

NOVAVAX INC  
Form 10-K/A  
March 15, 2005

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

**FORM 10-K/A**

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

**For the Fiscal Year Ended December 31, 2004**

**Commission File No. 0-26770**

**NOVAVAX, INC.**

**(Exact name of Registrant as specified in its charter)**

**Delaware**

(State or other jurisdiction of incorporation or  
organization)

**22-2816046**

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

**508 Lapp Road, Malvern, Pennsylvania**

(Address of principal executive offices)

**19355**

(Zip code)

Registrant's telephone number, including area code: **(484) 913-1200**

Securities registered pursuant to Section 12(b) of the Act: **NONE**

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock (\$.01 par value)**

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of 26,184,960 shares of the Registrant's Common Stock, par value \$.01 per share, held by non-affiliates of the Registrant at June 30, 2004, as computed by reference to the closing price of such stock, was approximately \$141,136,934.

The number of shares of the Registrant's Common Stock, par value \$.01 per share, outstanding at February 28, 2005 was 39,804,419 shares.

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**Documents Incorporated By Reference**

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Portions of the Registrant's Definitive Proxy Statement to be filed no later than 120 days after the fiscal year ended December 31, 2004 in connection with the Registrant's 2005 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K

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**EXPLANATORY NOTE**

On March 15, 2005, Novavax, Inc. filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2004 (the "Annual Report"). The purpose of this amendment to the Annual Report is to include the signature of the Company's independent registered public accounting firm, Ernst & Young LLP, on such firm's Report of Independent Registered Public Accounting Firm relating to the Company's financial statements appearing on page F-2 of the Annual Report as well as the Consent of Independent Registered Public Accounting Firm appearing on Exhibit 23 which signature was inadvertently omitted in the original filing of the Annual Report. The Form 10-K is being filed in its entirety. Novavax has not made any other changes to the Form 10-K.

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**PART I****Item 1. Business****Overview**

Novavax is a fully-integrated specialty biopharmaceutical company focused on the research, development and commercialization of products utilizing our proprietary drug delivery and vaccine technologies for large and growing markets. We have several proprietary technologies which are summarized in the following table:

<b>Technology</b>	<b>Description</b>	<b>Product/Examples</b>
Micellar Nanoparticles	Oil and water nanoemulsion that allows topical systemic delivery of certain molecules	ESTRASORB® and ANDROSORB
Novasomes®	Non-phospholipid liposomes that can be used as adjuvants to enhance vaccine effectiveness; also serve as a vehicle for topical or oral drug delivery of certain molecules	Influenza and HIV vaccines
Sterisomes®	Solvent and oil-free emulsion for depot delivery	ANDRO-Ject
Recombinant vaccines	Virus-like particle (VLP) vaccines produced in cultured insect cells	HIV/AIDS, influenza, SARS, melanoma (non VLP)
Recombinant tolerogens	Tolerization for prevention of inflammation leading to stroke and cardiovascular diseases	E-Selectin tolerogen

We are leveraging these technologies to develop new product candidates to be marketed by the Company, co-promoted or licensed to other drug companies. While our main therapeutic areas of concentration are women's health and infectious diseases, we believe our technologies can be applied more broadly. (See Product Development Candidates ).

Our micellar nanoparticle ( MNP ) technology involves the use of patented oil and water nanoemulsions that can be used as vehicles for the systemic delivery of a wide variety of drugs and other therapeutic products via topical application. We believe that our MNP technology has demonstrated for the first time that hormones, such as estrogen and testosterone, can be systemically delivered.

ESTRASORB, our first internally-developed product using our MNP technology and approved by the U.S. Food and Drug Administration, was launched in June 2004. ESTRASORB is the first topical emulsion for estrogen therapy approved by the FDA for the treatment of moderate to severe vasomotor symptoms (hot flashes) associated with menopause. Although prescription trends during the first nine months of launch have been slower than projected, we believe ESTRASORB is competitively positioned to address the estimated \$1.5 billion estrogen therapy market in the

United States.

In the first half of 2004, we underwent a successful plant inspection by the FDA and began to manufacture ESTRASORB for commercial sale in our dedicated, state-of-the-art 24,000 square foot facility in Philadelphia, Pennsylvania. In the second half of 2004, we installed and validated a new fill-finish machine, which we expect will help reduce our production time and costs.

In addition to ESTRASORB, we currently market, sell and distribute a line of prescription pharmaceuticals and prenatal vitamins. (See [Currently Marketed Products](#) ). Our sales force has experience selling to obstetricians, gynecologists, managed care organizations, wholesalers and retail pharmacies throughout the United States.

We also conduct research and development on preventative vaccines and proteins for infectious diseases and cancers, and tolerogens to prevent the initiation and progression of stroke, heart attack and other inflammatory diseases. During 2005, we estimate that we will receive government funding grants for our vaccine research in excess of \$2.5 million. To that end, during the first quarter of 2005 we announced the receipt of a three-year grant for \$1.1 million from the National Institutes of Health to develop a SARS vaccine using our virus-like particle technology. We are also applying for numerous contracts to fund our influenza vaccine projects.

Our current research and development candidates in drug delivery utilize our MNP, Novasome and Sterisome technologies. The most advanced candidate is ANDROSORB, a topical testosterone emulsion using our MNP technology that has completed two Phase I clinical trials. We also have several drug candidates that began animal testing in early 2005. Included in this group are two hormones, a women's health product, a smoking cessation drug and a drug for pain. Other additional drug test compounds are scheduled to begin preclinical trials in 2005.

In 2001 and 2002, we entered into co-promotion and licensing agreements with King Pharmaceuticals, Inc. for the promotion and marketing of ESTRASORB and ANDROSORB. These agreements were terminated in July 2004, with all worldwide product rights returned to Novavax for ESTRASORB and ANDROSORB, as well as all rights to products that we may develop using our MNP technology. As part of the transaction, we issued shares of our common stock to King and redeemed all of the \$40.0 million convertible notes held by King. In return for the redemption of the notes and termination of the license and co-promotion agreements, the Company paid King a net of \$14.0 million in cash and issued 3,775,610 shares of our common stock, which had a market value of \$18.1 million at the time of issuance.

The Company operates in one business segment, and is managed and operated as one business, with a single management team that reports directly to our Chief Executive Officer.

## **Our Strategy**

The primary elements of our strategy include:

***Leverage our unique drug delivery technology platforms to commercialize additional pharmaceutical products.*** A key component of our growth strategy is the introduction of new products based on our proprietary drug delivery technologies. We have succeeded in delivering testosterone transdermally with our MNP technology and have completed Phase I testing of ANDROSORB for the treatment of female sexual dysfunction. In addition, several different drug substances have been formulated by Novavax. Pharmacokinetic preclinical studies for these compounds have commenced in 2005, with the expectation to take at least two candidates to the Investigational New Drug stage by year end. We will continue to focus on developing improvements to approved drug therapies and intend to target large markets where our products can be clinically differentiated.

***Develop strategic partners/alliances.*** Given our limited resources, we believe we can optimize our economic returns by expanding into co-development, co-marketing, licensing or other partnering arrangements for existing and pipeline products.

***Maximize the commercial impact of ESTRASORB.*** We believe that the introduction of ESTRASORB has increased our presence in the women's health market, thereby enabling us to more effectively commercialize future products that we develop, acquire or in-license. Additionally, we are pursuing efforts to secure partners for ESTRASORB to increase our promotional sales presence in the United States and abroad.

***Continue to develop our capabilities as a fully-integrated specialty biopharmaceutical company.*** We have built an infrastructure for the development, testing, manufacture and marketing of our products. We believe that this fully-integrated platform differentiates us from many specialty biopharmaceutical companies and enhances our ability to successfully introduce new products, and to grow our existing line of women's health products. We plan to continue to focus our research and development efforts on advancing our existing product candidates towards commercialization and identifying and commercializing new therapies that can best be advantaged by our unique drug delivery techniques.

***Continue to expand our product lines through acquisition of new products and technologies.*** We believe opportunities exist to grow through the acquisition or licensing of product lines, individual products or additional technologies that are complimentary to our current business. Over the past few years, we have demonstrated our ability to successfully acquire and integrate products and research capabilities and anticipate being able to successfully do so in the future

***Build a competitive vaccine program addressing urgent medical needs for large and underserved markets.*** We believe we are one of the leaders in the use of insect cells for the manufacture of pharmaceutical proteins, which may be the most

competitive commercial process for making certain vaccines. Because of this expertise, we have collaborative contracts with and grants from the National Institutes of Health for the development of a second generation acquired immune deficiency syndrome vaccine and an avian flu vaccine to prevent a pandemic outbreak. We are also working with the NIH in the research and development of an E-selectin tolerogen for use in stroke prevention. If successful, we believe these products could address large and underserved markets. Our strategy for building a comprehensive vaccine business is to identify urgent medical needs, assess the scientific and clinical feasibility, identify those opportunities with large and sustainable markets, and ensure we have a competitive advantage by securing commercial rights and patent protection.

## **Our Products**

### ***Currently Marketed Prescription Products***

Our women's health product line is marketed using an established national sales force having extensive experience in selling to obstetricians and gynecologists throughout the United States. We currently market and sell the following women's health prescription products:

*ESTRASORB*. ESTRASORB is a topical estrogen replacement prescription product that was launched in June 2004 for the treatment of moderate to severe vasomotor symptoms (hot flashes) associated with menopause. It utilizes our patented MNP technology to deliver 17  $\beta$ -estradiol in the form of an emulsion. See below for a more detailed description of this product. ESTRASORB generated \$1.8 million of sales in 2004.

*NovaNatal<sup>®</sup>, NovaStart<sup>®</sup> & Nestabs<sup>®</sup> product line*. We market a line of prenatal multi-vitamins for use before, during and after pregnancy. The newest additions to our family of prenatal vitamins are NovaNatal and NovaStart. NovaNatal is a convenient, once-a-day dosing prenatal vitamin that is a patient-friendly, small and easy to swallow tablet. NovaStart is designed as a preconception vitamin. Our prenatal vitamin product line generated \$2.3 million of sales in 2004, \$5.7 million in 2003 and \$8.8 million in 2002.

*AVC Cream*. AVC Cream is an established women's hygiene product effective for the treatment of vaginal infection. We believe there is opportunity for future sales growth for AVC Cream because it is the only sulfanilamide cream on the market for vaginal use. AVC generated \$0.9 million in sales in 2004, \$1.8 million in 2003 and \$1.9 million in 2002.

*Gynodiol<sup>™</sup>*. Gynodiol is an FDA approved option for women who require oral estrogen therapy, and is available in four dosage strengths. Gynodiol is indicated for the relief of moderate to severe vasomotor symptoms associated with menopause, the treatment of vulval and vaginal atrophy, the treatment of hypoestrogenism and the prevention of osteoporosis. Total sales for Gynodiol in 2004 were \$1.0 million, \$2.2 million in 2003 and \$1.7 million in 2002.

*Analpram HC<sup>®</sup>*. Analpram HC is a topical prescription of corticosteroids that are anti-inflammatory and anti-pruritic agents targeted at women suffering from hemorrhoids. We began selling this product in August 2002 after entering into a co-promotion agreement with Ferndale. We received \$0.4 million in co-promotion revenues from Ferndale in 2004, \$0.5 million in 2003 and \$0.3 million in 2002.

We distribute our women's health products primarily through three national distributors and a number of regional distributors in the United States, which in turn supply our products to retail pharmacies. In 2004, sales to these three distributors accounted for 81% of the Company's revenues and 74% of the Company's accounts receivable. We consider our relationship with these companies, which are the primary distributors for pharmaceutical companies in the United States, to be good. However, in the event that one or more of these distributors terminated their relationship with us, it could have a material, adverse effect on our business.

***More on Our Newest Approved Product ESTRASORB***

ESTRASORB was approved by the FDA in October 2003 for the treatment of moderate to severe vasomotor symptoms associated with menopause, and was commercially launched in June 2004. ESTRASORB utilizes our patented MNP to deliver estrogen in the form of 17  $\beta$ -estradiol through the skin when applied topically in the form of an emulsion. We believe that this formulation provides a unique and appealing option to many women suffering from vasomotor symptoms. The efficacy of ESTRASORB was demonstrated in a Phase III clinical trial. The results of this trial showed a statistically significant reduction in moderate and severe vasomotor symptoms at weeks four, eight and twelve of the clinical trial. Specifically, the occurrence of hot flashes was reduced by approximately 85% at week twelve when compared to the trial's baseline.

*Market Overview.* As a woman approaches menopause, ovulation becomes less frequent and the production of estrogen decreases. Eventually the estrogen produced naturally is insufficient to bring about menstruation. Menopause is typically defined as the absence

of menstruation for at least one year. The average age at which women experience menopause is approximately 51 years and menopausal symptoms are experienced by about 75% of women. Millions of women currently take estrogen therapy and as the baby boomer generation ages, the number of patients reaching menopause and needing estrogen therapy is expected to increase.

The primary goal of hormone therapy is the safe and convenient relief of menopausal symptoms with minimal side effects. Estrogen therapy is used worldwide by menopausal women to relieve vasomotor symptoms, such as hot flashes and night sweats, and by post-menopausal women to prevent osteoporosis and other adverse health conditions. There are a variety of estrogen products available including oral, vaginal and transdermal preparations. Patients taking oral preparations may complain of nausea. Transdermal patches for estrogen therapy were developed in large part to eliminate the side effect of nausea and were first commercially available in the mid-1980's. Patches generally use alcohol to drive estrogen through the skin to achieve therapeutic blood levels. Patches may cause skin irritation and inconvenience associated with wearing and changing the patch.

*Clinical Trials of ESTRASORB.* There are several preclinical and human safety and efficacy studies for ESTRASORB. A Phase II study completed in the first quarter of 1999 involved a 35-day randomized, double-blind, placebo-controlled dosing protocol that included 120 patients at six clinical sites in the United States. The study demonstrated a statistically significant reduction in the number of hot flashes per day. The Phase III study supporting the efficacy of ESTRASORB was a randomized, double-blind, placebo-controlled, parallel-group study with 200 participants. The study demonstrated that ESTRASORB treatment caused a statistically significant reduction in the frequency and severity of moderate to severe vasomotor symptoms at weeks four, eight and twelve. The Phase III study further demonstrated that ESTRASORB has a mild and manageable adverse event profile.

*Marketing of ESTRASORB.* The U.S. marketplace for estrogen therapy is currently estimated to be \$1.5 billion according to 2004 Verispan data and highly competitive. In response, we have a focused marketing strategy for ESTRASORB, with the primary aim to leverage the unique profile of ESTRASORB as the first and only FDA-approved estrogen topical emulsion. Our efforts target healthcare professionals who prescribe high volumes of estrogen therapy and who have demonstrated a propensity to adopt new products, specifically transdermal products. We believe that post-menopausal women suffering from vasomotor symptoms will embrace ESTRASORB as a natural and appealing product that offers potential advantages to oral and transdermal products. We are also seeking partners for domestic and international markets to help generate increased prescription volume for ESTRASORB.

In July 2002, the *Journal of the American Medical Association* published data from the Women's Health Initiative, a large-scale study to examine the long-term health effects of hormone therapy in healthy women. Published results of the trial indicated that the group of women on combination hormone therapy (in this case a single orally-administered product combining conjugated equine estrogens and a synthetic progestin) demonstrated overall health risks that warranted the discontinuation of this group from the study. The results have had a negative impact primarily on orally-administered, combination hormone therapy products and have led to uncertainty by women about the long-term use of hormone therapy, especially for uses other than the treatment of vasomotor symptoms.

In addition to the clinical advantages of transdermal delivery noted below in *Drug Delivery*, it is important to note that ESTRASORB is a single agent estrogen therapy product indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause. Specific key differences when comparing ESTRASORB to the combination products in the Women's Health Initiative include:

ESTRASORB utilizes a proprietary topical delivery system that avoids first-pass liver metabolism; and

ESTRASORB contains 17  $\beta$ -estradiol, which is identical to the estrogen produced by a woman's body.

#### **Research and Development Activities**



***Drug Delivery***

Our strategy is to exploit our patented novel technologies to enhance drug delivery. The molecules we have identified for development have all been approved for marketing by the FDA in conventional dosage forms. Their safety and efficacy profile is therefore already established, and we believe substantially reduces the development cost and time to market compared to new chemical entities. In addition, our approach enables us to identify projects with a high probability of success early in development and on the basis of preclinical testing, one of the least expensive phases of pharmaceutical product development.

Most of our product development focus is on transdermal delivery. The clinical advantages of transdermal delivery include: bypassing the stomach, avoiding the first-pass effect many drugs undergo in the liver, better patient compliance, and steadier blood

levels. In some applications, the high concentration of drug achieved at the site of application may have advantages with respect to both safety and efficacy.

Novavax has three drug delivery platform technologies:

Micellar Nanoparticles (MNPs) are proprietary oil and water MNP nanoemulsions. The MNP emulsion formulations we use for the topical delivery of drugs have properties similar to creams and lotions. When rubbed into the skin, the micellar nanoparticles deposit in the outermost skin layer, functionally creating a drug depot. The active drug gradually diffuses into the deeper layers of the skin until it reaches the bloodstream. MNP are the fundamental technology platform for our hormone therapies, including our approved product ESTRASORB and our ANDROSORB product candidate. We believe that our patent on this technology lasts until 2014.

Novasomes are proprietary non-phospholipid liposomes in which vaccines can either be encapsulated or mixed with for delivery into the body by injection. They are made using our patented manufacturing processes from a variety of readily available chemicals called amphiphiles. We believe that our Novasome technology may provide an effective and safe adjuvant system for a variety of vaccines. Our initial use of this technology will be in the development of vaccines for HIV/AIDS, pandemic flu, SARS and other infectious diseases. We believe that Novasomes can also be used for topical or oral drug delivery.

Sterisomes are our proprietary oil-free emulsions, which operate as a drug delivery system comprised predominately of water. Sterisomes can be used as a depot delivery system for certain steroidal hormones. We currently have in preclinical development a long-acting subcutaneous injectable formulation of testosterone and a vaginal progesterone product utilizing this delivery system.

The most advanced product in our pipeline is ANDROSORB, which utilizes our patented MNP technology to deliver testosterone through the skin when applied topically as an emulsion. ANDROSORB may be useful to treat the symptoms of testosterone deficiency, a condition that studies show is increasingly prevalent in our aging population. To date, there have been no approved testosterone therapy products for women in the United States other than a product that combines estrogen and methyltestosterone. Current testosterone therapy products for men include deep intramuscular injections, transdermal patches and gels. Injections require frequent visits to a physician and may be associated with pain at the injection site and abscess. Transdermal patches may cause skin irritation and patient inconvenience associated with wearing and changing patches.

We believe that ANDROSORB may offer several advantages over these current therapies. ANDROSORB is an emulsion that may be applied to the skin, thus eliminating the need for intramuscular injections. In addition, ANDROSORB does not contain materials that may cause the skin irritation associated with transdermal patches. We completed a Phase I study involving ANDROSORB in 2000 and completed a second Phase I study in 2002. We are proceeding cautiously with regard to commencing Phase II trials. We have recognized there would be significant investment required for extensive clinical trials to prove safety and efficacy for testosterone in the new indication for female sexual dysfunction (FSD). The decision was made to initiate further clinical development of ANDROSORB only after the safety and efficacy of topical testosterone therapy for the treatment of FSD is established in the market to the satisfaction of the FDA.

In addition to other hormone product candidates, our drug delivery technology has the potential to be used with a wide variety of drug classes. Our strategy is to develop a broad range of proprietary products that provide a means of clinical differentiation, pharmacological advantages in achieving clinically relevant blood concentrations of drug and opportunities in the life cycle management of medications.



The table below illustrates our drug delivery pipeline:

Preclinical Development Delivery	Solubility	Clinical Development Candidates Stability	Blood Levels	Topical Phase I	Phase
II	Phase II	NDA			

#### **Women's Health**

Androsorb (Female Sexual Dysfunction)

NX-200 (Female Hormone Replacement)

NX-201 (Contraceptive)

NX-205 (Post Menopausal Health Product)

#### **Pain**

NX-300 (Chronic Pain)

#### **Other Products Being Evaluated**

NX-301 (Smoking Cessation)

NX-302 (Anti-Hypertensive)

NX-303 (Bladder Control)

NX-401 (Allergy)

#### ***Vaccines, Infectious Diseases and Tolerogens***

We develop and produce biopharmaceutical proteins for use as vaccines against infectious diseases and as tolerogens to prevent inflammatory responses in the initiation and progression of stroke and other illness. We collaborate with governmental, commercial and leading academic institutions in development, safety testing and clinical trials involving such proteins. It is important to note that in almost all cases, grants, contracts and other arrangements with the federal government and agencies thereof are subject to termination at any time for the government's convenience.

