

VIRAGEN INC
Form S-1/A
October 06, 2006
[Table of Contents](#)

As Filed With the Securities and Exchange Commission on October 6, 2006

Registration No. 333-136144

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
PRE-EFFECTIVE AMENDMENT NO. 2 TO
FORM S-1
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)

2836

(Primary Standard Industrial Classification Code Number)

59-2101668

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

865 S.W. 78th Avenue, Suite 100

Plantation, Florida 33324

(954) 233-8746

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Edgar Filing: VIRAGEN INC - Form S-1/A

Dennis W. Healey

Executive Vice President and Chief Financial Officer

Viragen, Inc.

865 S.W. 78th Avenue, Suite 100

Plantation, Florida 33324

Telephone: (954) 233-8746

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copies to:

**Steven I. Weinberger, Esq.
Schneider Weinberger & Beilly LLP
2200 Corporate Blvd., N.W., Suite 210
Boca Raton, Florida 33431
Telephone: (561) 362-9595
Facsimile: (561) 362-9612**

**Jane K. Storero, Esq.
Blank Rome LLP
One Logan Square
18th & Cherry Streets
Philadelphia, Pennsylvania 19103
Telephone: (215) 569-5488
Facsimile: (215) 832-5488**

As soon as possible following the effective date of the registration statement

(Approximate Date of Commencement of Proposed Sale to the Public)

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, please check the following box. ☒ x

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 post-effective amendment filed pursuant to Rule 462(d) 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. "

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

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion Dated October 6, 2006

Preliminary Prospectus

67,000,000 Units

This prospectus covers our offering of 67,000,000 units, each unit consisting of one share of common stock and one common stock purchase warrant. Each warrant permits the holder to purchase one share of common stock at an exercise price of \$ per share. The warrants will become exercisable on the date of separation from the unit which will be , 2007 or earlier if so determined by the underwriter and will expire on , 2011. The estimated public offering price of a unit ranges from \$ to \$ per unit.

The units will begin trading on or promptly after the date of this prospectus. Each of the common stock and warrants will trade separately on a date at least six months after the date of this prospectus unless the underwriter determines that an earlier date is acceptable, based on their assessment of the relative strengths of the securities markets and our industry in general, and the trading pattern of, and demand for, our securities in particular. For more information see Description of Securities Units.

We have granted the underwriter a 45-day option to purchase up to 10,050,000 units solely to cover over-allotments, if any. We have also agreed to sell to the underwriter, for \$100, an option to purchase up to 5,360,000 units at \$ per unit, identical to those offered by this prospectus except that each of the warrants underlying such units entitles the holder to purchase one share of our common stock at \$. The purchase option and its underlying securities have been registered under the registration statement of which this prospectus forms a part.

There is presently no public market for our units. We have applied for listing of the units on the American Stock Exchange under the expected symbol VRA.U . Once the securities comprising the units begin separate trading, we anticipate the warrants will be listed on the American Stock Exchange under the symbol VRA.WS . Our common stock is listed on the American Stock Exchange under the symbol VRA . On September 29, 2006, the last reported sale price for our common stock was \$0.32 per share. We cannot assure you that our securities will continue to be listed on the American Stock Exchange.

This investment involves a high degree of risk. You should purchase these securities only if you can afford a complete loss of your investment. See Risk Factors beginning at page 8.

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.

	Per Unit	Total
Public Offering Price (1)		
Underwriting Discount		
Proceeds to us before expenses (2)		

- (1) Does not give effect to the sale of up to 10,050,000 additional units in the event an over-allotment option granted to the underwriter is exercised.
- (2) Does not include the payment to the underwriter of a non-accountable expense allowance equal to 2% of the gross proceeds from the sale of the units and other fees paid on behalf of the underwriter. The non-accountable expense allowance will not be paid on units issuable in

the event the over-allotment option is exercised.

We are offering the units for sale on a firm commitment basis. The underwriter expects to deliver the units to investors in this offering on or about , 2006.

DAWSON JAMES SECURITIES, INC.

The date of this prospectus is , 2006.

Table of Contents

PROSPECTUS SUMMARY

Because this is a summary, it does not contain all the information about us that may be important to you and that you should consider in making your investment decision. To understand this offering fully, you should read this summary together with the additional detailed information included elsewhere in this prospectus, or incorporated by reference into this prospectus, including the financial statements and related notes. You should carefully consider, among other things, the matters discussed in Risk Factors.

