Arch Therapeutics, Inc.
Form 10-K
December 05, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended September 30, 2016

OR

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

Commission File Number: **000-54986**

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

Nevada (State or other jurisdiction of incorporation or organization)	**46-0524102** (I.R.S. Employer Identification No.)
235 Walnut Street, Suite 6 **Framingham, MA** (Address of principal executive offices)	**01702** (Zip Code)

(617) 431-2313
(Registrant’s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, par value $0.001 per share**

(Title of Class)

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

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

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 x 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 x No ¨

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

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

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

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

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates as of the last business day of the registrant's most recently completed second fiscal quarter, computed by reference to the average of the bid and asked price of such common equity, was approximately $27,300,000. For purposes of this calculation, it has been assumed that shares of common stock held by each director, each officer and each person who owns 10% or more of the registrant's outstanding common stock are held by affiliates.

As of December 2, 2016, 137,882,075 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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This Annual Report on Form 10-K contains forward-looking statements. We make forward-looking statements, as defined by the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, and in some cases, you can identify these statements by forward-looking words such as "if," "shall," "may," "might," "will likely result," "should," "ex "plan," "anticipate," "believe," "estimate," "project," "intend," "goal," "objective," "predict," "potential" or "continue," or the these terms and other comparable terminology. Such forward-looking statements contained in this Form 10-K are based on various underlying assumptions and expectations and are subject to risks, uncertainties and other unknown factors, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business and include risks and uncertainties relating to Arch's current cash position and its need to raise additional capital in order to be able to continue to fund its operations; the stockholder dilution that may result from future capital raising efforts and the exercise or conversion, as applicable of Arch's outstanding options and warrants; restrictions under its existing loan agreement with the Massachusetts Life Sciences Center that may restrict or prohibit Arch's ability to raise capital or borrow funds on terms favorable to the Company and its current stockholders; Arch's limited operating history which may make it difficult to evaluate Arch's business and future viability; Arch's ability to timely commercialize and generate revenues or profits from our anticipated products; Arch's ability to achieve the desired regulatory approvals in the United States or elsewhere; Arch's ability to retain its managerial personnel and to attract additional personnel; the strength of Arch's intellectual property, the intellectual property of others and any asserted claims of infringement; and other risk factors identified in the documents Arch has filed, or will file with the Securities and Exchange Commission ("**SEC**"). Copies of Arch's filings with the SEC may be obtained from the SEC internet site at http://www.sec.gov. We undertake no duty to update any of these forward-looking statements after the date of filing of this report to conform such forward-looking statements to actual results or revised expectations, except as otherwise required by law.

As used in this Annual Report on Form 10-K unless otherwise indicated, the "Company", "we", "us", "our", and "Arch" refer t Arch Therapeutics, Inc. and its consolidated subsidiary, Arch Biosurgery, Inc.

We have either filed or intend to file trademark applications for AC5 Surgical Hemostatic Device™, AC5 Surgical Hemostat™, AC5 Topical Hemostatic Device™, AC5 Topical Hemostat™, AC5 Device™, AC5™, Crystal Clear Surgery™, NanoDrape™ and NanoBioBarrier™. All other trademarks, trade names and service marks included in this Annual Report on Form 10-K *are the property of their respective owners.*

PART I

ITEM 1. BUSINESS

The following discussion should be read in conjunction with our consolidated financial statements and the related notes and other financial information included in this Annual Report on Form 10-K.

Corporate Overview

Arch Therapeutics, Inc., (together with its subsidiary, the "**Company**" or "**Arch**") was incorporated under the laws of the State of Nevada on September 16, 2009, under the name "Almah, Inc." to pursue the business of distributing automobile spare parts online. Effective June 26, 2013, the Company completed a merger (the "**Merger**") with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation ("**ABS**"), and Arch Acquisition Corporation ("**Merger Sub**"), the Company's wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company abandoned its prior business plan and changed its operations to the business of a biotechnology company. Our principal offices are located in Framingham, Massachusetts.

For financial reporting purposes, the Merger represented a "reverse merger". ABS was deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the accumulated deficit and the historical operations that are reflected in the Company's consolidated financial statements prior to the Merger are those of ABS. All share information has been restated to reflect the effects of the Merger. The Company's financial information has been consolidated with that of ABS after consummation of the Merger on June 26, 2013, and the historical financial statements of the Company before the Merger have been replaced with the historical financial statements of ABS before the Merger in this report.

ABS was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc. On April 7, 2008, ABS changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

Our Current Business

We are a biotechnology company in the development stage. We have generated no revenues to date and are devoting substantially all of our operational efforts to the development of our core technology. We aim to develop products that make surgery and interventional care faster and safer by using a novel approach to stop bleeding (referenced as "**hemostatic**" or "**hemostasis**"), control leaking (referenced as "**sealant**" or "**sealing**"), and provide other advantages during surgery and trauma care. Our core technology is based on self-assembling peptides that creates a physical, mechanical barrier, which could be applied to seal organs or wounds that are leaking blood and other fluids. We believe our technology could support an innovative platform of potential products in the field of stasis and barrier applications. Our plan and business model is to develop products that apply that core technology for use with bodily fluids and tissues.

To date, the Company has principally raised capital through borrowings and the issuance of convertible debt and units consisting of its common stock, par value $0.001 per share ("**Common Stock**"), and warrants. The Company expects to incur substantial expenses for the foreseeable future relating to the research, development, clinical trials, and commercialization of its potential products. As of December 2, 2016, the Company believes that our current cash on hand will meet our anticipated cash requirements into the fourth quarter of Fiscal 2017. The Company will be required to raise additional capital in order to continue to fund operations. There can be no assurance that the Company will be successful in securing additional resources when needed on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern.

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Our Core Technology

Our primary product candidates, known collectively as the AC5 Devices™ (which we sometimes refer to as "**AC5™**", "**AC5 Surgical Hemostatic Device™**", "**AC5 Surgical Hemostat™**", "**AC5 Topical Hemostatic Device™**", or "**AC5 Topical Hemostat™**"), are being designed to achieve hemostasis in surgical procedures. They rely on our self-assembling peptide technology and are being designed to achieve hemostasis in skin wounds and in minimally invasive and open surgical procedures. We intend to develop other product candidates based on our technology platform for use in a range of indications.

AC5 is being designed as a product containing synthetic biocompatible peptides comprising L amino acids, commonly referred to as naturally occurring amino acids. When applied to a wound, AC5 intercalates into the interstices of the connective tissue where it self-assembles into a physical, mechanical nanoscale structure that provides a barrier to leaking substances, such as blood. AC5 may be applied directly as a liquid, which we believe will make it user-friendly and able to conform to irregular wound geometry. Additionally, AC5 does not possess sticky or glue-like handling characteristics, which we believe will enhance its utility in several settings, including minimally invasive surgical procedures. Further, in certain settings, AC5 lends itself to a concept that we call Crystal Clear Surgery™; the transparency and physical properties of AC5 may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as it starts.

We believe that the results of early data from preclinical tests have shown quick and effective hemostasis with the use of AC5 relative to that reported with other types of hemostatic agents, and that time to hemostasis is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called "blood thinners". Based on testing results to date, we believe that AC5 is biocompatible.

We have devoted much of our operational effort to date to the research and development of our core technology, including selecting our initial product composition, conducting initial safety and other related tests, conducting an initial human trial for safety and performance of AC5, developing methods for scale-up, reproducibility, manufacturing and formulation, and developing and protecting the intellectual property rights underlying our technology platform. Manufacturing method and formulation optimization are important parts of peptide development. Manufacturing and formulation optimization for our product candidates has been and continues to be done with extensive collaboration among our team and partners. The processes are focused on optimizing traditional product parameters to target specifications covering performance, biocompatibility, physical appearance, stability, and handling characteristics, among others. We and our partners intend to monitor manufacturing processes and formulation methods closely, as success or failure in both setting and realizing appropriate

Clinical Development

Recently we completed a single-center, randomized, single-blind prospective clinical study (NCT 02704104) of the AC5 Topical Hemostatic Device in skin lesion patients with bleeding wounds. This was the first study assessing the safety and performance of AC5 in humans. The objectives of the study were to evaluate the safety and performance of AC5 in patients scheduled to undergo excision of skin lesions on their trunk or upper limbs. The primary endpoint was safety throughout the surgical procedure and until the end of a 30-day follow-up period post procedure. Safety of the clinical investigation device was determined by monitoring for treatment related adverse events. The primary objective was met, as the safety outcomes of both the AC5 treatment group and the control group were similar. No serious adverse events were reported.

A secondary endpoint was performance as assessed by time to hemostasis. The median time to hemostasis of wounds in the AC5 treatment group was 41% faster than for those in the control group. This result was statistically significant ($p < 0.001$, Wilcoxon signed rank test). An additional secondary endpoint of healing of treated wounds was assessed as measured by the ASEPSIS wound score at Days 7 and 30. There was no evidence, at either follow-up day, of an adverse effect of AC5 treatment on the wound ASEPSIS score. The ASEPSIS score did not appear to be compromised, as the majority of patients had an ASEPSIS score of 0 in both wounds at Days 7 and 30. All AC5-treated wounds healed satisfactorily as per wound healing scoring criteria.

The clinical study enrolled 46 patients, including 10 who were taking antiplatelet monotherapy. Each patient had bleeding wounds created as a result of the excision of at least two skin lesions under local anesthetic in the same setting. On a randomized basis, one lesion received AC5 and the other(s) received a control treatment consisting of standard therapy plus a sham. Each subject was followed-up for safety assessment both on Day 7 and again on Day 30, which marked the end of the subject's participation in the clinical study.

Additionally, the clinical study indicated that AC5 shortened time to hemostasis ("TTH") versus a control whether or not patients were taking antiplatelet therapy, suggesting that AC5 performance is not affected by antiplatelet therapy. The reduced median TTH of the AC5 treated wounds versus the control wounds was statistically significant for both the overall group of 46 patients ($p<0.001$) and for the subgroup of 10 patients on antiplatelet therapy ($p=0.005$). Further, the median TTH for wounds treated with AC5 was less than 30 seconds for both the overall study group and for the subset of patients taking antiplatelet therapy.

Preclinical Development

Previously, we completed the components of the planned preclinical program for AC5 that were required before we started our first human safety and performance trial, which was completed in 2016. We are focused on scale-up of selected manufacturing methods and formulation optimization. In parallel, we are conducting further *in vivo* and *in vitro* tests, while additional testing will continue after completion of manufacturing scale-up and formulation optimization steps and the clinical trial. Self-assembling peptide manufacturing and formulation optimization are challenging, and any delays could negatively impact anticipated clinical trial and subsequent commercialization timelines. In order to market and sell AC5 and other Arch planned products, successful human clinical trials, additional testing, and regulatory approvals and certifications will be required. A co-founding inventor of certain of our technology, Dr. Rutledge Ellis-Behnke, performed a significant portion of the early preclinical animal experimentation conducted on our technology. Some of the most significant findings from Dr. Ellis-Behnke's studies have been published. Additionally, through collaboration with the National University of Ireland system, preclinical bench-top and animal studies have been performed in Dublin and Cork, Ireland. As a continuation of our commitment to our product development we entered into a collaboration agreement with National University of Ireland Galway ("**NUIG**") in Galway, Ireland on May 28, 2015 (the "**Project Agreement**"). Pursuant to the Project Agreement, NUIG will provide, via the CÚRAM Centre for Research in Medical Devices ("**CÚRAM**"), which is a major national research center headquartered at NUIG established in January 2015 as part of a six-year grant from the Irish government, personnel, infrastructure support and grant funding in connection with a research program intended to facilitate the continued development of the Company's core technology (the "**Project**"). Under the terms of the Project Agreement, which has a term that will end upon the earlier of the completion of the Project the sixth anniversary of the execution date of the Project Agreement, or termination by either party, we may contribute up to a maximum of two hundred and fifty thousand euro (€250,000) to the Project per year, and NUIG will match such funds at a 2:1 ratio using funds allocated to NUIG by Science Foundation Ireland's ("**SFI**") Research Centres Programme. In addition, while NUIG will initially retain ownership of all intellectual property developed in connection with the Project (collectively, "**Project IP**"), any such Project IP that was either based on or derived from our existing intellectual property ("**Derivative IP**") will be assigned back to us for a nominal fee. For any Project IP that does not constitute Derivative IP ("**Non-Derivative IP**"), we will have a right of first negotiation for an exclusive license to such Non-Derivative IP on customary terms for agreements of that nature including royalties on net sales in the low single-digits, in each case subject to a grant-back to NUIG for research and academic purposes. We have also engaged, on a fee for service basis, several private third party facilities in the United States and abroad to perform certain preclinical bench-top and animal studies, which are often conducted with assistance from our scientific team, and we continue to engage third parties for such services as needed and as appropriate.

