VIREXX MEDICAL CORP Form 20-F April 02, 2007

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

### FORM 20-F

(Mark One)

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

OR

x 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

Common Shares, No Par Value

The American Stock Exchange ("AMEX")

Toronto Stock Exchange ("TSX")

#### 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.

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

o Yes X 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. O Yes X 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. XYes O No Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. O Large Accelerated filer O Accelerated filer X Non-accelerated filer

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

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).

o Yes X 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.

o Yes O No

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ica to follow.

xItem 17 O Item 18

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### FORWARD LOOKING STATEMENTS

This Annual Report on Form 20-F (the "Annual Report") contains "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995. A holder of shares ("Shareholders") can identify these forward looking statements when they see us using words such as "expect", "anticipate", "estimate", "believe", "may", "poten "intends", "plans" and other similar expressions or statements incorporating a modal verb such that an action, event or result "will", "may", "could" or "should" be taken, occur or be achieved, or the negative thereof, or other similar statements These statements are only predictions and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Important factors that could cause or contribute to such differences include our ability to successfully develop our product candidates and commercialize them into saleable products, the introduction of competing products, the difficulty of predicting Food and Drug Administration ("FDA"), European Medicines Agency ("EMEA") and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, our ability to successfully identify, consummate and integrate acquisitions, our potential exposure to product candidates, product liability claims, our dependence on patent and other protections for our product candidates, fluctuations in currency, exchange and interest rates and operating results and other risks and uncertainties described under "Item 3 - Key Information - Risk Factors" and elsewhere in this Annual Report.

Forward-looking statements are based on the beliefs, opinions and expectations of our management on the date the statements are made. Although we believe that the forward-looking statements presented in this document are reasonable, we do not guarantee that they accurately or completely predict, reflect or state future results, levels of activity, performance, achievements or occurrence and we do not assume responsibility for failure to do so. Except as required by law we do not undertake to update forward-looking information to reflect actual results, new information, occurrence of future events, or changes in management's beliefs, opinions or expectations. No undue reliance should be placed on such forward-looking statements.

### PART I

In this Annual Report, except where otherwise indicated, all references to the "Corporation," "we," "our" and "ViRexx" refer to ViRexx Medical Corp., its subsidiaries, and where the context requires, its predecessors. References to "dollars" as "CDN\$" or "\$" are to Canadian dollars and references to "U.S.\$" are to United States dollars.

### ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

### A. Directors and Senior Management

Not applicable

### **B.** Advisors

Not applicable.

### C. Auditors

Not applicable.

### Item 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable.

### **ITEM 3. KEY INFORMATION**

### A. Selected Financial Data

The selected consolidated financial data presented below is derived from the audited annual financial statements for the years ended December 31, 2006, December 31, 2005, December 31, 2004, December 31, 2003 and December 31, 2002.

The selected financial data should be read in conjunction with Item 5 - "Operating and Financial Review and Prospects," the financial statements and other financial information included elsewhere in this Annual Report.

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We prepared our Consolidated Financial Statements in accordance with Canadian Generally Accepted Accounting Principles ("GAAP"). GAAP differs in certain material respects from United States Generally Accepted Accounting Principles ("U.S. GAAP"). For discussion of the principal differences between Canadian GAAP and U.S. GAAP as they pertain to us, see Note 18 to our audited Consolidated Financial Statements for the year ended December 31, 2006, included elsewhere in this Annual Report. Note 18 to our Consolidated Financial Statements also provides a reconciliation of our Consolidated Financial Statements to United States Generally Accepted Accounting Principles.

Our fiscal year ends on December 31. We designate our fiscal year by the year in which that fiscal year ends; e.g., fiscal year 2006 refers to our fiscal year ended December 31, 2006.

(In thousands, except per share data)		Years ended December 31,						
	2006 (1)	2005 (1)	2004 (1)	2003 (1)	2002 (1)			
Revenues	_	_	_	_	-			
Operating expenses:								
Research and development	5,786	4,692	1,727	383	272			
Corporate administration	4,523	3,251	1,577	682	816			
Amortization	2,771	2,499	71	31	37			
Fair value of stock options issued to employees related to:								
Research and development	151	58	70	-	-			
Corporate administration	454	399	311	211	-			
-								
Total operating expenses	13,685	10,899	3,756	1,307	1,125			
Loss from operations	(13,685)	(10,899)	(3,756)	(1,307)	(1,125)			
Interest income	400	222	143	8	-			
Debenture interest	-	(95)	(62)	(76)	(40)			
Loss (gain) on foreign exchange	(31)	(46)	15	4				
Gain (loss) on disposal of property								
and equipment	1	-	2	(13)	(95)			
Loss before income taxes	(13,315)	(10,818)	(3,658)	(1,384)	(1,260)			
Income tax (expense) recovery	(4,179)	3,358	-	-	-			
Net loss	(17,494)	(7,460)	(3,658)	(1,384)	(1,260)			
Basic and diluted loss per common share	(0.25)	(0.13)	(0.14)	(0.15)	(0.14)			
Weighted average no. shares								
outstanding	68,921	55,827	25,268	9,129	8,763			

### Selected Canadian GAAP Financial Data

(In thousands, except per share data)	Years ended December 31,						
	2006 (1)	2005 (1)	2004 (1)	2003 (1)	2002 (1)		
Balance Sheet Data:							
Cash and short-term investments	10,742	5,572	9,463	2,709	131		
Total assets	38,950	36,286	45,722	3,742	1,093		

Long-term liabilities	5,352	1,168	6,750	35	657
Total shareholders' equity (deficit)	31,999	34,448	37,191	2,095	(56)

(1) Derived form the audited financial statements for the year then ended.

### Selected U.S. GAAP Financial Data

(In thousands, except per share data)	data) Years ended December 31,					
	2006 (1)	2005 (1)	2004	(1) 20	03 (1)	2002 (1)
Revenues					_	
Operating expenses:						
Research and development		5,786	4,692	1,727	383	272
Corporate administration		4,523	3,251	1,577	682	816
Amortization		150	142	69	29	35
Fair value of stock options issued to emp	loyees					
related to:						
Research and development		151	58	70	-	-
Corporate administration		454	399	311	945	-
Total operating expenses		11,064	8,542	3,754	2,039	1,123
Loss from operations		(11,064)	(8,542)	(3,754)	(2,039)	(1,123)
Interest income		400	222	143	8	-
Debenture interest		-	(95)	(62)	(76)	(40)
(Loss) gain on foreign exchange		(31)	(46)	15	4	(1)
Gain (loss) on disposal of property and e	quipment	1	-	2	(13)	(95)
Acquired intellectual property						
Acquired intellectual property				(27,804)	(75)	(131)
Loss before income taxes		(10,694)	(8,461)	(31,459)	(2,191)	(1,390)
Income tax (expense) recovery		-	-	-	-	-
Net loss		(10,694)	(8,461)	(31,459)	(2,191)	(1,390)
Basic and diluted loss per common share		(0.16)	(0.15)	(1.25)	(0.24)	(0.16)
Weighted average no. shares outstanding		68,921	55,827	25,268	9,129	8,763

(In thousands, except per share data)		Years ended December 31,				
	2006 (1)	2005 (1)	2004 (	1)	2003 (1)	2002 (1)
Balance Sheet Data:						
Cash and short-term investments		10,742	5,572	9,463	2,709	131
Total assets		11,580	6,296	11,152	3,480	904
Long-term liabilities		5	-	-	35	746
Total shareholders' equity (deficit)		9,977	5,626	9,311	1,774	(245)

(1) Derived form the audited financial statements for the year then ended.

### **Currency and Exchange Rates**

The following table sets out the exchange rates for U.S. dollars expressed in terms of one Canadian dollar in effect at the end of the following periods, and the average exchange rates (based on the average of the exchange rates on the last day of each month in such periods)):

			U.S. Dollars Per One Canadian Dollar Year Ended December 31					
	January - February 2007	2006	2005	2004	2003	2002		
End of period	0.85	0.86	0.86	0.83	0.77	0.63		
Average for the period	0.85	0.88	0.82	0.76	0.71	0.63		

The following table sets out the high and low exchange rates for U.S. dollars expressed in terms of one Canadian dollar in effect at the end of the following periods:

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	<b>U.S. Dollars per One Canadian Dollar</b>							
	February 2007	January 2007	December 2006	November 2006	October 2006	September 2006		
High for the month	0.86	0.86	0.88	0.89	0.90	0.90		
Low for the month	0.84	0.85	0.86	0.87	0.88	0.89		

Exchange rates are based upon the noon buying rate in New York City for cable transfers in foreign currencies, as certified for customs purposes by the United States Federal Reserve Bank of New York. The noon rate of exchange on March 2, 2007 as reported by the United States Federal Reserve Bank of New York for the conversion of Canadian dollars into United States dollars was CDN\$1.00 = U.S.\$0.85.

### B. Capitalization and Indebtedness

### **Common Shares**

We are authorized to issue an unlimited number of common shares. As of December 31, 2006, we had 72,760,717 common shares outstanding. A summary of transactions during the twelve month period ended December 31, 2005 is outlined below:

	Common shares		
	#	\$	
Balance - December 31, 2005	58,443,445	45,989,189	
Exercise of stock options	590,000	439,341	
Private placements	13,527,272	9,032,430	
Common shares issued	200,000	148,000	
Share issue costs	-	(1,544,280)	
Balance - December 31, 2006	72,760,717	54,064,680	

All cash proceeds from the issuance of common shares are used for general working capital purposes.

### Normal Course Issuer Bid

On December 21, 2004, we received approval for a Normal Course Issuer Bid allowing ViRexx to repurchase up to 2,663,824 common shares during the period beginning December 23, 2004 to December 22, 2005, at the market price at the time of purchase. We repurchased 2,056,900 common shares at a weighted average price of \$1.10 per share for the period January 1, 2005 to December 22, 2005, which resulted in a charge of \$1,645,113 to share capital and a charge of \$610,663 to the deficit. (See *Item 16E*).

### **Stock Options**

See Note 13 of Item 18. Our stock option plan permits the issuance of stock options equivalent to 8,256,000 common shares. As at December 31, 2006, we had 6,096,241 stock options outstanding of which 5,282,401 are exercisable. The expiry dates of outstanding stock options range from April 30, 2007 to March 28, 2016.

A summary of transactions during the period ending December 31, 2006 is outlined below:

	Weighted
Stock	exercise
Options	price

**************************************	\$
Outstanding Balance - December 31, 2005 6,670,20	0.84
Granted 837,36	1.00
Cancelled (821,32	.2) 0.91
Exercised (590,00	00) 0.50
Balance - December 31, 2006 6,096,24	1 0.81

On February 1, 2005, we granted 300,000 stock options as an inducement to an individual to join ViRexx as an officer. The options are exercisable at \$1.17 per share and expire on February 1, 2015. These options were not issued under the Plan. One-third of these options vested immediately and the remaining options will vest over a period of two years. Effective April 13, 2005, 30,000 options were granted as an inducement for an individual to join ViRexx. These options expire on April 13, 2015 and are exercisable at a price of \$1.46 per share. Effective May 1, 2005, 50,000 options were granted to a consultant to ViRexx. These options expire on May 1, 2007 and are exercisable at a price of \$1.39 per share. Effective November 1, 2005, 60,000 options were granted as partial inducement for an individual to join ViRexx as Director, Business Development. The options are exercisable at \$0.99 per share and expire on November 1, 2015. These options vest over a period of three years. Effective November 1, 2005, 500,000 options were granted as an inducement for an individual to join ViRexx as Director, Business Development. The options are exercisable at \$0.99 per share and expire on November 1, 2015. These options vest over a period of three years. Effective Officer. These options are exercisable at \$0.99 per share and expire on November 1, 2015. These options are exercisable at \$0.99 per share and expire on November 1, 2015. These options are exercisable at \$0.99 per share and expire on November 1, 2015. These options are exercisable at \$0.99 per share and expire on November 1, 2015. These options are exercisable at \$0.99 per share and expire on November 1, 2015. These options are exercisable at \$0.99 per share and expire on November 1, 2015. These options vest over a period of three years.

### Warrants

See Note 13 of Item 17. As at December 31, 2006, we had 17,077,471 warrants outstanding at a weighted average price of \$1.48. The expiry date of outstanding warrants range from September 9, 2007 to December 6, 2008. A summary of transactions during the period is outlined below:

	Warrants #	Weighted exercise price \$
Balance - December 31, 2005	2,819,299	1.56
Granted	14,618,172	1.48
Exercised	-	-
Cancelled/Expired	(360,000)	4.00
Balance - December 31, 2006	17,077,471	1.48

### C. Reasons for the Offer and Use of Proceeds

Not applicable.

### **D.** Risk factors

An investment in our common shares involves a high degree of risk and should be considered speculative. You should carefully consider the risks and uncertainties described below, as well as other information contained in this Annual Report, including under Item 5: "Operating and Financial Review and Prospects" and in our financial statements and accompanying notes, before making any investment. If any of the following risks occur, our business, financial condition, and results of operations could be seriously harmed and you could lose all or part of your investment.

### **RISKS RELATED TO OUR FINANCIAL CONDITION**

## THERE IS EXPRESSED DOUBT ABOUT OUR ABILITY TO CONTINUE AS A GOING CONCERN, WHICH MAY HINDER OUR ABILITY TO OBTAIN FUTURE FINANCING.

Our financial statements included in this Annual Report were prepared assuming that the Company will continue as a going concern. However, we have incurred operating losses, expect to continue to incur significant losses, and have not achieved any significant revenues since our inception. During the fiscal year ended December 31, 2006, we did secure \$15,000,000 of additional financing. While the proceeds of this financing have significantly aided our liquidity difficulties, our ability to sustain operations for more than a 12 month period without further financing cannot be

assured. Without additional funding and milestone payments from potential product out-licensing, we will have inadequate funds to continue our existing corporate, administrative, and operational functions beyond the fourth quarter of 2007. We also have commitments under our University of Alberta license agreement to make milestone payments of \$250,000 when we enter Phase III clinical trials on each of the product candidates derived from the intellectual property licensed under that Agreement.

Our ability to continue as a going concern is subject to our ability to generate revenues, a profit and/or obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities, increasing sales or obtaining loans and grants from various financial institutions where possible. The going concern uncertainty modification in the auditor's report increases the difficulty in meeting such goals and there can be no assurances that such methods will prove successful.

### WE MUST RAISE MONEY FROM INVESTORS TO FUND OUR OPERATIONS. IF WE ARE UNABLE TO FUND OUR OPERATIONS, WE MAY CEASE DOING BUSINESS.

As at December 31, 2006, we had cash reserves, consisting of cash and short-term investments, of \$10,742,191. In fiscal year ended December 31, 2006, we incurred a net loss of \$17,493,375. In fiscal year ended December 31, 2005, we incurred a net loss of \$7,459,714, and in fiscal year ended December 31, 2004, we incurred a net loss of \$3,657,760. In February 2006 we completed a private placement of 10,909,090 units for \$12,000,000 with the addition of broker warrants, and as a result of this financing there remains outstanding 11,999,990 common share purchase warrants expiring on February 15, 2008, exercisable at \$1.50 per share. In March 2006 we completed a private placement of 800,000 units for \$1,000,000 with the addition of broker warrants and as a result of this financing there remains outstanding 17, 2008, exercisable at \$1.75 per share. In December 2006 we completed a private placement of 1,818,182 units for \$2,000,000 with the addition of broker warrants and as a result of this financing there remains outstanding 1,818,182 common share purchase warrants expiring on December 6, 2008, exercisable at \$1.25 per share.

Without additional funding and milestone payments from potential product out-licensing, we will have inadequate funds to continue our existing corporate, administrative, and operational functions beyond the fourth quarter of 2007. We also have commitments under our University of Alberta license agreement to make milestone payments of \$250,000 when we enter Phase III clinical trials on each of the product candidates derived from the intellectual property licensed under that Agreement. The average monthly amount of cash that we are using, and expect to use over the next 12-18 months for all of our operations, is approximately \$900,000. For a further discussion of our liquidity and capital resources, you should also refer to Item 5: "Operating and Financial Review and Prospects" in this Annual Report. We expect to continue to seek additional sources of funding to finance operations into the future, through public or private equity or debt financings, collaborative arrangements with pharmaceutical companies and/or from other sources. We cannot assure you that additional financing will be available or, even if it is available, that it will be sufficient and available on terms acceptable to us.

# WITH THE EXCEPTION OF MILESTONE PAYMENTS FROM POTENTIAL PRODUCT OUT-LICENSING, WE HAVE NOT DERIVED ANY REVENUE TO DATE FROM THE COMMERCIAL SALE OF PRODUCT CANDIDATES, HAVE NEVER HAD ANY REVENUES FROM COMMERCIAL SALES AND HAVE RELIED ON EQUITY AND DEBT FINANCINGS TO SUPPORT OUR OPERATIONS.

We have not derived any revenue to date from the commercial sale of product candidates and have no product candidates for sale. Our future profitability will depend upon our ability to enter into suitable licensing or partnering arrangements to commercialize our product candidates obtain regulatory approvals and bring product candidates to market in a timely manner. We have relied solely on equity and debt financing, government grants, and milestone payments from potential product out-licensing to support our operations. We have not commercially introduced any product candidates and the product candidates are in varying stages of development and testing. Our ability to sell an approved commercial product will depend upon our ability to develop products that are safe, effective and commercially viable, to obtain regulatory approval for the manufacture and sales of our product candidates and to license or otherwise market our product candidates successfully. We may never commercialize an approved product and may have to rely on equity and debt financings to support ongoing operations.

## WE HAVE A HISTORY OF OPERATING LOSSES AND WE EXPECT TO INCUR FUTURE LOSSES. IF WE ARE UNABLE TO ACHIEVE SIGNIFICANT REVENUES IN THE FUTURE, WE WILL CEASE DOING BUSINESS.

Since our inception, we have incurred significant losses each year. Our accumulated loss from inception to December 31, 2006 is CDN\$32,444,237. Our accumulated deficit from inception to December 31, 2006 is CDN\$33,814,171. We expect to continue to incur significant operating losses as we continue our product-candidate research and development and continue our clinical trials. These losses, among other things, have had and will continue to have an adverse effect on our shareholders' equity and working capital. Unless we are able to generate sufficient product revenue, we will continue to incur losses from operations and may not achieve or maintain profitability.

We will need to generate significant revenues in order to achieve and maintain profitability. Our ability to generate revenue in the future is dependent, in large part, on completing product development, obtaining regulatory approvals, and commercializing, or entering into agreements with third parties to commercialize, our product candidates. We cannot assure you that we will ever successfully commercialize or achieve revenues from sales of our therapeutic product candidates if they are successfully developed or that we will ever achieve or maintain profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

Until we receive regulatory approval for sales of product candidates incorporating our licensed and/or patented technologies, we cannot sell our product candidates and will not have revenues from sales. The research, development, production, and marketing of new products require the application of considerable technical and financial resources. However, any revenues generated from such product candidates, assuming they are successfully developed, marketed, and sold, may not be realized for a number of years.

