FORM 10-K

Annual report pursuant to section 13 and 15(d)

Filing Date: **2011-05-31** | Period of Report: **2011-02-28**
SEC Accession No. 0001104659-11-032257

FILER

BURZYNSKI RESEARCH INSTITUTE INC

CIK:**724445**| IRS No.: **760136810** | State of Incorp.:**DE** | Fiscal Year End: **0228**
Type: **10-K** | Act: **34** | File No.: **000-23425** | Film No.: **11880291**
SIC: **2835** In vitro & in vivo diagnostic substances

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended February 28, 2011

☐ **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 000-23425

BURZYNSKI RESEARCH INSTITUTE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**76-0136810**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
9432 Old Katy Road, Suite 200 Houston, Texas	**77055**
(Address of principal executive offices)	(Zip Code)

Registrant' s telephone number, including area code: **(713) 335-5697**

Securities registered under Section 12(b) of the Exchange Act:

None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, $.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not contain, to the best of registrant' s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment of this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of August 30, 2010, the aggregate market value of the Common Stock held by non-affiliates was approximately $1,954,740, based on the last reported sales price on August 30, 2010, the last business day of the Registrant' s most recently completed second fiscal quarter. For purposes of this disclosure, shares of Common Stock held by persons who hold more than 5% of the outstanding shares of common stock and shares held by officers and directors of the registrant have been excluded as such persons may be deemed to be affiliates.

As of May 1, 2011, there were 131,448,444 shares of the Registrant' s Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Documents incorporated by reference: **None**.

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BURZYNSKI RESEARCH INSTITUTE, INC.

FORM 10-K

FISCAL YEAR ENDED FEBRUARY 28, 2011

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FORWARD LOOKING STATEMENTS

This report contains forward-looking statements, including statements regarding future financial performance and results and other statements that are not historical facts. Such statements are included in "Business," "Management' s Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report. When used in this report, words such as "may," "will," "should," "could," "anticipate," "believe," "expect," "estimate," "intend," "plan," "predict," "potential," "continue" and similar expressions are intended to identify forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, there can be no assurance that actual results or developments anticipated by the Company will be realized or, even if realized, that they will have the expected effects on its business or operations. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors beyond the Company' s control including: the ability to develop safe and efficacious drugs, the failure to achieve positive clinical trials, the failure to successfully commercialize our products, competition and technological change and existing and future regulations affecting our business.

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PART I

ITEM 1. BUSINESS

General

Burzynski Research Institute, Inc. (the "Company") was incorporated under the laws of the State of Delaware in 1984 in order to engage in the research, production, marketing, promotion and sale of certain medical chemical compounds composed of growth-inhibiting peptides, amino acid derivatives and organic acids which are known under the trade name "Antineoplastons." The Company believes Antineoplastons are useful in the treatment of human cancer and is currently conducting Phase II clinical trials of Antineoplastons relating to the treatment of cancer. Antineoplastons have not been approved for sale or use by the Food and Drug Administration of the United States Department of Health and Human Services ("FDA") or anywhere in the world. In the event Antineoplastons receive such approval and are registered in the United States, Canada, or Mexico, of which there can be no assurance, the Company will commence commercial operations, which shall include the production, marketing, promotion and sale of Antineoplastons in the United States, Canada, or Mexico. In 2004, the FDA approved the designation of Antineoplastons as an "orphan drug" under the Orphan Drug Act of 1983. See "−Orphan Drug Designation" below for a detailed description of this designation and its meaning. The Company currently provides Antineoplastons solely for the use of Stanislaw R. Burzynski, M.D., Ph.D. ("Dr. Burzynski") in clinical research.

The Company has not generated any significant operating revenue since its inception. The Company' s sole source of funding for its operations has been and continues to be payments made by Dr. Burzynski from funds generated from Dr. Burzynski' s medical practice pursuant to various arrangements between the Company and Dr. Burzynski. *See* "*Certain Relationships and Related Transactions, and Director Independence*." The Company reports funds pursuant to such arrangements as additional paid-in capital. *See* "*Management' s Discussion and Analysis of Financial Condition and Results of Operations*." The Company does not expect to generate significant operating revenue until such time, if any, as Antineoplastons are approved for use and sale by the FDA. However, the Company may seek additional funding for operations through the sale of its securities.

Antineoplastons

Dr. Burzynski commenced his cancer research in 1967 focusing on the isolation of various biochemicals produced by the human body as part of the body' s possible defense against cancer. In the course of his research, Dr. Burzynski identified certain peptides, amino acid derivatives and organic acids in these biochemicals which appear to inhibit the growth of cancer cells. These derivatives were given the name "Antineoplastons" by Dr. Burzynski.

Antineoplastons are found in the bodily fluids of humans and food and were initially isolated by Dr. Burzynski from normal human blood and urine. Dr. Burzynski believes these substances counteract the development of cancerous growth through a biochemical process which does not inhibit the growth of normal tissues. To date, Dr. Burzynski has developed six formulations of natural Antineoplastons and six synthetic formulations of Antineoplastons. All of the Phase II clinical trials currently sponsored by the Company involve the use of four formulations of synthetic Antineoplastons known as A10 and AS2-1 in capsules and injections. The Company is also conducting laboratory research involving new generations of Antineoplastons A10 and AS2-1.

Orphan Drug Designation

On September 7, 2004, the FDA granted "orphan drug" status to the Company' s Antineoplastons under the Orphan Drug Act of 1983. In enacting the Orphan Drug Act of 1983, Congress sought to provide incentives to promote the development of drugs for the treatment of rare diseases. A drug may be considered for orphan drug designation if the drug is intended to treat a rare disease or condition affecting fewer than 200,000 people in the United States or, even if the drug treats a disease affecting more than 200,000 people in the United States, the drug is not expected to be profitable from sales in the United States. Subject to applicable laws and regulations, the first sponsor to obtain FDA marketing approval for a drug with orphan drug designation for the designated disease or condition receives limited marketing exclusivity for seven years; no other sponsor may bring to market the "same drug" for the treatment of the same disease or condition for a period of seven years from the date the application is approved by the FDA. A drug with orphan drug designation must meet the same criteria for safety and efficacy as a drug without orphan drug designation.

Please see "–Government Regulation" for a complete description of the regulatory approval process with the FDA and other regulatory agencies.

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Phase II Clinical Trials

The Company began Phase II clinical studies in 1994 with four studies. At that time, a number of patients were also receiving Antineoplastons at Dr. Burzynski' s clinic in Houston, Texas (the "Burzynski Clinic") outside these clinical trials. On February 23, 1996, the FDA requested that all then-current patients of the Burzynski Clinic desiring to continue Antineoplaston treatment be admitted to a Phase II Study, according to Protocol CAN-1. This action resulted in the formation of six cohorts of patients in the CAN-1 study, with the largest group suffering from primary brain tumors. New patients either were admitted to the CAN-1 study or have been admitted to one of the other studies sponsored by the Company, as appropriate.

The Company currently sponsors two ongoing Phase II clinical trials that are open for enrollment, which are conducted pursuant to investigational new drug applications ("INDs") filed with the FDA and approved by an Institutional Review Board ("IRB") designated according to federal regulations.

All clinical trials are for the treatment of a wide variety of cancers using only a combination of Antineoplastons A10 and AS2-1. Most of the trials involve the use of intravenous formulations of Antineoplastons; however, a few trials use oral formulations. Dr. Burzynski acts as principal investigator for all clinical trials pursuant to a Royalty Agreement between the Company and Dr. Burzynski. See "*Certain Relationships and Related Transactions, and Director Independence*." All of the clinical trials are conducted at the Burzynski Clinic. Each trial provides for the admission of up to 40 patients, except the CAN-1 study, in which 133 patients were enrolled. Please see *"–Active Phase II Clinical Trials"* for a list of all of these clinical trials.

Prior to approving a New Drug Application ("NDA"), the FDA requires that a drug' s safety and efficacy be demonstrated in "well-controlled" clinical trials. Several types of controls are acceptable to the FDA. One of these is a "Historic Control." Under a "Historic Control" if the course of a disease is well-known, the response of patients taking a drug can be compared to a historic group of patients with that disease who have not had medical intervention. For example, it is known that the tumors of patients suffering from primary malignant brain tumors ("PMBT") will continue to grow, eventually causing the patient' s death. If a drug is administered to a patient with PMBT and the tumors of the patient disappear or shrink significantly, an assumption is made that there has been a response to the drug.

All of the Company' s clinical trials, except one, involve the use of Historic Controls. Further, all trials except the CAN-1 study are "prospective clinical trials" ("PCT"). A PCT is a clinical trial wherein patients are accrued into and follow the clinical trial protocol from the very beginning of the trial. A retrospective trial is a trial in which data from patients treated prior to the start of a clinical trial is considered. Results of retrospective trials are, in most instances, not acceptable to the FDA. In addition, there are no clinical trials being conducted that involve "double blind" studies and all but one clinical trial involve no randomization into multiple treatment groups.

The ultimate goal of any treatment for cancer is patient survival. However, the FDA has determined that requiring exhaustive data showing improved patient survival may unnecessarily delay the approval of new cancer drugs. For that reason, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug has an effect on a surrogate endpoint ("Milestone") that is reasonably likely to predict clinical benefit. Each of the Company' s Phase II trials describes such Milestones which are used to determine success or failure of the treatment employed. In most of the trials, the Milestones are radiographic evidence of tumor shrinkage by X-ray, computer aided tomography or magnetic resonance imaging. Where appropriate, tumor markers such as Prostate Specific Antigen, blood counts, or bone marrow biopsy are used in order to assess a tumor' s growth.

Where tumor size is used as the Milestone, each clinical trial protocol that is open for enrollment describes a "complete response" as a complete disappearance of all tumors with no reoccurrence of tumors for at least four weeks. A "partial response" is described as at least a 50% reduction in total tumor size, with such reduction lasting at least four weeks. An "objective response" is described as either a complete or

partial response for protocols BT-08, BT-09, BT-11, BT-12, BT-13, BT-15, BT-18, BT-21 and BT-23. “Stable disease” is described as less than 50% reduction in size but no more than 50% increase in size of the tumor mass, lasting for at least twelve weeks.

The protocols of the Company’ s clinical trials involve a two-stage design, wherein the first stage proceeds until the Company admits twenty patients into the trial. After a specified time period, if there are zero responses by the first twenty patients, the trial will be discontinued and the drug declared to have less than desired activity. If there is at least one response, the trial will be continued until forty patients have been accrued. If the study continues, the following conclusions according to protocols based on forty patients can be made: If there are three or fewer responses, then there is less than desired activity. If there are four or more responses, then there is sufficient evidence to conclude that the Antineoplaston regimen used shows beneficial activity.

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As of May 1, 2011 certain prospective clinical trials have reached a Milestone. These are:

- Protocol BT-07, involving the study of Antineoplastons A10 and AS2-1 in patients with glioblastoma multiforme, not treated with radiation therapy or chemotherapy.
- Protocol BT-08, involving the study of Antineoplastons A10 and AS2-1 in patients with anaplastic astrocytoma.
- Protocol BT-09, involving the study of Antineoplastons A10 and AS2-1 in patients with brain tumors.
- Protocol BT-11, involving the study of Antineoplastons A10 and AS2-1 in patients with brainstem glioma.
- Protocol BT-12, involving the study of Antineoplastons A10 and AS2-1 in children with primitive neuroectodermal tumors (PNET).
- Protocol BT-13, involving the study of Antineoplastons A10 and AS2-1 in children with low grade astrocytoma, a type of PMBT.
- Protocol BT-15, involving the study of Antineoplastons A10 and AS2-1 in adult patients with anaplastic astrocytoma, a type of PMBT.
- Protocol BT-18, involving a study of Antineoplastons A10 and AS2-1 in the treatment of “mixed glioma,” a type of PMBT.
- Protocol BT-20, involving the study of Antineoplastons A10 and AS2-1 in patients with glioblastoma multiforme, which recurred after standard radiation and/or chemotherapy.
- Protocol BT-21, involving the study of Antineoplastons A10 and AS2-1 in adults with primary malignant brain tumors.
- Protocol BT-23, involving a study of Antineoplastons A10 and AS2-1 in children with visual pathway glioma.

