FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

Filing Date: **2009-10-15** | Period of Report: **2009-08-31**
SEC Accession No. 0001104659-09-059014

(HTML Version on secdatabase.com)

FILER

BURZYNSKI RESEARCH INSTITUTE INC

CIK:**724445**| IRS No.: **760136810** | State of Incorp.:**DE** | Fiscal Year End: **0228**
Type: **10-Q** | Act: **34** | File No.: **000-23425** | Film No.: **091120958**
SIC: **2835** In vitro & in vivo diagnostic substances

Business Address
12000 RICHMOND AVE
HOUSTON TX 77082

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended August 31, 2009

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE 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)	(IRS Employer Identification No.)

9432 Old Katy Road, Suite 200, Houston, Texas 77055
(Address of principal executive offices)

(713) 335-5697
(Registrant' s telephone number)

(Former name, former address, and former fiscal year, if changed since last report)

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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large 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 Securities Exchange Act of 1934). Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuers classes of common stock, as of the latest practicable date: As of August 31, 2009, 131,388,444 shares of the Registrant' s Common Stock were outstanding.

Table of Contents

BURZYNSKI RESEARCH INSTITUTE, INC.

Form 10-Q

Table of Contents

Table of Contents

Item 1. Financial Statements

BURZYNSKI RESEARCH INSTITUTE, INC.

BALANCE SHEETS
(UNAUDITED)

	August 31, 2009	February 28, 2009
ASSETS		
Current assets		
Cash and cash equivalents	$ 13,496	$ 10,695
TOTAL CURRENT ASSETS	13,496	10,695
Property and equipment, net of accumulated depreciation of $17,129 and $16,654 at August 31, 2009 and February 28, 2009, respectively	5,286	5,761
TOTAL ASSETS	$ 18,782	$ 16,456
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 177,561	$ 78,457
Accrued liabilities	25,225	25,348
CURRENT AND TOTAL LIABILITIES	202,786	103,805
Commitments and contingencies	–	–
Stockholders' deficit		
Common stock, $.001 par value; 200,000,000 shares authorized, 131,388,444 issued and outstanding	131,389	131,389
Additional paid-in capital	86,579,668	84,362,821
Retained deficit	(86,895,061)	(84,581,559)
TOTAL STOCKHOLDERS' DEFICIT	(184,004)	(87,349)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 18,782	$ 16,456

See accompanying notes to financial statements.

Table of Contents

BURZYNSKI RESEARCH INSTITUTE, INC.
STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended	
	August 31, 2009	August 31, 2008
Operating expenses		

Research and development	$ 1,075,784	$ 1,254,049
General and administrative	118,666	35,427
Depreciation	249	474
Total operating expenses	1,194,699	1,289,950
Net loss before provision for income tax	(1,194,699)	(1,289,950)
Provision for income tax		
State tax	(474)	391
NET LOSS	$ (1,194,255)	$ (1,290,341)
Earnings per share information:		
Basic and diluted loss per common share	$ (0.01)	$ (0.01)
Weighted average number of common shares outstanding	131,388,444	131,388,444

	Six Months Ended	
	August 31, 2009	August 31, 2008
Operating expenses		
Research and development	$ 2,067,807	$ 2,466,859
General and administrative	245,220	101,465
Depreciation	475	948
Total operating expenses	2,313,502	2,569,272
Net loss before provision for income tax	(2,313,502)	(2,569,272)
Provision for income tax		
State tax	–	3,202
NET LOSS	$ (2,313,502)	$ (2,572,474)
Earnings per share information:		
Basic and diluted loss per common share	$ (0.02)	$ (0.02)
Weighted average number of common shares outstanding	131,388,444	131,388,444

See accompanying notes to financial statements.

Table of Contents

BURZYNSKI RESEARCH INSTITUTE, INC.
STATEMENT OF STOCKHOLDERS' DEFICIT
FOR THE SIX MONTHS ENDED AUGUST 31, 2009

(UNAUDITED)

	Common Stock		Additional		Total Stockholders'
	Shares	Amount	Paid-in Capital	Retained 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.	–	–	265,599	–	265,599
FDA clinical trial expenses paid directly by S.R. Burzynski, M.D., Ph.D.	–	–	1,951,248	–	1,951,248
Net loss	–	–	–	(2,313,502)	(2,313,502)
Balance August 31, 2009	131,388,444	$ 131,389	$ 86,579,668	$ (86,895,061)	$ (184,044)

See accompanying notes to financial statements.

