

BURZYNSKI RESEARCH INSTITUTE INC
Form 10QSB
July 15, 2004

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

FORM 10-QSB

OMB APPROVAL

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(Mark One)

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

For the quarterly period ended May 31, 2004

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**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 small business issuer as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or
organization)

76-0136810

(IRS Employer Identification No.)

9432 Old Katy Road, Suite 200, Houston, Texas 77055

(Address of principal executive offices)

(713) 335-5697

(Issuer's telephone number)

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

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY

PROCEEDINGS DURING THE PRECEDING FIVE YEARS

Check whether the registrant filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Exchange Act after the distribution of securities under a plan confirmed by a court. Yes ☐ No ☐

APPLICABLE ONLY TO CORPORATE ISSUERS

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date:
As of May 4, 2004, 131,388,444 shares of the Registrant's Common Stock were outstanding.

Transitional Small Business Disclosure Format (Check one): Yes ☐ No ☒

BURZYNSKI RESEARCH INSTITUTE, INC.

Form 10-QSB

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PART I FINANCIAL INFORMATION**Item 1. Financial Statements****CONDENSED BALANCE SHEETS****BURZYNSKI RESEARCH INSTITUTE, INC.**

	May 31, 2004 (Unaudited)	February 29, 2004
ASSETS		
Current assets		
Cash and cash equivalents	\$ 15,647	\$ 18,962
Other current assets	250	1,000
TOTAL CURRENT ASSETS	15,897	19,962
Property and equipment, net of accumulated depreciation and amortization	52,830	54,150
TOTAL ASSETS	\$ 68,727	\$ 74,112
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 45,170	\$ 56,114
Accrued liabilities	47,183	50,624
CURRENT AND TOTAL LIABILITIES	92,353	106,738
COMMITMENTS AND CONTINGENCIES		
Stockholders' equity		
Common stock, \$.001 par value; 200,000,000 shares authorized, 131,388,444 issued and outstanding	131,389	131,389
Additional paid-in capital	62,200,757	60,898,836
Discount on common stock	(100)	(100)
Retained deficit	(62,355,672)	(61,062,751)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(23,626)	(32,626)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 68,727	\$ 74,112

See accompanying notes to financial statements.

CONDENSED STATEMENTS OF OPERATIONS

BURZYNSKI RESEARCH INSTITUTE, INC.

(UNAUDITED)

	Three Months Ended	
	May 31, 2004	May 31, 2003
Operating expenses		
Research and development	\$ 1,234,959	\$ 1,011,388
General and administrative	56,642	48,935
Depreciation	1,320	4,503
Total operating expenses	1,292,921	1,064,826
Net (loss) before income tax	(1,292,921)	(1,064,826)
Provision for income tax		
NET (LOSS)	\$ (1,292,921)	\$ (1,064,826)
Earnings per share information:		
Basic and diluted (loss) per common share	\$ (0.0098)	\$ (0.0081)
Weighted average number of common shares outstanding	131,388,444	131,388,444

See accompanying notes to financial statements.

STATEMENTS OF STOCKHOLDERS DEFICIT

BURZYNSKI RESEARCH INSTITUTE, INC.

(UNAUDITED)

	Common Stock	Additional Paid-in Capital	Discount on Common Stock	Retained Deficit
Balance, February 29, 2004	\$ 131,389	\$ 60,898,836	\$ (100)	\$ (61,062,751)
Cash contributed by S.R. Burzynski, M.D., Ph.D.		177,000		
FDA clinical trial expenses paid directly by S.R. Burzynski, M.D., Ph.D.		1,124,921		
Net loss				(1,292,921)
Balance, May 31, 2004	\$ 131,389	\$ 62,200,757	\$ (100)	\$ (62,355,672)

See accompanying notes to financial statements.

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

	Three Months Ended	
	May 31, 2004	May 31, 2003
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (loss)	\$ (1,292,921)	\$ (1,064,826)
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	1,320	4,503
FDA clinical trial expenses paid directly by S.R. Burzynski, M.D., Ph.D.	1,124,921	861,341
(Increase) decrease		
Other current assets	750	(1,433)
Increase (decrease)		
Accounts payable	(10,944)	22,992
Accrued liabilities	(3,441)	15,676
NET CASH (USED BY) OPERATING ACTIVITIES	(180,315)	(161,747)
CASH FLOWS FROM INVESTMENT ACTIVITIES		
Purchase of equipment		(267)
NET CASH (USED BY) INVESTMENT ACTIVITIES		(267)
CASH FLOWS FROM FINANCING ACTIVITIES		
Additional paid-in capital	177,000	185,000
NET CASH PROVIDED BY FINANCING ACTIVITIES	177,000	185,000
NET (DECREASE) INCREASE IN CASH	(3,315)	22,986
CASH AT BEGINNING OF PERIOD	18,962	1,926
CASH AT END OF PERIOD	\$ 15,647	\$ 24,912

See accompanying notes to financial statements.