There can be no assurance that the results of any of these trials can be repeated or that the other clinical trials will result in the same or similar responses.

The results of Protocols BT-07, BT-08, BT-09, BT-11, BT-12, BT-13, BT-15, BT-18, BT-20, BT-21 and BT-23 are set forth below (as of May 1, 2011).

Protocol Number	Patients Accrued	Evaluable Patients	Number and Percentage of Patients Showing	Number and Percentage of	Number and Percentage of Patients	Number and Percentage of Patients

			Complete Response		Patients Showing Partial Response		Showing Stable Disease		Showing Progressive Disease	
BT-07	40	24	2	8.3%	1	4.2%	3	12.5%	18	75.0%
BT-08	19	14	4	28.6%	0	0.0%	6	42.9%	4	28.6%
BT-09	40	26	4	15.4%	6	23.1%	11	42.3%	5	19.2%
BT-11	40	28	5	17.9%	4	14.3%	12	42.9%	7	25.0%
BT-12	13	11	3	27.3%	1	9.1%	3	27.3%	4	36.4%
BT-13	11	9	5	55.6%	1	11.1%	3	33.3%	0	0.0%
BT-15	27	20	3	15.0%	2	10.0%	9	45.0%	6	30.0%
BT-18	20	13	3	23.1%	1	7.7%	3	23.1%	6	46.2%
BT-20	40	22	1	4.5%	1	4.5%	12	54.5%	8	36.4%
BT-21	40	23	2	8.7%	2	8.7%	9	39.1%	10	43.5%
BT-23	12	8	3	37.5%	1	12.5%	3	37.5%	1	12.5%

The Phase II Study according to Protocol CAN-1 included 35 evaluable brain tumor patients. Complete and partial responses were obtained in patients diagnosed with glioblastoma multiforme, astrocytoma, oligodendroglioma, mixed glioma, medulloblastoma, and malignant meningioma. The treatment with Antineoplastons A10 and AS2-1 resulted in 48.6% cases of objective responses and 31.4% cases of stable disease. The largest group of evaluable patients involved in the study had glioblastoma multiforme. Six of the cases were classified as complete and partial responses, four obtained stabilization and four developed progression of the disease.

Notwithstanding the response results of the trials that have reached a Milestone, management believes it is likely that the FDA may require additional clinical trials based upon such protocols to be conducted by an institution not affiliated with the Company or Dr. Burzynski before advising that an NDA filing is warranted. In addition, the FDA has indicated it will not accept the efficacy

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data, but will accept toxicity data generated by the Phase II study according to Protocol CAN-1 because the trial was partially retrospective. At this time, the Company cannot predict if and/or when it will submit an NDA to the FDA, nor can the Company estimate the number or type of additional trials the FDA may require. Further, there can be no assurance that an NDA for Antineoplastons, as a treatment for cancer, will ever be approved by the FDA.

No assurance can be given that any new IND for clinical tests on humans will be approved by the FDA for human clinical trials on cancer or other diseases, that the results of such human clinical trials will prove that Antineoplastons are safe or effective in the treatment of cancer or other diseases, or that the FDA would approve the sale of Antineoplastons in the United States.

Open for Enrollment Phase II Clinical Trials

The following table sets forth the title of each active Protocol and the number of persons currently enrolled in each study. All of the following trials are Phase II studies and, except as otherwise indicated, are of Antineoplastons A10 and AS2-1 in patients with the conditions listed. For purposes of this table, active means that the study is still under open enrollment. In addition, all of the studies listed have a maximum of 40 patients who may ultimately participate in the study. The information in this table is updated as of May 1, 2011.

Title of Protocol	Subject of Protocol	Number of Persons Enrolled
BT-10	Children with Brain Tumors	25
BT-22	Children with Primary Malignant Brain Tumors	7

Phase III Clinical Trials

On January 13, 2009, the Company announced that it has reached an agreement with the FDA that enables the Company to move forward immediately with a pivotal Phase III clinical trial of combination Antineoplaston therapy plus radiation therapy in patients with newly-diagnosed, diffuse, intrinsic brainstem glioma. The agreement was made under the FDA' s Special Protocol Assessment procedure and means that the design and planned analysis of the Phase III study is acceptable to support a regulatory submission seeking new drug approval.

On February 23, 2010, the Company entered into an agreement with Cycle Solutions, Inc., dba ResearchPoint ("Research Point") to initiate and manage a pivotal Phase III clinical trial of combination Antineoplastons A10 and AS2-1 plus radiation therapy (RT) in patients with newly-diagnosed, diffuse, intrinsic brainstem glioma. Research Point is currently conducting a feasibility assessment. Research Point has secured interest and commitment from a number of sites selected. Upon completion of this assessment, a randomized, international Phase III study will commence. The study' s objective is to compare overall survival of children with newly-diagnosed, diffuse, intrinsic brainstem glioma (DBSG) who receive combination Antineoplastons A10 and AS2-1 plus RT versus RT alone.

Government Regulation

The FDA imposes substantial requirements upon, and conditions precedent to, the introduction of therapeutic drug products through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time consuming procedures. To obtain FDA approval for Antineoplastons, we must submit extensive preclinical and clinical data and supporting information to the FDA to establish the safety and efficacy of Antineoplastons. The approval process takes many years, requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies. Additional government regulation may be established that could prevent or delay regulatory approval of Antineoplastons. Moreover, there can be no assurance that the Company can satisfy FDA requirements to gain approval for Antineoplastons in the United States or that FDA approval for the sale of Antineoplastons in the United States will be obtained. If regulatory approval is granted, the approval may include significant limitations on the indicated uses for which Antineoplastons may be marketed.

The effect of the FDA drug approval process for Antineoplastons may impose costly procedures upon the Company' s activities which may furnish a competitive advantage to the other companies that compete with the Company in the field of cancer treatment drugs. The extent of potentially adverse government regulations which might arise from future legislation or administrative action cannot be predicted.

The Investigational New Drug Application Process in the United States is governed by regulations established by the FDA which strictly control the use and distribution of investigational drugs in the United States. The guidelines require that an IND, filed by a sponsor, contain sufficient information to justify administering the drug to humans, that the application include relevant information on the chemistry, pharmacology and toxicology of the drug derived from chemical, laboratory and animal or in vitro testing, and that a protocol be provided for the initial study of the new drug to be conducted on humans.

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In order to conduct a clinical trial of a new drug in humans, a sponsor must prepare and submit to the FDA a comprehensive IND. Such application must contain an investigator' s brochure, a description of the composition, manufacture and control of the drug substance and the drug product, sufficient information to assure the proper identification, quality, purity and strength of the investigational drug, a description of the drug substance, including its physical, chemical, and biological characteristics, the general method of preparation of the drug substance, a list of all components including interactive ingredients, adequate information about pharmacological and toxicological studies of the drug involving laboratory animals or in vitro tests on the basis of which the sponsor has concluded that it is reasonably safe to conduct the proposed clinical investigation and a summary of any previous human experience with the drug. Where there has been widespread use of the drug outside of the United States or otherwise, it is possible in some limited circumstances to use well-documented clinical experience in place of some other pre-clinical work.

The focal point of the IND is on the general investigational plan and the protocols for specific human studies. The plan is carried out in three phases: Phase I includes the initial introduction of an investigational new drug into humans and may be conducted in patients or

normal volunteer subjects. The studies are closely monitored to determine the metabolism and pharmacologic actions of the drug in humans, the potential side effects and, if possible, to gain early evidence on effectiveness. During Phase I testing, sufficient information about the drug is gathered to design well-controlled, scientifically valid Phase II studies. Phase II includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase II studies are controlled, closely monitored and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. Phase III includes expanded controlled and uncontrolled trials and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase III studies usually include anywhere from several hundred to several thousand subjects.

An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns about issues such as the conduct of the trials as outlined in the IND. After the IND becomes effective, the investigation is permitted to proceed, during which the sponsor must keep the FDA informed of new studies, including animal studies, make progress reports on the study or studies covered by the IND, and also be responsible for informing FDA and clinical investigators immediately of unforeseen serious side effects or injuries. There can be no assurance that Phase I, Phase II or Phase III testing will be completed successfully by the Company within any specified period of time, if at all. Furthermore, the Company or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the clinical studies, the results of the studies, together with other detailed information, including, among other information, details concerning the manufacture and composition of the drug, proposed labeling, environmental impact and the scientific rationale for the drug, its intended use and the potential benefits of the drug product, are submitted to the FDA in the form of an NDA requesting approval to market the drug. If the FDA finds the NDA submission and the manufacturing process to be acceptable, the FDA will issue an approval letter. If the FDA does not find the NDA submission or the manufacturing process to be sufficient, it will issue a "not approvable letter" describing the deficiencies in the NDA and allowing the NDA applicant to either amend the NDA, withdraw the NDA or request a hearing. Even if the NDA is amended or a hearing is held, the FDA ultimately may decide that the NDA does not satisfy the regulatory criteria for approval. In addition, as a result of the Company' s use of Milestones to predict the benefits of Antineoplastons, the FDA may subject any such approval to the requirement that the Company study the drug further, to verify and describe its clinical benefit (Phase IV testing). Further, the FDA may also impose post-marketing restrictions on Antineoplastons. The FDA may withdraw approval of any drug if the Phase IV trials fail to verify clinical benefit, use of the drugs demonstrates that post-marketing restrictions are inadequate to assure safe use of the drug, the Company fails to adhere to the post-marketing restrictions agreed upon, the promotional materials are false or misleading or other evidence demonstrates that the drug is not shown to be safe or effective under its conditions of use.

The testing and approval process requires substantial time, effort and financial resources, and there can be no assurance that any approval will be granted for any product or that approval will be granted according to any schedule. Moreover, if regulatory approval of a drug is granted, the approval will be limited to specific indications. There can be no assurance that any of the Company' s product candidates will receive regulatory approvals for commercialization.

The FDA has implemented an accelerated review process for pharmaceutical agents that treat serious or life-threatening disease and conditions, subject to payment of user fees. Approval may be conditioned on a requirement that, following product launch, a company continue to study the drug to verify and describe its clinical benefit. Under "fast track" procedures, the FDA may withdraw approval on an expedited basis if the company fails to show due diligence in conducting post-marketing clinical trials or if the post-approval clinical trials fail to demonstrate that the product is safe or effective. When appropriate, the Company intends to pursue opportunities for accelerated review of its products. The Company cannot predict the ultimate effect of this review process on the timing or likelihood of FDA review of any of its products.

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Please see *"–Orphan Drug Designation"* for a description of the FDA' s orphan drug designation under the Orphan Drug Act of 1983 as it applies to the Company' s Antineoplastons.