### WE EXPECT TO CONTINUE TO INCUR SIGNIFICANT EXPENSES.

We expect to continue to incur significant expenses connection with:

- the regulatory marketing authorization process to approve the sale of OvaRex® MAb in Europe and other jurisdictions. OvaRex® MAb will be the first of our product candidates to complete Phase III trials in any jurisdiction and the first of our product candidates for which we will seek marketing authorization. The work involved in seeking regulatory marketing authorization for OvaRex® MAb in theses jurisdictions is extensive, time consuming and expensive;
- our expenses will increase as we commence new preclinical and clinical trials as we progress existing products to more advanced phases of pre-clinical and of clinical development in the event that we are not able to obtain a licensing partner. The more advanced trials typically require more clinical trial participants, clinical trial sites and research investigators than earlier stage clinical trials and are consequently more expensive;

We also expect to incur significant general and administrative expenses in support of our increased operations as well as the ongoing costs to operate as a company listed on the American Stock Exchange and on the Toronto Stock Exchange.

Over the longer term, the costs referred to above will fluctuate, primarily dependant on the number and type of preclinical and clinical trials being undertaken at any one time and the number of regulatory marketing authorizations being sought. Costs will also increase if we are able to progress any further product candidates from preclinical testing to clinical trials or if we are able to complete clinical trials in the event that we are not able to obtain a licensing partner of any product candidates and seek regulatory marketing authorizations.

## WE WILL CONTINUE TO NEED SIGNIFICANT AMOUNTS OF ADDITIONAL CAPITAL THAT MAY NOT BE AVAILABLE TO US ON FAVORABLE TERMS OR AT ALL OR WHICH MAY BE DILUTIVE.

To date, we have funded our operations and capital expenditures with proceeds from the sale of our securities, government grants and interest on investments.

In order to achieve our goal of being a biotechnology company and to conduct the lengthy and expensive research, preclinical studies, clinical trials, regulatory approval process, manufacture, sales and marketing necessary to complete the full development of our product candidates, we may require substantial additional funds in addition to the funds received in connection with the US private offerings and the various Canadian placements completed in 2006.

To meet these financing requirements, we may raise funds through public or private equity offerings, debt financings, and through other means, including collaborations and license agreements. Raising additional funds by issuing equity or convertible debt securities may cause our shareholders to experience significant additional dilution in their ownership interests. Raising additional funds through debt financing, if available, may involve covenants that restrict our business activities. Additional funding may not be available to us on favorable terms, or at all. If we are unable to obtain additional funds, we may be forced to delay, reduce the scope of or terminate preclinical and/or clinical trials

and the development, manufacturing and marketing of our products. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights and control over our technologies, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

## IF WE FAIL TO OBTAIN ADDITIONAL FINANCING, WE MAY BE UNABLE TO FUND OUR OPERATIONS AND COMMERCIALIZE OUR PRODUCT CANDIDATES.

We expect that our cash expenditure will remain relatively constant over 2007 and 2008, and that we will spend substantial amounts to complete the commercialization of OvaRex® MAb in Europe and for Occlusin<sup>TM</sup>500 Device. We also expect to incur costs in supporting the clinical development and to license other product candidates from our T-ACT<sup>TM</sup> and Chimigen<sup>TM</sup> Platforms. We believe that our existing cash and short-term investments will be sufficient to meet our projected operating requirements to the fourth quarter of 2007.

Our future funding requirements will depend on many factors, including:

• the scope, results, rate of progress, timing and costs of preclinical studies and clinical trials and other development activities. Specifically, the funding requirements for clinical trials of Occlusin<sup>™</sup> 500 Device, Occlusin<sup>™</sup> 500 Injection and HepaVaxx B Vaccine are significant. The funding requirements for the preclinical testing and potential future clinical testing of our earlier-stage product candidates and any other testing that we may initiate are also significant. As a result, we will be looking to partner out product candidates prior to initiating Phase II clinical trials and /or funding selected projects based on funding availability;

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- the costs and timing of seeking and obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs of developing sales and marketing capabilities and establishing distribution capabilities;
- the cost of developing our commercial-scale capabilities;
- the cost of additional management, scientific, manufacturing, and sales and marketing personnel. We will be required to increase the number of our personnel over time;
- the terms, timing and cash requirements of any future acquisitions, collaborative arrangements, licensing of product candidates or investing in businesses, product candidates and technologies;
- the costs of securing coverage, payment and reimbursement of our product candidates, if any of our product candidates receive regulatory approval; and
- the effects of competing clinical, technological and market developments.

If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or future commercialization efforts.

### RISKS RELATED TO OUR BUSINESS AND INDUSTRY

WE ARE IN THE EARLY STAGES OF PRODUCT CANDIDATE DEVELOPMENT. OUR PRODUCT CANDIDATES MAY NOT BE EFFECTIVE AT A LEVEL SUFFICIENT TO SUPPORT A PROFITABLE BUSINESS VENTURE. IF THEY ARE NOT, WE WILL BE UNABLE TO CREATE MARKETABLE PRODUCT CANDIDATES AND DERIVE ANY MEANINGFUL REVENUES. UNLESS WE ARE ABLE TO GENERATE SUFFICIENT PRODUCT REVENUE, WE WILL CONTINUE TO INCUR LOSSES FROM OPERATIONS AND MAY NOT ACHIEVE OR MAINTAIN PROFITABILITY AND WE WILL HAVE TO CEASE OPERATIONS.

Some of our product candidates are in the preliminary development stage, have not been approved for marketing by any regulatory authority and cannot be commercially distributed in any markets until such approval is obtained. We cannot assure you that our monoclonal antibody therapies, Chimigen<sup>TM</sup> vaccines and tumor starvation therapies will be effective at a level sufficient to support a profitable business venture. The science on which our technologies are based may also fail due to flaws or inaccuracies in the data, or because the data is not predictive of future results. The scientific theories, upon which our business is based, like all science, will evolve over time and become increasingly predictive of the world in which we live. One potential consequence of imperfect theories may be that we will never be able to create a marketable product. If we are unable to do so, we will not generate revenues, will have to cease operations, and investors will be at risk of losing their entire investment.

In addition, it takes a significant period of time for new vaccines, monoclonal antibody therapies, medical devices and therapeutic drugs to be developed, to obtain the necessary regulatory approvals to permit sales, to establish appropriate distribution channels and market acceptance, and to obtain insurer reimbursement approval. This time period is generally not less than 10 years. None of our therapeutic product candidates have been commercialized and completion of the commercialization process for any of our product candidates will require significant investments of time and funds. We cannot predict either the total amount of funds that will be required, or assure you that we will be successful in obtaining the necessary funds. It is also not possible for us to predict the time required to complete the

regulatory process or if there will be sufficient market demand at such time. If any of our product candidates are approved, we cannot give assurances that it will be possible to produce them in commercial quantities at reasonable cost, successfully market them, or whether any investment made by us in the commercialization of any product candidates would be recovered through sales, license fees, or related royalties. Furthermore, the time it takes for product candidates to reach market acceptance exposes us to significant additional risks, including the development of competing products, loss of investor interest, changing market needs, changes in personnel, and regulatory changes.

Since the process of discovering and developing cancer therapies and treatments for chronic viral infections is our core business, we anticipate that we will remain engaged in research and development for the foreseeable future. As one or two product candidates advance to commercialization, we expect that other potential products will replace them as research and development candidates. We estimate that OvaRex® MAb if approved is a minimum of one year away from commercialization in the U.S., Occlusin<sup>TM</sup> 500 Artificial Embolization Device if approved is a minimum of one year away from commercialization in any jurisdiction, and HepaVaxx B Vaccine, if approved, is a minimum of seven years away from commercialization in any jurisdiction, although these processes could take much longer.

### WE RELY ON, AND INTEND IN THE FUTURE TO CONTINUE TO RELY ON, TECHNOLOGY LICENSES FROM THIRD PARTIES AND ANY BREACH OR TERMINATION OF THESE LICENSE ARRANGEMENTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, AND RESULTS OF OPERATIONS.

We cannot assure you that we will obtain any additional required licenses, that our existing licenses or new licenses, if obtained, will not terminate, or that they will be renewed. The failure to obtain, the termination of, or the failure to renew any of these licenses would have a material adverse effect on our pre-clinical and clinical programs and may cause us to suspend or cease our operations. In addition, we cannot assure that these licenses will remain in good standing or that the technology we have licensed under these agreements has been adequately protected or is free from claims of infringement of the intellectual property rights of third parties.

Pursuant to the terms of the licenses and any agreements we may enter into in the future, we are and could be obligated to exercise diligence in bringing potential products to market and to make license payments and certain potential milestone payments that, in some instances, could be substantial. We are obligated and may in the future be obligated, to make royalty payments on the sales, if any, of product candidates resulting from licensed technology and, in some instances, may be responsible for the costs of filing and prosecuting patent applications. Because we require additional funding, we may not be able to make payments under current or future license agreements, which may result in our breaching the terms of any such license agreements. Any breach or termination of any license could have a material adverse effect on our business, financial condition, and results of operations.

## OUR FAILURE TO PROTECT OUR INTELLECTUAL PROPERTY OR OUR INFRINGEMENT ON THE PROPERTY RIGHTS OF OTHERS MAY IMPEDE OUR ABILITY TO OPERATE FREELY.

We continually evaluate our technology to determine whether to make further patent filings and rely significantly upon proprietary technology. We protect our intellectual property through patents, copyrights, trademarks, trade secrets and contractual agreements as appropriate. We own or exclusively license 8 issued U.S. patents having expiration dates ranging from 2016 to 2021. As we develop our product candidates, we may discover additional patentable subject matter that we may elect to prosecute.

Prior to filing a patent, data developed by the Company or its licensees is held in confidence, which confidence is secured by contractual arrangement. From time to time management may make a determination that superior economic gain made be attained by perpetually protecting an invention as a trade secret rather than disclosing it in a patent application. Inventions held as trade secrets can be independently discovered by others. In addition, the contractual agreements by which we protect our unpatented technology and trade secrets may be breached. If technology similar to ours is independently developed or our contractual agreements are breached, our technology will lose value and our business will be irreparably harmed.

There is always a risk that issued patents may be subsequently invalidated, either in whole or in part, and this could diminish or extinguish our patent protection for key elements of our technology. We are not involved in any such litigation or proceedings, nor are we aware of any basis for such litigation or proceedings. We cannot be certain as to the scope of patent protection, if any, which may be granted on our patent applications.

Having patents issued does not guarantee that our business activities are not infringing intellectual property rights of third parties. Any claims against us or any purchaser or user of our potential products asserting that such product or process infringes intellectual property rights of third parties could have a material effect on our business, financial condition or future operations. Any asserted claims of infringement, with or without merit, could be time consuming, result in costly litigation, divert the efforts of our technical and management personnel, or require us to enter into royalty or licensing agreements, any of which could materially adversely affect our operating results. Such royalty or licensing agreements, if required, may not be available on terms acceptable to us, if at all. In the event a claim is

successful against us and we cannot obtain a license to the relevant technology on acceptable terms, license a substitute technology or redesign our potential products to avoid infringement, our business, financial condition and operating results would be materially adversely affected.

## OUR BUSINESS IS SUBJECT TO SIGNIFICANT GOVERNMENT REGULATION AND FAILURE TO ACHIEVE REGULATORY APPROVAL OF OUR DRUG CANDIDATES WOULD SEVERELY HARM OUR BUSINESS.

The U.S. Food and Drug Administration ("FDA") regulates the development, testing, manufacture, record-keeping, labeling, distribution, and promotion of pharmaceutical products in the United States pursuant to the Food, Drug, and Cosmetic Act and related regulations. We must receive approval by the FDA prior to commercial sale in the U.S. of any of our product candidates. Similar regulations are enforced by Health Canada, the European Medicines Agency ("EMEA") and by other regulatory agencies in each jurisdiction in which we seek to do business. The regulatory review process is lengthy and expensive, and the outcome of the approval process is uncertain. Before receiving approval we must

acquire and submit extensive preclinical and clinical data and supporting information for each indication to establish the safety and efficacy of our drug candidates. In addition, we must show that we can produce our drug candidates consistently at quality levels suitable for administration in humans in accordance with a complex set of regulations known in the U.S. as current Good Manufacturing Practices (cGMP's). Premarket approval is a lengthy and expensive process and takes several years. Future legislation or changes in FDA policy may change during the period of potential product development and clinical trials. We may not be able to obtain FDA approval or approval from other regulatory agencies for any commercial sale of any drug candidate. We may encounter delays or rejections in the regulatory approval process at any time. Even if approval is obtained, agencies may determine that additional clinical trials are required after marketing has begun. Except for any potential licensing or marketing arrangements with other pharmaceutical or biotechnology companies, we will not generate any revenues in connection with our drug candidates unless and until we obtain clearance from the FDA, Health Canada, EMEA, or comparable agencies to commercialize our product candidates. Given the uncertainty, extensive time, and financial expenditures involved in moving a drug through the regulatory and clinical trial process in the United States, Canada, and Europe and elsewhere, we may never be able to successfully develop safe, commercially viable products. If we are unable to do so, we may have to cease operations.

## WE ARE DEPENDENT ON THE SUCCESSFUL OUTCOME OF PRECLINICAL TESTING AND CLINICAL TRIALS.

None of our product candidates are currently approved for sale by the FDA, EMEA, and Health Canada or by any other regulatory agency in the world, and they may never receive approval for sale or become commercially viable. Before obtaining regulatory approval for sale, each of our product candidates must be subjected to extensive preclinical and clinical testing to demonstrate safety and efficacy for each proposed indication for human use. Our success will depend on the successful outcome of these preclinical testing and clinical trials. There are multiple risk factors associated with conducting clinical trials of our investigational drug and device product candidates. There may be unforeseen delays in identifying and reaching agreement on acceptable terms with Institutional Review Boards of clinical trial providers with respect to proposed clinical study protocols. There may also be delays in reaching satisfactory financial agreements with prospective clinical trial sites and the investigators themselves.

There may be regulatory delays of clinical trials related to obtaining FDA, Health Canada, European Medicines Agency ("EMEA"),, or other regulatory agency clearance to begin patient treatment in a clinical trial. A common issue in conducting a clinical trial is that delays encountered in the enrollment of patients may significantly prolong the length of time required to conduct clinical studies.

A prime risk factor of clinical trials is that the study outcome may reveal that the product candidate does not demonstrate the anticipated level of effectiveness in the target patient population. Such outcomes may adversely affect the approvability of the potential product by regulatory agencies. Similarly, clinical trials may show that an investigational product causes unacceptable adverse events in the patient population to be treated with the drug.

Historically, the results from preclinical testing and from early clinical trials often have not always been predictive of results obtained in later clinical trials. Frequently, drugs that have shown promising results in preclinical or early clinical trials subsequently fail to demonstrate sufficient evidence of safety or effectiveness necessary to obtain regulatory approval. Our success will depend on the success of our current clinical trials and subsequent clinical trials that have not yet begun. Moreover, regulatory agencies such as the FDA, EMEA and Health Canada may impose specific standards on the evaluation of disease response in individual patients which may differ from those anticipated by ViRexx or its clinical advisors. These different standards may lead the regulatory agency to conclude that study subjects receiving any of our product candidates have had a more modest clinical response than that determined by ViRexx or its clinical advisors.

In addition to the risks mentioned, there are a number of other difficulties and risks associated with clinical trials. The possibility exists that:

- (a) we may discover that our product candidates may cause, alone or in combination with another therapy, unacceptable side effects or are not effective at all;
- (b) we may discover that our product candidates, alone or in combination with another therapy, do not exhibit the expected therapeutic results in humans;
- (c) results from early trials may not be predictive of results that will be obtained from large-scale, advanced clinical trials as mentioned above;
- (d) we or the FDA or other regulatory agencies may suspend the clinical trials of one or more of our product candidates;
- (e) patient recruitment may be slower than expected;
- (f) patients may drop out of our clinical trials; and
- (g) there may be cost overruns.

Although the FDA and EMEA have granted OvaRex®MAb Orphan Drug Status for its use in ovarian cancer, this status does not diminish any of the requirements for market approval. Given the uncertainty surrounding the regulatory and clinical trial process, we may not be able to develop safety, efficacy or manufacturing data necessary for approval of this or any of our product candidates. In addition, even if we receive

approval, such approval may be limited in scope and affect the commercial viability of such product candidate. If we are unable to successfully obtain approval to commercialize any product candidate, this would materially harm our business, impair our ability to generate revenues and adversely impact our stock price.

### DELAYS IN CLINICAL TRIALS WILL CAUSE US TO INCUR ADDITIONAL COSTS, WHICH COULD JEOPARDIZE THE TRIALS AND ADVERSELY AFFECT OUR LIQUIDITY AND FINANCIAL RESULTS.

For internally funded clinical trials and the due to the associated high costs, a delay for any reason, will require us to spend additional funds to keep our product candidates moving through the regulatory process. If we do not have or cannot raise the necessary additional funds, the testing of our product candidates could be cancelled. If we are required to spend additional funds, it will require us to spend funds that could have been used for other purposes and could adversely affect our liquidity and financial results. Delays in obtaining clinical -trial results will also delay profitability from commercialization of any given product candidate and accordingly negatively effects our financial results.

## WE RELY ON CLINICAL INVESTIGATORS AND CONTRACT RESEARCH ORGANIZATIONS TO CONDUCT OUR CLINICAL TRIALS.

We rely, in part, on independent clinical investigators and contract research organizations to conduct our clinical trials. Contract research organizations also assist us in the collection and analysis of the data generated from these clinical trials. These investigators and contract research organizations are not our employees and we cannot control, other than by contract, the amount of resources, including time that they devote to our product candidates and our clinical trials. If independent investigators fail to devote sufficient resources to our clinical trials, or if their performance is substandard, these factors may delay any possible approval and commercialization of our product candidates and could harm our chances of obtaining regulatory approval. Further, most regulatory agencies require that we comply with standards, commonly referred to as Good Clinical Practice ("GCP") for conducting, recording, and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected.

If our independent clinical investigators and contract research organizations fail to comply with GCP, the results of our clinical trials could be called into question and the clinical development of our product candidates could be delayed or halted. The failure of clinical investigators and contract research organizations to meet their obligations to us or comply with good clinical practice procedures could adversely affect the clinical development of our product candidates, and have a material adverse effect on our business, financial condition, and results of operations.

### THERE ARE RISKS INHERENT IN RELYING ON SOLE SOURCE SUPPLIER FOR SOME OF OUR MATERIALS.

We are reliant upon the supply of raw materials from key suppliers in the manufacture of our product candidates. These key suppliers currently meet our manufacturing requirements but they could default in the supply of the raw material for several reasons, including insolvency, lack of regulatory compliance, inability to manufacture sufficient quantities of the raw material, fire, and natural disasters. Although we have made every effort to identify alternate source suppliers of these raw materials, there is no guarantee that supply agreements would be established with these suppliers if the primary supplier defaults in the supply of raw material. If we are unable to procure the requisite raw materials for the manufacture of product candidates, then we might not be able to manufacture sufficient quantities of the drug candidate for pre-clinical and clinical testing purposes.

WE ARE DEPENDENT ON STRATEGIC PARTNERS, SUCH AS UNITHER AND THE SIGMA TAU GROUP OF COMPANIES, AS PART OF OUR PRODUCT CANDIDATE DEVELOPMENT STRATEGY, AND WE WOULD BE NEGATIVELY AFFECTED IF WE ARE NOT ABLE TO INITIATE OR MAINTAIN THESE

### RELATIONSHIPS.

In April 2002, our subsidiary, AltaRex Medical Corp., entered into an Exclusive License Agreement with Unither Pharmaceuticals Inc. ("Unither"), a wholly owned subsidiary of United Therapeutics for the development and commercialization of OvaRex® MAb and four other antibody-based products worldwide, with the major exception of certain member nations of the European Union and certain other countries. In August of 2003, the Exclusive License Agreement was extended to include Germany. Under the Exclusive License Agreement, Unither is responsible for the development of our intellectual property with respect to the five antibodies, including the commercialization of the five antibodies in the licensed territory. Unither has agreed to pay us certain amounts based upon the achievement of specified milestones together with royalties based upon sales of products utilizing or incorporating the licensed technology sold in the licensed territory. If Unither does not devote the resources necessary or does not advance the clinical development of the potential products, particularly OvaRex® MAb, we would be materially adversely affected. Under the Exclusive License Agreement, Unither is permitted to develop intellectual property with respect to five antibodies but has granted AltaRex an exclusive royalty-free license to use these new technologies outside of the Unither territories.