In the preclinical animal tests conducted to date, AC5 has demonstrated rapid average time to hemostasis ("**TTH**") when applied to a range of animal tissues. Certain studies have tested TTH when using AC5 during surgical procedures compared to TTH when using a control substance, a saline control substance, a control peptide, and a cautery control substance during those same procedures. The results of those tests have shown a TTH of approximately 10 – 30 seconds when AC5 was applied, compared to a TTH ranging from 80 seconds to significantly more than 300 seconds when various control substances were applied, depending on the nature of the control substance and procedure performed. In several studies comparing AC5 to popular commercially available branded hemostatic agents (absorbable cellulose, flowable gelatin with and without thrombin, and fibrin) applied to stop the bleeding from full thickness penetrating wounds surgically created in rat livers, AC5 achieved hemostasis in significantly less than 30 seconds, whereas the control products took from 50% to over 400% longer than AC5 to achieve hemostasis.

Additionally, the preclinical tests that have been conducted to date provide evidence that AC5 can stop bleeding in models of liver bleeding in animals that had been treated with therapeutic amounts of anticoagulant and antiplatelet medications, commonly called “blood thinners.” In one preclinical study, an independent third-party research group obtained positive data assessing the use of AC5 in animals that had been treated with therapeutic doses of the antiplatelet medications Plavix® (clopidogrel) and aspirin, alone and in combination. The results of the study were consistent with data obtained from two prior preclinical studies, in which AC5 quickly stopped bleeding from surgical wounds created in rats following treatment with clinically relevant doses of the anticoagulant medication heparin. In these studies, the average TTH after AC5 was applied to bleeding liver wounds of animals that had been medicated with anticoagulants was comparable to the average TTH as measured in their non-anticoagulated counterparts. Similar results were obtained in independent third-party studies assessing the use of AC5 in patients on the anticoagulant heparin and in patients on the anti-platelet medication, ticagrelor (Brilinta® in the US, Brilique in Europe®.)

In preclinical tests conducted to date, AC5 has demonstrated biocompatibility and normal healing of tissue treated with the product. Further, animals whose liver, spleen, femoral artery, eye or brain was treated with AC5 have shown no ill effects. We believe that the peptide degrades into the amino acids from which it was originally synthesized, which are molecules that already exist in large quantities in the human body.

Our current and planned near-term activities are focused on manufacturing scale-up, formulation optimization, and other preclinical activities, and conducting clinical trial testing of AC5. In its first clinical study for safety and performance, AC5 was demonstrated to be safe and to reduced TTH in wounds versus controls. Our clinical study also demonstrated that in a subgroup of 10 patients who were taking a prescribed antiplatelet medication, commonly known as a blood thinner, such as aspirin, AC5 had similar effects.

Development and Commercialization Strategy

Our present business model is to operate with a relatively small internal team of key personnel and engage third party service providers to conduct larger scale research, development and manufacturing activities. Our internal team collectively has a broad range of expertise and experience working with and managing third party vendors. This general approach enables us to use the services of third party entities, which are expert, in various aspects of our operations, while preserving capital and efficiencies by avoiding certain internal scale-up costs and resource duplication.

Research and Development; Manufacturing

Use of Third Party Relationships

To date, we have engaged third party laboratory facilities run by experts in the U.S. and abroad to perform both research and preclinical and clinical development activities. Those engagements have assisted in our development of our primary product candidate, as well as our generation of appropriate analytical methods, scale-up, and other procedures for use as a "blueprint" for third party manufacturers to produce the product on a larger scale for purposes of further preclinical and clinical testing and ultimately, if required approvals are obtained, commercialization.

We have initiated the transition to traditional contract manufacturing and related organizations. We have commenced relationships and work with manufacturers operating with the current good manufacturing practices ("**cGMP**") required by applicable regulatory agencies in order to scale up and produce formulation material to be used for final preclinical testing and clinical trials.

Manufacturing Methods

We believe that the manufacturing methods used for a product, including the type and source of ingredients and the burden of waste byproduct elimination, are important determinants of its opportunity for profitability. Industry participants are keenly aware of the downsides of technologies that rely on expensive biotechnology techniques and facilities for manufacture, onerous and expensive programs to eliminate complex materials, or ingredients that are sourced from the complicated process of human or other animal plasma separation, since those products typically are expensive, burdensome to produce, and at greater risk for failing regulatory oversight.

The manufacturing methods that we intend to use to produce AC5 and other potential future product candidates rely on detailed, complex and difficult to manage synthetic organic chemistry processes. Although use of those methods requires that we engage manufacturers that possess the expertise, skill and know-how involved with those methods, the required equipment to use those methods is widely available. Furthermore, improvements in relevant synthetic manufacturing techniques over the past decade have reduced their complexity and cost, while increasing large-scale cGMP capacity. Moreover, our planned product candidates, including AC5, will be synthesized from naturally occurring ingredients that are not sourced from humans or other animals, but do exist in their natural state in humans. That type of ingredient may be more likely to be categorized as "generally recognized as safe", or "**GRAS**", by the U.S. Food and Drug Administration ("**FDA**").

Regulatory

Medical Device Classification

In February of 2015, we announced that The British Standards Institution (“**BSI**”), a Notified Body (which is a private commercial entity designated by the national government of a European Union (“**EU**”) member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements) in the EU, confirmed that AC5 fulfills the definition of a medical device within the EU and will be classified as such in consideration for CE mark designation. The FDA and other regulatory authorities or related bodies finally determine the classification of AC5, and we anticipate that they will rule similarly to BSI. We believe that our primary product candidate meets the criteria for a medical device. Generally, a product is a medical device if it requires neither metabolic nor chemical activity to achieve the desired effect. Furthermore, a medical device can achieve its desired effects without requiring a body (animal/human), whereas a drug or a biologic requires a body in order to operate. The AC5 mechanism of assembly into a barrier can occur outside of a body and is accordingly consistent with the medical device definition.

Medical devices in the EU and the U.S. are classified along a spectrum. Class III status, which is the higher-level classification for devices compared to Classes II and I involves additional procedures and regulatory scrutiny of the product candidate to obtain approvals. AC5 could be regulated as either a Class III or a Class II medical device in these jurisdictions, depending upon the application, subject to the process for obtaining a CE mark in the EU and the premarketing authorization process in the U.S.

Biocompatibility Tests and Clinical Trials

Before initiating our European or most other human clinical trials, we are required to have completed the biocompatibility assessment of AC5. Standard required tests to assess biocompatibility, as set forth in ISO 10993 issued by the International Organization for Standardization, may include:

- in vitro cytotoxicity;
- in vitro blood compatibility;
- in vitro Ames assay (mutagenic activity);
- irritation/intracutaneous reactivity;

- sensitization (allergenic reaction);
- implantation (performed on devices that contact the body’s interior);
- pyrogenicity (causing fever or inflammation);
- systemic toxicity; and

- in vitro chromosome aberration assay (structural chromosome changes).

We have completed the biocompatibility studies required to initiate our first human trial of AC5 in Western Europe. We will perform further biocompatibility testing that we deem necessary for additional indications, classifications, jurisdictions, and/or as required by regulatory authorities.

On August 15, 2016, we announced that the AC5 Topical Hemostatic Device met its primary and secondary endpoints in our first clinical trial for safety and performance. On October 31, 2016, the Company further announced that additional analysis of the subgroup of 10 patients who were taking a prescribed antiplatelet medication, commonly known as a blood thinner, such as aspirin, indicated that AC5 had similar effects for this subgroup. The Company plans to include data from this trial in a CE mark application that we intend to submit in 2017 and approval of which is required in order to market and commercialize AC5 as a medical device in Europe. We also expect to use this data in support of U.S. regulatory filings.

We expect that we will pursue approvals for use of AC5 as a hemostatic agent and wound care agent in surgical and dermatological settings, and we may also seek to obtain approvals for additional potential indications for use of the product, which we may pursue either opportunistically or once initial regulatory approval for the product is obtained.

Commercialization

Our long-term commercialization plan for at least some of our product candidates could entail entering into one or more collaboration agreements or strategic partnerships. Based on our current general approach and strategy of utilizing the expertise and resources of third party service providers and maintaining a relatively small internal team, we currently expect that we may pursue some degree of strategic collaborations or partnerships with third parties, which could include licensing arrangements, distribution and supply partnerships, engagement of external regulatory experts and/or marketing and sales teams, among other types of potential relationships. We presently believe that certain relationships could improve our ability to obtain regulatory approval for our product candidates and attain market acceptance for and profitable sales of those product candidates, and that our current and planned activities and milestones relating to AC5 are well-aligned with the needs of the market and potential partners and collaborators that may wish to enter or expand their presence in our target markets.

We envision the potential future customers in the marketplace for AC5 and any other hemostatic or sealant agent we may pursue will include surgeons and other doctors, government agencies such as the Department of Defense, hospital and operating room management and ambulance and other trauma specialists.

Plan of Operations

Our long-term business plan includes the following goals:

- conducting required biocompatibility studies and, subsequently, additional clinical trials on AC5 and related products;
- expanding and maintaining protection of our intellectual property portfolio;
- developing appropriate third party relationships to manufacture, distribute, market and otherwise commercialize AC5;
- obtaining regulatory approval or certification of AC5 and related products in the EU, the U.S., and other jurisdictions as we may determine;
- continuing or developing academic, scientific and institutional relationships to collaborate on product research and development; and
- developing additional product candidates in the hemostatic, sealant, and/or other fields.

In furtherance of our long-term business goals, we expect to continue to focus on the following activities during the next twelve months:

- seek additional funding as required to support the milestones described previously and our operations generally;
- work with our large scale manufacturing partners to scale up production of product compliant with current good manufacturing practices ("cGMP"), which activities will be ongoing as we seek to advance toward, enter into, and, if successful, subsequently increase commercialization activities;
- further clinical development of our product platform;
- continue to expand and enhance our financial and operational reporting and controls;
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, which activities will be ongoing as we seek to expand our product candidate portfolio; and

- assess our self-assembling peptide platforms in order to identify and select product candidates for advancement into development.

In addition to capital required for operating expenses, depending upon additional input form EU and US regulatory authorities, as well as the potential for more than one regulatory filing and approval in 2017, up to $5,000,000 may be required to complete an initial European CE Mark approval and an initial US regulatory clearance or approval. These estimated capital requirements potentially could increase significantly if a number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading "**RISK FACTORS**" in this filing. We anticipate that our operating and other expenses will continue to increase as we continue to implement our business plan and pursue and achieve these goals. After giving effect to the funds received in past equity and debt financings and assuming our use of that funding at the rate we presently anticipate, as of December 2, 2016, we believe that our current cash and cash equivalents on hand will meet our anticipated cash requirements into the fourth quarter of Fiscal 2017. We could spend our financial resources much faster than we expect, in which case our current funds may not be sufficient to operate our business for the entire duration of that period.

We have no commitments for any future capital. As indicated above, we will require significant additional financing to fund our planned operations, including further research and development relating to AC5, seeking regulatory approval of that or any other product we may choose to develop, commercializing any product for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or business, and maintaining our intellectual property rights, pursuing new technologies and for financing the investor relations and incremental administrative costs associated with being a public corporation. We do not presently have, nor do we expect in the near future to have, revenue to fund our business from operations, and we will need to obtain all of our necessary funding from external sources for the foreseeable future. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail and our stockholders could lose all of their investment.

Since inception, we have funded our operations primarily through debt borrowings and the issuance of convertible debt and units consisting of Common Stock and warrants, and we may continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders' ownership will be diluted. The terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors. Further, newly issued securities may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. If we obtain additional financing by incurring debt, we may become subject to significant limitations and restrictions on our operations pursuant to the terms of any loan or credit agreement governing the debt. Further, obtaining any loan, assuming a loan would be available when needed on acceptable terms, would increase our liabilities and future cash commitments. We may also seek funding from additional collaboration or licensing arrangements in the future, which may require that we relinquish potentially valuable rights to our product candidates or proprietary technologies or grant licenses on terms that are not favorable to us. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment-banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs.

Industry and Competition

Arch is developing technology for surgery and trauma care applications. Planned products include, among others, barriers for both bleeding tissues and leaking fluids that create an environment permissive to normal healing. The initial focus has been on procedures and surgeries, with plans to follow with trauma applications. The initial clinical trial assessed AC5's use in an external application, while internal human studies are intended to follow. Our intent is to provide a product set with broad utility and relatively few constraints based on bleeding, leakage, and wound type. Features of the technology highlight its potential utility in a range of settings, including traditional open procedures and the often more challenging minimally invasive surgeries.