Even if the regulatory approvals for the Company' s products are obtained, its products and its manufacturing facility are subject to continuous review and periodic inspection. The FDA will require post-marketing reporting to monitor the safety of the Company' s products. The Company' s drug manufacturing facility must be inspected and approved by the FDA and must comply with the FDA' s current good manufacturing practice regulations, which are strictly enforced. Full technical compliance requires manufacturers to expend funds, time and effort in the area of production and quality control. In addition, discovery of problems with a product after approval or failure to comply with applicable FDA or other applicable regulatory requirements may result in restrictions on a product, manufacturer, or holder of an approved NDA, including restrictions on the product, manufacturer or facility, including warning letters, suspension of regulatory approvals, operating restrictions, delays in obtaining new product approvals, withdrawal of the product from the market, product recalls, fines, injunctions and criminal prosecution. New government requirements may be established that could delay or prevent regulatory approval of the Company' s products under development.

The Company' s research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. Although the Company believes its procedures for handling and disposing of those materials comply with state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident of this type occurs, the Company could be held liable for resulting damages, which could be material to its financial condition and business. The Company is also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures and the handling of biohazardous materials. Additional federal, state and local laws and regulations affecting the Company may be adopted in the future. Any violation of these laws and regulations, and the cost of compliance, could materially and adversely affect the Company. The Company spends approximately $40,000 per year on environmental compliance matters and expects to spend approximately $5,000 for repairs and upgrades during the fiscal year ending February 28, 2012.

Research And Development

The Company' s principal research and development efforts currently focus on Antineoplastons. The anticancer activity of these compounds has been documented in preclinical studies employing the methods of cell culture, pharmacology, cell biology, molecular biology, experimental therapeutics and animal models of cancer. At the level of Phase II clinical studies, the Company believes the anticancer activity of Antineoplastons is supported by preliminary results from ongoing, FDA-authorized, Phase II clinical trials.

The cellular mechanism underlying the anticancer effects of Antineoplastons continues to be investigated in both the Company' s own basic preclinical research program and in independent laboratories around the world. A review of this work suggests several mechanisms that may underlie the antineoplastic activity of Antineoplastons. For example, it has been found, in cell culture experiments, that Antineoplastons induce pathologically undifferentiated cancer cells to assume a more normal state of differentiation. Cell culture experiments have also shown that Antineoplaston components can kill some cancer cells by activating the cell' s intrinsic "suicide" program. It must be noted that data collected in cell culture experiments may or may not indicate the mechanism of action of Antineoplastons in humans.

At a more molecular or sub-cellular level, cell culture experiments have shown that Antineoplastons can block biochemical pathways involving oncogenes required to produce abnormal cell growth. In addition, cell culture experiments have shown that Antineoplastons can increase the expression of anticancer tumor suppressor genes. Although these experiments were conducted using human cancer cells, they may or may not indicate the mechanism of Antineoplaston action in humans.

In addition to the original family of Antineoplaston compounds (the "Parental Generation"), the Company continues its development of a second generation of Antineoplastons. In cell culture experiments, the second generation Antineoplastons, which were developed by the Company, have been shown to be significantly more potent than the Parental Generation.

The Company is also developing a third generation of structurally altered Antineoplastons that the Company believes will exhibit markedly improved anticancer activity in human cancer cell lines that have been resistant to the Parental Generation. However, increases of antineoplastic activity in cell culture experiments may or may not translate into increased efficacy in humans.

The Company is also involved in ongoing studies examining the pharmacokinetics (absorption, distribution, metabolism, and excretion) and pharmacodynamics (dose-response) of Antineoplastons in patients with neoplastic disease.

The Company uses various scientific reagents from several different suppliers to conduct its research activities.

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Total research and development costs for the fiscal years ended February 28, 2011 and February 28, 2010 were approximately $4,780,000 and $4,480,000, respectively.

Intellectual Property

Since 1984, eight patents involving the formulation, preparation, manufacture, production, use, dosage and treatment of cancer with Antineoplastons (the "Patents") have been issued to Dr. Burzynski by the United States Patent Office and the Patent Offices of 34 other countries. The Patents for cancer treatment and diagnosis in the United States and Canada are licensed to the Company pursuant to a License Agreement dated June 29, 1983, as superseded by an Amended License Agreement dated April 24, 1989 and a Second Amended License Agreement dated March 1, 1990 (collectively, the "License Agreement"). Pursuant to the License Agreement, the Company holds an exclusive right in the United States, Canada, and Mexico (the "Territory") to use, manufacture, develop, sell, distribute, sub-license and otherwise exploit all of Dr. Burzynski' s rights, title, and interests, including patent rights, in Antineoplastons in the treatment and diagnosis of cancer. See "*Certain Relationships and Related Transactions, and Director Independence.*" The Company will not be able to exploit such rights until such time as Antineoplastons are approved, of which there can be no assurance, by the FDA for sale in the United States. The License Agreement is to continue in effect until the expiration of the last Patent that was licensed under the agreement or termination pursuant to certain other provisions. The Company and Dr. Burzynski also entered into a Royalty Agreement, dated March 25, 1997, and a First Amended Royalty Agreement, dated September 29, 1997 (collectively, the "Royalty Agreement"), pursuant to which Dr. Burzynski will receive a royalty interest from all future sales, distribution, and manufacture of Antineoplastons by the Company. The Company owns, pursuant to the License Agreement, exclusive rights to eight issued United States Patents, four issued Canadian Patents and one issued Mexican Patent.

The five initial United States Patents (the "Initial Patents") relate to: (i) Determination of Antineoplastons in body tissue or fluids as a testing procedure to aid in the diagnosis of cancer; (ii) Processes for the preparation of purified fractions of Antineoplastons from human urine; (iii) Processes for the synthetic production of Antineoplastons and methods of treating neoplastic disease (cancer); (iv) Administration of Antineoplastons to humans; and (v) Methods of synthesizing A-10. The last of the Initial Patents expired on January 11, 2009, however, the Company does not believe the expiration of any of the Initial Patents will have a material adverse effect on the Company.

The sixth United States Patent (the "2000 U.S. Patent") covers Liposomal Antineoplaston therapies with markedly improved anti-cancer activity. The 2000 U.S. Patent expires on May 14, 2017.

The seventh United States Patent (the "2001 U.S. Patent") is for a treatment regimen for the administration of phenylacetylglutamine, phenylacetylisoglutamine, and/or phenylacetate. The 2001 U.S. Patent expires on July 23, 2018.

The eighth United States Patent (the "2005 U.S. Patent") relates to a divisional application to the 2001 U.S. Patent. The 2005 U.S. Patent issued in September 2005 and will expire July 31, 2018.

The four Canadian Patents (the "Canadian Patents") relate to: (i) Processes for the preparation of purified fractions of Antineoplastons from human urine, (ii) Processes for the synthetic production of Antineoplastons and methods of treating neoplastic disease (cancer), (iii) Liposomal formulation of Antineoplastons and (iv) Treatment regimen for the administration of phenylacetylglutamine. The Canadian Patents expired or will expire on June 4, 2002, November 14, 2006, May 14, 2017 and July 2, 2019, respectively; however, the Company does not believe the expiration of the Canadian Patents will have a material adverse effect on the Company.

The Mexican Patent relates to a treatment regimen for the administration of phenylacetylglutamine. This patent will expire in the year 2019.

The Company also depends upon unpatented proprietary technology, and may determine in appropriate circumstances that its interest would be better served by reliance upon trade secrets or confidentiality agreements rather than patents.

The Company' s success will depend in part on its ability to enforce patent protection for its products, preserve its trade secrets, and operate without infringing on the proprietary rights of third parties in the United States, Canada, and Mexico. Because of the substantial length of time and expense associated with bringing new products through development and regulatory approval to the marketplace, the pharmaceutical and biotechnology industries place considerable importance on obtaining and maintaining patent and trade secret protection for new technologies, products and processes. There can be no assurance that the Company will develop additional products and methods that are patentable or that present or future patents will provide sufficient protection to the Company' s present or future technologies, products and processes. In addition, there can be no assurance that others will not independently develop substantially equivalent proprietary information, design around the Company' s patents or obtain access to the Company' s know-how or that others will not successfully challenge the validity of the Company' s patents or be issued patents which

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may prevent the sale of one or more of the Company' s product candidates, or require licensing and the payment of significant fees or royalties by the Company to third parties in order to enable the Company to conduct its business. Legal standards relating to the scope of claims and the validity of patents in the fields in which the Company is pursuing research and development are still evolving, are highly uncertain and involve complex legal and factual issues. No assurance can be given as to the degree of protection or competitive advantage any patents issued to the Company will afford, the validity of any such patents or the Company' s ability to avoid violating or infringing any patents issued to others. Further, there can be no guarantee that any patents issued to or licensed by the Company will not be infringed by the products of others. Litigation and other proceedings involving the defense and prosecution of patent claims can be expensive and time-consuming, even in those instances in which the outcome is favorable to the Company, and can result in the diversion of resources from the Company' s other activities. An adverse outcome could subject the Company to significant liabilities to third parties, require the Company to obtain licenses from third parties or require the Company to cease any related research and development activities or sales.

The Company depends upon the knowledge, experience and skills (which are not patentable) of its key scientific and technical personnel. To protect its rights to its proprietary information, the Company requires all employees, consultants, advisors and collaborators to enter into confidentiality agreements which prohibit the disclosure of confidential information to anyone outside the Company and require disclosure and assignment to the Company of their ideas, developments, discoveries and inventions. There can be no assurance that these agreements will effectively prevent the unauthorized use or disclosure of the Company' s confidential information.

ANTINEOPLASTON® is a trademark registered with the U.S. Patent and Trademark Office.

Competition

There are many companies, universities, research teams and scientists, both private and government-sponsored, that are engaged in research to produce cancer treatment agents and that have greater financial resources and larger research staffs and facilities than the Company. In addition, there are other companies and entities, both private and government-sponsored, that are engaged in research aimed at compounds similar or related to the Company' s Antineoplastons. To the extent that the United States Government also conducts research or supports other companies or individuals in their research, such companies or individuals may have a competitive advantage over the Company.

Employees

As of May 1, 2011, the Company had three employees, all of whom were full-time employees. None of the Company' s employees is a party to a collective bargaining agreement. The Company considers the relations with its employees to be good.

ITEM 2. PROPERTIES

The Company does not own or invest in real estate, interests in real estate, real estate mortgages or securities of or interests in persons primarily engaged in real estate activities.

The Company conducts its business in premises owned by Dr. Burzynski and his wife, Dr. Barbara Burzynski (the "Burzynskis"). Pursuant to arrangements with the Burzynskis (see "*Certain Relationships and Related Transactions, and Director Independence–Research Funding Arrangements*"), the Company occupies (i) 675 square feet at 12707 Trinity Drive, Stafford, Texas for office, laboratory and medical research purposes and (ii) 540 square feet at 9432 Old Katy Road, Suite 200 for its executive offices. Management of the Company believes that each of these properties is adequately covered by insurance.

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ITEM 3. LEGAL PROCEEDINGS

The Company' s activities are subject to regulation by various governmental agencies, including the FDA, which regularly monitor the Company' s operations and often impose requirements on the conduct of its clinical trials and other aspects of the Company' s business operations. The Company' s policy is to comply with all such regulatory requirements. From time to time, the Company is also subject to potential claims by patients and other potential claimants commonly arising out of the operation of a medical practice. The Company seeks to minimize its exposure to claims of this type wherever possible.

Currently, the Company is not a party to any material pending legal proceedings. Moreover, the Company is not aware of any such legal proceedings that are contemplated by governmental authorities with respect to the Company or any of its properties.