In November 2006, we entered into a License and Supply Agreement with Defiante Farmaceutica, Lda. ("Defiante"), a subsidiary of Sigma Tau Farmaceutica ("Sigma Tau") for the marketing of OvaRex® MAb for the remaining unlicensed countries in Europe. At the same time, ViRexx International Corp. Limited entered into a Manufacturing and Supply Agreement with Tecnogen S.C.p.A ("Tecnogen"), another subsidiary of Sigma Tau, for Tecnogen to manufacture OvaRex® MAb for most of Europe and the Middle East. If Sigma Tau and Tecnogen do not devote the resources necessary or do not advance the scale up and manufacture of OvaRex® MAb, we will be materially adversely affected.

Once any of our product candidates advance to a Phase II clinical trial stage, we intend to enter into strategic partnerships whereby third parties will finance further clinical development. We cannot assure, however, that we will be able to find partners and establish such relationships on favorable terms, if at all, or that any such future arrangements will be successful.

Should any partner fail to develop or commercialize successfully any product candidates to which we have licensed product rights, our business, financial condition, and results of operations may be adversely affected. The failure of any collaborative partner to continue funding any particular program, for any reason, could delay or halt the development or commercialization of any potential product arising out of a particular program. In addition, we cannot assure that any of our future partners would not pursue alternative technologies or develop alternative product candidates either on their own or in collaboration with others, including our competitors, as a means for developing treatments for the diseases targeted by our programs.

## WE RELY ON COLLABORATIVE ARRANGEMENTS FOR MANUFACTURING OUR TRIAL MATERIAL AND PRODUCT CANDIDATES

We are reliant upon Unither for all manufacturing responsibilities for OvaRex® MAb and the four other monoclonal antibodies included in the Unither Agreement for their territories. We are reliant upon Tecnogen for all manufacturing responsibilities for OvaRex® MAb in our territories. We can make no assurance that delays will not be encountered in the manufacturing activities required for regulatory filings for OvaRex® MAb and the other antibodies, or that Unither's and/or Tecnogen's manufacturing decisions would be appropriate for ViRexx and its other collaborators.

ViRexx has made arrangements with contract manufactures for producing OvaRex® MAb Europe. However, if long-term arrangements for the production of the other antibody-based products cannot be entered into, we may experience delays in the development and commercialization of our product candidates. In addition, if these contract suppliers fail to perform under the terms of the agreement, we may incur significant costs.

Successful scale-up of production and producing multiple consistency lots of cell culture-derived materials will enable us, Unither, and Tecnogen to further pursue regulatory approval and commercialization of OvaRex® MAb and the other antibodies. Such regulatory approval and commercialization is dependent upon our, Unither's and Tecnogen's ability to achieve such improvements in production.

### EVEN IF OUR PRODUCT CANDIDATES RECEIVE ALL OF THE REQUIRED REGULATORY APPROVALS, WE HAVE NO GUARANTEE OF MARKET ACCEPTANCE OR COMMERCIALIZATION OF THE RESULTING PRODUCT CANDIDATES, WHICH WILL BE DETERMINED BY OUR SALES, MARKETING, AND DISTRIBUTION CAPABILITIES AND THE POSITIONING AND COMPETITIVENESS OF OUR PRODUCT CANDIDATES COMPARED WITH ANY ALTERNATIVES.

Even if our product candidates receive all necessary regulatory approvals and clearances, they may not gain market acceptance among physicians, patients, healthcare payers, and the medical community. The degree of market acceptance of any product candidate that we may develop will depend on a number of factors, including marketing and distribution support for the product candidates, establishment and demonstration of the cost-effectiveness of the

product candidates, and the potential advantage of our product candidates over any alternatives. Even after successful commercialization of one or more product candidates, we may never achieve profitability. We currently depend on our Licensees for their sales, marketing, or distribution capabilities, and therefore must rely on these third parties to perform these services optimally.

These distribution partners may not promote our product candidates as aggressively as we would like, may not be successful in their sales and distribution efforts, may experience financial difficulty or lack the marketing or financial ability to adequately market our product candidates, or may fail to promote our product candidates altogether. Third party marketers may be involved in the sale of competing products and fail to market our product candidates due to this conflict. In addition, if the profit margins on our product candidates may not be promoted as readily. As in the case of any contractual relationship if either party defaults under the marketing agreement, sales of our product candidates may suffer. If we terminate a marketer of our product candidates, we may not be able to find an immediate replacement. Any of these events would have a material adverse effect on our business, financial condition, and results of operations. These events may also lead us to try to establish our own marketing and sales force. The acquisition or development of a sales and distribution infrastructure would require substantial resources, which may divert the attention of our management and key personnel, and have a negative impact on our potential product development efforts. Moreover, we may not be able to establish in-house sales and distribution capabilities or relationships with third parties.

If successfully developed, our product candidates will compete with a number of drugs and therapies currently manufactured and marketed by major pharmaceutical and biotechnology companies. Our product candidates may also compete with new products currently under development by other pharmaceutical and biotechnology companies, and with products which may cost less than our product candidates or that may be more effective than our product candidates. If our product candidates do not achieve significant market acceptance, our business, financial condition, and results of operations will be materially adversely affected.

## REIMBURSEMENT PROCEDURES AND FUTURE HEALTHCARE REFORM MEASURES ARE UNCERTAIN AND MAY ADVERSELY AFFECT OUR ABILITY TO SUCCESSFULLY SELL OR LICENSE ANY PHARMACEUTICAL PRODUCT CANDIDATE.

If any of our potential products is approved for commercialization by national regulatory authorities, the extent of sales will depend upon the availability of reimbursement from third-party payers such as Medicare in the United States and similar government health administration authorities in other countries, as well as private health insurers and other organizations. Our ability to successfully sell or license any pharmaceutical product candidate will depend in part on the extent to which government health administration authorities, private health insurers and other organizations will reimburse patients or providers for the costs of any future pharmaceutical product candidates and related treatments. Each jurisdiction has its own regulatory requirements. Significant variation exists as to the reimbursement status of newly approved healthcare products, and we cannot assure you that adequate third party coverage will be available to establish price levels sufficient for us to realize an appropriate return on our investment in developing new product candidates or for existing product candidates. Increasingly, government and other third-party payers are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic product candidates. Reimbursement levels may be related to issues of cost-effectiveness, which are evaluated differently in different jurisdictions. Inadequate coverage or reimbursement could adversely affect market acceptance of our product candidates. Recently, the prices of medical products and services have been examined and challenged by third parties and consumers of such products and services. Successful challenges or government reform in this area could negatively affect our profitability.

In the United States, government and other third-party payers have sought to contain healthcare costs by limiting both coverage and the level of reimbursement for new pharmaceutical products approved for marketing by the FDA. In some cases, these may place conditions on the use of new products which limit their market penetration or may refuse to provide any coverage for uses of approved products to treat medical conditions even though the FDA has granted marketing approval. Healthcare reform may increase these cost containment efforts. U.S. managed care organizations and government health insurance programs may seek to restrict the use of new products, delay authorization to use new products or limit coverage. New rule making by the Center for Medicare and Medicaid Services could affect drug

coverage and payments by Medicare. Internationally, where government healthcare systems are prevalent, little if any funding may be available for new products, and cost containment and cost reduction efforts can be more pronounced than in the United States.

## COMPETITIVE PRODUCTS AND TECHNOLOGIES MAY REDUCE DEMAND FOR OUR PRODUCT CANDIDATES AND TECHNOLOGIES.

Our success depends upon maintaining our competitive position in the research, development, and commercialization of products and technologies in our area of expertise. Competition from pharmaceutical, chemical and biotechnology companies as well as universities and research institutes, is intense and is expected to increase. Many of these competitors have substantially greater research and development capabilities, more experience in manufacturing and marketing, as well as superior financial and managerial resources than we do and represent significant competition for us.

We cannot assure you that developments by others will not render our product candidates or technologies non-competitive or obsolete, or that we will be able to achieve the level of acceptance within the medical community necessary to compete successfully. We are aware of several potential competitors that are at various stages of development or that have commercial sales of products that may address similar indication as do our products. The success of our competitors and their products may have a material adverse impact on our business, financial condition, and results of operations.

### OUR INDUSTRY IS CHARACTERIZED BY RAPID CHANGE AND A FAILURE BY US TO REACT TO THESE CHANGES COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS.

The biotechnology industry is characterized by rapid and substantial technological change. Alternative forms of medical treatment may render our technologies or product candidates of low or no value in the future. Our future success depends on our ability to adapt to this change and keep pace with new technological developments and emerging industry standards, and we cannot assure that we will be able to do so.

## IF WE FAIL TO HIRE OR RETAIN NEEDED PERSONNEL, THE IMPLEMENTATION OF OUR BUSINESS PLAN COULD SLOW AND FUTURE GROWTH COULD SUFFER.

Our success depends in large part upon our ability to attract and retain highly qualified scientific and management personnel. Competition to retain personnel in the biotechnology field from other companies, academic institutions, government entities, and other organizations is intense. We cannot assure that we will retain our current personnel and will be able to continue to attract qualified personnel, and any failure to do so could slow implementation of our business plan or future growth. To date, however, we have had no difficulties attracting and retaining highly qualified scientific and management personnel. Additionally, none of our scientific or management personnel have indicated that they have plans to retire or leave our company in the foreseeable future.

## THE LOSS OF THE SERVICES OF OUR CHIEF EXECUTIVE/CHIEF SCIENTIFIC OFFICER COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS.

We are highly dependent on the knowledge and services of our Chief Executive/Chief Scientific Officer. If we were to lose his services, it would be difficult and costly to find a replacement, and it may have a severe impact on the implementation of our business plans.

## WE ARE RELIANT ON KEY EMPLOYEES, OUR SENIOR EXECUTIVES AND QUALIFIED MANAGERS, EMPLOYEES AND TECHNOLOGISTS, WHOSE DEPARTURES COULD LIMIT OUR GROWTH AND MAY HAVE A MATERIAL ADVERSE IMPACT ON OUR BUSINESS AND OPERATIONS.

We believe that Dr. Lorne Tyrrell, Mr. Marc Canton, Dr. Hubert Eng and Mr. Michael Stewart are the only persons employed by us that we would consider key employees upon whom we are critically dependent. Dr. Tyrrell occupies the dual roles of Chief Executive Officer and Chief Scientific Officer. Dr. Marc Canton, our President and Chief Operating Officer, also carries a major role in Business Development. He will play a key role in working with our licensing partners in Europe, our major territory for commercialization of OvaRex® MAb. Dr. Hubert Eng is the key individual coordinating technology transfer from Unither to our European partners for the production and licensing of OvaRex® MAb in Europe. Mr. Michael Stewart is leading the development of our T-ACT<sup>TM</sup> products - Occlusin<sup>TM</sup> 50 Injection and Occlusin<sup>TM</sup> 500 Artificial Embolization Device. These key individuals play critical roles in bringing our near-term product candidates to market.

We do not have "key person" insurance with respect to Dr. Tyrrell, Mr. Canton, Dr. Eng, or Mr. Stewart. While we have entered into employment agreements with each Dr. Tyrrell, Mr. Canton, Dr. Eng, and Mr. Stewart, such may be terminated by either party upon proper and timely written notice without cause or by us without prior notice for

reasons of just cause. The terms of each of the employment agreements are continuing terms until either party chooses to terminate the employment agreement.

## WE CONDUCT CERTAIN ELEMENTS OF OUR BUSINESS INTERNATIONALLY, AND THE DECISIONS OF SOVEREIGN GOVERNMENTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR FINANCIAL CONDITION.

We may conduct certain elements of our business internationally. We intend to, and may conduct clinical trials in other jurisdictions. Sovereign governments, including Canada, may establish laws or regulations that will be deleterious to our interests or that will affect our ability, as a foreign corporation, to obtain access to regulatory agencies in foreign jurisdictions. Governments have also, from time to time, established foreign exchange controls which could have a material adverse effect on our business, financial condition, and results of operations. To date, neither our operations nor our financial conditions have been detrimentally affected in any material way due to laws or regulations of sovereign governments.

## OUR OPERATING RESULTS MAY BE SUBJECT TO CURRENCY FLUCTUATIONS, AS OUR OPERATIONS ARE BASED LARGELY IN CANADA, WHILE SOME OF OUR EXPENSES ARE IN U.S. DOLLARS OR OTHER FOREIGN CURRENCIES.

Our operations are based in Canada, while some of our expenses, in particular those related to manufacturing clinical products, are in U.S. dollars or currencies other than Canadian dollars. As at December 31, 2006, approximately 60% of our payments made in relation to accounts payable were made in Canadian dollars, approximately 40% were made in U.S. dollars. Currency fluctuations could, therefore, cause our costs to increase and revenues to decline. The exchange rates of the Canadian dollar to the U.S. dollar, the British pound and the European Euro have fluctuated in recent years. In circumstances where the Canadian dollar devalues against any or all of the U.S. dollar, the British pound or the European Euro, this may have an adverse effect on our costs incurred in either the U.S. or Europe (as applicable) but may have a positive effect on any revenues which we source from the U.S. or Europe (as applicable). The same principles apply in respect of our costs and revenues in other jurisdictions. In addition, we manufacture some of our product candidates outside of Canada, which exposes us to potential cost increases resulting from fluctuations in exchange rates. We do not currently have any plans to hedge the effect of currency fluctuations on our overseas expenditures. We manage our currency risks by settling foreign currency payables immediately upon recognition of a foreign currency liability.

OUR INSURANCE MAY NOT BE SUFFICIENT AND WE MAY BE EXPOSED TO LAWSUITS AND OTHER CLAIMS RELATED TO OUR PRODUCT CANDIDATES IN CLINICAL STUDIES AND PRODUCT LIABILITY WHICH COULD INCREASE OUR EXPENSES, HARM OUR REPUTATION, AND KEEP US FROM GROWING OUR BUSINESS.

The sale and use of human therapeutic products, including those product candidates we are developing, involve an inherent risk of product liability claims and adverse publicity. Clinical studies involve trials on humans. These studies create a risk of liability for side effects to participants resulting from an adverse reaction to the product candidates being tested or resulting from negligence or misconduct. While we currently maintain limited insurance related to our ongoing clinical trials, we cannot assure you that this insurance will continue to be available to us on commercially reasonable terms. Any claims might also exceed the amounts of this coverage. If we are unable to obtain our insurance at reasonable rates or otherwise protect ourselves against potential liability proceedings, we may be required to slow down any future development of product candidates or may even be prevented from developing the product candidates at all. Our obligation to pay indemnities or withdraw a product candidate from clinical trials following complaints could have a material adverse effect on our business, financial condition, and results of operations. Claims against us, regardless of their merit or potential outcome, may also result in severe public relations problems that could seriously damage our reputation and business viability.

In addition, certain drug retailers require minimum product liability insurance coverage as a condition of purchasing or accepting products for retail distribution. If any of our product candidates are successfully developed and approved for commercial sale, it is our intention to obtain adequate product liability insurance before the product candidates are marketed. Failure to satisfy these insurance requirements could impede our ability or that of any potential distributors of our product candidates to achieve broad retail distribution of these product candidates, which would have a material adverse effect on our business, financial condition, and results of operations.

### WE USE HAZARDOUS MATERIALS THAT ARE HIGHLY REGULATED AND WE MAY BE EXPOSED TO POTENTIAL LIABILITY IN THE EVENT OF AN ACCIDENT INVOLVING THESE MATERIALS; OUR COMPLIANCE WITH ENVIRONMENTAL REGULATIONS COULD BE COSTLY IN THE FUTURE.

Our discovery and development processes involve the controlled use of radioactive and hazardous materials. We are subject to Canadian federal, provincial, and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. The risk of accidental contamination or injury
from these materials cannot be completely eliminated. In the event of an accident of this nature, we could be held liable for any damages that result and any liability of this kind could exceed our resources and, if so, we may have to cease operations. We have general liability insurance but it may not be sufficient to cover the cost of any injuries or other damage sustained in respect of these risks. Our coverage limitations under our insurance policies are described above under "OUR INSURANCE MAY NOT BE SUFFICIENT AND WE MAY BE EXPOSED TO LAWSUITS AND OTHER CLAIMS RELATED TO OUR PRODUCT CANDIDATES IN CLINICAL STUDIES AND PRODUCT LIABILITY WHICH COULD INCREASE OUR EXPENSES, HARM OUR REPUTATION, AND KEEP US FROM GROWING OUR BUSINESS". We cannot assure that we will not be required to incur significant costs to comply with environmental laws and regulations in the future, or that our operations, business, or assets will not be materially adversely affected by current or future environmental laws or regulations.

IT IS POSSIBLE THAT OUR AIT<sup>™</sup>, CHIMIGEN<sup>™</sup> AND T-ACT<sup>™</sup> TECHNOLOGIES HAVE ADVERSE SIDE EFFECTS OR CAUSE UNDESIRABLE REACTIONS ALTHOUGH WE ARE NOT AWARE OF ANY AT PRESENT.

#### AIT<sup>TM</sup> platform

The AIT<sup>TM</sup> platform is based on the delivery of small amounts of a murine monoclonal antibody to patients with cancer. There is a risk that a patient may develop an anaphylactic adverse event upon exposure to this foreign antibody. This risk is tempered by preliminary studies with OvaRex® MAb in more than 700 ovarian cancer patients demonstrating a benign safety profile for this product candidate.

# Chimigen<sup>™</sup> Platform

Since the Chimigen<sup>TM</sup> protein incorporates a portion of a murine (foreign) antibody fragment; it is possible that patients receiving a Chimigen<sup>TM</sup> Vaccine could develop an anaphylactic adverse event similar to that discussed for the AIT<sup>TM</sup> platform above. This risk is mitigated somewhat by the completion of the 15 patient Phase I safety trial which showed the benign safety properties of HepaVaxx B Vaccine. In addition, a Chimigen<sup>TM</sup> Vaccine is designed to induce both humoral and cellular immune responses against the viral antigen epitope(s) contained in the vaccine. These immune responses can lead to the death of cells infected with the target virus. Patients chronically infected with hepatitis B or C viruses could suffer adverse events associated with the destruction of liver cells following immunization with a Chimigen<sup>TM</sup> Vaccine such as the HepaVaxx B Vaccine or HepaVaxx C Vaccine. This could be important in patients that have impaired liver function and could render a patient ineligible to receive a Chimigen<sup>TM</sup> platform-based therapy.

# T-ACT<sup>TM</sup> platform

T-ACT<sup>TM</sup> technology is based on the induction of a specific platelet-dependent clot at a desired location. A potential risk of this technology is that a clot may break-up and localize to other locations in the body. Another potential risk is that with Occlusin<sup>TM</sup> product candidates, injected material could reach the systemic circulation through arterio-venous shunts in the target vasculature. These risks are mitigated using angiographic imaging of the target blood vessels prior to treatment.

All of these risks will be continuously monitored during the conduct of all phases of clinical trials and should any serious adverse event occur, this event will be reported to the appropriate regulatory agencies for immediate action.

