BURZYNSKI RESEARCH INSTITUTE INC

FORM 10-Q
(Quarterly Report)

Filed 07/17/17 for the Period Ending 05/31/17

Address	12000 RICHMOND AVE
	HOUSTON, TX, 77082
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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 May 31, 2017

☐ **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 Katy Freeway, 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 ☒

APPLICABLE ONLY TO CORPORATE ISSUERS

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: As of May 31, 2017, 131,448,444 shares of the Registrant's Common Stock were outstanding.

BURZYNSKI RESEARCH INSTITUTE, INC.

Form 10-Q

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Item 1. Financial Statements

BURZYNSKI RESEARCH INSTITUTE, INC.
BALANCE SHEETS
(UNAUDITED)

	May 31, 2017	February 28, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 382	$ 731
Retainer	—	10,000
TOTAL CURRENT ASSETS	382	10,731
TOTAL ASSETS	$ 382	$ 10,731
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 60,167	$ 19,652
Accrued liabilities	29,080	24,080
CURRENT AND TOTAL LIABILITIES	89,247	43,732
Commitments and contingencies	—	—
Stockholders' deficit		
Common stock, $.001 par value; 200,000,000 shares authorized; 131,448,444 issued and outstanding at May 31, 2017 and February 28, 2017	131,449	131,449
Additional paid-in capital	119,014,431	118,609,079
Retained deficit	(119,234,745)	(118,773,529)
TOTAL STOCKHOLDERS' DEFICIT	(88,865)	(33,001)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 382	$ 10,731

See accompanying notes to financial statements.

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

	Three Months Ended May 31,	
	2017	**2016**
Operating expenses		
Research and development	$ 367,530	$ 349,457
General and administrative	94,686	20,325
Depreciation	—	171
TOTAL OPERATING EXPENSES	462,216	369,953
Operating loss before other income	(462,216)	(369,953)
Other income	1,000	—
Loss before provision for income tax	(461,216)	(369,953)
Provision for income tax	—	—
NET LOSS	$ (461,216)	$ (369,953)
Loss per share information:		
Basic and diluted loss per common share	$ (0.00)	$ (0.00)
Weighted average number of common shares outstanding	131,448,444	131,448,444

See accompanying notes to financial statements.

BURZYNSKI RESEARCH INSTITUTE, INC.
STATEMENT OF STOCKHOLDERS' DEFICIT
For the Three Months Ended May 31, 2017
(UNAUDITED)

	Common Stock		Additional		Total Stockholders'
	Shares	Amount	Paid-in Capital	Retained Deficit	Deficit
Balance February 28, 2017	131,448,444	$ 131,449	$ 118,609,079	$ (118,773,529)	$ (33,001)
Cash contributed by S.R. Burzynski, M.D., Ph.D. and related parties	—	—	54,217	—	54,217
FDA clinical trial expenses paid directly by S.R. Burzynski, M.D., Ph.D.	—	—	351,135	—	351,135
Net loss	—	—	—	(461,216)	(461,216)
Balance May 31, 2017	131,448,444	$ 131,449	$ 119,014,431	$ (119,234,745)	$ (88,865)

See accompanying notes to financial statements.

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

	Three months Ended May 31,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (461,216)	$ (369,953)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	—	171
FDA clinical trial expenses paid directly by S.R. Burzynski, M.D., Ph.D.	351,135	333,437
Changes in operating assets and liabilities		
Retainer	10,000	—
Accounts payable	40,515	(18,153)
Accrued liabilities	5,000	(23,538)
NET CASH USED IN OPERATING ACTIVITIES	(54,566)	(78,036)
CASH FLOWS FROM FINANCING ACTIVITIES		
Contribution of capital	54,217	75,592
NET CASH PROVIDED BY FINANCING ACTIVITIES	54,217	75,592
NET DECREASE IN CASH	(349)	(2,444)
CASH AT BEGINNING OF PERIOD	731	3,303
CASH AT END OF PERIOD	$ 382	$ 859

See accompanying notes to financial statements

BURZYNSKI RESEARCH INSTITUTE, INC.
NOTES TO FINANCIAL STATEMENTS

NOTE A. BASIS OF PRESENTATION

The financial statements of Burzynski Research Institute, Inc. (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 approximately 81.0% of the outstanding common stock of the Company, 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, 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.

