

VIRAGEN INC  
Form S-3  
May 25, 2007  
Table of Contents

As Filed With the Securities and Exchange Commission on May 25, 2007

Registration No. 333-\_\_\_\_\_

---

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

---

**FORM S-3**  
**REGISTRATION STATEMENT**

*UNDER*  
*THE SECURITIES ACT OF 1933*

---

**VIRAGEN, INC.**

(Exact name of registrant as specified in its charter)

---

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**59-2101668**

(I.R.S. Employer Identification No.)

**865 S.W. 78<sup>th</sup> Avenue, Suite 100**

**Plantation, Florida 33324**

**(954) 233-8746**

(Address, including zip code, and telephone number, including area code,

Edgar Filing: VIRAGEN INC - Form S-3

of registrant's principal executive offices)

---

*Copies to:*

**DENNIS W. HEALEY**  
**EXECUTIVE VICE PRESIDENT**  
**VIRAGEN, INC.**  
**865 S.W. 78<sup>th</sup> AVENUE, SUITE 100**  
**PLANTATION, FLORIDA 33324**  
**TELEPHONE: (954) 233-8746**

**STEVEN I. WEINBERGER, ESQ.**  
**SCHNEIDER WEINBERGER & BEILLY LLP**  
**2200 CORPORATE BLVD., N.W., SUITE 210**  
**BOCA RATON, FL 33431**  
**TELEPHONE: (561) 362-9595**  
**FACSIMILE: (561) 362-9612**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

---

**Approximate date of commencement of proposed sale to the public:** From time to time as described in the Prospectus.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, please check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

---

**CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered	Amount to be registered	Proposed maximum offering price per unit (1)	Proposed	
			maximum aggregate offering price (1)	Amount of registration fee (1)
Common stock, \$.01 par value per share, issuable upon conversion of Series K 18% Cumulative Convertible Preferred Stock (2)	30,000,000	\$ 0.10	\$ 3,000,000	\$ 92.10
Common stock, \$.01 par value per share, issuable upon exercise of common stock purchase warrants (3)	15,000,000	\$ 0.10	1,500,000	46.05
			\$ 4,500,000	\$ 138.15

## Edgar Filing: VIRAGEN INC - Form S-3

- (1) The registration fee has been calculated pursuant to Rule 457 of the Securities Act of 1933.
- (2) Represents shares of our common stock issuable upon the conversion of Series K 18% Cumulative Convertible Preferred Stock. The registration fee is based on the \$0.10 conversion rate of the shares of Series K 18% Cumulative Convertible Preferred Stock, which is higher than the last sale price of our common stock, \$.01 par value per share, as reported by the American Stock Exchange on May 18, 2007.
- (3) Represents shares of our common stock issuable upon the exercise of common stock purchase warrants issued in connection with our Series K 18% Cumulative Convertible Preferred Stock. The registration fee is based on the \$0.10 price at which the common stock purchase warrants are exercisable into shares of our common stock, which was greater than the last sale price of our common stock, \$.01 par value per share, as reported by the American Stock Exchange on May 18, 2007.

Pursuant to Rule 416 under the Securities Act of 1933, there are also being registered such additional number of shares as may be issuable as a result of stock splits, dividends, reclassifications and similar adjustment provisions applicable to the securities being registered.

Viragen, Inc. hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until Viragen shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

---

**Table of Contents**

Subject to Completion

Dated May 25, 2007

**Selling Security Holder Offering Prospectus**

**Viragen, Inc.**

**45,000,000 shares of common stock**

This prospectus covers the resale of an aggregate of 45,000,000 shares of our common stock, consisting of 30,000,000 shares issuable upon conversion of Series K 18% Cumulative Convertible Preferred Stock and 15,000,000 shares issuable upon exercise of outstanding common stock purchase warrants issued in connection with the sale of our Series K 18% Cumulative Convertible Preferred Stock. We will not receive any proceeds from the sale of shares by the selling security holders.

Our common stock is listed on the American Stock Exchange under the symbol **VRA** . On May 18, 2007, the last reported sale price for our common stock was \$0.05 per share.

*This investment involves a high degree of risk. You should purchase shares only if you can afford a complete loss. See **Risk Factors** beginning at page 12.*

---

*Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.*

The date of this prospectus is \_\_\_\_\_, 2007.

**Table of Contents**

No dealer, sales representative or any other person has been authorized to give any information or to make any representations other than those contained in this prospectus and, if given or made, such information or representation must not be relied upon as having been authorized by Viragen. This prospectus does not constitute an offer of any securities other than those to which it relates or an offer to sell, or a solicitation of any offer to buy, to any person in any jurisdiction where such an offer or solicitation would be unlawful. Neither the delivery of this prospectus nor any sale made hereunder shall, under any circumstances, create an implication that the information set forth herein is correct as of any time subsequent to the date hereof.

**TABLE OF CONTENTS**

	<b>Page</b>
<u>About Viragen</u>	3
<u>Where You Can Find More Information</u>	9
<u>Forward-Looking Statements</u>	11
<u>Risk Factors</u>	12
<u>Use of Proceeds</u>	36
<u>Selling Security Holders</u>	36
<u>Plan of Distribution</u>	39
<u>Description of Securities</u>	41
<u>Legal Matters</u>	43
<u>Experts</u>	43

You should rely only on the information provided or incorporated by reference in this prospectus. We have not authorized anyone to provide you with additional or different information. This document may only be used where it is legal to sell these securities. You should not assume that any information in this prospectus is accurate as of any date other than the date of this prospectus.

---

**Table of Contents**

**ABOUT VIRAGEN**

Because this is a summary, it does not contain all the information about us that may be important to you. You should read the more detailed information and the financial statements and related notes which are incorporated by reference in this prospectus.

With international operations in the U.S., Scotland and Sweden, we are a bio-pharmaceutical company engaged in the research, development, manufacture and commercialization of therapeutic proteins for the treatment of cancers and viral diseases. Our product and product candidate portfolio includes: *Multiferon*<sup>®</sup> (multi-subtype, human alpha interferon) uniquely positioned in valuable niche indications, such as high-risk malignant melanoma, other niche cancer indications and selected infectious diseases; VG102, a highly novel humanized monoclonal antibody that binds selectively to an antigen that is over-expressed on nearly all solid tumors and VG106, an in-house developed cytokine that has been shown, in preliminary studies, to prevent proliferation of several difficult-to-treat cancers. We are also pioneering the development of the OVA System (Avian Transgenics), with the renowned Roslin Institute, the creators of Dolly the Sheep, as a revolutionary manufacturing platform for the large-scale, efficient and economical production of human therapeutic proteins and antibodies, by expressing these products in the egg whites of transgenic hens.

With *Multiferon*<sup>®</sup> being approved in Sweden for the first-line adjuvant treatment of high-risk malignant melanoma in February 2006, we are highly focused on expanding this approval into other countries throughout the European Union, while securing additional licensees to effectively market the product. We are an international company, with *Multiferon*<sup>®</sup> manufacturing operations in Umeå, Sweden, research and development activities in Edinburgh, Scotland, and our headquarters in Plantation, Florida.

We own approximately 77.0% of Viragen International, Inc., whose shares of common stock are traded on the over-the-counter Bulletin Board under the symbol VGNI. Viragen International owns 100% of ViraNative AB, our Swedish subsidiary, and 100% of Viragen (Scotland) Ltd., our Scottish research center.

Since our organization in December 1980, we have incurred operating losses. Our operating losses were approximately \$18.2 million, \$26.2 million and \$18.2 million for the fiscal years ended June 30, 2006, 2005 and 2004, respectively, and \$26.7 million for the nine months ended March 31, 2007. At March 31, 2007, we had cash on hand of approximately \$87,000, a working capital deficit of approximately \$1.2 million, an accumulated deficit since organization of approximately \$193.8 million and stockholders' equity of approximately \$3.4 million. These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders' equity. In light of our recurring losses, accumulated deficit and cash flow difficulties, the report of our independent registered public accounting firm on our financial statements for the fiscal year ended June 30, 2006 contains an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result from the outcome of these uncertainties.

We have commenced implementing, and will continue to implement, various measures to address our financial condition, including:

Continuing to seek debt and equity financing, funding through strategic partnerships, as well as distribution partners for *Multiferon*<sup>®</sup> to generate licensing and sales revenues.

## **Table of Contents**

Curtailing operations where feasible to conserve cash through a combination of: staff reductions in the United States, Sweden and Scotland; reducing leased space in the United States, Sweden and Scotland and; deferring certain of our research and development activities until our cash flow improves and we can recommence these activities with appropriate funding.

Investigating and pursuing transactions including mergers, asset sales and other business combinations deemed by the board of directors to present attractive opportunities to enhance stockholder values.

In the event our capital raising efforts, which may involve dilution of existing stockholders, and revenue-generation efforts are unsuccessful, and if we are unable to identify and consummate an acceptable business combination, we may, in the interest of stakeholders, elect to seek reorganization of the business under protection of Title 11 of the United States Code. However, before we seek such reorganization, we would contact creditors, including trade creditors and debt holders, to discuss payment extensions, conversion of debt to equity and/or other concessions.

We were incorporated under the laws of the state of Delaware in December 1980. Our executive offices are located at 865 SW 78th Avenue, Suite 100, Plantation, Florida 33324. Our telephone number is (954) 233-8746; our facsimile number is (954) 233-1414. You can learn more about us by visiting our web site at [www.viragen.com](http://www.viragen.com). The information on our website is neither incorporated into, nor a part of, this report. Our common stock trades on the American Stock Exchange under the symbol **VRA**. Unless otherwise indicated, references in this report to **we**, **us** and **our** are to Viragen, Inc., and our wholly-owned and majority-owned subsidiaries.

## ***Recent Events***

### **Notice of Delisting**

On May 17, 2007, Viragen, Inc. received a notice from the Staff of the American Stock Exchange (AMEX) indicating that Viragen no longer complies with the AMEX's continued listing standards and, accordingly, the AMEX intends to file an application with the Securities and Exchange Commission to strike Viragen's common stock, units and warrants from listing and registration on the AMEX. The bases for the Staff's notice are that Viragen fails to meet AMEX's combined net loss and stockholder equity requirements for continued listing, Viragen's financial condition is so impaired that it is questionable whether Viragen can continue operations and/or meet its financial obligations as they mature and Viragen has failed to implement a reverse split of its common stock notwithstanding that its shares have been selling at a low price per share for a substantial period of time. Since September 2005, Viragen's securities have been listed on AMEX pursuant to a temporary exception that required the Company to demonstrate compliance with AMEX's listing criteria on or before March 20, 2007. The AMEX Staff notice includes a determination that Viragen failed to regain compliance with the AMEX continued listing standards by the end of the exception period or as of the date of its determination letter. Viragen has appealed the AMEX Staff determination by requesting a hearing before an AMEX Listing Qualifications Panel. The filing of the hearing request operates to stay delisting of the Company's securities pending the hearing panel's determination. However, there is no assurance that the AMEX hearing panel will permit the Company's securities to remain listed on the AMEX. The delisting of our securities from the AMEX would impact our financial statements and adversely affect our financial condition. Additional information relating to our receipt of this notice from the AMEX is contained elsewhere in this prospectus under the caption **Risk Factors**.

## Table of Contents

### OVA System

In May 2007, we and our collaborative partners in the field of avian transgenics, Roslin Institute and Oxford Biomedica, announced a significant breakthrough in the development of the OVA System, resulting in a more efficient bio-manufacturing platform for the cost-effective production of human therapeutic proteins. Our researchers in Scotland and collaborators at Roslin Institute were able to significantly increase expression levels of interferon alpha-2a, a human protein often prescribed for the treatment of hepatitis C and certain malignant diseases, by at least 10-fold over previously reported results. The high quantities of active protein now being recovered from these transgenic hens' eggs builds a compelling case for using the OVA System as a primary manufacturing system. Additional protein drug candidates will be evaluated in confirmatory studies.

### Multiferon® Study

In May 2007, we announced results from a sponsored in vitro study conducted at Umea University in Sweden, which found that *Multiferon*® suppressed development of resistant human melanoma clones to a far greater degree than recombinant alpha interferon. The study has been accepted for publication in *AntiCancer Research*, *International Journal of Cancer Research and Treatment*. The study, conducted by Professor Erik Lundgren, Head of Research at the Department of Molecular Biology, Umea University, and a consultant and director of ViraNative, was designed to compare *Multiferon*® and Intron® A (Interferon alpha-2b, recombinant) with respect to the abilities of each product to inhibit the development of interferon-resistant melanoma cells in vitro, in order to better understand the reason for melanoma treatment failures. Intron® A is registered trademark of Schering-Plough Corporation.