According to a 2012 report produced by MedMarket Diligence, LLC, approximately 114 million surgical and procedure-based wounds occur annually worldwide, including 36 million from surgery in the U.S. Since the early days of modern minimally invasive surgery in the 1990s, the percent of surgeries performed minimally invasively has increased significantly such that it is now widespread and common. Minimally invasive surgery is often called laparoscopic surgery, although there are additional types. Minimally invasive surgical procedures often present the surgeon with fewer margins for potential error and less capacity to deal with certain risks, such as excessive bleeding, without converting the surgery to a traditional open procedure. We believe that the performance and safety of both minimally invasive and traditional surgeries and other procedures could benefit from newer hemostatic agents and sealants, because surgical and trauma patients are at significant risk for morbidity and mortality from bleeding and/or leaking body fluid.

Additional trends that support a demand for hemostatic and sealant products include the following:

- overall procedure volume growth;
- ambulatory same day surgery volume growth;
- minimally invasive surgery procedure volume growth;
- efforts to reduce operating room time; and
- increased use of anticoagulants, which predispose patients to bleeding.

As a result of this demand, use of hemostatic agents and sealants is increasing. According to a 2015 MedMarket Diligence report, the market for these products achieved approximately $4.2 billion in worldwide sales in 2015 and is projected to reach $4.8 billion in 2017 and surpass $7.5 billion in 2022. Approximately three quarter of those sales are for hemostats, which are currently growing faster than sealants, as defined in the data survey. However, we believe that due to a currently poorly met need and pent up demand, the projected growth rate for sealants could become greater than that for hemostats once additional products become available.

In spite of the large size of the market for these products, many available hemostatic agents and sealants possess a combination of limitations, including slow onset of action, general unreliability, user-unfriendliness, and risk for adverse effects, such as healing problems, adhesion formation, infection and other safety concerns. Many of the deficiencies of currently available hemostatic agents and sealants are comparable to those of their earlier-generation counterparts, as revolutionary advances in underlying technologies have been elusive.

In the course of developing AC5, we engaged commercial strategy and marketing consultants and communicated directly with care providers to understand the needs of potential customers and to assess product feature preferences. As we expected, better efficacy and reliability were identified as product features important to those customers, and we discovered that other product features are important to achieving broad market acceptance. Surgeons, operating room managers, sales representatives for currently available hemostatic products, and hospital decision-makers identified a number of desirable characteristics for a hemostatic agent, which we carefully consider while developing AC5. These features include that a product is:

- laparoscopic friendly;
- easily handled and applied;
- able to promote a clear field of vision and not obstruct view;
- non-viscous and flowable;
- non-sticky (to tissue or equipment);
- able to permit normal healing;
- indifferent to status of coagulation cascade or “blood thinning” drugs;
- non-toxic; and
- not sourced from human or other animal blood or tissue components.

We anticipate that AC5 will meet these particular market demands, and we anticipate its use in minimally invasive or laparoscopic surgery as well as open surgical procedures. While open procedures represents the more established market for hemostatic agents, the number of surgeries performed by minimally invasive techniques, including laparoscopic surgery, has been growing over the past two decades and is significant. Less invasive laparoscopic procedures tend to result in shorter recovery times, faster discharges, less scarring, less pain and less need for pain medications. Many of the hemostasis products currently available do not possess certain features and handling characteristics that are ideal for use in a laparoscopic setting. For instance, many available products are difficult to use laparoscopically because they tend to be sticky, powdery, fabric-based or are otherwise difficult to control and/or insert into the small tubes used during many laparoscopic procedures. We believe that the novel features and differentiating characteristics of AC5 will make it more suitable for laparoscopic surgeries than many or most presently available alternatives.

Further, available data indicates that there may be increased pressure to perform more complex surgeries at reduced costs, including conducting operations in less expensive outpatient settings. Although accurate current statistics are difficult to obtain, a National Health Statistics Report from 2006 and updated in 2009 indicates that outpatient surgery volume was increasing by approximately 5% annually, and a 2009 report covering U.S. surgical procedures suggests that inpatient surgery volume was declining 1% per year. We believe that a motivating factor of this trend may be the increased costs associated with hospital inpatient procedures performed in operating rooms, which, according to MedMarket Diligence, have been estimated to cost between $2,000 and $10,000 per hour. These costs likely motivate increased operating room throughput and increased volume of procedures performed in outpatient settings. Both of those trends highlight the need for highly effective hemostatic agents and sealants that can decrease operating room time for inpatient procedures and help to increase the safety of performing more types of procedures in less expensive outpatient settings.

Participants in the hemostatic and sealant market currently include large companies, such as Johnson & Johnson and its affiliated companies, C. R. Bard, Inc., Baxter International Inc., Mallinckrodt plc, as well as various smaller companies. Certain companies in other sectors, such as pharmaceuticals, wound care, and orthopedics, among others, are also interested in these markets.

Commercially available products in the hemostasis field with which we would expect AC5 to compete if it obtains required regulatory approvals can cost between $50 and $500 per procedure, with the higher value added products generally priced at the upper end of that range. Production costs of many of those products are significant, as they may require biotechnology or plasma separation technologies to manufacture, and they may require ingredients or other materials that are expensive to obtain. We believe that, assuming receipt of required regulatory approvals, AC5 will be well positioned to compete against currently available products as a result of its broad applicability in various types of surgical settings and its features that address drawbacks seen in many available hemostatic agents. Furthermore, our planned use of a manufacturing method that we expect will be relatively simple and cost-effective compared to methods used to manufacture many currently available hemostatic products could enable any future sales to be made at competitive price points within the market range.

Potential Disadvantages of AC5 Compared to the Competition

Some potential disadvantages of AC5 compared to the hemostatic agents currently on the market with which we would expect AC5 to compete if it obtains required regulatory approvals are as follows:

- The favorable handling characteristics of AC5 are the result of its non-sticky and non-glue-like nature. However, if a surgeon or healthcare provider requires a product to adhere tissues together, or provide similar glue-like action, then AC5 in its current form would not achieve that effect.

- While we project that AC5 will be relatively economical to manufacture at scale, it may not be able to compete from a price perspective with inexpensive means to stop bleeding, such as application of pressure or use of bandages or other inexpensive hemostatic agents.

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Research and Development Expenditures

Our research and development expenses to date have primarily included labor and third party consulting costs to develop our core technology and AC5. Research and development expense during the year ended September 30, 2016 was $1,683,299, a decrease of $76,738 compared to $1,760,037 for the year ended September 30, 2015. We expect our research and development activities and expenses to increase significantly as we execute on our business plan and commence additional clinical trials

Regulation by the FDA and Similar Foreign Agencies

Our research, development and clinical programs, as well as our manufacturing and marketing operations that may be performed by us or third party service providers on our behalf, are subject to extensive regulation in the U.S. and other countries. Most notably, we believe that AC5 will be subject to regulation as a medical device under the U.S. Food Drug and Cosmetic Act (the "**FDCA**") as implemented and enforced by the FDA and equivalent regulations enforced by foreign agencies in any other countries in which we desire to pursue commercialization. The FDA and its foreign counterparts generally govern the following activities that we do or will perform or that will be performed on our behalf, as well as potentially additional activities, to ensure that products we may manufacture, promote and distribute domestically or export internationally are safe and effective for their intended uses:

- product design, preclinical and clinical development and manufacture;
- product premarket clearance and approval;
- product safety, testing, labeling and storage;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

Pre-Marketing Regulation by the U.S. FDA

Medical Device Classification

As described previously, we expect that AC5 will be classified as a medical device because its primary desired activity does not depend on metabolic or chemical activity in a body. The FDA classifies medical devices into one of the following three classes on the basis of the amount of risk associated with the medical device and the controls deemed necessary to reasonably ensure their safety and effectiveness:

- Class I, requiring general controls, including labeling, device listing, reporting and, for some products, adherence to good manufacturing practices through the FDA's quality system regulations and pre-market notification;
- Class II, requiring general controls and special controls, which may include performance standards and post-market surveillance; or
- Class III, requiring general controls and approval of a premarket approval application ("**PMA**"), which may include post-market approval conditions and post-market surveillance.

Class III devices are those that are deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or that have a new intended use or use advanced technology that is not substantially equivalent to that of a legally marketed device. As a result of the intended use of AC5 and the novel technology on which is it based, we anticipate that the FDA will classify it as a Class III or Class II medical device.

As described previously, AC5 fulfills the definition of a medical device in Europe. We anticipate that the FDA will rule similarly. We further anticipate that AC5 could be regulated as either a Class III or a Class II medical device in these jurisdictions, depending upon the application.

US Regulatory Approval Process

Products that are regulated as medical devices and that require review by the FDA are subject to either a premarket notification, also known as a 510(k), which must be submitted to the FDA for clearance, or a PMA application, which the FDA must approve prior to marketing in the U.S. The FDA will ultimately determine the appropriate regulatory path.

We believe that the products we are currently pursuing for internal use will require a PMA approval prior to commercialization. However, we believe that we may commercialize an initial product for external use upon clearance through the 510(k) process, which we expect to seek during the second half of calendar year 2017. We have had preliminary discussions with the FDA about the 510(k) process and are encouraged by the FDA’s guidance on key elements of that pathway.

To obtain 510(k) marketing clearance for a medical device, an applicant must submit a premarket notification application to the FDA demonstrating that the device is "substantially equivalent" to a predicate device, which is typically a legally marketed Class II device in the United States. A device is substantially equivalent to a predicate device if it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding substantial equivalence.

A PMA must be submitted to the FDA if a device cannot be cleared through another approval process or is not otherwise exempt from the FDA’s premarket clearance and approval requirements. A PMA is required for most Class III medical devices. A PMA must generally be supported by extensive data, including without limitation technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA’s satisfaction the safety and efficacy of the device for its intended use. During the review period, the FDA will typically request additional information or clarification of the information previously provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the PMA and provide recommendations to the FDA as to the approvability of the device, although the FDA may or may not accept any such panel’s recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the manufacturing facility or facilities involved with producing the device to ensure compliance with the cGMP regulations. Upon approval of a PMA, the FDA may require that certain conditions of approval, such as conducting a post-market approval clinical trial, be met.

The PMA approval process can be lengthy and expensive and requires an applicant to demonstrate the safety and efficacy of the device based, in part, on data obtained from clinical trials. The PMA process is estimated to take from one to three years or longer, from the time the PMA application is submitted to the FDA until an approval is obtained.

Further, if post-approval modifications are made that affect the safety or efficacy of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling or design, then new PMAs or PMA supplements would be required. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is typically limited to information needed to support the changes from the device covered by the original PMA and accordingly may not require as extensive clinical and other data.

We have not submitted to the FDA a PMA or commenced the required clinical trials, and we have not submitted a premarket notification. Ever if we conduct successful preclinical and clinical studies and submit a PMA for an approval or premarket application for clearance, the FDA may not permit commercialization of AC5 for the desired indications of use, on a timely basis, or at all. Our inability to achieve regulatory approval for AC5 in the U.S., a large market for hemostatic products, would materially adversely affect our ability to grow our business.

Clinical Trials

Obtaining PMA approval requires the completion of human clinical trials that produce successful results demonstrating the safety and efficacy of the product. Clinical trials for a Class III medical device typically require an application for an investigational device exemption ("**IDE**"), which would need to be approved in advance by the FDA for a specified number of patients and study sites. Human clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements, and must be conducted under the oversight of an institutional review board ("**IRB**") for the relevant clinical trial sites and comply with applicable FDA regulations, including those relating to good clinical practices ("**GCP**").

In order to complete a clinical trial, we are required to enroll a sufficient number of patients to conduct the trial after obtaining each patient's informed consent in a form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. Many factors could lead to delays or inefficiencies in conducting clinical trials, some of which are discussed under the heading "**RISK FACTORS**" in this Annual Report on Form 10-K. Further, we, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to the subjects of the trial outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the U.S.

On December 16, 2015, we announced that we had received clearance from a regulatory authority in Western Europe to initiate a human clinical trial to assess the safety and performance of AC5 in humans. The initial patient was treated in the first quarter of 2016 and on June 6, 2016, we announced we had completed patient enrollment in this study. On August 15, 2016, we announced that the AC5 Topical Hemostatic Device met its primary and secondary endpoints in our first clinical trial. On October 31, 2016, the Company announced that additional analysis of the subgroup of 10 patients who were taking a prescribed antiplatelet medication, commonly known as a blood thinner, such as aspirin, indicated that AC5 had similar effects for this patient population.