Our Company

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*[®] (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; VG101, a humanized monoclonal antibody that binds selectively to an antigen over-expressed on Stage IV malignant melanoma tumors; and VG102, a highly novel humanized monoclonal antibody that binds selectively to an antigen that is over-expressed on nearly all solid tumors. 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*[®] 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 a licensee to effectively market the product. We continue to seek to expand the approved indications for *Multiferon*[®] to include certain viral and infectious diseases, and anti-viral evaluation studies are ongoing with several prestigious research organizations including the U.S. Army Medical Research Institute of Infectious Diseases. Our VG101 and VG102 antibodies are nearing development stages where we will be seeking a third party Good Manufacturing Practices, or GMP, manufacturer of both products in order to conduct final pre-clinical studies and schedule regulatory meetings, leading up to the filing of an investigational new drug application, or IND. We are continuing to progress the OVA System to advanced development stages that demonstrate the economical viability of the platform and the quality inherent in the proteins expressed in this system.

We are an international company, with our state-of-the-art *Multiferon*[®] 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. At June 30, 2006, we had cash on hand of approximately \$443,000, working capital of approximately \$229,000 and an accumulated deficit since organization of approximately \$166.2 million. These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders' (deficit) 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 that may be necessary in the event we are unable to continue as a going concern. We believe the net proceeds from this offering, together with results of operations and licensing fees, will be sufficient to fund our operations through our fiscal year ending June 30,

Table of Contents

2007. In the event that we raise fewer net proceeds than anticipated and 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.

As more fully described elsewhere in this prospectus, we received deficiency letters from the American Stock Exchange, or AMEX, advising us that we did not meet AMEX's continued listing standards. Specifically, we have not met AMEX's combined minimum stockholders' equity and net losses requirements since June 30, 2005. We submitted a plan to AMEX to regain compliance with AMEX's continued listing standards, which was accepted by AMEX. AMEX has granted us a conditional extension of time until March 20, 2007 to regain compliance with AMEX's continued listing standards. We are subject to periodic review by AMEX during the extension period and if we fail to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the extension period, our shares of common stock will be delisted from AMEX, and if approved for listing, our units and common stock purchase warrants will be delisted from AMEX. In addition, our outstanding convertible debt contains a provision that in the event our common stock is no longer traded on the AMEX, New York Stock Exchange or NASDAQ, the debt holders have the right to request repayment of their investment with related accrued interest. Given our current financial position and our failure to meet the AMEX continued listing requirements, if our common stock were delisted from AMEX, we would be unable to repay these amounts and would be in default of these agreements.

Our Product, Product Candidates and Technology

Our product, product candidates and technology portfolio includes:

Multiferon[®], a leukocyte-derived multi-subtype interferon alpha, is marketed for the treatment of a number of viral diseases and cancer indications. On February 17, 2006, we were notified that the Swedish Medical Products Agency approved *Multiferon*[®] for the first-line adjuvant treatment of high-risk (Stages IIB-III) malignant melanoma following dacarbazine, or DTIC, after surgical removal of tumors. We are currently seeking approval from the Swedish Medical Products Agency for the pre-filled syringe presentation of *Multiferon*[®] for this indication. This malignant melanoma indication will be our primary focus in seeking broader approvals throughout the European Union for the pre-filled syringe presentation of *Multiferon*[®]. Working with the Swedish authorities and external regulatory consultants, we are planning for an application for broad European registration for *Multiferon*[®] using the mutual recognition procedure, or MRP. This process is being planned and documentation assembled to support registration filing early in 2007, with the anticipation of MRP approval toward mid-2007. In addition to Sweden, *Multiferon*[®] is approved for sale in Bulgaria, Chile, Mexico, the Philippines, Egypt, Hong Kong, Indonesia and South Africa for different indications. We are also seeking regulatory approval in Costa Rica and South Korea for the same indications for which *Multiferon*[®] is approved in Sweden. There can be no assurance that we will receive regulatory approvals in the countries in which we seek approval and for the indications which we seek approval and there can be no assurance that we will realize sales in these countries.

We have agreed to initiate a Phase III post-marketing clinical trial for malignant melanoma which is expected to take from six to eight years with an approximate cost of \$16 million to \$18 million. We anticipate approximately 1,000 patients to be enrolled in this new trial possibly in as many as 20 different countries around the world, excluding the United States. We plan to initiate enrollment in this trial in early 2007.