For this study, three human melanoma cell lines were grown at a range of different cell concentrations in the presence of graded doses of either *Multiferon*® or Intron® A. After four weeks, the number of melanoma cell colonies was assessed and their properties analyzed. Long-term treatment with *Multiferon*® was found to result in substantially fewer interferon-resistant melanoma clones than treatment with Intron® A. When treated with the single-subtype, recombinant alpha interferon, not only were distinct colonies found, but scattered individual cells were also observed. In contrast, during short term treatment, there was no difference in potency between the two interferon types with respect to growth and survival. The results of this study suggest that the mixture of six human alpha subtypes present in *Multiferon*® (a1, a2, a8, a10, a14, a21) provides distinct benefits versus other alpha interferon products in vitro with respect to reducing the number of resistant clones.

### Expiration of Collaboration and Refocus of Resources

In May 2007, we announced that Sloan-Kettering Institute for Cancer Research and the Company have decided to end the collaboration on VG101, a jointly-owned humanized antibody being developed for the treatment of Stage IV malignant melanoma. The collaborative research agreement between Sloan-Kettering Institute for Cancer Research and the Company, which was entered into in February 2002 and subsequently amended, expired on May 1, 2007. Viragen intends to refocus resources on preclinical studies planned for two of Viragen's anti-cancer product candidates: VG102, a monoclonal antibody that has the potential to target nearly all solid tumors; and VG106, an in-house developed cytokine that has been shown, in preliminary studies, to prevent proliferation of several difficult-to-treat cancers.



## Table of Contents

### Multiferon® License Agreement

On April 16, 2007, our majority owned subsidiary, Viragen International, entered into a license agreement with Swedish Orphan International that grants exclusive rights to Swedish Orphan International to market *Multiferon*® (multi-subtype, human alpha interferon) in the European Union (excluding previously licensed member states). Under the agreement, Viragen International received approximately \$2 million ( 1.5 million) as an up-front license fee. In addition, Orphan International will pay Viragen for *Multiferon*® at an agreed upon sales price, and, in addition, Viragen will receive double-digit royalties from Swedish Orphan International on their net sales of *Multiferon*®.

### Series K 18% Cumulative Convertible Preferred Stock

On April 12, 2007, Viragen completed a private placement of Series K 18% Cumulative Convertible Preferred Stock and warrants to purchase 15,000,000 shares of our common stock. The series K preferred stock is convertible into shares of our common stock, at the option of the holder, together with accrued and unpaid dividends, at a conversion price or rate of \$0.10 per share (an aggregate of 30,000,000 shares of our common stock). Each warrant entitles the holder to purchase one share of Viragen common stock at an exercise price of \$0.10 per share at any time prior to April 11, 2012. Viragen received net proceeds of approximately \$2.9 million in connection with this transaction.

### Convertible Debt Exchange

On March 19, 2007, we completed a transaction with certain holders of our convertible notes and debentures, who held an aggregate principal amount of \$9.05 million of convertible notes, \$106,250 of convertible debentures, and related warrants to purchase an aggregate of approximately 4.6 million shares of our common stock at \$1.25 per share, to exchange the principal, and accrued interest of approximately \$139,000, and the related warrants, for shares of our common stock. The exchange provided for the holders of the convertible notes and debentures to receive an aggregate of approximately 93 million shares of our common stock.

### Agreement with Orphan Australia

On December 22, 2006, Viragen International entered into a licensing agreement with Orphan Australia Proprietary Limited that grants exclusive rights to Orphan Australia to market, sell and distribute *Multiferon*® (multi-subtype, human alpha interferon) in Australia and New Zealand. Under the agreement, Viragen International received an up-front license fee, with additional milestone payments to be paid upon receipt of necessary reimbursement authorization for *Multiferon*® in Australia.

### November 2006 Public Offering

In November 2006, we completed an underwritten public offering of 72,004,951 Units at a price to the public of \$0.26 per Unit, which included 5,004,951 Units purchased to cover over-allotments. Each Unit consists of one share of Viragen common stock and one warrant to purchase one share of Viragen common stock, exercisable at a price of \$0.31 per share through October 2011. We also issued an option for \$100 to the underwriter to purchase 4,020,000 Units at a price of \$0.29 per Unit. The warrants underlying the underwriter's Units are exercisable at \$0.39 per share, but otherwise have the same terms and conditions as the warrants underlying the Units offered to the public.

**Table of Contents**

This offering raised gross proceeds of approximately \$18.7 million, and after fees and expenses, we received net proceeds of approximately \$17.0 million. We utilized approximately \$11.5 million of the net proceeds for the redemption of all of our outstanding Series J cumulative convertible preferred stock and all of Viragen International's outstanding Series C and D cumulative preferred stock, including the payment of the related accrued and unpaid dividends, and the retirement of a portion of our convertible debentures.

**Table of Contents****Selected Financial Data**

The following selected financial data should be read together with Management's Discussion and Analysis of Financial Condition and Results of Operations, the consolidated financial statements and notes thereto and other financial information included in our Annual Report on Form 10-K for the year ended June 30, 2006, which is incorporated by reference into this prospectus. The consolidated statements of operations data set forth below of Viragen for the fiscal years ended June 30, 2006, 2005, 2004, 2003 and 2002 and the consolidated balance sheet data as of June 30, 2006, 2005, 2004, 2003 and 2002 have been derived from Viragen's audited consolidated financial statements. The consolidated statement of operations data set forth below for the nine months ended March 31, 2007 and March 31, 2006 and the consolidated balance sheet data as of March 31, 2007 have been derived from Viragen's unaudited consolidated financial statements included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, which is incorporated by reference into this prospectus. The following information does not give effect to Viragen's receipt of net proceeds of approximately \$2.9 million from the sale of its Series K 18% Cumulative Convertible Preferred Stock, the issuance of an aggregate of 300,344 shares of our common stock valued at \$0.09 per share as payment of quarterly interest due April 1, 2007 totaling approximately \$26,000 on our convertible notes or the issuance of an aggregate of 4 million shares of our common stock upon conversion of \$400,000 of our convertible notes at \$0.10 per share, subsequent to March 31, 2007. In addition, the following information does not give effect to the reclassification of the long-term portion of our convertible notes and debentures to current in the event our securities are delisted from the AMEX.

	Nine months ended						
	March 31,		2006	2005	Year Ended June 30,		
	2007	2006			2004	2003	2002
	(Unaudited)						
<b>STATEMENT OF OPERATIONS DATA</b>							
Product sales	\$ 299,249	\$ 300,802	\$ 391,213	\$ 278,784	\$ 266,137	\$ 630,785	\$ 1,275,264
Other income (expense), net	434,435	656,709	(145,873)	1,538,067	632,378	535,428	333,130
Net loss	(26,720,074) <sup>a</sup>	(13,324,398)	(18,214,897)	(26,207,706) <sup>b</sup>	(18,177,164)	(17,348,686)	(11,088,832)
Net loss attributable to common stock	(27,623,524)	(14,293,404)	(19,496,484)	(26,209,856)	(18,179,714)	(17,351,336)	(11,091,482)
Basic and diluted net loss per common share (c)	(0.30)	(0.35)	(0.46)	(0.71)	(0.55)	(1.21)	(1.10)
Weighted average common shares outstanding (c)	91,713,625	40,779,807	42,018,617	36,697,852	33,183,832	14,393,803	10,041,571

	At March 31,			At June 30,			
	2007	2006	2005	2004	2003	2002	
	(Unaudited)						
<b>BALANCE SHEET DATA</b>							
Working capital (deficit)		\$ (1,179,625)	\$ 229,056	\$ (7,300,733)	\$ 25,181,900	\$ 4,070,504	\$ (209,519)
Total assets		7,561,698	13,973,966	21,984,792	48,219,996	27,867,417	20,796,604
Convertible notes and debentures, current (d)		3,903	453,918	16,104,994 <sup>e</sup>		2,224,599	711,982
Convertible notes and debentures, long-term (d)		454,778	11,145,816		12,490,919	1,827,163	
Long-term debt, less current portion		628,543	627,265	598,104	1,072,087	1,124,335	1,023,948
Stockholders' equity (deficit)		3,371,711	(1,613,647)	2,593,617	29,189,581	15,720,208	11,470,620

- (a) Net loss for the nine months ended March 31, 2007 includes debt conversion expenses of approximately \$9.3 million due to the exchange of shares of our common stock for convertible debt and a goodwill impairment charge of approximately \$4.1 million.
- (b) Net loss for the fiscal year ended June 30, 2005 includes a goodwill impairment charge of approximately \$6.9 million.
- (c) Outstanding share and per share amounts have been adjusted retroactively to reflect the 1:10 reverse stock split that became effective on June 15, 2004.

## Edgar Filing: VIRAGEN INC - Form S-3

- (d) Net of discounts.
- (e) Subsequent to June 30, 2005, Viragen entered into agreements to extend the maturity date of its convertible notes from March 31, 2006 to August 31, 2008. As a result of the extension of the maturity date, the convertible notes were reclassified from current to long-term.

**Table of Contents**

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the Securities and Exchange Commission a registration statement on Form S-3 under the Securities Act covering the resale of the common stock offered by this prospectus. This prospectus, which is a part of the registration statement, does not contain all of the information in the registration statement and the exhibits filed with it, portions of which have been omitted as permitted by the SEC rules and regulations. For further information concerning Viragen and the securities offered by this prospectus, we refer to the registration statement and the exhibits filed with it. Statements contained in this prospectus as to the content of any contract or other document referred to are not necessarily complete. Where a contract or other document is an exhibit to the registration statement, you should review the provisions of the exhibit to which reference is made. You may obtain these exhibits from the SEC, as discussed below.

We are required to file annual, quarterly, and current reports, proxy statements and other information with the SEC. You may read and copy these filings, as well as the registration statement of which this prospectus forms a part, at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. You may request copies of these documents by writing to the SEC and paying the required fee for copying. Please call the SEC at 1-800-SEC-0330 for more information about the operation of their public reference rooms. The SEC also maintains an Internet site that contains reports, proxy and information statements and other information filed electronically with the SEC. The address of that site is [www.sec.gov](http://www.sec.gov).

The SEC allows us to incorporate by reference into this prospectus information that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file with the SEC following the date of this prospectus will automatically update and supercede this information. We incorporate by reference the documents listed below and any documents we subsequently file with the SEC, under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934:

Our Current Report on Form 8-K filed with the SEC on May 24, 2007;

Our Current Report on Form 8-K filed with the SEC on May 18, 2007;

Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007 filed with the SEC on May 15, 2007;

Our Current Report on Form 8-K/A filed with the SEC on May 7, 2007;

Our Current Report on Form 8-K filed with the SEC on May 4, 2007;

Our Current Report on Form 8-K filed with the SEC on April 19, 2007;

Our Current Report on Form 8-K filed with the SEC on April 17, 2007;

Our Current Report on Form 8-K filed with the SEC on March 23, 2007;

Our Quarterly Report on Form 10-Q for the quarter ended December 31, 2006 filed with the SEC on February 14, 2007;

Our Current Report on Form 8-K filed with the SEC on December 28, 2006;

## Edgar Filing: VIRAGEN INC - Form S-3

Our Current Report on Form 8-K filed with the SEC on November 22, 2006;

Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 filed with the SEC on November 14, 2006;

The description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on October 13, 2006;

Our Current Report on Form 8-K filed with the SEC on October 6, 2006; and

Our Annual Report on Form 10-K for the fiscal year ended June 30, 2006 filed with the SEC on September 27, 2006.

**Table of Contents**

We will deliver without charge a copy of all of the information incorporated by reference in this prospectus to each person receiving a copy of this prospectus. If you need an additional copy of these documents, or if you would like to receive a copy of the other items referenced above, you may request copies, at no cost, by writing or telephoning us at the following address and number:

Dennis W. Healey

Chief Financial Officer

Viragen, Inc.

865 S.W. 78<sup>th</sup> Avenue, Suite 100

Plantation, Florida 33324

Telephone Number: (954) 233-8746

Copies of our SEC filings and other information about us are also available free of charge on our website at [www.viragen.com](http://www.viragen.com). The information on our website is neither incorporated into, nor a part of, this prospectus.

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

This prospectus, and other documents that we have incorporated by reference or included by attachment, contain forward-looking statements. Forward-looking statements express our expectations or predictions of future events or results. They are not guarantees and are subject to many risks and uncertainties. There are a number of factors many beyond our control that could cause actual events or results to be significantly different from those described in the forward-looking statement. Any or all of our forward-looking statements in this report or in any other public statements we make may turn out to be wrong.

We caution that these statements are further qualified by important factors that could cause actual results to differ materially from those contemplated in the forward-looking statements, including, without limitation, the following:

our ability to procure additional funding;

our failure to achieve significant revenues;

our failure to service our debt and preferred stock;

regulation by federal, state and foreign regulatory authorities in the manufacturing and selling of our *Multiferon*® product;

our failure to develop and commercialize our avian transgenics platform and antibody product candidates;

our reliance on third parties to market and distribute our *Multiferon*® product;

the effect of competition in the pharmaceutical and biotechnology industry;

our reliance on foreign third party manufacturers;

the availability of human leukocytes and other materials used in the production of our products;

an adverse change in foreign currency exchange rates;

our ability to protect our intellectual property;

our exposure to litigation;

our dependence on our key managers and scientific personnel and our scientific collaborators;



## Edgar Filing: VIRAGEN INC - Form S-3

a decline in demand for shares of our common stock;

volatility in the market for shares of our common stock;

our ability to regain and maintain compliance with AMEX listing standards;

our ability to redeem and pay dividends on preferred stock under Delaware law;

the effect of economic conditions generally; and

regulation by federal, state and foreign regulatory authorities in connection with developing, marketing, manufacturing and selling our product candidates.

Forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts. They use words such as anticipate, estimate, expect, project, intend, plan, believe or words of similar meaning. They may also use words such as, would, may. Factors that may cause our actual results to differ materially include the risks described herein. These risks and uncertainties are not the only ones we face. There may be additional risks and uncertainties that are not known to us or that we do not consider to be material at this time. If the events described in these risks occur, our business, financial condition and results of operations could be adversely affected.

---

**Table of Contents**

**RISK FACTORS**

*An investment in our common stock is highly speculative. You should be aware you could lose the entire amount of your investment. Prior to making an investment decision, you should carefully read this entire prospectus and consider the following risk factors. The risks and uncertainties described below are not the only ones we face. There may be additional risks and uncertainties that are not known to us or that we do not consider to be material at this time. If the events described in these risks occur, our business, financial condition and results of operations could be adversely affected. This prospectus contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. This section discusses the business risk factors that might cause those differences.*

**Risks Related to Our Financial Condition and Business**

*We have a history of operating losses and we expect to continue to incur losses and may never be profitable. If we do not develop profitable operations, we will have to terminate our operations. As a result, investors will lose their entire investment.*

Since our organization, we have incurred operating losses and negative cash flow from operating activities as a result of minimal sales coupled with our significant clinical development, research and development, general and administrative, sales and marketing and business development expenses. We expect to incur losses for at least the next several years as we expand our sales and marketing capabilities, make use of the sales and marketing capabilities of third parties and continue our clinical trials and research and development activities. Losses have totaled approximately:

\$26.7 million for the nine months ended March 31, 2007;

\$18.2 million for our fiscal year ended June 30, 2006;

\$26.2 million for our fiscal year ended June 30, 2005; and

\$18.2 million for our fiscal year ended June 30, 2004.

At March 31, 2007, we had cash on-hand of approximately \$87,000, a working capital deficit of approximately \$1.2 million, an accumulated deficit since organization of approximately \$193.8 million and stockholders' equity of approximately \$3.4 million. Our operating losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders' equity. In light of our recurring losses, accumulated deficit and cash flow difficulties, the report of our independent registered public accounting firm on our financial statements for our fiscal year ended June 30, 2006 contains an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may be necessary in the event we are unable to continue as a going concern.

We believe we have sufficient cash to support our operations, including those of our subsidiaries, through June 2007. However, we will require substantial additional capital to support our operations subsequent to June 2007. No assurance can be given that additional capital will be available when required or upon terms acceptable to us. Our inability to generate substantial revenue or obtain additional capital through equity or debt financings would have a material adverse effect on our financial condition and our ability to continue operations. Accordingly, we could be forced to significantly curtail or suspend our operations, including laying-off employees, recording asset impairment write-downs and other measures. We may also consider a merger, asset sale and/or other business combination designed to enhance stockholder values.

## Table of Contents

We have commenced implementing, and will continue to implement, various measures to address our financial condition, including:

Continuing to seek debt and equity financing, funding through strategic partnerships, as well as distribution partners for *Multiferon*® to generate licensing and sales revenues.

Curtailing operations where feasible to conserve cash through a combination of: staff reductions in the United States, Sweden and Scotland; reducing leased space in the United States, Sweden and Scotland and; deferring certain of our research and development activities until our cash flow improves and we can recommence these activities with appropriate funding.

Investigating and pursuing transactions including mergers, asset sales and other business combinations deemed by the board of directors to present attractive opportunities to enhance stockholder values.

As described elsewhere in this prospectus, we have received a notice of delisting of our securities from the AMEX. While we have appealed AMEX's determination, in the event our securities are delisted from AMEX, (a) the holder of approximately \$1.1 million of our outstanding convertible debt will have the right to accelerate payment of the amount due, plus an additional 10%, on demand, (b) approximately \$700,000 of unamortized discounts and deferred financing costs associated with the \$1.1 million of our outstanding convertible debt will be immediately recorded as interest expense and (c) our ability to raise additional financing to alleviate our cash flow difficulties will be adversely affected.

In the event our capital-raising efforts, which may involve dilution of existing stockholders, and revenue-generation efforts are unsuccessful, and if we are unable to identify and consummate an acceptable business combination, we may, in the interest of stakeholders, elect to seek reorganization of the business under protection of Title 11 of the United States Code. However, before we seek such reorganization, we would contact creditors, including trade creditors and debt holders, to discuss payment extensions, conversion of debt to equity and/or other concessions.

We must generate significant revenues to achieve and maintain profitability. While *Multiferon*® is in its early stage of commercialization deriving nominal revenue, most of our products and technologies are either in the research stage or in pre-clinical stages of development and will require substantial additional funding to reach the commercialization stage. Even if we succeed in developing and commercializing one or more of our product candidates, we may not be able to generate sufficient revenues or achieve or maintain profitability. Our failure to achieve and maintain profitability would depress the market price of our common stock and could impair our ability to raise additional capital, expand our business, diversify our product offerings and continue operations. Additionally, investors could lose their entire investment in our securities.

***Our business is capital intensive, and we do not currently generate sufficient revenues to offset our debt service obligations, research and development activities and other operating expenses. If we are unable to obtain additional funding, as and when required, we may have to significantly curtail or completely terminate our operations.***

We will require substantial future capital in order to continue to complete research, development and commercialization of our products and technologies, to meet our debt service obligations, to fund other operating expenses and to otherwise execute our business plan. If we are unable to obtain additional financing or generate licensing and sales revenue sufficient to sustain our operations, as needed, we could be forced to significantly curtail or suspend our operations, including laying-off employees, recording asset impairment write-downs and other measures.

---

## Table of Contents

Additional capital may not be available to us when needed, or on terms that are acceptable to us, or at all. For instance, our common stock price may not permit us to conduct future financings. Additionally, pursuant to the terms of our convertible debt issued in June 2004 and September 2005, we are not permitted to incur additional indebtedness except in limited circumstances. Our ability to raise additional funds through the issuance of additional debt will be limited absent a waiver from the debt holder. There can be no assurance the debt holder will provide a waiver, if requested to do so.

We anticipate research and development costs to increase over the next twelve months, particularly in the area of regulatory-related consulting fees, toxicology studies and clinical trial costs. Our future capital requirements will depend on many factors including:

our ability to conduct future financings;

revenue generated from licensing *Multiferon*®, our antibody product candidates or our avian transgenics technology;

revenue generated from the sale of *Multiferon*®;

our ability to service our convertible debt and convertible preferred stock;

progress with future research, development, pre-clinical studies and clinical trials;

the costs associated with obtaining regulatory approvals;

the costs involved in patent applications and potential patent enforcement;

competing technologies and market developments; and

our ability to establish collaborative arrangements and effective commercialization activities.

Based on our current operating plans, for the last quarter of our fiscal year ending June 30, 2007, we anticipate that we will need approximately \$3.0 million for operating activities, \$50,000 for investing activities and \$100,000 to service our current financing obligations. Actual expenditures in these areas could vary based on the amount of capital we are able to obtain.

***We will be substantially dependent on licensing fees and sales of our human alpha interferon product, Multiferon®, to generate revenue for the foreseeable future. If we are unable to obtain or maintain the necessary required regulatory approvals to manufacture and sell Multiferon® throughout the European Union, or if Multiferon® is not widely accepted by the markets in which we manufacture and sell it, we may have to significantly curtail or cease operations and our investors may lose their entire investment.***

Our prospects for achieving profitability will depend primarily on how successful we are in executing our business plan to license, market and sell our human alpha interferon product under the brand *Multiferon*®. We expect sales of *Multiferon*® to be a significant source of income for the foreseeable future. We cannot assure you of the success of our commercialization efforts. The product is approved in Sweden for the first-line adjuvant treatment of high-risk (Stages IIB-III) malignant melanoma following dacarbazine (DTIC) after surgical removal of tumors. The product is also approved for sale in Bulgaria, Chile, Mexico, the Philippines and Sweden as a second-line treatment of any and all diseases in which patients show an initial response to recombinant alpha interferon followed by treatment failure, likely to be caused by neutralizing antibodies. The product is also approved for sale in Egypt, Hong Kong, Indonesia and South Africa as a second-line therapy for the treatment of chronic myelogenous leukemia and hairy cell leukemia. *Multiferon*® is not approved for sale in the United States or European Union countries, other than Sweden. We have not sought the approval of *Multiferon*® from the United States Food and Drug Administration or its European

## Edgar Filing: VIRAGEN INC - Form S-3

Union counterparts, except Sweden. We will focus on seeking new approvals for *Multiferon*® in the European Union for the same indications for which it is approved in Sweden. We may seek approval for other indications in the European Union in the future. In the foreseeable future, we do not expect to seek regulatory approval in the United States unless we secure licensees to fund such activities or other sources of funding, including government or private grant funding. We cannot assure you that we will be able to obtain regulatory approval of *Multiferon*® for the indications for which *Multiferon*® is approved in Sweden or for other indications in the European Union or in the United States.

---

**Table of Contents**

Our ability to generate sufficient revenues to attain profitable operations depends in part upon our ability to establish and maintain manufacturing and distribution agreements with third parties. We will not be able to significantly reduce our losses or operate profitably until we obtain the necessary approvals to manufacture and sell *Multiferon*® on a widely accepted basis throughout the European Union. The successful commercialization of *Multiferon*® will require additional marketing and promotional activities and the completion of planned clinical trials, which are dependent upon our ability to raise significant additional funding, or our ability to generate sufficient cash flow from operating activities. Investors must understand that *Multiferon*® may never receive new approvals sought from regulatory authorities, or be able to maintain current approvals over time. In addition, even if new approvals are received, we may not be able to achieve sufficient profit from the sale of *Multiferon*®, unless we successfully meet our long-term sales objectives. If we do not obtain the required approvals, or we do not achieve profitable operations from the sale of *Multiferon*®, we may be forced to significantly curtail or cease operations. In the event we cease operations, our investors will lose their entire investment.

***We may not be able to successfully develop and commercialize our antibody or anti-cancer therapeutic product candidates, which are in early stage development where there is a significant risk of failure.***

Our future growth will depend on our ability, or our licensees' ability, to successfully develop, obtain regulatory approval for and commercialize our product candidates, including VG102 and VG106.

We will have to conduct significant additional tests with respect to these product candidates, including pre-clinical studies and clinical trials, and obtain regulatory approval before commercialization may commence. We must demonstrate to the applicable regulatory authorities that each product candidate is safe and effective for their intended use. Product development is time consuming, expensive and an uncertain process. Pre-clinical studies consist of laboratory testing using chemical and animal models, and must be completed in order to submit an investigational new drug application for authorization to conduct human studies. There can be no assurance that a submission of an investigational new drug application will result in authorization to start clinical trials. Clinical testing consists of assessment of product safety and efficacy of the product candidate in humans under rigidly controlled conditions. We are currently conducting pre-clinical research studies on VG102 and VG 106. We expect to conduct additional studies in the future. It may take several years to complete the various stages of testing for each product candidate, and failure can occur at any stage. Many factors may delay our commencement and completion of clinical trials, including:

the number of patients that participate in the trial;

the length of time required to enroll suitable subjects;

the duration of patient follow-up;

the number of clinical sites included in the trial;

changes in regulatory requirements or regulatory delays or clinical holds requiring suspension or termination of the trials;

delays, suspensions or termination of clinical trials due to the institutional review board overseeing the study at a particular site;

unforeseen safety issues; and

inability to manufacture, through third party manufacturers, adequate supplies of the product candidate being tested.

## **Table of Contents**

We may suffer significant setbacks in advanced clinical trials, even after obtaining promising results from earlier studies. At any point during clinical trials, undesirable side effects could be detected. These side effects could interrupt, delay or halt clinical trials of the product candidates being tested and related product candidates and could result in regulatory authorities denying approval of such product candidates for any or all targeted uses. Also, we rely on third party consultants to conduct studies of the effects of our product candidates on animals and humans. Our reliance on these third parties may result in delays in completing, or in failure to complete, these trials if the third parties fail to perform under our agreements with them.

Based on results at any stage of product development, we may decide to repeat or redesign pre-clinical studies or clinical trials, conduct entirely new studies or discontinue development of one or more of our product candidates. In addition, our product candidates may not demonstrate sufficient safety and efficacy in pending or any future pre-clinical testing or clinical trials to obtain the requisite regulatory approvals and even if such approvals are obtained for a product candidate, it may not be accepted in the market as a viable alternative to other products already approved or pending approvals.