Our lead vaccine technology platform is based on virus-like particles (VLPs), which are self-assembling protein structures that resemble viruses. These are non-infectious particles that can generate immune responses when administered as vaccines. We have several ongoing development programs involving VLPs, including HIV/AIDS, pandemic and annual influenza, and SARS.

Included below is a table setting forth our vaccine pipeline:

#### **Vaccine Pipeline:**

#### **Government Stage Funded**

HIV/AIDS Non-human primates

VLP vaccine

Pandemic flu Small animal

VLP vaccine

Melanoma Phase 1

vaccine

E-Selectin to Small animal  
prevent 2°  
stroke

E-Selectin to Small animal  
prevent heart  
attack

SARS                      Discovery

**Partnered**

**or**

**Internally**

**Funded**

Hepatitis E      Phase III  
Virus  
vaccine

Trivalent flu      Discovery  
VLP vaccine

*HIV/AIDS VLP Vaccine.* The human toll of AIDS is staggering and now kills more people worldwide than any other infectious disease. Nearly 40 million people are infected with HIV, including an estimated five million people who were newly infected with HIV in 2004 according to the World Health Organization ( WHO ). Under a NIH grant we are working with one of the leading scientific teams in the development of a second generation AIDS vaccine. The HIV vaccine candidates will be based on our knowledge and experience in producing VLP vaccines and manufactured using our insect cells technology. Promising HIV virus-like particle vaccine candidates will also be formulated with Novasome adjuvants, our proprietary Novavax technology that is designed to boost the body's immune response to certain vaccine formulations. The HIV vaccine candidates will be used in animal studies and subsequent clinical studies in humans.

*Avian (pandemic) VLP Flu Vaccine.* The NIH has given Novavax a grant to develop an avian flu vaccine using our VLP technology. Using cloned genes, we have produced a VLP flu vaccine which we have sent to the Center for Disease Control for animal testing. The VLP vaccine findings in mice reported by the CDC in September 2004 showed that it was safe, created an immune response and included a protective response against a highly pathogenic strain of influenza. Funding from the NIH has been extended to August 2005 in preparation for Phase I testing.

We believe the U. S. Department of Homeland Security may also be interested in purchasing pandemic flu vaccines to have on hand in response to an outbreak of an influenza pandemic. At present, the disease is largely confined to poultry, though there have been approximately 55 human cases reported in Asia with a mortality rate of over 76%, according to the February 2, 2005, WHO data.

*Annual (trivalent) Flu VLP Vaccine.* The 2004 shortage of annual flu vaccine highlighted the need for more reliable flu vaccines and additional manufacturers to enter the market. The current injectable vaccine production process, which hasn't changed in 50 years, is based on hen eggs. This has resulted in long lead times, the risk of contamination, egg allergies and the need for preservatives. The newer nasal vaccine uses live virus, is also made in eggs, is limited to the 5-49 year old population and is expensive to manufacture. The cell-based vaccine technologies currently in development have shown variability in protection levels and are also costly to produce.

The Novavax flu vaccine, on the other hand, does not use hen eggs, can be developed more rapidly with a match to the current year's flu strain and, more importantly, can be manufactured at a lower cost. We are also exploring alternate administration routes beyond traditional injection. This project is still in the early stages of development and we anticipate that we will need a partner in order to commercialize this product.

*SARS VLP Vaccine.* The NIH recently awarded Novavax a \$1.1 million, three-year grant to develop a vaccine to prevent Severe Acute Respiratory Syndrome. SARS is a severe form of pneumonia, accompanied by a fever, caused by a coronavirus. The World Health Organization has reported over 8,000 SARS cases with nearly 800 deaths since the first case of SARS was reported in February 2003.

*Melanoma Vaccine.* Melanoma is a cancer of the melanocytes, the cells that produce pigment in the skin. This type of cancer is most common among people with fair skin, but it can strike people of all races and skin pigmentations. The risk of melanoma increases with overexposure to the sun and with sunburns. For this reason, fair skinned people and those with a family history of melanoma should always use a sunscreen with high SPF whenever they are outdoors. Detected early, melanoma is usually treatable, but undetected or untreated melanomas can spread and are often fatal.

Novavax is currently developing two anti-cancer vaccines for the treatment of melanoma in collaboration with the National Cancer Institute. These vaccines are in the early stages of development, but we believe hold great promise in the treatment of this often deadly form of skin cancer. The first vaccine is in Phase I clinical trials conducted by the NCI / NIH and the second is anticipated to begin trials in 2005.

*Hepatitis E Vaccine.* Hepatitis E, caused by the hepatitis E virus, is the most prevalent form of acute hepatitis in the developing world. Hepatitis E is transmitted through contaminated water and is indistinguishable from the disease caused by Hepatitis A virus. The disease is rarely fatal, although the risk of death and the intensity of the illness increase with age, with pregnant women being at particularly high risk.

Novavax, in collaboration with the NIAID, Walter Reed Army Institute for Research, and GlaxoSmithKline Pharmaceuticals, has developed vaccines to prevent hepatitis caused by Hepatitis E virus. The recombinant HEV ORF2 subunit protein vaccine produced by Novavax is in Phase III clinical trials conducted by GlaxoSmithKline. GlaxoSmithKline has commercial rights and Novavax and the NIH will share royalties, if marketed.

*E-Selectin Tolerogen.* Novavax and the National Institute of Neurological Disorders and Stroke have been developing E-selectin-based molecularly-derived products for the prevention of strokes. In September 2002, a published report in the professional journal *Stroke* provided experimental evidence on prevention of stroke in stroke-prone rats. These results provided supportive evidence that E-selectin tolerization may be useful in the prevention of strokes and other illness where inflammatory and immune responses are involved in the initiation and progression of disease.

### ***Research and Development Funding***

Total externally contracted research and development costs were \$1.7 million in 2004, \$1.3 million in 2003 and \$1.0 million in 2002. Total internally-sponsored research and development costs were \$4.0 million in 2004, \$3.4 million in 2003 and \$5.8 million in 2002. The Company's manufacturing start-up costs related to preparing our manufacturing facility for commercial production of ESTRASORB were included in research and development until April 2004, at which time the manufacturing costs have been included in cost of sales and inventory. Total manufacturing start-up costs related to ESTRASORB included in research and development were \$1.7 million in 2004, \$5.4 million in 2003 and \$4.7 million in 2002.

### **Manufacturing**

The development and manufacture of our products are subject to good laboratory practices and current good manufacturing practices prescribed by the FDA and to other standards prescribed by the appropriate regulatory agencies in other countries. We currently utilize contract manufacturers to produce several existing marketed product lines. We completed the build-out of a 24,000 square foot manufacturing facility within a Cardinal Health, Inc. facility in Philadelphia, Pennsylvania to our specifications and requirements, and have installed manufacturing equipment to accommodate commercial production of ESTRASORB. We have completed the validation of the facility and equipment and we are now manufacturing bulk and packaged ESTRASORB for commercial distribution using our machinery and employees. Cardinal Health performs the final fill of ESTRASORB on our dedicated line and provides us with warehousing, distribution, customer service and collection activities for all of our products. Despite this new facility, we may also need to rely on collaborators, licensees or access to other manufacturing facilities for future later-stage clinical trials and commercial production efforts. There can be no assurance that we will be able to enter into such relationships or obtain needed facilities to manufacture products in a timely manner at acceptable quality and prices, or that we or our suppliers will be able to comply with good laboratory practices or good manufacturing practices, as applicable, or manufacture adequate supplies.

We also currently have a facility in Rockville, Maryland dedicated to our vaccine business, with a focus on research. This facility currently produces product for preclinical and clinical trials.

### **Competition**

The specialty biopharmaceutical industry is intensely competitive and is characterized by rapid technological progress. In particular, our vitamin line of products have been particularly affected by generic competition. We compete with specialized biopharmaceutical firms and large pharmaceutical companies in the United States, Europe and elsewhere that are engaged in the discovery, development and marketing of hormone therapies, vaccine products and other products that do or could compete with our currently marketed products and our product candidates. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants.

The estrogen therapy market is highly competitive, well-established and includes many products marketed by major pharmaceutical companies. The oral segment, which accounts for over 75% of the estrogen therapy market, is



dominated by Wyeth's Premarin®, an oral estrogen tablet. Wyeth commits significant resources to promoting its portfolio of estrogen products and has a dominant presence with healthcare professionals that utilize oral estrogen therapy products. We compete with Wyeth and numerous other companies marketing oral products, including manufacturers of generic 17  $\beta$ -estradiol. Gynodiol, our marketed oral estrogen therapy product also competes in the crowded, competitive oral estrogen therapy market. Transdermal estrogen therapy products (patches) currently account for approximately 15% of the estrogen therapy market. Patch products are well accepted and many such as Vivelle DOT® have been marketed for several years. Solvay Pharmaceuticals, a large international pharmaceutical company, recently introduced an ethanol-based gel product, Estrogel, that is directly competing with ESTRASORB. In addition to the currently approved and marketed products, several estrogen therapy products are in development.

The prenatal vitamin market is very fragmented with many competitors. A number of larger companies with greater resources sell prenatal vitamins that compete with our line of prenatal vitamins, including KV Pharmaceuticals, First Horizon Pharmaceuticals, Mission Pharmacal Company and several other branded and generic manufacturers. The competition to develop new prenatal vitamins is also intense.

In general, competition among pharmaceutical products will be based in part on product efficacy, safety, reliability, availability, price and patent position. An important factor will be the relative timing of the market introduction of our products and our competitors' products. Accordingly, the speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market is expected to be an important competitive factor. Our competitive position will also depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes, and secure sufficient capital resources for the often substantial period between technological conception and commercial sale.

### **Patents and Proprietary Information**

We currently have 51 U.S. patents and corresponding foreign patents and patent applications covering our technologies. We have pending United States patent applications in both the United States and worldwide covering the composition, manufacture and use of our organized lipid structures and related technologies. A current U.S. patent issued in 1997 covers our micellar nanoparticles technology and methods of their production.

Consistent with statutory guidelines issued under the Federal Technology Transfer Act of 1986 designed to encourage the dissemination of science and technology innovation and provide sharing of technology that has commercial potential, the Company's collaborative research efforts with the U.S. government and with other private entities receiving federal funding provide that developments and results will be freely published, that information or materials supplied by us will not be treated as confidential and that we will be required to negotiate a license to any such developments and results in order to commercialize products. There can be no assurance that we will be able to successfully obtain any such license at a reasonable cost, or that such developments and results will not be made available to our competitors on an exclusive or nonexclusive basis.

### **Government Regulations**

Our research and development activities are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the United States and other countries. In the United States, the development, manufacturing and marketing of human pharmaceuticals are subject to regulation for safety and efficacy by the FDA in accordance with the Food, Drug and Cosmetic Act.

The steps required before new products for use in humans may be marketed in the United States include (i) preclinical tests, (ii) submission to the FDA of an Investigational New Drug application, which must be approved before human clinical trials commence, (iii) adequate and well-controlled human clinical trials to establish the safety and efficacy of the product, (iv) submission of a New Drug Application for a new drug and (v) FDA approval of the New Drug Application or Product License Application prior to any commercial sale or shipment of the product. Preclinical tests include laboratory evaluation of product formulation and animal studies (if an appropriate animal model is available) to assess the potential safety and efficacy of the product. Formulations must be manufactured according to good manufacturing practices and preclinical safety tests must be conducted by laboratories that comply with FDA regulations regarding good laboratory practices.

The results of the preclinical tests are submitted to the FDA as part of an Investigational New Drug application and are reviewed by the FDA prior to the commencement of human clinical trials. There can be no assurance that submission of an Investigational New Drug application will result in FDA authorization to commence clinical trials. The FDA may deny a New Drug Application or Product License Application if applicable regulatory criteria are not satisfied or additional testing or information is required. The FDA may also require post-marketing testing and surveillance to monitor the safety of the applicable products.

In addition to obtaining FDA approval for each Product License Application, an Establishment License Application must be filed and approved by the FDA for the manufacturing facilities of a biologic product before commercial marketing of the biologic product is permitted. This regulatory process may take many years and requires the expenditure of substantial resources.

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. Our research and development involves the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and any such liability could exceed our resources. Additionally, for formulations containing controlled substances, we are subject to Drug Enforcement Agency regulations.

There have been a number of federal and state proposals during the last few years to subject the pricing of pharmaceuticals to government control and to make other changes to the medical care system of the United States. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for medical goods and services may take in response to any medical reform proposals or legislation. We cannot predict the effect medical or health care reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

## **Employees**

We currently have 160 full-time employees, 26 of whom are employed in research and development. Of those 26 employees in research and development, seven have earned Ph.D. degrees and three are medical doctors. We have no collective bargaining agreement with our employees and believe that our employee relations are good.

## **Risks and Uncertainties**

*You should carefully read the following risk factors in evaluating our business. Some of the following risks relate principally to our business and the industry in which we operate. Other risks relate principally to the securities market and ownership of our common stock. If any of the following risks occur, our business, financial condition or operating results could be adversely affected. You should also consider the other information described in this Annual Report on Form 10-K for the 2004 fiscal year.*

### ***Our success is heavily dependent on the market acceptance of ESTRASORB.***

ESTRASORB was approved for commercial sale by the FDA in October 2003 and commercially launched in June 2004. Even with ESTRASORB's approval, there is no guarantee that ESTRASORB will be a commercial success. Many factors could negatively affect our ability to successfully commercialize ESTRASORB, including:

our inability to timely and effectively promote and sell ESTRASORB so that ESTRASORB gains a meaningful share of the estrogen therapy market, which currently is dominated by Premarin®, an oral estrogen tablet sold by Wyeth; estrogen patches sold by several companies including Novartis Pharma AG and Berlex Laboratories, Inc.; and gels currently sold by Solvay Pharmaceuticals, Inc.;

our inability to manufacture ESTRASORB at acceptable gross margins;

the inability to obtain coverage and favorable reimbursement rates for ESTRASORB from insurers and other third-party payors; and

the market acceptance of physicians and patients of this new technology.

***We face substantial competition in connection with the sale of ESTRASORB, our other products and our product candidates.***

We compete with numerous other companies worldwide that have developed or are developing products that compete or may compete with ESTRASORB, our other currently marketed products and our product candidates. These competitors include both large and small pharmaceutical companies, biotechnology firms, universities and other research institutions. We may not succeed in developing technologies and products that are more effective than those being developed by our competitors.

Many large companies currently produce and sell estrogen products for clinical indications identical to those for ESTRASORB. Currently, the oral and patch product segments account for approximately 75% and 15% of the market,

respectively, according to 2004 Verispan data. Wyeth commits significant resources to the sale and marketing of its product, Premarin®, in order to maintain its market leadership position. Several other companies compete in the estrogen category including Berlex, Novartis and Solvay. Recently, Solvay introduced an ethanol-based gel product, Estrogel, that is directly competitive with ESTRASORB.

These and other products sold by our competitors have all achieved some degree of market penetration. ESTRASORB competes in the United States for market share with these products and we cannot guarantee that we will be able to effectively promote ESTRASORB against these competitive products. In order to effectively compete, we have and will continue to make substantial investments in sales and marketing. Many of these products are sold by companies with greater resources and experience and there is no assurance that we will be successful in gaining significant market share for ESTRASORB or in earning a return on our investment in ESTRASORB or our product candidates, if approved.

Our technologies and products may be rendered obsolete or noncompetitive as a result of products introduced by our competitors. Our vitamin products have faced sustained and increasing generic competition which recently has resulted in low sales volumes and a high volume of returns for this product line. Most of our competitors have substantially greater financial and technical resources, production and marketing capabilities, and related experience which may enable them to develop, manufacture and market their products more successfully and at a lower cost. In addition, many of our competitors have significantly greater experience in conducting preclinical testing and clinical trials of human pharmaceuticals and obtaining regulatory approvals to market such products. Accordingly, our competitors may succeed in obtaining FDA approval for products more rapidly than we will, which may give them an advantage in achieving market acceptance of their products.

***We are not certain that we will be able to obtain future financing and the effects of such financing.***

We do not anticipate in the near term generating revenues from product sales in an amount sufficient to fund our operations, and we will require additional funds to continue our research and development programs, commence future preclinical and clinical trials, seek regulatory approvals, establish commercial-scale manufacturing capabilities, and market our products. We may seek such additional funds through public or private equity or debt financings, collaborative arrangements and other sources. We cannot be certain that adequate additional funding will be available to us on acceptable terms, if at all. If we cannot raise the additional funds required for our anticipated operations, we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our selling, marketing, general and administrative infrastructure or programs, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or products. If we raise additional funds through future offerings of shares of our common stock or other securities, such offerings would cause dilution of existing stockholders' percentage ownership in the Company. These future offerings also could have a material and adverse effect on the price of our common stock.

***We have a history of losses and our future profitability is uncertain.***

Our expenses have exceeded our revenues since our formation in 1987, and our accumulated deficit at December 31, 2004 was \$130.7 million. Our net revenues for the last three years were \$8.3 million in 2004, \$11.8 million in 2003 and \$15.0 million in 2002. We cannot be certain when or if we will generate substantial revenues from the sale of ESTRASORB. We have received a limited amount of product-related revenue from research contracts, licenses and agreements to provide vaccine products, services and adjuvant technologies. We cannot be certain that we will be successful in entering into strategic alliances or collaborative arrangements with other companies that will result in other significant revenues to offset our expenses. Our net losses for the last three years were \$25.9 million in 2004, \$17.3 million in 2003 and \$22.7 million in 2002.

Our losses have resulted from research and development expenses, sales and marketing expenses for ESTRASORB, protection of our intellectual property and other general operating expenses. Our losses increased due to the launch of ESTRASORB as we expanded our manufacturing capacity and sales and marketing capabilities, and will increase as and when we conduct additional and larger clinical trials for our product candidates. Therefore, we expect our cumulative operating loss to increase until such time, if ever, product sales, licensing fees and royalty payments generate sufficient revenue to fund our continuing operations. We cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

We are allocating a significant portion of our sales force's time to the sales and marketing of ESTRASORB and, consequently, the sales of our other women's health products has been adversely affected. The costs of maintaining our own sales force to market our current products including ESTRASORB currently exceed product revenues. If we continue to market ESTRASORB or future products directly, significant additional expenditures and management

resources will be required to sustain the size of our internal sales force.

***We need additional manufacturing capability to commercialize our products***

We currently manufacture ESTRASORB within a facility of Cardinal Health in Philadelphia, Pennsylvania. Cardinal Health provides packaging services for ESTRASORB that we manufacture in their facility. In early 2004, we completed the build-out of the facility to meet FDA requirements and installed manufacturing equipment for commercial production. We have been successful in manufacturing for our current commercial requirements; however, we have limited experience with the large capacity manufacturing which may be required for the commercial sale of our product. Although we have had the ability to produce the limited quantities of products needed to support our current research and development programs and clinical trials (including utilizing contract manufacturing organizations), we may need more production capacity for larger, later-stage clinical studies and commercial sales. Our potential products may be too difficult or costly to manufacture on a large scale, to develop into commercially viable products, or to market.

In the near term, we intend to continue manufacturing ESTRASORB only in the Philadelphia facility. We may determine to qualify an additional site or sites for the manufacture of ESTRASORB if our production requirements increase or we have opportunities to improve our cost of sales. If we are unable to utilize the Philadelphia facility to manufacture ESTRASORB prior to our qualification of a second site, however, we would not have immediate access to ESTRASORB and would be required to reestablish our validation process at a different facility, which could cause us to lose sales of ESTRASORB and would adversely affect our business.

We currently utilize third-party contract manufacturers to manufacture our other products. Any contract manufacturer's facility that we may use, including the Cardinal Health facility, must adhere to the FDA's regulations on current good manufacturing practices, which are enforced by the FDA through its facilities inspection program. These facilities are subject to periodic inspection by the FDA. The manufacture of products at these facilities will be subject to strict quality control testing and record-keeping requirements. If compliance issues exist at these facilities, thereby interfering with the manufacture of our products, we would be required to seek alternative manufacturing arrangements. There can be no assurance that we would be able to enter into alternative manufacturing arrangements at commercially acceptable rates, if at all. Moreover, the manufacturers we use may not provide sufficient quantities of product to meet our specifications or our delivery, cost and other requirements.

If we decide to manufacture our own products, we will need to acquire additional manufacturing facilities and improve our manufacturing technology. Establishing additional manufacturing facilities will require us to spend substantial funds, hire and retain a significant number of additional personnel and comply with extensive regulations applicable to such facilities in the United States and abroad, including the current good laboratory practices and good manufacturing practices required by the FDA. If we elect or are required to manufacture our own products, we risk the possibility that we may not be able to do so in a timely fashion at acceptable quality and prices or in compliance with good laboratory practices and good manufacturing practices.