# WE FACE COSTS ASSOCIATED WITH IMPORTING OUR PRODUCTS INTO MARKETS OUTSIDE OF CANADA.

We may face difficulties importing our products into various jurisdictions as a result of, among other things, import inspections, incomplete or inaccurate import documentation or defective packaging. There will be increased costs associated with importing/exporting our product.

#### IF THERE ARE FEWER INDIVIDUALS IN OUR TARGET MARKETS THAN WE ESTIMATE, WE MAY NOT GENERATE SUFFICIENT REVENUES TO CONTINUE DEVELOPMENT OF OUR PRODUCT CANDIDATES OR CONTINUE OPERATIONS.

Our estimate of the patient population of our target markets is based on published studies as well as internal analyses and studies we have commissioned. If the results of these studies or our analysis of them do not accurately reflect the number of patients in our target markets, our assessment of the market may be wrong, making it difficult or impossible for us to meet our revenue goals. In addition, it is difficult to determine the portion of the patient population that might use our other product candidates.

# WE WILL NEED TO SIGNIFICANTLY INCREASE THE SIZE OF OUR ORGANIZATION, AND WE MAY EXPERIENCE DIFFICULTIES IN MANAGING GROWTH.

We are currently a small company with 25 full time employees as of December 31, 2006. In order to continue our preclinical and clinical trials and commercialize our product candidates, including manufacturing commercial quantities and marketing and selling OvaRex® MAb, we will need to increase our operations, including expanding our employee base. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our preclinical and clinical trials effectively;
- undertake and manage the manufacturing of products effectively;
- undertake and manage sales and marketing effectively;
- integrate current and additional management, administrative, financial and sales and marketing personnel;
- develop our administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

# RISKS RELATING TO A POTENTIAL CHANGE IN THE MAJORITY OF OUR BOARD OF DIRECTORS.

We were made aware that a Schedule 13D dated February 12, 2007, was filed with the United States Securities and Exchange Commission on February 14, 2007 followed by an amended Schedule 13D filed on February 21, 2007 by a Bahamian company, Smetek, Van Horn & Cormack, Inc. The Schedule 13DA states that on February 12, 2007 the holders of 27,744,105 common shares of ViRexx, purportedly representing 40% of our issued and outstanding shares (the "Smetek Group") held a telephone conference and have agreed to vote in favor of a change in the majority of our Board of Directors.

Pursuant to our By-laws, at each annual meeting of shareholders at which an election of directors is required or at a special meeting of our shareholders called for that purpose, the shareholders, by ordinary resolution, must elect directors to hold office for a term expiring not later than the close of the next annual meeting of our shareholders following the election. At every meeting of our shareholders, all questions proposed for the consideration of shareholders must be decided by the majority of votes, unless otherwise required by the Act or the Articles. Should the Smetek Group elect to vote as a group for the purpose of effecting a change in the majority of our Board of Directors, and such change is actually effected via attainment of a sufficient number of votes, the constitution of our Board of Directors may change, and our corporate and operations focus might also change as a result.

Currently we are discussing with external advisors our possible actions in light of the filing of the aforementioned Schedule 13D, and intend to continue to focus our resources on our operations and business development. As of the date of this Annual Report, we have not yet determined the date of our 2007 annual meeting, but expect to hold it before June 30, 2007.

# **RISKS RELATING TO OUR COMMON SHARES**

# AS WE ARE A CANADIAN COMPANY, THERE MAY BE LIMITATIONS ON THE ENFORCEMENT OF CERTAIN CIVIL LIABILITIES AND JUDGMENTS OBTAINED IN THE UNITED STATES AGAINST US.

We are amalgamated under the laws of the province of Alberta, Canada and our assets are located outside of the United States. Except for one of our directors, all of our directors and officers, as well as the expert named in this Annual Report, are residents of Canada, and all or a substantial portion of the assets of these persons are located outside of the United States. As a result, it may not be possible for shareholders to enforce against us or them in the United States judgments obtained in U.S. courts based upon the civil liability provisions of the U.S. Federal securities laws or other laws of the U.S. Therefore, it may not be possible to enforce those actions against us, most of our directors and officers or the expert named in this Annual Report. In addition, there is doubt as to the enforceability, in original actions in Canadian courts, of liabilities based upon the U.S. Federal securities laws.

# WE HAVE NOT PAID, AND DO NOT INTEND TO PAY, ANY CASH DIVIDENDS ON OUR COMMON SHARES AND THEREFORE OUR SHAREHOLDERS MAY NOT BE ABLE TO RECEIVE A RETURN ON THEIR SHARES UNLESS THEY SELL THEM.

We have never paid dividends on our common shares and we do not expect to have the ability to pay dividends in the foreseeable future. If we generate earnings in the future, we expect that they will be retained to finance further growth. Our Board of Directors will determine if and when dividends should be declared and paid in the future based on our financial position and other factors relevant at the particular time. Until we pay dividends, which we may never do, you will not be able to receive a return on your investment in our common shares unless you sell them, which you may only be able to do at less than the price you paid for them.

THE MARKET PRICE AND TRADING VOLUME OF OUR COMMON SHARES MAY BE VOLATILE.

The market price and trading volume of our common shares on the TSX and since we listed on the AMEX on December 22, 2005, has experienced significant volatility and will likely continue to do so, which has been or could be in response to numerous factors, including:

(a) macroeconomic factors such as a change in the bank rate;

(b) quarterly variations in operating results;

- (c) market conditions in the industry;
- (d) announcements of results of testing, technological innovations;

(e) announcements by our customers or competitors, developments affecting government regulations, developments concerning proprietary rights, litigation, and public concerns as to the safety of our product candidates;

(f) announcements of acquisitions;

- (g) general fluctuations in the stock market; and
- (h) revenues and results of operations below the expectations of the public market.

Any of these factors could result in a sharp decline in the market price of our common shares.

From January 1, 2005, to December 31, 2006, the trading price of our common shares has ranged from a low of \$0.66 per share to a high of \$1.62 per share on the TSX and from December 22, 2005, to December 31, 2006, it has ranged from U.S.\$0.50 to U.S.\$1.43 per share on the AMEX.

During 2006 and the first two months of 2007 an average of approximately 43,584 of our shares traded per day on the TSX and following our listing on the AMEX an average of 49,900 of our shares per day traded on the AMEX. On some trading days our shares have had limited trading volume. In addition, stock markets have occasionally experienced extreme price and volume fluctuations. Historically, the market prices for the securities of biotech companies, including ours, have been particularly affected by these market fluctuations, and these effects have often been unrelated to the operating performance of these particular companies. These broad market fluctuations may cause a decline in the market price of our common shares.

# THE SIGNIFICANT COSTS THAT WE WILL INCUR AS A RESULT OF BEING A PUBLIC COMPANY IN THE UNITED STATES AND CANADA COULD ADVERSELY AFFECT OUR BUSINESS.

We have listed our common shares on AMEX, and therefore we will incur significant legal, accounting and other expenses as a public company on both AMEX and the TSX. These expenses include, among others, costs with respect to preparing securities regulatory filings, costs in connection with compliance with the internal control audit provisions of the Sarbanes-Oxley Act of 2002 and Canadian Bill 52-109, costs in connection with other provisions of the Sarbanes-Oxley Act and 52-109, AMEX listing fees and potentially higher director and officer insurance premiums. In addition, the requirements we face by being listed on AMEX will impose significant time demands on our management. Although it has not yet been a problem for us, becoming subject to the reporting obligations of the Exchange Act could make it more difficult for us to attract and retain qualified individuals to serve on our Board of Directors or as our executive officers.

# AS A FOREIGN PRIVATE ISSUER, WE ARE SUBJECT TO DIFFERENT U.S. SECURITIES LAWS AND RULES THAN A DOMESTIC ISSUER, WHICH MAY, AMONG OTHER THINGS, LIMIT THE INFORMATION AVAILABLE TO HOLDERS OF OUR SECURITIES.

As a foreign private issuer, we are subject to requirements under the Securities Act and the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are different from the requirements applicable to domestic U.S. issuers. For example, our officers, directors, and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules there under with respect to their purchases and sales of our common shares. The periodic disclosure required of foreign private issuers is more limited than the periodic disclosure required of U.S. issuers and therefore there may be less publicly available information about us than is regularly published by or about U.S. public companies in the United States. Also, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

# Item 4. Information on ViRexx

# A. History and Development of ViRexx

The legal and commercial name of the Corporation is ViRexx Medical Corp.

ViRexx is a corporation amalgamated under the laws of the Province of Alberta, Canada pursuant to the provisions of the Alberta *Business Corporations Act* ("ABCA"). Our head office is located at 8223 Roper Road, Edmonton, Alberta, Canada, T6E 6S4, and our registered office is located at 1500 Manulife Place, 10180 - 101 Street, Edmonton, Alberta, Canada T5J 4K1. Our common shares are listed and posted for trading on the Toronto Stock Exchange ("TSX") under

the symbol "VIR" and the American Stock Exchange ("AMEX") under the symbol "REX".

ViRexx is the corporation resulting from the amalgamation of ViRexx Research Inc. ("ViRexx Research"), Norac Industries Inc. ("Norac") and Norac Acquisitions Inc. ("NAI"), a wholly owned subsidiary of Norac, under the ABCA on December 23, 2003 (the "ViRexx Amalgamation"). Pursuant to the ViRexx Amalgamation holders of Norac subordinate voting shares (the "Norac A Shares") received 0.2244667 common shares of ViRexx ("ViRexx Shares") for each Norac A Share held and holders of Norac multiple voting shares (the "Norac B Shares") received 0.0000004 ViRexx Shares for each Norac B Share held. The issued and outstanding class A shares of NAI (the "NAI Shares") was cancelled without any repayment of capital in respect of such shares as part of the ViRexx Amalgamation, and therefore Norac, as the sole shareholder of NAI, did not receive any ViRexx Shares. Holders of shares of ViRexx Research received 0.5285974 ViRexx Shares for each share of ViRexx Research held.

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Norac was incorporated under the ABCA on September 22, 1986. Norac has been a reporting issuer in the Province of Alberta since October 2, 1986, pursuant to the issuance of a receipt for a final prospectus under the Securities Act (Alberta). The Norac A Shares began trading on the TSXV (formerly, the Canadian Venture Exchange and prior to that the Alberta Stock Exchange) in April 1987 under the symbol "NRC.A" which was subsequently changed to the symbol "NRC.T". On June 23, 2003, trading of Norac's securities was halted upon the announcement of the ViRexx Amalgamation. On August 18, 2003, Norac's listing was moved to the NEX board of the TSX Venture Exchange ("TSXV") as a result of its inactive status, and Norac's symbol was changed to "NRC.H". Norac has been a reporting issuer in the Province of British Columbia since November 26, 1999.

ViRexx Research was the corporation resulting from the amalgamation of Novolytic Corp. and ViRexx Research Inc. ("Original ViRexx") under the ABCA on August 1, 2002. On August 1, 2002, immediately prior to the said amalgamation, the shareholders of Original ViRexx exchanged the 1,000,000 issued and outstanding class A common shares of Original ViRexx for 16,746,007 common shares of Novolytic Corp. and as a result Original ViRexx became a wholly owned subsidiary of Novolytic Corp. The share exchange ratio for the amalgamation of Original ViRexx and Novolytic Corp. was established by agreement between their respective boards of directors in consultation with an independent investment banking firm.

Novolytic Corp. was incorporated under the laws of the State of Nevada, U.S.A. on October 30, 2000 and was continued into the Province of Alberta as a corporation subject to the ABCA on May 31, 2002. On June 1, 2002, Novolytic Corp. was amalgamated under the laws of Alberta with Novolytic Inc. with the amalgamated corporation continuing under the name "Novolytic Corp." On June 1, 2002, immediately prior to the amalgamation of Novolytic Corp. and Novolytic Inc. the shareholders of Novolytic Inc. exchanged the 100 issued and outstanding shares of Novolytic Inc. for 100 class "A" common shares of Novolytic Corp. with Novolytic thereby becoming a wholly owned subsidiary of Novolytic Corp.

Novolytic Inc. was incorporated under the ABCA on April 8, 1999 under the name "A.C.T. Technologies Corp.", and on November 10, 1999 changed its name to Novolytic Inc.

The original ViRexx was incorporated as "ViRexx Corporation" under the ABCA on June 6, 2001, and on October 26, 2001 changed its name to "ViRexx Research Inc."

On December 10, 2004, ViRexx completed a plan of arrangement pursuant to Section 193 of the ABCA involving ViRexx and AltaRex Medical Corp. ("AltaRex"), whereby amongst other things, ViRexx acquired all of the outstanding common shares of AltaRex (the "AltaRex Arrangement"). For each common share of AltaRex owned, AltaRex shareholders received one half of one ViRexx Share. Also pursuant to the arrangement, all outstanding AltaRex stock options and warrants were deemed transferred to ViRexx (free of any claims) in consideration of new stock options or warrants for ViRexx Shares on the basis of one stock option or warrant for a ViRexx Share for every two AltaRex stock options or warrants with the exercise price of the such new ViRexx stock options and warrants being the price of the prior AltaRex stock options or warrants multiplied by two.

AltaRex was incorporated pursuant to the provisions of the ABCA as "AltaRex Medical Corp." on December 8, 2003. Effective December 23, 2003, AltaRex amended its articles of incorporation to remove its private company restrictions and restrictions on share transfer.

On February 3, 2004, AltaRex completed a plan of arrangement pursuant to Section 193 of the ABCA involving AltaRex, AltaRex Corp., the holders of the securities of AltaRex Corp. and Nova Bancorp Investments Ltd. (the "Bancorp Arrangement") whereby, amongst other things, AltaRex acquired substantially all the assets of AltaRex Corp. with a legally effective date of December 31, 2003, and has since carried on the business substantially as carried on by AltaRex Corp. prior to the completion of the Bancorp Arrangement.

Prior to the AltaRex Arrangement, the AltaRex common shares were listed and posted for trading on the Toronto Stock Exchange ("TSX") under the symbol "ALT". AltaRex was delisted from the TSX on December 16, 2004 as a result of the AltaRex Arrangement and ceased to be a reporting issuer in Canadian jurisdictions. ViRexx has not made any capital acquisitions or divestitures other than as described above and all of the funds it has in Treasury will be used to further its research and development programs.

On December 22, 2005, our common shares were listed on the AMEX. In 2006, we incorporated our wholly owned subsidiary named ViRexx International Corp under the laws of Ireland.

The principal capital expenditures for the last three fiscal years of ViRexx were as follows:

	2006	2005	2004
Laboratory Equipment	\$ 22,960	\$ 5,783	\$ 290,422
Leasehold Improvements	-	2,125	36,303
Office Furniture & Equipment	8,440	44,310	32,269
Computer hardware	37,812	56,600	32,269
Computer software	23,272	23,173	12,101
-	\$ 92,484	\$ 131,991	\$ 403,364

The expenditures were incurred in Canada. We do not expect any material increase in our capital expenditures in the current year.

# **B** Business Overview

We are a Canadian-based biotechnology company focused on the development of novel therapeutic products for the treatment of cancer and chronic viral infections. Our most advanced clinical programs include drug candidates for the treatment of ovarian cancer, chronic hepatitis B and C infection and solid tumours. These product candidates can be categorized using our three proprietary technology platforms:

- 1. The AIT (Antibody-based Immunotherapy) platform, which enhances the ability of the patient's immune system to produce a highly specific and effective anti-tumor response. This technology allows a patient to break tolerance to cancer-associated antigens by altering the recognition pathway used by the host immune system.
- 2. The T-ACT (Targeted Autothrombogenic Cancer Therapy) platform, which is a tumor starvation technology that offers multiple mechanisms of solid tumor destruction. This technology causes thrombus formation at the site of a hypervascular tumor, thereby interrupting the blood supply to the tumor and causing tumor death.
- 3. The Chimigen<sup>™</sup> Platform, which is a highly versatile technology designed to induce broad immune responses by using chimeric molecules that are fusion proteins, adding any that consist of a relevant antigen fused to a "xenotypic" murine monoclonal antibody fragment. This technology is used to induce broad immune responses against viruses and cancers that are normally unrecognized by the host immune system.

# AIT<sup>TM</sup> Technology

Based on the AIT<sup>™</sup> platform the Company's lead product candidate is OvaRex® MAb (monoclonal antibody). OvaRex® MAb represents a first-in-class therapy, fulfilling a currently unmet medical need; a need for which there is no existing treatment. OvaRex® MAb is intended for the treatment of ovarian cancer during the 'Watchful Waiting' period - that period of time after surgery and chemotherapy when the patient is waiting for the cancer to return, which occurs in more than 80% of patients. In Phase IIB studies, OvaRex® MAb demonstrated a delay in disease relapse (an extension of the watchful waiting period) by approximately 13 months versus placebo in patients who had undergone successful front line therapy (surgery and chemotherapy). The two ongoing Phase III studies, being funded by development partner Unither Pharmaceuticals, a subsidiary of United Therapeutics, are fully recruited and results are expected in the second half of 2007. OvaRex® MAb has been licensed worldwide, the most recent agreements being struck with Defiante Farmaceutica and Tecnogen, both subsidiaries of Sigma Tau of Rome, Italy, for the manufacturing, supply and distribution of OvaRex® MAb throughout most of Europe and the Middle East.

Other products in development using the AIT<sup>TM</sup> technology include BrevaRex® MAb for breast cancer and ProstaRex® MAb for prostate cancer.

# **T-ACT<sup>TM</sup> Platform Technology**

The T-ACT<sup>™</sup> platform is designed to interrupt the blood supply to hypervascular tumors, leading to tumor tissue starvation and tumor death. The lead product candidate of the T-ACT<sup>™</sup> platform is Occlusin<sup>™</sup> 50 Injection, a treatment for primary cancer of the liver. The Occlusin<sup>™</sup> 50 Injection safety trial is being conducted at the Toronto General Hospital under the direction of Dr. Morris Sherman and at the Foothills Hospital in Calgary, Alberta by Dr. Kelly Burak. The trial is designed to examine the safety of Occlusin<sup>™</sup> 50 Injection when used as an embolizing agent as part of the transcatheter arterial chemoembolization ("TACE") procedure used for the treatment of liver cancer. Ten patients had received treatment as of December 31, 2006. Interim data analysis demonstrated a decrease in tumor volume in four of the five patients treated with Occlusin<sup>™</sup> 50 Injection. The adverse events experienced by the study patients were similar to those normally encountered by patients undergoing the TACE procedure with standard embolic devices. Total costs expended in 2006 for the T-ACT<sup>™</sup> Platform were \$1,639,985. Partnering discussions have been initiated with numerous companies interested in Occlusin<sup>™</sup> 50 Injection. Specifically, ViRexx is evaluating potential partners interested in licensing the marketing and distribution rights to Occlusin<sup>™</sup> 50 Injection for Asia, where the prevalence of liver cancer is higher than anywhere else in the world. Successful completion of an agreement with a partner for this territory will result in an accelerated clinical development program for Occlusin<sup>™</sup> 50 Injection. The Corporation estimates the market for Occlusin<sup>™</sup> 50 Injection in Asia at more than \$300 million.

