Advaxis, Inc.
Form 10KSB
February 13, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-KSB

(MARK ONE)

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

FOR THE FISCAL YEAR ENDED - OCTOBER 31, 2006

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO_____

COMMISSION FILE NUMBER 000-28489

ADVAXIS, INC.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	84-1521955 (I.R.S. Employer Identification No.)
Technology Centre of New Jersey 675 US Highway One, Suite B113 North Brunswick, New Jersey (Address of principal executive offices)	08902 (Zip Code)
Registrant's telephone number, including area code:	(732) 545-1590
Securities registered pursuant to Section 12(b) of the Act:	Common Stock - $.001 par value The Common Stock is listed on the Over-The-Counter Bulletin Board (OTC:BB)
Securities registered pursuant to Section 12(g) of the Act:	[None]

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 Registrant was required to file such reports) and (2) has been subject to such filing requirements for at least the past 90 days. Yes x No o

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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB. o

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

The aggregate market value of the voting common equity held by non-affiliates of the registrant as of December 31, 2006 was approximately $4,587,000 based upon the closing bid price of the registrant’s Common Stock on the Over the Counter Bulletin Board, at December 29, 2006. (For purposes of determining this amount, only directors, executive officers, and 10% or greater stockholders and their respective affiliates have been deemed affiliates).

Registrant had 41,147,363 shares of Common Stock, par value $0.001 per share, issued and outstanding as of December 31, 2006.

DOCUMENTS INCORPORATED BY REFERENCE

The Exhibits to this Annual Report have been incorporated by reference from other filings by the Company with the Securities and Exchange Commission.

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PART 1
FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-KSB contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. 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. When used in this Annual Report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "plan", "intend", "may," "will," "expect," "believe", "could," "anticipate," "estimate," or "continue" or similar expressions or oth comparable terminology are intended to identify such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1: Business

History of the Company

We were originally incorporated in the State of Colorado on June 5, 1987 under the name Great Expectations, Inc. We were administratively dissolved on January 1, 1997 and reinstated June 18, 1998 under the name Great Expectations and Associates, Inc. In 1999, we became a reporting company under the Securities Exchange of 1934 (the "Exchange Act'). Until November 2004, we were a publicly-traded "shell" company without any business until November 12, 2004 when we acquired Advaxis, Inc., a Delaware corporation ("Advaxis"), through a Share Exchange and Reorganization Agreement, dated as of August 25, 2004 (the "Share Exchange"), by and among Advaxis, the stockholders of Advaxis and us. As a result of such acquisition, Advaxis become our wholly-owned subsidiary and our sole operating company. On December 23, 2004, we amended and restated our articles of incorporation and changed our name to Advaxis, Inc. On June 6, 2006 our shareholders approved the reincorporation of the company from the state of Colorado to the state of Delaware by merging the Company into its wholly-owned subsidiary. As used herein, the words "Company" and "Advaxis" refer to the current Delaware corporation only unless the context references such entity prior to the June 20, 2006 reincorporation into Delaware. Our principal executive offices are located at Technology Centre of NJ, 675 US Highway One, North Brunswick, NJ 08902 and our telephone number is (732) 545-1590.

On July 28, 2005 we began trading on the Over-The-Counter Bulletin Board (OTC:BB) under the ticker symbol ADXS.

Recent Developments

Pursuant to a Securities Purchase Agreement dated February 2, 2006, we sold to Cornell Capital Partners, LP ("Cornell") $3,000,000 principal amount of our 6% Secured Convertible Debentures (the "Debentures") due February 1, 2009 ($1,500,000 on February 2, 2006 and $1,500,000 on March 8, 2006) and five year Warrants to purchase 4,200,000 shares of Common Stock at the price of $0.287 per share and five year B Warrants to purchase 300,000 shares of Common Stock at a price of $0.3444 per share. The Debentures are convertible at a price equal to the lesser of (i) $0.287 per share ("Fixed Conversion Price"), or (ii) 95% of the lowest volume weighted average price of the Common Stock on the market on which the shares are listed or traded during the 30 trading days immediately preceding the date of conversion ("Market Conversion Price"). Interest is payable at maturity at the rate of 6% per annum in cash or shares of Common Stock valued at the conversion price then in effect.