***We have not completed the development of other products and we may not succeed in obtaining the FDA approval necessary to sell any additional products.***

The development, manufacture and marketing of our pharmaceutical products are subject to government regulation in the United States and other countries. In the United States and most foreign countries, we must complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. ESTRASORB is our only product to have been approved for sale in the United States. Approval outside the U.S. may take longer or may require additional clinical trials. Our product candidate ANDROSORB has completed two Phase I human clinical studies. Additional product candidates are in preclinical laboratory or animal studies. Before applying for FDA approval to market any additional product candidates, we must conduct larger-scale Phase II and III human clinical trials that demonstrate the safety and efficacy of our products to the satisfaction of the FDA and other regulatory authorities. These processes are expensive and can take many years to complete, and we may not be able to demonstrate the safety and efficacy of our products to the satisfaction of such regulatory authorities. We may also be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies and we may be unable to do so without conducting further clinical studies.

We may fail to obtain regulatory approval for our products on a timely basis. Delays in obtaining regulatory approval can be extremely costly in terms of lost sales opportunities and increased clinical trial costs. The speed with which we complete our clinical trials and our applications for marketing approval will depend on several factors, including the following:

the rate of patient enrollment, which is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the nature of the protocol;



institutional review board approval of the protocol and the informed consent form;

prior regulatory agency review and approval;

analysis of data obtained from preclinical and clinical activities, which are susceptible to varying interpretations and which interpretations could delay, limit or prevent regulatory approval;

changes in the policies of regulatory authorities for drug approval during the period of product development; and

the availability of skilled and experienced staff to conduct and monitor clinical studies and to prepare the appropriate regulatory applications.

We have limited experience in conducting and managing the preclinical and clinical trials necessary to obtain regulatory marketing approvals. We may not be able to obtain the approvals necessary to conduct clinical studies. We also face the risk that the results of our clinical trials may be inconsistent with the results obtained in preclinical studies or that the results obtained in later phases of clinical trials may be inconsistent with those obtained in earlier phases. A number of companies in the specialty biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal and human testing. If regulatory approval of a drug is granted, such approval is likely to limit the indicated uses for which it may be marketed. Furthermore, even if a product gains regulatory approval, the product and the manufacturer of the product will be subject to continuing regulatory review. We may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered.

***Our success depends on our ability to maintain the proprietary nature of our technology.***

Our success in large part depends on our ability to maintain the proprietary nature of our technology and other trade secrets, including our proprietary drug delivery and vaccine technologies. To do so, we must prosecute and maintain existing patents, obtain new patents and pursue trade secret and other intellectual property protection. We also must operate without infringing the proprietary rights of third parties or letting third parties infringe our rights. We currently have 51 U.S. patents and corresponding foreign patents and patent applications covering our technologies. However, patent issues relating to pharmaceuticals involve complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of biotechnology patent claims that are granted by the U.S. Patent and Trademark Office or enforced by the federal courts. Therefore, we do not know whether our patent applications will result in the issuance of patents, or that any patents issued to us will provide us with any competitive advantage. We also cannot be sure that we will develop additional proprietary products that are patentable. Furthermore, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

There is a risk that third parties may challenge our existing patents or claim that we are infringing their patents or proprietary rights. We could incur substantial costs in defending patent infringement suits or in filing suits against others to have their patents declared invalid or claim infringement. It is also possible that we may be required to obtain licenses from third parties to avoid infringing third-party patents or other proprietary rights. We cannot be sure that such third-party licenses would be available to us on acceptable terms, if at all. If we are unable to obtain required third-party licenses, we may be delayed in or prohibited from developing, manufacturing or selling products requiring such licenses.

Although our patents include claims covering various features of our products and product candidates, including composition, methods of manufacture and use, our patents do not provide us with complete protection against the development of competing products. For example, our patents do not prohibit third parties from developing and selling products for estrogen therapy that deliver estrogen through a topical emulsion, ointment or similar medium.

Some of our know-how and technology is not patentable. To protect our proprietary rights in unpatentable intellectual property and trade secrets, we require employees, consultants, advisors and collaborators to enter into confidentiality agreements. These agreements may not provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure.

***Health care insurers and other payors may not pay for our products or may impose limits on reimbursement.***

Our ability to commercialize ESTRASORB and future products will depend, in part, on the extent to which reimbursement for such products will be available from third-party payors such as Medicare, Medicaid, health maintenance organizations, health insurers and other public and private payors. If we succeed in bringing future

products to the market in addition to ESTRASORB, we cannot be assured that third-party payors will pay for ESTRASORB or such future products or establish and maintain price levels sufficient for realization of an appropriate return on our investment in product development. For example, ESTRASORB currently is being sold as an outpatient prescription drug. Medicare does not cover the costs of most outpatient prescription drugs. We expect that over time ESTRASORB will be treated the same as other estrogen therapy products with respect to government and third-party payor reimbursement, however, additional time is required to increase the number of payors who currently accept our product for reimbursement. There can be no assurance that ESTRASORB will receive similar reimbursement treatment.

Many health maintenance organizations and other third-party payors use formularies, or lists of drugs for which coverage is provided under a health care benefit plan, to control the costs of prescription drugs. Each payor that maintains a drug formulary makes its own determination as to whether a new drug will be added to the formulary and whether particular drugs in a therapeutic class will have preferred status over other drugs in the same class. This determination often involves an assessment of the clinical appropriateness of the drug and, in some cases, the cost of the drug in comparison to alternative products. There can be no assurance that ESTRASORB or any of our future products will be added to payors' formularies, that our products will have preferred status to

alternative therapies, or that the formulary decisions will be conducted in a timely manner. We may also decide to enter into discount or formulary fee arrangements with payors, which could result in us receiving lower or discounted prices for ESTRASORB or future products.

***We may have product liability exposure.***

The administration of drugs to humans, whether in clinical trials or after marketing clearances are obtained, can result in product liability claims. We maintain product liability insurance coverage in the total amount of \$10.0 million for claims arising from the use of our currently marketed products and products in clinical trials prior to FDA approval. Coverage is becoming increasingly expensive, however, and we may not be able to maintain insurance at a reasonable cost. There can be no assurance that we will be able to maintain our existing insurance coverage or obtain coverage for the use of our other products in the future. This insurance coverage and our resources may not be sufficient to satisfy liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert management's attention.

***We have made loans to certain of our directors, and have guaranteed a brokerage margin loan for one of these directors, which could have a negative impact on our stock price.***

In 2002, pursuant to our 1995 Stock Option Plan, we approved the payment of the exercise price of options by two of our directors through the delivery of full-recourse, interest-bearing promissory notes, in the aggregate principal amount of approximately \$1.5 million, secured by a pledge of the underlying shares. As of December 31, 2004, accrued interest receivable related to the borrowing was \$209,000. In addition, in 2002 we executed a conditional guaranty of a brokerage margin account for a director in the amount of \$500,000. Due to heightened sensitivity in the current environment surrounding related-party transactions, these transactions could be viewed negatively in the market and our stock price could be negatively affected. Our corporate governance policies have been revised and our proposed 2005 stock incentive plan has been drafted to prohibit any additional loans or guarantees to directors.

***The price of our common stock has been, and may continue to be, volatile.***

Historically, the market price of our common stock has fluctuated over a wide range. In fiscal year 2004, our common stock traded in a range from a low of \$2.88 to a high of \$6.99. It is likely that the price of our common stock will fluctuate in the future. The market prices of securities of small-capitalization, specialty biopharmaceutical companies, including ours, from time to time experience significant price and volume fluctuations unrelated to the operating performance of these companies. In particular, the market price of our common stock may fluctuate significantly due to a variety of factors, including:

governmental agency actions including the FDA's determination with respect to new drug applications for new products;

our ability to obtain financing;

our ability to develop additional products; and

sales of our products, particularly ESTRASORB.

In addition, the occurrence of any of the risks described in this Risk and Uncertainties section could have a material and adverse impact on the market price of our common stock.

***Our substantial indebtedness could adversely affect our cash flow and prevent us from fulfilling our obligations.***

We currently have \$37.2 million of outstanding indebtedness. Our substantial amount of outstanding indebtedness could have significant consequences. For example, it:

could increase our vulnerability to general adverse economic and industry conditions;

requires us to dedicate a substantial portion of our cash flow from operations to service payments on our indebtedness, reducing the availability of our cash flow to fund future capital expenditures, working capital, execution of our growth strategy, research and development costs and other general corporate requirements;

could limit our flexibility in planning for, or reacting to, changes in our business and the pharmaceutical industry, which may place us at a competitive disadvantage compared with competitors that have less indebtedness; and

could limit our ability to borrow additional funds, even when necessary to maintain adequate liquidity.

We may incur additional indebtedness for various reasons, which would increase the risks associated with our substantial leverage.

### Availability of Information

Novavax was incorporated in 1987 under the laws of the State of Delaware. Our principal executive offices are located at 508 Lapp Road, Malvern, Pennsylvania 19355. Our telephone number is (484) 913-1200 and our Internet address is [www.novavax.com](http://www.novavax.com). The contents of our website are not part of this Annual Report on Form 10-K.

We make available, free of charge and through our website, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after filed with or furnished to the SEC.

### Item 2. Properties

By the end of the first quarter 2005, we will have operations in four leased facilities. We lease approximately 32,900 square feet for administrative office space and future product development activities at our corporate headquarters in Malvern, Pennsylvania. We will be renewing the lease of our facility in Rockville, Maryland for 11,700 square feet for contract vaccine research, development and manufacturing of Phase I products. We have another approximately 2,800 square foot facility in Pacific Grove, California for new product research and development activities. Our manufacturing facility for ESTRASORB is in Philadelphia, Pennsylvania where we lease approximately 24,000 square feet of manufacturing space to meet our current and anticipated future production requirements. We completed the build-out and approval of this manufacturing space in 2004 and have been in production since April 2004.

In December 2003, we closed our facility in Maryland Heights, Missouri, which was used for the repackaging of our vitamin lines and warehousing of our products. We have moved those operations to a third-party repackager and a third-party warehouse distribution company. We are currently attempting to sublease our former administration offices in Columbia, Maryland. A summary of our current facilities is set forth below.

Property Location	Approximate Square Footage	Purpose
Malvern, Pennsylvania	32,900	Corporate headquarters and future product development activities
Rockville, Maryland	11,700	Vaccine research and development activities and office space
Pacific Grove, California	2,800	Research and development activities
Philadelphia, Pennsylvania	24,000	Manufacturing and packaging of ESTRASORB, and office space
Columbia, Maryland	12,000	Prior corporate headquarters; lease expires October 2006; currently attempting to sublease

### Item 3. Legal Proceedings

The Company is a defendant in a lawsuit filed by a former director alleging that the Company wrongfully terminated the former director's stock options. Management believes that the termination and cancellation of the options was in accordance with the terms of the option agreement following his termination for cause by a former

parent company, IGI, Inc, and the lawsuit is without merit and intends to vigorously defend the claim. Management cannot reasonably estimate the liability, if any, related to this claim, or the likelihood of an unfavorable settlement. Accordingly, no liability related to this contingency is accrued in the consolidated balance sheet as of December 31, 2004. An unfavorable settlement, however, may have a material adverse impact on future operating results.

The Company is a defendant or co-defendant in various other legal actions related to claims incident to the conduct of its businesses. Management does not expect the Company to suffer any material liability by reason of such actions.

**Item 4. *Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2004.

**PART II****Item 5. Market For Registrant's Common Equity Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock (\$.01 par value) is traded on the NASDAQ National Market under the symbol NVAX. The following table sets forth, for the periods presented, the high and low sales prices for our common stock.

<b>Quarter Ended:</b>	<b>High</b>	<b>Low</b>
December 31, 2004	\$ 4.10	\$ 2.98
September 30, 2004	5.71	2.88
June 30, 2004	6.47	4.11
March 31, 2004	6.99	5.15
December 31, 2003	\$ 8.62	\$ 5.00
September 30, 2003	7.94	4.76
June 30, 2003	6.87	3.26
March 31, 2003	4.75	2.52

Our common stock was held by approximately 573 stockholders of record as of February 28, 2005. We have never paid cash dividends on our common stock. We currently anticipate that we will retain all of our earnings for use in the development of our business and do not intend to pay any cash dividends in the foreseeable future.

**Unregistered Sales of Equity Securities and Use of Proceeds**

The Company entered into agreements with respect to two financing transactions during the year ended December 31, 2004, one of which closed on July 16, 2004 and the other on July 19, 2004. With respect to the former, the Company issued 952,381 shares of its common stock for cash to an accredited investor at a price of \$5.25 per share, for aggregate gross proceeds of \$5.0 million, in reliance on the safe harbor afforded by Regulation D promulgated under the Securities Act of 1933, as amended. With respect to the latter, the Company entered into agreements for the private placement of \$35.0 million aggregate principal amount of senior convertible notes to a group of institutional investors, also in reliance on Regulation D. The Company later registered 952,381 shares of common stock issued to the accredited investor and 7,398,374 shares of common stock issuable upon conversion or redemption of the convertible notes issued to the institutional investors on separate Form S-3 registration statements, both of which became effective in August 2004.

Subject to certain limitations, holders of the senior convertible notes may convert such notes at any time into shares of common stock of the Company. The initial conversion price is \$6.15 per share, subject to adjustment. If the Company fails to timely convert or redeem a note, it is subject to penalties and may also be required to reimburse the holder for its costs in the event the holder is required to purchase shares of the Company's common stock in satisfaction of a sale obligation.

Holders are entitled to redeem their notes if an event of default occurs under the notes. Event of default is defined to include, among other things, the Company's failure to pay when due amounts owing under the notes; any default, redemption or acceleration prior to maturity of any material indebtedness of the Company or its subsidiaries; or the Company's or a subsidiary's commencement of a voluntary bankruptcy case, consent to the entry of an order for relief in an involuntary case, consent to the appointment of a receiver, trustee, liquidator or similar official, general assignment for the benefit of creditors, or admission in writing of its inability to pay debts when due.



A change of control, as that term is defined in the notes, also triggers the holders' right to require the Company to redeem all or any portion of the notes. On the other hand, if a cash transaction (as that term is defined in the notes) is announced, the Company has the right to require all (but not less than all) of the outstanding notes be redeemed at a price equal to the change of control redemption price. Redemptions occur at prices and premiums that vary according to the event that triggered the right to redemption and, in certain cases, the applicable redemption premium varies depending on when the event occurs.

If at any time during the term of the notes the Company issues or sells, or is deemed to have issued or sold, shares of common stock at a price less than the then-applicable conversion price of the notes, then the conversion price of the notes then in effect will be reduced on a weighted average basis. The applicable conversion price will also be proportionately increased or decreased in the event that the Company subdivides or combines one or more classes of its outstanding shares of common stock or any similar event.

If at any time after the third anniversary of the issue date of the notes, the weighted average price of a share of common stock exceeds \$10.76 (subject to the adjustments described above) for 15 trading days out of any 30 consecutive trading days, and certain equity conditions have been satisfied or waived, the Company has the right to require the holders to convert. Similarly, holders have

the right to require that the Company redeem the notes if the weighted average price of the common stock is less than the then-applicable conversion price on each of 30 trading days out of the 40 consecutive trading days immediately preceding either the third or fourth anniversary of the issue date, *provided* that such redemption right ceases once the Company meets the ESTRASORB revenue target, defined as the recognition by the Company of revenue from the sales of ESTRASORB of (a) not less than \$40 million for the twelve month period ending December 31, 2006, and (b) not less than \$25 million for the six month period ending December 31, 2006.

During the period to which this annual report relates, the Company also entered in to an Exchange Agreement and Termination Agreement with King to, among other things, terminate the co-promotion agreement and several licenses between the Company and King. In connection with the King transaction, the Company redeemed all of the convertible notes held by King in the aggregate principal amount of \$40.0 million. The Company paid a net of \$14.0 million in cash and issued 3,775,610 shares of its common stock, valued at approximately \$18.1 million at closing, to King in reliance on Regulation D in connection with the transaction, which closed on July 19, 2004. The shares of common stock issued to King were subsequently registered by the Company on a Form S-3 registration statement, which became effective in August 2004.

See Sale of Common Stock in Note 8 to the Consolidated Financial Statements included herewith as well as the Developments in 2004 section of our Management's Discussion and Analysis in Item 7 below for further discussion of these transactions.

#### **Securities Authorized for Issuance under our Equity Compensation Plans**

See Part III, Item 12.

#### **Issuer Purchases of Equity Securities**

During the fourth quarter of the fiscal year ended December 31, 2004, neither the Company nor any affiliated purchaser of the Company purchased shares of the Company's common stock.

**Item 6. Selected Financial Data**

The selected financial data set forth below has been derived from our audited consolidated financial statements. This information should be read in conjunction with the financial statements and the related notes thereto, Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 herein, and the Risks and Uncertainties section, and other financial information included elsewhere in this Annual Report on Form 10-K.

	For the years ended December 31,				
	2000	2001	2002	2003	2004
	(amounts in thousands, except share and per share information)				
<b>Statement of Operations Data:</b>					
Revenues	\$ 2,475	\$ 24,066	\$ 15,005	\$ 11,785	\$ 8,260
Loss from operations	(12,742)	(9,255)	(21,558)	(16,054)	(24,464)
Net loss	(12,191)	(9,745)	(22,697)	(17,273)	(25,920)
Basic and diluted per share information:					
Loss applicable to common stockholders	\$ (0.64)	\$ (0.43)	\$ (0.93)	\$ (0.58)	\$ (0.70)
Weighted average number of shares outstanding	19,015,719	22,670,274	24,433,868	29,852,797	36,926,034

	As of December 31,				
	2000	2001	2002	2003	2004
<b>Balance Sheet Data:</b>					
Total current assets.	\$ 17,036	\$ 25,027	\$ 6,242	\$ 32,062	\$ 23,937
Working capital	12,331	18,030	378	27,226	15,361
Total assets	56,529	67,115	57,505	84,159	77,993
Long term obligations	20,000	30,000	41,103	41,100	35,970
Stockholders' equity	31,824	27,493	8,073	35,944	33,281

**Summarized Quarterly Financial Information for the Fiscal Years ended December 31, 2004 and 2003:**

	Quarter Ended (in thousands except per share data) unaudited			
	March 31	June 30	September 30	December 31
2004				
Revenues	\$ 3,220	\$ 3,005	\$ (11)	\$ 2,046
Cost of sales	263	1,501	364	1,362
Research and development costs	3,047	1,229	1,552	1,539
Selling and marketing	2,774	5,556	8,931	6,327
General and administrative	2,032	2,059	1,901	2,724
Facility exit costs			723	
Gain on redemption of debt			(11,162)	

Net loss	(5,258)	(7,717)	(2,657)	(10,288)
Net loss per share	\$ (.15)	\$ (.22)	\$ (.07)	\$ (.26)

2003				
Revenues	\$ 1,194	\$ 2,275	\$ 4,269	\$ 4,047
Cost of sales	234	388	761	674
Research and development costs	2,365	2,792	2,554	2,347
Selling and marketing	2,156	1,917	2,003	1,714
General and administrative	1,840	1,810	1,911	2,373
Net loss	(5,802)	(5,028)	(3,361)	(3,082)
Net loss per share	\$ (.22)	\$ (.17)	\$ (.11)	\$ (.10)

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following discussion may contain statements that are not purely historical. Certain statements contained herein or as may otherwise be incorporated by reference herein constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding product sales, future product development and related clinical trials and statements regarding future research and development, including Food and Drug Administration approval. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements.

Such factors include, among other things, the following: general economic and business conditions; competition; unexpected changes in technologies and technological advances; ability to obtain rights to technology; ability to obtain and enforce patents; ability to commercialize and manufacture products; ability to establish and maintain commercial-scale manufacturing capabilities; ability to

enter into future collaborative arrangements with industry partners; results of clinical studies; progress of research and development activities; business abilities and judgment of personnel; availability of qualified personnel; changes in, or failure to comply with, governmental regulations; ability to obtain adequate financing in the future; and other factors referenced herein.

All forward-looking statements contained in this document are based on information available to the Company on the date hereof, and the Company assumes no obligation to update any such forward-looking statements, except as specifically required by law. Accordingly, past results and trends should not be used to anticipate future results or trends.

## Overview

Novavax is a fully-integrated specialty biopharmaceutical company focused on the research, development and commercialization of products utilizing our proprietary drug delivery and vaccine technologies for large and growing markets, concentrating on the areas of women's health and infectious diseases.

We currently market, sell and distribute a line of prescription pharmaceutical and prenatal vitamins through our national sales force, including our marketed product, ESTRASORB, the first topical emulsion for estrogen therapy. We completed the validation of the manufacturing facility for ESTRASORB in 2004 and are in full commercial manufacturing. In addition, we are conducting research and development on preventative vaccines and proteins, developing new products using our drug delivery technologies and expanding and consolidating our facilities.