ITEM 4. REMOVED AND RESERVED

PART II

ITEM 5. MARKET FOR REGISTRANT' S COMMON EQUITY; RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Since October 15, 2001, the Company' s Common Stock has remained in good standing for trading on the OTCBB. Nevertheless, a public trading market having the characteristics of depth, liquidity and orderliness depends upon the existence of market makers as well as the presence of willing buyers and sellers, which are circumstances over which the Company does not have control. There can be no assurance that the market will provide significant liquidity for the Company' s Common Stock. As a result, an investment in the Company' s Common Stock may be highly illiquid. Investors may not be able to sell their shares readily or at all when the investor needs or desires to sell.

The following table sets forth closing high and low bid prices of the shares of Common Stock of the Company for the periods indicated (as reported by OTC Markets Group Inc.).

	Price Range	
	High	Low
Fiscal year ended February 28, 2010		
First Quarter	$ 0.18	$ 0.07
Second Quarter	0.18	0.04
Third Quarter	0.21	0.11
Fourth Quarter	0.20	0.12
Fiscal year ended February 28, 2011		

First Quarter	$ 0.22	$ 0.11
Second Quarter	0.17	0.08
Third Quarter	0.15	0.08
Fourth Quarter	0.15	0.11

The quotations set forth above reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

On June 1, 2009, the Company approved the issuance of 60,000 shares of the Company' s Common Stock as compensation for services rendered to the Company and valued at approximately $9,400. The shares were sold pursuant to an exemption from registration under Section 4(2) of the Securities Act of 1933, as amended, to a single accredited investor and did not involve a public offering, and were issued to such investor on June 2, 2010.

As of May 1, 2011, there were approximately 2,000 holders of record of the Company' s Common Stock, as shown on the records of the Transfer Agent and Registrar of the Common Stock. Since many shares may be held by investors in nominee names, such as the name of their broker or their broker' s nominee, the number of record holders often bears little relationship to the number of beneficial owners of the Common Stock.

The Company has never paid cash dividends on its Common Stock and the Board of Directors intends to retain all of its earnings, if any, to finance the development and expansion of its business. However, there can be no assurance that the Company can successfully expand its operations, or that such expansion will prove profitable. Future dividend policy will depend upon the Company' s earnings, capital requirements, financial condition and other factors considered relevant by the Company' s Board of Directors.

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ITEM 6. SELECTED FINANCIAL DATA

None.

ITEM 7. MANAGEMENT' S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following is a discussion of the financial condition of the Company as of February 28, 2011 and February 28, 2010 and the results of operations for the fiscal years ended February 28, 2011 and February 28, 2010. It should be read in conjunction with the financial statements and the notes thereto included elsewhere in this report. The following discussion contains forward-looking statements.

Introduction

The Company has generated no significant revenue since its inception, and does not expect to generate any operating revenues until such time, if any, as Antineoplastons are approved for use and sale by the FDA. The Company' s sole source of funding is Dr. Burzynski, who funds the Company' s operations from his medical practice pursuant to certain agreements between Dr. Burzynski and the Company. *See* "*Certain Relationships and Related Transactions, and Director Independence*." Funds received by the Company from Dr. Burzynski are reported as additional paid-in capital to the Company.

The Company is primarily engaged as a research and development facility of Antineoplaston drugs currently being tested for use in the treatment of cancer, and provides consulting services. The Company is currently conducting two FDA-approved clinical trials. The Company holds the exclusive right in the United States, Canada and Mexico to use, manufacture, develop, sell, distribute, sublicense and otherwise exploit all the rights, titles and interest in Antineoplaston drugs used in the treatment of cancer, once the drugs are approved for sale by the FDA. See "*Certain Relationships and Related Transactions, and Director Independence.*"

Results Of Operations

Fiscal Year Ended February 28, 2011 Compared to Fiscal Year Ended February 28, 2010

Research and development costs were approximately $4,780,000 and $4,480,000 for the fiscal years ended February 28, 2011 and 2010, respectively. The increase of $300,000 or 7% was due to an increase in personnel cost of $395,000, an increase in consulting and quality control costs of $28,000, and an increase in other research and development costs of $8,000, offset by a decrease in material costs of $101,000 and a decrease in facility and equipment costs of $30,000.

General and administrative expenses were approximately $250,000 and $349,000 for the fiscal years ended February 28, 2011 and 2010, respectively. The decrease of $99,000 or 28% was due to a decrease in legal and professional fees of $56,000, and a decrease in other general and administrative expenses of $43,000.

The Company had net losses of approximately $5,031,000 and $4,831,000 for the fiscal years ended February 28, 2011 and 2010, respectively. The increase in the net loss from 2010 to 2011 was primarily due to an overall increase in research and development cost offset by an overall decrease in general and administrative expenses of the Company described above. As of February 28, 2011, the Company had a total stockholders' deficit of $(51,000).

Liquidity and Capital Resources

The Company' s operations have been funded entirely by Dr. Burzynski with funds generated from Dr. Burzynski' s medical practice. Effective March 1, 1997, the Company entered into a Research Funding Agreement with Dr. Burzynski (the "Research Funding Agreement"), pursuant to which the Company agreed to undertake all scientific research in connection with the development of new or improved Antineoplastons for the treatment of cancer and Dr. Burzynski agreed to fund the Company' s Antineoplaston research for that purpose. Under the Research Funding Agreement, the Company hires such personnel as is required to conduct Antineoplaston research, and Dr. Burzynski funds the Company' s research expenses, including expenses to conduct the clinical trials. Dr. Burzynski also provides the Company laboratory and research space as needed to conduct the Company' s research activities. The Research Funding Agreement also provides that Dr. Burzynski may fulfill his funding obligations in part by providing the Company such administrative support as is necessary for the Company to manage its business. Dr. Burzynski pays the full amount of the Company' s monthly and annual budget of expenses for the operation of the Company, together with other unanticipated but necessary

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expenses which the Company incurs. In the event the research results in the approval of any additional patents for the treatment of cancer, Dr. Burzynski shall own all such patents, but shall license to the Company the patents based on the same terms, conditions and limitations as are in the current license between Dr. Burzynski and the Company. Dr. Burzynski has unlimited and free access to all equipment which the Company owns, so long as such use does not conflict with the Company' s use of such equipment, including without limitation, all equipment used in the manufacturing of Antineoplastons used in the clinical trials. The amounts which Dr. Burzynski is obligated to pay under the agreement shall be reduced dollar for dollar by the following: (1) any income which the Company receives for services provided to other companies for research and/or development of other products, less such identifiable marginal or additional expenses necessary to produce such income, or (2) the net proceeds of any stock offering or private placement which the Company receives during the term of the agreement up to a maximum of $1,000,000 in a given Company fiscal year.

The Company entered into a third amendment to the Research Funding Agreement, effective March 1, 2007, whereby the Company and Dr. Burzynski extended the term thereof until February 28, 2008, with an automatic renewal for an additional one-year term, unless one party notifies the other party at least thirty days prior to the expiration of the term of the agreement of its intention not to renew the agreement. Subject to the foregoing, the term of the Research Funding Agreement has renewed and extended until February 28, 2011, which

extended term is also automatically renewable for an additional one-year term unless one party notifies the other party at least thirty days prior to the expiration of the term of the agreement of its intention not to renew the agreement.

The Research Funding Agreement automatically terminates in the event that Dr. Burzynski owns less than fifty percent of the outstanding shares of the Company, or is removed as President and/or Chairman of the Board of the Company, unless Dr. Burzynski notifies the Company in writing of his intention to continue the agreement notwithstanding this automatic termination provision.

The Company estimates that it will spend approximately $5.0 million in the fiscal year ending February 28, 2012. The Company estimates that ninety-five percent (95%) of this amount will be spent on research and development and the continuance of FDA-approved clinical trials. While the Company anticipates that Dr. Burzynski will continue to fund the Company' s research and FDA-related costs, there is no assurance that Dr. Burzynski will be able to continue to fund the Company' s operations pursuant to the Research Funding Agreement or otherwise. However, because the net assets available to Dr. Burzynski from his personal assets and the assets of his medical practice currently exceed the Company' s projected twelve-month funding requirements, the Company believes Dr. Burzynski will be financially able to fund the Company' s operations at least through the fiscal year ending February 28, 2012. In addition, Dr. Burzynski' s medical practice has successfully funded the Company' s research activities over the last 26 years and, in 1997, his medical practice was expanded to include traditional cancer treatment options such as chemotherapy, immunotherapy, hormonal therapy and gene targeted therapy in response to FDA requirements that cancer patients utilize more traditional cancer treatment options in order to be eligible to participate in the Company' s Antineoplaston clinical trials. As a result of the expansion of Dr. Burzynski' s medical practice, the financial condition of the medical practice has improved Dr. Burzynski' s ability to fund the Company' s operations.

Because the Company currently is entirely dependent upon the contributions for research provided by Dr. Burzynski under the Research Funding Agreement, the Company would not be able to continue conducting its clinical trials if Dr. Burzynski ceased funding the Company' s research. In such event, the Company would be required to find immediate funding which may not be available on acceptable terms or at all. If this were to occur and the Company were not able to find adequate sources of funding, the Company would be required to cease operations. Even with Dr. Burzynski' s continued contributions under the Research Funding Agreement, the Company may be required to seek additional capital through equity or debt financing or the sale of assets until the Company' s operating revenues are sufficient to cover operating costs and provide positive cash flow; however, there can be no assurance that the Company will be able to raise such additional capital on acceptable terms to the Company. In addition, there can be no assurance that the Company will ever achieve positive operating cash flow.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Company' s Annual Financial Statements, Notes to Financial Statements and the report of Pannell Kerr Forster of Texas, P.C., independent registered public accounting firm, with respect thereto, referred to in the Table of Contents to the Financial Statements, appear elsewhere in this report beginning on Page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

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ITEM 9A(T). CONTROLS AND PROCEDURES

(a) *Evaluation of Disclosure Controls and Procedures.* Within the 90 days prior to the date of this report, the Company carried out an evaluation, under the supervision and with the participation of the Company' s management, including the Company' s principal executive officer and principal financial officer, of the effectiveness of the Company' s disclosure controls and procedures pursuant to Rule 13a-14 under the Securities Exchange Act of 1934, as amended. Based upon that evaluation, the Company' s principal executive officer and principal

financial officer concluded that the Company' s disclosure controls and procedures are effective and designed to ensure that the information required to be included in periodic Securities and Exchange Commission filings is recorded, processed, summarized and reported on a timely basis. A controls system cannot provide absolute assurance, however, that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management' s Annual Report on Internal Control over Financial Reporting. The Company' s management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our 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 accounting principles generally accepted in the United States.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives.

The Company' s management, with the participation of the Company' s principal executive officer and principal financial officer, evaluated the effectiveness of the Company' s internal control over financial reporting as of February 28, 2011. In making this assessment, the Company' s management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control − Integrated Framework. Based on this evaluation, the Company' s management, with the participation of the principal executive officer and principal financial officer, concluded that, as of February 28, 2011, the Company' s internal control over financial reporting was effective.

This annual report does not include an attestation report of the Company' s registered public accounting firm regarding internal control over financial reporting. Management' s report was not subject to attestation by the Company' s registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the company to provide only management' s report in this annual report.

(b) *Changes in Internal Control Over Financial Reporting*. There were no significant changes in the Company' s internal controls or in other factors that could significantly affect internal controls subsequent to the date of the evaluation above.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Set forth below are the names, ages and positions of the Company' s directors and executive officers:

Name	Age	Office
Stanislaw R. Burzynski, M.D., Ph.D.	68	Director, President, Secretary, and Treasurer
Barbara Burzynski, M.D.	70	Director
Michael H. Driscoll, J.D.	65	Director
Carlton Hazlewood, Ph.D.	75	Director

STANISLAW R. BURZYNSKI, M.D., PH.D., has been the President and Chairman of the Board of Directors of the Company since its inception in 1984. He also serves as the Company' s Secretary and Treasurer. Dr. Burzynski is a physician in private practice in Houston, Texas specializing in the treatment of cancer. Dr. Burzynski is the husband of Barbara Burzynski, M.D., who is a director of the Company.