In March 2006 we began our first phase I clinical study and June 6, 2006 our shareholders approved the reincorporation of the company from the state of Colorado to the state of Delaware by merging the company into its wholly-owned subsidiary.

Our Website

We maintain a website at www.advaxis.com which contains descriptions of our technology, our drugs and the trial status of each drug.

General

We are a development stage biotechnology company with the intent to develop safe and effective cancer vaccines that utilize multiple mechanisms of immunity. We use the Listeria System licensed from the University of Pennsylvania (Penn) to secrete a protein sequence containing a tumor-specific antigen. Using the Listeria System, we believe we will force the body's immune system to process and recognize the antigen as if it were foreign, creating the immune response needed to attack the cancer. We believe that the Listeria System is a broadly enabling platform technology that can be applied to many types of cancers. In addition, we believe there may be useful applications in infectious diseases and auto-immune disorders.

The therapeutic approach that comprises the Listeria System is based upon the innovative work of Yvonne Paterson, Ph.D., Professor of Microbiology at Penn, involving the creation of genetically engineered Listeria that stimulate the innate immune system and induce an antigen-specific immune response involving humoral and cellular components.

We have focused our initial development efforts upon cancer vaccines targeting cervical, breast, prostate, ovarian, lung and other cancers. Our lead products in development are as follows:

Product	Indication	Stage
Lovaxin C	Cervical, Head and Neck	Phase I/II; Phase I anticipated to be complete in the fiscal second /third quarter 2007. Phase II study in cervical cancer anticipated to commence in late 2007
Lovaxin B	Breast cancer	Preclinical; Phase I study anticipated to commence in late fiscal 2007/early 2008
Lovaxin P	Prostate cancer	Preclinical; Phase I study anticipated to commence in late fiscal 2008
Lovaxin T	Cancer through control of telomerase	Preclinical

See "Item 1. Business - Research and Development Programs".

Since our formation, we have had a history of losses that as of October 31, 2006 have aggregated $9,662,173, and because of the long development period for new drugs, we expect to continue to incur losses for an extended period of time. Our business plan to date has been realized by substantial outsourcing of virtually all-major functions of drug development including scaling up for manufacturing, research and development, grant applications, clinical studies, and others. The expenses of these outsourced services account for most of our accumulated loss. We cannot predict when, if ever, any of our product candidates will become commercially viable or FDA approved. Even if one or more of our products receives FDA approval or becomes commercially viable we are not certain that we will ever become a profitable business.

Strategy

During the next 12 to 24 months our strategic focus will be to achieve several objectives. The foremost of these objectives are as follows:

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Complete our Phase I clinical study of Lovaxin C to document the practicability of using this agent safely in the therapeutic treatment of cervical cancer;

- *Initiate our Phase II clinical study of Lovaxin C in the therapeutic treatment of cancers.*
- *Initiate a Phase I/II clinical study of Lovaxin B in the therapeutic treatment of breast cancer.*
- *Initiate a Phase I/II clinical study of Lovaxin P in the therapeutic treatment of prostate cancer.*
- *Continue the pre-clinical development of our product candidates, as well as continue research to expand our technology platform; and*
- *Initiate strategic and development collaborations with biotechnology and pharmaceutical companies.*

Complete the Ongoing Phase I Clinical Study of Lovaxin C. We have had several meetings with the FDA and the Recombinant Advisory Committee of the National Institutes of Health (the "NIH") and have designed and fielded a Phase I/II clinical study, to assess the safety of Lovaxin C. We plan to complete this clinical study in the fiscal second/third fiscal quarter 2007. The study includes 20 patients with advanced cervical cancer the sites are located in Serbia, Mexico and Israel, of which 10 patients have successfully completed the trial.