Additionally, the conduct of clinical trials is expensive and competition in the bio-pharmaceutical industry is intense. We have a very limited source of revenue at this time, and we will require significant additional funding to conduct the clinical trials that will be necessary in order to receive regulatory approvals. We must obtain additional funding from outside sources to conduct these trials. If we are unable to locate funding or obtain funding on reasonable terms, we may be forced to cease operations. In that case, our investors will lose their entire investment.

***If we are unable to produce safe, efficacious, proteins in egg whites of transgenic chickens in commercially viable quantities and required quality, we may be unable to recoup our research and development expenses and we may be unable to successfully market the OVA System used to manufacture these drugs.***

Our avian transgenics project, still in the research stage, is designed to enable us to produce therapeutic proteins and antibodies inside the egg whites of transgenic hens. To date, neither we nor any competitor has commercialized any therapeutic proteins or antibody therapeutic products based on avian transgenics technologies. Even if we are successful in producing the targeted commercial proteins in egg whites, we are unable to predict whether this technology will yield commercially viable quantities of products that are safe and efficacious for patients or that regulators may approve for human use. Our inability to produce commercially viable quantities of high quality protein-based drugs may require us to discontinue our avian transgenics activities.

***Success in early pre-clinical studies may not be indicative of results obtained in later trials and studies and our product candidates may not commercialize and we may not recover our investment.***

Results of our early pre-clinical studies and those of our partners using our humanized antibody products, including our VG102 project, are based on a limited number of studies and may, upon review, be revised or negated by further analysis or by later stage study results, which may prevent them from ever reaching human clinical evaluations. Historically, the results from pre-clinical studies and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in initial clinical trials, but subsequently failed to establish sufficient safety and effectiveness data to obtain necessary regulatory approvals. Data obtained from pre-clinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval.

In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

## **Table of Contents**

***We rely, and expect to rely in the foreseeable future, on third parties in various international territories to effectively market and distribute Multiferon® and our other product candidates after receipt of regulatory approval. If these third parties are unable to effectively market Multiferon®, we may be unable to achieve significant product sales.***

One of our business strategies is to license our technologies and products to third parties for marketing and distribution. For instance, we have entered into agreements with third parties in Mexico, Greece, Chile and South Africa for the distribution of *Multiferon*®. These third parties are not our employees and we do not have control over their performance. To date, we have not recognized significant revenue from these agreements, as some of these markets are relatively small and highly competitive. The majority of these agreements require that the distributor obtain the necessary regulatory approvals, which, in some cases, have not yet been obtained. Regulatory approval is a mandatory step in the marketing of a drug, but it is by no means the final challenge in marketing a bio-pharmaceutical product. In many countries, a separate process may be required for obtaining reimbursement authorization. In addition, physicians must be educated about the merits of the product over time and, in some of these territories, government and/or hospital formularies govern the acceptance for use of a new product. Therefore, we are unable to predict the timing of approvals or sales in these various countries and we have previously terminated such third party agreements due to non-performance. The failure of these third parties to sell our product or reach targeted sale amounts would negatively impact our sales growth. To the extent that we transfer technology to third parties on an exclusive basis, we will be precluded from granting other parties the opportunity to conduct successful marketing activities.

***If we are unable to establish sales and marketing capabilities or enter into additional agreements with third parties to market and sell product candidates, we may be unable to generate significant product revenue to support our continuing operations.***

We have no commercial products, other than *Multiferon*®, and, while we have entered into licensing and distribution agreements with third parties, we do not currently have our own organization for the sales, marketing and distribution of these products. If we do enter into arrangements with additional third parties to perform sales and marketing services, our net product revenues will be lower than if we directly sold and marketed our products and any revenues received under such arrangements will depend on the skills and efforts of others. If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to generate significant product revenue to support our continuing operations.

***Possible side effects from the use of Multiferon® could adversely affect potential revenues and physician/patient acceptability of our product.***

Like any medication *Multiferon*® can have side effects. The most common side effects are: fever, chills, sweats, fatigue, stiffness, joint and muscle pain, headache, loss of appetite and nausea. These acute side effects can usually be relieved by taking acetaminophen and often decrease during the course of treatment.

There can be no assurance that unexpected or unacceptable side effects will not be found in the future for this use or other potential uses of *Multiferon*® which could threaten or limit such product's usefulness.



## **Table of Contents**

***Our products may not gain market acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenue.***

Market acceptance of our products will depend on the benefits of our products in terms of safety, efficacy, convenience, ease of administration and cost effectiveness and our ability to demonstrate these benefits to physicians, payers and patients. Additionally, there can be no assurance that our products will not have unexpected or unacceptable side effects that limit the usefulness of the products. We believe that market acceptance also depends on the pricing of our products and the reimbursement policies of government and third-party payers, as well as the effectiveness of our sales and marketing activities. Physicians may not prescribe our products, and patients may determine, for any reason, that our products are not useful to them. The failure of any of our products, once approved, to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

***Some of the indications we are targeting represent smaller patient populations with currently unmet medical needs, which may not result in significant revenue.***

As we identify new indications for our approved product and initial indications for our product candidates, we tend to focus on urgent unmet medical needs. The market potential for these indications may be small and there can be no assurances that any one or multiple approvals for an indication will result in significant revenue. While competition in these indications may be less than for other indications, there can be no assurances that there will not be competition with better products and technologies and more funding to conduct necessary clinical trials than we are able to provide.

***Our potential products may not be commercially viable if we fail to obtain an adequate level of reimbursement for those products by governments, private health coverage insurers and other organizations, our revenues from these products could be less than anticipated, which could have a negative impact on our ability to achieve profitable operations.***

Sales of pharmaceutical products such as ours largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the governments or third-party payers, the market opportunity for our products will be limited. These third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved pharmaceutical products and services. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products. Such studies may require us to dedicate a significant amount of resources including funding. Our product candidates may not be considered cost-effective. Third-party payers may elect not to reimburse for our products, or enable us or our partners to sell them at profitable price. If third party payers decline or limit reimbursement for our products, our product revenue would be less than anticipated, which would negatively impact our ability to achieve profitable operations.

## **Table of Contents**

*If our competitors develop and market products faster than we do or if those products are more effective, safer or less expensive than our approved products, our commercial opportunity will be reduced or may not exist and we may be forced to suspend operations.*

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. Many of our competitors, including major pharmaceutical companies, have more experience in research, development and clinical testing of bio-pharmaceutical products. We have not yet developed a pharmaceutical product and gained regulatory approvals such that it can be widely marketed in an international competitive environment. Many of our competitors also have greater financial, marketing and human resources capabilities that we do.

Some of our competitors in the alpha interferon markets include Hoffmann-La Roche, Inc. and Schering-Plough Corporation, both of whom have received approvals for their recombinant and sustained-release alpha interferon products. These companies have been researching, developing and marketing their products and have received wide acceptance from the medical community, payers and the patient population for their products. This may make it more difficult for us to introduce our alpha interferon product and penetrate the market, in certain indications, if and when we receive the necessary regulatory approvals.

We are aware of many pharmaceutical and biotechnology companies actively engaged in research and development of antibody-based products that have commenced human clinical trials with or have successfully commercialized antibody products. Some of these companies, such as Pfizer Inc., ImClone Systems Incorporated, Johnson & Johnson, Medarex, Inc., Wyeth, Inc., Amgen Inc., Abbott Laboratories, UCB Pharma, Biogen Idec, Inc., Abgenix, Inc., Genentech, Inc., Human Genome Sciences, Inc. and Millennium Pharmaceuticals, Inc. are addressing diseases and disease indications that are being targeted by us and certain of our research partners. Additionally, there are many more antibody-based products in various stages of discovery, research and development.

Despite the receipt of regulatory approvals there can be no assurance that our products will be accepted as a treatment superior to our competitors.

Several companies are attempting to develop avian transgenic biomanufacturing systems similar to our OVA System. Some of these companies include AviGenics, Inc., Origen Biomedical, Inc. and GeneWorks, Inc., however, none have commercialized such technology to date.

In addition, technological advances made by our competitors may reduce the market potential for our products. We may not be able to keep pace with technological advances by others, either because we do not have sufficient resources or because we cannot achieve greater improvements in our technology. If we are unable to compete with our larger, more experienced competitors, we will likely cease operations or eliminate products with limited potential returns.

Our competitors may succeed in developing products that are more effective, safer and less expensive than our products or the ones we have under development or that render our approved or proposed products or technologies noncompetitive or obsolete. In addition, our competitors may achieve product commercialization before we do. If any of our competitors develop a product that is more effective, safer or more convenient for patients, or is able to obtain regulatory approval for commercialization before we do, we may not be able to achieve market acceptance for our products, which would adversely affect our ability to generate revenue and recover the substantial development costs we have incurred and will continue to incur.

**Table of Contents**

*The regulatory approval process for Multiferon® and our product candidates is lengthy, and we may not be able to obtain all of the regulatory approvals required to manufacture and commercialize Multiferon® and our product candidates, which could limit our revenue and, ultimately, could require us to cease operations.*

All pharmaceutical manufacturers are subject to local, state, federal and foreign rules and regulations, such as those of the United States Food and Drug Administration and the European Union regulatory authorities. In the United States and in many foreign jurisdictions, rigorous pre-clinical testing and clinical trials and an extensive regulatory review process must be successfully completed before a new drug can be sold. We and our collaboration partners must demonstrate to the satisfaction of the applicable regulatory authority that *Multiferon®* and our product candidates are safe and effective for their intended uses. *Multiferon®* and our product candidates may not be approved for all of the intended uses that we request, which would limit the uses for which we can promote them and adversely impact our ability to generate revenues. If the approvals we obtain are limited, we may choose to conduct costly, post-marketing follow-up studies to expand the product uses, but those studies may not produce data sufficient to permit approval for an expanded product use. We have only received regulatory approval for *Multiferon®* in Bulgaria, Chile, Mexico, Sweden, Egypt, Hong Kong, Indonesia, the Philippines and South Africa for certain indications. We have not received regulatory approval for *Multiferon®* in the United States or in the European Union, other than Sweden. We are in preparations for requesting approval of *Multiferon®* in other countries in the European Union for the same indication for which it was approved in Sweden, however, there are no assurances it will be approved. We have not received regulatory approval for any of our product candidates. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. For instance, we have initiated the process to conduct a Phase III post-marketing clinical trial with *Multiferon®* on an international basis, which is expected to cost between \$16 million to \$18 million and take six to eight years to complete. Additionally, these rules and regulations may be different in each jurisdiction that we seek regulatory approval and can involve additional and costly pre-clinical and clinical testing and data review. Despite the time, expense and resources invested by us in the approval process, we may never receive these regulatory approvals for any specific illness or range of illnesses that we are attempting to treat with our product candidates.

The time required to obtain approval from the appropriate regulatory authority is unpredictable and the type and magnitude of the testing required for regulatory approval varies depending on the regulatory authority, the product candidate and the disease or condition for which it is being developed. Regulatory agencies can delay, limit or deny approval of a product for many reasons, including:

our failure to demonstrate to the satisfaction of the regulatory authority that a product candidate is safe and effective for a particular use;

the results of clinical trials may not meet the level of statistical significance required by the regulatory authority for approval;

our inability to demonstrate that a product candidate's benefits outweigh its risks;

our inability to demonstrate that the product candidate presents an advantage over existing therapies;

the regulatory authority's disagreement with the manner in which we interpret the data from pre-clinical studies and clinical trials;

the regulatory authority's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

a change in the approval policies or regulations of the regulatory authority or a change in the laws governing the approval process.

## **Table of Contents**

Any delay or failure by us or our collaboration partners to obtain regulatory approvals for *Multiferon*<sup>®</sup> or our product candidates would adversely affect our ability to generate revenues from them and could impose significant additional costs on us. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory approval process in others. Identification of side effects or occurrence of manufacturing problems could cause subsequent withdrawal of approval. Our inability to receive and maintain regulatory approvals will limit our revenues and, ultimately, could require us to cease operations.

***Our product candidates will remain subject to ongoing regulatory requirements even if they receive marketing approval, and if we fail to comply with these requirements, we could lose these approvals, and the sale of any approved commercial products could be suspended, and fines could be imposed on us.***

Even if we receive regulatory approval to market a particular product candidate, the product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, which could reduce our revenues, increase our expenses and render the approved product candidate not commercially viable. In addition, as clinical experience with a drug expands after approval because it is typically used by a greater number and more diverse group of patients after approval than during clinical trials, side effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials or other studies. Any adverse effects observed after the approval and marketing of a product candidate could result in limitations on the use of or withdrawal of any approved product from the marketplace. Absence of long-term safety data may also limit the approved uses of our products, if any. If we fail to comply with the regulatory requirements of the applicable regulatory authority, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including:

restrictions on the product, manufacturer or manufacturing process;

warning letters;

civil or criminal penalties;

fines;

injunctions;

product seizure or detention;

import or export bans or restrictions;

voluntary or mandatory product recalls and related publicity requirements;

suspension or withdrawal of regulatory approvals;

total or partial suspension of production; and

refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

If we or our collaboration partners are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we or our collaboration partners may lose marketing approval for our products when and if any of them are approved, resulting in decreased revenue.