Pre-Marketing Regulation in the EU

Medical Device Classification

Similar to the U.S., the EU recognizes different classes of medical devices. The EU recognizes Class I, Class IIa, Class IIb or Class III medical devices, with the classification determination depending on the amount of potential risk to the patient associated with use of the medical device. Classification involves rules found in the EU's Medical Device Directive. Key questions of relevance include the degree of the device's contact with the patient, invasiveness, active nature, and indications for use. The medical device classes recognized in the EU are as follows:

- Class I, which are considered low risk devices, such as wheelchairs and stethoscopes, and require pre-market notification prior to placing the devices onto the EU market;

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- Class IIa, which are considered low-medium risk devices and require certification by a Notified Body;
- Class IIb, which are considered medium-high risk devices and require certification by a Notified Body; and
- Class III, which are considered high-risk devices and require certification by a Notified Body.

In February of 2015, we announced that BSI confirmed that AC5 fulfills the definition of a medical device within the EU and will be classified as such in consideration for CE mark designation. We anticipate that AC5 could be regulated as either a Class III or a Class II medical device in these jurisdictions, depending upon the application.

CE Mark Approval Process

Approval Process

The EU has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Each EU member state has implemented legislation applying these directives and standards at a national level. Many countries outside of the EU have also voluntarily adopted laws and regulations that mirror those of the EU with respect to medical devices.

Under applicable EU medical device directives, a CE mark is a symbol placed on a product that declares the product's compliance with the essential requirements of applicable EU health, safety and environmental protection legislation. In order to receive a CE mark for a product candidate, the company producing the product candidate must select a country in which to apply. Each country in the EU has one competent authority ("**CA**") that implements the national regulations by interpreting the EU directives. CAs also designate and regulate Notified Bodies. An assessment by a Notified Body in the selected country within the EU is required in order to commercially distribute the device. In addition, compliance with ISO 13485 issued by the International Organization for Standardization, among other standards, establishes the presumption of conformity with the essential requirements for CE marking. Certification to the ISO 13485 standard demonstrates the presence of a quality management system that can be used by a manufacturer for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

Devices that comply with the requirements of the laws of the selected member state applying the applicable EU directive are entitled to bear a CE mark and can be distributed throughout the member states of the EU, as well as in other countries that have mutual recognition agreements with the EU or have adopted the EU's regulatory standards.

We have identified several potential countries through which we may pursue a CE mark for AC5.

Clinical Trials

As with U.S. Class III and certain Class II medical device approvals, EU Class III and certain Class II medical device approvals require the successful completion of human clinical trials. However, there are several key differences between the jurisdictions with respect to the approvals and processes. Obtaining a CE mark is not equivalent to obtaining FDA approval, in that a CE mark confirms the safety, but not the effectiveness, of a product. Furthermore, a CE mark affixed to a product serves as a declaration by the responsible party that the product conforms to applicable provisions and that relevant conformity assessment procedures have been completed with respect to the product. Accordingly, we anticipate that the required EU clinical trial(s) for AC5 will be smaller, faster, and less expensive than what we expect would be required for AC5 to obtain equivalent approvals in the U.S.

Post-Approval Regulation

After a medical device obtains approval from the applicable regulatory agency and is launched in the market, numerous post-approval regulatory requirements would apply. Many of those requirements are similar in the U.S. and in member states of the EU, and include:

- product listing and establishment registration;
- requirements that manufacturers, including third-party manufacturers, follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and other advertising regulations, including prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- approval of product modifications that affect the safety or effectiveness of any of our devices that may achieve approval;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the device;

- the recall authority of the applicable government agency and regulations pertaining to voluntary recalls; and
- reporting requirements, including reports of incidents in which a product may have caused or contributed to a death or serious injury or in which a product malfunctioned, and notices of corrections or removals.

Failure by us or by our third-party manufacturers and other suppliers to comply with applicable regulatory requirements could result in enforcement action by various regulatory authorities, which may result in monetary fines, the imposition of operating restrictions, product recalls, criminal prosecution or other sanctions.

Regulation by Other Foreign Agencies

International sales of medical devices outside the EU may be subject to government regulations in each country in which the device is marketed and sold, which vary substantially from country to country. The time required to obtain approval by a non-EU foreign country may be longer or shorter than that required for FDA or CE mark clearance or approval, and the requirements may substantially differ.

Other Governmental Regulations and Environmental Matters

We are or may become subject to various laws and regulations regarding laboratory practices and the use of animals in testing, as well as environmental laws and regulations governing, among other things, any use and disposal by us of hazardous or potentially hazardous substances in connection with our research. At this time, costs attributable to environmental compliance are not material. In each of these areas, applicable U.S. and foreign government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on our business. Additionally, if we are able to successfully obtain approvals for and commercialize our product candidates, then the Company and our products may become subject to various federal, state and local laws targeting fraud, abuse, privacy and security in the healthcare industry.

Intellectual Property

We are focused on the development of self-assembling compositions, particularly self-assembling peptide compositions, and methods of making and using such compositions primarily in healthcare applications. Suitable applications of these compositions include limiting or preventing the movement of bodily fluids and contaminants within or on the human body, preventing adhesions, treatment of leaky or damaged tight junctions, and reinforcement of weak or damaged vessels, such as aneurysms. Our strategy to date has been to develop an intellectual property portfolio in high-value jurisdictions that tend to uphold intellectual property rights.

Our patent portfolio, which covers self-assembling peptides and methods of use thereof, includes six granted, issued or allowed patents, and seventeen pending applications in nine jurisdictions.

We have also entered into a license agreement with MIT pursuant to which we have been granted exclusive rights under one portfolio of patents and non-exclusive rights under another portfolio of patents. The portfolio exclusively licensed from MIT and Versitech Limited ("MIT") includes fifteen patents that have been either allowed, issued or granted and seven applications that are pending in nine jurisdictions. The portfolio non-exclusively licensed from MIT includes a number of PCT applications which have now entered the national and regional phases outside of the US, including eight issued patents in four jurisdictions that expire between 2016 and 2027 (absent patent term extension), and one pending patent application in one jurisdiction. Because a portion of our patent portfolio has been in-licensed on a non-exclusive basis, other parties may be able to develop, manufacture, market and sell products with similar features covered by the same patent rights and technologies, which in turn could significantly undercut the value of any of our product candidates and adversely affect our business. A complaint for an invalidation trial has been filed by a competitor against one of our licensed MIT Japanese patents. The corresponding European patent licensed by Arch from MIT was recently opposed, but was maintained in amended form following an administrative hearing. This decision has been appealed.

Our license agreement with MIT imposes certain diligence, capital raising, and other obligations on us, including obligations to raise certain amounts of capital by specific dates. Additionally, we are responsible for all patent prosecution and maintenance fees under that agreement. Our breach of any material terms of our license agreement with MIT could permit the counterparty to terminate the agreement, which could result in our loss of some or all of our rights to use certain intellectual property that is material to our business and our lead product candidate. Our loss of any of the rights granted to us under our license agreement with MIT could materially harm our product development efforts and could cause our business to fail.

We also were granted a non-exclusive sub-license of a patent assigned to MIT and in turn licensed by MIT to the sub-licensing third party. This patent expired in 2014. This sub-license was a fully-paid and royalty-free license and did not provide any outbound license grant to any ABS owned or exclusively licensed intellectual property. We presently do not anticipate any material impact on our business or operations resulting from the expiration of this patent in 2014.

We have pending trademark applications for AC5 Surgical Hemostatic Device™, AC5 Surgical Hemostat™, AC5™, Crystal Clear Surgery™, NanoDrape™ and NanoBioBarrier™.

Employees

We presently have six full-time employees and one part-time employee, and make extensive use of third party contractors, consultants, and advisors to perform many of our present activities. We expect to increase the number of our employees as we increase our operations.

ITEM 1A. RISK FACTORS

Investment in our Common Stock involves a high degree of risk. You should carefully consider the following risk factors before making an investment decision. If any of the following risks and uncertainties actually occurs, our business, financial condition, and results of operations could be negatively impacted and you could lose all or part of your investment.

Risks Related to our Business

There is substantial doubt about our ability to continue as a going concern.

We are a development stage company with no commercial products. Our primary product candidate is in the process of being developed, and will require significant additional clinical development and investment before it could potentially be commercialized. As a result, we have not generated any revenue from operations since inception, and we have incurred substantial net losses to date. Moreover, our cash position is vastly inadequate to support our business plans and substantial additional funding will be needed in order to pursue those plans, which include research and development of our primary product candidate, seeking regulatory approval for that product candidate, and pursuing its commercialization in the U.S., Europe and other markets. Those circumstances raise substantial doubt about our ability to continue as a going concern. In particular and as discussed in greater detail below under the risk factor entitled "***We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail***," as of December 2, 2016, we believe that our current cash and cash equivalents on hand will meet our anticipated cash requirements into the fourth quarter of Fiscal 2017.

We have incurred significant losses since inception. We expect to continue to incur losses for the foreseeable future, and we may never generate revenue or achieve or maintain profitability.

As noted above under the risk factor entitled "***There is substantial doubt about our ability to continue as a going concern***," *w*e are a development stage company with no commercial products. Consequently, we have incurred losses in each year since our inception and we expect that losses will continue to be incurred in the foreseeable future in the operation of our business. To date, we have financed our operations entirely through equity and debt investments by founders, other investors and third parties, and we expect to continue to rely on these sources of funding, to the extent available in the foreseeable future. Losses from operations have resulted principally from costs incurred in research and development programs and from general and administrative expenses, including significant costs associated with establishing and maintaining intellectual property rights, significant legal and accounting costs incurred in connection with both the closing of the Merger and complying with public company reporting and control obligations, and personnel expenses. We have devoted much of our operations to date to the research and development of our core technology, including selecting our initial product composition, conducting initial safety and other related tests, generating scale-up, reproducibility and manufacturing and formulation methods, and developing and protecting the intellectual property rights underlying our technology platform.

We expect to continue to incur significant expenses and we anticipate that those expenses and losses may increase in the foreseeable future as we seek to:

- develop our principal product candidate, AC5, and the underlying technology, including advancing applications and conducting biocompatibility and other preclinical studies;
- raise capital needed to fund our operations;
- build and enhance investor relations and corporate communications capabilities;
- conduct additional clinical trials relating to AC5 and any other product candidate we seek to develop;
- attempt to gain regulatory approvals for product candidates;
- build relationships with contract manufacturing partners, and invest in product and process development through such partners;
- maintain, expand and protect our intellectual property portfolio;

- advance additional product candidates and technologies through our research and development pipeline;
- seek to commercialize selected product candidates which may require regulatory approval; and
- hire additional regulatory, clinical, quality control, scientific, financial, and management, consultants and advisors.

To become and remain profitable, we must succeed in developing and eventually commercializing product candidates with significant market potential. This will require us to be successful in a number of challenging activities, including successfully completing preclinical testing and clinical trials of product candidates, obtaining regulatory approval for our product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of many of those activities. We may never succeed in those activities and may never generate operating revenues or achieve profitability. Even if we do generate operating revenues sufficient to achieve profitability, we may not be able to sustain or increase profitability. Our failure to generate operating revenues or become and remain profitable would impair our ability to raise capital, expand our business or continue our operations, all of which would depress the price of our Common Stock. A further decline or lack of increase in the prices of our Common Stock could cause our stockholders to lose all or a part of their investment in the Company.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.

Based on our current operating expenses and working capital requirements, as of December 2, 2016, we believe that our current cash and cash equivalents on hand will meet our anticipated cash requirements into the fourth quarter of Fiscal 2017. In addition to the funds raised from our previous equity and convertible debt financings and borrowings under the Life Sciences Accelerator Funding Agreement (the "**MLSC Loan Agreement**") that we entered into with MLSC, we will need to obtain additional cash to continue operations and fund our planned future operations, including the continuation of our ongoing research and development efforts, the licensing or acquisition of new assets, and researching and developing any potential patents, the related compounds and any further intellectual property that we may acquire. In addition, our plans may change and/or we may use our capital resources more rapidly than we currently anticipate. We presently expect that our expenses will increase in connection with our ongoing activities to support our business operations inclusive of regulatory applications and approval of AC5 in the U.S. and Europe and therefore we will require additional funding. Our future capital requirements will depend on many factors, including:

- the scope, progress and results of our research, preclinical, and clinical development activities;

- the scope, progress and results of our research and development collaborations;
- the extent of potential direct or indirect grant funding for our research and development activities;
- the scope, progress, results, costs, timing and outcomes of any regulatory process and clinical trials conducted for any of our product candidates;
- the timing of entering into, and the terms of, any collaboration agreements with third parties relating to any of our product candidates;
- the timing of and the costs involved in obtaining regulatory approvals for our product candidates;
- the costs of operating, expanding and enhancing our operations to support our clinical activities and, if our product candidates are approved, commercialization activities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the costs associated with maintaining and expanding our product pipeline;
- the costs associated with expanding our geographic focus;
- operating revenues, if any, received from sales of our product candidates, if any are approved by the U.S. Food and Drug Administration ("**FDA**") or other applicable regulatory agencies;

- the cost associated with being a public company, including obligations to regulatory agencies, and increased investor relations and corporate communications expenses; and

- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources employees.