Currently listed in Who' s Who In The World and a member in good standing with both the American and World Medical Associations, Dr. Burzynski is an internationally recognized physician and scientist who has pioneered the development and use of biologically active peptides in diagnosing, preventing, and treating cancer since 1967. In 1967, Dr. Burzynski graduated with

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distinction with an M.D. degree from the Medical Academy in Lublin, Poland, finishing first in his class of 250, and he subsequently earned his Ph.D. in Biochemistry.

From 1970 to 1977, he was a researcher and Assistant Professor at Baylor College of Medicine in Houston. At Baylor, Dr. Burzynski' s research was sponsored and partially funded by the National Cancer Institute. Also at Baylor, he authored and co-authored sixteen publications, including five concerning his research on peptides and their effect on human cancer. Four of these publications were also co-authored by other doctors associated with M.D. Anderson Hospital and Tumor Institute and Baylor College of Medicine. In May 1977, Dr. Burzynski received a Certificate of Appreciation from Baylor College of Medicine and in that same year founded the Company.

Dr. Burzynski is a member of the American Medical Association, American Association for Cancer Research, Harris County Medical Society, New York Academy of Sciences, Society for Neuroscience, Texas Medical Association, the Society of Sigma Xi, and the Society of Neuro-oncology. He is the author of over 300 scientific publications, presenter of scientific papers at major international conventions, and has been awarded 241 patents covering 42 countries for his Antineoplaston treatment and other inventions. Other groups are working in conjunction with him, including researchers at the University of Kurume Medical School in Japan.

BARBARA BURZYNSKI, M.D., a Director since 1984 and the wife of Dr. Burzynski, has been the Chairman of the Department of Pharmacy of the Burzynski Clinic since 1977. From January 1976 to July 1977, she was a Research Assistant in the Department of Pediatrics at Baylor College of Medicine. She was a physician at the Medical Academy, Lublin, Poland, from 1970 to 1975. Dr. Barbara Burzynski graduated with an M.D. in 1966 from the Medical Academy, Lublin, Poland, and has published six publications on studies with Antineoplastons.

MICHAEL H. DRISCOLL, J.D. has been a Director of the Company since 1984. Mr. Driscoll was formerly a judge and served as the County Attorney of Harris County, Texas from 1981 until he retired in 1997.

CARLTON HAZLEWOOD, PH.D. has been a Director of the Company since 1997. He also serves as Chairman of the IRB, an independent review board for the Company' s clinical trials designated according to federal regulations. Dr. Hazlewood currently operates his own consulting company, Research Consultant' s International, is president of Petroclean, L.L.C. and is an adjunct professor at Kingwood College. In addition, Dr. Hazlewood was employed in various capacities by the Baylor College of Medicine from 1965 until December 31, 1997, where he was a professor of Molecular Biology and Biophysics. Dr. Hazlewood received his Ph.D. in Medical Physiology from the University of Tennessee. Dr. Hazlewood is a prolific writer on medical topics and has been recognized for his research with numerous awards, honors and research grants.

Audit Committee Financial Expert

The Company has not established an Audit Committee. Therefore, the Board of Directors has not designated any of its members as an "audit committee financial expert" as defined by the rules and regulations of the Securities and Exchange Commission.

Section 16(a) Beneficial Ownership Reporting Compliance

Based solely upon a review of Forms 3 and 4 and amendments thereto furnished to the Company under Rule 16a-3(e) during the fiscal year ended February 28, 2011 and Form 5 and amendments thereto furnished to the Company with respect to such period, the Company is not aware of any director, officer, or beneficial owner of more than 10% of any class of equity securities of the Company registered

pursuant to Section 12 of the Securities Exchange Act of 1934 (the "Exchange Act") that has failed to file on a timely basis, as disclosed in the above forms, reports required by Section 16(a) of the Exchange Act during the Company' s most recent fiscal year.

Code of Ethics

The Company has adopted a code of ethics that applies to our chief executive officer, chief financial officer, chief accounting officer and all persons performing similar functions. The Company hereby undertakes to provide a copy of this code of ethics to any person, without charge upon request made in writing to: Investor Relations, 9432 Old Katy Road, Suite 200, Houston, Texas 77055.

ITEM 11. EXECUTIVE COMPENSATION

SUMMARY COMPENSATION TABLE

		Annual Compensation			Long-Term Compensation			
Name and Principal Position	Fiscal Year Ending	Salary($)	Bonus ($)	Other Annual Compensation ($)	Restricted Stock Awards($)	Securities Underlying Options/SARs($)	LTIP Payouts ($)	All Other Compensation ($)
Stanislaw R. Burzynski,	2009	-0-	-0-	-0-	-0-	-0-	-0-	-0-
M.D., Ph.D., President,	2010	-0-	-0-	-0-	-0-	-0-	-0-	-0-
Secretary and Treasurer(1)	2011	-0-	-0-	-0-	-0-	-0-	-0-	-0-

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(1) In May of 2000, Dr. Burzynski began drawing his entire salary through his medical practice and is not currently compensated by the Company for his services.

Directors do not receive any compensation for serving as directors; however, directors are reimbursed for all ordinary and necessary expenses incurred in attending meetings of the Board of Directors or otherwise incurred in their capacity as directors. In addition, any director also serving as a director of the IRB, the independent review board for the Company' s clinical trials designated according to federal regulations, is compensated by the IRB approximately $1,200 annually for serving as a director of the IRB.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth, as of May 1, 2011, the number of outstanding shares of Common Stock (the Company' s only class of voting securities) owned by (i) each person known by the Company to beneficially own more than 5% of its outstanding Common Stock, (ii) each director, (iii) each named executive officer, and (iv) all officers and directors as a group. The address for all of the beneficial owners listed below is the Company' s address.

Name of beneficial owner	Amount and nature of beneficial ownership	Percent of class (1)
Stanislaw R. Burzynski, M.D., Ph.D.	106,444,190	81.0%
Barbara Burzynski, M.D.	106,444,190(2)	81.0%
Michael H. Driscoll	570,000	*
Carlton Hazlewood	0	*
All Current Directors and Executive Officers as a group (4 persons)	107,014,190	81.41%

* Less than one percent.

(1) Percentages shown are based upon 131,448,444 shares of Common Stock outstanding as of May 1, 2011. Certain shares are deemed beneficially owned by more than one person listed in the table.

(2) All of the shares listed above for Dr. Barbara Burzynski are included in the total number of shares for Dr. Burzynski, her husband.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Dr. Burzynski is the President, Secretary, Treasurer and Chairman of the Board of the Company, as well as the beneficial owner of 81.0% of the Company' s outstanding Common Stock. Since 1983, Dr. Burzynski has personally funded and supported the Company' s operations out of funds generated from his medical practice pursuant to various agreements with the Company.

License Agreement

The Company entered into the License Agreement with Dr. Burzynski which gives the Company the exclusive right in the Territory (composed of the United States, Canada and Mexico) to use, manufacture, develop, sell, distribute, sublicense and otherwise exploit all of his rights, title and interests in Antineoplastons in the treatment and diagnosis of cancer, including but not limited to any patent rights which may be granted in these countries. The License Agreement will terminate upon the earlier of the expiration of the last patent licensed to the Company, or termination by Dr. Burzynski, at his option, if he is removed as a director or officer of the Company without his consent, if the Company files for bankruptcy or is the subject of any proceeding under applicable bankruptcy laws where such proceeding is not dismissed within 90 days from the date a petition is filed, or if any shareholder or group of shareholders acting in concert becomes the beneficial owner of the Company' s securities having voting power equal to or greater than the voting power of the securities Dr. Burzynski holds. Amendments to the License Agreement on April 24, 1984 and on March 1, 1990 granted Dr. Burzynski the limited right to manufacture, use, and exploit Antineoplastons in the Company' s exclusive territory solely for the purpose of enabling Dr. Burzynski to treat patients in his medical practice until such date that the FDA may approve the sale of Antineoplastons for the treatment of cancer in the United States.

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Research Funding Arrangements

Effective March 1, 1997, the Company entered into the Research Funding Agreement with Dr. Burzynski and terminated all of the prior funding agreements between the Company and Dr. Burzynski. Pursuant to the Research Funding Agreement:

- The Company agreed to undertake all scientific research in connection with the development of new or improved Antineoplastons for the treatment of cancer and other diseases. The Company will hire such personnel as is required to fulfill its obligations under the agreement;
- Dr. Burzynski agreed to fund in its entirety all basic research which the Company undertakes in connection with the development of other Antineoplastons or refinements to existing Antineoplastons for the treatment of cancer and other diseases;
- Dr. Burzynski agreed to pay the expenses to conduct the clinical trials for the Company;
- Dr. Burzynski agreed to provide the Company such laboratory, research space and office space as the Company needs at no charge to the Company;
- The parties agreed that Dr. Burzynski may fulfill his obligations in part by providing such administrative staff as is necessary for the Company to manage its business, at no cost to the Company;

- Dr. Burzynski agreed to pay the full amount of the monthly and annual budget of expenses for the operation of the Company, together with such other unanticipated but necessary expenses which the Company incurs. Payments from Dr. Burzynski to the Company of the monthly budget shall be made in two equal installments on the first and fifteenth of each month;

- In the event the research described in the agreement results in the approval of any additional patents, Dr. Burzynski shall own all such patents, but shall license to the Company the patents based on the same terms, conditions and limitations as provided by the License Agreement;

- Dr. Burzynski shall have unlimited and free access to all equipment which the Company owns, so long as such use is not in conflict with the Company' s use of such equipment, including without limitation to all equipment used in manufacturing of Antineoplastons used in the clinical trials;

- The amounts which Dr. Burzynski is obligated to pay under the agreement shall be reduced dollar for dollar by the following:

    - Any income which the Company receives for services provided to other companies for research and/or development of other products, less such identifiable marginal or additional expenses necessary to produce such income (such as the purchase of chemicals, products or equipment solely necessary to engage in such other research and development activity); and

    - The net proceeds of any stock offering or private placement which the Company receives during the term of the agreement up to a maximum of $1,000,000 in a given Company fiscal year.

Effective March 1, 2007, the Company entered into a third amendment to the Research Funding Agreement, whereby the Company and Dr. Burzynski extended the term thereof until February 28, 2008, with an automatic renewal for an additional one-year term, unless one party notifies the other party at least thirty days prior to the expiration of the term of the agreement of its intention not to renew the agreement. In addition to the foregoing termination provisions, the agreement automatically terminates in the event that Dr. Burzynski owns less than fifty percent of the outstanding shares of the Company, or is removed as President and/or Chairman of the Board of the Company, unless Dr. Burzynski notifies the Company in writing of his intention to continue the agreement notwithstanding this automatic termination provision. Subject to the foregoing, the term of the Research Funding Agreement has renewed and extended until February 28, 2012, which extended term is also automatically renewable for an additional one-year term unless one party notifies the other party at least thirty days prior to th expiration of the term of the agreement of its intention not to renew the agreement.