VG101 is an antibody to the GD3 antigen, which is over-expressed on malignant melanoma tumors, thereby preventing the body's natural immune system from stopping cancer cell growth and proliferation. Pre-clinical research studies continue under a collaborative research agreement with Sloan-Kettering Institute. The agreement provides that the rights in work product created under the agreement including research results, data, and records will be owned by the party that generated them.

Table of Contents

and that if work product is generated jointly, it will be jointly owned by us and Sloan-Kettering Institute. This agreement will expire in February 2007 unless extended or unless we exercise our option for an exclusive license agreement. Although we have entered into discussions and negotiations with the Sloan-Kettering Institute to license the anti-GD3 antibody, it is not known if or when a license agreement will be executed.

VG102 is an antibody to the CD55 antigen, which is over-expressed on nearly all solid cancerous tumors and which plays a role in preventing the body's natural immune system from killing cancer cells. Pre-clinical research studies continue under a worldwide exclusive license agreement with Cancer Research Technology (UK). This agreement expires on the expiration of a licensed patent, which differs from country to country and typically provides protection for at least 10 years after a product is placed on market.

The OVA System (Avian Transgenics), is a technology whereby we intend to develop and use transgenic chickens to produce therapeutic proteins and antibodies for human use in the whites of eggs. This project is in the research phase of development. On January 18, 2006, we announced that our OVA System achieved expression of significant quantities of the human protein, interferon beta-1a, in the whites of eggs laid by transgenic hens. Interferon-beta is a key component of the human immune system and is the active ingredient in several leading multiple sclerosis therapies. While recent proof-of-principle studies suggest that the OVA System represents a novel biomanufacturing system for the production of human therapeutic proteins, this technology must be further developed in order to validate and confirm its viability and economic benefits before initiating necessary clinical trials or entering into commercial production. It is this project's aim to develop a cost-effective biomanufacturing system for the large-scale production of human therapeutic proteins. To date, no one has commercialized any therapeutic proteins or antibody therapeutic products based on avian transgenics technologies. There can be no assurance that our studies will be successful or that any products produced via this technology will be brought to market.

Recent Events

In October 2006, our majority-owned subsidiary, Viragen International, Inc., completed a private placement of 7,697 shares of Viragen International Series D 24% Cumulative Preferred Stock. Viragen International received net proceeds of approximately \$712,000 in connection with this transaction.

In August 2006, Viragen International completed a private placement of 3,154 shares of Viragen International Series D 24% Cumulative Preferred Stock. Viragen International received net proceeds of approximately \$284,000 in connection with this transaction.

In July 2006 Viragen International completed a private placement of 18,000 units with each unit consisting of one share of Viragen International Series C 24% Cumulative Preferred Stock and 200 shares of Viragen International common stock. Accordingly, 18,000 shares of its Series C cumulative preferred stock and 3,600,000 shares of its common stock were issued. Viragen International received net proceeds of approximately \$1.6 million in connection with this transaction.

We and Viragen International intend that Viragen International will redeem the Viragen International Series C and Series D cumulative preferred stock upon completion of this offering.

Corporate Information

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. Unless otherwise indicated, references in this prospectus to we, us and our are to Viragen, Inc., and our wholly-owned and majority-owned subsidiaries.