---

## **Table of Contents**

***If we and our third-party suppliers do not maintain high standards of manufacturing in accordance with all applicable regulations, our development and commercialization activities could suffer significant interruptions or delays and thus prevent us from realizing revenues and may cause us to significantly curtail or cease operations.***

We and our third-party suppliers on which we currently or may in the future rely, must continuously adhere to corresponding regulations. In complying with these regulations, we and our third-party suppliers must expend significant time, money and effort in the areas of design and development, testing, production, validation, inspection, record-keeping and quality control to assure that our products meet applicable specifications and other regulatory requirements. The failure to comply with these regulations could result in an enforcement action against us, including seizure of products and shutting down of production. Any of these third-party suppliers and we also may be subject to audits by the applicable regulatory authorities. If any of our third-party suppliers or we fail to comply with applicable manufacturing regulations, our ability to develop and commercialize our products could suffer significant interruptions and prevent us from realizing revenues and may cause us to significantly curtail or cease operations.

***Our reliance on foreign third party manufacturers may disrupt operations, which could materially harm our business and financial condition.***

We depend and will continue to depend upon third parties for the processing of materials to manufacture *Multiferon*® and our product candidates and for the filling, labeling and packaging of our products. Third party manufacturers may encounter difficulties involving production yields, quality control and assurance, shortage of qualified personnel, shortage of capacity, compliance with applicable regulations, production costs, and development of advanced manufacturing techniques and process controls. Also, third party manufacturers may not perform as agreed to or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our products. Any failure of third party manufacturers to deliver the required quantities of *Multiferon*® and our product candidates for clinical use on a timely basis and at commercially reasonable prices, and our failure to find replacement manufacturers could materially harm our business and financial condition.

Foreign manufacturing could expose us to risks involved with fluctuations in exchange rates of foreign currencies. In addition, reliance on international vendors exposes us to all the risks of dealing with a foreign manufacturing source. These risks include:

unexpected changes in regulatory requirements;

tariffs and other trade barriers, including import and export restrictions;

political or economic instability;

compliance with foreign laws;

transportation delays and interruptions;

difficulties in protecting intellectual property rights in foreign countries; and

currency exchange risks.

Foreign manufacturing arrangements may also limit our control, and could disrupt our operations, which, in turn, could negatively impact upon your investment in us.

The process of manufacturing antibody therapeutic products is complex. Third party manufacturing facilities must adhere to current Good Manufacturing Practice regulations, enforced through facility inspection programs. If we are unable to manufacture product candidates in

## Edgar Filing: VIRAGEN INC - Form S-3

accordance with Good Manufacturing Practices and applicable regulations, we may not be able to obtain regulatory approval for our products, which could materially harm our business and financial condition.

## **Table of Contents**

***Our operations involve hazardous materials and are subject to environmental, health and safety controls and regulations, which can be expensive to comply with and we may be liable for damages.***

As a bio-pharmaceutical company, we are subject to environmental, health and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with environmental, health and safety regulations may be substantial. Our business activities involve the controlled use of hazardous materials and we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may exceed our financial resources and could materially harm our business, financial condition and results of operations.

***If third-party contract research organizations and consultants do not perform in an acceptable and timely manner, our pre-clinical studies or clinical trials could be delayed or unsuccessful.***

We do not have the ability to conduct all aspects of our pre-clinical studies or clinical trials ourselves. We rely and will continue to rely on clinical investigators, third-party contract research organizations and consultants to perform some or all of the functions associated with pre-clinical testing or clinical trials. The failure of any of these vendors to perform in an acceptable and timely manner in the future, including in accordance with any applicable regulatory requirements, such as good clinical or laboratory practices, or pre-clinical testing or clinical trial protocols, could cause a delay or otherwise adversely affect our pre-clinical testing or clinical trials and ultimately the timely advancement of our development programs. Additionally, competition for consultants, animal colonies and human patients may be intense and we may experience delays in development projects or suspension of studies if we are unable to fund or gain access to consultants, animals or human patients.

***We conduct most of our operations in foreign countries and we anticipate marketing our products in foreign countries, which presents numerous challenges. If we are unable to efficiently manage these challenges, our revenue, cost of operations and ability to attain profitable operations could be materially adversely affected.***

There are challenges associated with international marketing activities including language and cultural barriers, variations in compliance procedures in certain countries and/or changes in regulatory requirements where our products may be marketed, performance of our distribution channels, government's willingness to promote cheaper generic versions of competing products, the general population's inability to afford private care drug products, changes in economic conditions and instability from country to country, changes in a country's political condition, trade protection measures, tariffs and other trade barriers, including import and export restrictions, and tax issues. Our future revenues, costs of operations and profit results could be materially adversely affected by any or all of these factors. It may take significant time to overcome these challenges with no assurance that a particular market will ever be effectively penetrated.



---

**Table of Contents**

***Our international operations expose us to the risk of fluctuations in currency exchange rates, which could negatively impact our revenues and anticipated sales margins.***

We conduct operations in several different countries. The balance sheet accounts of our operations in Scotland and Sweden, including intercompany accounts that are considered long-term in nature, are translated to U.S. dollars for financial reporting purposes and resulting adjustments are made to stockholders' (deficit) equity. The value of the respective local currency may strengthen or weaken against the U.S. dollar, which would impact the value of stockholders' investment in our common stock. Fluctuations in the value of the British Pound and Swedish Krona against the U.S. dollar have occurred during our history, which have resulted in unrealized foreign currency translation gains and losses, which are included in accumulated other comprehensive income and shown in the stockholders' (deficit) equity section of our consolidated balance sheet. Intercompany trading accounts, which are short-term in nature, are remeasured at current exchange rates as of the balance sheet dates and any gains or losses are recorded in other expense (income), net.

We also conduct transactions that are denominated in currencies other than the U.S. dollar, British Pound and Swedish Krona. Transactions denominated in other currencies are accounted for in the respective local currency at the time of the transaction. Upon settlement of this type of transaction, any foreign currency gain or loss results in an adjustment to income.

Our results of operations may be impacted by the fluctuating exchange rates of foreign currencies, especially the British Pound and Swedish Krona, in relation to the U.S. dollar. Most of the revenue and expense items of our foreign subsidiaries are denominated in the respective local currencies. The strengthening of these local currencies against the U.S. dollar will result in higher expenses and liabilities when translated into U.S. dollars, which would lower or possibly eliminate completely our revenues and anticipated sales margins on product sales.

We do not currently engage in hedging activities with respect to our foreign currency exposure.

***If we cannot protect our intellectual property, our ability to develop and commercialize our products could be severely limited and may cause us to terminate activities on such products and never realize a return on our investments in such products.***

Our success is dependent in part on our ability to obtain, maintain and enforce our intellectual property rights (owned and licensed) domestically and abroad. The patent position of biotechnology and pharmaceutical companies is highly uncertain, involves complex legal and factual issues and has in recent years been the subject of much litigation. The validity, enforceability and commercial value of these rights, therefore, are highly uncertain.

Fundamentally, a patent is a grant of a right to exclude others from making, using or selling an invention. However, our patents may not protect us against our competitors. The issuance of a patent is not conclusive as to its scope, validity or enforceability. The scope, validity or enforceability of our patents can be challenged in litigation. Such litigation can involve substantial costs and distraction. If the outcome of such litigation is adverse to us, third parties may be able to use our patented inventions and compete directly with us, without payment to us. Third parties may also be able to circumvent our patents by design innovations. We may not receive any additional patents based on the applications currently pending.

Our patents may not contain claims that are sufficiently broad to prevent others from practicing our technologies or developing competing products. Competitors may be able to use technologies in competing products that perform substantially the same function as our technologies but avoid infringing our patent claims. Under such "workaround" circumstances, our patents would be of little commercial value to us.

---

**Table of Contents**

Patent applications we file may not result in the issuance of a patent. Because patent applications are typically not published for several months after filing, or in some cases, not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors or collaborators can be certain that we or they were the first to make the inventions claimed in patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. Assuming the other requirements for patentability are met, in the United States, the first to invent is entitled to the patent, and outside of the United States, the first to file is entitled to the patent.

Intellectual property rights are fundamentally territorial in nature, and depend on the differing laws of separate nations and entities. Accordingly, we may not be able, alone or with our licensors or collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. The actual protection we receive from a foreign patent may vary from one country to another. Thus, any patents that we own or license from third parties may not provide commercially meaningful protection from competition.

***We rely on maintaining as trade secrets our competitively sensitive know-how and other information. Intentional or unintentional disclosure of this information could impair our competitive position.***

As to many technical aspects of our business, we have concluded that competitively sensitive information is either not patentable or that for competitive reasons it is not commercially advantageous to seek patent protection. In these circumstances, we seek to protect this know-how and other proprietary information by maintaining it in confidence as a trade secret. To maintain the confidentiality of our trade secrets, we generally enter into confidentiality agreements with our employees, consultants, collaborators, contract manufacturers and advisors upon commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. We may not obtain these agreements in all circumstances, and the agreements we have may be breached. We may not become aware of, or have adequate remedies in the event of, any such breach. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators, contract manufacturers or advisors have previous employment or consulting relationships. To the extent that our employees, consultants, collaborators, contract manufacturers or advisors use trade secrets or know-how owned by others in their work for us, disputes may arise as to the ownership of relative inventions. Also, others may independently develop substantially equivalent trade secrets, processes and know-how, and competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business. The disclosure of our trade secrets could impair our competitive position. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information.

***If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are important to our business and incur financial obligations based on our exercise of such license rights.***

In April 2005, we executed a global exclusive license with Cancer Research Technology UK for the rights to develop and commercialize an anti-CD55 antibody. This license provides to us use of intellectual property that is important to our business, and we may enter into additional agreements with other partners in the future that provide license to us of valuable technology. The license imposes, and future licenses may impose, various commercialization milestone payments and other payment obligations on us. If we fail to reach the material milestones set forth in our development plan contained in the agreement by more than six months, the licensor may have the right to terminate the license specified in the agreement, in which event we would lose valuable rights and our ability to develop our product candidates.

---

**Table of Contents**

*If third parties successfully assert that we have infringed their patents and proprietary rights, or successfully challenge the validity of our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and which could delay or prevent the development or commercialization of our product candidates and may cause us to seek a license to continue to develop or commercialize our product candidates, which could have a material adverse affect on our business.*

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. In the event that our technologies infringe or violate the patent or other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, marketing and selling of our product that utilizes such technologies. There may be patents held by others of which we are unaware that contain claims that our products or operations infringe. In addition, given the complexities and uncertainties of patent law, there may be patents of which we know that we may ultimately be held to infringe, particularly if the claims of the patent are determined to be broader than we believe them to be. For instance, United States and foreign patents have been issued to others for genetically engineered and human-derived interferons and methods and processes for producing transgenic birds. While we are not currently aware of any patent issues, this does not preclude a third party from filing a claim against us. In the event a third party claims that we infringe its patents, any of the following may occur:

we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor's patent;

a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and

we may have to redesign our product so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

Additionally, licenses may not be exclusive in which case our competitors might gain access to the same technology as to that which was licensed to us. If we failed to obtain a required license or were unable to alter the design of our product candidates to make the licenses unnecessary, we might be unable to commercialize one or more of our product candidates, which could significantly affect our ability to establish and grow our commercial business.

Many of our employees, consultants, contractors and others may use the trade secret information of others in their work for us or they may disclose our trade secret information to others. Either of these events could lead to disputes over the ownership of inventions derived from that information or expose us to potential damages or other penalties.

If any of these events occurs, our business will suffer.

## **Table of Contents**

***We may incur substantial costs as a result of litigation or other proceedings relating to patent or other intellectual property rights.***

There has been substantial litigation and other proceedings regarding patent and intellectual property rights in the bio-pharmaceutical industry. We may be forced to defend claims of infringement brought by our competitors and others, and we may institute litigation against others who we believe are infringing our intellectual property rights. In the future, we expect our license agreements may include certain provisions that could require us to defend claims against our licensed patents and could subject us to significant legal expenses in defense and enforcement activities. The outcome of intellectual property litigation is subject to substantial uncertainties and may, for example, turn on the interpretation of claim language by the court, which may not be to our advantage, or on the testimony of experts as to technical facts upon which experts may reasonably disagree. Our involvement in intellectual property litigation could result in a significant expense to us. Some of our competitors have considerable resources available to them and a strong economic incentive to undertake substantial efforts to stop or delay us from commercializing products. We, on the other hand, are a relatively small company with comparatively few resources available to us to engage in costly and protracted litigation. Moreover, regardless of the outcome, intellectual property litigation against or by us could significantly disrupt our development and commercialization efforts, divert our management's attention, quickly consume our financial resources or require us to disclose confidential information. In addition, if third parties file patent applications or issue patents claiming technology that is also claimed by us in pending applications, we may be required to participate in interference proceedings with the applicable regulatory authority, including oppositions, to determine priority of invention or patentability. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel will be diverted in pursuit of these proceedings.