# Chimigen<sup>™</sup> Platform Technology

The lead product candidate from the Chimigen<sup>™</sup> platform is HepaVaxx B Vaccine, a therapeutic vaccine for the treatment of chronic hepatitis B infection. In early 2005, the Corporation entered into an agreement with a contract manufacturer, Protein Sciences Corporation ("PSC") of Meriden, Connecticut, for the production of HepaVaxx B Vaccine. PSC successfully manufactured GMP product in the fourth quarter of 2005. The treatment of normal, healthy volunteers in a Phase I safety study was completed in the third quarter of 2006. Our second Chimigen<sup>™</sup> vaccine candidate, HepaVaxx C Vaccine, will be a therapeutic vaccine for the treatment of chronic hepatitis C infection. Continued efforts in 2007 will be directed to select a Chimigen<sup>™</sup> hepatitis C therapeutic vaccine candidate for clinical testing. Partnering discussions have also been initiated for HepaVaxx B Vaccine. Specifically; ViRexx is targeting potential partners with a strong presence in Asia where almost three quarters of the world's chronic hepatitis B sufferers exist. The Corporation estimates the market for a successful therapeutic vaccine in Asia at more than \$1 billion.

# **Product Candidate Pipeline**

A summary of the development stage for each of the drug candidates is as follows:

# **Business Strategy**

As announced on November 28, 2006, we have adopted a strategy of prioritizing research activities to focus on the completion of existing product candidates within its existing technology pipeline that provide near term potential revenue stream. As the development of OvaRex® MAb has progressed towards a potential market launch, we have invested in management and human resources personnel with expertise and experience in handling the commercialization process. This represents an increased commitment to anticipated commercialization needs in addition to meeting the traditional scientific and development requirements. Based on our analysis of existing resources, we have reduced our internal research budget by over 65% of its original budget for 2007/2008, and increased business development budget by 62% over that of 2006.

Our strategic plan includes the following:

• Focus research expenditures on near term product opportunities,

• Control expenditures on longer term opportunities by partnering or licensing earlier stage programs to strong development and commercialization partners,

• Reduce overall expenditures to minimize the level of additional capital required, and

• Maximize the allocation of existing capital prior to the data analysis of the two ongoing Phase III OvaRex® MAb trials.

# Key Milestones

Our strategic plan calls for the achievement of a number of significant milestones over the next 12 months:

- Release of the results of the Phase III clinical trials of OvaRex® MAb;
- Completion of GMP manufacturing of a clinical batch of Occlusin' 500 Artificial Embolization Device;
- Completion of an ongoing Phase II study of OvaRex® MAb in combination with frontline chemotherapy;
- Submission of an application to Health Canada for an Investigational Testing Authorization (CTA) for a pilot study I of the Occlusin' 500 Artificial Embolization Device and
- Initiation of a Phase I pilot study of for Occlusin' 500 Artificial Embolization Device;
- Completion of the ongoing Phase I HepaVaxx B Vaccine trial.

Our main focus in 2007-2008 is to concentrate our resources on two products, Occlusin' 500 Artificial Embolization Device and OvaRex® MAb, both expected to be launched at approximately the same time, in 2008-2009.

Following the anticipated commercialization of OvaRex® MAb and Occlusin<sup>TM</sup> 500 Artificial Embolization Device, we may search for possible strategic in-licensing of potential product candidates to supplement our existing technologies. The Corporation will also continue to develop its existing technologies. The projected income streams from OvaRex® MAb and the Occlusin<sup>TM</sup> 500 Artificial Embolization Device, in the midterm and from HepaVaxx B Vaccine and Occlusin<sup>TM</sup> 50 Injection product licensing and sales in the long term are expected to fund the ongoing development of the Corporation's product pipeline.

In order to minimize expenditures in the short to mid-term time period for product candidates that have a launch window of 2010 and later, we will accelerate business development efforts to identify a development partner for its lead Chimigen<sup>™</sup> product candidate, HepaVaxx B Vaccine. Partnering the HepaVaxx B Vaccine program prior to a Phase II trial will provide the benefit of a partner with late-stage clinical development expertise and commercial expertise in regions that have the highest incidence of hepatitis B infection, such as Asia, while minimizing some of our development costs.

# AIT<sup>TM</sup> Platform Technology

# Technology Overview

The Corporation's antibody-based AIT<sup>TM</sup> products are designed to induce the immune system to recognize a patient's circulating tumor antigens as foreign, thereby triggering the immune system to respond to and attack the antigens and the cells that display them. The resulting robust response employs both the humoral (antibody-based) and cellular (T-cell based) arms of the immune system. Circulating tumor antigens are ideal targets for antibody-based immunostimulation since they are readily available for processing by the antigen-presenting cells of the immune system.

# Harnessing the Immune System

Monoclonal antibodies (MAbs) were once thought to be magic bullets that would bind to tumor cells and thereby deliver therapeutic entities to a tumor. One of the historical challenges to the monoclonal antibody (MAb) field has been the natural shedding by tumors of antigens into the bloodstream. Once in circulation, these shed tumor antigens bind with the MAbs before they reach their destination (the tumor) to provide a direct pharmacological effect. When select monoclonal antibodies bind to the antigen in circulation our antibodies trigger the immune system to recognize and attack epitopes of the antigen which are also found on the tumor cells. Our research has further demonstrated that our antibody-based products facilitate and modify tumor antigen processing to trigger T-cell immunity.

# OvaRex® MAb

# Product Candidate Overview

OvaRex® MAb is a murine antibody-based product that has a high degree of specificity to the tumor associated antigen CA125 that is over-expressed on tumor cells in over 80% of women with stage III/IV ovarian cancer. We believe that OvaRex® MAb acts as an immunotherapeutic agent by inducing and/or amplifying the human body's immune response against ovarian cancer.

#### OvaRex® MAb

§ Based on a fully foreign monoclonal antibody (MAb) that targets CA125 in circulation

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§ Induces broad immune responses against CA125 and consequently against the patient's CA125 positive ovarian tumors

§ in final stages of clinical development - ongoing Phase II and Phase III trials

§ benign safety profile and good quality of life during treatment

§ has been granted Orphan Drug status in U.S. and Europe and Fast Track status in U.S.

OvaRex® MAb has shown promise in treating cancer patients in both remission and recurrent stages of the disease. It will primarily be used in patients who only have a residual tumor burden following surgery and chemotherapy.

Our data suggests that a positive correlation exists between the extent of the immunogenic response against CA125 and the progression-free and survival times of patients. OvaRex® MAb recognizes only a single epitope on the CA125 molecule, yet following administration of OvaRex® MAb the patient is able to generate antibodies directed against multiple epitopes (distinct submolecular regions) of CA125, indicating that a highly effective immune response has been brought on by the product candidate.

Over 700 ovarian cancer patients have participated in seven comprehensive OvaRex® MAb clinical trials conducted in North America and Germany. Clinical results have demonstrated an increase in time to disease relapse, coupled with a benign safety profile. Results from five studies have been reported, including results from the Corporation's largest study in 345 ovarian cancer patients in the "Watchful Waiting" period, the interval of disease remission following first-line treatment of surgery and chemotherapy. These clinical results demonstrate a six-to-ten month prolongation in time to disease relapse for OvaRex® MAb-treated patients (versus placebo) in well-defined populations of 29%-48% of the 345 patients in the study. These well-defined populations also demonstrate a 19%-41% reduced risk of relapse for OvaRex® MAb treated patients (versus placebo). A decreased risk of relapse of 20%-25% is generally considered clinically significant by practicing physicians. A snapshot of the clinical development program for OvaRex® MAb is provided in the following figure.

Unither Pharmaceuticals (Unither) has initiated two identical Phase III pivotal trials to study the effect of OvaRex® MAb treatment in advanced ovarian cancer during the "watchful waiting" period. Currently there are no approved therapies for the treatment of ovarian cancer in the "watchful waiting" period. The trials are being conducted in the U.S. on Stage III/IV ovarian cancer patients who have successfully completed surgery and chemotherapy. Treatment will continue until disease relapse occurs. The studies are randomized, placebo-controlled trials and will each enroll 177 patients randomized 2:1 to OvaRex® MAb and placebo treatment. In December 2005, Unither announced the first of two Phase III OvaRex® MAb trials (IMPACT I) had reached its target enrolment of 177 patients. In June 2006, the second Phase III trial (IMPACT II) was fully enrolled. The studies could take up to an additional year or longer to complete, depending on how long it takes to reach 118 relapse events in IMPACT II. As of October 20, 2006, the reported number of relapse events was 117 and 96, respectively, in each of the trials.

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<sup>TM</sup> 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 22,491,491 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-oopharectomy), as well as the uterus (hysterectomy).

In recent years, new chemotherapeutic agents used either as single treatments or in combination with other therapeutic agents have demonstrated an increase in survival time. Despite their apparent positive effect on survival time, these agents are associated with significant toxicity and side effects that reduce the patient's quality of life. Currently, the most common chemotherapy for patients with newly diagnosed ovarian cancer is carboplatin (Paraplatin®) or cisplatin (Platinol®) with paclitaxel (Taxol®). Carboplatin and cisplatin are "platinum agents" (chemicals that contain platinum). Given the rigors of repeated chemotherapeutic treatments, and taking into account the modest effect on prolonging survival time, patient quality of life has become a major issue. This is increasingly true as ovarian cancer affects a larger number of older and postmenopausal women.

# Competition

To our knowledge, the only known potential competitor is Menarini Group, an Italian company, who currently has a product candidate in Phase III stage trial that commenced in approximately December of 2006. There are no products available for commercial sale for the treatment of advanced ovarian cancer in the "watchful waiting" period.

#### Chimigen<sup>™</sup> Platform Technology

#### Technology Overview

In a healthy individual, foreign antigens (such as proteins derived from a bacterium, virus or parasite) normally elicit an immune response. This immune response consists of two components:

Humoral (Antibody) Response: Antibodies produced by B-cells are secreted into the blood and/or lymph in response to an antigenic stimulus. The antibody then neutralizes the pathogen (virus, bacteria or parasite) by binding specifically to antigens on its surface, marking it for destruction by phagocytic cells and/or complement-mediated mechanisms.

Cellular Response: The cellular immune response leads to the selection and expansion of specific helper and killer T-cell clones capable of directly eliminating cells that carry the antigen.

In some individuals, the immune system does not respond normally to certain antigens or pathogens. When an antigen does not stimulate the production of a specific antibody and/or cellular response, the immune system is not able to ward off the resultant infection. As a result, the host will develop tolerance to the infectious agent and thus becomes a chronic carrier of the disease.

Chimigen<sup>TM</sup> vaccines contain two domains, the "Target Binding Domain" and the "Immune Response Domain". The Target Binding Domain targets the Chimigen<sup>TM</sup> vaccine to specific receptors on antigen presenting cells and the Immune Response Domain contains selected antigens. These vaccines can be produced as fusion proteins using recombinant methods. Our recombinant technology allows for efficient substitution of a desired antigen (the Immune Response Domain) onto the Target Binding Domain backbone of the Chimigen<sup>TM</sup> Vaccine. This enhances our ability to produce highly desirable and effective multivalent vaccines. Thus the Chimigen<sup>TM</sup> is a platform that lends itself to the development of multiple products incorporating antigens that occur in a number of disease conditions including cancer.

We are in the process of testing the efficacy of our Chimigen<sup>TM</sup> vaccines to induce both arms of the body's immune system to attack the infectious agent. We hope that the tests will show the Chimigen<sup>TM</sup> therapeutic vaccines will break tolerance to the infectious agent and stimulate the immune system to eliminate infected cells as well as the disease-causing agent located in the circulation.

# HepaVaxx B Vaccine

# Product Candidate Overview

HepaVaxx B Vaccine is a Chimigen<sup>™</sup> therapeutic vaccine developed by ViRexx for the treatment of chronic hepatitis B viral infections. In the candidate being tested, the Immune Response Domain is a hepatitis B viral antigen and the Target Binding Domain is created from select segments of a murine monoclonal antibody. Expression of HepaVaxx B Vaccine insect cells enhances the "foreignness" of the protein composition. Validation of the uptake, processing and activation of the cells responsible for modulating the immune response was conducted by us using specialized assay systems.

# Market Overview

The market for ViRexx's HepaVaxx B is global as shown in the chart below:

#### Hepatitis B Virus Market Size

People Chronically Infected New Cases Per Year Globally 370 million Not Available U.S. 1.25 million 78,000

Source: Center for Disease Control Hepatitis B Fact Sheet (2003) Source: World Health Organization 2000

Hepatitis B is one of the major diseases of mankind and is a serious global public health problem. The World Health Organization estimates that one out of every three people have been infected with the Hepatitis B Virus ("HBV") of whom approximately 350 million have developed a chronic HBV infection.

The virus is very common in Asia, (especially Southeast Asia), Africa, and the Middle East where there are more than 350 million chronically infected carriers representing approximately 5% of the world's population. Approximately 1.25 million chronic carriers of HBV live in the U.S. an estimated 10 to 30 million people worldwide will be newly infected with the virus each year.

People with a chronic hepatitis infection are at risk for significant liver damage. Approximately 20-30% of chronically infected people (30-35% of chronically infected males) develop cirrhosis of the liver and/or liver carcinoma over a 20-30 year time period. There are approximately one million deaths each year attributed to chronic HBV infection.

# Competition

At least 28 companies including several major international pharmaceutical companies are developing new and novel products for the treatment or prevention of chronic hepatitis B virus infection. The developmental strategies being employed by these biotech and pharmaceutical companies may be categorized as (a) nucleoside reverse transcriptase inhibitors of viral replication (e.g., Entecavir), (b) non-nucleoside reverse transcriptase inhibitors of viral replication (e.g., Robustaflavone), (c) monoclonal antibodies (HepX <sup>TM</sup> -B), (d) vaccines (e.g., Hepatitis B DNA vaccine), and (e) other immunologic therapies (e.g., EHT899).

We believe that the majority of these approaches do not eradicate the reservoir of the HBV that remains inside the patient's cells and therefore frequently do not permanently cure the patient of hepatitis B viral infection. The approaches noted above will likely reduce the viral load in the patient's blood, but unfortunately for the majority of patients, once the therapy is stopped the hepatitis virus will begin to replicate again within the patient's cells that contain the viral "covalently closed circular" (ccc) DNA. In contrast, we believe that HepaVaxx B Vaccine will elicit both humoral and cellular immune responses in chronic hepatitis B patients and that a strong cellular immune response directed against hepatitis B antigens will have the potential to eradicate the patient's cells that harbor hepatitis B viral DNA.

Furthermore, experience has shown that during long term therapy with existing antiviral agents (e.g., lamivudine), the patients that had the best chance of eliminating the virus were the patients who had an immune response to the virus prior to starting the antiviral agent. We believe the predicted humoral and cellular immune responses induced by HepaVaxx B Vaccine will increase the effectiveness of antiviral therapy when used in combination with antiviral agents such as lamivudine.

# HepaVaxx C

# **Product Candidate Overview**

HepaVaxx C Vaccine is a Chimigen<sup>™</sup> vaccine being developed for the treatment of chronic hepatitis C viral infections. HepaVaxx C Vaccine is a recombinant chimeric molecule containing the elements of both hepatitis C viral antigen and a murine antibody fragment. The molecule is designed to target antigen presenting cells, especially dendritic cells that play a dominant role in the body's immune system. Plans are in place for the pre-clinical evaluation of vaccine candidates using specialized assay systems.

# Market Overview

The market for ViRexx's HepaVaxx C is global.

#### HCV Market Size

People Chronically Infected New Cases Per Year Globally 170 million 3-4 million U.S. 2.7 million 25,000

Sources: World Health Organization Fact Sheet WHO/164 - October (2000)

Source: World Health Organization (2000)

The World Health Organization estimates that 170 million people are chronically infected with HCV (more than four times as many as infected with HIV) and conservatively 3 to 4 million people are newly infected each year. (Source: WHO Fact Sheet WHO/164 - October 2000.)

An estimated 4 million people have been infected with HCV in the U.S., of whom 2.7 million are chronically infected. According to the U.S. Centre for Disease Control and Prevention ("CDC"), new infections in the U.S. have dropped from approximately 240,000 annually in the 1980s to less than 25,000 in 2001. This is largely due to the availability of a diagnostic antibody test, which was introduced in 1990 to screen and eliminate HCV-infected blood from the nation's blood supply. (Source: Centre for Disease Control Hepatitis C Fact Sheet (2003).

Since 1990, all donated blood in the U.S. has been screened for the presence of the virus, thus eliminating almost all cases of transmission through transfusion. While this screening test has also been adopted by many other industrialized nations, the rest of the world is still at risk from transfusions as well as the other common routes of transmission (especially contaminated needles). In the absence of blood screening, many, if not most carriers, have no idea that they are infected, or that they should take precautions against infecting others.

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While the incidence of infection in the U.S. has decreased since the 1980s, the rate of deaths attributable to HCV continues to increase as people infected decades ago begin to manifest the disease. According to the CDC, 8,000 to 10,000 people currently die each year from HCV-related liver disease. HCV continues to be the number one reason for liver transplants. The CDC has previously predicted that the death toll will triple by the year 2010 and exceed the number of U.S. deaths due to AIDS. In addition, HCV is now the most common blood-borne infection in the U.S.

According to Hepatitis Central, chronic HCV is predicted to become a major burden on the health care system over the next 10 to 20 years as many patients who are currently asymptomatic will progress to end-stage liver disease and cancer. Approximately 75% to 85% of individuals infected with HCV will develop a chronic infection, of which approximately 15% to 20% will develop chronic liver disease progressing to cirrhosis. Between 1% and 5% of people with chronic infections will develop liver cancer over a period of 20 to 30 years. Predictions in the U.S. indicate that there will be a 60% increase in the incidence of cirrhosis, a 68% increase in hepatoma, a 279% increase in hepatic decomposition, a 528% increase in the need for transplantation, and a 223% increase in liver death rate.

At present there is neither a therapeutic or prophylactic vaccine commercially available to treat or prevent hepatitis C infections. Current therapy for hepatitis C infection uses interferon and ribavirin. However, this combination is expensive, has significant side effects and is only effective in approximately 40% - 50% of a select group of patients. The epidemic proportions of HCV infection, the limited efficacy and expensive nature of approved therapeutics, the high cost of liver transplants (about \$250,000 each) and the huge burden on the healthcare system in Canada alone (about \$600 million in 1998, just in medical and work-loss costs), all point to the need for prophylactic vaccines and new therapies to treat the disease. (Source: Health Canada News Release, September 18, 1998 and Fields Virology (2000) Volumes I and II (Fourth Edition).

The specific target population that can be treated with HepaVaxx C Vaccine will be defined through the clinical development process. HepaVaxx C Vaccine is currently in the pre-clinical stage of development.

# Competition

We believe the Chimigen<sup>™</sup> can potentially be used to develop a therapeutic vaccine as well as a prophylactic vaccine against Hepatitis C infection.

We have determined that there are more than 14 companies, including several major international pharmaceutical companies (e.g. Roche, Schering-Plough, and Eli Lilly), developing innovative drugs for the treatment of hepatitis C. The development strategies can be categorized as (a) biological response modifiers (e.g. interferon -2b), (b) antiviral nucleosides (e.g., Viramidine), (c) immune globulins (e.g., Civacir<sup>TM</sup> hepatitis C immune globulin), (d) monoclonal antibodies (e.g., XTL-002), (e) ribozymes (e.g., Heptazyme<sup>TM</sup>), (f) antisense drugs (e.g. ISIS 14803), (g) small molecule protease inhibitors (e.g., LY570310 / BILN2061, VX-950), (h) polymerase inhibitors (e.g. NM283) and (i) other strategies (e.g. human recombinant lactoferrin).