Table of Contents

The Offering

<i>Securities Offered:</i>	67,000,000 units, each unit consisting of one share of our common stock and one common stock purchase warrant to purchase one share of common stock.
<i>Offering Price:</i>	\$ per unit.
<i>Separation of Units:</i>	<p>The units will begin trading on or promptly after the date of this prospectus. Each of the common stock and warrants will trade separately on a day at least six months after the date of this prospectus unless the underwriter determines that an earlier date is acceptable, based on its assessment of the relative strengths of the securities markets and our industry in general, and the trading pattern of, and demand for, our securities in particular. Dawson James may decide to allow continued trading of the units following separation. In no event will the underwriter allow for separate trading until:</p> <p style="padding-left: 40px;">the preparation of a balance sheet reflecting receipt by us of the proceeds of this offering and the filing of the balance sheet with the Securities and Exchange Commission on a Form 8-K or similar Form by us, which includes the balance sheet;</p> <p style="padding-left: 40px;">we file a Form 8-K and issue a press release announcing when separate trading will begin; and</p> <p style="padding-left: 40px;">the business day following the earliest to occur of the expiration of the underwriter's over-allotment option or the exercise of the underwriter's over-allotment option in full.</p>
Common Stock	
<i>Number Outstanding Prior to Offering:</i>	At September 29, 2006, 47,726,773 shares of our common stock are outstanding, without giving effect to the issuance of 15,529,149 shares in the event of conversion of outstanding convertible debt at \$1.05 per share and convertible preferred stock at \$1.25 per share, 15,979,434 shares in the event of exercise of outstanding warrants at a weighted average price of \$1.13 per share and 1,136,783 shares in the event of exercise of outstanding options at a weighted average price of \$1.56 per share.
<i>Number Outstanding Following the Offering:</i>	shares of our common stock will be outstanding, without giving effect to the issuance of 11,357,149 shares in the event of conversion of outstanding convertible debt at \$1.05 per share and Series A cumulative convertible preferred stock, shares in the event of exercise of outstanding warrants (including the warrants included in the units offered by this prospectus) at a weighted average price of \$ per share and 1,136,783 shares in the event of exercise of outstanding options at a weighted average price of \$1.56 per share.

Table of Contents

Warrants Underlying Units

Number Outstanding Prior to the Offering: None

Number Outstanding Following the Offering:

Exercisability Each warrant is exercisable for one share of common stock.

Exercise Price: \$ per share

Exercise Period: The warrants will become exercisable on the date of separation from the unit which will be , 2007, six months from the date of this prospectus or earlier if so determined by the underwriter. The warrants will expire at 5:00 p.m., New York City time, on , 2011, five years from the date of this prospectus.

Redemption: We may redeem the outstanding warrants with Dawson James prior consent:
in whole and not in part;
at a price of \$ per warrant at any time after six months from the date the warrants become exercisable;
upon a minimum of 30 days prior written notice of redemption; and
if, and only if, the last sale price of our common stock equals or exceeds \$ per share for any 20 trading days within a 30 trading day period ending three business days before we send the notice of redemption.

We established the last criterion to provide warrant holders with a premium to the initial warrant exercise price, as well as a degree of liquidity to cushion the market reaction, if any, to our redemption call. If the foregoing conditions are satisfied and we call the warrants for redemption, the warrant holders will then be entitled to exercise their warrants prior to the date scheduled for redemption. However, there can be no assurance that the price of the common stock will exceed \$ or the warrant exercise price after the redemption call is made.

Since we may redeem the warrants only with the prior written consent of Dawson James and Dawson James may hold warrants subject to redemption, Dawson James may have a conflict of interest in determining whether or not to consent to such redemption. We cannot assure you that Dawson James will consent to such redemption if the exercise of the warrants is not in its best interest even if the exercise of the warrants is in our best interest.

AMEX Symbols

Units: Expected to be VRA.U

Common Stock: VRA

Warrants: Expected to be VRA.WS

Risk Factors See Risk Factors immediately following this prospectus summary to read about factors you should consider before purchasing units.

Table of Contents

General

We have granted the underwriter an option to purchase up to an additional 10,050,000 units to cover over-allotments, if any. Unless otherwise indicated, the information in this prospectus relating to the outstanding units, shares of common stock and common stock purchase warrants immediately following this offering does not give effect to exercise of the over-allotment option.

Unless otherwise indicated, all discussion in this prospectus relating to proceeds of the offering and use of these proceeds do not give effect to receipt of the proceeds from the exercise of the warrants included in the units. If all of these warrants are exercised and assuming no exercise of the over-allotment option, we would receive \$ in net proceeds for working capital and general corporate purposes, assuming an exercise price of \$ per share upon exercise of the warrants. There is no assurance that any or all of the warrants will be exercised.

We have assumed, solely for the purposes of calculating various capitalization and dilution items, that the offering price of the units to the public will be \$. However, such price is subject to discussion between the underwriter and us and may vary substantially from our assumed price.

Table of Contents

FORWARD-LOOKING STATEMENTS

This prospectus, and other documents that we have incorporated by reference, contain forward-looking statements. Also, our management may make forward-looking statements orally to investors, analysts, the media and others. 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, those set forth in our annual report on Form 10-K for the fiscal year ended June 30, 2006 and the following:

our failure to achieve significant revenues;

our failure to service our debt and preferred stock;

our ability to procure additional funding;

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-1/A

a decline in demand for shares of our common stock;

volatility in the market for shares of our common stock;

ability of holders to effect resales of securities if we are delisted from AMEX;

ability of holders to exercise warrants offered;

our ability to regain compliance with American Stock Exchange listing standards;

our ability to pay dividends on common 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 from those described in forward-looking statements include the risks discussed elsewhere in this prospectus under the caption Risk Factors.

