portfolio includes 111 patents and applications that provide strong and defensible protection for its product candidates.

SENIOR MANAGEMENT

Donald Beeman	CEO
Robert Goodwin, Ph.D.	President & COO
Robert Bargatze, Ph.D.	Founder & CSO
Charles Richardson, Ph.D.	EVP of Development
Paul Mendelman, Ph.D.	EVP and CMO
Larry Mikkola, MBA, CPA	Director of Finance

INDUSTRY	Biopharmaceutical
SECTOR	Vaccines
FOUNDED	1998
EMPLOYEES	39
SHAREHOLDERS	Forward Ventures, JAFCO Ventures, Novartis VF, MedImmune, Mitsubishi International, Fidelity Biosciences, Athenian VP and GSK

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DEVELOPMENT PROGRAMS

Clinical / Norovirus Program

LigoCyte's lead vaccine program targets norovirus gastroenteritis. The company has developed two novel vaccine formulations for the prevention of norovirus infection. The lead candidate is a traditional liquid formulation for standard, intramuscular administration. The vaccine is based on the company's proprietary VLP platform and contains aluminum hydroxide and GSK's MPL adjuvant. Preliminary human clinical data indicate that the formulation is highly immunogenic and generally well tolerated. LigoCyte's alternate candidate is a dry-powder, nasally-delivered formulation. This approach was developed to induce an immune response at the critical site of infection, the gastrointestinal epithelium, and offer a shelf-stable formulation and simple, pain-free delivery via topical administration in the nose. Like the intramuscular formulation, the dry powder vaccine is based on the LigoCyte's VLP platform and includes an excipient for maximizing the nasal residence time, as well as GSK's MPL. Notably, in a recent live norovirus challenge study in adult volunteers, the dry powder vaccine candidate met all of its primary endpoints, including statistically significant reductions in illness, infection and severity of illness. These results confirm for the first time that norovirus illness can be prevented by vaccination, and that LigoCyte's VLP technology is effective for immunizing against norovirus illness.

Norovirus infection, more commonly known as the "winter vomiting disease" or the "stomach flu", is the most common cause of acute gastroenteritis in the U.S., estimated by the Centers for Disease Control (CDC) to afflict 21 million Americans and 267 million cases worldwide per year. Historically labeled as food poisoning, the "flu" or even rotavirus, norovirus is now known to be ubiquitous; its incidence in the U.S. is second only to the common cold. The norovirus landscape compares favorably with other infectious disease markets where immunization has become standard practice. The market is anchored by the young and elderly populations where infection can result in severe complications, including significant morbidity and death. With over 4 million children born annually in the U.S. and an aging population that will double in the next two decades, this creates an enormous socioeconomic burden and supports age-based recommendations in pediatric and geriatric populations. In contrast to other pediatric and geriatric vaccines, there is an additional opportunity to immunize major segments of the healthy population who suffer from widespread outbreaks, including members of the military, travelers and health care workers.

Preclinical / Additional Programs

LigoCyte is also applying the company's proprietary VLP technology to two of the most common causes of respiratory viral infections, respiratory syncytial virus and influenza, as well as a rotavirus vaccine candidate. Each program has achieved proof-of-principle in industry-standard models. LigoCyte's RSV VLP vaccine presents the RSV-F antigen, the protein that mediates cell entry, in its native form. In preclinical studies, the vaccine candidate has achieved neutralizing and protective responses against challenge in widely accepted models of infection. LigoCyte's influenza candidates, for the prevention of seasonal and pandemic influenza in humans, are designed to address the shortcomings of current influenza technologies by utilizing cell-based manufacturing techniques, disposable manufacturing processes, and a technology platform that supports rapid antigen engineering and the potential for enhanced protection. In preclinical studies, both the seasonal and pandemic influenza vaccines have demonstrated 100% protection across multiple influenza subtypes from a single VLP construct using only hemagglutinin and neuraminidase antigens. Notably, LigoCyte's VLP vaccine constructs may potentially address both pandemic avian influenza and the emergence of new or drifted subtypes of influenza virus. In contrast to the orally-delivered, live virus rotavirus vaccines currently on the market, the company's rotavirus vaccine program is focusing on non-replicating recombinant VLP antigens administered intramuscularly in a traditional liquid formulation. Designed to be compatible with LigoCyte's lead norovirus candidate, the approach could enable a combination vaccine for viral acute gastroenteritis in children.

MANAGEMENT TEAM

LigoCyte is led by Donald P. Beeman, who has 30 years of pharmaceutical experience. Formerly, Don ran Merck's U.S. commercial vaccine operations and, just prior to joining LigoCyte, founded Topaz

Pharmaceuticals. LigoCyte's management team also includes President and COO Robert Goodwin, who was formerly the director of technology transfer at the University of Rochester and has significant biomedical development, technology transfer, and product licensing experience; EVP and CSO, Robert Bargatzke, who has immunology research and development experience at the Scripps Clinic and Research Foundation and Stanford University; EVP of Research and Development, Charles Richardson, previously a Vice President at Corixa, RibImmunoChem Research, and Syntro Corporation; EVP and CMO Paul Mendelman, M.D., brings clinical research management experience from MedImmune, Aviron and Merck; and Controller and Director of Finance Larry Mikkola, with over twenty years of finance and accounting experience.



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