Table of Contents

BURZYNSKI RESEARCH INSTITUTE, INC.
STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Six Months Ended August 31,	
	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (2,313,502)	$ (2,572,474)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation	475	948
FDA clinical trial expenses paid directly by S.R. Burzynski, M.D., Ph.D.	1,951,248	2,375,780
Changes in operating assets and liabilities		
Accounts payable	99,104	40,760
Accrued liabilities	(123)	(20,836)
NET CASH USED BY OPERATING ACTIVITIES	(262,798)	(175,822)
CASH FLOWS FROM FINANCING ACTIVITIES		
Contribution of capital	265,599	185,000
NET CASH PROVIDED BY FINANCING ACTIVTIES	265,599	185,000
NET INCREASE IN CASH	2,801	9,178
CASH AT BEGINNING OF PERIOD	10,695	3,161

CASH AT END OF PERIOD	$ 13,496	$ 12,339
SUPPLEMENTAL CASH FLOW DISCLOSURES:		
Cash paid for income taxes	$ –	$ 2,211

See accompanying notes to financial statements

Table of Contents

BURZYNSKI RESEARCH INSTITUTE, INC.
NOTES TO FINANCIAL STATEMENTS

NOTE A. BASIS OF PRESENTATION

The financial statements of Burzynski Research Institute, Inc., a Delaware corporation (the "Company"), include expenses incurred directly by S.R. Burzynski, M.D., Ph.D. ("Dr. Burzynski") within his medical practice, related to the conduct of U.S. Food and Drug Administration ("FDA") approved clinical trials for Antineoplaston drugs used in the treatment of cancer. These expenses have been reported as research and development costs and as additional paid-in capital. Cash contributions received from Dr. Burzynski have also been reported as additional paid-in capital, which are used to fund general operating expenses. 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 80% of the outstanding stock of the Company, and also is the inventor and original patent holder of certain drug products known as "Antineoplastons," which he has licensed to the Company.

The Company and Dr. Burzynski have entered into various agreements 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 an Antineoplaston drug is approved for sale by the FDA.

The Company is primarily engaged as a research and development facility for Antineoplaston drugs being tested for the use in the treatment of cancer. The Company is currently conducting clinical trials on various Antineoplastons in accordance with FDA regulations. At this time, however, none of the Antineoplaston drugs have received FDA approval; further, there can be no assurance that FDA approval will be granted. In September 2004, the Company announced that the FDA awarded orphan drug status to Antineoplastons A10 and AS2-1 for the treatment of brain stem glioma. During 2008, the FDA awarded orphan drug status to Antineoplastons A10 and AS2-1 for the treatment of all glioma.

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Certain disclosures and information normally included in financial statements have been condensed or omitted. In the opinion of management of the Company, these financial statements contain all adjustments necessary for a fair presentation of financial position as of August 31, 2009 and February 28, 2009, results of operations for the three months and six months ended August 31, 2009 and 2008, and cash flows for the six months ended August 31, 2009 and 2008. All adjustments are of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results to be expected for a full year. These statements should be read in conjunction with the financial statements and footnotes thereto included in the Company' s Annual Report on Form 10-K for the year ended February 28, 2009.

Table of Contents

NOTE B. ECONOMIC DEPENDENCY

The Company has not generated significant revenues since its inception and has suffered losses from operations, has a working capital deficit and has an accumulated deficit. Dr. Burzynski has funded the capital and operational needs of the Company through his medical practice since inception, and has entered into various agreements to continue such funding.

The Company is economically dependent on its funding through Dr. Burzynski' s medical practice. A portion of Dr. Burzynski' s patients are admitted and treated as part of the clinical trial programs, which are regulated by the FDA. 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 the Company.

It is also 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 the Company' s operating deficit until it achieves positive operating cash flow. There can be no assurance that the Company will be able to raise such additional capital.