We have demonstrated in over 100 publications in peer reviewed journals that Lovaxin C generates a therapeutic effect in animal cancer models. The preliminary safety data was deemed adequate by both national and institutional regulators in each of the countries in which our trial is being conducted under the International Harmonization Treaties (ICH) which govern international drug development. A safety panel comprised of a founder of the National Cancer Institute (NCI) Gynecologic Oncology Group, the investigator for the phase III Merck Gardasil trial, an oncologist, the principal investigator of the study and a representative of the sponsor was convened according to the clinical protocol, which states that all severe and life threatening adverse events (grade 3 & 4) are to be promptly reported to this panel who are empowered to stop the trial at any time in the event of a safety risk to patients. At the time of this writing, the first two cohorts have completed dosing and no grade 3 or 4 adverse events associated with Lovaxin C have been observed.

The Gynecologic Oncology Group, (GOG) a collaborative treatment group associated with the NCI has agreed to conduct the field work for the Phase II study at their expense (an estimated value of about $1,500,000 to $2,000,000). We estimate that we will conduct lab work valued at $250,000 to support of this study.

Following the completion of the Phase I study and assuming that the results of this study are favorable, we intend to prepare Phase II clinical studies to demonstrate therapeutic efficacy, as well as to optimize the dosage and dosing regimen, the tests and assessments to be performed in phase III, to characterize the responding patient population, and to understand all factors possible for the purpose of defining and conducting a definitive test of the safety and efficacy of Lovaxin C for regulatory approval. Thereafter, and assuming that the results of this Phase II study are favorable, we intend to conduct Phase III clinical studies to demonstrate safety, efficacy and the potency of the investigational vaccine. Such studies are expected to occur in the next five to ten years. Throughout this process, we will be meeting with the FDA prior to and at the conclusion of each phase to reach a consensus before initiating any studies, in order to minimize regulatory risks during this clinical development process.

At the conclusion of the Phase III studies, we intend to prepare and file a Biologics License Application (BLA) with the FDA. Prior to submission of the BLA, depending upon the data, we intend to possibly seek a Special Protocol Assessment and/or a Fast Track designation from the FDA, which shortens the internal FDA review process. As we accrue clinical data demonstrating the safety, efficacy and potency of Lovaxin C in Phase I and II clinical studies we will also explore other regulatory approval options with the FDA that could expedite the licensure of the final vaccine.

We intend to continue to devote a portion of our resources to the continued pre-clinical development of our product candidates as well as the continued research to expand our technology platform. Specifically, we intend to focus upon research relating to combining our Listeria System with new and additional tumor antigens which, if successful, may lead to additional cancer vaccines and other therapeutic products. These activities may require significant financial resources, as well as areas of expertise beyond those readily available. In order to provide additional resources and capital, we may enter into research, collaborative, or commercial partnerships, joint ventures, or other arrangements with competitive or complementary companies, including major international pharmaceutical companies, or with universities, such as Penn and UCLA. See “Item 1. Business - Partnerships and Agreements - Penn”.

Background

Cancer

Despite tremendous advances in science, cancer remains a major health problem, and for many it continues to be the most feared of diseases. Although age-adjusted mortality rates for all cancer fell during the 1990’s, particularly for the major cancer sites (lung, colorectal, breast, and prostate), mortality rates are still increasing in certain sites such as liver and non-Hodgkin’s lymphoma. The American Cancer Society estimates that more than eight million Americans were treated for cancer in 1999. According to the HCUP, in 2000, treatment of the top five cancers resulted in $10.8 billion in hospital costs.

Cancer is the second largest cause of death in the United States, exceeded only by heart disease. Approximately 1,399,790 new cases of cancer were expected to be diagnosed in 2006, and 564,830 Americans were expected to die from the disease. The NIH estimates the overall cost for cancer in the year 2005 at $209.9 billion: $74.06 billion for direct medical costs, $17.5 billion for indirect morbidity costs (loss of productivity due to illness) and, $118.4 billion for indirect mortality costs (cost of lost productivity due to premature death). (Source: cancer facts & figures 2006, American Cancer Society). Cervical cancer is estimated to cause the death in the US of approximately 3,700 patients in 2006.

