# ViroMed Co., Ltd.

## March 7, 2011

# Company Summary

### Company Description

- Company Name : ViroMed Co., Ltd.
- Co-CEOs : Yongsoo Kim
- Established : Nov. 1996
- Listing: KOSDAQ (ticker number 084990), Dec. 2006

### Products in the Pipeline

- VM202-CAD/PAD/DPN (Therapeutic Angiogenesis for Cardiovascular Disease and Nerve Cell Regeneration for Diabetic Neuropathy)
- VM501 (Protein-Based Medicine for Thrombocytopenia)
- VM206 (Therapeutic Cancer Vaccine)
- PG102 (Botanical Drug for Allergic Disease)

### Product in the market

- Allex (Nutraceutical for Allergies and Allergic Disease)

### Company History

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|---|---|
| 2009.11 | Domestic launch of Allex™, a nutraceutical designed to improve immune hypersensitivity and AtoLatte™, a topical solution for atopic dermatitis. |
| 2009.11 | Acquisition of Helixir, a developer of botanical drugs and nutraceuticals |
| 2009.7 | US FDA approval of Phase II clinical trial for VM202-PAD (peripheral artery disease) |
| 2009.3 | US FDA approval of collaborative Phase I/II clinical trial for VM202-CAD (coronary artery disease) with BDS of Cordis Corp., a Johnson & Johnson company |
| 2009.3 | US FDA approval of Phase I/II clinical trial for VM202-DPN (diabetic peripheral neuropathy) |
| 2008.6 | China State Food and Drug Administration (SFDA) approval of Phase I clinical trial for VM202-PAD (peripheral artery disease) |
| 2006.11 | US FDA approval of Phase I clinical trial for VM202-PAD (peripheral artery disease) |
| 2005.12 | IPO – KOSDAQ, Korean stock exchange |

# Technology Overview

**ViroMed has two main areas of focus: DNA/protein-based biopharmaceuticals and phytotherapeutics (botanical drugs/nutraceuticals). ViroMed now has five main products in its pipeline targeting cardiovascular disease, cancer, and immune-related disorder, with clinical trials in the US, Korea, and China.**

### VM202 – Therapeutic Angiogenesis

VM202 is a DNA-based medicine to treat ischemic cardiovascular diseases via therapeutic angiogenesis. It is designed to express isoforms of hepatocyte growth factor (HGF) for the treatment of coronary artery disease (VM202-CAD) and peripheral artery disease (VM202-PAD) by the formation of new blood vessels when injected into the ischemic sites. These new collateral vessels will increase blood flow and tissue perfusion, thereby effectively treating ischemia.

VM202 has also been shown to stimulate the growth and regeneration of nerve cells. Therefore, it is also being developed for the treatment of diabetic neuropathy (VM202-DPN), a common complication of type 2 diabetes mellitus that usually manifests itself as a disease affecting the nerves in the leg, causing intense pain and difficulty in movement.

Evidence of VM202's superior therapeutic effect has been shown through studies that compare its effectiveness against competitors' products in new blood vessel creation in various kinds of animal models. The findings have been published in international medical journals such as AJP – Heart and Circulatory Physiology (295): H522-532, 2008 and Radiology (249):1-2, 107-118, 2008 by a University of California, San Francisco (UCSF) research team.

VM202 is under clinical development in the US, Korea, and China. In March 2008 ViroMed entered into a co-development with Biologics Delivery Systems Group (BDS) of Cordis Corporation, a Johnson & Johnson Company, which will evaluate the efficacy of VM202 for treatment of coronary artery disease using BDS' NOGA® Cardiac Navigation System and the Myostar™ injection catheter.

| Product | Target Disease | Technology | Country | Development Stage | Partner(s) |
|---|---|---|---|---|---|
| VM202-PAD | Critical Limb Ischemia | DNA | USA | Phase II | |
| | | | Korea | Phase II | Reyon Pharmaceutical |
| | | | China | Phase II (completed IND application) | Beijing Northland Biotech |
| VM202-CAD | Chronic Refractory Myocardial Ischemia | DNA+Noga XP | USA | Phase I/II (IND approved) | BDS of Cordis Corp. (a Johnson & Johnson company) |
| | | DNA+CABG | Korea | Phase I completed | Reyon Pharmaceutical |
| VM202-Stent | Myocardial Ischemia | DNA+Stent | | Pre-clinical | |
| VM202-DPN | Diabetic Peripheral Neuropathy | DNA | USA | Phase I/II | |

### VM501 – Protein Therapeutic for Thrombocytopenia

VM501 is a re-engineered form of interleukin 11 (IL-11) targeting chemotherapy-induced thrombocytopenia (CIT). It has been shown to induce an increase in the number of blood platelets. In the Phase I and Phase II clinical trials performed in China, it showed significant therapeutic effects without severe adverse events.