NOTE C. STOCK OPTIONS

At August 31, 2009, the Company had one stock-based employee compensation plan, which is described below.

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. In addition, for a period of 10 years from the grant date, they increase in the same percentage of any new shares of stock issued; however, no additional shares have been issued since September 14, 1996. None of the options have been exercised as of August 31, 2009.

Table of Contents

BURZYNSKI RESEARCH INSTITUTE, INC.
NOTES TO FINANCIAL STATEMENTS - continued

NOTE C. STOCK OPTIONS - continued

The Company follows the fair value recognition provisions of Statement of Financial Accounting Standards ("SFAS") No. 123(R), "*Share-Based Payment*." Under this method, compensation cost for all share-based payments is based on the grant-date fair value amortized to expense over the requisite service period, generally the vesting period.

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 loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123(R).

NOTE D. INCOME TAXES

The Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes*," ("FIN 48") on March 1, 2007. As a result of the implementation of FIN 48, the Company had no material change in the amounts of unrecognized tax benefits as a result of tax positions taken during a prior period or the current period.

The federal income tax returns of the Company for 2008, 2007, and 2006 are subject to examination by the IRS, generally for three years after they are filed.

The Company recognizes interest and penalties as interest expense when they are accrued or assessed.

Table of Contents

BURZYNSKI RESEARCH INSTITUTE, INC.
NOTES TO FINANCIAL STATEMENTS - continued

NOTE D. INCOME TAXES - continued

The actual provision for income tax for the three and six months ended August 31, 2009 and 2008, respectively, 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:

	Three Months Ended August 31,	
	2009	2008
Expected income tax benefit	$ (406,198)	$ (438,583)
Effect of expenses deducted directly by Dr. Burzynski	406,018	438,716
Nondeductible expenses and other adjustments	26,092	3,442
Change in valuation allowance	(25,912)	(3,575)
State tax	(474)	391
Income tax expense	$ (474)	$ 391

	Six Months Ended August 31,	
	2009	2008
Expected income tax benefit	$ (786,591)	$ (873,552)
Effect of expenses deducted directly by Dr. Burzynski	786,572	874,641
Nondeductible expenses and other adjustments	32,862	6,510
Change in valuation allowance	(32,843)	(7,599)
State tax	–	3,202
Income tax expense	$ –	$ 3,202

At August 31, 2009, the Company had a net deferred tax asset of $0, which includes a valuation allowance of $497,007. 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 deferred tax assets has been provided. At August 31, 2009, the Company had net operating loss carryforwards available to offset future income in the amount of $1,327,454, which may be carried forward in varying amounts until 2030.

Table of Contents

BURZYNSKI RESEARCH INSTITUTE, INC.
NOTES TO FINANCIAL STATEMENTS - continued

NOTE E. SUBSEQUENT EVENTS

On September 9, 2009, the Company entered into a Clinical Study Agreement (the "Agreement") with the University of Alabama at Birmingham (the "University"), pursuant to which the Company retained the University to provide the following services in connection with the clinical trials of Antineoplastons: (i) develop and implement statistical plans, (ii) analyze and manage data, (iii) review and amend Case Report Forms (CRFs) and (iv) prepare statistical reports for the Data Safety Monitoring Boards (DSMB) and U.S. Food and Drug Administration (the "FDA"). The services will be performed for certain protocols listed in the Agreement. The Agreement will terminate at the completion of the protocols listed in the Agreement, however, either party may terminate the Agreement, with or without cause, by giving thirty (30) calendar days' prior written notice to the other party. The Company paid the University $24,641 for services previously provided from May 1, 2007 through August 31, 2009, which was accrued during the three month period ended August 31, 2009. Subsequent services are billed to the Company on a monthly basis. All rights, title and interest in all data and reports generated in the performance of the services, pursuant to the Agreement, are the sole and exclusive property of the Company.

The Company has performed an evaluation of subsequent events through October 15, 2009, the date that the financial statements as of and for the three and six month periods ended August 31, 2009 have been issued.

Table of Contents

Item 2. Management' s Discussion and Analysis of Financial Condition and Results of Operation

The following is a discussion of the financial condition of the Company as of August 31, 2009, and the results of operations comparing the three and six months ended August 31, 2009 and August 31, 2008. It should be read in conjunction with the financial statements and the notes thereto included elsewhere in this report and in conjunction with the Annual Report on Form 10-K for the year ended February 28, 2009.