Among these developmental strategies, the biological response modifiers "(BRMs") (e.g., interferon-alpha) have promise for treatment of hepatitis C infection. BRMs enhance, direct or restore the body's ability to fight disease and provide a non-specific boost to the patient's immune system, which will then mount an attack on cells harboring the hepatitis C viruses. Although BRMs such as interferon-alpha impart a general immune boost that is effective in some patients, the side effect profile is very poor and many patients choose to discontinue therapy because they cannot tolerate the adverse effects.

We believe that the side effect profile associated with treatment of chronic hepatitis C patients with HepaVaxx C Vaccine may be very mild. Furthermore, we believe that the HepaVaxx C Vaccine will elicit both humoral and cellular immune responses in chronic hepatitis C patients that may eliminate the hepatitis C infection from the body.

# Chiron Corporation

Chiron Corporation is developing prophylactic and therapeutic vaccines using recombinant HCV antigens and adjuvants.

Schering-Plough Corp.:

Schering-Plough Corp.'s ("Schering-Plough") interferon product ("alpha-interferon"), PEG-INTRON®, is currently the preferred treatment for HCV because it appears to be less toxic than Rebetol®. Schering-Plough has developed a combination therapy with this product and ribavirin that was approved by European regulators in March 2001 and has been approved by the FDA.

# F. Hoffman-La Roche Ltd. :

F. Hoffman-La Roche Ltd. ("Roche") has a therapeutic for the treatment of HCV infections. In a head-to-head Phase III clinical trial conducted by researchers at the University of Carolina, it was found that patients treated with Roche's PEG interferon -2a or Pegasys®, combined with the antiviral agent ribavirin, was effective in 56% of patients tested, relative to 45% of subjects taking Schering-Plough's Rebetol®, the current industry standard.

In the Roche trial, researchers discovered that the most common side effects, depression and flu-like symptoms, were less frequently exhibited in the Pegasys and ribavirin group than in the group taking ribavirin alone. Depression occurred in 21% of those taking the combination therapy, compared with 30% in the ribavirin alone group, and 20% in the group taking Pegasys without ribavirin. (Source: Roche Press Release - May 22, 2001:http://www.natap.org/2002/Nov/111902-4.html.) However, the high cost (approximately U.S. \$31,000 for a year's supply) and the frequency of side effects with moderate efficacy make this therapy less than desirable. (Source: Fields Virology (2000) Volumes I and II (Fourth Edition).

There are also a number of drugs under development, such as Vertex's VM-950 protease inhibitor and Idenix's NM283 polymerase inhibitor, that have shown great promise during Phase II clinical testing. These drugs are being developed rapidly in collaboration with major pharmaceutical partners. If approved, they may re-define the standard of care for the treatment of Hepatitis C infections.

# **T-ACT<sup>TM</sup> Platform Technology**

#### **Technology** Overview

It is well known in the medical community that depriving a tumor of its blood supply has great potential in the fight against cancer and the treatment of benign tumors. Many large pharmaceutical companies conducting clinical studies have clearly established the concept that cutting off the blood supply to tumors causes them to regress and become dormant. Furthermore, cutting off the blood supply reduces the ability of cancers to invade tissues and to spread to other parts of the body.

Our T-ACT<sup>TM</sup> platform is a novel and proprietary targeted tumor starvation technology. The platform consists of two complementary product candidate groups, Occlusin<sup>TM</sup> and Tactin<sup>TM</sup>, and is based on site-specific platelet-mediated thrombosis of solid tumor vasculature. The T-ACT<sup>TM</sup> technology platform has the potential to produce a wide range of product candidates that interrupt the flow of blood to solid tumors, both malignant (cancer) and non-malignant (benign). Blockage of tumor tissue vasculature by targeted thrombosis starves the tumor of oxygen and essential nutrients, resulting in tumor regression and ultimately in tumor tissue death.

The T-ACT<sup>TM</sup> platform technology harnesses the body's natural ability to produce a blood clot in response to immobilized von Willebrand Factor ("VWF"). VWF and other "platelet capture" agents circulate in the blood stream in an inactive state. When a blood vessel is damaged VWF becomes immobilized on the vessel wall, and is thereby able to capture circulating platelets and stop the flow of blood from the injured vessel.

The Occlusin<sup>TM</sup> technology includes several types of particles coated with VWF or other platelet binding proteins. These particles, delivered through a catheter, are tailor-made for the specific indication for which they are being delivered. Particle size is selected such that upon initiation of platelet reactivity with the particles (i.e., platelet binding to the particles) progression of the particles beyond the capillary bed cannot occur. By varying the particle size, shape and composition, while maintaining a clot forming component (e.g., VWF), the Occlusin<sup>TM</sup> agents will rapidly and efficiently block target blood vessels of various sizes and locations. Furthermore, Occlusin<sup>TM</sup> agents can be made of either materials that are biodegradable or materials that would remain permanently resident in the body.

We believe that the Occlusin<sup>TM</sup> product candidates are ideal for the treatment of uterine fibroids (a benign tumor) and hepatocellular carcinoma (primary cancer of the liver).

# **Occlusin<sup>TM</sup>Product Candidates**

# **Product Candidate Overview**

Occlusin<sup>TM</sup> product candidates are under development for the treatment of uterine fibroids and hypervascular tumors (e.g., liver cancer). Based on the T-ACT<sup>TM</sup> platform technology, the product candidates consist of solid biodegradable particles coated with a platelet-binding agent. These agents are delivered by catheter to the main vessels feeding the tumor.

# Market Overview

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The Occlusin <sup>TM</sup> product candidate indications constitute a global market.

### Uterine Fibroid Market Size

	Globally	U.S.
Prevalence	2020 - 40% of women 30>35 yrs of age	> 225 million
Target Market of the 200,000		
hysterectomies performed annually		
to relieve debilitating symptoms of		
uterine fibroids	20% experience debilitating symptoms	> 55 million

Source: National Institutes of Health (NIH); Central Intelligence Agency Population Statistics; Society of Interventional Radiology.

Uterine fibroids, also called leiomyomas, are benign tumors that can grow on the inside or outside of the uterus, or within the uterine wall. Their size can vary from that of a pea to the size of a full-term pregnancy. While most women with fibroids are symptom-free, approximately 25% to 30% experience prolonged bleeding, which can lead to anemia and/or pain in the pelvis, abdomen, back or during sexual intercourse. Fibroids can also prevent a woman from conceiving, or can induce a miscarriage or premature labor. As fibroids grow and expand, they exert pressure upon the bladder and lower intestine and can cause difficult or increased urination, constipation, and a feeling of fullness.

The Society of Interventional Radiology estimates the incidence of uterine fibroids of significant size at 20% to 40% of women 35 years of age and older and 20% (two million women) experience severe debilitating effects. Corresponding numbers of women in the rest of the world are similarly afflicted. ViRexx will determine the target market for its Occlusion<sup>TM</sup> product candidates by continued market analysis and through the clinical trial process.

Hysterectomy (complete removal of the uterus) or myomectomy (partial removal of the uterine wall) has been the treatment of choice for women suffering from severe side effects of uterine fibroids. These invasive surgical procedures require long hospital stays and recovery time, post surgery. In contrast, uterine fibroid embolization ("UFE") is a minimally invasive technique delivered as an outpatient procedure with minimal recovery time.

UFE involves delivering tiny embolic microspheres to the blood vessels feeding the fibroid. The microspheres are delivered by catheter and function to block the vasculature associated with this benign tumor. Once the blood supply is cut off, the fibroids shrink resulting in symptom relief.

A recent publication in the New England Journal of Medicine (January 25, 2007) comparing treatments for uterine fibroids underlined the benefits of UFE over surgery (hysterectomy or myomectomy). The UFE group had a shorter median stay in hospital (1 versus 5 days; p<.001) and a shorter recovery time before returning to work (20 days versus 61 days; p<0.001) in comparison to the surgery group. There was no difference in major adverse events between the two groups.

#### *Liver Cancer Market Size (primary + secondary to colorectal cancer)*

	Globally	U.S.
Prevalence	385,985	13,363
New Cases per year	626,162	14,991
	Source: GLOBOCAN 2002	

While primary liver cancer is not as prevalent in North America, in the less developed parts of the world such as Africa, Southeast Asia, and China, it is responsible for 50% of all cancer cases. This dramatic difference is believed to be due to the much higher prevalence of hepatitis B virus carriers in those regions, which predisposes to the

development of hepatocellular carcinoma ("HCC").

According to GLOBOCAN 2002, the worldwide incidence of primary liver cancer was estimated to be 626,162 cases and, of these, over 411,000 were located in China, 18,000 in North America and 38,000 in Europe. The number of patients who died worldwide from primary liver cancer in 2002 was estimated to be 600,000. ViRexx will determine the target market for its Occlusion<sup>TM</sup> 5050 Injection product candidate(s) by continued market analysis and through the clinical trial process.

In the U.S., the five-year survival rate for patients with all stages of liver cancer is 10.5%. The five year survival rate of American patients diagnosed with localized liver cancer is 21.9% and a mere 3.3% for patients with distant disease. There has been little improvement in the five-year survival rate for U.S. liver cancer patients since the mid 1970s when the overall survival rate was 4%. (Source: American Cancer Society, 2007 Statistics.)

Competition

Embolotherapy, the blocking of blood vessels feeding a target tissue, has been practiced for more than 30 years. Several companies, in recent years, have focused on producing specific embolic agents for the treatment of various forms of solid tumors.

#### Biosphere Medical Inc.:

Biosphere Medical Inc.'s Embosphere<sup>TM</sup> microsphere technology is the perceived market leader in the area of embolotherapy. This company has developed several forms of its acrylic-based microspheres to treat both liver cancer and uterine fibroids. Embosphere<sup>TM</sup> Microspheres was recently approved by the FDA for the treatment of uterine fibroids.

# Cook Incorporated:

Cook Incorporated markets polyvinyl alcohol ("PVA") foam particles. This company markets several different sizes of the particles to block various sizes of blood vessels. Cook Incorporated also markets materials such as catheters required in UFE procedures.

PVA particles are inert and serve only to physically interfere with the blood flow to the target tissue. In addition, the irregular shape of the PVA particles can result in clogging of the catheter through which the particles are delivered.

# Boston Scientific Corporation:

Boston Scientific markets Contour SE<sup>TM</sup> Microspheres for the treatment of hypervascular tumors and uterine fibroids. The microspheres consist of polyvinyl alcohol and are available in various size ranges. PVA particles are inert and serve only to physically interfere with the flow of blood to the target tissue.

Occlusin<sup>TM</sup> particles, in contrast to conventional particles bind to the vessel wall by way of the clot as well as being a physical blockage. We believe that this advantage will reduce the need for multiple interventions.

# **Tactin Technology**

# Technology Overview

Tactin agents are systemically delivered (injected intravenously) and include a series of cancer targeting components against markers such as TAAs found on the surface of a number of cancers including cancers of the liver, breast, lung, prostate and head and neck. The Tactin agents are capable of localizing platelets at a predetermined site by (a) binding to tumor cells that display unique TAAs and (b) by subsequently capturing a separately administered thrombus formation component ("TFC"). We believe that our TFC is an exceptional platelet binding and activating protein, that when fixed to the tumor by the cancer-targeting component induces a thrombus only within the confines of the tumor vasculature. Thus, the Tactin product candidates utilize a tumor-localized platelet collection and activation process through binding of a targeting agent to a tumor associated antigen, which subsequently leads to thrombus formation and limits the blood supply to the target area, and does this without inducing a generalized or systemic pro-thrombotic state.

Tactin agents affect the vascular system supplying tumors. The tumor targets are directly accessible to arterially or intravenously administered agents permitting rapid localization of a large percentage of the injected dose. We expect this to result in rapid occlusion of the tumor vasculature. Each capillary in a tumor provides oxygen and nutrients to thousands of tumor cells, so that even limited damage to the tumor vasculature has the potential to produce extensive tumor cell death.

Various targeting agents can be used in combination with the common TFC to achieve an effective response in a broad range of tumor and hyperplastic tissue pathologies. As an example, a targeting agent that binds to alpha-fetoprotein ("AFP") can be coupled to the same thrombus-inducing agent. This same thrombus-inducing agent can also be linked, in vivo, to other targeting agents that bind to other specific antigens (e.g., TAG-72, associated with colorectal cancer).

# Market Overview

Please refer to the "Market Overview" section of the Occlusin<sup>™</sup> Injection technology in this Annual Report for an in-depth discussion of the existing market.

#### **Intangible Properties**

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We are a party to collaborative agreements with third parties relating to OvaRex® MAb and four other product candidates from the AIT<sup>TM</sup> platform. The Corporation is dependent on the success of its strategic relationships with United Therapeutics and other third parties" for further details.

# **Proprietary Protection**

We rely upon patent protection and trademarks to preserve its proprietary technology and its right to capitalize on the results of its research and development activities and, to the extent it may be necessary or advisable, to exclude others from appropriating its proprietary technology.

# Confidentiality

Since some of our technology is not patented or licensed but protected by the law of trade secrets, our ability to maintain the confidentiality of our technology is crucial to our ultimate possible commercial success. In order to protect our confidential information, we have adopted the following procedures:

all of our employees must sign and are bound by confidentiality agreements;

•no sensitive or confidential information is disclosed to any party unless appropriate confidential disclosure agreements are first signed; and

•all confidential material that is provided to a party is marked as confidential and is requested to be returned when the user no longer has a need to have the material, or when the term of any applicable confidential disclosure agreement governing the use of the material expires.

We are unaware of any violations of our confidentiality procedures, and to date we have never experienced a violation of our confidentiality procedures that has caused our company material harm. Nevertheless, we cannot assure you that our procedures to protect confidentiality are effective, that third parties will not gain access to our trade secrets or disclose our technology, or that we can meaningfully protect our rights to our trade secrets. We cannot prevent a person from violating the terms of any confidential disclosure agreement. Furthermore, by seeking patent protection in various countries, it is inevitable that important technical information will become available to our competitors, through publication of such patent applications. If we are unable to maintain the confidentiality of our technology in appropriate circumstances, this could have a material adverse impact on our business, financial condition, and results of operations.

# Our Patents

Our success depends in part on our ability to obtain patents, operate without having third parties circumvent our rights, operate without infringing the proprietary rights of third parties, and maintain trade secret protection. As of the date of this Annual Report, we had 72 issued patents and 141 pending patent applications relating to our various technologies in the United States, Canada, the European Union, and other countries, of which we have been granted eight patents in the United States. The expiry dates for these eight patents are between 2016 and 2021. The dates reflecting the expiration date of the longest-lived patent rights listed herein do not take into consideration the possibility that a failure to maintain these patents, a terminal disclaimer or other future actions may affect the actual expiration date of the patents. Pending applications may never mature into patents, which could affect the lifespan of certain licenses. Finally, future applications could result in the extension of the license term beyond the dates listed above.

The patent position of pharmaceutical and biotechnology companies is uncertain and involves complex legal and financial questions for which, in some cases, important legal principles are largely unresolved. Patent offices vary in their policies regarding the breadth of biopharmaceutical patent claims that they allow. In addition, the coverage claimed in a patent application can be significantly reduced during prosecution before a patent is issued. We may not be granted patents of meaningful scope based on the applications we have filed and those we intend to file. We cannot assure you that our pending patent applications will result in patents being granted, that we will develop additional proprietary product candidates that are patentable, that patents that have already been granted to us will provide us with any competitive advantage or will not be challenged or invalidated by any third parties, or that patents of others will not have an adverse effect on our ability to do business. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of Canada or the United States. We cannot assure you that others will not independently develop similar products or processes, duplicate any of our potential products or processes, or design around the potential products or processes we may patent.

# Our Patent Policy

We pursue a policy of obtaining patent protection both in the U.S. and in selected foreign countries for subject matter considered patentable and important to our business. Our patent portfolio currently includes patents with respect to our unique approaches to immunotherapy, compositions of matter, their immunological utilities, broad claims to therapeutic methods, specific claims for use of these compositions to treat various disease states, and the pharmaceutical formulation of these compositions. We have also sought patent protection with respect to embolotherapy, related compounds, methods and strategies for therapy, routes of administration and pharmaceutical formulations. In addition, a portion of our proprietary position is based upon the use of technology and potential products we have licensed from others, including the master cell bank licensed from Biomira Inc. for OvaRex® MAb. The license agreement generally requires ViRexx to pay royalties upon commercialization of potential products covered by the licensed technology. We also currently have exclusive licenses from the University of Alberta to two patent applications.

# Third-Party Patents

Our commercial success also depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. From time to time, companies may possess rights to technologies in the same areas of research and development as ours, may have patents similar to ours, and may notify us that we may require licenses from them in order to avoid infringing their rights in that technology or in order to enable us to commercialize our own technology. Patent applications are, in many cases, maintained in secrecy until patents are issued. Our competitors or potential competitors may have filed applications for, or may have received patents and may obtain additional and proprietary rights to compounds or processes used by us or are competitive with ours. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications are filed. In the event of infringement or violation of another party's patent, we may be prevented from pursuing potential product development or commercialization. In addition, we may be required to obtain licenses under patents or other proprietary rights of third parties. We cannot assure you that any licenses required under such patents or proprietary rights will be available on terms acceptable to us. If we do not obtain such licenses, we could encounter delays in introducing one or more of our product candidates to the market, without infringing third-party patents, or we could find that the development, manufacturing or sale of potential products requiring these licenses could be foreclosed.

# Patent Litigation

Patent litigation is becoming widespread in the biopharmaceutical industry and we cannot predict how this will affect our efforts to form strategic alliances, conduct clinical testing, or manufacture and market any of our product candidates that we may successfully develop. We are unaware of any potential issues related to our possible infringement or violation of another party's patent. If challenged, however, our patents may not be held to be valid. We could also become involved in interference or impeachment proceedings in connection with one or more of our patents or patent applications to determine priority of invention. If we become involved in any litigation, interference, impeachment, or other administrative proceedings, we will likely incur substantial expenses and the efforts of our technical and management personnel will be significantly diverted. We have the obligation to protect and bear the cost of defending the patent rights of the patents we own. With respect to our licensed patents we have the right but not the obligation to bear the cost of defending patent rights from third parties. A decision to pursue a patent infringement action may be prohibitively expensive.

More specifically, we cannot assure you that we will have the financial or other resources necessary to enforce or defend a patent infringement or proprietary rights violation action. Moreover, if our potential products infringe the patents, trademarks, or proprietary rights of others, we could, in certain circumstances, become liable for substantial damages, which also could have a material adverse effect on our business, financial condition, and results of

operations. Where there is any sharing of patent rights, either through co-ownership or different licensed "fields of use", one owner's actions could lead to the invalidity of the entire patent.

In relation to the License Agreement established between us and Biomira Inc. dated November 24, 1995, we are responsible for the maintenance of existing patents and the prosecution of all patent applications related to the licensed technology. In addition, we are responsible for the payment of all fees and costs incurred related to the filing, prosecution and maintenance of the patent applications and patents included in the licensed technology.

In relation to the License Agreement established between us and the Governors of the University of Alberta ("U of A") for the rights to use Methods of Eliciting a Th1-specific Immune Response, the U of A is responsible for the maintenance of existing and prosecution of all patent applications related to the licensed technology. As of the effective date of the agreement, May 1, 2002, we are responsible for the payment of all fees and costs incurred by the U of A related to the filing, prosecution and maintenance of the patent applications and patents included in the licensed technology. These obligations are not considered material.