Table of Contents

RISK FACTORS

An investment in our units, common stock or common stock purchase warrants 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 documents incorporated by reference into this 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. As a result, the trading price of our units, common stock or warrants could decline. This prospectus and the documents incorporated by reference into this prospectus contain 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:

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

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

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

At June 30, 2006, we had cash on-hand of approximately \$443,000, working capital of approximately \$229,000, an accumulated deficit since organization of approximately \$166.2 million and a stockholders' deficit of approximately \$1.6 million. These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders' (deficit) 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 that may be necessary in the event we are unable to continue as a going concern.

While, subsequent to June 30, 2006, our majority-owned subsidiary, Viragen International, received net proceeds of approximately \$2.6 million from the sale of its preferred stock and common stock, we continue to experience operating losses and cash flow difficulties. We believe the net proceeds of this offering, together with results of operations and licensing fees, will provide sufficient cash to support our operations through at least June 30, 2007. In the event that we raise fewer net proceeds than anticipated and 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. We will require substantial additional funding to support our operations subsequent to June 30, 2007. 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, if we are unable to complete this offering or obtain additional financing by the end of October 2006, we could be forced to significantly curtail or suspend our operations, including laying-off employees, recording asset impairment write-downs and other measures.

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

Table of Contents

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, units and warrants 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. We believe the net proceeds of this offering will be sufficient to fund our operations through our fiscal year ending June 30, 2007. In the event that licensing and sales revenue are insufficient to sustain our operations after such time, we anticipate that it will be necessary for us to raise additional capital in order to continue our operating activities.

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. We also anticipate selling related expenses will increase over the next twelve months due to the planned expansion of our *Multiferon*[®] sales and marketing efforts. Our future capital requirements will depend on many factors including:

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

revenue generated from the sale of *Multiferon*[®];

our ability to conduct future financings;

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 operating plans for our fiscal year ending June 30, 2007, we anticipate that we will need approximately \$9.0 million for operating activities, \$500,000 for investing activities and \$11.0 million to redeem our outstanding Series J cumulative convertible preferred stock, Viragen International's outstanding Series C and Series D cumulative preferred stock and service our current debt obligations. Actual expenditures in these areas could vary based on anticipated *Multiferon*[®] sales, licensing fees and the net proceeds realized from this secondary offering. In the event that we raise fewer net proceeds than anticipated and 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. In the future, we may require additional funds, which may not be

Edgar Filing: VIRAGEN INC - Form S-1/A

available to us when we need them 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 debt holders. There can be no assurance that debt holders will provide waivers, if required.

See We have received deficiency notices from the American Stock Exchange, or AMEX, and if we are unable to satisfy the AMEX that we will regain compliance with its continued listing criteria, our common stock and units and warrants, if approved for listing on AMEX in connection with this offering, may be delisted from AMEX, which could accelerate repayment of outstanding indebtedness, adversely affecting investor perception and may result in institutional and other investors refraining from purchasing our common stock, units or

Table of Contents

warrants, which would adversely affect your ability to sell our common stock, units or warrants. If adequate funds are not available to us on a timely basis, we may be required to significantly curtail or suspend a portion or all of our operations. Further, sufficient funding may not be available to finance planned future scientific collaborations, planned marketing efforts or planned capital expenditures. Any failure to raise additional funds in the future may also result in our inability to successfully promote *Multiferon*[®], complete existing and/or undertake new research and development projects, take advantage of business opportunities or respond to competitive pressures, any of which would have a material adverse effect on our financial condition, results of operations and ability to continue operations.

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 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.

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 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 VG101 and VG102.

Table of Contents

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 VG101 and VG102. 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.

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

Table of Contents

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 VG101 and VG102 projects, 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.

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 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 we do not currently have an organization for the sales, marketing and distribution of these products. We do have two sales representatives in Sweden to promote *Multiferon*® to prescribing physicians. In order to successfully commercialize these products that may be approved in the future by applicable regulatory authorities, we must either build our sales and marketing capabilities or make arrangements with third parties to perform these services. If we do enter into arrangements with third parties to perform sales and marketing services, our net product revenues will be lower than if we

Table of Contents

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.

