

VIREXX MEDICAL CORP
Form 20-F/A
April 05, 2007

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

**FORM 20-F/A
(Amendment No. 1)**

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2006

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 1-32608

ViRexx Medical Corp.

(Exact name of Registrant as specified in its charter)

Alberta, Canada

(Jurisdiction of incorporation or organization)

8223 Roper Road NW, Edmonton, Alberta, Canada T6E 6S4

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Name of each exchange on which registered
<u>Common Shares, No Par Value</u>	<u>The American Stock Exchange ("AMEX")</u> <u>Toronto Stock Exchange ("TSX")</u>

Securities registered or to be registered pursuant to Section 12(g) of the Act.

None

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

None

(Title of Class)

As of December 31, 2006, there were 72,760,717 outstanding common shares of ViRexx.

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Indicate by check mark if the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act.

Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer.

Large Accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark which financial statement item the registrant has elected to follow.

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If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of the securities under a plan confirmed by a court.

Yes No

Explanatory Note

This amended Annual Report on Form 20-F/A is being filed by ViRexx Medical Corp. (the “Company”) solely to (i) correct the disclosure mistake on page 28 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2006 initially filed by the Company with the Securities and Exchange Commission on April 2, 2007 (the “Annual Report”), and (ii) file the exhibits indicated as being filed in the Exhibit Index of the Annual Report that were erroneously omitted as part of the Company’s initial filing of the Annual Report.

The Orphan Drug Designation for OvaRex® MAb is intended for the treatment of ovarian cancer during the “watchful waiting period”. This affords 7 years marketing exclusivity in the United States and 10 years marketing exclusivity in Europe. Although the incidence of ovarian cancer is relatively low in North America with 16,210 projected deaths in 2005 based on the American Cancer Society (“ACS”) latest report and 40,000 new cases in Europe, based on GLOBOCAN 2002 statistics, there is no approved therapy for the treatment of ovarian cancer in the “watchful waiting” period. The Corporation has issued patents and patents pending protecting the AIT™ technology. Benchmark monoclonal antibody-based therapy reimbursements to treat other solid tumors suggest that the Corporation could receive a premium for its OvaRex® MAb in the treatment of ovarian cancer patients. However, there is no guarantee that the Corporation or its licensees including Unither will receive sufficient reimbursement to justify continued development of OvaRex® MAb.

Market Overview

Ovarian cancer is a malignant growth located in the ovaries in the female reproductive system. In the U.S., Canada, and Europe, ovarian cancer causes more deaths than any other cancer of the female reproductive tract, representing 4% of all cancers among women, and is the fifth most common cause of cancer fatality for women, according to statistics compiled by the American Cancer Society (ACS). Specifically, the ACS estimates that there were 22,491 new cases and 16,210 deaths resulting from ovarian cancer in 2006. Approximately 3,000 new cases of ovarian cancer are reported in Canada each year.

Although detection of ovarian cancer at an early stage is now associated with an improved chance for successful treatment, survival figures have not changed significantly over the past 15 years. This is partially due to a lack of efficient diagnostic methods or markers for routine tests that could increase the number of patients diagnosed at the early stage of their disease. Consequently, in approximately three quarters of diagnosed patients, the tumor has already progressed to an advanced stage (Stage III/IV) (ASC 2003), making treatment difficult.

In estimating the global market for treating ovarian cancer we have conducted the following analysis. We have started with a conservatively estimate that there are 70,000 new ovarian cancer patients per year in only those countries with top tier medical systems. Of these patients, approximately 27,500 will be eligible for treatment with OvaRex® MAb, during the “watchful waiting period” for which there currently is currently no approved therapy.

In 2006, Monoclonal Antibody therapies commercially available in the U.S. range in price (ex-factory) from U.S.\$25,000/patient/year to U.S.\$43,000/patient/year. OvaRex® MAb is expected to be priced at the upper end of this range, at about U.S.\$39,000/patient/year. At this price, the U.S. market for the ‘watchful waiting’ indication is estimated at U.S.\$47 million per year, and the global market at U.S.\$1.1 billion per year. A second indication is being explored for OvaRex® MAb for frontline use in conjunction with front line chemotherapy. This indication could open up the ovarian cancer market to the full 70,000 patients/year and therefore translates to a market size of U.S.\$1.9 billion annually.

OvaRex® MAb has been granted Orphan Drug status in the U.S. and Europe and Fast Track designation in the U.S. The timeline for regulatory submission of OvaRex® MAb will be determined by United Therapeutics for their licensed territories (as per the April 17, 2002 licensing agreement). The Orphan Drug Designation for OvaRex® MAb is for the treatment of ovarian cancer during the “watchful waiting period” (i.e. after treatment by chemotherapy and surgical removal of the tumor). This affords 7years marketing exclusivity in the United States and 10 years marketing exclusivity in Europe. Further, ViRexx has issued patents and patents pending that will afford further protection from competitors in this segment of the cancer treatment market. Benchmark monoclonal antibody-based therapy reimbursements to treat other solid tumors suggest that ViRexx could receive a premium for its OvaRex® MAb in the treatment of ovarian cancer patients. However, there is no guarantee that ViRexx or its licensees, including Unither,

will receive sufficient reimbursement to justify continued development of OvaRex® MAb. Further, there is no guarantee that a competitor will not develop a therapeutic agent that will directly compete with OvaRex® MAb for the specified target market.

Treatment

Ovarian cancer typically exhibits vague symptoms, and is therefore called “The Disease That Whispers”. It is particularly difficult to detect given the location of the ovaries and is often not diagnosed until at a late stage in the disease, at which point, it has already spread to other parts of the body. Consequently, only approximately 25% of ovarian cancers are diagnosed in the early stages (Am Cancer Soc 2003).

Treatments and patient prognosis are highly dependent upon the type of ovarian cancer and the extent to which the disease has spread prior to diagnosis. More than 80% of Stage III/IV patients express the tumor associated antigen CA125 an antigen that is self produced and is highly associated with ovarian cancer. The therapeutic approach prescribed for these patients whose tumors have progressed to an advanced stage consists of surgery to remove all visible cancerous growth followed by adjuvant chemotherapy. The procedure may also involve the removal of one or both ovaries and fallopian tubes (salpingo-oophorectomy), as well as the uterus (hysterectomy).

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

VIREXX MEDICAL CORP.

By:

D. Lorne Tyrrell

Name: Dr. D. Lorne Tyrrell
Title: Chief Executive Officer

Date: April 5, 2007

By:

Scott Langille

Name: Scott Langille
Title: Chief Financial Officer

Date: April 5, 2007