Our micellar nanoparticle technology involves the use of patented oil and water nanoemulsions that we believe can be used as vehicles for the topical delivery of a wide variety of drugs and other therapeutic products, including hormones. We believe that our technologies represents the first time that hormones, such as estrogen and testosterone, have been encapsulated and delivered. In October 2003, we received our first commercial product approval utilizing our MNP technology. ESTRASORB was approved by the FDA for the treatment of moderate to severe vasomotor symptoms associated with menopause. The commercial launch of ESTRASORB occurred in the second quarter of 2004.

The approval by the FDA of ESTRASORB and the subsequent launch of the product have been major milestones for Novavax and have presented us with numerous current and future opportunities and challenges. In addition, in the third quarter of 2004 we reacquired the worldwide rights to ESTRASORB from King Pharmaceuticals, Inc. (See Developments in 2004 ). Since its launch, ESTRASORB prescription trends have not met our initial expectations. We attribute the slow start to the disruption of our marketing efforts as a result of the termination of the King relationship, the unanticipated simultaneous approval and launch of a competing product, the long lasting effects of the Women's Health Initiative Study, and an overall intensely competitive market. Despite the slow start, ESTRASORB is an important product and asset to us. The product has been well accepted by physicians who are prescribing it and patients that are using it. In order to grow the commercial sales of ESTRASORB worldwide, to internally develop products, identify partners for ESTRASORB or future products using our drug delivery vehicles, and to expand our total product lines, we are continuing to focus our efforts and financial resources on:

the further development of marketing plans and programs to effectively compete in the highly competitive estrogen therapy and women's health markets;

the effective deployment, sizing and optimization of our sales force and resources;

the manufacture of ESTRASORB at increasing commercial quantities and improved gross margins;

the identification and selection of worldwide partners for sales of ESTRASORB;

the acquisition or co-promotion of new products; and

the internal or partnered identification and development of future product candidates.

Following the approval of ESTRASORB, we raised approximately \$27.7 million in November 2003 through the public offering of 4,500,000 shares of common stock, and in July 2004 we raised approximately \$40.0 million through the private placement of \$35.0 million of convertible notes and the issuance of \$5.0 million of common stock (See

Developments in 2004 ). We may decide, or be required, to obtain additional financing, depending on the success of ESTRASORB and our marketing programs, the realization of our strategic objectives, and our success in identifying and developing product development candidates. Over the past two years we have added key senior management personnel in the areas of sales, marketing, human resources, vaccine development, manufacturing,

clinical and drug delivery product development. We will also continue to dedicate significant financial and human resources to create awareness about ESTRASORB and our unique drug delivery system.

In 2002, we entered into an agreement with Cardinal Health, Inc. to lease a 24,000 square foot facility within its existing facility in Philadelphia, Pennsylvania. We completed the validation of this facility and installation of the manufacturing equipment to accommodate commercial production of ESTRASORB early in 2004, and began full commercial manufacturing of the product in the second quarter of the year. This facility was designed to be able to produce commercial quantities that we believe could meet our marketing requirements for the next two to four years. However, due to the fixed costs associated with building and maintaining a facility for full capacity, until our production requirements reach higher levels, our costs of goods sold will be higher than industry averages. We believe we can significantly lower our costs of goods sold for ESTRASORB per unit and improve our margins as we increase production quantities and manufacturing efficiencies. In addition, we are making progress towards introducing alternative packaging solutions for ESTRASORB and to streamline and lower costs of production.

While a significant portion of our efforts will be placed on expanding the commercial sales potential of ESTRASORB and the development of future pharmaceutical products utilizing our proprietary drug delivery platform delivery system, we will continue to support and market our existing line of women's health products and look for opportunities to expand our products through the acquisition or further development of our prenatal vitamin line.

We also conduct research and development on preventative vaccines and proteins for infectious diseases and cancers, and tolerogens to prevent the initiation and progression of stroke, heart attack and other inflammatory diseases. Currently, the major impetus is the development and exploitation of the Company's core VLP technology, while continuing advances of more traditional vaccines. VLPs are genetically-engineered particles that imitate the important three-dimensional structures of viruses but are composed of recombinant proteins and therefore are believed incapable of causing infection and disease. Our proprietary production technology employs insect cells rather than eggs. We can more rapidly produce a safe, effective low-cost vaccine as compared with the labor-intensive egg-based process. Key advantages of the technology are the ability to rapidly respond to emerging threats or new strains and reduced risk allergic reaction. Projects in development using our proprietary VLP technology include vaccines for HIV, SARS, and pandemic and seasonal influenza. We are also developing E-Selectin tolerogen for the prevention of secondary strokes.

## **Developments in 2004**

In July 2004, we announced that we had agreed with King Pharmaceuticals, Inc. to terminate several license and co-promotion agreements, for ESTRASORB, which enabled us to obtain all rights worldwide for the product, and ANDROSORB, as well as all rights to other women's health products that we may successfully develop utilizing our drug delivery technology (the "King Transaction"). As part of the King Transaction, we also redeemed all of the \$40.0 million of convertible notes held by King. In return for the redemption of the notes and the termination of the license and co-promotion agreements, we paid King a net of \$14.0 million in cash and issued King 3,775,610 shares of our common stock, which shares were subsequently registered for resale.

The King Transaction resulted in a gain on the redemption of debt of \$11.2 million. This gain was determined based on the fair value of the convertible notes plus accrued interest as of the transaction date compared to the notes book value. In addition, an intangible asset for ESTRASORB rights of \$2.5 million was recorded, which represents the difference between assets and liabilities acquired or written off, the net cash paid in the transaction, the common stock issued and transaction fees and expenses. The intangible asset for ESTRASORB rights is being amortized over the patent life for ESTRASORB.

Concurrent with the King Transaction, in July 2004 the Company also entered into definitive agreements for the private placement of \$35.0 million aggregate principal amount of senior convertible notes to a group of institutional investors. The notes carry a 4.75% coupon, payable semi-annually, mature in five years and are generally convertible into shares of common stock at \$6.15 per share. From the third anniversary of the issue date of the notes, and subject to certain conditions, the Company shall have the right to effect a mandatory conversion of the notes if the weighted average price of the common stock exceeds 175% of the conversion price as of the issue date for each of 15 trading days out of any 30 consecutive trading days. Note holders shall have the right to require the Company to redeem all or a portion of the notes if the weighted average price of the common stock for each of 30 trading days out of 40 consecutive trading days prior to either the third or fourth anniversary of the issue date of the notes is less than the then applicable conversion price of the Company's common stock, *provided* that a holder's right to effect this optional redemption will not apply if certain revenue targets for ESTRASORB are achieved. The notes are also redeemable upon the occurrence of specified events of default as well as a change of control (as that term is defined in the notes) of Novavax. In addition, in July 2004 the Company issued 952,381 shares of common stock at \$5.25 per share, for gross proceeds of \$5.0 million, to an additional accredited investor. Aggregate gross proceeds of the notes and common stock issuances were \$40.0 million.



As a result of these transactions, we incurred \$3.4 million of transaction expenses, which increased the intangible asset for ESTRASORB rights by \$1.0 million (included in the total intangible asset of ESTRASORB rights of \$2.5 million), decreased additional paid-in capital by \$0.3 million, and increased deferred financing costs by \$2.1 million. The deferred financing costs will be amortized to interest expense over the life of the convertible notes.

In July 2004, we also entered into an agreement to lease a 32,900 square foot facility in Malvern, Pennsylvania, for the consolidation and expansion of corporate headquarters and to address the need for additional product development facilities. We moved out of our facility in Columbia, Maryland and into this new facility in September 2004. The majority of the cost of this move and the required leasehold improvements were funded by agencies of the Commonwealth of Pennsylvania. This facility move follows other facility consolidation efforts which began at the end of 2003. During 2005, we plan to have consolidated from six to four facilities, with our manufacturing in Philadelphia, Pennsylvania, vaccine development in Rockville, Maryland, corporate headquarters and product development in Malvern, Pennsylvania, and a research lab in Pacific Grove, California.

In July 2004, we announced that the National Institute of Allergy and Infectious Diseases, a component of the National Institutes of Health, had cancelled its five-year contract with the Company for the development of human immunodeficiency virus vaccine candidates due to programmatic considerations for the government's convenience. We had been the prime contractor, with Emory University, Tulane University, and the University of Pittsburgh as subcontractors. The cancellation is not expected to have a material financial impact and we expect to recover costs incurred to date in association with this contract. We also have a second HIV vaccine program funded by the NIH which was not impacted by this event.

### **Critical Accounting Policies and Changes to Accounting Policies**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base our estimates on historical and anticipated results and trends and on various other assumptions that we believe are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. By their nature, estimates are subject to an inherent degree of uncertainty. Actual results could differ, and actual results that do differ from our estimates could have a significant adverse effect on our operating results and financial position. We believe that the following significant accounting policies and assumptions may involve a higher degree of judgment and complexity than others.

For further discussion of our accounting policies see Note 3 *Summary of Significant Accounting Policies* in the Notes to the Consolidated Financial Statements included herewith.

#### *Revenue Recognition and Allowances*

We recognize revenue in accordance with the provisions of Staff Accounting Bulletin No. 104, *Revenue Recognition*. For our product sales, revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred to our distributor, the seller's price to the buyer is fixed or determinable and collectibility is reasonably assured. We recognize these sales net of allowances for returns, rebates and chargebacks. A large part of our product sales are to distributors who resell the products to their customers. We provide rebates to members of certain buying groups who purchase from our distributors, to distributors that sell to their customers at prices determined under a contract between us and the customer, and to state agencies that administer various programs such as the federal Medicaid and Medicare programs. Rebate amounts are usually based upon the volume of purchases or by reference to a specific price for a product. We estimate the amount of the rebate

that will be paid, and record the liability as a reduction of revenue when we record our sale of the products. Settlement of the rebate generally occurs from three to 12 months after sale. We regularly analyze the historical rebate trends and make adjustments to recorded reserves for changes in trends and terms of rebate programs. In a similar manner, we estimate amounts for returns based on historical trends, distributor and estimated wholesaler inventory levels and product prescription data and adjust those reserves as product returns occur.

A non-recurring reserve of \$1.3 million for anticipated returns of vitamins negatively impacted by generic competition was netted against product sales for 2004. We based this reserve on estimated current wholesaler inventory levels compared to projected demand until product expiration.

The shipping and handling costs we incur are included in cost of sales in the accompanying statements of operations.

For up-front payments and licensing fees related to our contract research or technology, we defer and recognize revenue as earned over the life of the related agreement. Milestone payments are recognized as revenue upon achievement of contract-specified events

and when there are no remaining performance obligations.

For 2004 and 2003, revenues earned under current research contracts were recognized per the terms and conditions of such contracts for invoicing of costs incurred and defined milestones. In 2002, revenue earned under research contracts was recognized on the percentage of completion method whereby revenue was recognized in proportion to the estimated percentage to complete the contract.

#### *Research and Development Costs*

Research and development costs are expensed as incurred. We will continue to incur research and development costs as we expand our product development activities in our women's health and vaccine programs. Our research and development costs have included, and will continue to include, expenses for internal development personnel, supplies and facilities, clinical trials, regulatory compliance and reviews, validation of processes and start-up costs to establish commercial manufacturing capabilities. At the time our new product candidates are approved by the FDA and we begin commercial manufacturing, we will allocate costs at our manufacturing location to inventory cost of sales. In 2004, we began allocating our costs to manufacture ESTRASORB to inventory and cost of sales. As a result, our research and development costs decreased and our inventory and cost of sales increased.

#### *Depreciation and Amortization*

Depreciation of furniture, fixtures and equipment is provided under the straight-line method over the estimated useful lives, generally three to 10 years. Amortization of leasehold improvements is provided over the estimated useful lives of the improvements or the term of the lease, whichever is shorter.

We have completed the build-out and validation to meet FDA requirements of our new manufacturing facility in Philadelphia. In addition, we purchased, validated and installed equipment for ESTRASORB manufacturing in 2004. The total investment in the facility and equipment is approximately \$13.8 million. We began recognizing amortization or depreciation on these assets with the later of when manufacturing for commercialization began in 2004 or when the specific equipment was validated and placed in service. The annualized amortization and depreciation expense is estimated to be \$1.8 million per year.

#### *Accounting for Facility Exit Costs*

In July 2004, the Company entered into a long-term agreement to lease a 32,900 square foot facility in Malvern, Pennsylvania for the consolidation and expansion of corporate headquarters and product development activities. The lease, with a commencement date of September 15, 2004, has an initial term of 10 years with two five-year renewal options. Standard annual escalation rental rates are in effect during the initial lease term. With advance notice, the Company also has an option to lease adjoining space of 17,000 square feet, which could be built out for future manufacturing needs.

The Company applied the principles of SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, in accounting for contract termination costs and associated costs that will continue to be incurred under the operating lease expiring on October 31, 2006 relating to its former corporate offices located in Columbia, Maryland. The Company recorded a liability of \$252,000 as of September 30, 2004 for the difference between the fair value of the remaining lease payments, reduced by current estimated sublease rentals that could be reasonably obtained and included the corresponding expense in facility exit costs. As of December 31, 2004 the remaining liabilities were \$200,000.

The Company applied the principles of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, and APB No. 20, *Accounting Changes*, in writing off the remaining useful lives of the leasehold assets relating to the Columbia facility. For the year ended December 31, 2004, \$471,000 was included in facility exit costs associated with the moving of corporate offices.

*Goodwill and Intangibles Assets*

Goodwill principally resulted from business acquisitions, such as the \$35.5 million of goodwill we recognized for our acquisition of Fielding Pharmaceuticals in December 2000. Assets acquired and liabilities assumed are recorded at their fair values; the excess of the purchase price over the identifiable net assets acquired is recorded as goodwill. Intangible assets other than goodwill are the result of product acquisitions, non-compete arrangements, and internally-discovered patents. Other assets are amortized on a straight-line basis over their estimated useful lives, ranging from five to 15 years. The Company periodically evaluates the periods of amortization to determine whether later events and circumstances warrant revised estimates of useful lives.

In June 2001, the Financial Accounting Standards Board issued SFAS No. 142, *Goodwill and Other Intangible Assets*, which is

effective for fiscal years beginning after December 15, 2001. Under these rules, goodwill and intangible assets deemed to have indefinite lives are no longer amortized but are subject to impairment tests annually or more frequently should indicators of impairment arise. Other intangible assets continued to be amortized over their useful lives beginning in the first quarter of 2002. The Company utilizes a discounted cash flow analysis, which includes profitability information, estimated future operating results, trends and other information in assessing whether the value of indefinite-lived intangible assets can be recovered. Under SFAS No. 142, goodwill impairment is deemed to exist if the carrying value of a reporting unit exceeds its estimated fair value. In accordance with the requirements of SFAS No. 142, the Company tested its goodwill for impairment as of January 1, 2002 and determined that no impairment was present. In the fourth quarters of 2002, 2003, and 2004, the Company performed the required annual impairment test on the carrying amount of its goodwill, which indicated the Company's estimated fair value of goodwill exceeded its carrying value; therefore, no impairment was identified at December 31, 2002, 2003 or 2004. If the appraisal had determined that the goodwill was impaired, the write down would have increased our net loss by a comparable amount.

### *Stock Options*

We apply the principles of APB No. 25, *Accounting for Stock Issued to Employees*, in accounting for stock options issued to our employees. APB No. 25 generally does not require that options granted to employees be expensed. Had we applied the fair value principles of SFAS No. 123, *Accounting for Stock-Based Compensation*, our net loss for the years ended December 31, 2004, 2003 and 2002 would have increased to approximately \$30.1 million, \$23.5 million and \$25.9 million, respectively, as compared to approximately \$25.9 million, \$17.3 million and \$22.7 million, respectively. The Financial Accounting Standards Board eliminated the alternative use of APB No. 25's intrinsic value method of accounting starting with the first interim reporting period that begins after June 15, 2005. We will be required to record the effect of applying this revision at such time.

During 2004, the Company granted stock options to purchase an aggregate 26,450 shares of common stock to two consultants as compensation for services in 2004. We included \$53,000 of non-cash stock compensation expense in sales and marketing expense, which represents the fair value as of the grant date.

### **Guarantee**

In April 2002, we executed a conditional guaranty of a brokerage margin account for a director, in the amount of \$500,000. Prior to demanding payment from the Company, the brokerage firm must first make demand for payment to the director and then liquidate the account. Thereafter, if there remains a shortfall, they may demand payment from the Company. As of December 31, 2004 and 2003, the Company has not recorded any liability on its balance sheet related to this guarantee as we believe the possibility of required payment by the Company to be unlikely.

### **Results of Operations for Fiscal Years 2004, 2003 and 2002 (In thousands, except percentage changes and share and per share information)**

#### **Revenues:**

	<b>2004</b>			<b>2003</b>			<b>2002</b>
		<b>Change from</b>			<b>Change from</b>		
		<b>2003</b>			<b>2002</b>		
<b>Revenues:</b>							
Vitamins (1)	\$ 2,285	\$ (3,418)	-60%	\$ 5,703	\$ (3,123)	-35%	\$ 8,826
Gynodiol	1,023	(1,181)	-54%	2,204	457	26%	1,747

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AVC line	940	(899)	-49%	1,839	(71)	-4%	1,910
ESTRASORB	1,792	1,792	100%				
Other	357	(106)	-23%	463	137	42%	326
Net product sales	6,397	(3,812)	-37%	10,209	(2,600)	-20%	12,809
Contract research	1,738	437	34%	1,301	330	34%	971
Milestone and licensing fees	125	(150)	-55%	275	(950)	-78%	1,225
	\$ 8,260	\$ (3,525)	-30%	\$ 11,785	\$ (3,220)	-21%	\$ 15,005

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(1) Includes a reserve in 2004 for anticipated returns of \$1.3 million.

Revenues for 2004 consisted of product sales of \$6.4 million, compared to \$10.2 million in 2003; contract revenues of \$1.7 million, compared to \$1.3 million in 2003; and milestone and licensing fees of \$0.1 million in 2004, compared to \$0.3 million in 2003. Total revenues for 2004 were \$8.3 million, as compared to \$11.8 million for 2003, a \$3.5 million or 30% decrease. Of the total decrease in revenues, product sales accounted for \$3.8 million. The reason for this net decrease is primarily due to:

An overall reduction in sales of prenatal vitamins, Gynodiol and AVC Cream, as well as increased returns for these products from our wholesalers. We feel the lower sales orders and the high volume of returns from our customers are primarily due to wholesaler orders in late 2002 and 2003 that projected product growth and could not anticipate the future effects of generic and new product competition on their inventory requirements.

A non-recurring reserve of \$1.3 million taken in 2004 for anticipated returns of vitamins negatively impacted by generic competition. We based this reserve on current estimated wholesaler inventory levels compared to projected demand until product expiration.

These decreases were offset by a \$1.8 million increase in sales of ESTRASORB during 2004. The commercial launch of ESTRASORB occurred during the quarter ended June 30, 2004 and initial shipments to wholesalers were \$1.5 million in June 2004.

Contract revenues increased by \$0.4 million or 34% primarily due to \$0.8 million we received from an NIH grant to develop a second generation AIDS vaccine, as well as, \$0.5 million we received from an NIH contract that was cancelled in July 2004 (see Developments in 2004 ). This increase in contract revenues was offset by the completion of several contracts in 2003.

Revenues for the fiscal year ended December 31, 2003 were \$11.8 million compared to \$15.0 million in 2002. This represents a year-to-year decrease of \$3.2 million, or 21%. Of the \$3.2 million total revenue decrease from 2002 to 2003, a decline in product sales accounted for \$2.6 million of that shortage. The product sales decrease was attributable to an overall decline in our prenatal vitamin lines due to generic competition, offset by slightly higher sales from the Gynodiol product line and the fourth quarter introduction of our new prenatal vitamins, NovaNatal and NovaStart. Milestone revenue decreased approximately \$1.0 million, primarily due to a one-time recognition of \$0.8 million on a milestone payment in 2002. Contract research revenue increased \$0.3 million from \$1.0 million in 2002 to \$1.3 million in 2003.

### **Operating Costs and Expenses:**

	<b>2004</b>			<b>2003</b>			
	<b>Change from</b>			<b>Change from</b>			<b>2002</b>
	<b>2003</b>			<b>2002</b>			
<b>Operating costs and expenses:</b>							
Cost of products sold	\$ 3,490	\$ 1,433	70%	\$ 2,057	\$ (1,502)	-42%	\$ 3,559
Research and development	7,369	(2,689)	-27%	10,058	(1,443)	-13%	11,501
Selling	10,981	3,423	45%	7,558	(993)	-12%	8,551
Marketing	12,607	12,375	5334%	232	(4,065)	-95%	4,297
General and administrative	8,716	782	10%	7,934	(721)	-8%	8,655
Facility exit costs	723	723	100%				
Gain on redemption of debt	(11,162)	(11,162)	-100%				
	\$ 32,724	\$ 4,885	18%	\$ 27,839	\$ (8,724)	-24%	\$ 36,563

### **Cost of Sales**

Cost of sales increased to \$3.5 million in 2004, compared to \$2.1 million in 2003, despite the decrease in product sales of \$3.8 million. The \$1.4 million increase was primarily due to the launch and sale of ESTRASORB in the

second quarter of 2004. ESTRASORB accounted for 21% of net product sales and carries a much higher cost of sales than our other products. In the initial periods of ESTRASORB production, the cost of sales percentages have been and will be unusually high until we increase production volumes to offset the fixed costs and depreciation related to the build-out of the manufacturing facility, on-going facility costs and costs associated with the minimum number of personnel required to manufacture the product. We are also making progress on the introduction of alternative packaging solutions to further streamline and lower costs of production. A high volume of returns for our products, other than ESTRASORB, in 2004 has also negatively affected our margins.