***Licenses to third parties may not result in revenue to us and exclusive licenses will preclude us from seeking alternative revenue streams.***

One of our business strategies is to license our products or technologies to third parties. They, in turn, will use this license to produce and/or market our products and technologies. We cannot guarantee that these third parties will be able to successfully produce or market the products or technologies or that we will receive revenue from their efforts. To the extent that we grant exclusive licenses to third parties, we may be precluded from granting other parties the opportunity to conduct successful marketing activities.

***Our copyrightable and trademark works are assets that must be protected. If we are unable to protect these assets, our competitive position could be weakened.***

Copyright law in the U.S. protects those original works of authorship fixed in a tangible medium of expression. While our intellectual property largely resides in our portfolio of patents, trademarks, and trade secrets, our works of authorship embody certain rights and may deserve protection. To the extent we create written works such as brochures, web sites, or trade show presentations, we are publishing works of authorship that may well be presented to competitors. While copyright protection subsists in such works once they are fixed (e.g., on paper or in electronic format), the added layer of protection that comes from registration is important. Without registration of a work at the appropriate territorial copyright office, it may be difficult, if not impossible, to initiate actions against alleged infringement.

---

**Table of Contents**

*We may be exposed to product liability claims, and our product liability insurance may not be sufficient to cover all claims or continue to be available to us.*

We are exposed to the risk of product liability claims. We may be subject to claims against us even if the injury is due to the actions of others. For example, if the medical personnel that use our products on patients are not properly trained or are negligent in the use of our products, the patient may be injured through the use of our products, which may subject us to claims. The use of our product candidates in clinical trials could also expose us to product liability claims. Persons who claim to be injured from use of our products or processes, may file claims for personal injuries or other damages against us. Directives in the European Union, for example, provide for strict liability and permit compensation claims to be made within a ten year period from when the product is placed on the market, and three years from the event giving rise to the claim, thereby creating a 13 year period within which compensation claims could be asserted. Regulations in other countries and regions may differ and may expose us to incremental risks of liability. We maintain product liability insurance in the amount of \$10 million.

Generally, our clinical trials, including our melanoma trials, are conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product is used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products.

We cannot predict all of the possible harms or side effects that may result from the use of our products to cover all liabilities or defense costs we might incur. We cannot be sure that our insurance coverage will be adequate to insulate us from liabilities that may result from the use of our products. Also, in the future this type of insurance may not be available, or we may not be able to afford this form of insurance. A product liability claim or series of claims brought against us could give rise to substantial liability that could exceed our resources. Even if claims are not successful, the costs of defending such claims and potential adverse publicity could be harmful to our business.

*Our reliance on third party suppliers to supply our raw materials may disrupt operations and our ability to develop and commercialize products.*

We currently rely, and we expect to rely on third-party suppliers to supply our raw materials to produce our products and develop our product candidates. All of these suppliers are outside of the United States. Reliance on third-party suppliers exposes us to risks. These risks include:

unexpected changes in regulatory requirements;

tariffs and other trade barriers, including import and export restrictions;

political or economic instability;

compliance with foreign laws;

possible breach of the manufacturing agreement by the third party because of factors beyond our control;

the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly and inconvenient for us;

transportation delays and interruptions;

## Edgar Filing: VIRAGEN INC - Form S-3

limitations on supply availability resulting from capacity and scheduling constraints of the third party;

difficulties in protecting intellectual property rights in foreign countries; and

currency exchange risks.

## **Table of Contents**

Foreign supply arrangements may also limit our control, and could disrupt our operations, which, in turn, could negatively impact upon your investment in us. Our dependence upon others for the raw materials to produce our products and product candidates may adversely affect our business and our ability to develop our product candidates and commercialize any products that receive regulatory approval on a timely basis.

***The production of Multiferon® is highly dependent on the availability of human leukocytes, and any interruption in supply could adversely affect our ability to manufacture Multiferon®.***

We are dependent upon third party blood collection agencies to supply human leukocytes as a key raw material in the manufacture of *Multiferon®*. We currently maintain supply agreements, including, through our Swedish subsidiary, with the German Red Cross. The failure to maintain such agreements or obtain new ones could have a material adverse affect on us.

If we are unable to obtain the necessary leukocytes, we may be required to scale back our operations or stop manufacturing *Multiferon®*. The costs and availability of leukocytes are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and governmental regulations that may limit or prevent their availability.

***If we lose the services of our key management or scientific personnel, scientific collaborators or other advisors, our business and ability to attain profitable operations would suffer.***

The success of our business is highly dependent on our management as well as our senior manufacturing and scientific personnel. We also rely on our scientific collaborators and other advisors, particularly with respect to our research and development efforts. In addition, we require skilled personnel in areas such as business and clinical development. We do not maintain key-person life insurance on any of our officers, employees or consultants. In addition, although we have employment agreements with key members of management, each of our employees, subject to applicable notice requirements, may terminate his or her employment at any time. The pool of individuals with relevant experience in bio-technology is limited, and retaining and training personnel with the skills necessary to operate our business effectively is challenging, costly and time-consuming. If we lose the services of any key personnel, our business, financial condition and results of operations could be materially and adversely affected.

---

**Table of Contents**

**Risks Related to our Common Stock**

*We have received a notice of delisting from the American Stock Exchange. Absent a successful appeal from the notice, the delisting of our securities will impact on our financial statements, could accelerate the payment of outstanding indebtedness, could cause institutional investors to sell or refrain from purchasing our securities, make it more difficult to buy and sell our securities and otherwise adversely affect our financial condition and the market for our securities.*

On May 17, 2007, Viragen received a notice from the Staff of the American Stock Exchange (AMEX) indicating that Viragen no longer complies with the AMEX's continued listing standards and, accordingly, the AMEX intends to file an application with the Securities and Exchange Commission to strike Viragen's common stock, units and warrants from listing and registration on the AMEX. The bases for the Staff's notice are that

Viragen had stockholders' equity of less than \$4 million and net losses in three of its four most recent fiscal years, and stockholders' equity of less than \$6 million and net losses in its five most recent fiscal years, as a result of which Viragen is not in compliance with Sections 1003(a)(ii) and 1003(a)(iii) of the AMEX Company Guide;

Viragen has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired, that, in the AMEX's opinion, it is questionable whether Viragen can continue operations and/or meet its obligations as they mature, as a result of which Viragen is not in compliance with Section 1003(a)(iv) of the AMEX Company Guide; and

Viragen has failed to effect a reverse split of its common stock notwithstanding that its common stock has been selling at a low price per share for a substantial period of time, as a result of which Viragen is not in compliance with Section 1003(f)(v) of the AMEX Company Guide.

Since September 2005, Viragen's securities have been listed on AMEX pursuant to a temporary exception that required the Company to demonstrate compliance with AMEX's listing criteria on or before March 20, 2007. The AMEX Staff notice includes a determination that Viragen failed to regain compliance with the AMEX continued listing standards by the end of the exception period or as of the date of its determination letter.

Viragen has appealed the AMEX Staff notice by requesting a hearing before an AMEX Listing Qualifications Panel. The filing of the hearing request operates to stay delisting of the Company's securities pending the hearing panel's determination. However, there is no assurance that the AMEX hearing panel will permit the Company's securities to remain listed on the AMEX.

In the event our securities are delisted from AMEX, (a) the holder of approximately \$1.1 million of our outstanding convertible debt will have the right to accelerate payment of the amount due, plus an additional 10%, on demand, (b) approximately \$700,000 of unamortized discounts and deferred financing costs associated with the \$1.1 million of our outstanding convertible debt will be immediately recorded as interest expense and (c) our ability to raise additional financing to alleviate our cash flow difficulties will be adversely affected.



---

**Table of Contents**

In addition, in the event our securities are delisted from AMEX, we believe our securities are eligible to continue trading on the over-the-counter Bulletin Board; however, certain institutional investors have policies against investments in Bulletin Board companies and other investors may refrain from purchasing our securities if they are not listed on a national securities exchange. Also, we would lose some of our existing analyst coverage and our efforts to obtain new analyst coverage would be significantly impaired. Further, our ability to sell our equity securities and debt would be significantly limited in numerous states because the exemption we utilize to sell these securities without registration under applicable state securities laws requires that our common stock be listed on a major exchange, including AMEX. If we were required to register our equity securities or debt offerings under the securities laws of various states, no assurance will be given as to whether we would be able to obtain the necessary approvals from states' securities administrators. To the extent our securities were to be delisted from trading on AMEX, the value of our equity securities and our ability to sell equity securities and debt would be negatively impacted. The occurrence of these events could have a material adverse effect on our ability to repay our outstanding debt and other obligations and otherwise fund our operations.

Additionally, if we are delisted from AMEX, and the price of our common stock does not increase significantly, our common stock would be a low-priced security under the penny stock rules promulgated under the Securities Exchange Act of 1934, as amended. In accordance with these rules, broker-dealers participating in transactions in low-priced securities must first deliver a risk disclosure document that describes the risks associated with such stocks, the broker-dealer's duties in selling the stock, the customer's rights and remedies and certain market and other information. Furthermore, the broker-dealer must make a suitability determination approving the customer for low-priced stock transactions based on the customer's financial situation, investment experience and objectives. Broker-dealers must also disclose these restrictions in writing to the customer, obtain specific written consent from the customer, and provide monthly account statements to the customer. The effect of these restrictions may decrease the willingness of broker-dealers to make a market in our common stock, decrease liquidity of our common stock and increase transaction costs for sales and purchases of our common stock as compared to other securities. Our management is aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent abuses normally associated with low-priced securities from being established with respect to our securities.

***An effective registration statement may not be in place when an investor desires to exercise warrants obtained in our underwritten public offering completed in November 2006, thus precluding such investor from being able to exercise his, her or its warrants and causing such warrants to be practically worthless.***

No warrant obtained in our underwritten public offering completed in November 2006 held by public stockholders or issuable upon exercise of the underwriter's purchase option will be exercisable and we will not be obligated to issue shares of common stock unless at the time a holder seeks to exercise such warrant, a prospectus relating to the common stock issuable upon exercise of the warrant is current and the common stock has been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Under the terms of the warrant agreement, we have agreed to use our best efforts to meet these conditions and to maintain a current prospectus relating to the common stock issuable upon exercise of the warrants until the expiration of the warrants. However, while the shares underlying the warrants are currently covered by a current prospectus, we cannot assure you that we will be able to maintain a current prospectus related to the common stock issuable upon exercise of the warrants, and holders would be unable to exercise their warrants and we would not be required to settle any such warrant exercise. If the prospectus relating to the common stock issuable upon the exercise of the warrants is not current or if the common stock is not qualified or exempt from qualification in the jurisdictions in which the holders of the warrants reside, the warrants held by public stockholders or issuable upon exercise of the underwriter's purchase option may have no value, the market for such warrants may be limited and such warrants may expire worthless. Even if the prospectus relating to the common stock issuable upon exercise of the warrants is not current, the warrants issued to our initial security holders may be exercisable for unregistered shares of common stock.

**Table of Contents**

*If our securities are delisted from the AMEX, investors in our underwritten secondary offering completed in November 2006 may engage in resale transactions only in those states in which we registered that offering and certain other jurisdictions for which an applicable exemption from registration exists.*

Under the National Securities Markets Improvement Act of 1996, the resale of the units and, once they became separately transferable, the common stock and warrants comprising the units, are exempt from state registration requirements because the securities are listed on the AMEX. However, each state retains jurisdiction to investigate and bring enforcement actions with respect to fraud or deceit, or unlawful conduct by a broker or dealer, in connection with recapitalization, reorganization, merger or consolidation. If our securities are delisted from the AMEX, investors in our underwritten secondary offering completed in November 2006 may engage in resale transactions only in those states in which we registered that offering and certain other jurisdictions for which an applicable exemption from registration exists.

*The financings that we have consummated are, and future financings may be, dilutive to stockholders and may adversely affect the market price for our shares of common stock.*

Our success in attracting additional funding has been limited to transactions in which our equity is used as currency. Financing activities during this period often have consisted of sales of our common stock at a discount to the market price and the issuance of securities convertible into or exercisable for shares of our common stock, sometimes at a discount to prevailing market prices. In light of the availability of this type of financing, and the lack of alternative proposals, our board of directors has determined that the continued use of our equity for these purposes may be necessary if we are to sustain operations. Equity financings of the type we have been required to pursue are dilutive to our stockholders and may adversely impact the market price for our shares of common stock.