Immune System and Normal Antigen Processing

Living creatures, including humans, are continually confronted with potentially infectious agents. The immune system has evolved multiple mechanisms that allow the body to recognize these agents as foreign, and to target a variety of immunological responses, including innate, antibody, and cellular immunity, that mobilize the body’s natural defenses against these foreign agents and will eliminate them.

Innate Immunity:

Innate immunity is the first step in the recognition of a foreign antigen by lymphocytes is antigen processing by Antigen Processing Cells (APC). APCs are phagocytic cells that ingest particulate material, infectious agents and cellular debris. This non-specific ingestion Phagocytosis by these cells results in their activation and the release of soluble mediators called cytokines that assist the immune response.

Exogenous pathway of Adapative Immunity (Class II pathway):

Proteins and foreign molecules ingested by APC are broken down in digestive vacuoles into small pieces, called peptides, and the pieces are combined with proteins called Class 2 MHC (for Major Histocompatibility Complex) in a part of the cell called the endoplasmic reticulum. The MHC-peptide, termed and MHC-2 complex from the Class 2 (or exogenous) pathway, is then pushed out to the cell surface where it interacts with certain classes of lymphocytes (CD4+) such as helper T-cells that produce induce a proliferation of stimulate B-cells, which produce antibodies, or helper T cells that assist in the maturation of cytotoxic T-lymphocytes. This system is called the exogenous pathway, since it is the prototypical response to an exogenous antigen like bacteria.

Endogenous pathway of Adaptive Immunity (Class I pathway)

There exists another pathway, called the endogenous pathway. In this system, when one of the body's cells begins to create unusual proteins (as happens in most viral infections and in cancer cells), the protein is broken up into peptides in the cytoplasm and directed into the endoplasmic reticulum, where it is incorporated into an MHC-1 protein and traffics to the cell surface. This signal then calls effector cells of the cellular immune system, especially CD8+ cytotoxic T-lymphocytes, to come and kill the cell. The endogenous pathway is primarily for elimination of virus-infected or cancerous cells.

In clinical cancer, the body does not always recognize the cancer cells as foreign. *Listeria* based vaccines are unique for many reasons, one of which is that unlike viral vectors, DNA or peptide antigens or other vaccines, *Listeria* stimulates all of the above mechanisms of immune action.Our technology forces the body to recognize tumor-associated or tumor-specific antigens as foreign, thus creating the immune response needed to attack the cancer. It does this by combining elements of the endogenous and exogenous pathways utilizing a number of biologic characteristics of the Listeria bacteria.

Mechanism of Action

Listeria is a bacterium well known to medical science because it can cause an infection in humans. Because Listeria is a live bacterium it stimulates the innate immune system, thereby priming the adaptive immune system to better respond to the specific antigens that the Listeria carries, which viruses and other vectors do not do. This is a non-specific stimulation of the overall immune system that results when certain classes of pathogens such as bacteria (but not viruses) are detected. It provides some level of immune protection and also serves to prime the elements of adaptive immunity to respond in a stronger way to the specific antigenic stimulus.

When Listeria enters the body, it is seen as foreign by the antigen processing cells and ingested into cellular compartments called lysosomes, whose destructive enzymes kill most of the bacteria. A certain percentage of these bacteria, however, are able to break out of the lysosomes and enter into the cytoplasm of the cell, where they are relatively safe from the immune system. The bacteria multiply in the cell, and the Listeria is able to force the cell to move the bacteria to its cell surface so it can push into neighboring cells and spread. *Listeria* is a pathogen that causes food poisoning, typically in people who are either immunocompromised or who eat a large quantity of the microbe as can occur in spoiled dairy products. It is not laterally tranmitted from person to person, and is a common microbe in our environment. Most people ingest *Listeria* without being aware of it, but in high quantities or in immune suppressed people Listeria can cause various clinical conditions, including sepsis, meningitis and placental infections in pregnant women. Fortunately, many common antibiotics can kill and sterilize *Listeria*,

Figs 1-7. When Listeria enters the body, it is seen as foreign by the antigen processing cells and ingested into cellular compartments called lysosomes, whose destructive enzymes kill most of the bacteria, fragments of which are then presented to the immune system via the exogenous pathway.