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 one clinical trial on 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 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, 2017 and February 28, 2017, results of operations for the three months ended May 31, 2017 and 2016, and cash flows for the three months ended May 31, 2017 and 2016. 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, 2017.

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.

NOTE C. STOCK OPTIONS AND WARRANTS

At May 31, 2017, 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 :

	Vesting Date
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 shares were issued during such 10-year periods from the grant dates. None of the options have been exercised as of May 31, 2017.

The Company accounts for stock-based compensation under the provisions of Financial Accounting Standards Board Accounting Standards Codification ("FASB ASC") 718, *Compensation — Stock Compensation* , which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and non-employee officers based on estimated fair values as of the date of grant. Compensation expense is recognized on a straight-line basis over the requisite service period.

The Company accounts for share-based payments to non-employees, with guidance provided by FASB ASC 505-50, *Equity-Based Payments to Non-Employees* .

The Company did not grant any options and no options previously granted vested in any of the periods presented in these financial statements. Thus, there was no effect on net loss or loss per share regarding the provisions of FASB ASC 718 or FASB ASC 505-50 in any of the periods presented.

Effective July 5, 2012, the Company entered into a Marketing and Consulting Agreement (the "Marketing Agreement") with Worldwide Medical Consultants, Inc. ("WMC") and CARIGEN, LTD ("SRB"), an entity wholly-owned and controlled by Dr. Burzynski, pursuant to which WMC will (i) provide SRB with various marketing and consulting services to assist SRB in locating and developing cancer or health related centers in certain foreign markets and (ii) make payments to the Company equal to 10% of each consulting fee received by WMC for the aforementioned services provided to SRB, net of certain expenses incurred by WMC ("WMC Payment"). In consideration of the WMC Payment, the Company agreed to grant to WMC warrants to acquire an aggregate of 2,000,000 shares of the Company's Common Stock, exercisable at $0.10 per share with a ten year exercise period, with 1,000,000 shares vesting upon execution of the agreement and the remaining 1,000,000 shares to vest upon the first closing of a transaction by SRB as a result of the services provided by WMC under the Marketing Agreement. The fair market value of the vested warrants as of the date of grant was measured using the Black-Scholes option pricing model and totaled approximately $160,000 or $0.16 per warrant. As of May 31, 2017, none of the aforementioned warrants have been exercised and no additional vesting has occurred .

NOTE D. LOSS PER COMMON SHARE

The Company accounts for loss per share in accordance with FASB ASC 260, *Earnings Per Share* . Basic loss per share amounts are calculated by dividing net loss by the weighted average number of common shares outstanding during each period. Diluted loss per share is calculated by dividing net loss by the weighted average number of common shares outstanding for the periods, including the dilutive effect of all common stock equivalents. Dilutive options and warrants that are issued during a period or that expire or are canceled during a period are reflected in the computations for the time they were outstanding during the periods being reported. During the three months ended May 31, 2017 and 2016, 1,600,000 warrants and stock options were excluded from the calculation of diluted loss per share because their effect would be anti-dilutive.

NOTE E. INCOME TAXES

The Company follows the provisions of FASB ASC 740-10, *Accounting for Uncertainty in Income Taxes* . The Company is not aware of any material unrecognized tax uncertainties as a result of tax positions previously taken.

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

The federal income tax returns of the Company for 2016, 2015, and 2014 are subject to examination by the IRS, generally for three years after they are filed.