NOTES TO CONDENSED FINANCIAL STATEMENTS

BURZYNSKI RESEARCH INSTITUTE, INC.

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. 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 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 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 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.

The accompanying unaudited condensed 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 May 31, 2004 and February 29, 2004, results of operations for the three months ended May 31, 2004 and 2003, and cash flows for the three months ended May 31, 2004 and 2003. All such 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-KSB for the year ended February 29, 2004.

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 significant 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. INCOME TAXES

The actual provision for income tax for the three months ended differ from the amounts computed by applying the U.S. federal income tax rate of 34% to the pretax income as a result of the following:

	Three Months Ended	
	May 31, 2004	May 31, 2003
Expected expense (benefit)	\$ (439,593)	\$ (362,041)
Taxed directly to Dr. Burzynski	439,788	355,756
Nondeductible expenses and other adjustments	2,865	(2,556)
Change in valuation allowance	(3,060)	8,841
Provision for income tax	\$	\$

Item 2. Management's Discussion and Analysis or Plan of Operation

The following is a discussion of the financial condition of the Company as of May 31, 2004, and the results of operations for the three months ended May 31, 2004. It should be read in conjunction with the financial statements and the notes thereto included elsewhere in this report.

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 Dr. Burzynski, who 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 approximately 36 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.

The Company has applied for orphan drug designation of Antineoplastons A10 and AS2-1 for treating patients with brain stem gliomas. A drug with orphan drug designation must meet the same criteria for safety and efficacy as a drug without orphan drug designation. Due to numerous variables and uncertainties in this area, there can be no assurance that the FDA will approve the Company's orphan drug application.

Results of Operations

Three Months Ended May 31, 2004 Compared to Three Months Ended May 31, 2003

Research and development costs were approximately \$1,236,000 and \$1,011,000 for the three months ended May 31, 2004 and 2003, respectively. The increase of \$225,000 or 22% was due to increases in personnel cost of \$226,000, material costs of \$14,000 and facility and equipment costs of \$17,000, decreased by decreases in consulting and quality control costs of \$17,000 and other research and development costs of \$15,000.

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General and administrative expenses were approximately \$56,000 and \$49,000 for the three months ended May 31, 2004 and 2003, respectively. The increase of \$7,000 or 14% was due to increases in legal and professional fees of \$16,000, decreased by decreases in other general and administrative expenses of \$9,000.

The Company had net losses of approximately \$1,293,000 and \$1,065,000 for the three months ended May 31, 2004 and 2003, respectively. The increase in the net loss from 2003 to 2004 is primarily due to the increases in

research and development costs and general and administrative expenses. As of May 31, 2004, the Company has a total stockholders' deficit of \$23,626.

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 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.

Effective February 29, 2004, the Company and Dr. Burzynski extended the term of the Research Funding Agreement until February 28, 2005, with an automatic renewal for two additional one-year terms, 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 an aggregate amount of approximately \$3,400,000 during the last three quarters of the fiscal year ending February 28, 2005 and that it will spend approximately \$1,100,000 during the first quarter of the fiscal year ending February 28, 2006. The Company estimates that ninety-five percent (95%) of these amounts 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 first quarter of the fiscal year ending February 28, 2006. In addition, Dr. Burzynski's medical practice has successfully funded the Company's research activities over the last 20 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.

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 3. 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 and financial officer (who is the same person), 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 and financial officer concluded that the Company's disclosure controls and procedures are effective in timely alerting them to material information required to be included in periodic filings with the Securities and Exchange Commission. 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 evaluation above.

PART II OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

Exhibits

31 Certification pursuant to Rules 13a-14 and 15d-14 of the Securities Exchange Act of 1934, as amended, filed herewith.

32 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, filed herewith.

Reports on Form 8-K

None.

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 (Chief Financial Officer) and
Chairman of the Board of Directors

Date: July 14, 2004