Figs 8-10 A certain percentage of bacteria are able to break out of the lysosomes and enter into the cytoplasm of the cell, where they are safe from lysosomal destruction. The bacteria multiply in the cell, and the Listeria is able to migrate into neighboring cells and spread without entering the extracellular space. Antigen produced by these bacteria enter the Class I pathway and directly stimulate a cytotoxic T cell response.

It is the details of Listeria intracellular activity that are important for understanding Advaxis technology. Inside the lysosome, Listeria produces listeriolysin-O ("LLO"), a protein that digests a hole in the membrane of the lysosome that allows the bacteria to escape into the cytoplasm. Once in the cytoplasm, however, LLO is also capable of digesting a hole in the outer cell membrane. This would destroy the host cell, and spill the bacteria back out into the intercellular space where it would be exposed to more immune cell attacks and destruction. To prevent this, the body has evolved a mechanism for recognizing enzymes with this capability based upon their amino acid sequence. The sequence of approximately 30 amino acids in LLO and similar molecules is called the PEST sequence (for the predominant amino acids it contains) and it is used by normal cells to force the termination of proteins that need only have a short life in the cytoplasm. This PEST sequence serves as a routing tag that tells the cells to route the LLO in the cytoplasm and to the proteosome for digestion, which terminates its action and provides fragments that then go to

the endoplasmic reticulum, where it is processed just like a protein antigen in the endogenous pathway to generate MHC-1 complexes.

This mechanism is used by Listeria to its benefit for the Listeria is that the LLO is neutralized and the bacteria do not kill the host cell. Advaxis is co-opting this mechanism by creating a protein that is comprised of the cancer antigen fused to a non-hemolytic portion of the LLO molecule that contains the PEST sequence. This serves to route the molecule for accelerated proteolytic degradation which accelerates both the rate of antigen breakdown and the amount of antigen fragments available for incorporation in to MHC-1 complexes; thus increasing the stimultus to activate cytotoxic T cells.

Thus, Listeria vaccines stimulate every immune pathway simultaneously. It has long been recognized that cytotoxic T lymphocytes (CTL) are the elements of the immune system that kill and clear cancer cells. The amplified CTL response to Listeria vaccines are arguably the strongest stimulator of CTL yet developed. The strength of this response is reflected in the data.

It is important to note that Advaxis proprietary LLO fusion protein has other salutary actions that facilitate a therapeutic cancer killing action. We have published findings which show that *Listeria* engineered to deliver our LLO fusion protein are different from *Listeria* engineered to deliver the same antigen without the fusion tag in that the antigen-only system stimulates T regulatory cells (Tregs) and the LLO fusion protein delivery does not. This is very important since T regulatory cells are activated along with other T cells during immune stimulation; however they inhibit the anti-tumor response. It is believed that these cells serve as a brake on the immune system to minimize potentially dangerous autoimmune reactions. Most vaccines stimulate Tregs, and this is currently believed to be a reason for less than optimal therapeutic responses. Currently there are drugs in development to treat cancer that function exclusively by inhibiting these Tregs.

Also, many investigators have shown that LLO has adjuvant effects which result in the release of a variety of chemicals with in the body, and within the tumor, termed cytokines, chemokines and co-stimulatory molecules. These agents facilitate the tumor killing effects of activated T cells by creating a local tumor environment that is most conducive for these actions to occur. Taken together, this is why it is believed that live *Listeria* which secrete LLO and escape from the phagocytotic vacuole exerts such profound immuno-stimulatory effects, while ingested *Listeria* that are digested within the vacuole and do not escape don’t show these effects.