The actual provision for income tax for the three months ended May 31, 2017 and 2016 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 May 31,	
	2017	2016
Expected income tax benefit	$ (156,813)	$ (125,784)
Effect of expenses deducted directly by Dr. Burzynski	156,813	125,784
Nondeductible expenses and other adjustments	18,994	(13,286)
Change in valuation allowance	(18,994)	13,286
State tax	—	—
Income tax expense	$ —	$ —

At May 31, 2017, the Company had a net deferred tax asset of $0, which includes a valuation allowance of $261,196. 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 full valuation allowance for deferred tax assets has been provided. At May 31, 2017, the Company had net operating loss carryforwards available to offset future taxable income in the amount of $642,921 which may be carried forward and will expire if not used between 2022 and 2037.

Item 2. 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 May 31, 2017, and the results of operations comparing the three months ended May 31, 2017 and 2016. 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, 2017.

Introduction

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 one FDA approved clinical trial initiated in April 2016 for children and adults with Diffuse Intrinsic Pontine Glioma (DIPG) (protocol "BT-55"). 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 .

On September 3, 2004, the FDA granted the Company's request for "orphan drug designation" ("ODD") for the Company's Antineoplastons (A10 & AS2-1 Antineoplaston) for treatment of patients with brain stem glioma and, on October 30, 2008, the FDA granted the Company's request for ODD for Antineoplastons (A10 and AS2-1 Antineoplaston) for the treatment of 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 pivotal Phase III clinical trial of combination Antineoplaston therapy plus radiation therapy in patients with newly diagnosed diffuse, intrinsic brainstem gliomas ("DBSG"). The agreement was made under the FDA's Special Protocol Assessment procedure, meaning that the design and planned analysis of the Phase III study of combination Antineoplastons A10 and AS2-1 plus radiation therapy ("RT") in patients with newly-diagnosed, diffuse, intrinsic brainstem glioma (protocol "BT-52"), are acceptable to support a regulatory submission seeking new drug approval. A randomized, international Phase III study of BT-52 will commence upon availability of funds. The study's objective is to compare overall survival of children with newly-diagnosed DBSG who receive combination Antineoplastons A10 and AS2-1 plus RT versus RT alone.

Partial Clinical Hold on Phase II and Phase III Clinical Trials

In a letter dated June 25, 2012, the Company informed the FDA of a serious adverse event in which a patient who was receiving Antineoplastons developed grade 4 hypernatremia and subsequently died. The Antineoplaston-related hypernatremia was categorized by the investigator as possibly related to the study drug. Of the 2,298 patients who have received at least one dose of Antineoplastons, the serious adverse events (SAEs) which have been experienced are as follows: hemoglobin (grade 3: 0.13%; grade 4: 0.04%), extravasation (grade 3: 0.04%), pain (grade 3: 0.04%), fatigue (grade 3: 0.09%; grade 4: 0.04%), fever (grade 3: 0.09%), injection site reaction (grade 3: 0.04%), vomiting (grade 3: 0.09%), hypernatremia (grade 3: 0.09%; grade 4: 1.12%; grade 5: 0.26%), confusion (grade 3: 0.04%), seizure (grade 3: 0.04%), somnolence (grade 3: 0.35%; grade 4: 0.04%), pain: head/headache (grade 3: 0.09%) and pain: joint (grade 3: 0.04%).