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Royalty Agreement

The Company and Dr. Burzynski entered into the Royalty Agreement, pursuant to which Dr. Burzynski agreed to act as the principal clinical investigator of the clinical trials necessary for obtaining FDA approval for interstate marketing of Antineoplastons. The Company and Dr. Burzynski agreed that in the event the Company receives FDA approval for interstate marketing and distribution, of which there can be no assurance, the Company shall pay Dr. Burzynski a royalty of 10% (ten percent) of the Company' s gross income, which royalty shall be paid on all gross receipts from all future sales, distributions and manufacture of Antineoplastons.

Pursuant to the Royalty Agreement, Dr. Burzynski retains the right to either (i) produce Antineoplaston products for use in his medical practice to treat up to 1,000 patients, at any one time, without paying any fees to the Company or (ii) purchase from the Company Antineoplaston products to treat up to 1,000 patients, at any one time, at a price equal to cost plus 10% (ten percent). Dr. Burzynski has the right to lease or purchase all the manufacturing equipment located at 12707 Trinity Drive, Stafford, Texas at a fair market price. The Royalty Agreement further provides that the Company will have the right, when and if Antineoplastons are approved for use and sale by the FDA,

(i) to produce all Antineoplaston products to be sold or distributed in the United States, Canada and Mexico for the treatment of cancer and (ii) to lease from Dr. Burzynski the entire premises located at 12707 Trinity Drive, Stafford, Texas at terms and rates competitive with those available in the real estate market at that time, provided that Dr. Burzynski does not need the facility for his use.

Other Transactions

Since Tadeusz Burzynski' s death on June 13, 1998, the Company has paid his widow, Zofia Burzynski, $1,000 per month as death benefit payments. Tadeusz Burzynski was formerly an officer and a director of the Company and the brother of Dr. Burzynski. Effective February 1, 2010, Dr. Burzynski has taken over the death benefit payments to the widow.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fitts, Roberts & Co., P.C. was the Company' s principal accounting firm for the fiscal year ended February 28, 2009 and up through May 18, 2009. The Board of Directors concurrently accepted the resignation of Fitts, Roberts & Co., P.C. ("Fitts Roberts") and approved the appointment of Pannell Kerr Forster of Texas, P.C. ("PKF") as the Company' s independent registered public accounting firm. PKF examined the financial statements of the Company for the fiscal year ended February 28, 2010 and provided its services as the Company' s independent registered public accounting firm since its appointment.

The following table sets forth the aggregate fees billed to the Company by its independent registered public accounting firm, PKF, for fiscal years ended February 28, 2011 and February 28, 2010, respectively:

	2011	2010
Audit Fees	$ 43,000	$ 43,000
Audit-Related Fees	0	0
Tax Fees	0	0
All Other Fees	0	0
Total	$ 43,000	$ 43,000

Audit Fees were for professional services rendered for the audit of BRI' s financial statements and review of the interim financial statements included in quarterly reports and services that are normally provided in connection with statutory and regulatory filings or engagements.

Audit-Related Fees are for assurance and related services that are reasonably related to the performance of the audit or review of BRI' s financial statements and are not reported under "Audit Fees." There were no Audit-Related Fees incurred in fiscal years 2011 or 2010.

Tax Fees were for professional services for federal and state tax compliance, tax advice and tax planning. There were no Tax Fees incurred in fiscal years 2011 or 2010.

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All Other Fees were for services other than the services reported above. There were no Other Fees incurred in fiscal years 2011 or 2010.

Audit Committee' s Pre-Approval Policies and Procedures. As disclosed above in Item 9, the Company does not have an Audit Committee. The Board of Directors has not adopted any pre-approval policies or procedures.

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ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

EXHIBIT NO.	EXHIBIT NAME
3.1	Certificate of Incorporation of the Company, as amended (incorporated by reference from Exhibit 3(i) − (iii) to Form 10-SB filed with the Securities and Exchange Commission on November 25, 1997 (File No. 000-23425)).
3.2	Amended Bylaws of the Company (incorporated by reference from Exhibit (3)(iv) to Form 10-SB filed with the Securities and Exchange Commission on November 25, 1997 (File No. 000-23425)).
4.1	Form of Certificate Representing Common Stock (incorporated by reference from Exhibit 4.1 to Form 10-KSB filed with the Securities and Exchange Commission on May 2, 2001 (File No. 000-23425)).
10.1	License Agreement, effective as of June 29, 1983, by and between the Company and Dr. Stanislaw R. Burzynski (incorporated by reference from Exhibit 10(1) to Form 10-SB filed with the Securities and Exchange Commission on November 25, 1997 (File No. 000-23425)).
10.2	Amended License Agreement, dated April 2, 1984, by and between the Company and Dr. Stanislaw R. Burzynski (incorporated by referenced from Exhibit 10(2) to Form 10-SB filed with the Securities and Exchange Commission on November 25, 1997 (File No. 000-23425)).
10.3	Second Amended License Agreement, dated March 1, 1990, by and between the Company and Dr. Stanislaw R. Burzynski (incorporated by reference from Exhibit 10(3) to Form 10-SB filed with the Securities and Exchange Commission on November 25, 1997 (File No. 000-23425)).
10.4	Research Funding Agreement, effective as of March 1, 1997, by and between the Company and Dr. Stanislaw R. Burzynski (incorporated by reference from Exhibit 10(4) to Form 10-SB filed with the Securities and Exchange Commission on November 25, 1997 (File No. 000-23425)).
10.5	First Amendment to Research Funding Agreement, effective as of March 1, 2001, by and between the Company and Dr. Stanislaw R. Burzynski (incorporated by reference from Exhibit 10.5 to Form 10-KSB filed with the Securities and Exchange Commission on May 2, 2001 (File No. 000-23425)).
10.6	Second Amendment to the Research Funding Agreement, effective as of February 29, 2004, by and between the Company and Dr. Stanislaw R. Burzynski (incorporated by reference from Exhibit 10.6 to Form 10-KSB filed with the Securities and Exchange Commission on June 1, 2004 (File No. 000-23425)).
10.7	Royalty Agreement, dated March 25, 1997, by and between the Company and Dr. Stanislaw R. Burzynski (incorporated by reference from Exhibit 10(5) to Form 10-SB filed with the Securities and Exchange Commission on November 25, 1997 (File No. 000-23425)).
10.8	First Amended Royalty Agreement, dated September 29, 1997, by and between the Company and Dr. Stanislaw R. Burzynski (incorporated by reference from Exhibit 10(6) to Form 10-SB filed with the Securities and Exchange Commission on November 25, 1997 (File No. 000-23425)).

10.9	Third Amendment to Research Funding Agreement, effective as of March 1, 2007, by and between the Company and Dr. Stanislaw R. Burzynski (incorporated by reference from Exhibit 10.9 to Form 10-KSB filed with the Securities and Exchange Commission on May 29, 2007 (File No. 000-23425)).
24	Power of Attorney (Included with the Signature Page).
31.1	Certification pursuant to Rules 13a-14 and 15d-14 of the Securities Exchange Act of 1934, as amended, filed herewith (Chief Executive Officer and Principal Financial Officer).
32.1	Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer and Principal Financial Officer).

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SIGNATURES

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

BURZYNSKI RESEARCH INSTITUTE, INC.

By: /s/ Stanislaw R. Burzynski
Stanislaw R. Burzynski, President,
Secretary, Treasurer and Chairman of the
Board of Directors

Date: May 31, 2011

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Each person whose signature appears below constitutes and appoints Dr. Stanislaw R. Burzynski his/her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, severally, for him/her in his/her name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he/she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent may lawfully do or cause to be done by virtue hereof.

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

/s/ Stanislaw R. Burzynski
Stanislaw R. Burzynski
President, Secretary, Treasurer and

Date: May 31, 2011

Chairman of the Board of Directors

/s/ Barbara Burzynski
Barbara Burzynski
Director

Date: May 31, 2011

/s/ Michael H. Driscoll
Michael H. Driscoll
Director

Date: May 31, 2011

/s/ Carlton Hazlewood
Carlton Hazlewood
Director

Date: May 31, 2011

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Burzynski Research Institute, Inc.

Financial Statements

For the years ended
February 28, 2011 and February 28, 2010

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
of Burzynski Research Institute, Inc.

We have audited the accompanying balance sheets of Burzynski Research Institute, Inc. as of February 28, 2011 and 2010 and the related statements of operations, stockholders' deficit, and cash flows for the years then ended. 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, audits of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company' s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit 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 financial position of Burzynski Research Institute, Inc. as of February 28, 2011 and 2010, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

May 31, 2011
Houston, Texas

/s/ Pannell Kerr Forster of Texas, P.C.

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BURZYNSKI RESEARCH INSTITUTE, INC.
BALANCE SHEETS

	February 28, 2011	February 28, 2010
ASSETS		
Current assets		
Cash and cash equivalents	$ 17,476	$ 18,122
Total current assets	17,476	18,122
Property and equipment, net of accumulated depreciation	4,120	4,856
Total assets	$ 21,596	$ 22,978
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		

Accounts payable	$ 39,223	$ 41,771
Accrued liabilities	33,628	29,685
Total current liabilities	72,851	71,456
Total liabilities	72,851	71,456
Commitments and contingencies	–	–
Stockholders' deficit		
Common stock, $.001 par value; 200,000,000 shares authorized; 131,448,444 and 131,388,444 shares issued and outstanding as of February 28, 2011 and February 28, 2010, respectively	131,449	131,389
Additional paid-in capital	94,260,707	89,232,302
Retained deficit	(94,443,411)	(89,412,169)
Total stockholders' deficit	(51,255)	(48,478)
Total liabilities and stockholders' deficit	$ 21,596	$ 22,978

The accompanying notes are an integral part of these financial statements.

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BURZYNSKI RESEARCH INSTITUTE, INC.
STATEMENTS OF OPERATIONS

	Year Ended February 28,	
	2011	**2010**
Operating expenses		
Research and development	$ 4,780,072	$ 4,480,497
General and administrative	250,434	349,208
Depreciation	736	905
Total operating expenses	5,031,242	4,830,610
Operating loss before other income	(5,031,242)	(4,830,610)
Other income	–	–
Loss before provision for income tax	(5,031,242)	(4,830,610)
Income tax expense	–	–
Net loss	$ (5,031,242)	$ (4,830,610)

Net loss per common share:

Basic and diluted	$ (0.04)	$ (0.04)
Weighted average common shares outstanding:		
Basic and diluted	131,443,156	131,388,444

The accompanying notes are an integral part of these financial statements.

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BURZYNSKI RESEARCH INSTITUTE, INC.
STATEMENTS OF STOCKHOLDERS' DEFICIT
For the Years Ended February 28, 2011 and 2010

	Common Stock		Additional Paid-in	Retained	Total Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance February 28, 2009	131,388,444	$ 131,389	$ 84,362,821	$ (84,581,559)	$ (87,349)
Cash contributed by S.R. Burzynski M.D., Ph.D.	–	–	616,605	–	616,605
Obligation to issue shares (60,000) for services rendered	–	–	9,400	–	9,400
FDA clinical trial expenses paid directly by S.R. Burzynski M.D., Ph. D.	–	–	4,243,476	–	4,243,476
Net loss	–	–	–	(4,830,610)	(4,830,610)
Balance February 28, 2010	131,388,444	131,389	89,232,302	(89,412,169)	(48,478)
Cash contributed by S.R. Burzynski M.D., Ph.D.	–	–	505,110	–	505,110
Shares issued (60,000) for services rendered pursuant to prior year obligation	60,000	60	(60)	–	–
FDA clinical trial expenses paid directly by S.R. Burzynski M.D., Ph. D.	–	–	4,523,355	–	4,523,355
Net loss	–	–	–	(5,031,242)	(5,031,242)
Balance February 28, 2011	131,448,444	$ 131,449	$ 94,260,707	$ (94,443,411)	$ (51,255)

The accompanying notes are an integral part of these financial statements.