Thus, what makes Advaxis live Listeria vaccines so effective are a combination of effects that stimulate multiple arms of the immune system simultaneously in a manner that generates an integrated physiologic response conducive to the killing and clearing of tumor cells. These mechanisms include:

1. Innate immunity: the non-specific stimulation of all aspects of the immune system in response to a bacterial infection
2. Exogenous pathway: the stimulation of helper T cell function that stimulates and supports cytotoxic T cell function.
3. Endogenous pathway: the direct stimulation of cytotoxic T cells in an amplified fashion due accelerated antigen fragment generation
4. Lack of Tregs: the stimulation of the facilitory aspects of an anti-tumoral immune response without the inhibitory aspects as a result of the LLO antigen fusion protein
5. Supportive local tumor environment: the adjuvant stimulation of various chemical factors within the tumor that support the anti-tumor effect of the immune system stimulated by the effective delivery of the specific antigen.

Research and Development Program

Overview

We use genetically engineered Listeria monocytogenes as a therapeutic agent. We start with an attenuated strain of Listeria, and then add to this bacterium a plasmid that encodes a protein sequence that includes a portion of the LLO molecule (including the PEST[1] sequence) and the tumor antigen of interest. This protein is secreted by the Listeria inside the antigen processing cells, which then results in the immune response as discussed above.

We can use different tumor antigens (or other antigens: e.g. allergy or infectious disease) in this system. By varying the antigen, we create different therapeutic agents. Our lead agent, Lovaxin C, uses a human papillomavirus derived antigen that is present in cervical cancers. Lovaxin B uses her2/neu, an antigen found in many breast cancer and melanoma cells, to induce an immune response that should be useful in treating these conditions. The table below shows a list of potential products and their current status:

Product	Indication	Stage
Lovaxin C	Cervical, Head and Neck	Phase I/II; Phase I anticipated to be complete in the fiscal second /third quarter 2007 Phase II study in cervical cancer anticipated to commence in late fiscal 2007
Lovaxin B	Breast cancer	Preclinical; Phase I study anticipated to commence in late fiscal 2007/early 2008
Lovaxin P	Prostate cancer	Preclinical; Phase I study in late fiscal 2008
Lovaxin T	Cancer through control of telomerase	Preclinical

Partnerships and Agreements

University of Pennsylvania

On July 1, 2002 (effective date) we entered into a 20-year exclusive worldwide license, with the University of Pennsylvania (Penn) with respect to the innovative work of Yvonne Paterson, Ph.D., Professor of Microbiology in the area of innate immunity, or the immune response attributable to immune cells, including dentritic cells, macrophages and natural killer cells, that respond to pathogens non-specifically. This agreement has been amended from time to time and has been amended and restated February 13, 2007.

This license, unless sooner terminated in accordance with its terms, terminates upon the later (a) expiration of the last to expire Penn patent rights; or (b) twenty years after the effective date. The license provides us with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date, in connection with Dr. Paterson and requires us to raise capital, pay various milestone, legal, filing and licensing payments to commercialize the technology. In exchange for the license, Penn received shares of our common stock which currently represents

approximately 16% of our common stock outstanding on a fully-diluted basis. In addition, Penn is entitled to receive a non-refundable initial license fee, license fees, royalty payments and milestone payments based on net sales and percentages of sublicense fees and certain commercial milestones, as follows: Under the licensing agreement, Penn is entitled to receive 1.5% royalties on net sales in all countries. Notwithstanding these royalty rates, we have agreed to pay Penn a total of $525,000 over a three-year period as an advance minimum royalty after the first commercial sale of a product under each license (which payments we are not expecting to begin paying within the next five years). In addition, under the license, executed on February 13, 2007 we are obligated to pay an annual maintenance fee starting on December 31, 2008, until the first commercial sale of a Penn licensed product. Under the amended and restated agreement we are also required to pay a total of $157,134 in license payments in addition to the $215,700 previously paid or a total of $372,834 in Pen