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

Table of Contents

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.

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. Any delay or failure by us or our collaboration partners to obtain regulatory approvals for *Multiferon®* 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

Table of Contents

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

Edgar Filing: VIRAGEN INC - Form S-1/A

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 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.

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, units and warrants. 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

Table of Contents

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.

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.

Table of Contents

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.

In addition, we entered in a collaborative research and development agreement with Sloan-Kettering Institute for the joint development of an antibody to the GD3 antigen. This agreement will expire in February 2007, unless extended by mutual consent or unless we exercise our option to negotiate an exclusive license agreement. The agreement provides that the rights in work product created under the agreement including research results, data, and records will be owned by the party that generated them and that if work product is generated jointly, it will be jointly owned by us and Sloan-Kettering. We do not have payment obligations pursuant to Sloan-Kettering collaboration. Although we have entered into discussions and negotiations with the Sloan-Kettering Institute to license the anti-GD3 antibody, it is not known if or when a license agreement will be executed.

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

Table of Contents

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.

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,

Table of Contents

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.

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.

Table of Contents

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;

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.

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.

The financings that we have consummated and intend to consummate are dilutive to stockholders and may adversely affect the market price for our shares of common stock, units and warrants.

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, units and warrants.

Table of Contents

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.

Risks Related to this Offering

We have received deficiency notices from the American Stock Exchange, or AMEX, and if we are unable to satisfy the AMEX that we will regain compliance with its continued listing criteria, our common stock and units and warrants, if approved for listing on AMEX in connection with this offering, may be delisted from AMEX, which could accelerate repayment of outstanding indebtedness, adversely affect investor perception and may result in institutional and other investors refraining from purchasing our common stock, units or warrants, which would adversely affect your ability to sell our common stock, units or warrants.

We have received two deficiency letters from the AMEX, dated September 20, 2005 and March 1, 2006, advising us that, based upon our Annual Report on Form 10-K for the fiscal year ended June 30, 2005 and our Quarterly Report on Form 10-Q for the quarter ended December 31, 2005, respectively, we were not in compliance with AMEX's continued listing standards.

On September 22, 2005, we received a deficiency letter from the AMEX, dated September 20, 2005, advising we are not in compliance with continued listing standards. Specifically, since the filing of our financial statements for the fiscal year ended June 30, 2005, we have not been in compliance with Section 1003(a)(ii) of the AMEX Company Guide with stockholders' equity of less than \$4 million and losses from continuing operations and/or net losses in three out of its four most recent fiscal years and Section 1003(a)(iii) with stockholders' equity of less than \$6 million and losses from continuing operations and/or net losses in its five most recent fiscal years.

In order to maintain our current listing, we submitted a compliance plan on October 19, 2005 advising of the actions we are taking to regain compliance with AMEX's continued listing standards. This plan was approved by AMEX on October 25, 2005, and AMEX granted us a conditional trading extension until March 20, 2007 to regain compliance with their continued listing standards.

Additionally, on March 1, 2006, the AMEX notified us that we failed to meet an additional continued listing standard, Section 1003(a)(i) of the AMEX Company Guide with stockholders' equity of less than \$2 million and losses from continuing operations and/or net losses in two of its three most recent fiscal years. AMEX noted that if we are not in compliance with all continued listing standards by March 20, 2007 or do not make progress consistent with the plan during the plan period, AMEX will initiate delisting proceedings.

We will be subject to periodic review by AMEX during the extension period granted by AMEX. Failure to make progress consistent with the plan we submitted to AMEX or to regain compliance with the continued listing standards by the end of the extension period could result in our common stock and units and common stock purchase warrants, if approved for listing on AMEX in connection with this offering, being delisted from AMEX.

Table of Contents

In the event our common stock, units or warrants are delisted from AMEX, we would apply to have our common stock, units and warrants listed 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 common stock, units and warrants 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 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 common stock 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.

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.

In addition, our outstanding convertible debt contains a provision that in the event our common stock is no longer traded on the AMEX, New York Stock Exchange or NASDAQ, the debt holders have the right to request repayment of their investment with related accrued interest. Given our current financial position and our failure to meet the AMEX continued listing requirements, if our common stock was delisted from AMEX, we would be unable to repay these amounts and would be in default of these agreements, which would significantly hamper our ability to raise additional capital to fund our ongoing operations.