Cost of sales was \$2.1 million in 2003, compared to \$3.6 million in 2002. The year-to-year decrease was primarily due to decreases in product sales for the same periods. As a percentage of sales, cost of sales decreased to 20% in 2003 from 28% in 2002, due to product mix and sampling protocols which changed per the product mix year to year.



## Research and Development Expenses

Research and development costs decreased from \$10.1 million in 2003 to \$7.4 million in 2004. The decrease of \$2.7 million or 27% was due to manufacturing start-up costs in 2003 being accounted for in the research and development category until April 2004. The 2003 manufacturing costs were incurred to prepare and validate the ESTRASORB facility for good manufacturing practices and FDA compliance and not to build inventory. Beginning in April 2004, manufacturing costs have been included in cost of sales and inventory.

Research and development expenses were \$10.1 million in 2003, compared to \$11.5 million for 2002. The decrease of \$1.4 million, or 13%, was primarily attributable to decreased spending in our vaccines programs, offset slightly by increased spending on manufacturing start-up costs related to preparing our manufacturing facility for commercial production of ESTRASORB. The manufacturing start-up costs relate primarily to facility lease expenses, validation services, product stability testing and personnel costs.

### *Reconciliation of Significant Research and Development Projects*

The following table reconciles the direct and indirect costs incurred to date for our major projects to our total research and development expense.

<b>Project</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>
ESTRASORB	\$ 1,704	\$ 5,417	\$ 4,738
ANDROSORB	32	269	678
Vaccine contracts and research	3,183	3,001	3,755
Allocated project costs	4,919	8,697	9,171
Other unallocated costs	2,450	1,371	2,330
<b>Total</b>	<b>\$ 7,369</b>	<b>\$ 10,058</b>	<b>\$ 11,501</b>

### *Estimated Cost and Time to Complete Major Projects*

The expenditures that will be necessary to execute our business plan are subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. As of December 31, 2004, our proprietary product candidates were in early stages of development. Due to the inherent nature of product development, future market demand for products and factors outside of our control, such as clinical results and regulatory approvals, we are unable to estimate the completion dates and the estimated total costs for those product candidates. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical trial protocol, including, but not limited to, the following:

number of patients that ultimately participate in the trial;

duration of the patient follow-up that seems appropriate in view of the results;

number of clinical sites included in the trials; and

length of time required to enroll suitable patient subjects.

In addition, we test our potential products in numerous preclinical studies to identify, among other things, the daily dosage amounts. We may conduct multiple clinical trials to cover a variety of indications for each product candidate. As we obtain results for our trials we may elect to discontinue clinical trials for certain product candidates or indications. We further believe that it is not possible to predict the length of regulatory approval time. Factors that are outside our control could significantly delay the approval and marketability of our product candidates.

As a result of the uncertainties discussed above and other risks and uncertainties, the duration and completion costs of our research and development projects are difficult to estimate and are subject to numerous variations. Our inability to complete our research and development projects in a timely manner could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek external sources of financing from time to time in order to continue pursuing our business strategy. For more discussion of the risks and uncertainties and our liquidity, see **Risks and Uncertainties** and **Liquidity and Capital Resources**.

### **Selling Expenses**

Selling expenses were \$11.0 million in 2004 compared to \$7.6 million in 2003. The increase of \$3.4 million, or 45%, was

primarily due to the addition of 50 sales personnel resulting from the termination of our co-promotion agreements with King in July 2004 and the hiring of King sales personnel.

Selling expenses were \$7.6 million in 2003 compared to \$8.6 million in 2002. With the initial anticipation of the FDA's approval of ESTRASORB in 2002, the Company began incurring selling costs associated with the product launch. Later, the Company withdrew its application, which resulted in the decrease in selling costs for 2003.

### **Marketing Expenses**

Marketing expenses were \$12.6 million in 2004 compared to \$0.2 million in 2003. The increase of \$12.4 million, or 5334%, was due to the 2004 product launch advertising and promotion for ESTRASORB, as well as increases in marketing personnel.

Marketing expenses were \$0.2 million in 2003 compared to \$4.3 million in 2002. With the initial anticipation of the FDA's approval of ESTRASORB in 2002, the Company began incurring marketing costs to actively develop marketing materials and programs for the product launch. When the Company withdrew its application, all further marketing costs were stopped.

### **General and Administrative**

General and administrative costs were \$8.7 million in 2004 compared to \$7.9 million in 2003. The \$0.8 million increase, or 10%, is primarily due to increases in accounting and consulting fees related to the implementation of internal control evaluation and reporting procedures as required by the Sarbanes-Oxley Act of 2002, as well as other increases in legal, insurance and facility expenses.

General and administrative expenses were \$7.9 million in 2003 and \$8.7 million in 2002. The reduction of \$0.8 million in 2003 over 2002 was due to major reductions in administrative and executive personnel and other expenses in the second half of 2002, resulting from the delay in the approval of ESTRASORB. These reductions continued through the third quarter of 2003, at which time we began rehiring in anticipation of the approval of ESTRASORB.

### **Other**

A one time charge for facility exit costs of \$0.7 million was recorded in 2004. As previously described, in September 2004 we moved to Malvern, Pennsylvania for the consolidation and expansion of corporate headquarters and product development activities. We vacated our facility in Columbia, Maryland and recorded a liability of \$0.2 million for contract termination costs and wrote-off the net value of the Columbia leasehold assets of \$0.5 million.

The one time gain on the redemption of debt of \$11.2 million we recorded in 2004 relates to the King Transaction (See Developments in 2004 ).

### **Interest Income/ (Expense):**

	<b>2004</b>	<b>2003</b>	
	<b>Change from</b>	<b>Change from</b>	
	<b>2003</b>	<b>2002</b>	<b>2002</b>
<b>Interest income (expense)</b>			

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Interest income	\$ 318	\$ 123	-63%	\$ 195	\$ (41)	-21%	\$ 200
Interest expense	(1,844)	(430)	30%	(1,414)	(39)	3%	(1,339)
	\$ (1,526)	\$ (307)	25%	\$ (1,219)	\$ (80)	7%	\$ (1,139)

Net interest expense was \$1.5 million in 2004, \$1.2 million in 2003, and \$1.1 million in 2002. Our interest expense relates primarily to the promissory notes with King of \$40.0 million in 2002 through July 2004, at which time these notes were redeemed and we issued new convertible notes totaling \$35.0 million to a group of institutional investors. Net interest expenses remained relatively unchanged from 2003 to 2002.

**Net Losses:**

	<b>2004</b>			<b>2003</b>			<b>2002</b>		
		<b>Change from</b>		<b>Change from</b>		<b>Change from</b>		<b>Change from</b>	
		<b>2003</b>		<b>2002</b>		<b>2002</b>		<b>2002</b>	
<b>Net loss</b>	\$	(25,920)	\$ (8,647)	-50%	\$	(17,273)	\$ 5,424	24%	\$ (22,697)
<b>Net loss per share</b>	\$	(0.70)	\$ (0.12)	-21%	\$	(0.58)	\$ 0.35	38%	\$ (0.93)

**Weighted shares  
outstanding**

36,926,034

29,852,797

24,433,868

Net loss for 2004 was \$25.9 million or \$(0.70) per share, as compared to \$17.3 million or \$(0.58) per share for 2003, an increase of \$8.6 million, or \$0.12 per share. The increased loss was due to the gain on redemption of debt of \$11.2 million, offset by a decrease in revenues of \$3.5 million, \$0.7 million for facility exit costs and an increase in other operating expenses of \$15.3 million, all previously discussed.

Net loss for 2003 was \$17.3 million, or \$(0.58) per share, compared to \$22.7 million, or \$(0.93) per share for 2002. The decreased loss of \$5.4 million from 2002 to 2003 related primarily to the \$5.1 million reduction of sales and marketing expenses that was incurred in 2002 principally for the anticipated product launch of ESTRASORB, \$0.7 million reductions in general and administrative expenses for similar reasons, \$1.4 million reductions in research and development, as described above, offset by revenue reductions of \$3.2 million, as previously discussed.

**Liquidity and Capital Resources**

Our capital requirements depend on numerous factors, including but not limited to product sales and returns, the ability to gain market share for ESTRASORB, the marketing and manufacturing costs of ESTRASORB, the commitments and progress of our research and development programs, the progress of preclinical and clinical testing, the time and costs involved in obtaining regulatory approvals, the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, and changes in our development of commercialization activities and arrangements. We plan to have multiple products in various stages of product development and we believe our research and development as well as selling, marketing and general administrative expenses and capital requirements will continue to increase. Future activities, including the potential expansion of sales and marketing personnel and programs, increases in commercial-scale manufacturing capabilities and product development are subject to our ability to raise funds through debt or equity financing, or collaborative arrangements with industry partners.

**Year ended  
December 31,  
2004  
(in thousands)**

**Summary of Cash Flows:**

Net cash (used) provided by:

Operating activities

\$ (30,099)

Investing activities	(1,608)
Financing activities	21,950
Net change in cash and cash equivalents	(9,757)
Beginning cash and cash equivalents	27,633
Ending cash and cash equivalents	\$ 17,876

In addition to product and contract research revenues of \$35.1 million from 2002 through December 31, 2004, we have financed our operations primarily from:

<b>(In Millions)</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>Total</b>
Net proceeds from issuance of convertible notes	\$	\$	\$ 32.9	\$ 32.9
Net proceeds associated with the King Transaction			(15.0)	(15.0)
Net proceeds from sale of common stock to an accredited investor			4.7	4.7
Net proceeds from notes with King	9.4			9.4
Private placement of 4,750,000 shares of common stock		16.6		16.6
Public offering of 4,500,000 shares of common stock		25.9		25.9
Net proceeds from exercise of stock options and warrants	2.9	1.6	0.4	4.9
	\$ 12.3	\$ 44.1	\$ 23.0	\$ 79.4

Cash and cash equivalents were \$17.9 million at December 31, 2004, a decrease of \$9.7 million from the December 31, 2003 balance of \$27.6 million. The King Transaction and the financings in July 2004, as previously discussed, added over \$22.6 million to our cash balance, reduced our debt by \$5.0 million and extended our debt terms. Of the \$9.7 million of cash used in 2004, \$30.1 million was used for operating activities, \$1.6 million for investing activities and a net \$22.0 million was obtained from financing activities. Operating activities consisted of the net loss of \$25.9 million, as previously discussed, and non-cash activities of \$(6.9) million, including the \$11.2 million gain on the redemption of debt, offset by \$2.7 million of net changes in balance sheet accounts. Cash used in investing activities consisted primarily of capital expenditures associated with the validation of our manufacturing facility for ESTRASORB and \$0.4 million of costs for the new corporate office leasehold improvements (See Developments in 2004 ). In the future, we expect similar or even greater cash needs as we anticipate additional hires for production, sales and marketing, as well as increased marketing costs for ESTRASORB, particularly in light of the termination of our co-promotion agreements with King. Additionally, as we approach full production capacity, increased inventory needs will reduce our operating funds. Working capital was \$15.4 million at December 31, 2004 compared to \$27.1 million at December 31, 2003. The decrease in working capital of \$11.7 million, or 43% was primarily due to the \$30.1 million used for operating activities, offset by the new cash of \$22.6 million from the King and financing transactions in July of 2004.

As noted in the Overview, we received FDA approval for ESTRASORB in October 2003 and the commercial launch of ESTRASORB occurred in the second quarter of 2004. During 2004, we incurred substantial selling, marketing and manufacturing expenses associated with the initial year of commercial production, including recruiting and retaining personnel and developing marketing programs necessary for the sale of ESTRASORB. In addition, our first year sales of ESTRASORB were below our initial expectations. We did not receive any receipts from product sales of ESTRASORB until a few months after the initial shipments, and our projected 2005 sales for ESTRASORB and subsequent cash receipts likely will not offset the 2005 expenses and cost of manufacturing. In addition to the costs related to ESTRASORB, we may incur increasing costs in 2005 to build our organization and to develop our other product candidates that will utilize our drug delivery technologies.

The Company will continue to pursue obtaining capital through co-promotion arrangements, product licensing or the public or private sale of securities of the Company. The Company has demonstrated our ability to obtain capital, as required, however, there can be no assurance that we will be able to obtain additional capital or, if such capital is available, that the terms of any financing will be satisfactory to the Company. Based on our assessment of the availability of capital and our business operations as currently contemplated, in the absence of new financings, licensing arrangements or partnership agreements, we believe we will have adequate resources for the third quarter of 2005. If we are unable to obtain additional capital, we will continue to assess our capital resources and based on those resources we may be required to delay, reduce the scope of, or eliminate one or more of our product research and development programs, downsize our organization, reduce or defer our marketing expenses, or reduce general and administrative infrastructure. See Note 2 Management's Plans Related to Liquidity and Capital Needs.



*Contractual Obligations and Commitments*

The following table summarizes our current obligations and commitments (in thousands) as of December 31, 2004:

		Less than 1 Year	1 - 3 Years	4 - 5 Years	After 5 Years
<b>Commitments &amp; Obligations</b>	<b>Total</b>				
Convertible notes	\$ 35,000	\$	\$	\$ 35,000	\$
Operating leases	5,147	1,189	1,530	672	1,756
Financing leases	1,962	1,070	434	445	13
Manufacturing facility lease	3,460	1,700	1,760		
Total commitments & obligations	\$ 45,569	\$ 3,959	\$ 3,724	\$ 36,117	\$ 1,769

*Off-balance sheet arrangements*

The Company is not in any off-balance-sheet agreements that have or are reasonably likely to have a material future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

The Company is exposed to interest rate risk primarily through its investments in cash equivalents. The Company's investment policy requires investments in short-term, low-risk instruments. At December 31, 2004, the Company had \$17.9 million in cash and cash equivalents. If interest rates fall, floating rate securities will generate less interest income. The Company does not believe that it is exposed to any material interest rate risk as a result of its investments in cash equivalents.

At December 31, 2004, the Company had a total debt of \$37.2 million, most of which bears interest at fixed interest rates. The Company therefore does not believe that it is exposed to any material interest rate risk as a result of its borrowing activities.

Information required under this section is also contained in Part I, Item I of this report under the caption Risk and Uncertainties and in Item 8 of this report, and is incorporated herein by reference.

**Item 8. Financial Statements and Supplementary Data**

The financial statements and notes thereto listed in Item 15 Exhibits, Financial Statement Schedules, are filed as part of this Annual Report on Form 10-K and are incorporated herein by reference. Supplementary data thereto included in Item 6 Selected Financial Data, is incorporated herein by reference.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

Not applicable.

**Item 9A. Controls and Procedures**

## **Evaluation of Disclosure Controls and Procedures**

The Company's chief executive officer and chief financial officer have reviewed and evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this annual report. Based on that review and evaluation, which included the participation of management and certain other employees of the Company, the chief executive officer and chief financial officer have concluded that the Company's current disclosure controls and procedures, as designed and implemented, are reasonably adequate to ensure that such officers are provided with information relating to the Company required to be disclosed in the reports the Company files or submits under the Exchange Act and that such information is recorded, processed, summarized and reported within the specified time periods.

## **Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal

control over financial reporting as of December 31, 2004 based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included elsewhere herein.

#### **Changes in Internal Control over Financial Reporting**

During the year, the Company took the necessary actions necessary to fully comply with all criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). As part of this process, the Company increased and/or tightened internal control over financial reporting. None of the changes in our internal control over financial reporting materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Item 9B. Other Information**

Not applicable.

**PART III****Item 10. Directors and Executive Officers of the Registrant**

Certain of the information required by this item is set forth below. The remainder is contained in our Definitive Proxy Statement for our 2005 Annual Meeting of Stockholders to be held on May 4, 2005 (the 2005 Proxy Statement ) under the caption Proposal One Election of Directors and is incorporated herein by this reference. We expect to file the 2005 Proxy Statement within 120 days after the close of the fiscal year ended December 31, 2004.

**Executive Officers of the Registrant**

Our executive officers hold office until the first meeting of the Board of Directors following the annual meeting of stockholders and until their successors are duly chosen and qualified, or until they resign or are removed from office in accordance with our By-laws.

The following table provides certain information with respect to our executive officers.

Name	Age	Principal Occupation and Other Business Experience During the Past Five Years
Nelson M. Sims	57	President, Chief Executive Officer and a Director of Novavax since August 2003. Executive management positions at Eli Lilly included Executive Director of Strategic Alliance Management for Eli Lilly and Company from November 1999 to June 2001, President of Eli Lilly Canada Inc. from January 1991 to November 1999, and Vice President of Hybritech, Inc., a Lilly subsidiary. Currently a director of MDS, Inc.
Denis M. O'Donnell, M.D.	51	Chairman of the Board of Directors of Novavax since May, 2000. Chief Executive Officer and President of Molecular Diagnostics, Inc. since February 2004. General Partner at Seaside Partners, LP, a private equity firm, from 1997 to 2003. Vice Chairman of the Board of Directors of Novavax, Inc. from June 1999 to May 2000. Senior Advisor to Novavax from 1997 to 1998. President of Novavax from 1995 to 1997. Currently a director of Columbia Laboratories, Inc., ELXSI Corporation and Molecular Diagnostics, Inc.
Dennis W. Genge	52	Vice President, Chief Financial Officer and Treasurer of Novavax since October 2000. Vice President and Controller of Pyxis Corporation from April 1999 to September 2000. Executive Director of Accounting and Finance and Controller of Ligand Pharmaceuticals, Inc. from July 1991 to March 1999.
Ford R. Lynch	58	Senior Vice President of Sales and Marketing of Novavax since October 2003. Area Director, Women's Health

Products, Eli Lilly and Company from 1998 to 2003. Area Director, CNS Division, Eli Lilly and Company from 1992 to 1998. Director of Marketing and Sales, Eli Lilly Canada, Inc. from 1985 to 1992.

### **Code of Ethics**

The Company has adopted a Code of Business Conduct and Ethics applicable to its principal executive officer, principal financial officer, controller, and persons performing similar functions, and has made the code an exhibit to its Annual Report on Form 10-K for the 2003 Fiscal Year ended December 31, 2003. The Code is also available, and the Company will file and post a current report on Form 8-K for amendments to and waivers of its Code for its principal executive and financial officers, on its website at [www.novavax.com](http://www.novavax.com).

**Item 11. Executive Compensation**

The information required by this item is contained in the 2005 Proxy Statement under the captions Executive Compensation and Proposal One Election of Directors and is incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

Certain of the information required by this item is contained in the 2005 Proxy Statement under the captions Beneficial Ownership of Common Stock and Executive Compensation Stock Options and is incorporated herein by reference.

The following table provides the Company's equity compensation plan information as of December 31, 2004. Under these plans, the Company's common stock may be issued upon the exercise of options. See also the information regarding stock options of the Company in Note 10, Stock Options and Warrants to the Consolidated Financial Statements included herewith.

**Equity Compensation Plan Information**

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights (b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)</b>
Equity compensation plans approved by security holders (1)	5,331,968	\$ 5.41	980,224
Equity compensation plans not approved by security holders	70,000(2)	\$ 6.00	
Total	5,401,968	\$ 5.42	980,224

(1) Includes the Company's 1995 Stock Option Plan and 1995 Director Stock Option Plan.

(2) Amount relates to a warrant issued to a consultant in 2002 to purchase 70,000 shares of common stock at an exercise price of \$6.00 per share. The warrant expires in August 2005.

**Item 13. Certain Relationships and Related Transactions**

The information required by this item is contained in the 2005 Proxy Statement under the caption "Proposal One Election of Directors Certain Relationships and Related Transactions" and is incorporated herein by reference.

**Item 14. *Independent Registered Public Accounting Firm Fees and Services***

The information required by this item is contained in the 2005 Proxy Statement under the caption "Proposal Four Ratification of Appointment of Independent Registered Public Accounting Firm" and is incorporated herein by reference.

## **PART IV**

### **Item 15. Exhibits, Financial Statement Schedules**

(a)(1) Financial Statements:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2004 and 2003

Consolidated Statements of Operations for the years ended December 31, 2004, 2003 and 2002

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2004, 2003 and 2002

Consolidated Statements of Cash Flows for the years ended December 31, 2004, 2003 and 2002

Notes to Consolidated Financial Statements

(a)(2) Financial Statement Schedules:

Schedules are either not applicable or not required because the information required is contained in the financial statements or notes thereto. Condensed financial information of Novavax is omitted since there are no substantial amounts of restricted net assets applicable to Novavax's wholly-owned, consolidated, subsidiary.