Introduction

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. 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 S.R. Burzynski, M.D., Ph.D. ("Dr.

Burzynski"), the Company' s President and Chief Executive Officer. Dr. Burzynski funds the Company' s operations from his medical practice pursuant to certain agreements between Dr. Burzynski and the Company. 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 drugs currently being tested for the use in the treatment of cancer, and provides consulting services. The Company is currently conducting 12 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 and diagnosis of cancer, once an Antineoplaston drug is approved for sale by the FDA.

In September 2004, the Company announced that the FDA awarded orphan drug status to Antineoplastons A10 and AS2-1 for treating patients with brain stem gliomas.

On January 13, 2009, the Company announced that the Company had reached an agreement with the FDA for the Company to move forward with a Phase III clinical trial of combination Antineoplaston therapy plus radiation therapy in patients with newly diagnosed, diffuse, intrinsic brain stem gliomas. The agreement was made under the FDA' s Special Protocol Assessment procedure, meaning that the design and planned analysis of the Phase III study is acceptable to support a regulatory submission seeking new drug approval. The Company intends to enter into a clinical development agreement with a contract research organization for services relating to the Phase III clinical study, including initially a feasibility analysis of the patient enrollment and site requirements of the planned study.

Results of Operations

Three Months Ended August 31, 2009 Compared to Three Months Ended August 31, 2008

Research and development costs were approximately $1,076,000 and $1,254,000 for the three months ended August 31, 2009 and 2008, respectively. The decrease of $178,000 or 14% was due to decreases in personnel cost of $51,000, material costs of $133,000, offset by increases in facility and equipment costs of $3,000, consulting and quality control costs of $1,000 and other research and development costs of $2,000.

General and administrative expenses were approximately $119,000 and $35,000 for the three months ended August 31, 2009 and 2008, respectively. The increase of $84,000 or 240% was due to increases in legal and professional fees of $73,000, and other general and administrative expenses of $11,000.

The Company had a net loss of approximately $1,194,000 and $1,290,000 for the three months ended August 31, 2009 and 2008, respectively. The decrease in the net loss from 2008 to 2009 is primarily due to the decreases in research and development costs due to decreases in personnel costs and material costs offset by increase in facility and equipment costs, consulting and quality control costs and other research and development costs; further offset by increases in general and administrative expenses due to increases in legal and professional fees and other general and administrative cost.

Six Months Ended August 31, 2009 Compared to Six Months Ended August 31, 2008

Research and development costs were approximately $2,068,000 and $2,467,000 for the six months ended August 31, 2009 and 2008, respectively. The decrease of $399,000 or 16% was due to decreases in personnel cost of $79,000, and material costs of

Table of Contents

$330,000, offset by increases in facility and equipment costs of $8,000, consulting and quality control costs of $1,000 and other research and development costs of $1,000.

General and administrative expenses were approximately $245,000 and $101,000 for the six months ended August 31, 2009 and 2008, respectively. The increase of $144,000 or 143% was due to increases in legal and professional fees of $106,000, and other general and administrative expenses of $38,000.

The Company had a net loss of approximately $2,314,000 and $2,572,000 for the six months ended August 31, 2009 and 2008, respectively. The decrease in the net loss from 2008 to 2009 is primarily due to the decreases in research and development costs due to decreases in personnel costs and material costs offset by increase in facility and equipment costs, consulting and quality control costs, and other research and development costs; further offset by increases in general and administrative expenses due to increases in legal and professional fees and other general and administrative cost.

Liquidity and Capital Resources

The Company' s operations have been funded entirely by contributions from Dr. Burzynski and from 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 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.