BURZYNSKI RESEARCH INSTITUTE, INC.
STATEMENTS OF CASH FLOWS

	Year Ended February 28,	
	2011	**2010**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (5,031,242)	$ (4,830,610)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation	736	905
FDA clinical trial expenses paid directly by S.R. Burzynski M.D., Ph. D.	4,523,355	4,243,476
Obligation to issue shares (60,000) for services rendered	–	9,400
Change in Operating Assets & Liabilities		
Accounts payable	(2,548)	(36,686)
Accrued liabilities	3,943	4,337
NET CASH USED IN OPERATING ACTIVITIES	(505,756)	(609,178)
CASH FLOWS FROM FINANCING ACTIVITIES		
Cash contribution recorded	505,110	616,605
NET CASH PROVIDED BY FINANCING ACTIVITIES	505,110	616,605
NET INCREASE (DECREASE) IN CASH	(646)	7,427
CASH AT BEGINNING OF YEAR	18,122	10,695
CASH AT END OF YEAR	$ 17,476	$ 18,122
SUPPLEMENTAL CASH FLOW DISCLOSURES:		
Cash Paid During the Year For:		
Income Taxes	$ 0	$ 0

The accompanying notes are an integral part of these financial statements.

BURZYNSKI RESEARCH INSTITUTE, INC.
NOTES TO FINANCIAL STATEMENTS

1. Background, Basis of Presentation, Economic Dependency and Significant Accounting Policies:

Background and Basis of Presentation

The financial statements of Burzynski Research Institute, Inc. (BRI or the Company), a Delaware corporation, include expenses incurred related to clinical trials, which were sanctioned by the U.S. Food and Drug Administration (FDA) in 1993, for antineoplaston drugs used in the treatment of cancer. These expenses are incurred directly by S.R. Burzynski, M.D., Ph.D. (Dr. Burzynski or "SRB") on behalf of the Company and have been reported as research and development costs and as additional paid-in capital. Other funds received from Dr. Burzynski have also been reported as additional paid-in capital. Expenses related to Dr. Burzynski' s medical practice (unrelated to the clinical trials) have not been included in these financial statements. Dr. Burzynski is the President, Chairman of the Board and owner of over 81% of the outstanding common stock of Burzynski Research Institute, Inc., and also is the inventor and original patent holder of certain drug products knows as "antineoplastons," which he has licensed to the Company.

The Company and Dr. Burzynski have entered into various agreements, as further described in Note 2, which provide the Company the exclusive right in the United States, Canada and Mexico to use, manufacture, develop, sell, distribute, sublicense and otherwise exploit all the rights, titles and interest in antineoplaston drugs used in the treatment of cancer, once the drug is approved for sale by the FDA.

BRI' s administrative offices are located in Houston, Texas; its research and production facilities are in Stafford, Texas. The Company operates primarily as a research and development facility of antineoplaston drugs currently being tested for the use in the treatment of cancer, and provides consulting services. Segment information is not presented since all of the Company' s operations are attributed to a single reportable segment. The Company has had no significant revenue from external sources. BRI is currently conducting clinical trials on various antineoplastons in accordance with FDA regulations, however, at this time none of the antineoplaston drugs have received FDA approval; further, there can be no assurance FDA approval will be granted.

Economic Dependency

BRI has generated no significant revenues since its inception. As of February 28, 2011, the Company had a working capital deficit of approximately $55,000 and accumulated deficit of approximately $94,443,000. For the years ended February 28, 2011 and 2010 the Company incurred losses of approximately $5,031,000 and $4,831,000, respectively.

Dr. Burzynski has funded the capital and operational needs of the Company since its inception from revenues generated through his medical practice pursuant to various agreements as described in Note 2.

BRI is economically dependent on its funding from Dr. Burzynski through his medical practice. Management estimates that approximately one-tenth of Dr. Burzynski' s patients are admitted and treated as part of the clinical trial programs which the FDA regulates. The FDA imposes numerous regulations and requirements' regarding these patients and the Company is subject to inspection at any time by the FDA. These regulations are complex and subject to interpretation and though it is management' s intention to comply fully with all such regulations, there is the risk that the Company is not in compliance and is thus subject to sanctions imposed by the FDA.

In addition, as with any medical practice, Dr. Burzynski is subject to potential claims by patients and other potential claimants commonly arising out of the operation of a medical practice. The risks associated with Dr. Burzynski' s medical practice directly affect his ability to fund the operations of BRI.

It is the intention of the directors and management to seek additional capital through the sale of securities. The proceeds from such sales will be used to fund BRI' s operating deficit until it achieves positive operating cash flow. However, there can be no assurance that the Company will be able to raise such additional capital.

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Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets, which range from 5 to 10 years. Expenditures for major renewals and betterments that extend the useful lives of property and equipment are capitalized; maintenance and repairs are charged against earnings as incurred. Upon disposal of assets, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized currently.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes, under which deferred income taxes are recognized for the tax consequences of temporary differences by applying the enacted statutory tax rate applicable to future years to differences between financial statement carrying amounts and the tax basis of existing assets and liabilities.

Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities. The costs incurred related to the conduct of FDA approved clinical trials incurred directly by Dr. Burzynski within his medical practice are deducted by Dr. Burzynski and are not included in the Company' s tax provision. The portion of the Texas gross margin tax that is based on income is treated as income taxes and included in the income tax provision.

Loss Per Common Share

Basic and diluted loss per common share information for all periods is presented under the requirements of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 260 "Earnings per Share". Basic loss per common share has been computed using the weighted average number of common shares outstanding during the period. Potentially dilutive securities have been excluded from the computation of diluted loss per common share, as their inclusion would be antidilutive.

Management Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect reported amounts of assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reported periods. The significant estimates are the allocation of payroll and other expenses between the clinical trial expenses reported with Burzynski Research Institute, Inc. expenses and Dr. Burzynski' s medical practice expenses. Department managers review at least quarterly the duties of each employee in their department and estimate the percentage of time each employee spends between clinical trials and the medical practice. Payroll costs are allocated between clinical trials and the medical practice based on these percentages. Other expenses are allocated based on the percentage of payroll allocated to either clinical trials or the medical practice. Management believes that the estimates and allocations are reasonable. Actual results could differ from these estimates.

Stock Options

The Company uses the fair value recognition provisions of FASB ASC 718 "Compensation-Stock Compensation" using the modified-prospective-transition method. Under that transition method, compensation cost recognized after March 1, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of March 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of FASB ASC 718, and (b) compensation cost for all share-based

payments granted subsequent to March 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of FASB ASC 718.

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The Company did not grant any options and no options previously granted vested in any of the periods presented in these financial statements. Due to this fact there was no effect on net loss and earnings per share regarding the provisions of FASB ASC 718 in any of the periods presented.

Research and Development

Research and development cost are charged to operations in the period incurred. Equipment used in research and development activities, which have alternative uses, is capitalized.

Fair Value of Financial Instruments

The carrying value of cash, receivables and accounts payables approximates fair value due to the short term maturity of these instruments. None of the financial instruments are held for trading purposes.

2. Agreements With, and Other Related Party Transactions:

The Company has agreements with its majority shareholder and President Dr. Burzynski as further described below:

License Agreement

Dr. Burzynski is the owner of patents involving the formulation, preparation, manufacture, production, use, dosage and treatment with antineoplastons. The United States Patent Office and Patent Offices and Patent Officers of thirty-four other countries have issued the patents. The Patents for cancer treatment and diagnosis in the United States and Canada are licensed to the Company pursuant to a License Agreement.

The License Agreement grants to the Company the exclusive right, in the United States, Canada, and Mexico, to use, manufacture, develop, sell, distribute, sub-license and otherwise exploit all of Dr. Burzynski' s rights, title, and interests, including patent rights, in antineoplaston drugs in the treatment and diagnosis of cancer. The Company will not be able to exploit such rights until such time as antineoplastons are approved, of which there can be no assurance, by the FDA for sale in the United States and the appropriate authority in Canada and Mexico.

The Agreement gives Dr. Burzynski the right to make, use, sell, distribute, and otherwise exploit antineoplastons in connection with the treatment of patients in his medical practice.

The License Agreement will terminate upon the earlier of the expiration of the last patent licensed to the Company, or termination by Dr. Burzynski, at his option, if he is removed as a director or officer of the Company without his consent, if the Company files for bankruptcy or if any shareholder or group of shareholders acting in concert becomes the beneficial owner of the Company' s securities having voting power equal to or greater than the voting power of the securities Dr. Burzynski holds.

Under the License Agreement, the Company currently owns exclusive rights to eight (8) issued United States Patents, four (4) issued Canadian Patents and one (1) issued Mexican Patent.

The five initial United States Patents (the "Initial Patents") relate to: (i) Determination of Antineoplastons in body tissue or fluids as a testing procedure to aid in the diagnosis of cancer; (ii) Processes for the preparation of purified fractions of Antineoplastons from

human urine; (iii) Processes for the synthetic production of Antineoplastons and methods of treating neoplastic disease (cancer); (iv) Administration of Antineoplastons to humans; and (v) Methods of synthesizing A-10. All of these Initial Patents have expired as of February 28, 2009. The Company does not believe the expiration of any of the Initial Patents will have a material adverse effect on the Company.

The sixth United States Patent (the "2000 U.S. Patent") covers Liposomal Antineoplaston therapies with markedly improved anti-cancer activity. The 2000 U.S. Patent expires May 14, 2017.

The seventh United States Patent (the "2001 U.S. Patent") is for a treatment regimen for the administration of phenylacetylglutamine, phenylacetylisoglutamine, and/or phenylacetate. The 2001 U.S. Patent expires on July 23, 2018.

The eighth United States Patent (the "2005 U.S. Patent") relates to a divisional application to the 2001 U.S. Patent. The 2005 U.S. Patent was issued in September 2005 and will expire July 31, 2018.

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The four Canadian Patents (the "Canadian Patents") relate to: (i) Processes for the synthetic production of Antineoplastons and methods of treating neoplastic disease (cancer), (ii) Processes for the preparation of purified fractions of Antineoplastons from human urine, (iii) Liposomal Formulation of Antineoplastons and (iv) Treatment regimen for the administration of phenylacetylglutamine. The Canadian Patents expired or will expire on June 4, 2002, November 14, 2006, May 14, 2017, and July 2, 2019, respectively; however, the Company does not believe the Canadian Patents that expired in 2002 or in 2006 will have a material adverse effect on the Company.

The Mexican Patent relates to a treatment regimen for the administration of phenylacetylglutamine. This patent will expire January 14, 2019.

Research Funding Agreement

Effective March 1, 1997, Dr. Burzynski restructured his funding arrangement with the Company and entered into a Research Funding Agreement. Under this agreement the two parties agreed to the following:

1. BRI agrees to undertake all scientific research in connection with the development of new or improved antineoplastons for the treatment of cancer. BRI will hire such personnel as is required to fulfill its obligations under the agreement.

2. Dr. Burzynski agrees to fund in its entirety all basic research, which BRI undertakes in connection with the development of other antineoplastons or refinements to existing antineoplastons for the treatment of cancer.

3. As FDA approval of antineoplastons will benefit both parties, Dr. Burzynski agrees to pay the expenses to conduct the clinical trials for BRI.

4. Dr. Burzynski agrees to provide BRI such laboratory and research space as BRI needs at the Trinity Drive facility in Stafford, Texas, and such office space as is necessary at Trinity Drive and at his medical facility.