An effective registration statement may not be in place when an investor desires to exercise warrants, thus precluding such investor from being able to exercise his, her or its warrants and causing such warrants to be practically worthless.

No warrant held by public stockholders or issuable upon exercise of the underwriters' 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, we cannot assure you that we will be able to do so, and if we do not maintain a current prospectus related to the common stock issuable upon exercise of the warrants, holders will be unable to exercise their warrants and we will not be required to settle any such warrant exercise. If the prospectus relating to the common stock issuable upon the exercise of the

Table of Contents

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 underwriters' 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 securityholders may be exercisable for unregistered shares of common stock.

If our securities are delisted from AMEX, investors in this offering may engage in resale transactions only in those states in which we register this 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 become separately transferable, the common stock and warrants comprising the units, are exempt from state registration requirements because the securities are listed on 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 AMEX, investors in this offering may engage in resale transactions only in those states in which we register this offering and certain other jurisdictions for which an applicable exemption from registration exists.

The issuance of our shares in this offering or upon exercise of the warrants issued in this offering or upon the exercise or conversion of other 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, units and warrants.

As of the date of this prospectus, there were 48,280,153 shares of our common stock outstanding. The issuance of our shares in this offering or upon exercise of the warrants issued in connection with this offering 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, which would also negatively affect the price of our units and warrants.

As of the date of this prospectus, exclusive of this offering, there were 32,651,282 shares of our common stock issuable upon exercise or conversion of the following securities. These securities represent approximately 68% of our outstanding shares of common stock as of the date of this prospectus.

Convertible preferred stock, Series A	916
Convertible preferred stock, Series J (convertible at \$1.25 per share)*	4,172,000
Officers, employees, and directors options (exercisable at an average price of \$1.56 per share through March 2014)**	1,136,783
Consultant warrants (exercisable at an average price of \$3.05 per share through February 2009)	5,000
Debt and equity offering warrants (exercisable at an average price of \$1.13 per share through March 2011)	15,979,434
Convertible notes or related warrants issuable upon redemption of the notes (convertible/exercisable at \$1.05 per share through August 2008)	10,047,622
Convertible debentures (convertible at \$1.05 per share through September 2008)	1,309,527
	32,651,282

Table of Contents

* To be retired from the proceeds of this offering.

** Includes options to purchase an aggregate of 843,000 shares of our common stock, which were granted in April 2006 under our 2006 Equity Compensation Plan. No shares issuable upon exercise of these options can be issued until our 2006 Equity Compensation Plan is approved by our stockholders. We intend to seek stockholder approval of our 2006 Equity Compensation Plan at our next annual stockholders meeting.

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.

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 \$0.25 since January 1, 2005. The daily trading volume of our shares since January 1, 2005 has been volatile ranging between 23,500 and approximately 11.6 million shares in a single day.

Changes in the market for our common stock could also negatively impact the price and volume volatility of our units and warrants.

Table of Contents

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 convertible debentures prohibit us from directly or indirectly paying cash dividends or distributions on our common stock. Provisions of our convertible debentures and 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. 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. 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.

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 Series A cumulative convertible preferred stock and 52,150 shares of Series J cumulative convertible preferred stock are issued and outstanding on the date of this prospectus. 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

Gross proceeds from the sale of the units is anticipated to be \$ prior to the payment of underwriting discounts of \$ and expenses of \$ and other estimated expenses of this offering of \$. Absent unforeseen circumstances, the anticipated net proceeds of approximately \$ (without giving effect to exercise of the over-allotment option, the common stock purchase warrants included in the units or the underwriter's option to purchase units) will be applied substantially as follows:

Redemption of \$5,215,000 of our Series J 24% Cumulative Convertible Preferred Stock and payment of \$1,251,600 in dividends accrued through February 28, 2007;

Redemption of \$1,800,000 of Viragen International's Series C 24% Cumulative Preferred Stock and payment of \$432,000 in dividends accrued through July 14, 2007;

Redemption of \$1,085,100 of Viragen International's Series D 24% Cumulative Preferred Stock and payment of \$260,424 in dividends accrued through August 18, 2007;

Monthly principal payments aggregating \$62,500, plus a 10% premium, on our outstanding convertible debentures;

Quarterly interest payments on the outstanding balance of our convertible promissory notes;

Research and development activities;

Sales and marketing activities;

Administrative expenses; and

Working capital needs.