On July 30, 2012, the FDA placed a partial clinical hold for enrollment of new pediatric patients under single patient protocols or in any of the active Phase II or Phase III studies under investigational new drug application ("IND") 43,742. The FDA imposed this partial clinical hold because, according to the FDA, insufficient information had been submitted by the Company to allow the FDA to determine whether the potential patient benefit justifies the potential risks of treatment use, and that the potential risks are not unreasonable in the context of the disease or condition to be treated. The FDA cited 21 C.F.R. § 312.42(b)(2)(i), 21 C.F.R. § 312.42(b)(1)(iv), and 21 C.F.R. § 312.42(b)(3)(i), as grounds for imposition of a clinical hold; and 21 C.F.R. § 312.305(a)(2), a criteria for expanded access use. The FDA advised the Company that until it resolved the matter to the FDA's satisfaction, the Company could not enroll new pediatric patients in any protocol under such IND. The Company later notified the FDA in a September 24, 2012 letter that it was closing pediatric protocol BT-10 (under IND 43,742) for enrollment effective September 25, 2012, and that it would also terminate the protocol once all active patients had completed the study. As of February 17, 2015, all patients discontinued treatment under protocol BT-10 and such protocol was closed as of March 10, 2015.

In a teleconference on January 9, 2013 between the FDA and the Company, followed by a letter of the same date, the FDA notified the Company that the agency was placing IND 43,742 on partial clinical hold, due to a lack of a complete response to the issues raised by the FDA and what the FDA deemed a misleading, erroneous, and incomplete investigator brochure. The FDA cited 21 C.F.R. § 312.42(b)(2)(i) and 21 C.F.R. § 312.42(b)(1)(iii), as grounds for imposition of a clinical hold. The FDA further advised the Company that until it resolved the matter to the FDA's satisfaction, that the Company could not enroll new adult or pediatric patients in any protocol under such IND. The FDA also placed protocol BT-52 on clinical hold due to what the FDA deemed to be an unreasonable and significant risk of illness or injury to human subjects. The FDA cited 21 C.F.R. § 312.42(b)(2)(i) and 21 C.F.R.§ 312.42(B)(1)(i), as grounds for imposition of a clinical hold. The FDA advised the Company that until it resolved the matter to the FDA's satisfaction, the Company could not legally conduct the identified clinical study under such IND. In a teleconference with the FDA on September 16, 2013 and pursuant to the Company's notification letter dated September 17, 2013, the Company notified the FDA that the proposed Phase III protocol BT-54 had been withdrawn from further consideration.

After several amendments to the IND which were reviewed by the FDA, the FDA concluded that BT-52 can be initiated and the partial clinical hold was removed by the FDA on June 20, 2014.

Additionally, the Company received IRB approval on February 4, 2015 for FDA reviewed protocol BT-55 open label, Phase II study of Antineoplaston A10 and AS2-1 in patients with a Diffuse Intrinsic Brainstem Glioma (DIPG) in five treatment groups based on patients age and prior treatment.

On April 20, 2016, the Company received a full clinical hold letter from the FDA based on FDA's inspection of S.R. Burzynski's manufacturing facility in March 2015. On April 27, 2016, the Company requested to change the full clinical hold to partial clinical hold to allow patient #1 to continue the Antineoplaston treatment according to protocol BT-55, since the patient was enrolled before the full clinical hold was imposed. Based on the FDA's position regarding the Company's request on April 27, 2016 and the Company's teleconference with the FDA on May 3, 2016, the Company removed patient #1 from the study.

A temporary restraining order from the US District Court of Rhode Island allowed the resumption of patient #1's Antineoplaston therapy on May 17, 2016. As a result of such temporary restraining order, a subsequent letter from the FDA dated May 26, 2016 informed the Company that the full clinical hold was replaced and a partial clinical hold was imposed. As a result, patient #1 restarted treatment under IND 43742.

On June 14, 2016, the FDA issued a letter to the Company in connection with the FDA's inspection of S.R. Burzynski's manufacturing facility in March 2015. The Company addressed the issues raised in the letter in a response letter submitted to the FDA on July 5, 2016 and in subsequent letters.

On February 20, 2017, BRI informed the FDA the death of patient #1 on February 19, 2017. No new patients can be enrolled to protocol BT-55 or BT-52 until partial hold on IND 43742 is lifted.