Thrombocytopenia is described as an abnormally low presence of blood platelets. CIT occurs in cancer patients following chemotherapy. The only currently available treatments are platelet transfusion (which is dependent on availability) and the administration of Neumega (marketed by Wyeth), a recombinant IL-11 protein that is the only FDA-approved drug for the disease. However, due to the modest therapeutic activity and severe side effects, its use is limited and has only managed to attain a fraction of the total CIT market. In contrast, VM501 is more effective in low doses and shows less toxicity compared with Neumega. This is expected to allow VM501 to capture a significant share of the CIT market.

The Phase IIb clinical trial has been completed in China. The IND for the Phase III trial was submitted to the SFDA and is awaiting approval.

PEG-VM501 is the PEGylated version of VM501 that improves upon VM501's biopharmaceutical properties. Pre-clinical studies in primates have demonstrated that this form of VM501 shows greatly improved pharmacodynamic and pharmacokinetic features.

| Product | Target Disease | Technology | Country | Development Stage | Partner(s) |
|---|---|---|---|---|---|
| VM501 | Thrombocytopenia | Protein | China | Phase III (IND submitted) | Beijing Northland Biotech |
| PEG-VM501 | Thrombocytopenia | PEGylated Protein | | Pre-clinical | |

**VM206 – Therapeutic Cancer Vaccine**

VM206 is a therapeutic cancer vaccine that has potential applications for breast, ovarian, and pancreatic cancers. The product induces an immune response against the tumor-associated antigen Her2/neu, which is found in high levels in several types of cancer cells. The product consists of naked DNA and an adenovirus, which delivers the gene for truncated Her2/neu and cytokine GM-CSF as a genetic adjuvant. Pre-clinical studies have been completed and the efficacy data was published in the international journal Gene Therapy (2008, 15, 1351-1360). The product is being developed for injection directly into the muscle of patients who have received surgery and/or chemotherapy.

Preventive cancer vaccines such as Gardasil can prevent cancer from developing in healthy people. In contrast, therapeutic cancer vaccines such as VM206 can treat the already existing cancer while also preventing relapse and metastases. These effects are mediated by enhancing both humoral and cellular immune responses against cancers.

The Phase I IND application has been approved in Korea and the clinical trial is planned to start in 2011.

| Product | Target Disease | Technology | Country | Development Stage | Partner(s) |
|---|---|---|---|---|---|
| VM206 | Breast Cancer | DNA+Virus | Korea | Phase I | Reyon Pharmaceutical |

**Phytotherapeutics**

ViroMed's phytotherapeutics program is composed of nutraceuticals and botanical drugs. These products have a relatively shorter development program than biopharmaceuticals, giving the company the opportunity to obtain revenue and become profitable earlier than many other biotech companies.

PG102 is an "anti-allergy" agent that is effective in treating allergic diseases by restoring the immune balance, thus lowering the levels of overreacted immune responses, including cellular and humoral responses. It also has a strong anti-inflammatory activity. PG102 is an extract of an edible hardy kiwifruit, containing the active compounds that are essential for the treatment of allergic diseases.

PG201 is an anti-arthritic treatment, aiding in the relief of joint-related pain and other arthritic conditions. PG201 consists of a highly specific mixture of twelve herbal components, most of which are described in the Pharmacopoeia in Korea.

| Product | Target Disease | Country | Development Stage | Partner(s) |
|---|---|---|---|---|
| Allex™ (PG102-based) | Allergic Disease | Korea | Launched - nutraceutical | |
| AtoLatte™ (PG102-based) | Atopic Dermatitis & Dry Skin | Korea | Launched - cosmetic | |
| PG102 | Atopic Dermatitis | Korea | Pre-clinical | |
| | Allergic Disease | USA | Development - pet food | Efficas, Inc. |
| | Allergic Rhinitis | Japan | Pre-clinical completed | SBI Biotech |
| PG201 | Arthritis (RA/OA) | Korea | Phase III | PMG Pharm. Co., Ltd. |
| HX108CS | Muscular Fatigue | Korea | Clinical trial for nutraceutical | |

## Specific Patent Information

**ViroMed has registered or applied for patents in all relevant markets to protect its proprietary technology. Specific patent information is available upon request.**