We intend to obtain additional financing for our business through public or private securities offerings, the incurrence of additional indebtedness, or some combination of those sources. We have obtained research and development support through collaborative arrangements, such as the Project Agreement that we entered into with the National University of Ireland Galway ("**NUIG**") on May 28, 2015, and we may continue to seek funding through additional collaborative arrangements with strategic partners if we determine them to be necessary or appropriate, although these arrangements could require us to relinquish rights to our technology or product candidates and could result in our receipt of only a portion of any revenues associated with the partnered product. We cannot provide any assurance that additional financing from these sources will be available on favorable terms, if at all. In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the MLSC Loan Agreement (i) restricting our ability to incur certain types of additional indebtedness, and (ii) that would cause all amounts under the MLSC Loan Agreement to become immediately due and payable if we receive cumulative net proceeds of $5,000,000 or more in one or more financing transactions at any time after October 3, 2016. These restrictions and provisions, which are discussed in greater detail below under the risk factor entitled "***Our current and any future debt facilities or instruments may require us to use our limited capital to repay amounts owed and may impose limitations on our operations, which could negatively affect our business plans***," could make it more challenging for us to raise capital through the incurrence of additional debt or through future equity issuances. Further, if we do raise capital through the sale of equity, or securities convertible into equity, the ownership of our then existing stockholders would be diluted, which dilution could be significant depending on the price at which we may be able to sell our securities. Also, if we raise additional capital through the incurrence of indebtedness, we may become subject to additional covenants restricting our business activities, and the holders of debt instruments may have rights and privileges senior to those of our equity investors. Finally, servicing the interest and principal repayment obligations under our debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

If we are unable to obtain adequate financing on a timely basis or on acceptable terms in the future, we would likely be required to delay, reduce or eliminate one or more of our product development activities, which could cause our business to fail.

The terms of the 2016 Private Placement Financing could impose additional challenges on our ability to raise funding in the future.

The subscription agreements that we entered into between May 24, 2016 and May 26, 2016 (the "**2016 Subscription Agreements**") in connection with our private placement financing that closed on May 26, 2016 (the "**2016 Private**

Placement Financing”) impose certain restrictions on our ability to issue equity or debt securities, including the following: (i) until the six-month anniversary of the first date on which all the Registrable Securities (as defined in the registration rights agreement that we entered into with the investors in the 2016 Private Placement Financing)(the “**2016 Registrable Securities**”) are covered by one or more effective registration statements, which occurred on July 13, 2016 (the “**2016 Registration Statement Effective Date**”), the 2016 Investors shall have certain notice and participation rights with respect to offers and sales of securities that we may pursue; and (ii) until the earlier of the nine-month anniversary of the 2016 Registration Statement Effective Date and the date on which the 2016 Investors have sold all such 2016 Registrable Securities, we may not effect or enter into an agreement for a VRT, where a “**VRT**” is a transaction in which we (1) issue convertible securities at (A) a conversion, exercise or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, the shares of our Common Stock at any time after the initial issuance of such convertible securities; or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such convertible securities or upon the occurrence of specified or contingent events directly or indirectly related to our business or the market for the common stock, other than pursuant to a customary “weighted average” anti-dilution provision; or (2) enter into any agreement (including, without limitation, an “equity line of credit” or an “at-the-market offering”) whereby we or any subsidiary may sell securities at a future determined price, other than standard and customary “preemptive” or “participation” rights. These provisions could make our securities less attractive to investors and could limit our ability to obtain adequate financing on a timely basis or on acceptable terms in the future, which could have significant harmful effects on our financial condition and business and could include substantial limitations on our ability to continue to conduct operations.

Our current and any future debt facilities or instruments may require us to use our limited capital to repay amounts owed and may impose limitations on our operations, which could negatively affect our business plans.

On September 30, 2013, we entered into the MLSC Loan Agreement with MLSC pursuant to which MLSC has provided us an unsecured subordinated loan in principal amount of $1,000,000 (such loan, the “**MLSC Loan**”). Under the original terms of the MLSC Loan Agreement, the MLSC Loan bore interest at a rate of 10% per annum, and became fully due and payable on the earlier of (i) September 30, 2018; (ii) the occurrence of an event of default under the MLSC Loan Agreement; or (iii) the completion of a sale of substantially all of our assets, a change-of-control transaction or one or more financing transactions in which we receive from third parties other than our then existing shareholders net proceeds of $5,000,000 or more in a 12-month period. On September 28, 2016, we entered into an amendment (the “**Amendment**”). Under the terms of the Amendment, (i) interest on the MLSC Loan decreased from 10% per annum to 7% per annum beginning October 3, 2016; and (ii) the MLSC Loan becomes due and payable on the earlier of (a) October 3, 2017 (the “**Maturity Date**”); (b) the completion of a sale of substantially all of our assets, or a change-of-control transaction; or (c) one or more financing transactions in which we receive cumulative net proceeds of $5,000,000 or more in one or more financing transactions at any time after October 3, 2016, and the occurrence of an event of default under the MLSC Loan Agreement. In addition, under the terms of the Amendment, beginning October 3, 2016, the Company began repaying the principal and accrued interest under the MLSC Loan by making the first of 13 monthly payments of $106,022, with the last payment scheduled to occur on the Maturity Date. Accordingly, we will need substantial amounts of cash in order to repay the principal and interest owed under MLSC Loan, as it becomes due, which we may not have or be able to obtain. Any failure to make payments as required under the MLSC Loan Agreement would constitute an event of default, and could result in, among other things, MLSC’s acceleration of all amounts due thereunder.

Further, the MLSC Loan Agreement restricts our use of the proceeds of the MLSC Loan to funding working capital requirements and/or the purchase of capital assets in the life sciences field, and we are expressly prohibited from using any such proceeds for any severance payment, investment in certain securities or payment for goods or services to a related party of the Company. Additionally, the MLSC Loan Agreement provides that, for so long as any of the MLSC Loan remains outstanding, our headquarters and at least a majority of our employees must be located in Massachusetts and we must not take certain actions without obtaining MLSC's prior consent, including without limitation paying dividends on our capital stock, redeeming any of our outstanding securities, and completing a sale of substantially all of our assets or a change-of-control transaction. Further, our failure to remain a "certified life sciences company" under the Massachusetts General Law would constitute an event of default under the MLSC Loan Agreement. Our ability to pursue our business plans during the term of the MLSC Loan may be severely limited as a result of those restrictions, which could cause our operations and financial condition to suffer.

In addition, the MLSC Loan Agreement restricts our ability, without the prior written consent of MLSC, to incur certain types and amounts of additional indebtedness, including indebtedness senior or, in certain circumstances, equal to the MLSC Loan and any indebtedness to any of our stockholders or employees that is subject to a security interest and not expressly subordinated to the MLSC Loan. Our ability to finance our operations could be limited if, while the MLSC Loan is outstanding, the only source of capital available to us is prohibited by the restrictions set forth in the MLSC Loan Agreement, in which case we may be forced to curtail or eliminate some or all of our operations.

Our short operating history may hinder our ability to successfully meet our objectives.

We are a development stage company subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets. Our operations to date have been primarily limited to organizing and staffing, developing and securing our technology and undertaking funding preclinical studies of our lead product candidate, and funding one clinical trial. We have not demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

Because of our limited operating history, we have limited insight into trends that may emerge and affect our business, and errors may be made in developing an approach to address those trends and the other challenges faced by development stage companies. Failure to adequately respond to such trends and challenges could cause our business, results of operations and financial condition to suffer or fail. Further, our limited operating history may make it difficult for our stockholders to make any predictions about our likelihood of future success or viability.

If we are not able to attract and retain qualified management and scientific personnel, we may fail to develop our technologies and product candidates.

Our future success depends to a significant degree on the skills, experience and efforts of the principal members of our scientific and management personnel. These members include Terrence Norchi, MD, our President and Chief Executive Officer. The loss of Dr. Norchi or any of our other key personnel could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. Further, our operation as a public company will require that we attract additional personnel to support the establishment of appropriate financial reporting and internal controls systems. Competition for personnel is intense. We may not be able to attract, retain and/or successfully integrate qualified scientific, financial and other management personnel, which could materially harm our business.

If we fail to properly manage any growth we may experience, our business could be adversely affected.

We anticipate increasing the scale of our operations as we seek to develop our product candidates, including hiring and training additional personnel and establishing appropriate systems for a company with larger operations. The management of any growth we may experience will depend, among other things, upon our ability to develop and improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage any growth effectively, our operations and financial condition could be adversely affected.

If we fail to maintain appropriate internal controls in the future, we may not be able to report our financial results accurately, which may adversely affect our stock price and our business.

Our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting requires the commitment of significant financial and managerial resources.. Internal control over financial reporting has inherent limitations, including human error, the possibility that controls could be circumvented or become inadequate because of changed conditions, and fraud. If we are unable to maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or the Sarbanes-Oxley Act of 2002. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our stock and our business.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

We maintain sensitive data pertaining to our Company on our computer networks, including information about our research and development activities, our intellectual property and other proprietary business information. Our internal computer systems and those of third parties with which we contract may be vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, despite the implementation of security measures. System failures, accidents or security breaches could cause interruptions to our operations, including material disruption of our research and development activities, result in significant data losses or theft of our intellectual property or proprietary business information, and could require substantial expenditures to remedy. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research and development programs could be delayed, any of which would harm our business and operations.

Risks Related to the Development and Commercialization of our Product Candidates

Our business plan is dependent on the success of our initial product candidate, AC5.

Our business is currently focused almost entirely on the development and commercialization of one product candidate, AC5. Our reliance on one primary product candidate means that, if we are not able to obtain regulatory approvals and market acceptance of that product, our chances for success will be significantly reduced. We are also less likely to withstand competitive pressures if any of our competitors develops and obtains regulatory approval or certification for a similar product faster than we can or that is otherwise more attractive to the market than AC5. Our current dependence on one product candidate increases the risk that our business will fail if our development efforts for that product candidate experience delays or other obstacles or are otherwise not successful.

The Chemistry, Manufacturing and Control ("CMC") process may be challenging.

Because of the complexity of our lead product candidate, the CMC process, including product scale-up activities, may be difficult to complete successfully within the parameters required by the FDA or its foreign counterparts. Peptide formulation optimization is particularly challenging, and any delays could negatively impact our ability to conduct clinical trials and our subsequent commercialization timeline. Furthermore, we have, and the third parties with whom we may establish relationships may also have, limited experience with attempting to commercialize a self-assembling peptide as a medical device, which increases the risks associated with completing the CMC process successfully, on time, or within the projected budget. Failure to complete the CMC process successfully would impact our ability to start a clinical trial and could severely limit the long-term viability of our business.

Our principal product candidate is inherently risky because it is based on novel technologies.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of AC5 creates significant challenges with respect to product development and optimization, engineering, manufacturing, scale-up, quality systems, pre-clinical in vitro and in vivo testing, government regulation and approval, third-party reimbursement and market acceptance. Our failure to overcome any one of those challenges could harm our operations, ability to complete a clinical trial, and overall chances for success.

The manufacturing, production, and sterilization methods that we intend to be utilized are detailed and complex and are a difficult process to manage.

We intend to utilize third party manufacturers to manufacture and sterilize our products. We believe that our proposed manufacturing methods make our choice of manufacturer and sterilizer critical, as they must possess sufficient expertise in synthetic organic chemistry and device manufacturing. If such manufacturers are unable to properly manufacture to product specifications or sterilize our products adequately, that could severely limit our ability to market our products.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our technology.

The Animal Welfare Act ("**AWA**") is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and or obligations exist in many foreign jurisdictions. If our contractors or we fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

If the FDA or similar foreign agencies or intermediaries impose requirements or an alternative product classification more onerous than we anticipate, our business could be adversely affected.

The development plan for our lead product candidate is based on our anticipation of pursuing the medical device regulatory pathway, and in February 2015 we received confirmation from The British Standards Institution ("**BSI**"), a Notified Body (which is a private commercial entity designated by the national government of an European Union ("**EU**") member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements) in the EU, that AC5 fulfills the definition of a medical device within the EU and will be classified as such in consideration for CE mark designation. However, the FDA and other applicable foreign agencies, including European Competent Authorities, will have authority to finally determine the regulatory path for our product candidates in their jurisdictions. If the FDA or similar foreign agencies or intermediaries deem our product to be a member of a category other than a medical device, such as a drug or biologic, or impose additional requirements on our pre-clinical and clinical development than we presently anticipate, financing needs would increase, the timeline for product approval would lengthen, the program complexity and resource requirements world increase, and the probability of successfully commercializing a product would decrease. Any or all of those circumstances would materially adversely affect our business.