Complaint Filed by the Texas Medical Board Against Dr. Burzynski

On March 3, 2017, the Texas Medical Board issued their final ruling regarding the complaint filed on December 11, 2013 and subsequently amended in July 2014 and November 2014, against Dr. Stanislaw R. Burzynski, who serves as our President and the Chairman of our Board of Directors. The Texas Medical Board made allegations that Dr. Burzynski had acted unprofessionally and failed to meet standards of care under the state's Medical Practice Act. In the final ruling, the Texas Medical Board found that Dr. Burzynski was subject to sanction for various failures that included supervision of foreign medical graduates, untimely and insufficient informed consent, medical record support documentation, tumor measurement reporting inaccuracy, and lack of disclosure of ownership interest in a pharmacy. As a result, Dr. Burzynski was reprimanded. His Texas license was suspended for five years but that suspension was stayed and he was placed under probation under terms and conditions that include having billing practice monitored by a billing monitor for 12 consecutive monitoring cycles, enrolling and completing a physicians education program ethics course, following informed consent protocol, passing the Medical Jurisprudence Examination, and compliance with the Medical Practice Act and other statutes regulating Dr. Burzynski's practice. As requested as part of the terms and conditions, Dr. Burzynski has completed payment of an administrative penalty and restitution, submission of all informed consent forms for review, submission of an ownership interest disclosure form for review, and he has begun continuing medical education. The Company does not believe that the final order will have an adverse impact on current activities at the Burzynski clinic. However, if any outcomes or changes arise relating to similar matters or future allegations, this could result in substantial harm to the Company's business and operations.

Results of Operations

Three Months Ended May 31, 2017 Compared to Three Months Ended May 31, 2016

Research and development costs were approximately $368,000 and $349,000 for the three months ended May 31, 2017 and 2016, respectively. The increase of $19,000 or 5% was due to increases in personnel costs of $17,000, facility and equipment costs of $14,000, and quality control costs of $3,000, offset by a decrease in material costs of $14,000, and other research and development costs of $1,000 as a result of additional requests from regulatory agencies.

General and administrative expenses were approximately $95,000 and $20,000 for the three months ended May 31, 2017 and 2016, respectively. The increase of $75,000 or 375% was due to an increase in legal and professional fees of $76,000, offset by a decrease in general and administrative costs of $1,000, as a result of additional requests from regulatory agencies.

The Company had net losses of approximately $461,000 and $370,000 for the three months ended May 31, 2017 and 2016, respectively. The increase in the net loss from 2016 to 2017 is primarily due to an overall increase in research and development costs and an increase in general and administrative expenses of the Company as described above.

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, 2018. 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 $1,125,000 during the remaining three quarters of the fiscal year ending February 28, 2018. 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. 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, gene-targeted therapy, immunotherapy and hormonal therapy.

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.

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 4. 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 officers, 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 officers 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. 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 May 31, 2017 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 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)).
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 pursuant to Rules 13a-14 and 15d-14 of the Securities Exchange Act of 1934, as amended, filed herewith.
31.2	Certification of 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 pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, filed herewith.
32.2	Certification of 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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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 and Chairman of the Board of Directors
(Principal Executive Officer)

Date: July 17, 2017

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE 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: July 17, 2017

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

EXHIBIT 31.2

CERTIFICATION OF 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, Patryk P. Goscianski, 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: July 17, 2017

/s/ Patryk P. Goscianski
Patryk P. Goscianski,
Secretary and Treasurer
(Principal Financial Officer)

EXHIBIT 32.1

Certification of Chief Executive 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 May 31, 2017, 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: July 17, 2017

/s/ Stanislaw r. Burzynski
Stanislaw R. Burzynski
President and Chairman of the Board of Directors
(Principal Executive Officer)

EXHIBIT 32.2

Certification of 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 May 31, 2017, 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: July 17, 2017

/s/ Patryk P. Goscianski
Patryk P. Goscianski
Secretary and Treasurer
(Principal Financial Officer)