#### Economic Dependence and Foreign Operations

We are dependent upon foreign operations of United Therapeutics, Defiante, Tecnogen and other third parties. We, through our license agreement with United Therapeutics, via our license and supply agreement with Defiante, a subsidiary of Sigma Tau Farmaceutici, and a manufacturing and supply agreement with Tecnogen, another subsidiary of Sigma Tau Farmaceutici, are reliant on strategic relationships with third parties for the OvaRex® MAb, and in United Therapeutics' case, other product candidates. For further details, please refer to the following "Risk Factors": *"WE RELY ON OUR STRATEGIC RELATIONSHIP WITH UNITED THERAPEUTICS" AND "WE ARE IN THE EARLY STAGES OF PRODUCT CANDIDATE DEVELOPMENT. OUR PRODUCT CANDIDATES MAY NOT BE EFFECTIVE AT A LEVEL SUFFICIENT TO SUPPORT A PROFITABLE BUSINESS VENTURE. IF THEY ARE NOT, WE WILL BE UNABLE TO CREATE MARKETABLE PRODUCT CANDIDATES AND WE WILL HAVE TO CEASE OPERATIONS."* 

# Government Regulation and Product Approval

Regulation by governmental authorities in the United States and other countries is a significant factor in the development, manufacture and marketing of pharmaceuticals. All of our products will require regulatory approval by governmental agencies prior to commercialization. In particular, pharmaceutical drugs are subject to rigorous preclinical testing and clinical trials and other premarketing approval requirements by the FDA and regulatory authorities in other countries. In the United States, various federal, and in some cases state statutes and regulations, also govern or impact upon the manufacturing, safety, labeling, and storage, recordkeeping and marketing of pharmaceutical products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. Regulatory approval, when and if obtained for any of our product candidates, may be limited in scope which may significantly limit the indicated uses for which our product candidates may be marketed. Further, approved drugs and manufacturers are subject to ongoing review and discovery of previously unknown problems that may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

# Preclinical Studies

Before testing any compounds with potential therapeutic value in human subjects in the United States, stringent government requirements for preclinical data must be satisfied. Preclinical testing includes both *in vitro* and *in vivo* laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. Preclinical testing results obtained from studies in several animal species, as well as from *in vitro* studies, are submitted to the FDA as part of an Investigational New Drug Application, or IND, and are reviewed by the FDA prior to the commencement of human clinical trials. These preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial trials in human volunteers.

# Clinical Trials

If a company wants to test a new drug in humans in the United States, an IND must be prepared and filed with the FDA. The IND becomes effective if not rejected or put on clinical hold by the FDA within 30 days. In addition, an Institutional Review Board comprised in part of physicians at the hospital or clinic where the proposed trials will be conducted must review and approve the trial protocol and monitor the trial on an ongoing basis. The FDA may, at any time during the 30-day period or at any time thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. In some instances, the IND application process can result in substantial delay and expense.

# Clinical Trial Phases

Clinical trials typically are conducted in three sequential phases, phases I, II and III, with phase IV trials potentially conducted after marketing approval. These phases may be compressed, may overlap or may be omitted in some circumstances.

- *Phase I clinical trials.* These trials evaluate a drug's safety profile, and the range of safe dosages that can be administered to healthy volunteers and/or patients, including the maximum tolerated dose that can be given to a trial subject with the target disease or condition. Phase I trials also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and duration of its action.
- *Phase II clinical trials.* Phase II clinical trials typically are designed to evaluate the potential effectiveness of the drug in patients and to further ascertain the safety of the drug at the dosage given in a larger patient population.
• *Phase III clinical trials.* In phase III clinical trials, the drug is usually tested in a controlled, randomized trial comparing the investigational new drug to an approved form of therapy in an expanded and well-defined patient population and at multiple clinical sites. The goal of these trials is to obtain definitive statistical evidence of safety and effectiveness of the investigational new drug regime as compared to an approved standard therapy in defined patient populations with a given disease and stage of illness.

All clinical trials for our product candidates have been conducted in accordance with Health Canada and the ICH (International Conference on Harmonization) guidelines.

### New Drug Application

After completion of clinical trials, if there is substantial evidence that the drug is safe and effective, a New Drug Application, or NDA, is prepared and submitted for the FDA to review. The NDA must contain all of the essential information on the drug gathered to that date, including data from preclinical and clinical trials, and the content and format of an NDA must conform to all FDA guidelines. Accordingly, the preparation and submission of an NDA is a major undertaking for a company.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information from the sponsor rather than accepting an NDA for filing. In such an event, the NDA must be submitted with the additional information and, again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Typically, the FDA takes ten months to review and respond to the NDA. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation, but gives great weight to it. If the FDA evaluations of both the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or a non-approval letter, which usually contains a number of conditions that must be satisfied in order to secure final approval. If the FDA's evaluation of the NDA submission or manufacturing facility is not favorable, the FDA may refuse to approve the NDA or issue a non-approvable letter.

#### Other Regulatory Requirements

Any products we manufacture or distribute under FDA approvals are subject to pervasive and continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences with the products. Drug manufacturers and their subcontractors are required to register with the FDA and, where appropriate, state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with current GMP regulations, which impose procedural and documentation requirements upon us and any third party manufacturers we utilize.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates or approval of new indications for our existing products. We cannot predict the likelihood, nature or extent of adverse governmental regulations that might arise from future legislative or administrative action, either in the United States or abroad.

We received an orphan drug designation for OvaRex® MAb from the FDA in November, 1996 for its use in the treatment of ovarian cancer. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants the orphan drug designation, the identity of the applicant and the orphan-designated therapeutic agent are disclosed publicly by the FDA. The European Medicines Agency in July, 2002 also granted an orphan drug designation for OvaRex® MAb for its use in the treatment of ovarian cancer in Europe.

Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation is the first such product to receive FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, for seven years in the U.S. and 10 years in the European Union. The FDA may permit additional companies to market a drug for the designated condition if such companies can demonstrate clinical superiority. More than one product may also be approved by the FDA for the same orphan indication or disease as long as the products are different drugs. As a result, the FDA can still approve other drugs for use in treating the same indication or disease covered by OvaRex® MAb, which could create a more competitive market for us. Moreover, if a competitor obtains approval of the same drug for the same indication or disease before us, we would be blocked from obtaining approval for our product for seven years, unless our product can be shown to be clinically superior.

# Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized procedure, a mutual recognition procedure or a decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for a joint assessment of safety and efficacy by a number of EU member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the member state approving the first marketing authorization within the EU submits an application for recognition to other EU member states. Within 90 days of receipt of the application and the first member state's report of the assessment of the drug, the other member states are supposed to recognize the marketing authorization of the first member state or refer the application to the Committee for Human Medicinal Products, or CHMP, for arbitration, if one or more member states believe there is a potential serious risk to public health, and the member states cannot reach agreement on the approval of the product. The CHMP is a scientific expert committee of the European Medicines Agency, or EMEA. The EMEA is responsible for the protection of public health in the EU through the coordination and evaluation and supervision of medicinal products, including administering the centralized procedure and performing a more limited role in the mutual recognition procedures. After member states agree to mutual recognition of the first marketing authorization, national marketing authorizations must still be issued in each member state which recognized it, including approval of translations, labeling and the like. All marketing authorization applications for drugs that have received the orphan drug designation must be submitted under the centralized procedure.

# Legal Proceedings

We are not involved in any legal, arbitration or governmental proceedings which may have, or have had in the recent past, significant effects on our financial position or profitability. We are also not aware of any pending legal, arbitration or governmental proceedings against us which may have significant effects on our financial position.

# C. Organizational structure

# **Control of ViRexx**

We have two wholly owned subsidiaries named AltaRex Medical Corp. and ViRexx International Corp. Limited, and one wholly owned inactive subsidiary named AltaRex U.S. Corp. AltaRex (ViRexx International) was incorporated under the laws of the Province of Alberta, Canada, ViRexx International was incorporated under the laws of Ireland, and AltaRex U.S. Corp. is a Delaware corporation.

We carry on our OvaRex® MAb dealings directly through AltaRex.

#### **D.** Property and equipment

Our corporate headquarters are located at 8223 Roper Road, Edmonton, Alberta T6E 6S4. Our registered office is located at Suite 1500, Manulife Place, 10180-101 Street, Edmonton, Alberta T5J 4K1. We lease our head office space in Edmonton, Alberta. The terms of the premises leased are as follows:

Annual base rent: Term expires: Square footage: \$ 113,126 May 31, 2011 13,244

We do not deem our lease to be material. We believe that the physical facilities we lease are adequate to conduct our business during the next 12 months.

We have headquarters and laboratory space in Edmonton, Alberta. Our facilities include a three year-old office and laboratory space, which we consider to be world class and to represent a significant value to us. The facility includes offices, wet laboratories, and associated equipment. We also have access to the University of Alberta virus containment laboratory and animal research facility. Preferential privileges are accorded to us such as access to facilities and contact with key individuals, as a result of the present and past association of the senior corporate officers with the University of Alberta and the present contractual arrangements of technology transfer between the University of Alberta and us.

Property and equipment are described at cost less accumulated amortization in the financial statements. Amortization is provided for by using the declining balance method at the following annual rates:

Laboratory equipment	20%
Office, furniture and equipment	20%
Computer equipment	30%
Computer software	100%

Leasehold improvements are amortized over the term of the lease.

#### 4A. Unresolved Staff Comments

None

#### Item 5. Operating and Financial Review and Prospects

#### FORWARD-LOOKING STATEMENTS

Except for historical information, this "Management's Discussion and Analysis of Financial Condition and Operations" contains forward-looking statements which may not be based on historical fact. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such factors include, among others, risks associated with the completion of clinical trials and obtaining regulatory approvals, the ability to protect the Company's intellectual property, dependence on its collaborative partner, additional long-term capital requirements and ViRexx's stage of development. These factors should be considered carefully and readers are cautioned not to place undue reliance on such forward-looking statements.

The following discussion and analysis of results of operations and liquidity and capital resources should be read in conjunction with the financial data and the financial statements and the related notes thereto included elsewhere herein. This Management Discussion and Analysis of Financial Condition and Results of Operations as of March 19, 2007 provides information on the activities of ViRexx Medical Corp. ("ViRexx" or the "Company") on a consolidated basis. All amounts are expressed in Canadian dollars unless otherwise noted.

The Consolidated Financial Statements have been prepared in accordance with Canadian generally accepted accounting principles ("GAAP"). Canadian GAAP differs in certain material respects from United States generally

accepted accounting principles ("U.S. GAAP"). For a discussion of the principal differences between Canadian GAAP and U.S. GAAP as they pertain to ViRexx Medical Corp. see Note 18 to the audited Consolidated Financial Statements. Note 18 to the Consolidated Financial Statements also provides a reconciliation of the Company's Consolidated Financial Statements to U.S. GAAP.

# **OVERVIEW**

ViRexx is a Canadian, development-stage biotech-based company focused on developing innovative targeted therapeutic products that offer quality of life and a renewed hope for living. ViRexx's most advanced programs include product candidates for the treatment of late-stage ovarian cancer, selected solid tumors and chronic hepatitis B and C infections.

ViRexx currently has three platform technologies: AIT<sup>TM</sup> (antibody-based immunotherapy), T-ACT<sup>TM</sup> (targeted-autothrombogenic cancer therapy) and Chimigen<sup>TM</sup> Vaccines, all of which are based on the principle of harnessing the body's power to fight disease.

# AIT' Platform Technology

The lead product candidate from the AIT<sup>TM</sup> platform is OvaR<sup>®</sup>xMAb, a therapy for treatment of late-stage ovarian cancer. OvaRex<sup>®</sup> MAb is currently the subject of two pivotal Phase III clinical trials (IMPACT I and IMPACT II) being conducted at more than 60 sites in the United States. ViRexx has licensed exclusive rights of OvaRex<sup>®</sup> MAb to Unither Pharmaceuticals, Inc. ("Unither"), a subsidiary of United Therapeutics Corporation, in its territories.

In the fourth quarter of 2006, ViRexx's licensee, Unither continued to monitor progress from IMPACT I and IMPACT II for OvaRex<sup>®</sup> MAb. The database lock for analysis from these two pivotal trials is estimated to occur in the second half of 2007.

The technology transfer from ViRexx to Tecnogen S.C.p.A ("Tecnogen"), a subsidiary of Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") was initiated in the fourth quarter of 2006. Tecnogen will manufacture and supply ViRexx's European licensing partners.

All relevant documentation for manufacture of the drug substance has been completed; the transfer of relevant documentation for manufacture of the drug product is anticipated to be completed in early 2007.

# **T-ACT' Platform Technology**

The T-ACT<sup>TM</sup> platform is designed to cut off the blood supply to hypervascular tumors, leading to tumor tissue starvation and death. The lead product candidate of the T-ACT<sup>TM</sup> platform is Occlusin<sup>TM</sup> 50 Injection, a treatment for primary cancer of the liver. The Phase I study of Occlusin<sup>TM</sup> 50 Injection was conducted at the Toronto General Hospital and at the Foothills Hospital in Calgary. The trial is designed to examine the safety of Occlusin<sup>TM</sup> 50 Injection when used as an embolizing agent as part of transcatheter arterial chemoembolization ("TACE") procedures for the palliative treatment of cancer of the liver. Patient enrollment and treatment for this study ended December 31, 2006 with Phase I study results expected to be reported in the second quarter of 2007. Partnering discussions with several companies interested in Occlusin<sup>TM</sup> 50 Injection have been initiated.

The T-ACT<sup>TM</sup> platform has expanded to include the development of the Occlusin<sup>TM</sup> 500 Artificial Embolization Device ("Occlusin<sup>TM</sup> 500 Device"), an embolotherapeutic device, to treat hypervascular tumors and uterine fibroids. Preclinical proof of concept testing has been completed for Occlusin<sup>TM</sup> 500 Device. The path to regulatory approval of a medical device is approximately 50% shorter than that of a drug or biologic.

# <u>Chimigen<sup>TM</sup> Platform Technology</u>

The lead product candidate from the Chimigen<sup>™</sup> platform is HepaVaxx B Vaccine, an immunotherapeutic agent for the treatment of patients chronically infected with hepatitis B virus. ViRexx completed a Phase I study of HepaVaxx B Vaccine in normal, healthy volunteers. There were no significant adverse events reported with the treatment. The trial was conducted at McGill University Health Centre's Vaccine Study Centre in Montreal, Canada. The evaluation of the volunteers' immune responses to treatment with HepaVaxx B Vaccine is currently ongoing. A collaborative development agreement with Protein Sciences Corporation has been extended to April 20, 2009 ensuring that ViRexx can manufacture clinical grade material in conformance with Good Manufacturing Practices ("GMP") for Phase II trials.

ViRexx announced a research collaboration with the Department of Defence Research and Development Center at Suffield ("DRDC-Suffield") to develop Chimigen<sup>TM</sup> Vaccines for use in the biodefense area. These vaccine candidates are being tested for efficacy in experimental models at DRDC-Suffield. The Company is also continuing the preclinical studies in animals using Chimigen<sup>TM</sup> Vaccine candidates to evaluate their immune responses.

# HIGHLIGHTS

	For year ended December 31,					
Research and Development Costs		2006		2005		2004
	\$	5,937,122	\$	4,750,190	\$	1,796,680
Net Loss		(17,493,375)		(7,459,714		(3,657,760)
Basic and diluted loss per share		(0.25)		(0.13)		(0.14)
Ending Cash & Short Term Investments	\$	10,742,191	\$	5,571,850	\$	9,462,988

ViRexx had a very exciting year in 2006, accomplishing all of its planned research and development milestones which are highlighted below:

# First Half of 2006

· First volunteers dosed for HepaVaxx B Vaccine Phase I clinical study.

 $\cdot$  Unither completed enrollment of OvaRex® MAb Phase III Impact II.

#### Second Half of 2006

•Two potential partners were identified for HepaVaxx B Vaccine licensing and co-development.

•The Phase I clinical study of Occlusin<sup>TM</sup> 50 Injection was completed.

·Unither enrollment and dosing for OvaRex<sup>®</sup> MAb Phase II trial in combination with frontline chemotherapy was completed.

•The licensing, marketing and manufacturing agreements for OvaRex® MAb in Europe were completed.

•The technology transfer of the drug substance for OvaRex<sup>®</sup> MAb from ViRexx to European manufacturing facility was completed.

•The Phase I clinical study of HepaVaxx B Vaccine, the first-in-man trial for the Chimigen<sup>TM</sup> technology was completed.

•Two potential candidates for further development of HepaVaxx C Vaccine were identified.

In addition to accomplishing all 2006 planned major research and development milestones, ViRexx achieved the following important goals that strengthened the Company's balance sheet:

•On February 16, 2006, the Company completed a private placement of 10,909,090 units for gross proceeds of \$12,000,000. On April 7, 2006, the Company completed a private placement of 800,000 units for gross proceeds of \$1,000,000. On December 6, 2006, ViRexx received an equity investment of \$2,000,000 from Defiante Farmacêutica Lda ("Defiante"), a subsidiary of Sigma-Tau for 1,818,182 units of ViRexx at a price of \$1.10. For further information see Note 13 of the audited December 31, 2006 Consolidated Financial Statements.

•On November 28, 2006, ViRexx announced it had prioritized its research activities to focus on the completion of existing pipeline products providing near term potential revenue streams, specifically OvaRex<sup>®</sup> MAb and Occlusin<sup>TM</sup> 500 Device. This plan included a reduction in internal research expenditures in excess of 65%, resulting in a 2007/08 projected average monthly expenditure rate of under \$900,000. ViRexx will also accelerate business development efforts by identifying a development partner for its lead Chimigen<sup>TM</sup> Vaccine, HepaVaxx B Vaccine.

On November 6, 2006, ViRexx International Corp. entered into a Licensing and Supply Agreement and a Securities Purchase Agreement with Defiante. A Manufacturing and Supply Agreement with Tecnogen was also reached. Both companies are subsidiaries of Sigma-Tau of Rome, Italy. The territories covered by these agreements represent approximately 23% of the targeted ovarian cancer markets in North America and the European Union. Management believes Sigma-Tau's experience and network in Europe is a significant asset to ViRexx and views the comprehensive agreements as an important step in the path toward the European commercialization of OvaRex<sup>®</sup> MAb. In addition, to accessing a strong commercialization partner in Sigma-Tau, Tecnogen's manufacturing capabilities eliminate the need for ViRexx to make a significant capital expenditure in a stand alone manufacturing facility.

For the year ended December 31, 2006, the Company recorded a net loss of \$17,493,375 or (\$0.25) per share, as compared to \$7,459,714 or (\$0.13) per share for the corresponding year ended December 31, 2005. Approximately 75% of the change in the Company's net loss for the year ended December 31, 2006 is due to a non-cash change in the net future tax expense associated with the transfer of intellectual property to ViRexx International Corp. The

remaining 25% change is attributed to the following operational activities:

•Business development activities initiated to pursue licensing agreements for OvaRex<sup>®</sup> MAb in Europe and for T-ACT<sup>TM</sup> and Chimigen<sup>TM</sup> product candidates.

The formation of a dedicated commercialization team for OvaRex<sup>®</sup> MAb. The team expanded efforts to ensure worldwide protection of the intellectual property within the AIT<sup>TM</sup> platform, as well as increased activities on establishing partnerships for ViRexx's European territories.

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•Process development costs related to manufacturing Occlusin<sup>TM</sup> 500 Device research for the treatment of uterine hypervascular tumors and fibroids.

During the year ended December 31, 2006, research and development costs for the Chimigen<sup>TM</sup> platform were offset by a \$222,140 financial contribution from the National Research Council of Canada Industrial Research Assistance Program (NRC-IRAP).