If we are not able to secure and maintain relationships with third parties that are capable of conducting clinical trials on our product candidates and support our regulatory submissions, our product development efforts, and subsequent regulatory approvals could be adversely impacted.

Our management has limited experience in conducting preclinical development activities and clinical trials. As a result, we have relied and will need to continue to rely on third party research institutions, organizations and clinical investigators to conduct our preclinical and clinical trials and support our regulatory submissions. If we are unable to reach agreement with qualified research institutions, organizations and clinical investigators on acceptable terms, or if any resulting agreement is terminated prior to the completion of our clinical trials, then our product development efforts could be materially delayed or otherwise harmed. Further, our reliance on third parties to conduct our clinical trials and support our regulatory submissions will provide us with less control over the timing and cost of those trials, the ability to recruit suitable subjects to participate in the trials, and the timing, cost, and probability of success for the regulatory submissions. Moreover, the FDA and other regulatory authorities require that we comply with standards, commonly referred to as good clinical practices ("**GCP**"), for conducting, recording and reporting the results of our preclinical development activities and our clinical trials, to assure that data and reported results are credible and accurate and that the rights, safety and confidentiality of trial participants are protected. Additionally, both we and any third party contractor performing preclinical and clinical studies are subject to regulations governing the treatment of human and animal subjects in performing those studies. Our reliance on third parties that we do not control does not relieve us of those responsibilities and requirements. If those third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical development activities or clinical trials in accordance with regulatory requirements or stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Any of those circumstances would materially harm our business and prospects.

Any clinical trials that are planned or are conducted on our product candidates may not start or may fail.

Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures. While the Company has completed its first clinical trial in Western Europe, clinical trials that are planned or which have or shall commence for any of our product candidates could be delayed or fail for a number of reasons, including if:

- the FDA or other regulatory authorities, or other relevant decision making bodies do not grant permission to proceed or place a trial on clinical hold due to safety concerns or other reasons;
- sufficient suitable subjects do not enroll, enroll more slowly than anticipated or remain in our trials;
- we fail to produce necessary amounts of product candidate;
- subjects experience an unacceptable rate of efficacy of the product candidate;
- subjects experience an unacceptable rate or severity of adverse side effects, demonstrating a lack of safety of the product candidate;
- any portion of the trial or related studies produces negative or inconclusive results or other adverse events;
- reports from preclinical or clinical testing on similar technologies and products raise safety and/or efficacy concerns;

- third-party clinical investigators lose their licenses or permits necessary to perform our clinical trials, do not perform their clinical trials on the anticipated schedule or consistent with the clinical trial protocol, GCP or regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;

- inspections of clinical trial sites by the FDA or an institutional review board ("**IRB**") or other applicable regulatory authorities find violations that require us to undertake corrective action, suspend or terminate one or more testing sites, or prohibit us from using some or all of the resulting data in support of our marketing applications with the FDA or other applicable agencies;

- manufacturing facilities of our third party manufacturers are ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices ("**cGMP**") or other applicable requirements;

- third-party contractors become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements;

- the FDA or other regulatory authorities impose requirements on the design, structure or other features of the clinical trials for our product candidates that we and/or our third party contractors are unable to satisfy;

- one or more IRB refuses to approve, suspends or terminates a trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial;

- the FDA or other regulatory authorities seek the advice of an advisory committee of physician and patient representatives that may view the risks of our product candidates as outweighing the benefits;

- the FDA or other regulatory authorities require us to expand the size and scope of the clinical trials, which we may not be able to do; or

- the FDA or other regulatory authorities impose prohibitive post-marketing restrictions on any of our product candidates that attain regulatory approval.

Any delay or failure of one or more of our clinical trials may occur at any stage of testing. Any such delay could cause our development costs to materially increase, and any such failure could significantly impair our business plans, which would materially harm our financial condition and operations.

We cannot market and sell any product candidate in the U.S. or in any other country or region if we fail to obtain the necessary regulatory approvals, clearances or certifications from applicable government agencies.

We cannot sell our product candidates in any country until regulatory agencies grant marketing approval, clearance or other required certification. The process of obtaining such approval is lengthy, expensive and uncertain. If we are able to obtain such approvals for our lead product candidate or any other product candidate we may pursue, which we may never be able to do, it would likely be a process that takes many years to achieve.

To obtain marketing approvals in the U.S. for our product candidates, we believe that we must, among other requirements, complete carefully controlled and well-designed clinical trials sufficient to demonstrate to the FDA that the product candidate is safe and effective for each indication for which we seek approval. As described above, many factors could cause those trials to be delayed or to fail.

We believe that the pathway to marketing approval in the U.S. for our lead product candidate for internal use will likely require the process of FDA Premarket Approval ("**PMA**") for the product, which is based on novel technologies and likely will be classified as a Class III medical device. This approval pathway can be lengthy and expensive, and is estimated to take from one to three years or longer from the time the PMA application is submitted to the FDA until approval is obtained, if approval can be obtained at all.

Similarly, to obtain approval to market our product candidates outside of the U.S., we will need to submit clinical data concerning our product candidates to and receive marketing approval or other required certifications from governmental or other agencies in those countries, which in certain countries includes approval of the price we intend to charge for a product. For instance, in order to obtain the certification needed to market our lead product candidate in the EU, we believe that we will need to obtain a CE mark for the product, which entails scrutiny by applicable regulatory agencies and bears some similarity to the PMA process, including completion of one or more successful clinical trials.

We may encounter delays or rejections if changes occur in regulatory agency policies, if difficulties arise within regulatory or related agencies such as, for instance, any delays in their review time, or if reports from preclinical and clinical testing on similar technology or products raise safety and/or efficacy concerns during the period in which we develop a product candidate or during the period required for review of any application for marketing approval or certification.

Any difficulties we encounter during the approval or certification process for any of our product candidates would have a substantial adverse impact on our operations and financial condition and could cause our business to fail.

We cannot guarantee that we will be able to effectively market our product candidates.

A significant part of our success depends on the various marketing strategies we plan to implement. Our business model has historically focused solely on product development, and we have never attempted to commercialize any product. There can be no assurance as to the success of any such marketing strategy that we develop or that we will be able to build a successful sales and marketing organization. If we cannot effectively market those products we seek to commercialize directly, such products' prospects will be harmed.

Any product for which we obtain required regulatory approvals could be subject to post-approval regulation, and we may be subject to penalties if we fail to comply with such post-approval requirements.

Any product for which we are able to obtain marketing approval or other required certifications, and for which we are able to obtain approval of the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and comparable foreign regulatory authorities, including through periodic inspections. These requirements include, without limitation, submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. Maintaining compliance with any such regulations that may be applicable to us or our product candidates in the future would require significant time, attention and expense. Even if marketing approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or other conditions of approval, or may contain requirements for costly and time consuming post-marketing approval testing and surveillance to monitor the safety or efficacy of the product. Discovery after approval of previously unknown problems with any approved product candidate or related manufacturing processes, or failure to comply with regulatory requirements, may result in consequences to us such as:

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- restrictions on the marketing or distribution of a product, including refusals to permit the import or export of the product;
- the requirement to include warning labels on the products;
- withdrawal or recall of the products from the market;
- refusal by the FDA or other regulatory agencies to approve pending applications or supplements to approved applications that we may submit;
- suspension of any ongoing clinical trials;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals or certifications; or
- civil or criminal penalties.

If any of our product candidates achieves required regulatory marketing approvals or certifications in the future, the subsequent occurrence of any such post-approval consequences would materially adversely affect our business and operations.

Current or future legislation may make it more difficult and costly for us to obtain marketing approval or other certifications of our product candidates.

In 2007, the Food and Drug Administration Amendments Act of 2007 (the "**FDAAA**") was adopted. This legislation grants significant powers to the FDA, many of which are aimed at assuring the safety of medical products after approval. For example, the FDAAA grants the FDA authority to impose post-approval clinical study requirements, require safety-related changes to product labeling and require the adoption of complex risk management plans. Pursuant to the FDAAA, the FDA may require that a new product be used only by physicians with specialized training, only in specified health care settings, or only in conjunction with special patient testing and monitoring. The legislation also includes requirements for disclosing clinical study results to the public through a clinical study registry, and renewed requirements for conducting clinical studies to generate information on the use of products in pediatric patients. Under the FDAAA, companies that violate these laws are subject to substantial civil monetary penalties. The requirements and changes imposed by the FDAAA, or any other new legislation, regulations or policies that grant the FDA or other regulatory agencies additional authority that further complicates the process for obtaining marketing approval and/or further restricts or regulates post-marketing approval activities, could make it more difficult and more costly for us to obtain and maintain approval of any of our product candidates.

Public perception of ethical and social issues may limit or discourage the type of research we conduct.

Our clinical trials will involve human subjects, and third parties with whom we contract also conduct research involving animal subjects. Governmental authorities could, for public health or other purposes, limit the use of human or animal research or prohibit the practice of our technology. Further, ethical and other concerns about our or our third party contractors' methods, particularly the use of human subjects in clinical trials or the use of animal testing, could delay our research and preclinical and clinical trials, which would adversely affect our business and financial condition.

Use of third parties to manufacture our product candidates may increase the risk that preclinical development, clinical development and potential commercialization of our product candidates could be delayed, prevented or impaired.

We have limited personnel with experience in medical device development and manufacturing, do not own or operate manufacturing facilities, and generally lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently intend to outsource all or most of the clinical and commercial manufacturing and packaging of our product candidates to third parties. However, we have not established long-term agreements with any third party manufacturers for the supply of any of our product candidates. There are a limited number of manufacturers that operate under cGMP regulations and that are capable of and willing to manufacture our lead product candidate utilizing the manufacturing methods that are required to produce that product candidate, and our product candidates will compete with other product candidates for access to qualified manufacturing facilities. If we have difficulty locating third party manufacturers to develop our product candidates for preclinical and clinical work, then our product development programs will experience delays and otherwise suffer. We may also be unable to enter into agreements for the commercial supply of products with third party manufacturers in the future, or may be unable to do so when needed or on acceptable terms. Any such events could materially harm our business.

Reliance on third party manufacturers entails risks to our business, including without limitation:

- the failure of the third party to maintain regulatory compliance, quality assurance, and general expertise in advanced manufacturing techniques and processes that may be necessary for the manufacture of our product candidates;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
- failure of the third party manufacturers to meet the demand for the product candidate, either from future customers or for preclinical or clinical trial needs;
- the possible breach of the manufacturing agreement by the third party; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

The failure of any of our contract manufacturers to maintain high manufacturing standards could result in harm to clinical trial participants or patients using the products. Such failure could also result in product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could seriously harm our business or profitability. Further, our contract manufacturers will be required to adhere to FDA and other applicable regulations relating to manufacturing practices. Those regulations cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our product candidates and any products that we may commercialize in the future. The failure of our third party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval or other required certifications of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business, financial condition and operations.

Materials necessary to manufacture our product candidates may not be available on time, on commercially reasonable terms, or at all, which may delay or otherwise hinder the development and commercialization of those product candidates.

We will rely on the manufacturers of our product candidates to purchase from third party suppliers the materials necessary to produce the compounds for preclinical and clinical studies, and may continue to rely on those suppliers for commercial distribution if we obtain marketing approval or other required certifications for any of our product candidates. The materials to produce our products may not be available when needed or on commercially reasonable terms, and the prices for such materials may be susceptible to fluctuations. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements relating to the commercial production of any of these materials. If these materials cannot be obtained for our preclinical and clinical studies, product testing and potential regulatory approval of our product candidates would be delayed, which would significantly impact our ability to develop our product candidates and materially adversely affect our ability to meet our objectives and obtain operations success.

We may not be successful in maintaining or establishing collaborations, which could adversely affect our ability to develop and, if required regulatory approvals are obtained, commercialize our product candidates.

As demonstrated by the Project Agreement that we entered into with NUIG on May 28, 2015, we are interested in collaborating with physicians, patient advocacy groups, foundations, government agencies, and/or other third parties to assist with the development of our product candidates. If required regulatory approvals are obtained for any of our product candidates, then we may consider entering into additional collaboration arrangements with medical technology, pharmaceutical or biotechnology companies and/or seek to establish strategic relationships with marketing partners for the development, sale, marketing and/or distribution of our products within or outside of the U.S. If we elect to expand our current relationship with NUIG and/or seek additional collaborators in the future but are unable to reach agreements with NUIG and/or such other collaborators, as applicable, then we may fail to meet our business objectives for the affected product or program. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement, and we may not be successful in our efforts, if any, to establish and implement additional collaborations or other alternative arrangements. The terms of any collaboration or other arrangements that we establish may not be favorable to us, and the success of any such collaboration will depend heavily on the efforts and activities of our collaborators. Any failure to engage successful collaborators could cause delays in our product development and/or commercialization efforts, which could harm our financial condition and operational results.