(a)(3) Exhibits:

Exhibits marked with a single asterisk (\*) are filed herewith.

Exhibits marked with a double plus sign (++) refer to management contracts, compensatory plans or arrangements.

All other exhibits listed have previously been filed with the Commission and are incorporated herein by reference.

- 3.1 Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1996, File No. 0-26770, filed March 21, 1997 (the "1996 Form 10-K"), as amended by the Certificate of Amendment dated December 18, 2000 (Incorporated by reference to Exhibit 3.4 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000, File No. 0-26770, filed March 29, 2001 (the "2000 Form 10-K"), as further amended by the Certificate of Amendment dated July 8, 2004 (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2004, File No. 0-26770, filed August 9, 2004 (the "2004 2Q form 10-Q"))
- 3.2 Amended and Restated By-Laws of the Company (Incorporated by reference to Exhibit 3.5 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2001, File No. 0-26770, filed August 13, 2001 (the "2001 Q2 Form 10-Q"))



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- 4.1 Specimen stock certificate for shares of common stock, par value \$.01 per share (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 10, File No. 0-26770, filed September 14, 1995 (the "Form 10"))
- 4.2 Rights Agreement, dated as of August 8, 2002, by and between the Company and Equiserve Trust Company, which includes the Form of Summary of Rights to Purchase Series D Junior Participating Preferred Stock as Exhibit A, the Form of Right Certificate as Exhibit B and the Form of Certificate of Designation of Series D Junior Participating Preferred Stock as Exhibit C (Incorporated by reference to Form 8-K of the Company, File No. 000-26770, filed August 9, 2002)
- 4.3 Registration Rights Agreement, dated as of July 19, 2004, by and between the Company and King Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 4.8 to the Registration Statement on Form S-3, File No. 333-118181, filed August 12, 2004)
- 4.4 Registration Rights Agreement, dated as of July 16, 2004, by and between the Company and the Buyers identified therein (Incorporated by reference to Exhibit 4.7 to the Registration Statement on Form S-3, File No. 333-118210, filed August 13, 2004)

- 10.1 Novavax, Inc. 1995 Stock Option Plan, as amended (Incorporated by reference to Appendix A of the Company's Proxy Statement in connection with the Annual Meeting held on May 7, 2003)
- 10.2 Novavax, Inc. 1995 Director Stock Option Plan (Incorporated by reference to Exhibit 10.5 to the Form 10)
- 10.3 Employment Agreement, dated January 1, 2002, by and between the Company and Dennis W. Genge (Incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, File No. 0-26770, filed March 15, 2002 (the 2001 Form 10-K))
- 10.4 Employment Letter, dated September 24, 2003, by and between the Company and Ford R. Lynch (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003, File No. 000-26770, filed November 12, 2003)
- 10.5 Employment Agreement, dated August 7, 2003, by and between the Company and Nelson M. Sims (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, File No. 000-26770, filed August 13, 2003)
- 10.6 Secured Promissory Note, dated March 21, 2002, by and between the Company and Mitchell J. Kelly (Incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, File No. 0-26770, filed March 28, 2003 (the 2002 Form 10-K))
- 10.7 Pledge Agreement, dated March 21, 2002, by and between the Company and Mitchell J. Kelly (Incorporated by reference to Exhibit 10.10 to the 2002 Form 10-K)
- 10.8 Secured Promissory Note, dated March 21, 2002, by and between the Company and Denis M. O'Donnell, M.D. (Incorporated by reference to Exhibit 10.11 to the 2002 Form 10-K)
- 10.9 Pledge Agreement, dated March 21, 2002, by and between the Company and Denis M. O'Donnell, M.D. (Incorporated by reference to Exhibit 10.12 to the 2002 Form 10-K)
- 10.10 Guaranty of Account, dated April 29, 2002, by and between the Company and CIBC World Markets Corporation for Denis M. O'Donnell, M.D. (Incorporated by reference to Exhibit 10.13 to the 2002 Form 10-K)
- 10.11 Agreement of Lease, dated September 25, 1996, by and between the Company and Rivers Center Associates Limited Partnership (Incorporated by reference to Exhibit 10.7 to the 1996 Form 10-K)
- 10.12 Agreement of Lease, dated March 30, 1995, by and between W.M. Rickman Construction Co. and DynCorp Advanced Technology Services, Inc., as assigned to the Company by letter from W.M. Rickman Construction Co. dated September 1, 1999, and as amended by letter from the Company dated September 29, 1999 (Incorporated by reference to Exhibit 10.10 to the 2001 Form 10-K)
- 10.13 Agreement of Lease, dated March 8, 2002, by and between Association of Entrepreneurs Sciences, Inc. and the Company (Incorporated by reference to Exhibit 10.12 to the 2001 Form 10-K)
- 10.14 Facilities Reservation Agreement, dated as of February 11, 2002, by and between the Company and Packaging Coordinators, Inc. (Incorporated by reference to Exhibit 10.13 to the 2001 Form 10-K)

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- 10.15 Lease Agreement, dated as of July 15, 2004, between Liberty Property Limited Partnership and the Company (Incorporated by reference to Exhibit 10.1 to the 2004 2Q Form 10-Q)
- 10.16 License Agreement between IGEN, Inc. and Micro-Pak, Inc. (Incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1995, File No. 0-26770, filed April 1, 1996)
- 10.17 Agreement for Purchase and Sale of Assets Relating to AVCTM Product Line, dated as of January 8, 2001, by and between the Company and King Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed January 19, 2001)

- 10.18 Note, dated December 20, 2002, by and between the Company and PIDC Local Development Corporation (Incorporated by reference to Exhibit 10.35 to the 2002 Form 10-K)
- 10.19 Security Agreement, dated December 20, 2002, by and between the Company and PIDC Local Development Corporation (Incorporated by reference to Exhibit 10.36 to the 2002 Form 10-K)
- 10.20 Note, dated December 20, 2002, by and between the Company and PIDC Local Development Corporation (Incorporated by reference to Exhibit 10.37 to the 2002 Form 10-K)
- 10.21 Security Agreement, dated December 20, 2002, by and between the Company and PIDC Local Development Corporation (Incorporated by reference to Exhibit 10.38 to the 2002 Form 10-K)
- 10.22 Common Stock Purchase Agreement, dated as of February 17, 2003, by and among the Company and the purchasers named therein (Incorporated by reference to Exhibit 99.2 to the Company's Current Report on form 8-K, filed February 25, 2003)
- 10.23 HIV Vaccine Design and Development Agreement, effective September 26, 2003, by and between the Company and the National Institute of Allergy and Infectious Diseases, a component of the National Institutes of Health, an agency of the Department of Health and Human Services (Incorporated by reference to Exhibit 10.38 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, filed March 15, 2004)
- 10.24 Common Stock Purchase Agreement, dated as of July 16, 2004, between the Company and Joseph R. Gregory. (Incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K, filed July 19, 2004)
- 10.25 Securities Purchase Agreement, dated as of July 16, 2004, between the Company and Smithfield Fiduciary LLC, SF Capital Partners LTD, Portside Growth and Opportunity Fund, Winchester Global Trust Company Limited as Trustee for Caduceus Capital Trust, Caduceus Capital II, L.P., UBS Eucalyptus Fund, L.L.C., PW Eucalyptus Fund, LTD., HFR SHC Aggressive Fund, Finsbury Worldwide Pharmaceutical Trust and Deutsche Bank AG London (Incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K, filed July 19, 2004)
- 10.26 Form of Senior Convertible Note (Incorporated by reference to Exhibits 99.4 to the Company's Current Report on Form 8-K, filed July 19, 2004)
- 10.27 Exchange Agreement, dated July 16, 2004, between the Company, King Pharmaceuticals, Inc. and Parkedale Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 99.5 to the Company's Current Report on Form 8-K, filed July 19, 2004)
- 10.28 Termination Agreement, dated as of July 16, 2004 among King Pharmaceuticals, Inc., Parkedale Pharmaceuticals, Inc. and the Company (Incorporated by reference to Exhibit 99.6 to the Company's Current Report on Form 8-K, filed July 19, 2004)
- 14 Code of Business Conduct and Ethics (Incorporated by reference to Exhibit 14 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, filed March 15, 2004)

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List of Subsidiaries (Incorporated by reference to Exhibit 21 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, filed March 15, 2004)

- \*23 Consent of Independent Registered Public Accounting Firm
- \*31.1 Certification of principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- \*31.2 Certification of principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- \*32.1 Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Nelson M. Sims, President and Chief Executive Officer of the Company
- \*32.2 Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Dennis W. Genge, Vice President and Chief Financial Officer of the Company

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 15, 2005

NOVAVAX, INC.

By: /s/ Nelson M. Sims

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
<u>/s/ NELSON M. SIMS</u> Nelson M. Sims	President and Chief Executive Officer and Director	March 15, 2005
<u>/s/ DENNIS W. GENGE</u> Dennis W. Genge	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2005
<u>/s/ SUSAN B. BAYH</u> Susan B. Bayh	Director	March 15, 2005
<u>/s/ GARY C. EVANS</u> Gary C. Evans	Director	March 15, 2005
<u>/s/ MITCHELL J. KELLY</u> Mitchell J. Kelly	Director	March 15, 2005
<u>/s/ J. MICHAEL LAZARUS, M.D.</u> J. Michael Lazarus, M.D.	Director	March 15, 2005
<u>/s/ JOHN O. MARSH, JR.</u> John O. Marsh, Jr.	Director	March 15, 2005

<u>/s/ MICHAEL A. MCMANUS</u>	Director	March 15, 2005
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Michael A. McManus

<u>/s/ DENIS M. O DONNELL, M.D.</u>	Director	March 15, 2005
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Denis M. O Donnell, M.D.

<u>/s/ RONALD H. WALKER</u>	Director	March 15, 2005
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Ronald H. Walker

**INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**Years ended December 31, 2004, 2003 and 2002**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders of  
Novavax, Inc.

We have audited the accompanying consolidated balance sheets of Novavax, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Novavax, Inc. at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the financial statements, the Company's recurring losses from operations and negative cash flows from operations raise substantial doubt about its ability to continue as a going concern. Management's plans as to these matters are also described in Note 2. The 2004 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Novavax, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

March 11, 2005  
Philadelphia, Pennsylvania

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders of  
Novavax, Inc.

We have audited management's assessment, included in Item 9A. Controls and Procedures; Management's Report on Internal Control over Financial Reporting, that Novavax Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Novavax Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Novavax Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Novavax Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Novavax Inc. as of December 31, 2004 and 2003 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004 of Novavax, Inc. and our report dated March 11, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

March 11, 2005  
Philadelphia, Pennsylvania

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**NOVAVAX, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share information)

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 17,876	\$ 27,633
Trade accounts receivable, net allowance for doubtful accounts of \$752 and \$376 for the years ended December 31, 2004 and 2003	827	1,960
Inventory, net	3,464	855
Prepaid expenses and other current assets	1,770	1,614
Total current assets	23,937	32,062
Property and equipment, net	14,147	15,244
Goodwill, net	33,141	33,141
Other intangible assets, net	5,048	3,310
Other non-current assets	1,720	402
Total assets	\$ 77,993	\$ 84,159
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,242	\$ 2,342
Accrued expenses	4,140	1,179
Deferred revenue - current		250
Current portion of capital lease obligations and other liabilities	1,194	1,065
Total current liabilities	8,576	4,836
Convertible notes	35,000	40,000
Deferred revenue - non-current		2,125
Deferred rent	166	154
Non-current portion of capital lease obligations and other liabilities	970	1,100
Stockholders' equity:		
Preferred stock, \$.01 par value, 2,000,000 shares authorized; no shares issued and outstanding		
Common stock, \$.01 par value, 100,000,000 shares authorized; 39,807,724 issued and 39,553,876 outstanding at December 31, 2004, and 34,972,183 issued and 34,718,335 outstanding at December 31, 2003	398	349
Additional paid-in capital	167,496	144,288
Notes receivable from directors	(1,480)	(1,480)
Accumulated deficit	(130,720)	(104,800)
Treasury stock, 253,848 shares, cost basis, at December 31, 2004 and 2003, respectively	(2,413)	(2,413)

Total stockholders' equity	33,281	35,944
Total liabilities and stockholders' equity	\$ 77,993	\$ 84,159

See accompanying notes.

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**NOVAVAX, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share information)

	<b>For the years ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Revenues			
Net product sales	\$ 6,397	\$ 10,209	\$ 12,809
Contract research and development	1,738	1,301	971
Milestone and licensing fees	125	275	1,225
Total revenues	8,260	11,785	15,005
Operating costs and expenses:			
Cost of products sold	3,490	2,057	3,559
Research and development	7,369	10,058	11,501
Selling and marketing	23,588	7,790	12,848
General and administrative	8,716	7,934	8,655
Facility exit costs	723		
Gain on redemption of debt	(11,162)		
Total operating costs and expenses	32,724	27,839	36,563
Loss from operations	(24,464)	(16,054)	(21,558)
Interest expense, net	(1,526)	(1,219)	(1,139)
Other Income	70		
Net loss	\$ (25,920)	\$ (17,273)	\$ (22,697)
Basic and diluted loss per share	\$ (0.70)	\$ (0.58)	\$ (0.93)
Basic and diluted weighted average number of common shares outstanding	36,926,034	29,852,797	24,433,868

See accompanying notes.

**NOVAVAX, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**For the Years Ended December 31, 2004, 2003 and 2002**  
(in thousands, except share information)

	<b>Common Stock</b>		<b>Additional Paid-in Capital</b>		<b>Note Receivable From Directors</b>	<b>Accumulated Deficit</b>	<b>Treasury Stock</b>	<b>Total Stockholder Equity</b>
	<b>Shares</b>	<b>Dollars</b>	<b>Capital</b>					
<b>Balance, December 31, 2001</b>	<b>23,871,794</b>	<b>\$ 239</b>	<b>\$ 97,861</b>	<b>\$</b>	<b>\$</b>	<b>(64,830)</b>	<b>\$ (5,777)</b>	<b>\$ 27,493</b>
Exercise of stock options and warrants	987,998	9	4,392					4,401
Warrants issued as compensation			108					108
Notes receivable from directors				(1,480)				(1,480)
Shares issued to Fielding shareholders	362,318	4						4
Shares issued to King							232	232
Shares issued to 401K plan							12	12
Net loss						(22,697)		(22,697)
<b>Balance, December 31, 2002</b>	<b>25,222,110</b>	<b>\$ 252</b>	<b>\$ 102,361</b>	<b>\$ (1,480)</b>	<b>\$</b>	<b>(87,527)</b>	<b>\$ (5,533)</b>	<b>\$ 8,073</b>
Exercise of stock options	506,000	5	1,816				(212)	1,609
Shares retired	(5,927)		(31)				31	
Sales of common stock	9,250,000	92	42,385					42,477
Shares issued to King and other non-cash expense			(2,242)				3,300	1,058
Net loss						(17,273)		(17,273)
<b>Balance, December 31, 2003</b>	<b>34,972,183</b>	<b>\$ 349</b>	<b>\$ 144,288</b>	<b>\$ (1,480)</b>	<b>\$</b>	<b>(104,800)</b>	<b>\$ (2,413)</b>	<b>\$ 35,944</b>
Exercise of stock options	107,550	1	368					369
Stock options issued as compensation			53					53
Shares issued for King Transaction	3,775,610	38	18,085					18,123

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Sale of common stock	952,381	10	4,990				5,000
Financing costs allocated to raising additional capital			(288)			(288)	(288)
Net loss					(25,920)		(25,920)

**Balance,**  
**December 31, 2004**      **39,807,724**    **\$ 398**    **\$ 167,496**    **\$ (1,480)**    **\$ (130,720)**    **\$ (2,413)**    **\$ 33,281**

See accompanying notes.

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**NOVAVAX, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	<b>For the years ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
<b>Operating Activities</b>			
Net loss	\$ (25,920)	\$ (17,273)	\$ (22,697)
Reconciliation of net loss to net cash used by operating activities:			
Retirement of capital assets	58	129	
Amortization	776	656	655
Depreciation	2,277	530	483
Provision for bad debt	413	183	73
Deferred financing	166		
Deferred rent	12	64	90
Deferred revenue	(125)	(275)	(1,225)
Non-cash expense		258	343
Non-cash stock compensation	53		
Facility exit costs	672		
Gain on redemption of debt	(11,162)		
Changes in operating assets and liabilities:			
Trade accounts receivable	720	(261)	1,923
Inventory	(2,609)	(222)	(96)
Prepaid expenses and other assets	(1,128)	51	(95)
Accounts payable and accrued expenses	5,436	(1,387)	(520)
Other non-current assets	262		
Net cash used by operating activities	(30,099)	(17,547)	(21,066)
<b>Investing activities</b>			
Capital expenditures	(1,608)	(2,018)	(9,661)
Proceeds from disposal of property and equipment		100	
Net cash used in investing activities	(1,608)	(1,918)	(9,661)
<b>Financing activities</b>			
Net proceeds from issuance of convertible notes	32,943		9,448
Net payments associated with King Transaction	(15,010)		
Borrowing of long-term debt		226	1,332
Principal payment of capital lease obligations and notes payables	(1,064)	(219)	(18)
Net proceeds from sales of common stock	4,712	42,477	
Proceeds from the exercise of stock options and warrants	369	1,609	2,925
Net cash provided by financing activities	21,950	44,093	13,687
Net change in cash and cash equivalents	(9,757)	24,628	(17,040)

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Cash and cash equivalents at beginning of year	27,633	3,005	20,045
Cash and cash equivalents at end of year	\$ 17,876	\$ 27,633	\$ 3,005

**Non-cash transactions**

Equipment purchases included in accounts payable	\$ 101	\$ 330	\$ 705
Financed insurance premiums	\$ 861	\$ 844	\$
Cashless stock option exercises	\$	\$ 181	\$
Treasury stock reissued for accrued interest to King	\$	\$ 800	\$

See accompanying notes.

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**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2004, 2003 and 2002**

**1. Description of Business**

Novavax, Inc., a Delaware corporation ( Novavax or the Company ), was incorporated in 1987, and is a fully integrated specialty biopharmaceutical company engaged in the research, development and commercialization of proprietary products focused on women's health and infectious diseases. The Company sells, markets, and distributes a line of prescription pharmaceuticals and prenatal vitamins. The Company's principal technology platform involves the use of patented oil and water nanoemulsions which can be used as vehicles for the delivery of a wide variety of drugs and other therapeutic products, including hormones. On October 9, 2003, the Company's lead topical product candidate, ESTRASORB, the first topical emulsion for estrogen therapy, was approved for marketing by the Food and Drug Administration. The FDA approved ESTRASORB for the treatment of moderate to severe vasomotor symptoms (hot flashes) associated with menopausal women. The Company believes ESTRASORB has the potential to be competitively positioned to address the estimated \$1.5 billion estrogen therapy market in the United States. Following FDA approval, the Company expanded its sales force and manufacturing capabilities and initiated marketing programs for the commercial introduction of ESTRASORB which began in the second quarter of 2004. In addition, Novavax conducts research and development on preventative vaccines and proteins for infectious diseases.

The products currently under development or in clinical trials by the Company will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercial use. There can be no assurance that the Company's research and development efforts will be successful or that any of the Company's potential products will prove to be safe and effective in clinical trial. Even if developed, these products may not receive regulatory approval or be successfully introduced and marketed at prices that would permit the Company to operate profitably. The Company also recognizes that the commercial launch of any product is subject to certain risks including, but not limited to, manufacturing scale-up and market acceptance. No assurance can be given that the Company can generate sufficient product revenue to become profitable or generate positive cash flow from operations at all or on a sustained basis.

**2. Management's Plans Related to Liquidity and Capital Needs**

The Company has incurred significant and increasing losses from operations. At December 31, 2004 the Company had an accumulated deficit of \$130.7 million. Such losses have resulted principally from research and development costs, sales and marketing costs and general and administrative costs associated with the development of the Company's technologies and products and expanding its level of operations.

The Company is subject to all of the many risks inherent in growing a new enterprise, and the development and commercialization of new products, including changing technologies, competition from companies offering the same or similar products, managing growth and lack of financial resources. As with any growing enterprise, there can be no assurance that the Company will achieve or sustain profitability or positive cash flow from operations.

The accompanying financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Over the next few years the Company expects to incur losses from operations as it continues to develop future products and market its current products. The Company will need to raise additional capital through debt or equity financings or collaborative arrangements with industry partners to continue its business operations.