*The issuance of our shares upon the exercise or conversion of securities we have outstanding may cause significant dilution to our stockholders and may have an adverse impact on the market price of our common stock.*

As of the date of this prospectus, there were 218,660,475 shares of our common stock outstanding. The issuance of our shares upon the exercise or conversion of securities we have outstanding will increase the number of our publicly traded shares, which could depress the market price of our common stock.

The perceived risk of dilution may cause our stockholders to sell their shares, which would contribute to a downward movement in the stock price of our common stock. Moreover, the perceived risk of dilution and the resulting downward pressure on our stock price could encourage investors to engage in short sales of our common stock. By increasing the number of shares offered for sale, material amounts of short selling could further contribute to progressive price declines in our common stock.

**Table of Contents**

As of the date of this prospectus, there were 195,931,414 shares of our common stock issuable upon exercise or conversion of the following securities. This amount of issuable shares is approximately 90% of our outstanding shares of common stock as of the date of this prospectus.

Debt and equity offering warrants (exercisable at a weighted average price of \$0.24 per share through October 2011)	144,480,548
June 2004 convertible notes or related warrants issuable upon redemption of the notes (convertible/exercisable at \$0.10 per share through August 2008)	11,000,000
Underwriter's purchase option to purchase 4,020,000 units at \$0.29 per unit through October 2011. Each unit consists of one share of common stock and one warrant to purchase one share of common stock exercisable at \$0.39 per share.	8,040,000
Officers, employees, and directors options (exercisable at a weighted average price of \$0.63 per share through March 2014)	1,936,200
September 2005 convertible debentures (convertible at \$0.10 per share through September 2008)	468,750
Consultant warrants (exercisable at a weighted average price of \$3.05 per share through February 2009)	5,000
10% Series A Cumulative Convertible Preferred Stock	916
Series K 18% Cumulative Convertible Preferred Stock	30,000,000
	195,931,414

*The conversion and exercise prices of outstanding securities may be reduced, and the number of shares that we issue on conversion or exercise may be increased, in the event that we issue common stock or securities convertible into common stock in the future for consideration that is less than the conversion or exercise prices of the outstanding securities.*

The terms of certain of our outstanding convertible debt and warrants provide for a downward adjustment in the conversion and exercise prices in the event that we subsequently issue shares of our common stock, or securities convertible into or exercisable for our common stock, for consideration that is less than the conversion or exercise prices of the previously issued securities. Any reduction of the conversion or exercise prices of outstanding securities as a result of these adjustment provisions will require that we issue a greater number of shares upon conversion of convertible debt or exercise of warrants than we would have issued in the absence of these provisions. Any additional shares that we issue as a result of the adjustment provisions of these securities will cause further dilution to our existing stockholders.

*We are engaged in the bio-pharmaceutical industry; as a result, the market for our shares of common stock may be subject to extreme volatility.*

The market for securities of bio-pharmaceutical companies, including ours, has historically been more volatile than the market for stocks in general. As a result, the price and volume of our shares may be subject to wide fluctuations in response to factors, some of which are beyond our control, including, without limitation:

quarter-to-quarter variations in our operating results;

our announcement of material events;

price fluctuations in sympathy to others engaged in our industry; and

the effects of media coverage of our business.

## **Table of Contents**

Price and volume volatility may prevent you from selling your shares of our common stock when you desire to do so, and the inability to sell your shares in a rapidly declining market may substantially increase your risk of loss. Our shares have traded between a high of \$1.03 and a low of \$0.02 since January 1, 2005. The daily trading volume of our shares since January 1, 2005 has been volatile ranging between 23,500 and approximately 247.4 million shares in a single day.

***We may not have sufficient surplus to redeem our Series K 18% Cumulative Convertible Preferred Stock, and we may not have sufficient surplus or net profits to be able to pay dividends on such preferred stock.***

As a Delaware corporation, we may not declare and pay dividends on our capital if the amount paid exceeds an amount equal to the surplus which represents the excess of our net assets over paid-in-capital or, if there is no surplus, our net profits for the current and/or immediately preceding fiscal year. Also, under applicable Delaware case law, dividends may not be paid on our Series K 18% Cumulative Convertible Preferred Stock if we become insolvent or the payment of dividend will render us insolvent. In addition, to the extent we pay dividends and we are deemed to be insolvent or inadequately capitalized, a bankruptcy court could direct the return of any dividends.

Our ability to redeem the Series K 18% Cumulative Convertible Preferred Stock will generally depend upon the amount of surplus that each corporation possesses. Additionally, a corporation may redeem shares of its preferred stock by applying some or all of the capital represented by the shares being redeemed to the redemption so long as the assets of the corporation remaining after such reduction is sufficient to pay any debts of the corporation for which payment has not otherwise been provided.

***We do not expect to pay dividends on our common stock in the foreseeable future.***

We have never paid cash dividends on our common stock. We do not expect to pay cash dividends on our common stock any time in the foreseeable future. Our outstanding convertible debt prohibits us from directly or indirectly paying cash dividends or distributions on our common stock. Provisions of our outstanding convertible debt and 10% Series A Cumulative Convertible Preferred Stock also prohibit the payment of dividends on our common stock, subject to certain exceptions. Additionally, any future payment of dividends will directly depend upon our future earnings, capital requirements, financial requirements and other factors that our board of directors will consider. For the foreseeable future, we will use earnings from operations, if any, to finance our growth, and we will not pay dividends to our common stockholders. You should not rely on an investment in our common stock if you require dividend income. The only return on your investment in our common stock, if any, would most likely come from any appreciation of our common stock.

As a Delaware corporation, we may not declare and pay dividends on our capital if the amount paid exceeds an amount equal to the surplus which represents the excess of our net assets over paid-in-capital or, if there is no surplus, our net profits for the current and/or immediately preceding fiscal year. To the extent we pay dividends and we are deemed to be insolvent or inadequately capitalized, a bankruptcy court could direct the return of any dividends.

**Table of Contents**

*We could use preferred stock to fund operations or resist takeovers, and the issuance of preferred stock may cause additional dilution.*

Our certificate of incorporation authorizes the issuance of up to 1,000,000 shares of preferred stock, of which 2,150 shares of 10% Series A Cumulative Convertible Preferred Stock and 30,000 shares of Series K 18% Cumulative Convertible Preferred Stock are issued and outstanding as of the date of this report. Our certificate of incorporation gives our board of directors the authority to issue preferred stock without the approval of our stockholders. We may issue additional shares of preferred stock to raise money to finance our operations. We may authorize the issuance of the preferred stock in one or more series. In addition, we may set the terms of preferred stock, including:

dividend and liquidation preferences;

voting rights;

conversion privileges;

redemption terms; and

other privileges and rights of the shares of each authorized series.

The issuance of large blocks of preferred stock could possibly have a dilutive effect to our existing stockholders. It can also negatively impact our existing stockholders' liquidation preferences. In addition, while we include preferred stock in our capitalization to improve our financial flexibility, we could possibly issue our preferred stock to friendly third parties to preserve control by present management. This could occur if we become subject to a hostile takeover that could ultimately benefit us and our stockholders.

---

**Table of Contents**

**USE OF PROCEEDS**

We will not receive any of the proceeds from the sale of shares by the selling security holders. To the extent that warrants, the shares issuable upon exercise of which are covered by this prospectus, are exercised on other than a cashless basis, we could receive gross proceeds of up to approximately \$1.5 million. We intend to use any net proceeds we receive upon the exercise of warrants for general corporate purposes, including:

    funding of the commercialization of our *Multiferon*<sup>®</sup> product;

    funding collaborative research projects for the development of new technologies;

    financing capital expenditures;

    payment of financing obligations; and

    working capital.

Pending use of the net proceeds for any of these purposes, we may invest the net proceeds in short-term, investment grade, interest-bearing securities.

**SELLING SECURITY HOLDERS**

**Series K 18% Cumulative Convertible Preferred Stock and Warrants**

On April 12, 2007, we received gross proceeds of \$3 million in connection with the sale of units consisting in the aggregate of 30,000 shares of Series K 18% Cumulative Convertible Preferred Stock and warrants to purchase 15,000,000 shares of our common stock. The stated value of the series K preferred stock is \$100 per share, and the series K preferred stock is entitled to receive a cumulative dividend of 18% per annum when and if declared by our board of directors. Dividends are payable in cash, quarterly in arrears, commencing July 11, 2007, or upon redemption in accordance with the terms of the series K preferred stock.

The series K preferred stock is convertible into shares of our common stock, at the option of the holder, together with accrued and unpaid dividends, at a conversion price or rate of \$0.10 per share (an aggregate of 30,000,000 shares of our common stock). The holder also has the option, at such time as we complete a subsequent debt and/or equity financing resulting in gross proceeds of \$6,000,000 or more, to require us to redeem all or a portion of the series K preferred stock and any accrued and unpaid dividends, rounded up to the quarter-end of the quarter of redemption, plus, an amount equal to two additional quarters' dividends. In addition, we have the right, on notice to the holder, to redeem the series K preferred stock in its entirety, at the stated value, including any accrued but unpaid dividends, rounded up to the quarter-end of the quarter of redemption, plus, an amount equal to two additional quarters' dividends (a) at anytime after the third anniversary of the initial issuance of the series K preferred stock or (b) if our common shares trade at a volume weighted average price of \$0.25 or higher for a period of 15 consecutive trading days. The holder may convert its series K preferred stock at any time prior to the date fixed for redemption.

Each warrant entitles the holder to purchase one share of common stock at an exercise price of \$0.10 per share at any time prior to April 11, 2012. The warrants, which are not redeemable, also include a cashless exercise provision that permits the holder to pay the exercise price by surrendering a number of warrants having a fair market value equal to the exercise price of the warrants being surrendered.

## **Table of Contents**

We are obligated to file a registration statement to permit the resale of the common shares underlying the series K preferred stock and warrants on or prior to May 26, 2007, and to use our reasonable best efforts to cause the registration statement to be declared effective within 90 days of the filing date. The registration statement, of which this prospectus forms a part, has been filed to satisfy our registration obligation. We are obligated to pay liquidated damages to the holder if these requirements are not met or if the registration statement does not remain effective to permit the holder to publicly resell the shares issuable upon conversion of the series K preferred stock and/or exercise the warrants (unless such registration is not required).

The net proceeds from the offering are being used by us to continue funding the manufacturing, licensing, and regulatory programs for *Multiferon*®, to support our drug candidate research and development plans, payment of financing obligations and for working capital purposes.

Telkin Services & Trading ApS introduced us to the investor and received a cash finder's fee of \$90,000. The sale of the units was exempt from registration by reason of Section 4(2) of the Securities Act of 1933, as amended, Regulation S under the Securities Act, and the rules and regulations thereunder, as a transaction by an issuer not involving a public offering.

Resale of the 30,000,000 shares of our common stock issuable upon conversion of the series K preferred stock and 15,000,000 shares of our common stock issuable upon exercise of the related warrants are covered by this prospectus.

## **Ownership Table**

The following table sets forth:

the name of the selling security holder;

the amount of common stock owned beneficially by the selling security holder;

the number of shares being offered by the selling security holder pursuant to this prospectus;

the number of shares to be owned by the selling security holder following sale of the shares covered by this prospectus; and

the percentage of our common stock to be owned by the selling security holder following sale of the shares covered by this prospectus (based on 218,660,475 shares of common stock of Viragen outstanding as of the date of this prospectus), as adjusted to give effect to the issuance of shares upon the exercise of the selling security holder's warrants, but no other person's warrants or common stock equivalents.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to outstanding voting securities, as well as any voting securities which the person has the right to acquire within 60 days, through the conversion or exercise of any security or other right. The information as to the number of shares of our common stock owned by each selling security holder is based upon our books and records and the information provided by our transfer agent.

**Table of Contents**

We may amend or supplement this prospectus, from time to time, to update the disclosure set forth in the table. Because the selling security holders identified in the table may sell some or all of the shares owned by them which are included in this prospectus, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, no estimate can be given as to the number of shares available for resale hereby that will be held by the selling security holders upon termination of this offering. We have, therefore, assumed for the purposes of the following table, that the selling security holders will sell all of the shares owned beneficially by them, which are covered by this prospectus, but will not sell any other shares of our common stock that they presently own.

<b>Name of Selling Security Holder</b>	<b>Number of Shares Owned</b>	<b>Number of Shares to be Offered</b>	<b>Number of Shares Owned After Offering</b>	<b>Percent After Offering</b>
RAB Special Situations (Master) Fund Limited (1)	45,000,000	45,000,000		

- (1) Consists of 30,000,000 shares of common stock issuable upon conversion of 30,000 shares of Series K 18% Cumulative Convertible Preferred Stock and the balance consists of shares issuable upon exercise of common stock purchase warrants issued in connection with the Series K 18% Cumulative Convertible Preferred Stock. The persons making investment and voting decisions on behalf of the selling security holder are Jake Leavesley and Fraser McGee, whose addresses are 1 Adam Street, London, United Kingdom, WC2N 6LE. The selling security holder has not held any positions or offices or had material relationships with us or any of our affiliates within the past three years other than as a result of the ownership of our securities.