We compete with other pharmaceutical and medical device companies, including companies that may develop products that make our product candidates less attractive or obsolete.

The medical device, pharmaceutical and biotechnology industries are highly competitive. If our product candidates become available for commercial sale, we will compete in that competitive marketplace. There are several products on the market or in development that could be competitors with our lead product candidate. Further, most of our competitors have greater resources or capabilities and greater experience in the development, approval and commercialization of medical devices or other products than we do. We may not be able to compete successfully against them. We also compete for funding with other companies in our industry that are focused on discovering and developing novel improvements in surgical bleeding prevention.

We anticipate that competition in our industry will increase. In addition, the healthcare industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render our lead product candidate or any future product candidate we may seek to develop non-competitive or otherwise obsolete. Any such circumstances could cause our operations to suffer.

If we fail to generate market acceptance of our product candidates and establish programs to educate and train surgeons as to the distinctive characteristics of our product candidates, we will not be able to generate revenues on our product candidates.

Acceptance in the marketplace of our lead product candidate depends in part on our and our third party contractors' ability to establish programs for the training of surgeons in the proper usage of that product candidate, which will require significant expenditure of resources. Convincing surgeons to dedicate the time and energy necessary to properly train to use new products and techniques is challenging, and we may not be successful in those efforts. If surgeons are not properly trained, they may ineffectively use our product candidates. Such misuse could result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us. Accordingly, even if our product candidates are superior to alternative treatments, our success will depend on our ability to gain and maintain market acceptance for those product candidates among certain select groups of the population and develop programs to effectively train them to use those products. If we fail to do so, we will not be able to generate revenue from product sales and our business, financial condition and results of operations will be adversely affected.

We face uncertainty related to pricing, reimbursement and healthcare reform, which could reduce our potential revenues.

If our product candidates are approved for commercialization, any sales will depend in part on the availability of direct or indirect coverage and reimbursement from third-party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other healthcare related organizations. If our product candidates obtain marketing approval, pricing and reimbursement may be uncertain. Both the federal and state governments in the U.S. and foreign governments continue to propose and pass new legislation affecting coverage and reimbursement policies, which are designed to contain or reduce the cost of healthcare. Further, federal, state and foreign healthcare proposals and reforms could limit the prices that can be charged for the product candidates that we may develop, which may limit our commercial opportunity. Adoption of our product candidates by the medical community may be limited if doctors and hospitals do not receive adequate partial or full reimbursement for use of our products or procedures in which our products are used, if any are commercialized. In some foreign jurisdictions, marketing approval or allowance could be dependent upon pre-marketing price negotiations. As a result, any denial of private or government payer coverage or inadequate reimbursement for procedures performed using our products, before or upon commercialization, could harm our business and reduce our prospects for generating revenue.

In addition, the U.S. Congress recently adopted legislation regarding health insurance. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the U.S., including modifications to the existing system of private payers and government programs, such as Medicare, Medicaid and State Children's Health Insurance Program, creation of a government-sponsored healthcare insurance source, or some combination of those, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact reimbursement for medical devices such as our product candidates. If reimbursement for our approved product candidates, if any, is substantially less than we expect, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

The use of our product candidates in human subjects may expose us to product liability claims, and we may not be able to obtain adequate insurance or otherwise defend against any such claims.

We face an inherent risk of product liability claims and currently have clinical trial liability coverage. We will need to obtain additional product liability insurance coverage if and when we begin commercialization of any of our product candidates. If claims against us exceed any applicable insurance coverage we may obtain, then our business could be adversely impacted. Regardless of whether we would be ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources, which could significantly harm our business.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain protection for our intellectual property rights, the value of our technology and products will be adversely affected

Our success will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property rights covering or incorporated into our technology and products. The ability to obtain patents covering technology in the field of medical devices generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We may not be able to obtain and maintain patent protection relating to our technology or products. Even if issued, patents issued or licensed to us may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, or determined not to cover our product candidates or our competitors' products, which could limit our ability to stop competitors from marketing identical or similar products. One of our licensed MIT European patents was recently opposed, however this patent was maintained in amended form following an administrative hearing. Further, we cannot be certain that we were the first to make the inventions claimed in the patents we own or license, or that protection of the inventions set forth in those patents was the first to be filed in the U.S. Third parties that have filed patents or patent applications covering similar technologies or processes may challenge our claim of sole right to use the intellectual property covered by the patents we own or exclusively license. Moreover, changes in applicable intellectual property laws or interpretations thereof in the U.S. and other countries may diminish the value of our intellectual property rights or narrow the scope of our patent protection. Any failure to obtain or maintain adequate protection for our intellectual property would materially harm our business, product development programs and prospects.

In addition, our proprietary information, trade secrets and know-how are important components of our intellectual property rights. We seek to protect our proprietary information, trade secrets, know-how and confidential information, in part, with confidentiality agreements with our employees, corporate partners, outside scientific collaborators, sponsored researchers, consultants and other advisors. We also have invention or patent assignment agreements with our employees and certain consultants and advisors. If our employees or consultants breach those agreements, we may not have adequate remedies for any of those breaches. In addition, our proprietary information, trade secrets and know-how may otherwise become known to or be independently developed by others. Enforcing a claim that a party illegally obtained and/or for which a party is using our proprietary information, trade secrets and/or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time consuming litigation could be necessary to seek to enforce and determine the scope of our intellectual property rights, and failure to obtain or maintain protection thereof could adversely affect our competitive business position and results of operations.

We do not have exclusive rights to certain intellectual property as our patent portfolio includes certain patents that are jointly owned with our collaborators and others that have been in-licensed on a non-exclusive basis.

As of November 15, 2016, we either own or license from others a number of U.S. patents, U.S. patent applications and international (PCT) patent applications with certain of our collaborators. The rights of our collaborators to these patents, patent applications and other compounds under the collaborations may in the future restrict our ability to further develop or generate revenues from those compounds except through the collaborations.

Our patent portfolio includes a total of 23 patents and applications assigned to Arch Biosurgery, Inc. This portfolio covers self-assembling peptides and methods of use thereof, and includes six patents that have been either allowed, issued or granted, and seventeen pending applications in nine jurisdictions.

We have also entered into a license agreement with Massachusetts Institute of Technology (“MIT”) and Versitech Limited pursuant to which we have been granted exclusive rights under one portfolio of patents and non-exclusive rights under another portfolio of patents. The portfolio exclusively licensed from MIT and Versitech Limited includes fifteen patents that have been either allowed, issued or granted and seven applications that are pending in a total of nine jurisdictions.

The portfolio non-exclusively licensed from MIT includes a number of PCT applications which have now entered the national and regional phases outside of the US, including eight patents that have been either allowed, issued or granted in four jurisdictions that expire between 2016 and 2027 (absent patent term extension), and one pending patent application in one jurisdiction. A complaint for an invalidation trial has been filed by a competitor against one of our licensed MIT Japanese patents. The corresponding European patent licensed by Arch from MIT was recently opposed, but was maintained in amended form following an administrative hearing. This decision has been appealed.

If we lose certain intellectual property rights owned by third parties and licensed to us, our business could be materially harmed.

We have entered into certain in-license agreements with MIT and with certain other third parties, and may seek to enter into additional in-license agreements relating to other intellectual property rights in the future. To the extent we and our product candidates rely heavily on any such in-licensed intellectual property, we are subject to our and the counterparty's compliance with the terms of such agreements in order to maintain those rights. Presently, we, our lead product candidate and our business plans are dependent on the patent and other intellectual property rights that are licensed to us under our license agreement with MIT. Although that agreement has a durational term through the life of the licensed patents, it also imposes certain diligence, capital raising, and other obligations on us, our breach of which could permit MIT to terminate the agreement. Further, we are responsible for all patent prosecution and maintenance fees under that agreement, and a failure to pay such fees on a timely basis could also entitle MIT to terminate the agreement. Any failure by us to satisfy our obligations under our license agreement with MIT or any other dispute or other issue relating to that agreement could cause us to lose some or all of our rights to use certain intellectual property that is material to our business and our lead product candidate, which would materially harm our product development efforts and could cause our business to fail.

If we infringe or are alleged to infringe the intellectual property rights of third parties, our business and financial condition could suffer.

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other intellectual property under which we do not hold a license or other rights. Third parties may own or control those patents or other rights in the U.S. or abroad, and could bring claims against us that would cause us to incur substantial time, expense, and diversion of management attention. If a patent or other intellectual property infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales, if any, of the applicable product or product candidate that is the subject of the suit. In order to avoid or settle potential claims with respect to any of the patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. Any such license may not be available on acceptable terms, or at all. Even if we or our future collaborators were able to obtain a license, the rights granted to us or them could be non-exclusive, which could result in our competitors gaining access to the same intellectual property rights and materially negatively affecting the commercialization potential of our planned products. Ultimately, we could be prevented from commercializing one or more product candidates, or be forced to cease some aspects of our business operations, if, as a result of actual or threatened infringement claims, we are unable to enter into licenses on acceptable terms or at all or otherwise settle such claims. Further, if any such claims were successful against us, we could be forced to pay substantial damages. Any of those results could significantly harm our business, prospects and operations.

Risks Related to Ownership of our Common Stock

There is not now, and there may not ever be, an active market for our Common Stock, which trades in the over-the-counter market in low volumes and at volatile prices.

There currently is a limited market for our Common Stock. Although our Common Stock is quoted on the OTCQB, an over-the-counter quotation system, trading of our Common Stock is extremely limited and sporadic and generally at very low volumes. Further, the price at which our Common Stock may trade is volatile and we expect that it will continue to fluctuate significantly in response to various factors, many of which are beyond our control. The stock market in general, and securities of small-cap companies driven by novel technologies in particular, has experienced extreme price and volume fluctuations in recent years. Continued market fluctuations could result in further volatility in the price at which our Common Stock may trade, which could cause its value to decline. To the extent we seek to raise capital in the future through the issuance of equity, those efforts could be limited or hindered by low and/or volatile market prices for our Common Stock.

We do not now meet the initial listing standards of the Nasdaq Stock Market or any other national securities exchange. We presently anticipate that our Common Stock will continue to be quoted on the OTCQB or another over-the-counter quotation system. In those venues, our stockholders may find it difficult to obtain accurate quotations as to the market value of their shares of our Common Stock, and may find few buyers to purchase their stock and few market makers to support its price.

A more active market for our Common Stock may never develop. As a result, investors must bear the economic risk of holding their shares of our Common Stock for an indefinite period of time.

Our Common Stock is a "penny stock."

The SEC has adopted regulations that generally define "penny stock" as an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The market price of our Common Stock is, and is expected to continue to be in the near term, less than $5.00 per share and is therefore a "penny stock." Brokers and dealers effecting transactions in "penny stock" must disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. Those rules may restrict the ability of brokers or dealers to sell our Common Stock and may affect the ability of our stockholders to sell their shares of our Common Stock. In addition, if our Common Stock continues to be quoted on the OTCQB as we expect, then our stockholders may find it difficult to obtain accurate quotations for our stock, and may find few buyers to purchase our stock and few market makers to support its price.

If we issue additional shares in the future, including issuances of shares upon exercise of the Series E Warrants, the Series D Warrants, and the Series A Warrants, our existing stockholders will be diluted.

Our articles of incorporation authorize the issuance of up to 300,000,000 shares of Common Stock. In connection with the 2016 Private Placement Financing that closed on May 26, 2016, we issued an aggregate of 9,418,334 shares of our Common Stock, which equaled approximately 8% of the 118,592,070 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2016 Private Placement Financing. Upon the closing of the 2016 Private Placement Financing, we also issued Series E Warrants to acquire up to an additional 7,063,748 shares of our Common Stock at an initial exercise price of $0.4380 per share. As of December 2, 2016, up to 6,233,323 shares may be acquired upon the exercise of the Series E Warrants.

Similarly, in connection with our private placement financing that concluded on July 2, 2015 (the "**2015 Private Placement Financing**"), we issued an aggregate of 14,390,754 shares of our Common Stock, which equaled approximately 18% of the 78,766,487 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2015 Private Placement Financing. Upon the closing of the 2015 Private Placement Financing, we also issued Series D Warrants to acquire up to an additional 14,390,754 shares of our Common Stock at an initial exercise price of $0.25 per share. As of December 2, 2016, up to 10,951,663 shares may be acquired upon the exercise of the Series D Warrants.