The Company's ability to continue as a going concern is dependent on its success at obtaining additional capital sufficient to meet its obligations on a timely basis, and to ultimately attain profitability. Management is actively engaged in seeking to raise capital through product licensing, co-promotional arrangements, or public or private equity financing. The Company believes it has demonstrated the ability to raise the necessary funds for the Company's growth and development activities. However, there is no assurance that the Company will raise capital sufficient to enable the Company to continue its operations through the end of the fiscal year.

In the event the Company is unable to successfully obtain additional capital, it is unlikely that the Company will have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in the event additional capital is not obtained, the Company will likely further downsize the organization, defer marketing programs, reduce general and administrative expenses and delay or reduce the scope of research and development projects until it is able to obtain sufficient financing to do so.

These factors could significantly limit the Company's ability to continue as a going concern. The balance sheets do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts of classification of liabilities that might be necessary should the Company be unable to continue in existence.

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued**  
**December 31, 2004, 2003 and 2002**

**3. Summary of Significant Accounting Policies**

*Basis of Presentation*

The accompanying consolidated financial statements include the accounts of the corporation and its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

*Use of Estimates*

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Cash and Cash Equivalents*

The Company considers all highly liquid investments with insignificant interest rate risk and original maturities of three months or less from the date of purchase to be cash equivalents. Substantially all cash equivalents are held in short-term money market accounts with banks and brokerage accounts with large, high-quality financial institutions.

*Financial Instruments and Concentration of Credit Risk*

Financial instruments, which possibly expose the Company to concentration of credit risk, consist primarily of cash and cash equivalents, accounts receivable and convertible notes payable. The Company maintains its cash and cash equivalents in bank and brokerage accounts with high-quality financial institutions. The balances, at times, may exceed federally insured limits. The Company has not experienced any losses on such accounts and management believes the risk of loss to be minimal. The carrying value of cash and cash equivalents and accounts receivable approximates their fair value based on their short-term maturities at December 31, 2004 and 2003. The fair values of convertible notes approximate their carrying value as of December 31, 2004 and 2003 based on rates currently available to the Company for debt with similar terms and remaining maturities.

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**3. Summary of Significant Accounting Policies (Continued)**

*Trade Accounts Receivables*

Trade receivables are reported in the consolidated balance sheets as outstanding principal less any charge-offs and the allowance for doubtful accounts. The Company charges off uncollectible receivables when the likelihood of collection is remote. Generally, the Company considers receivables past due 30 days subsequent to the billing date; however, the Company may extend credit terms up to 180 days. The Company performs ongoing credit evaluations of its customers and generally extends credit without requiring collateral. The Company maintains an allowance for doubtful accounts that is determined based on historical experience and management's expectations of future losses. In 2004, losses were above management's expectations due to a high volume of returns as a result of generic competition. As of December 31, 2004 and 2003, the Company had an allowance for doubtful accounts of approximately \$752,000 and \$376,000, respectively.

As of December 31, 2004 and 2003, three customers accounted for 81% and 74% of the Company's gross product sales and 74% and 76% of the Company's product sales accounts receivable, respectively.

*Inventories*

Inventories are priced at the lower of cost or market using the first-in-first-out method and consist of the following at December 31:

	<b>2004</b>	<b>2003</b>
	<b>(in thousands)</b>	
Raw materials	\$ 351	\$ 500
Work-in-progress	700	31
Finished goods	2,413	324
	<b>\$ 3,464</b>	<b>\$ 855</b>

*Property and Equipment*

Property and equipment are recorded at cost. Depreciation of furniture, fixtures and equipment is provided under the straight-line method over the estimated useful lives of the assets, generally three to 10 years. Amortization of leasehold improvements is provided over the shorter of the estimated useful lives of the improvements or the term of the lease. Repairs and maintenance costs are expensed as incurred.

*Goodwill and Other Intangible Assets*

Goodwill principally results from business acquisitions. Assets acquired and liabilities assumed are recorded at their fair values; the excess of the purchase price over the identifiable net assets acquired is recorded as goodwill. Other intangible assets are a result of product acquisitions, non-compete arrangements, and internally-discovered patents. In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets* ( SFAS No. 142 ), goodwill and

intangible assets deemed to have indefinite lives are not amortized but are subject to impairment tests annually, or more frequently should indicators of impairment arise. The Company utilizes a discounted cash flow analysis that includes profitability information, estimated future operating results, trends and other information in assessing whether the value of indefinite-lived intangible assets can be recovered. Under SFAS No. 142, goodwill impairment is deemed to exist if the carrying value of a reporting unit exceeds its estimated fair value. In accordance with the requirements of SFAS No. 142, the Company initially tested its goodwill for impairment as of January 1, 2002 and determined that no impairment was present. The Company thereafter performed the required annual impairment test as of October 1 of each year on the carrying amount of its goodwill, which indicated the Company's estimated fair value of goodwill exceeded its carrying value, therefore, no impairment was identified during December 31, 2003 or 2004. Other intangible assets are amortized on a straight-line basis over their estimated useful lives, ranging from five to 17 years. Goodwill and other intangible assets consist of the following at December 31:

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**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**3. Summary of Significant Accounting Policies (Continued)**

*Goodwill and Other Intangible Assets (continued):*

	<b>Gross</b>	<b>2004 Accumulated Amortization</b>	<b>Net (in thousands)</b>	<b>Gross</b>	<b>2003 Accumulated Amortization</b>	<b>Net</b>
<b>Goodwill, net</b>						
Goodwill-Company acquisition	\$ 35,590	\$ (2,449)	\$ 33,141	\$ 35,590	\$ (2,449)	\$ 33,141
<b>Other intangible assets, net</b>						
Acquisition	\$ 148	\$ (148)	\$	\$ 148	\$ (131)	\$ 17
ESTRASORB rights	2,514	(136)	2,378			
AVC-Product acquisition	3,332	(1,904)	1,428	3,332	(1,428)	1,904
Patents	2,525	(1,283)	1,242	2,525	(1,136)	1,398
Total other intangible assets, net	\$ 8,519	\$ (3,471)	\$ 5,048	\$ 6,005	\$ (2,695)	\$ 3,310

Amortization expense was \$776,000, \$656,000 and \$655,000 for the years ended December 31, 2004, 2003 and 2002, respectively. Estimated future amortization expenses for intangible assets as of December 31, 2004 are as follows:

<b>Year</b>	<b>Amortization Expense</b>
2005	\$ 863
2006	863
2007	863
2008	387
2009	387
Thereafter	1,685
	\$ 5,048

The Company evaluates the recoverability of the carrying value of its long-lived assets and identifiable intangibles periodically and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Examples of events or changes in circumstances that indicate that the recoverability of the carrying value of an asset should be assessed include but are not limited to the following: a significant decrease in the market value of an asset, a significant change in the extent or manner in which an asset is used, a significant physical change in an asset, a significant adverse change in legal factors or in the business climate that could affect the value of an asset, an



adverse action or assessment by a regulator, an accumulation of costs significantly in excess of the amount originally expected to acquire or construct an asset, a current period operating or cash flow loss combined with a history of operating or cash flow losses, and/or a projection or forecast that demonstrates continuing losses associated with an asset used for the purpose of producing revenue. The Company considers historical performance and anticipated future results in its evaluation of potential impairment. Accordingly, when indicators of impairment are present, the Company evaluates the carrying value of these assets in relation to the operating performance of the business and future discounted and undiscounted cash flows expected to result from the use of these assets. Impairment losses are recognized when the sum of expected future cash flows is less than the assets' carrying value. No such impairment losses have been recognized to date, with the exception of the leasehold assets written off in relation to the facility exit mentioned in Long-term Lease and Accounting for Facility Exit Costs .

#### *Revenue Recognition and Allowances*

The Company recognizes revenue in accordance with the provisions of Staff Accounting Bulletin No. 104, *Revenue Recognition*. For product sales, revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred to the Company's distributor, the seller's price to the buyer is fixed or determinable and collectibility is reasonably assured. The Company recognizes these sales net of allowances for returns, rebates and chargebacks. A large part of the Company's product sales are to distributors who resell the products to their customers. The Company provides rebates to members of certain buying groups who purchase from the Company's distributors, to distributors that sell to their customers at prices determined under a contract between the Company and the customer and to state agencies that administer various programs such as the federal Medicaid and Medicare programs. Rebate amounts are usually based upon the volume of purchases or by reference to a specific price for a product. The Company estimates the amount of the rebate that will be paid, and records the liability as a reduction of revenue when the Company records our sale of the products. Settlement of the rebate generally occurs from three to 12 months after sale. The Company regularly analyzes the historical rebate trends and makes adjustments to recorded reserves for changes in trends and terms of rebate programs.

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**3. Summary of Significant Accounting Policies (Continued)**

*Revenue Recognition and Allowances (continued)*

In a similar manner, the Company estimate amounts for returns based on historical trends, distributor inventory levels and product prescription data and adjust those reserves as product returns occur. A non-recurring reserve of \$1,283,000 for anticipated returns of vitamins negatively impacted by generic competition was netted against product sales for the three months ended September 30, 2004.

The shipping and handling costs the Company incurs are included in cost of sales in its statements of operations.

For upfront payments and licensing fees related to contract research or technology, the Company defers and recognizes revenue as earned over the life of the related agreement. Milestone payments are recognized as revenue upon achievement of contract-specified events and when there are no remaining performance obligations.

In 2004 and 2003, revenue earned under current research contracts was recognized per the terms and conditions of such contracts for invoicing of costs incurred and defined milestones. In 2002, revenue earned under research contracts was recognized on the percentage of completion method, whereby revenue was recognized in proportion to the estimated percentage to complete the contract.

*Net Loss per Share*

Basic loss per share is computed by dividing the net loss available to common shareholders (the numerator) by the weighted average number of common shares outstanding (the denominator) during the period. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. The computation of diluted loss per share is similar to the computation of basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued (e.g. upon exercise of stock options). Potentially dilutive common shares are not included in the computation of diluted earnings per share if they are anti-dilutive. Net loss per share as reported was not adjusted for potential common shares, as they are anti-dilutive.

*Stock-Based Compensation*

The Company currently applies the principles of APB No. 25, *Accounting for Stock Issued to Employees*, in accounting for stock options issued to its employees; APB No. 25 generally does not require that options granted to employees be expensed. Had the Company applied the fair value principles of SFAS No. 123, *Accounting for Stock-Based Compensation*, for its employee options, its net loss for the years ended December 31, 2004, 2003 and 2002 would have increased as follows:

	<b>Year Ended December 31,</b>		
	<b>(in thousands, except per share data)</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net loss, as reported	\$ (25,920)	\$ (17,273)	\$ (22,697)
	(4,131)	(6,254)	(3,204)

Deduct: Total stock-based employee compensation expense determined  
under fair value-based method for all awards

Pro forma net loss	\$ (30,051)	\$ (23,527)	\$ (25,901)
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Net loss per share:

Basic and diluted as reported	\$ (0.70)	\$ (0.58)	\$ (0.93)
Basic and diluted pro forma	\$ (0.81)	\$ (0.79)	\$ (1.06)

These pro forma amounts are not necessarily indicative of future effects of applying the fair value-based method due to, among other things, the vesting period of the stock options and the fair value of the additional stock options issued in future years.

In September 2004, the Company granted stock options to purchase an aggregate 26,450 shares to two consultants as compensation for services through the end of October 2004. For the year ended December 31, 2004, \$53,000 of non-cash stock compensation expense was included in sales and marketing expense, which represents the fair value of the grants as of that date.

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**3. Summary of Significant Accounting Policies (Continued)**

*Advertising and Promotion Costs*

All costs associated with advertising and promotions are expensed as incurred. Advertising and promotion expense was \$12.6 million in 2004, insignificant in 2003 and \$3.8 million in 2002.

*Research and Development Costs*

Research and development costs are expensed as incurred. Research and development costs include salaries and benefits, outside services, materials and supplies, facility costs and allocations of certain support costs.

In July 2004, the Company announced that the National Institute of Allergy and Infectious Diseases, a component of the National Institutes of Health, had cancelled its five-year contract with the Company for the development of human immunodeficiency virus (HIV) vaccine candidates due to programmatic considerations for the government's convenience. The Company had been the prime contractor, with Emory University, Tulane University, and the University of Pittsburgh as subcontractors. The cancellation did not have a material financial impact and full recovery of costs incurred in association with this contract is expected.

The Company is also part of a consortium that received a NIAID project program grant to develop another set of HIV vaccine candidates. The Company expects to receive approximately \$4.0 million over four and a half years for its participation in this grant effort. This grant was not impacted by the July 2004 event mentioned above.

*Income Taxes*

The Company's income taxes are accounted for using the liability method. Under the liability method, deferred income taxes are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss carry forward. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled.

The effect of changes in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce net deferred tax assets to the amount expected to be realized. The Company has provided a full valuation allowance against its net deferred tax assets as of December 31, 2004 and 2003.

*Comprehensive Loss*

Under SFAS No. 130, *Reporting Comprehensive Income*, the Company is required to display comprehensive loss and its components as part of its consolidated financial statements. Comprehensive loss is comprised of the net loss and other comprehensive income (loss), which includes certain changes in equity that are excluded from the net loss. Comprehensive loss for the Company was the same as net loss for the years ended December 31, 2004, 2003 and 2002.

*Segment Information*

The Company currently operates in one business segment, which is the research, development and commercialization of products focused on women's health and infectious diseases. The Company is managed and operated as one business. A single management team that reports to the Chief Executive Officer comprehensively manages the entire business. The Company does not operate separate lines of business with respect to its products or product candidates. Accordingly, the Company does not have separately reportable segments as defined by SFAS No. 131, *Disclosure about Segments of an Enterprise and Related Information*.

*Recent Accounting Pronouncements*

In December 2003, the Financial Accounting Standards Board issued Interpretation No. 46 (revised), *Consolidation of Variable Interest Entities* ( FIN 46R ). FIN 46R clarifies the application of Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. Application of FIN 46R was required for public entities that have interests in variable interest entities or potential variable interest entities commonly referred to as special-purpose entities for periods ending after December 15, 2003. Application for all other types of entities is required for periods ending after March 15, 2004. The adoption of FIN 46R did not have a material effect on the Company's financial condition, results of operations or liquidity.

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**3. Summary of Significant Accounting Policies (Continued)**

*Recent Accounting Pronouncements (continued)*

In December 2004, the Financial Accounting Standards Board issued Statement No. 123 (revised) *Share-Based Payment* ( SFAS No. 123R ), which is a revision of Statement No. 123, *Accounting for Stock-Based Compensation* ( SFAS No. 123 ). SFAS No. 123R supersedes APB No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123R is similar to the approach described in SFAS No. 123. However, SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

SFAS No. 123R must be adopted in the first interim financial reporting period beginning after June 15, 2005. The Company expects to adopt SFAS No. 123R on July 1, 2005.

SFAS No. 123R permits public companies to adopt its requirements using one of two methods:

1. A modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date.
2. A modified retrospective method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either for (a) all prior periods presented or (b) prior interim periods of the year of adoption.

The Company plans to adopt SFAS No. 123R using the modified prospective method.

As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using the intrinsic value method permitted by APB No. 25 and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of SFAS No. 123R's fair value method will have a significant impact on the Company's results of operations, although it will have no impact on the Company's overall financial position. The impact of adoption of SFAS No. 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted SFAS No. 123R in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net income and earnings per share in Note 3 to the consolidated financial statements. SFAS No. 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. The Company cannot estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options. For the years ended December 31, 2004, 2003, and 2002, the Company did not pay any taxes, therefore, there was no effect on operating cash flows for such excess tax deductions.

**4. Product Agreements and Acquisitions**

*Cancellation of King Pharmaceuticals Agreements*

In January 2001, the Company entered into a co-promotion agreement with King Pharmaceuticals Inc. for the Company's topical estrogen therapy, ESTRASORB, in the United States and Puerto Rico (the Territory). The Company also entered into a license agreement with King for many countries outside the United States. The co-promotion and license agreements (the Agreements) granted King the right to share equally in the revenues and expenses for manufacturing and marketing ESTRASORB in the Territory and exclusive rights to many countries outside the United States. The Agreements also entitled the Company to up to \$5.0 million in milestone payments from King for achievement of milestones outlined in the Agreements.

In June 2001, the Company amended the Agreements (the Amended Agreements). The Amended Agreements clarified the terms of two milestone payments totaling \$5,000,000. These milestone payments were paid in 2001. The first \$2,500,000 milestone was recognized as revenue in 2001. The second \$2,500,000 was to be deferred and recognized as revenue over the estimated FDA review process.

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**4. Product Agreements and Acquisitions (Continued)**

*Cancellation of King Pharmaceuticals Agreements (continued)*

The Amended Agreements also granted King exclusive rights to promote, market and distribute ESTRASORB in Canada, Switzerland, Greece, Italy, Spain and the Netherlands, the only countries excluded from the original license agreement. In addition, the Amended Agreements included the co-promotion and license of ANDROSORB, a topical testosterone therapy for testosterone deficient women. Under the terms of the Amended Agreements, the Company received \$3.0 million from King in up-front licensing fees, which were recorded as deferred revenue and recognized as revenue ratably over the term of the Amended Agreements.

In January 2001, the Company also acquired the rights to AVC Cream and Suppositories from King for approximately \$3.3 million in cash. For the years ended December 31, 2004, 2003 and 2002, the AVC product line generated revenues of \$0.9 million, \$1.8 million and \$1.9 million, respectively.

In July 2004, King and the Company mutually agreed to terminate the Amended Agreements, among others, (the King Transaction). The King Transaction included the return to Novavax of all rights worldwide for ESTRASORB and ANDROSORB, as well as all rights to other women's health products that the Company may successfully develop utilizing the MNP technology. The transaction also included the redemption of \$40.0 million of the Company's convertible notes held by King. Additionally, Novavax hired 50 members of King's women's health sales force to provide competitive sales force coverage. As part of the King Transaction, the Company paid King a net of \$14.0 million in cash and issued King 3,775,610 shares of common stock, which at the time of closing were valued at approximately \$18,123,000.

The King Transaction resulted in a gain on the redemption of the convertible notes held by King of \$11,162,000. This gain was determined based on the fair value of the convertible notes plus accrued interest as of the transaction date compared to the notes' total book value. In addition, an intangible asset for ESTRASORB rights of \$2,514,000 was recorded, which represents the difference between assets and liabilities acquired or written off, the net cash paid in the transaction, the common stock issued and transaction fees and expenses. The intangible asset for ESTRASORB rights is being amortized using the straight line method over the remaining patent life for ESTRASORB. Included in the assets and liabilities written off were deferred financing costs of \$351,000 relating to the convertible notes held by King, and remaining deferred revenue of \$2,250,000 relating to previous licensing fees for ESTRASORB, mentioned above.

**5. Long-term Lease and Accounting for Facility Exit Costs**

In December 2003, the Company prepared for the consolidation of warehousing and distribution functions for all its products by closing its distribution facility in Maryland Heights, Missouri. The Company entered into a service arrangement with Cardinal Health in Nashville, Tennessee for customer service, warehousing and product shipment to distribute current and future products. Prior to this restructuring, the Company purchased its prenatal vitamins in bulk and packaged the vitamins at the Missouri facility. As part of the restructuring, the Company also entered into an agreement with a third-party packager for the vitamin line of products.

One time costs associated with this restructuring included moving costs of approximately \$15,000, along with transition payments to 10 production and support employees of approximately \$75,000 in the aggregate, which were



included in the general and administrative expenses in the accompanying consolidated statement of operations for the year ended December 31, 2003. In addition, the Company held an auction, selling off most of the fixed assets that were located at the facility. The auction resulted in a loss on disposal of assets of approximately \$129,000. As of December 31, 2004, all costs associated with the restructuring had been paid.

In July 2004, the Company entered into a long-term agreement to lease a 32,900 square foot facility in Malvern, Pennsylvania for the consolidation and expansion of corporate headquarters and product development activities. The lease, with a commencement date of September 15, 2004, has an initial term of 10 years with two five-year renewal options. Standard annual escalation rental rates are in effect during the initial lease term. With advance notice, the Company also has an option to lease adjoining space of 17,000 square feet, which could be built out for future manufacturing needs.

The Company applied the principles of SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, in accounting for contract termination costs and associated costs that will continue to be incurred under the operating lease expiring on October 31, 2006 related to its former corporate offices located in Columbia, Maryland. For the year ended December 31, 2004, \$252,000 was included in facility exit costs line in the accompanying consolidated statement of operations, which represents the difference between the fair value of the remaining lease payments, reduced by current estimated sublease rentals that could be reasonably obtained. As of December 31, 2004, \$123,000 was included in other current liabilities and \$77,000 in other non-current liability and \$52,000 had been paid in cash.

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**5. Long-term Lease and Accounting for Facility Exit Costs (Continued)**

The Company applied the principles of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, and APB No. 20, *Accounting Changes*, in writing off the remaining useful lives of the leasehold assets relating to the Columbia facility. For the year ended December 31, 2004, \$471,000 or (\$0.01) per share, was included in the facility exit costs line item in the accompanying consolidated statement of operations associated with the moving of corporate offices.