5. In the event the research described in the agreement results in the approval of any additional patents for the treatment of cancer, Dr. Burzynski shall own all such patents, but shall license to BRI the patents based on the same terms, conditions and limitations as is in the current license between the parties.

6. Dr. Burzynski shall have unlimited and free access to all equipment which BRI owns, so long as such use is not in conflict with BRI' s use of such equipment, including without limitation to all equipment used in manufacturing of antineoplastons used in the clinical trials.

7. The amounts, which Dr. Burzynski is obligated to pay under the agreement, shall be reduced dollar for dollar by the following:

a. Any income which BRI receives for services provided to other companies for research and/or development of other products, less such identifiable marginal or additional expenses necessary to produce such income (such as the purchase of chemicals, products or equipment) solely necessary to engage in such other research and development activity, and

b. The net proceeds of any stock offering or private placement, which BRI receives during the term of the engagement up to a maximum of $1,000,000 in a given BRI fiscal year.

8. Effective March 1, 2011, the term of the Research Funding Agreement was extended to February 28, 2012, and is automatically renewable for an additional one-year term thereafter, unless one party notifies the other party at least thirty days prior to the expiration of the term of the agreement of its intention not to renew the agreement. In addition to the foregoing termination provisions, the agreement automatically terminates in the event that Dr. Burzynski owns less than fifty percent of the outstanding shares of the Company, or is removed as President and/or Chairman of the Board of the Company, unless Dr. Burzynski notifies the Company in writing of his intention to continue the agreement notwithstanding this automatic termination provision.

Royalty Agreement

The Company entered into a royalty agreement with Dr. Burzynski whereby upon receiving FDA approval for interstate marketing and distribution, the Company agrees to pay Dr. Burzynski a royalty interest equivalent to 10% of the Company' s gross income, which royalty interest shall include gross receipts from all future sales, distributions and manufacture of antineoplastons. Dr. Burzynski will have the right to either produce antineoplaston products for use in his medical practice to treat up to 1,000 patients without paying any fees to the Company, or purchase from the Company antineoplaston products

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for use in his medical practice to treat up to 1,000 patients at a price of the Company' s cost to produce the antineoplaston products plus 10%. Dr. Burzynski will also have the right to either lease or purchase all the manufacturing equipment located at 12707 Trinity Drive, Stafford, Texas at a fair market price. The Company will also have the right to lease from Dr. Burzynski the entire premise located at 12707 Trinity Drive, Stafford, Texas at arms-length terms at rates competitive with those available in the market at that time, provided that Dr. Burzynski does not need the facility for his use.

The term of this agreement is indefinite and will continue until such time as both parties agree it is not in their mutual interest to continue.

Other Related Party Transactions

Since Tadeusz Burzynski' s death on June 13, 1998, the Company has paid his widow $1,000 per month as death benefit payments. Tadeusz Burzynski was formerly an officer and a director of the Company and the brother of Dr. Burzynski. Effective February 1, 2010, Dr. Burzynski has taken over the death benefit payments to the widow.

Dr. Burzynski owns the production facility located at Trinity Drive. There is no formal lease agreement between Dr. Burzynski and BRI; however, the Research Funding Agreement described above provides that Dr. Burzynski will allow the Company the use of the

building. In addition, the Royalty Agreement states that after FDA approval is granted (though approval is not assured) the Company may rent the facility at competitive rates if Dr. Burzynski does not need the facility for his use. The actual facility costs are included in the financial statements as set forth in Note 5. In addition, Dr. Burzynski' s medical clinic performs certain administrative functions such as accounting, and allows BRI the use of some office space. Since May of 2000, Dr. Burzynski' s entire salary is paid through his medical practice and he is not compensated directly by BRI for his services.

The Company has received all significant funding from Dr. Burzynski through either cash contributed to BRI or the payment of the cost to conduct FDA approved clinical trials through his medical practice, as disclosed in Note 1. Following is a summary of the capital contributed and clinical trial costs paid by Dr. Burzynski.

	2011	2010
Capital contributed	$ 505,110	$ 616,605
Clinical trial costs paid direct	$ 4,523,355	$ 4,243,476

3. Property and Equipment:

Property and equipment consists of the following as of February 28th:

	Estimated Useful Lives	2011	2010
Furniture and equipment	5 - 10 years	$ 22,415	$ 22,415
Total property and equipment		22,415	22,415
Accumulated depreciation		(18,295)	(17,559)
		$ 4,120	$ 4,856

Depreciation expense for the years ended February 28, 2011, and 2010 was $736 and $905, respectively.

4. Employee Benefits:

The employees of the Company and SRB participate in a self-funded employee benefit plan providing health care benefits for all its employees. It also provides for them group dental insurance, short-term and long-term disability insurance, and life insurance. Employees pay pre-tax premiums from $40 to $400 per month depending upon the insurance coverage selected by the employee. Employees can select from two coverage plans, both of which have a $500 deductible, varying out-of-pocket maximums, and a maximum lifetime benefit of $1,000,000 per covered participant.

Due to stop-loss insurance, benefits payable by the Company are limited to $25,000 per person during the policy year. The Company charged to operations a provision of $294,319 for 2011 and $244,079 for 2010, which represents the sum of actual

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claims paid and an estimate of liabilities relating to claims, both asserted and unasserted, resulting from incidents that occurred during the year. These amounts include costs related to employees of SRB that have been allocated to the Company.

The Company has a qualified 401(k) plan which covers substantially all employees meeting certain eligibility requirements. Participants may contribute a portion of their compensation to the plan, up to the maximum amount permitted under Section 401(k) of the Internal Revenue Code. At the Company' s discretion, it can match a portion of the participants' contributions. The Company' s matching contribution was $478 and $550 for the years ended February 28, 2011 and 2010, respectively.

5. Lease commitments:

Dr. Burzynski leases certain equipment used in the clinical trials under leases maturing in one to three years. Rent expense incurred under these leases was approximately $91,392 and $91,716 for the years ended February 28, 2011 and 2010, respectively. Future minimum lease payments are as follows:

2012	$ 55,440
2013	16,920
	$ 72,360

In addition, as explained in Note 2, Dr. Burzynski owns the facility used by the Company to perform research and produce its drug products. There is currently no lease agreement; however, the facility' s costs are included in the accompanying financial statements as rental expense. The rental expense is derived from not only utilities and expenses normally incurred by a tenant but also mortgage interest, insurance, property taxes and building depreciation. Rent expense totaled $252,604 and $250,509 for 2011 and 2010, respectively.

6. Income Taxes:

The costs incurred related to the conduct of FDA approved clinical trials incurred directly by Dr. Burzynski within his medical practice are deducted by Dr. Burzynski and are not included in the Company' s tax provision.

The actual income tax benefit attributable to the Company' s losses for the years ended February 28, 2011 and 2010 differ from the amounts computed by applying the U.S. federal income tax rate of 34% to the pretax loss as a result of the following:

	2011	2010
Expected benefit	$ (1,710,622)	$ (1,639,211)
Effect of expenses deducted directly by Dr. Burzynski	1,710,622	1,639,211
Other adjustments	77,251	13,235
Change in valuation allowance	(77,251)	(13,235)
Income tax expense	$ –	$ –

The components of the Company' s deferred income tax assets as of February 28, 2011 and 2010 are as follows:

	2011	2010
Deferred tax assets:		
Net operating loss carryforwards	$ 325,855	$ 404,208
Excess book (tax) depreciation	(672)	(632)
Accrued expenses	5,892	4,750
Alternative minimum tax credit carryforwards	42,603	42,603
Total deferred tax assets	373,678	450,929

Less valuation allowance	(373,678)	(450,929)
Net deferred tax assets	$ –	$ –

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The Company' s ability to utilize net operating loss carryforwards and alternative minimum tax credit carryforwards will depend on its ability to generate adequate future taxable income. The Company has no historical earnings on which to base an expectation of future taxable income. Accordingly, a valuation allowance for the total deferred tax assets has been provided.

The Company has net operating loss carryforwards available to offset future income in the amount of $958,398 as of February 28, 2011. The net operating loss carryforwards expire as follows:

Year ending February 28, or 29,		
2012	$	489,544
2013	$	52,840
2020	$	49,976
2021	$	24,116
2022	$	67,855
2023	$	73,401
2024	$	69,394
2025	$	13,475
2026	$	46,972
2027	$	31,220
2028	$	7,737
2029	$	31,868

In addition, the Company has alternative minimum tax credit carryforwards of $42,603 at February 28, 2011.

7. Equity Transactions:

On September 14, 1996, the Company granted 600,000 stock options, with an exercise price of $0.35 per share, to an officer who is no longer with the Company. The options vested as follows:

400,000 options	September 14, 1996
100,000 options	June 1, 1997
100,000 options	June 1, 1998

The options are valid in perpetuity. None of the options have been exercised as of February 28, 2011.

On June 1, 2009, the Company approved the issuance of 60,000 shares of the Company' s Common Stock as compensation for services rendered to the Company and valued at approximately $9,400. The shares were sold pursuant to an exemption from registration under Section 4(2) of the Securities Act of 1933, as amended, to a single accredited investor and did not involve a public offering, and were issued to such investor on June 2, 2010.

8. Commitments and Contingencies and Supply Source:

In the ordinary course of conducting business, the Company may be a party to legal proceedings and claims. As of February 28, 2011, the Company was not aware of any pending or threatening litigation.

As described in Note 2, the Company entered a Royalty Agreement with Dr. Burzynski. Under that agreement, upon FDA approval, the Company is obligated to provide Dr. Burzynski the right to produce antineoplaston products to treat up to 1,000 patients without paying any fees to the Company or the right to purchase antineoplaston products to treat up to 1,000 patients at cost plus 10%.

The Company produced antineoplaston products to treat approximately 35 to 40 patients during the year ended February 28, 2011 and 40 to 50 patients during the year ended February 28, 2010. Management estimates the current production facilities have the capacity to produce product to treat approximately 1,500 patients per year. There is space available at the current site to expand the facility for increased capacity if necessary.

The Company received approximately 83% of the chemicals used in producing antineoplastons from one supplier during the year ended February 28, 2011 and 89% during the year ended February 28, 2010. The Company has established additional

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vendors to supply these chemicals should there be a loss of this supplier.

EXHIBIT 31.1

CERTIFICATION PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Stanislaw R. Burzynski, certify that:

1. I have reviewed this annual report on Form 10-K of Burzynski Research Institute, Inc. ("BRI");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of BRI as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d15(f) for BRI and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to BRI, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, 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;

(c) Evaluated the effectiveness of BRI' s disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in BRI' s internal control over financial reporting that occurred during BRI' s most recent fiscal quarter (BRI' s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, BRI' s internal control over financial reporting;

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to BRI' s auditors and BRI' s board of directors (or persons performing the equivalent functions of an audit committee):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect BRI' s ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in BRI' s internal control over financial reporting.

Date: May 31, 2011

/s/ Stanislaw R. Burzynski

Stanislaw R. Burzynski,
President, Secretary, Treasurer, and
Chairman of the Board of Directors

(Chief Executive Officer and
Principal Financial Officer)

EXHIBIT 32.1

Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002)

In connection with the Annual Report of Burzynski Research Institute, Inc. (the "Company") on Form 10-K for the period ending February 28, 2011, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to Burzynski Research Institute, Inc. and will be retained by Burzynski Research Institute, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: May 31, 2011

/s/ Stanislaw R. Burzynski

Stanislaw R. Burzynski, President, Secretary,
Treasurer and Chairman of the
Board of Directors
(Chief Executive Officer and
Principal Financial Officer)