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 Research Funding Agreement, as amended, contains an annual automatic renewal provision providing for an additional one-year term, unless one party notifies the other party at least thirty days prior to the expiration of the then current term of the agreement of its intention not to renew the agreement. Subject to the foregoing, the term of the Research Funding Agreement was renewed and extended until February 28, 2010. It is expected that the Research Funding Agreement will continue to renew each year prospectively unless terminated under the provisions of 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 $2,400,000 during the remaining two quarters of the fiscal year ending February 28, 2010. 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. The Company believes Dr. Burzynski will be financially able to fund the Company' s operations for at least the next year. In addition, Dr. Burzynski' s medical practice has successfully funded the Company' s research activities

over the last 25 years and, in 1997, his medical practice was expanded to include traditional cancer treatment options such as chemotherapy, immunotherapy and hormonal 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.

Table of Contents

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.

Forward-Looking Statements

Certain matters discussed in this quarterly report, except for historical information contained herein, may constitute "forward-looking statements" that are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Forward-looking statements provide current expectations of future events based on certain assumptions. These statements encompass information that does not directly relate to any historical or current fact and often may be identified with words such as "anticipates," "believes," "expects," "estimates," "intends," "plans," "projects" and other similar expressions. Management' s expectations and assumptions regarding Company operations and other future results are subject to risks, uncertainties and other factors that could cause actual results to differ materially from the anticipated results or other expectations expressed in the forward-looking statements.

Item 4T. 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 (who is also the Company' s 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 on that evaluation, the Company' s principal executive officer (who is also the Company' s principal financial officer) concluded that the Company' s disclosure controls and procedures are effective in timely alerting him to material information required to be included in periodic filings with the Securities and Exchange Commission. 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. There were no significant changes in the Company' s internal controls or in other factors that could significantly affect internal controls over financial reporting that occurred during the fiscal quarter ended August 31, 2009 that have materially affected or are reasonably likely to materially affect our internal controls subsequent to that date.

PART II – OTHER INFORMATION

Item 1. 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 5. Other Information

On September 9, 2009, the Company entered into a Clinical Study Agreement (the "Clinical Study Agreement") with the University of Alabama at Birmingham (the "University"), pursuant to which the Company retained the University to provide the following services in connection with the clinical trials of Antineoplastons: (i) develop and implement statistical plans, (ii) analyze and manage data, (iii) review and amend Case Report Forms (CRFs) and (iv) prepare statistical reports for the Data Safety Monitoring Boards (DSMB) and U.S. Food and Drug Administration (the "FDA"). The University will perform such services for certain protocols listed in the Clinical Study Agreement (the "Protocols"). The Clinical Study Agreement will terminate at the completion of the Protocols, however, either party may terminate the Clinical Study Agreement, with or without cause, by giving thirty (30) calendar days' prior written notice to the other party. The Company paid the University $24,641 for services previously provided from May 1, 2007 through August 31, 2009. Subsequent services are billed to the Company on a monthly basis. All rights, title and interest in all data and reports generated in the performance of the services, pursuant to the Clinical Study Agreement, are the sole and exclusive property of the Company.

Item 6. Exhibits

3.1	Certificate of Incorporation of the Company, as amended (incorporated by reference from Exhibits 3(i) − (iii) to Form 10-SB filed with the Securities and Exchange Commission on November 25, 1997 (File No. 000-23425)).

Table of Contents

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)).
31.1	Certification of Chief Executive Officer and Principal Financial Officer pursuant to Rules 13a-14 and 15d-14 of the Securities Exchange Act of 1934, as amended, filed herewith.
32.1	Certification of Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, filed herewith.

Table of Contents

SIGNATURES

In accordance with the requirements of the Exchange Act, the Company 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
(Chief Executive Officer and
Principal Financial Officer)

Date: October 15, 2009

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULES 13a-14 AND 15d-14
OF THE SECURITIES EXCHANGE ACT OF 1934
(Section 302 of the Sarbanes-Oxley Act of 2002)

I, Stanislaw R. Burzynski, certify that:

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

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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 15d-15(f)) for BRI and have:

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

(b) Designated such internal control over financial reporting, or caused such internal control over financial reporting to be designated 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 quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and

(d) Disclosed in this quarterly 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; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to BRI' s auditors and the audit committee of 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: October 15, 2009 /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 of Chief Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. § 1350
(Section 906 of the Sarbanes-Oxley Act of 2002)

In connection with the Quarterly Report of Burzynski Research Institute, Inc. (the "Company") on Form 10-Q for the period ended August 31, 2009, 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: October 15, 2009

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