**6. Supplemental Financial Data**

*Allowance for Doubtful Accounts*

A roll-forward of the allowance for doubtful accounts is as follows:

	(in thousands)
<b>Balance, December 31, 2001</b>	\$ 120
Provision for bad debts	93
Write off bad debts	(20)
<b>Balance, December 31, 2002</b>	\$ 193
Provision for bad debts	257
Write off bad debts	(74)
<b>Balance, December 31, 2003</b>	\$ 376
Provision for bad debts	413
Other adjustments	(37)
<b>Balance, December 31, 2004</b>	\$ 752

*Prepaid Expenses and Other Current Assets*

Prepaid expenses consist of the following at December 31:

	2004	2003
	(in thousands)	
Prepaid insurance	\$ 898	\$ 1,014
Current portion of deferred financing	411	
Non-trade receivables	218	286
Deposits		114
Interest on shareholders notes	209	134
Other current assets	34	66
		106

\$ 1,770      \$ 1,614

*Property and Equipment*

Property and equipment is comprised of the following at December 31:

	<b>2004</b>	<b>2003</b>
	<b>(in thousands)</b>	
Machinery and equipment	16,082	15,718
Leasehold improvements	1,437	1,142
Computer software and hardware	480	509
	17,999	17,369
Less accumulated depreciation	(3,852)	(2,125)
	\$ 14,147	\$ 15,244

At December 31, 2004, property and equipment additions of \$101,000 are included in accounts payable. Depreciation expense was approximately \$2,277,000, \$530,000, and \$483,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**6. Supplemental Financial Data (Continued)**

*Accrued Expenses (continued)*

Accrued expenses consist of the following at December 31:

	<b>2004</b>	<b>2003</b>
	<b>(in thousands)</b>	
Sales return and rebate allowances	\$ 1,319	\$ 216
Employee benefit and compensation	1,427	776
Operating expenses	638	187
Interest	756	
	<b>\$ 4,140</b>	<b>\$ 1,179</b>

*Sales Return and Rebate Allowances*

A roll-forward of the sales return and rebate allowances is as follows:

	<b>Return</b>	<b>Rebate</b>
	<b>(in thousands)</b>	
<b>Balance, December 31, 2001</b>	\$	\$ 20
Provision for return	823	
Provision for rebates		210
Returns received	(779)	
Payment of rebates		(216)
<b>Balance, December 31, 2002</b>	44	14
Provision for returns	1,312	
Provision for rebates		103
Returns received	(1,198)	
Payment of rebates		(59)
<b>Balance, December 31, 2003</b>	158	58
Provision for returns	2,119	
Provision for rebates		107
Returns received	(1,003)	
Payment of rebates		(120)
<b>Balance, December 31, 2004</b>	<b>\$ 1,274</b>	<b>\$ 45</b>



**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**7. Long-term debt***Notes Payable*

Notes payable consist of the following at December 31:

	<b>2004</b>	<b>2003</b>
	<b>(in thousands)</b>	
Note payable; bears interest at 3.00% per annum; principal and interest due in monthly installments of \$6,600 through December 2009	\$ 356	\$ 423
Note payable; bears interest at 2.850% per annum; principal and interest due in monthly installments of \$6,573 through January 2010	373	440
Note payable; bears interest at 2.38% per annum; principal and interest due in monthly installments of \$6,468 through January 2010	371	439
Note payable; bears interest at 12.33% per annum; principal and interest due in monthly installments of \$2,359 through August 2004		18
Note payable; insurance financing; bears interest at 4.69% per annum; principal and interest due in monthly installments of \$88,035 through October 2005	862	
Note payable; insurance financing; bears interest at 5.25% per annum; principal and interest due in monthly installments of \$95,937 through September 2004		845
Total	1,962	2,165
Less current portion	(1,070)	(1,065)
Long-term portion	\$ 892	\$ 1,100

*Convertible Notes (continued)*

The notes (except for the notes payable for financing insurance premiums) are secured by \$2.4 million of the Company's machinery and equipment located in the Company's manufacturing site in Philadelphia, Pennsylvania.

*Convertible Notes*

From 2000 to 2002, the Company entered into a series of note purchase agreements with King. All of the notes would have matured on December 19, 2007 with interest payable in semi-annual installments on June 30 and December 31. Up to 50% of the interest could have been paid in common stock of the Company, subject to certain conditions. As part of the King Transaction, the Company redeemed these notes on July 19, 2004.

For the six months ended June 30, 2004, the Company accrued interest of \$800,000 relating to the King notes. This accrued interest was written off as part of the King Transaction and included in the resulting gain on the redemption of the convertible notes held by King. (See Note 4 Product Agreements and Acquisitions ).

For the year ended December 31, 2003, the Company made cash interest payments of \$1.6 million for the King notes. For the year ended December 31, 2002, the Company made cash interest payments of \$600,000 and accrued an additional \$800,000 for interest expense at year-end for which King agreed to accept payment in common stock. In February 2003, the Company issued King 307,692 shares of common stock to satisfy the accrued interest payable. For the years ending December 31, 2003 and 2002, the Company capitalized \$386,717 and \$173,915, respectively, for interest incurred on debt used to finance the build-out of its manufacturing facility.

Concurrent with the King Transaction, in July 2004 the Company also entered into definitive agreements for the private placement of \$35.0 million aggregate principal amount of senior convertible notes to a group of institutional investors. The notes carry a 4.75% coupon, payable semi-annually, mature in five years and are generally convertible into shares of common stock at \$6.15 per share. From the third anniversary of the issue date of the notes, and subject to certain conditions, the Company shall have the right to

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**7. Long-term debt (continued)**

effect a mandatory conversion of the notes if the weighted average price of the common stock exceeds 175% of the conversion price as of the issue date for each of 15 trading days out of any 30 consecutive trading days. Note holders shall have the right to require the Company to redeem all or a portion of the notes if the weighted average price of the common stock for each of 30 trading days out of 40 consecutive trading days prior to either the third or fourth anniversary of the issue date of the notes is less than the then applicable conversion price of the Company's common stock, *provided*, that a holder's right to effect this optional redemption will not apply if certain revenue targets for ESTRASORB are achieved. The notes are also redeemable upon the occurrence of specified events of default as well as a change of control (as that term is defined in the notes) of Novavax. For the year ended December 31, 2004, the Company accrued interest of \$756,000 relating to these notes.

As a result of both of the financing and the King Transaction, the Company incurred \$3,355,000 of transaction expenses, which increased the intangible asset for ESTRASORB rights by \$1,010,000 (included in the total intangible asset for ESTRASORB rights of \$2,514,000), decreased additional paid-in capital by \$288,000, and increased deferred financing costs by \$2,057,000. The deferred financing costs are being amortized over the life of the convertible notes. During the year ended December 31, 2004, \$184,000 amortization was included in interest expense.

*Convertible Notes (continued)*

Convertible notes consist of the following on December 31:

	<b>2004</b>	<b>2003</b>
	<b>(in thousands)</b>	
Note payable; 4.75% senior convertible, issued July 19, 2004, due July 15, 2009, convertible into 5,691,057 shares of Novavax Common Stock at \$6.15 per share	\$ 35,000	\$
Note payable; 4% senior convertible, issued December 19, 2000, due December 19, 2007, convertible into 2,297,530 shares of Novavax Common Stock at \$8.71 per share		20,000
Note payable; 4% senior convertible, issued September 7, 2001, due December 19, 2007, convertible into 574,383 shares of Novavax Common Stock at \$8.71 per share		5,000
Note payable; 4% senior convertible, issued September 7, 2001, due December 19, 2007, convertible into 431,220 shares of Novavax Common Stock at \$11.60 per share		5,000
Note payable; 4% senior convertible, issued June 26, 2002, due December 19, 2007, convertible into 1,885,014 shares of Novavax Common Stock at \$5.31 per share		10,000
Total	\$ 35,000	\$ 40,000

Aggregate future minimum principal payments on debt at December 31, 2004 are as follows:



<b>Year</b>	<b>Amount (in thousands)</b>
2005	\$ 1,070
2006	214
2007	220
2008	226
2009	35,219
Thereafter	13
	\$ 36,962

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**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**8. Sale of Common Stock**

In February 2003, the Company completed the private placement of 4,750,000 shares of common stock at \$3.50 per share to an accredited investor, for net proceeds of \$16.6 million. The shares were issued in reliance on Section 4(2) of the Securities Act of 1933, as amended. A resale registration statement was filed with the Commission on April 23, 2003, and was declared effective on May 2, 2003.

In May 2003, the Company received net proceeds of approximately \$1.5 million from the exercise of 400,000 common stock options at \$3.63 per share.

In November 2003, the Company completed an offering of 4,500,000 shares of common stock at \$6.15 per share. The stock was offered and sold pursuant to an effective shelf registration statement. Net proceeds after deducting underwriter fees of approximately \$1.7 million, as well as legal, accounting and other miscellaneous fees, were approximately \$25.9 million.

During 2004, the Company received net proceeds of \$369,000 from the exercise of 107,550 common stock options at a range of \$3.24 to \$4.30 per share.

Concurrent with the King Transaction, in July 2004 the Company issued 952,381 shares of common stock at \$5.25 per share, for gross proceeds of \$5.0 million to an accredited investor in reliance on Regulation D promulgated under the Securities Act of 1933, as amended. A resale registration statement was filed and declared effective for such shares in August 2004.

**9. Stockholders' Equity**

On August 7, 2002, the Company adopted a Shareholder Rights Plan which provides for the issuance of rights to purchase shares of Series D Junior Participating Preferred Stock, par value \$0.01 per share (the Preferred Shares), of the Company. Under the Shareholder Rights Plan, the Company distributed one preferred share purchase right (a Right) for each outstanding share of common stock, par value \$.01 (the Common Shares), of the Company. The Rights were distributed to stockholders of record on August 16, 2002.

Each Right entitles the holder to purchase from the Company one-thousandth of a Preferred Share at a price of \$40, subject to adjustment. The rights become exercisable, with certain exceptions, 10 business days after any party, without prior approval of the Board of Directors, acquires or announces an offer to acquire beneficial ownership of 15% or more of the Company's Common Shares. In the event that any party acquires 15% or more of the Company's common stock, the Company enters into a merger or other business combination, or if a substantial amount of the Company's assets are sold after the time that the Rights become exercisable, the Rights provide that the holder will receive, upon exercise, shares of the common stock of the surviving or acquiring company, as applicable, having a market value of twice the exercise price of the Right.

The Rights expire August 7, 2012, and are redeemable by the Company at a price of \$0.00025 per Right at any time prior to the time that any party acquires 15% or more of the Company's Common Shares. Until the earlier of the time that the Rights become exercisable, are redeemed or expire, the Company will issue one Right with each new Common Share issued.

In February 2003, the Company waived the provisions of the Shareholder Rights Plan with respect to the private placement of shares to SJ Strategic Investments, LLC.

#### **10. Stock Options and Warrants**

Under the Novavax 1995 Stock Option Plan (the Plan ), options may be granted to officers, employees, consultants and advisors to Novavax and any present or future subsidiary to purchase a maximum of 9,000,000 shares of Novavax common stock. Incentive stock options, having a maximum term of 10 years, can be granted at no less than 100% of the fair market value of Novavax's stock at the time of grant and are generally exercisable in cumulative increments over several years from the date of grant. Both incentive and non-statutory stock options may be granted under the Plan. There is no minimum exercise price for non-statutory stock options.

The 1995 Director Stock Option Plan (the Director Plan ) provided for the issuance of up to 500,000 shares of Novavax common stock to directors of the Company. The exercise price is the fair market value per share of the Company's common stock on

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**10. Stock Options and Warrants (Continued)**

the date of grant. Options granted to eligible directors are exercisable in full beginning six months after the date of grant and expire 10 years from the grant date. All options available under the Director Plan have been granted. Such options cease to be exercisable at the earlier of their expiration or three years after an eligible director ceases to be a director for any reason. In the event that an eligible director ceases to be a director on account of his or her death, any outstanding options (whether exercisable or not on the date of death) may be exercised within three years after such date (subject to the condition that no such option may be exercised after the expiration of 10 years from its date of grant).

Activity under the Plan and Director Plan was as follows

	<b>1995 Stock Option Plan</b>		<b>1995 Director Stock Option Plan</b>	
	<b>Stock Options</b>	<b>Weighted Average Exercise Price</b>	<b>Stock Options</b>	<b>Weighted Average Exercise Price</b>
<b>Balance, December 31, 2001</b>	4,400,406	\$ 6.17	350,000	\$ 4.03
Granted	539,470	8.77		
Exercised	(410,902)	4.69	(50,000)	4.14
Expired or canceled	(927,178)	8.60		
<b>Balance, December 31, 2002</b>	3,601,796	6.10	300,000	4.01
Granted	2,091,000	5.16		
Exercised	(506,000)	4.30		
Expired or canceled	(975,153)	7.93	(30,000)	3.85
<b>Balance, December 31, 2003</b>	4,211,643	5.61	270,000	4.03
Granted	1,308,150	5.46		
Exercised	(107,550)	3.43		
Expired or canceled	(350,275)	7.69		
<b>Balance, December 31, 2004</b>	5,061,968	\$ 5.48	270,000	\$ 4.03
<b>Shares exercisable at December 31, 2002</b>	2,540,483	\$ 5.17	300,000	\$ 4.01
<b>Shares exercisable at December 31, 2003</b>	2,180,439	\$ 5.32	270,000	\$ 4.03
<b>Shares exercisable at December 31, 2004</b>	2,683,195	\$ 5.40	270,000	\$ 4.03
<b>Available for grant at December 31, 2004</b>	980,224			

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The weighted-average fair value of the stock options granted during 2004, 2003 and 2002 is estimated as \$3.32, \$3.10, and \$8.32 per share, respectively. The fair value of awards was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	<b>Year Ended December 31</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Risk-free interest rate	3.0%	3.5%	4.0%
Dividend yield	0.0%	0.0%	0.0%
Volatility	59.0%	72.0%	85.0%
Expected life (in years):			
Employees	6.0	6.0	6.0
Directors	3.0	3.0	3.0

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**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**10. Stock Options and Warrants (Continued)**

The following table provides certain information with respect to stock options outstanding and exercisable at December 31, 2004:

	Number of Options  Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options Exercisable	Weighted Average Exercise Price
Options issued at below market value:					
\$0.00 - \$1.17	210,144	1.0	\$ 0.01	210,144	\$ 0.01
Options issued at market value:					
\$1.17 - \$2.33	46,094	3.7	1.85	46,094	1.85
\$2.33 - \$3.50	374,933	4.6	3.29	361,933	3.29
\$3.50 - \$4.66	1,368,728	7.2	4.01	763,521	4.01
\$4.66 - \$5.83	1,373,000	7.5	5.54	640,500	5.43
\$5.83 - \$6.99	981,183	9.0	6.01	155,083	6.13
\$6.99 - \$8.16	350,000	6.0	7.44	233,334	7.43
\$8.16 - \$9.32	370,750	6.0	8.92	337,800	8.91
\$9.32 - \$10.49	196,886	6.6	9.83	154,036	9.67
\$10.49- \$11.65	60,250	6.0	11.20	50,750	11.15
	5,331,968	7.0	\$ 5.41	2,953,195	\$ 5.27

In 2002, the Company issued a warrant to a consultant to purchase 70,000 shares of common stock at an exercise price of \$6.00 per share. The warrant expires in August 2005.

**11. Employee Benefits**

The Company maintains a defined contribution 401(k) retirement plan, pursuant to which employees who have completed 90 days of service may elect to contribute up to 15% of their compensation on a tax deferred basis up to the maximum amount permitted by the Internal Revenue Code of 1986, as amended.

The Company currently matches 25% of the first 6% of the participants' deferral. Contributions to the 401(k) plan vest equally over a three-year period. The Company has expensed approximately \$96,000, \$73,000, and \$48,000 in 2004, 2003, and 2002, respectively.

**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

**12. Income Taxes**

Deferred tax assets (liabilities) consist of the following at December 31:

	<b>2004</b>	<b>2003</b>
	<b>(in thousands)</b>	
Net operating losses	\$ 40,724	\$ 29,878
Research tax credits	2,667	2,478
Disqualifying stock options	673	673
Alternative-minimum tax credit	94	94
Equipment and furniture		4
Intangibles from acquisition	506	475
Allowance for doubtful accounts	290	131
Accrued vacation pay	115	69
Deferred revenues		917
Deferred rent	64	59
Facility exit costs	78	
 Total deferred tax assets	 45,211	 34,778
Deferred patent costs	(485)	(541)
ESTRASORB rights	(546)	
Depreciation	(49)	
State taxes	(2)	
 Total deferred tax liabilities	 (1,082)	 (541)
 Net deferred tax assets	 44,129	 34,237
Less valuation allowance	\$ (44,129)	\$ (34,237)
 Deferred tax assets, net		

The differences between the United States federal statutory tax rate and the Company's effective tax rate are as follows:

	<b>2004</b>	<b>2003</b>
Statutory federal tax rate	(34)%	(34)%
State income taxes, net of federal benefit	(4)%	(5)%
Research and development credit	(1)%	(4)%
Other	1%	(1)%
Change in valuation allowance	38%	42%
	%	%

Realization of net deferred tax assets is dependent on the Company's ability to generate future taxable income, which is uncertain. Accordingly, a full valuation allowance was recorded against these assets as of December 31, 2004 and 2003.

Novavax has recorded no net benefit for income taxes in 2004, 2003 and 2002 in the accompanying consolidated financial statements due to the uncertainty regarding ultimate realization of certain net operating losses and other tax credit carryforwards.

Federal net operating losses and tax credits available to the Company are as follows:

	<b>2004 (in thousands)</b>
Federal net operating losses expiring through the year 2024	\$ 105,403
State net operating losses expiring through the year 2024	105,403
Research tax credits expiring through the year 2024	2,667
Alternative-minimum tax credit (no expiration)	94

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**NOVAVAX, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2004, 2003 and 2002**

### 13. Commitments and Contingencies

#### *Litigation*

The Company is a defendant in a lawsuit filed by a former director alleging that the Company wrongfully terminated the former director's stock options. Management believes that the termination and cancellation of the options was in accordance with the terms of the option agreement following his termination for cause by a former parent company, IGI, Inc. and the lawsuit is without merit and intends to vigorously defend the claim. Management cannot reasonably estimate the liability, if any, related to this claim, or the likelihood of an unfavorable settlement. Accordingly, no liability related to this contingency is accrued in the consolidated balance sheet as of December 31, 2004; however, an unfavorable settlement may have a material adverse impact on future operating results.

The Company is a defendant or co-defendant in various other legal actions related to claims incident to the conduct of its businesses. Management does not expect the Company to suffer any material liability by reason of such actions.

#### *Operating Leases*

Novavax leases manufacturing, laboratory and office space, machinery and equipment and automobiles under non-cancelable operating lease agreements expiring at various dates through September 2014. Several of these leases contain renewal options at the Company's option and standard annual escalation rental rates. Future minimum rental commitments under non-cancelable leases as of December 31, 2004 are as follows:

Year	Operating Leases (in thousands)
2005	\$ 2,889
2006	2,724
2007	566
2008	333
2009	339
Thereafter	1,756
Total minimum lease payments	\$ 8,607

Aggregate rental expenses approximated \$3,199,000, \$3,940,000, and \$3,750,000 in 2004, 2003 and 2002, respectively.

### 14. Related Party Transactions

On March 21, 2002, pursuant to the Plan, the Company approved the payment of the exercise price of options by two of its directors, through the delivery of full-recourse, interest-bearing promissory notes in the aggregate amount of \$1,478,602. The borrowings accrue interest at 5.07% per annum and are secured by an aggregate of 261,667 shares of

common stock owned by the directors. The notes are payable upon the earlier to occur of the following: (i) payable in full upon the date on which the director ceases for any reason to be a director of the Company, (ii) payable in part to the extent of net proceeds, upon the date on which the director sells all or any portion of the pledged shares or (iii) payable in full on March 21, 2007. As of December 31, 2004 and 2003, accrued interest receivable related to the borrowing was \$209,000 and \$134,000, respectively.

In addition, in April 2002, the Company executed a conditional guaranty of a brokerage margin account for a director, in the amount of \$500,000. Prior to demanding payment from the Company, the brokerage firm must first make demand for payment to the director and then liquidate the account. Thereafter, if there remains a shortfall, they may demand payment from the Company. As of December 31, 2004 and 2003, the Company has not recorded any liability on its balance sheet related to this guarantee as the Company believes the possibility of required payment by the Company to be unlikely.

In August 2004, the Company approved the payment of \$75,000 to the employer of one of its directors as compensation for services as an advisor for the King Transaction and related financing. The King Transaction may also be deemed to be a related party transaction.