We may also use a portion of the net proceeds of this offering to invest in or acquire new technologies and/or other strategic relationships, although we have no present commitments or agreements with respect to any such material acquisition or investment.

The amounts actually expended for each of the purposes listed above (other than the redemption of our Series J cumulative convertible preferred stock and the redemption of Viragen International's Series C cumulative preferred stock and Series D cumulative preferred stock) and the timing of our actual expenditures will depend on numerous factors, including our ability to generate licensing fees, growth in sales revenues, research and development activities, sales and marketing activities and the other factors described in Risk Factors. We have not yet determined the amount or timing of expenditures for the corporate purposes listed above.

Any proceeds received upon exercise of the over-allotment option or the warrants included in the units will be used for general working capital purposes. There is no assurance that the over-allotment option or any of the warrants will be exercised.

Pending use of the offering proceeds, we may invest the net proceeds of the offering in short-term, investment grade, interest-bearing securities or guaranteed obligations of the United States government or its agencies.

Table of Contents**PRICE RANGE OF OUR COMMON STOCK**

Our common stock began trading on the American Stock Exchange on April 17, 2000, under the symbol VRA. The following table sets forth the high and low sales prices as reported on the American Stock Exchange for the periods indicated, as adjusted for our one for ten reverse stock split effective June 15, 2004.

	High	Low
2006-2007 Period		
Second Quarter ending December 31, 2006 (through October 4, 2006)	\$ 0.33	\$ 0.31
First Quarter ended September 30, 2006	0.45	0.25
2005-2006 Period		
Fourth Quarter ended June 30, 2006	0.61	0.36
Third Quarter ended March 31, 2006	0.80	0.42
Second Quarter ended December 31, 2005	0.79	0.30
First Quarter ended September 30, 2005	0.83	0.44
2004-2005 Period		
Fourth Quarter ended June 30, 2005	0.87	0.54
Third Quarter ended March 31, 2005	1.03	0.63
Second Quarter ended December 31, 2004	1.34	0.90
First Quarter ended September 30, 2004	1.42	0.83

The above quotations represent prices between dealers, and do not include retail mark-ups, markdowns or commissions and do not represent actual transactions.

As of September 29, 2006, we had approximately 2,600 stockholders of record. On September 29, 2006, the closing price of our common stock was \$0.32 per share.

We have never paid any dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future because:

provisions of our convertible debentures prohibit us from directly or indirectly paying cash dividends or distribution on our common stock;

provisions of our Series A cumulative convertible preferred stock and Series J cumulative convertible preferred stock prohibit the payment of dividends on our common stock, subject to certain exceptions;

applicable provisions of Delaware law described below limit our ability to pay dividends if we do not have net income;

we have experienced losses since inception;

we have significant capital requirements in the future; and

we presently intend to retain future earnings, if any, to finance the expansion of our business.
Future dividend policy will depend on:

our earnings, if any;

applicable provisions of Delaware law described below governing the payment of dividends;

capital requirements;

expansion plans;

legal or contractual limitations;

financial condition; and

other relevant factors.

The payment of dividends will also depend on our ability to declare dividends under Delaware law. Dividends may be paid only out of surplus, as that term is defined in the Delaware General Corporation Law, or, in the event there is no surplus, out of the net profits of the corporation for the fiscal year in which the

Table of Contents

dividend is declared and/or the immediately preceding fiscal year. Dividends may not be paid, however, out of net profits of the corporation if the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets is impaired.

Table of Contents

CAPITALIZATION

The following table presents our capitalization as of June 30, 2006. Our capitalization is presented:

on an actual basis at that date;

on a as adjusted basis to give effect at that date to the following subsequent events:

our receipt of the estimated net proceeds from the sale of 67,000,000 units in this offering (gross proceeds less the underwriting discount and the estimated offering expenses payable by us from the offering proceeds) and our anticipated application of those proceeds, including the redemption of our Series J cumulative convertible preferred stock, including related accrued and unpaid dividends and the redemption of Viragen International's Series C cumulative preferred stock issued in July 2006 and Series D cumulative preferred stock issued in August 2006 and October 2006, including related accrued and unpaid dividends.

You should read this capitalization table in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes that are incorporated by reference into this prospectus.

	Actual	As of June 30, 2006 As Adjusted (in thousands, except par value and number of shares)
Cash and cash equivalents	&	