The Company recorded a net loss for the year ended December 31, 2005 of \$7,459,714 or (\$0.13) per share, as compared with a net loss of \$3,657,760 or (\$0.14) per share for the corresponding period December 31, 2004. The expenditure increase is primarily attributable to an increase in preclinical, potential product development and clinical trial activity.

# **RESULTS OF OPERATIONS**

For the year ended December 31, 2006, the Company recorded a net loss of \$17,493,375 or (\$0.25) per share, as compared to \$7,459,714 or (\$0.13) per share for the corresponding period ended December 31, 2005. The changes in the Company's net loss for the year ended December 31, 2006, compared to the prior year are due primarily to the following:

### **Research and Development**

	For year ended December 31,						
		2006	-	2005	2004		
Contract research costs	\$	628,240	\$	410,052	\$	180	
Clinical trial costs		477,364		104,692		442,880	
Clinical material manufacturing costs		386,216		861,064		129,421	
Employee related costs		2,403,330		2,010,589		844,039	
Stock based compensation		150,959		57,879		70,129	
Other R&D costs (Legal, Lab Supplies, etc.)		1,891,013		1,305,914		310,031	
	\$	5,937,122	\$	4,750,190	\$	1,796,680	

Research and development expenses for the year ended December 31, 2006, were \$5,937,122 compared to \$4,750,190 for the year ended 2005, an increase of \$1,186,932 or 25%. This increase is due primarily to additional toxicology testing for HepaVaxx B Vaccine clinical studies and development of Occlusin<sup>™</sup> 500 Device. Additional costs were also incurred for the following areas:

Continued development of Occlusin<sup>™</sup> 50 Injection.

Preclinical studies for a Chimigen<sup>TM</sup> Vaccine candidate for Hepatitis C.

Development costs for Chimigen<sup>TM</sup> Vaccines for biodefense applications.

Initiating manufacturing activities in Europe for OvaRex<sup>®</sup> MAb.

Research and development expenses for the year ended December 31, 2005 totaled \$4,750,190, an increase of \$2,953,510 from \$1,796,680 for the corresponding period ended December 31, 2004. This difference was mainly due to manufacturing of clinical material for the HepaVaxx B Vaccine clinical program. Also, in order to support the

progression of each of the Company's product candidates, additional research and development staff were hired during 2005. Additional intellectual property expenses were also incurred in 2005 further strengthening protection of the Company's products subsequent to commercialization.

#### **Government Assistance**

		For year ended December 31,					
		2006		2005	2004		
IRAP and AHFMR	P and AHFMR \$ 222,1		\$	45,000	\$	864,430	

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Government assistance awarded for the year ended December 31, 2006, was \$222,140 an increase of \$177,140 compared to \$45,000 received in 2005. The Company, in collaboration with DRDC-Suffield, is actively pursuing development grants from both the U.S. and Canadian governments.

Government assistance awarded for the year ended December 31, 2005, was \$45,000, a decrease of \$819,430 compared to \$864,430 received in 2004. Government assistance relates to Industrial Research Assistance Program ("IRAP") grants from the National Research Council of Canada ("NRC"). In addition to the IRAP grants, ViRexx received a technology commercialization award from Alberta Heritage Foundation for Medical Research ("AHFMR") in 2004.

### **Corporate Administration**

	For year ended December 31,						
	2006		2005		2004		
Business development costs	\$ 527,487	\$	-	\$	-		
Employee related costs	1,212,808		1,456,086		451,889		
Stock based compensation	454,081		399,470		310,448		
Other administration costs	2,782,461		1,794,726		1,125,374		
	\$ 4,976,837	\$	3,650,282	\$	1,887,711		

Corporate administration expenses for the year ended December 31, 2006, totaled \$4,976,837, an increase of 36% from \$3,650,282 for the year ended December 31, 2005. The \$1,326,555 increase is primarily attributable to the following areas:

- ·Initiated business development activities relating to negotiations with potential manufacturers and distributors of OvaRex<sup>®</sup> MAb for European territories, and licensing rights discussions held with companies regarding HepaVaxx B Vaccine, Occlusin<sup>TM</sup> 50 Injection and Occlusin<sup>TM</sup> 500 Device.
- ·Increased TSX and American Stock Exchange ("AMEX") fees as a result of the Company issuing 13.5 million newly issued common shares for the \$15 million that was raised in three separate private placements.
- ·Incurred consulting and other related fees associated with the Canadian Multilateral Instrument 52-109 and US Sarbanes Oxley Act of 2002 compliance requirements.
- · Increased investor relations costs in support of creating more awareness of ViRexx in both the U.S. and Canada.
- •Incurred restructuring costs associated with the Company's announcement on November 26, 2006, to prioritize its research activities to focus on the completion of its existing pipeline products.
- •Increase legal and other related service fees for U.S. regulatory filing requirements including preparation of Annual 20-F and electronic filings on EDGAR.

Corporate administration expenses for the year ended December 31, 2005 totaled \$3,650,282, an increase of \$1,762,571 from \$1,887,711 in general and administration expenses recorded for the corresponding period ended December 31, 2004. The difference is attributable to stock-based compensation recorded for options granted and consulting costs associated with investor relations and corporate communication activities. Additional costs were also incurred due to an increase in the number of administrative staff required and costs related to the acquisition of AltaRex Medical Corp.

# **Future Income Taxes**

Future income tax expense for the year ended December 31, 2006, was \$4,178,613 compared to a recovery of \$3,358,426 for the year ended December 31, 2005, and a future income tax provision of \$nil for the year ended December 31, 2004.

The Company uses the liability method of accounting for income taxes. Under this method, future income tax assets and liabilities are determined based on differences between the financial reporting and tax bases of the assets and liabilities. These differences are measured using the substantively enacted tax rates and laws that will be in effect when the differences are expected to reverse.

On the acquisition of AltaRex in 2004, the premium paid by ViRexx over the carrying value of the net assets of AltaRex was allocated to the intellectual property owned by AltaRex. This resulted in a significant future tax liability based on the difference between the tax cost base of the intellectual property and its net book value for accounting purposes.

ViRexx, as the parent company, has incurred significant tax losses and has other tax assets that can be used to reduce future taxable income. Management's assessment of the value of tax operating losses is based on its best estimate of the ability of the Company to utilize these assets to offset future tax losses. Judgments as to the timing and potential use of such assets are made on the best information available and are reassessed periodically.

In 2005, management's assessment was that the Company had the ability and intent to employ a prudent and feasible tax planning strategy whereby losses accumulated in the parent ViRexx would be utilized to offset the future tax liability in AltaRex related to the intellectual property owned by AltaRex. The result of this assessment was that the benefit of the ViRexx losses was used to offset the AltaRex liability which resulted in a recovery of future income taxes for the year ended December 31, 2005.

In the fourth quarter of 2006, the Company completed an internal reorganization and an inter-company transfer of certain assets. Because of these changes, reliance on a feasible tax planning strategy to realize the benefit of the future tax assets in the ViRexx legal entity was not viable. As a result, a valuation allowance was recorded in the fourth quarter of 2006 which resulted in a future tax expense and an increase in the corresponding liability on the balance sheet. This liability is decreasing over time as the carrying value of the asset is amortized. At the point where the carrying value equals the tax cost base, there will be no future tax liability.

### SUBSEQUENT EVENT

On January 29, 2007, ViRexx announced that it had filed a preliminary short-form prospectus with Canadian securities regulators in connection with an offering with minimum gross proceeds of \$10,000,000 to a maximum of \$15,000,000. The Company's designated agents were to act as agents in connection with the offering. The Company granted the agents an over-allotment option, exercisable for a period of 60 days following the closing of the offering, to purchase an additional 15% of the aggregate common shares offered pursuant to the offerings. As part of the transaction the Agents were to be granted agents' warrants exercisable for the purchase of that number of common shares equal to 7% of the number of units sold as part of the transaction.

On February 14, 2007, and amended on February 21, 2007, a Schedule 13D was filed with the United States Securities and Exchange Commission by a Bahamian company, Smetek, Van Horn & Cormack, Inc. (the "Smetek Group"). The Schedule 13D states that the holders of 27,744,105 common shares (19,155,595 on February 14, 2007, and amended for an incremental 8,588,510 on February 21, 2007) of ViRexx, purportedly representing approximately 40% of the issued and outstanding shares of ViRexx, held a telephone conference and agreed to take action to recommend a change in the majority of the Board of Directors of ViRexx. This action has resulted in one of the agents, Rodman & Renshaw to not proceed toward the closing of the financing transaction. While ViRexx is currently discussing with its advisors its possible courses of action in light of the filing of the Schedule 13D, ViRexx intends to continue to focus its resources on its operating and business development activities.

# LIQUIDITY AND CAPITAL RESOURCES

	For year ended December 31,					
Cash	2006		2005	2005		
	\$ 405,354	\$	237,462	\$	645,012	
Short-term investments	10,336,837		5,334,388		8,817,976	

#### **\$ 10,742,191 \$** 5,571,850 **\$** 9,462,988

The Company has no contributing cash flows from operations. As a result, the Company relies on external sources of financing such as the issue of equity or debt securities, the exercise of options or warrants and investment income to finance operations. Revenues from operations are not expected until certain milestones and royalty payments from license and collaboration agreements have been earned, or commercialization of a product candidate has occurred.

As at December 31, 2006, the Company's cash totaled \$405,354, as compared with \$237,462 at December 31, 2005. The Company's net cash used in operating activities amounted to \$9,027,103 for the year ended December 31, 2006, reflecting the Company's use of cash to fund operating activities. As at December 31, 2006, the Company's short-term investments totaled \$10,336,837 compared with \$5,334,388 at December 31, 2005.

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On February 16, 2006, the Company completed a private placement of 10,909,090 units for gross proceeds of \$12,000,000. Each unit consists of one common share and one common share purchase warrant. Each common share warrant entitles the holder to purchase one common share of the Company at a price of \$1.50 for a period of two years. As a commission, the brokers for the private placement received compensation of 7% of the gross proceeds and 1,090,909 broker warrants valued at \$539,962. Each broker warrant entitles the brokers to acquire one common share of the Company for \$1.50 per share until February 15, 2008. Additional cash costs of \$64,603 were also incurred.

On April 7, 2006, the Company completed a private placement of 800,000 units for gross proceeds of \$1,000,000. Each unit consists of one common share and one common share purchase warrant. Each common share warrant entitles the holder to purchase one common share of the Company at a price of \$1.75 for a period of two years. The broker for the private placement received \$40,000 cash as a commission.

On December 6, 2006, as a condition to completing licensing, marketing and manufacturing agreements for OvaRex<sup>®</sup> MAb in Europe with Sigma-Tau, ViRexx received an equity investment of \$2,000,000 from Defiante for 1,818,182 units of ViRexx at a price of \$1.10 per unit. Each unit consists of one common share and one common share purchase warrant. Each common share warrant entitles the holder to purchase one common share of the Company at a price of \$1.25 for a period of two years.

At December 31, 2005, the Company's cash totaled \$237,462 as compared with \$645,012 at December 31, 2004. The Company's net cash used in operating activities amounted to \$7,551,102 for the year ended December 31, 2005, and reflects the Company's use of cash to fund its net operating losses and the net changes in non-cash working capital balances. During 2005, the Company completed a private placement of 4,035,665 units for gross proceeds of \$4,035,665. The broker for the private placement received cash of 7% of the gross proceeds and 403,567 warrants as a commission. An additional \$1,259,738 was received from the exercise of warrants and stock options. Also during 2005, the Company incurred \$2,255,776 of share repurchase costs pursuant to a Normal Course Issuer Bid.

The Company believes that its cash, cash equivalents and short-term investments will be sufficient to satisfy the Company's anticipated capital requirements until late 2007. Management is considering all financing alternatives and is seeking to raise additional funds for operations from all potential sources. This disclosure is not an offer to sell, nor a solicitation of an offer to buy securities of the Company. While the Company is striving to achieve the above plans, there is no assurance that such funding will be available or obtained on favorable terms. At December 31, 2006, there was substantial doubt that the Company would be able to continue as a going concern. The financial statements do not reflect adjustments in the carrying values of the assets and liabilities, the reported revenues and expenses, and the balance sheet classification used, that would be necessary if the going concern were not appropriate and these adjustments could be material.

Projections of further capital requirements are subject to substantial uncertainty. Working capital requirements may fluctuate in future periods depending upon numerous factors, including: results of research and development activities; progress or lack of progress in preclinical studies or clinical trials; drug substance requirements to support clinical programs; the ability to achieve milestone payments under current licensing partner collaborations or any other collaborations the Company establishes that provide

funding; changes in the focus, direction, or costs of research and development programs; the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; competitive and technological advances; the potential need to develop, acquire or license new technologies and products; establishment of marketing and sales capabilities; business development activities; new regulatory requirements implemented by regulatory authorities; and the timing and outcome of any regulatory review process or commercialization activities, if any.

#### CONTRACTUAL OBLIGATIONS AND COMMITMENTS

In continuing operations, the Company has periodically entered into long-term contractual arrangements for office and laboratory facilities and product candidate manufacturing for clinical trials. The following table presents commitments arising from these arrangements currently in force over the next five years:

	Total	< 1 year	1 - 3 years	> 3 years
Operating lease obligations <sup>1,2</sup>	\$ 509,066	\$ 113,126	\$ 231,770	\$ 164,170
Product candidates manufacturing				
obligations	49,932	31,932	18,000	-
Capital lease obligation	11,845	7,107	4,738	-
Total contractual obligations	\$ 570,843	\$ 152,165	\$ 254,508	\$ 164,170

Notes:

1) Lease on laboratory and offices of \$109,263 per annum until May 31, 2007

2) Lease on laboratory and offices of \$115,885 per annum from June 1, 2007 to May 31, 2011

#### **OFF-BALANCE SHEET ARRANGEMENTS**

As at December 31, 2006, the Company did not have any material off-balance sheet arrangements other than those listed under the Contractual Obligations and Commitments described above and those disclosed in Note 10 to the audited financial statements for the year ended December 31, 2006.

#### **RISKS AND UNCERTAINTIES**

The Company operates in a highly competitive environment that involves significant risks and uncertainties, some of which are outside of the Company's control. The Company is subject to risks inherent in the biotechnology industry, including:

#### **Risks Related to the Company's Financial Condition**

- •The need to raise money from investors to continue planned operations. If the Company is unable to fund operations, the Company may cease doing business.
- •With the exception of milestone payments from potential product out-licensing, the Company has not derived any revenue to date from the commercial sale of product candidates, nor had any revenues from other commercial sales that have relied on equity and debt financings to support operations.
- •The history of operating losses is expected to continue. If the Company is unable to achieve significant revenues in the future, the Company may cease doing business.

The Company expects to continue to incur significant expenses.

- •The Company will continue to need significant amounts of additional capital that may not be available to the Company on favorable terms, and may be dilutive.
- •The Company may fail to obtain additional financing and be unable to fund operations and commercialize its product candidates.

#### **Risks Related To Our Business and Operations**

• The Company is in various stages of development of product candidates and unless it is able to generate sufficient product revenue from these candidates, the Company will continue to incur losses from operations and may not achieve or maintain profitability and may have to cease operations.

•The Company relies on, and intends in the future to continue to rely on; revenue from technology licenses with or issued to third parties. Any breach or termination of these license arrangements could have a material adverse effect on the business, financial condition and results of operations.

•Failure to protect intellectual property, or infringement on the property rights of others, may impede the Company's ability to operate freely.

• The Company's business is subject to significant government regulation and failure to achieve regulatory approval of drug candidates would severely harm its business.

The Company is dependent on the successful outcome of preclinical testing and clinical trials.

•Delays in clinical trials will cause the Company to incur additional costs which could jeopardize the trials and adversely affect the Company's liquidity and financial results.

• The Company relies on clinical investigators and contract research organizations to conduct its clinical trials.

There are risks inherent in relying on a sole source supplier for some of the Company's materials.

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- . The Company is dependent on strategic partners, such as Unither and the Sigma-Tau group of companies, as part of its product candidate development strategy, and it would be negatively affected if it is not able to initiate or maintain these relationships.
- The Company relies on collaborative arrangements for manufacturing its trial material and product candidates.

•The Company is required to comply with regulations that are administered by regulatory authorities in the United States, Europe and Canada.

•Even if product candidates receive all of the required regulatory approvals, there is no guarantee of market acceptance or commercialization of the resulting product candidates, which will be determined by the Company's sales, marketing and distribution capabilities and the positioning and competitiveness of its product candidates compared with any alternatives.

•Reimbursement procedures and future healthcare reform measures are uncertain and may adversely affect the Company's ability to successfully sell or license any pharmaceutical product candidate.

•Competitive products and technologies may reduce demand for the Company's product candidates and technologies.

•The Company's industry is characterized by rapid change and a failure by the Company to react to these changes could have a material adverse effect on its business.

·If the Company fails to hire or retain needed personnel, the implementation of its business plan could slow and future growth could suffer.

• The loss of the services of the Company's Chief Executive Officer and Chief Scientific Officer could have a material adverse effect on its business.

The Company is reliant on key employees.

•The Company conducts certain elements of its business internationally, and the decisions of sovereign governments could have a material adverse effect on its financial condition.

•The Company's operating results may be subject to currency fluctuations as some of its expenses are in U.S. dollars or other foreign currencies.

•The Company's insurance may not be sufficient, exposing the Company to lawsuits. Claims related to product candidates in clinical studies and product liability could also increase its expenses, harm its reputation and keep it from growing its business.

•Hazardous materials that are highly regulated may expose the Company to potential liability in the event of an accident; therefore, compliance with environmental regulations could be costly in the future.

·It is possible that the AIT<sup>TM</sup>, Chimigen<sup>TM</sup> and T-ACT<sup>TM</sup> technologies have adverse side effects or cause undesirable reactions, of which the Company is not aware of any at present.

·If there are fewer individuals in the Company's target markets than the Company estimates, then it may not generate sufficient revenues to continue development of its product candidates or continue operations.

•The Company will need to significantly increase the size of its organization, and it may experience difficulties in managing growth.

#### Risks Relating To a Potential Change in the Majority of Our Board of Directors

The Company was made aware that a Schedule 13D was filed with the United States Securities and Exchange Commission on February 14, 2007, and amended February 21, 2007, by the Smetek Group. The Schedule 13D states that the holders of 27,744,105 common shares of ViRexx, purportedly representing approximately 40% of the Company's issued and outstanding shares held a telephone conference and have agreed to vote in favor of a change in the majority of the Board of Directors of the Company.

Pursuant to the Company's By-laws, at each annual meeting of shareholders at which an election of directors is required or at a special meeting of shareholders called for that purpose, the shareholders, by ordinary resolution, must elect directors to hold office for a term expiring not later than the close of the next annual meeting of the shareholders. At every shareholder meeting of the Company, all questions proposed for the consideration of shareholders must be decided by the majority of votes, unless otherwise required by the Act or the Articles. Should the Smetek Group elect to vote as a group for the purpose of effecting a change in the majority of the Board of Directors, and such change is actually effected via attainment of a sufficient number of votes, the constitution of the Board of Directors may change, and as a result, the corporate and operations focus might also change.

The Company is currently discussing with external advisors all possible actions relating to the filing of the aforementioned Schedule 13D, and intends to continue to focus its resources on planned operations.

#### **Risks Relating to the Company's Common Shares**

• The Company has not paid, and does not intend to pay any cash dividends on its common shares and therefore its shareholders may not be able to receive a return on their shares unless they sell them.