**Table of Contents**

**PLAN OF DISTRIBUTION**

The selling security holder and any of its pledgees, assignees and successors-in-interest may, from time to time, sell any or all of the shares covered by this prospectus on the AMEX or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling security holder may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

broker-dealers may agree with the selling security holders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or

any other method permitted pursuant to applicable law.

A selling security holder may also sell shares under Rule 144 under the Securities Act of 1933, as amended, if available, rather than under this prospectus.

Broker-dealers engaged by a selling security holder may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from a selling security holder (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440.

In connection with the sale of the shares covered by this prospectus or interests therein, a selling security holder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of Viragen common stock in the course of hedging the positions they assume. A selling security holder may also sell shares short and deliver these securities to close out their short positions, or loan or pledge the shares to broker-dealers that in turn may sell these securities. A selling security holder may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other

## Edgar Filing: VIRAGEN INC - Form S-3

financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling security holder and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling security holder has informed Viragen that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the shares.

**Table of Contents**

Viragen is required to pay the fees and expenses incident to the registration of the shares covered by this prospectus. Viragen has agreed to indemnify the selling security holder against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

To the extent that a selling security holder is deemed to be an underwriter within the meaning of the Securities Act, it may be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. The selling security holder has advised us that it has not entered into any written or oral agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling security holder.

We have agreed to keep this prospectus effective for a period of two years. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the shares for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling security holders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares covered by this prospectus by a selling security holder or any other person. We will make copies of this prospectus available to the selling security holder and have informed it of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

---

**Table of Contents**

**DESCRIPTION OF SECURITIES**

Viragen is currently authorized to issue up to 500,000,000 shares of common stock, par value \$.01 per share and 1,000,000 shares of preferred stock, par value \$1.00 per share. As of the date of this prospectus, there are 218,660,475 shares of common stock, 2,150 shares of 10% Series A Cumulative Convertible Preferred Stock and 30,000 shares of Series K 18% Cumulative Convertible Preferred Stock outstanding.

**Common Stock**

Subject to the dividend rights of preferred stockholders, common stockholders share dividends on a proportionate basis, as may be declared by the board of directors. Upon liquidation, dissolution or winding up of Viragen, after payment to creditors and holders of our outstanding preferred stock, Viragen's remaining assets, if any, will be divided proportionately on a per share basis among the holders of our common stock.

Each share of our common stock has one vote. Holders of our common stock do not have cumulative voting rights. This means that the holders of a plurality of the shares voting for the election of directors can elect all of the directors. In that event, the holders of the remaining shares will not be able to elect any directors. Viragen's By-Laws provide that a majority of the outstanding shares of our common stock constitute a quorum to transact business at a stockholders' meeting. Our common stock has no preemptive, subscription or conversion rights, and our common stock is not redeemable.

**Preferred Stock**

Viragen is authorized to issue a total of 1,000,000 shares of preferred stock, par value \$1.00 per share. Viragen's board of directors may issue preferred stock by resolutions, without any action of the stockholders. These resolutions may authorize issuance of preferred stock in one or more series. In addition, the board of directors may fix and determine all privileges and rights of the authorized preferred stock series including:

dividend and liquidation preferences;

voting rights;

conversion privileges; and

redemption terms.

Viragen includes preferred stock in its capitalization to improve its financial flexibility. However, Viragen could use preferred stock to preserve control by present management, in the event of a potential hostile takeover of Viragen. In addition, the issuance of large blocks of preferred stock could have a dilutive effect to existing holders of Viragen's common stock.

**Series A Preferred Stock**

Viragen established the 10% Series A Cumulative Convertible Preferred Stock in November 1986. Viragen is authorized to issue 375,000 shares of series A preferred stock. Each share of series A preferred stock is immediately convertible, at the option of the holder, into .426 shares of Viragen's common stock. Dividends on the series A preferred stock are cumulative and have priority over dividends, if any, paid on Viragen's common stock. These dividends are payable in either cash or common stock, at Viragen's option.

---

**Table of Contents**

The series A preferred stock has voting rights only if dividends are in arrears for five annual dividends. In such event, owners of series A preferred stock have the right to elect two directors. Voting rights terminate upon payment of the cumulative dividends. Viragen may redeem the series A preferred stock at any time after expiration of ten consecutive business days during which the bid or last sale price for our common stock is \$60.00 per share or higher. There is no mandatory redemption or sinking fund obligation for the series A preferred stock.

Owners of the series A preferred stock are entitled to receive \$10.00 per share, plus accrued and unpaid dividends, upon liquidation, dissolution or winding up of Viragen. As of March 31, 2007, the aggregate amount of dividends in arrears on the series A preferred stock was approximately \$1,000. This obligation must be satisfied before any distribution or payment is made to holders of the common stock or other stock of Viragen junior to the series A preferred stock.

**Series K Preferred Stock**

Viragen established the Series K 18% Cumulative Convertible Preferred Stock in April 2007. The stated value of the series K preferred stock is \$100 per share, and the series K preferred stock is entitled receive a cumulative dividend of 18% per annum when and if declared by our board of directors. Dividends are is payable in cash, quarterly in arrears, commencing July 11, 2007, or upon redemption in accordance with the terms of the series K preferred stock.

The series K preferred stock is convertible into shares of our common stock, at the option of the holder, together with accrued and unpaid dividends, at a conversion price or rate of \$0.10 per share (an aggregate of 30,000,000 shares of our common stock). The holder also has the option, at such time as we complete a subsequent debt and/or equity financing resulting in gross proceeds of \$6,000,000 or more, to require us to redeem all or a portion of the series K preferred stock and any accrued and unpaid dividends, rounded up to the quarter-end of the quarter of redemption, plus, an amount equal to two additional quarters dividends. In addition, we have the right, on notice to the holder, to redeem the series K preferred stock in its entirety, at the stated value, including any accrued but unpaid dividends, rounded up to the quarter-end of the quarter of redemption, plus, an amount equal to two additional quarters dividends (a) at anytime after the third anniversary of the initial issuance of the series K preferred stock or (b) if our common shares trades at a volume weighted average price of \$0.25 or higher for a period of 15 consecutive trading days. The holder may convert its series K preferred stock at any time prior to the date fixed for redemption.

The series K preferred stock has no voting rights, except if Viragen should amend its certificate of incorporation and such amendment would: (a) change the relative seniority rights of the owners of the series K preferred stock as to the payment of dividends in relation to the holders of any other capital stock of Viragen, or create any other class or series of capital stock entitled to seniority as to the payment of dividends in relation to the owners of the series K preferred stock; (b) reduce the amount payable to the owners of the series K preferred stock upon the voluntary or involuntary liquidation, dissolution or winding up of Viragen, or change the relative seniority of the liquidation preferences of the owners of the series K preferred stock to the rights upon liquidation of the holders of other capital stock of Viragen, or change the dividend rights of the owners of the series K preferred stock; (c) cancel or modify the conversion rights of the owners of the series K preferred stock; or (d) cancel or modify the rights of the owners of the series K preferred stock.

Owners of the series K preferred stock, subject to the rights of the series A preferred stock owners, are entitled to receive \$100.00 per share, plus accrued and unpaid dividends, upon liquidation, dissolution or winding up of Viragen. This obligation must be satisfied before any distribution or payment is made to holders of the common stock or other stock of Viragen junior to the series K preferred stock.

**Table of Contents**

**Transfer Agent**

The transfer agent for the shares of our common stock is Mellon Investor Services LLC, Newport Office Center VII, 480 Washington Boulevard, Jersey City, New Jersey 07310.

**LEGAL MATTERS**

Schneider Weinberger & Beilly LLP will review the validity of the issuance of the shares of common stock, the resale of which is covered by this prospectus. Schneider Weinberger & Beilly LLP is located at 2200 Corporate Blvd., N.W., Suite 210, Boca Raton, Florida 33431.

**EXPERTS**

The consolidated financial statements of Viragen, Inc. appearing in Viragen, Inc.'s Annual Report (Form 10-K) for the year ended June 30, 2006 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note A to the consolidated financial statements) and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

**Table of Contents**

Viragen, Inc.

Prospectus

\_\_\_\_\_, 2007

---

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.**

Other expenses in connection with the registration of the common stock hereunder are substantially as follows (all expenses other than the SEC registration fee are estimates):

<b>Item</b>	<b>Company Expense</b>
SEC registration fee	\$ 138
Printing and engraving expenses	2,000
Legal fees and expenses	7,000
Accounting fees and expenses	15,000
Miscellaneous	862
<b>Total</b>	<b>\$ 25,000</b>

II-1



**Table of Contents**

**ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.**

Section 145 of the General Corporation Law of Delaware allows a corporation to indemnify any person who was or is, or is threatened to be made a party to any threatened, pending, or completed suit or proceeding. This applies whether the matter is civil, criminal, administrative or investigative because he or she is or was a director, officer, employee or agent of the corporation.

A corporation may indemnify against expenses, including attorney's fees, and, except for an action by or in the name of the corporation, against judgments, fines and amounts paid in settlement as part of this suit or proceeding. This applies only if the person indemnified acted in good faith and in a manner he or she reasonably believed to be in the best interest of the corporation. In addition, with respect to any criminal action or proceeding, the person had no reasonable cause to believe his or her conduct was unlawful.

In the case of an action by or in the name of the corporation, no indemnification of expenses may be made for any claim, as to which the person has been found to be liable to the corporation. The exception is if the court in which this action was brought determines that the person is reasonably entitled to indemnity for expenses.

Section 145 of the General Corporation Law of Delaware further provides that if a director, officer, employee or agent of the corporation has been successful in the defense of any suit, claim or proceeding described above, he or she will be indemnified for expenses, including attorney's fees, actually and reasonably incurred by him or her.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling Viragen pursuant to the foregoing provisions, Viragen has been informed that in the opinion of the Securities and Exchange Commission, indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against these liabilities, other than the payment by Viragen in the successful defense of any action, suit or proceeding, is asserted, Viragen will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether indemnification by it is against public policy. Viragen will be governed by the final adjudication of this issue.

**Table of Contents**

**ITEM 16. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of document</b>
4.1	Certificate to set forth Designations, Preferences, and Rights of Series K 18% Cumulative Convertible Preferred Stock, \$1.00 par value per share (incorporated by reference to Exhibit 4.1 of Viragen, Inc. s Form 8-K filed with the Securities and Exchange Commission on April 17, 2007)
5.1	Opinion and Consent of Schneider Weinberger & Beilly LLP (includes Exhibit 23.2)*
10.1	Subscription Agreement relating to the sale of Series K 18% Cumulative Convertible Preferred Stock (incorporated by reference to Exhibit 10.1 of Viragen, Inc. s Form 8-K filed with the Securities and Exchange Commission on April 17, 2007)
10.2	Common Stock Purchase Warrant issued to purchaser of Series K 18% Cumulative Convertible Preferred Stock, \$1.00 par value per share (incorporated by reference to Exhibit 10.2 of Viragen, Inc. s Form 8-K filed with the Securities and Exchange Commission on April 17, 2007)
23.1	Consent of Independent Registered Public Accounting Firm*
23.2	Consent of Schneider Weinberger & Beilly LLP (included as part of Exhibit 5.1)*

---

\* Filed herewith

**Table of Contents**

**ITEM 17. UNDERTAKINGS**

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total value of securities would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) (§230.424(b) of this chapter) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that paragraphs (1)(i) and (1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

**Table of Contents**

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated; or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

The undersigned registrant hereby undertakes that, for the purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offering therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Plantation, State of Florida, on May 22, 2007.

**VIRAGEN, INC.**

By: /s/ Charles A. Rice  
Charles A. Rice

President and Principal Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<b>SIGNATURE</b>	<b>TITLE</b>	<b>DATE</b>
/s/ Carl N. Singer Carl N. Singer	Chairman of the Board of Directors	May 23, 2007
/s/ Charles A. Rice Charles A. Rice	President, Principal Executive Officer and Director	May 22, 2007
/s/ Dennis W. Healey Dennis W. Healey	Executive Vice President, Treasurer, Principal Financial Officer and Secretary	May 24, 2007
/s/ Nicholas M. Burke Nicholas M. Burke	Vice President, Controller and Principal Accounting Officer	May 24, 2007
/s/ Randolph A. Pohlman Randolph A. Pohlman	Director	May 23, 2007
/s/ Robert C. Salisbury Robert C. Salisbury	Director	May 22, 2007
/s/ Charles J. Simons Charles J. Simons	Director	May 23, 2007
Nancy A. Speck	Director	
/s/ C. Richard Stafford	Director	May 23, 2007

C. Richard Stafford

II-6

**Table of Contents**

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description of document</b>
5.1	Opinion and Consent of Schneider Weinberger & Beilly LLP (includes Exhibit 23.2)
23.1	Consent of Independent Registered Public Accounting Firm
23.2	Consent of Schneider Weinberger & Beilly LLP (included in Exhibit 5.1)