Upon the closing of our private placement financing on February 4, 2014 (the "**2014 Private Placement Financing**"), we issued an aggregate of 11,400,000 shares of our Common Stock, which equaled approximately 16% of our currently issued and outstanding Common Stock on the date the 2014 Private Placement Financing closed. Upon the closing of the 2014 Private Placement Financing, we also issued three series of Warrants to acquire up to an additional 34,200,000 shares of our Common Stock at initial exercise prices ranging from $0.30 per share (the Series A Warrants), $0.35 per share (the Series B Warrants), and $0.40 per share (the Series C Warrants). On December 1, 2014, the Company entered into that certain Amendment to Series A Warrants, Series B Warrants and Series C Warrants to Purchase Common Stock, dated as of December 1, 2014, with Cranshire pursuant to which, among other things, the exercise prices of the Series B Warrants and Series C Warrants were lowered to $0.20 per share. Following the December 1, 2014 amendment, (i) 4,000,000 shares underlying the Series B Warrants were exercised, and the remaining 7,400,000 expired unexercised on January 3, 2015 when the term of the Series B Warrants expired; and (ii) all 11,400,000 shares underlying the Series C Warrants were exercised prior to the expiration of the Series C Warrants at 5:00 p.m., New York time, on July 2, 2016. As a result of the conversion price of our Convertible Notes, the closing of the Notes Offering and the subsequent issuance of the Convertible Notes triggered the Anti-Dilution Provisions of the Series A Warrants, which in turn reduced the exercise price of the Series A Warrants to $0.20 per share and increased the aggregate number of shares issuable under the Series A Warrants by 5,700,000 shares (or fifty-percent (50%)) from 11,400,000 shares to 17,100,000 shares. As of December 2, 2016, up to 25,000 shares may be acquired upon the exercise of the Series A Warrants.

Additionally, as of December 2, 2016, 5,347,527 shares of Common Stock were reserved for future issuance under the 2013 Plan, of which 12,479,210 shares are subject to outstanding option awards granted under the 2013 Plan at exercise prices ranging from $0.17 to $0.72 per share and with a weighted average exercise price of $0.33 per share, and the numbers issuable under the 2013 Plan will increase by up to 3 million shares on the first business day of each following fiscal year as set forth in the 2013 Plan. Finally, in addition to the Series E Warrants granted in connection with the 2016 Private Placement Financing, the Series D Warrants granted in connection with the 2015 Private Placement Financing, and the Series A Warrants granted in connection with the 2014 Private Placement Financing, there are currently outstanding warrants to acquire up to 145,985 shares of our Common Stock. Any future grants of options, warrants or other securities exercisable or convertible into our Common Stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our Common Stock.

In addition to capital raising activities, other possible business and financial uses for our authorized Common Stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of Common Stock, issuing shares of our Common Stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, compensating consultants by issuing shares or options to purchase shares of our Common Stock, or other transactions and corporate purposes that our Board of Directors deems are in the Company’s best interest. By way of example, on August 6, 2015, we issued an aggregate of 600,000 shares of restricted stock in connection with our entrance into separate consulting agreements with two investor relations firms, Excelsior Global Advisors LLC and Acorn Management Partners, LLC, in each case in consideration of the services to be provided under and in accordance with the terms of each consulting agreement. Additionally, shares of Common Stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of Common Stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our Common Stock. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our Common Stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current shareholders. Further, such issuance may result in a change of control of our corporation.

Future sales of our Common Stock or rights to purchase Common Stock, or the perception that such sales could occur, could cause our stock price to fall.

As noted above under the risk factor entitled, "***We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail***," as of December 1, 2016, we believe that our current cash and cash equivalents on hand will meet our anticipated cash requirements into the fourth quarter of Fiscal 2017. To raise capital, we may sell Common Stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Any such sales of our Common Stock by us or resale of our Common Stock by our existing stockholders could cause the market price of our Common Stock to decline.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our stock.

In addition to the "penny stock" rules described above, FINRA has adopted rules that require that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative low priced securities will not be suitable for at least some customers. These FINRA requirements make it more difficult for broker-dealers to recommend that at least some of their customers buy our Common Stock, which may limit the ability of our stockholders to buy and sell our Common Stock and could have an adverse effect on the market for our shares.

There may be additional risks because we completed a reverse merger transaction in June 2013.

Additional risks may exist because we completed a "reverse merger" transaction in June 2013. Securities analysts of major brokerage firms may not provide coverage of the Company because there may be little incentive to brokerage firms to recommend the purchase of our Common Stock. There may also be increased scrutiny by the SEC and other government agencies and holders of our securities due to the nature of the transaction, as there has been increased focus on transactions such as the Merger in recent years. Further, since the Company existed as a "shell company" under applicable rules of the SEC up until the closing of the Merger on June 26, 2013, there will be certain restrictions and limitations on the Company going forward relating to any potential future issuances of additional securities to raise funding and compliance with applicable SEC rules and regulations.

The Company may have material liabilities that were not discovered before the closing of the Merger.

The Company may have material liabilities that were not discovered before the consummation of the Merger. We could experience losses as a result of any such unasserted liabilities that are eventually found to be incurred, which could materially harm our business and financial condition. Although the Merger Agreement contained customary representations and warranties from the Company concerning its assets, liabilities, financial condition and affairs, there may be limited or no recourse against the Company's prior owners or principals in the event those prove to be untrue. As a result, the stockholders of the Company bear risks relating to any such unknown or unasserted liabilities.

Certain of our directors and officers own a significant percentage of our capital stock and are able to exercise significant influence over the Company.

Certain of our directors and executive officers own a significant percentage of our outstanding capital stock. As of December 2, 2016, Dr. Terrence W. Norchi, our President, Chief Executive Officer and a director, Dr. Avtar Dhillon, the Chairman of our Board of Directors, and James R. Sulat, a director, beneficially own (as determined under Section 13(d) of the Exchange Act and the rules and regulations thereunder) approximately 17.9% of our shares of Common Stock. Accordingly, these members of our Board of Directors and management team have substantial voting power to approve matters requiring stockholder approval, including without limitation the election of directors, and have significant influence over our affairs. This concentration of ownership could have the effect of delaying or preventing a change in control of our Company, even if such a change in control would be beneficial to our stockholders.

The elimination of monetary liability against our directors and officers under Nevada law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenditures by us and may discourage lawsuits against our directors, officers and employees.

Our articles of incorporation eliminate the personal liability of our directors and officers to our Company and our stockholders for damages for breach of fiduciary duty as a director or officer to the extent permissible under Nevada law. Further, our amended and restated bylaws provide that we are obligated to indemnify any of our directors or officers to the fullest extent authorized by Nevada law and, subject to certain conditions, advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could result in our Company incurring substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to recoup. These provisions and resultant costs may also discourage us from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties, and may similarly discourage the filing of derivative litigation by our stockholders against our directors and officers even if such actions, if successful, might otherwise benefit us or our stockholders.

We are subject to the reporting requirements of federal securities laws, compliance with which involves significant time, expense and expertise.

We are a public reporting company in the U.S., and, accordingly, are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the obligations imposed by the Sarbanes-Oxley Act. The costs associated with preparing and filing annual, quarterly and current reports, proxy statements and other information with the SEC in the ordinary course, as well as preparing and filing audited financial statements, has caused, and could continue to cause, our operational expenses to remain at higher levels or continue to increase.

Our present management team has limited experience in managing public companies. It will be time consuming, difficult and costly for our management team to acquire additional expertise and experience in operating a public company, and to develop and implement the additional internal controls and reporting procedures required by Sarbanes-Oxley and other applicable securities laws.

Shares of our Common Stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144. In addition, any shares of our Common Stock that are held by affiliates, including any that are registered, will be subject to the resale restrictions of Rule 144.

Rule 144 imposes requirements on us and our stockholders that must be met in order to effect a sale thereunder. As a result, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend significant additional time and cash resources and which we presently have no intention to pursue. Further, it may be more difficult for us to compensate our employees and consultants with our securities instead of cash. We were a shell company prior to the closing of the Merger, and such status could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (although none are currently planned), and could cause the value of our securities to decline. In addition, any shares held by affiliates, including shares received in any registered offering, will be subject to certain additional requirements in order to effect a sale of such shares under Rule 144.

We do not intend to pay cash dividends on our capital stock in the foreseeable future.

We have never declared or paid any dividends on our shares and do not anticipate paying any such dividends in the foreseeable future. Any future payment of cash dividends would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of our Board of Directors. In addition, under the terms of the MLSC

Loan Agreement, we must obtain MLSC's prior consent before declaring or paying any dividends during the term of the MLSC Loan Agreement. As a result, our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock.

We are at risk of securities class action litigation that could result in substantial costs and divert management's attention and resources.

In the past, securities class action litigation has been brought against companies following periods of volatility of its securities in the marketplace, particularly following a company's initial public offering. Due to the volatility of our stock price, we could be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We do not own any real property. In October 2013, we entered into a one and one-half year operating sublease agreement pursuant to which we leased the office space of our relocated headquarters in Wellesley, Massachusetts for a base annual rent equal to $5,031 per month. In April 2015, we moved our corporate offices to a property in Framingham, Massachusetts. We entered into a month-to-month operating lease agreement, pursuant to which we are obligated to pay monthly rent of $2,000, with a minimum six month commitment. We are no longer party to the October 2013 lease, and we believe our present offices are suitable for our current and planned near-term operations.

ITEM 3. LEGAL PROCEEDINGS

In the ordinary course of business, we may become a party to legal proceedings involving various matters. We are unaware of any such legal proceedings presently pending to which we or our subsidiary is a party or of which any of our property is the subject that management deems to be, individually or in the aggregate, material to our financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our Common Stock is currently quoted on the OTCQB over-the-counter quotation system. Our Common Stock began quotation on the OTCBB and the OTCQB on June 27, 2013 and since that date has been primarily traded on the OTCQB. There was no trading of our Common Stock on the OTCBB, OTCQB or any other over-the-counter market prior to January 2, 2013. Although our Common Stock is currently quoted on the OTCQB, there is a limited trading market for our Common Stock and there have been few trades in our Common Stock to date. Because our Common Stock is thinly traded, any reported sale prices may not be a true market-based valuation of our Common Stock.

The table below sets forth reported high and low closing bid quotations for our Common Stock for the fiscal quarters indicated as reported on the OTCQB. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

	High	Low
Fiscal Year Ending September 30, 2015		
First Quarter ended December 31, 2014	$0.25	$0.16
Second Quarter ended March 31, 2015	$0.24	$0.18
Third Quarter ended June 30, 2015	$0.26	$0.18
Fourth Quarter ended September 30, 2015	$0.37	$0.23
Fiscal Year Ending September 30, 2016		
First Quarter ended December 31, 2015	$0.27	$0.17
Second Quarter ended March 31, 2016	$0.32	$0.18
Third Quarter ended June 30, 2016	$0.66	$0.34
Fourth Quarter ended September 30, 2016	$0.89	$0.55

As of December 1, 2016, there were approximately 100 holders of record of our common stock.

Dividends

We have never declared or paid any cash dividends or distributions on our capital stock. We currently intend to retain our future earnings, if any, to support operations and to finance expansion and therefore we do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. In addition, under the terms of the MLSC Loan Agreement, we must obtain MLSC's prior consent before declaring or paying any dividends during the term of the MLSC Loan Agreement.

Recent sales of unregistered securities

On August 9, 2016, we entered into a consulting agreement with an investor relations firm, Acorn Management Partners, LLC ("**Acorn**"). In consideration of the services to be provided under and in accordance with the terms of the consulting agreement, we issued (i) 225,000 shares of Common Stock under our 2013 Stock Incentive Plan at an agreed upon value of $0.72 per share, which was the closing price of our common stock on August 9, 2016; and (ii) an option under our 2013 Stock Incentive Plan to purchase up to 375,000 shares of Common Stock at an exercise price of price of $0.72 per share, in each case to John R. Exley, Acorn's Chief Executive Officer and the party designated by Acorn to receive its shares and option. The shares and option are subject to time-based vesting restrictions. Of the 225,000 shares of Common Stock granted to Mr. Exley, 75,000 vest 90 days from the date of the award, 75,000 vest 120 days from the date of the award and the remaining 75,000 shares are scheduled to vest 150 days from the date of the award. Of the stock options to purchase up to 375,000 shares of Common Stock awarded to Mr. Exley, 125,000 vest 90 days from the date of the award, 125,000 vest 120 days from the date of the award and the remaining 125,000 shares are scheduled to vest 150 days from the date of the award. The issuance and sale of the shares of Common Stock and option to Acorn has not been registered under the Securities Act, and such securities may not be offered or sold in the United States absent registration under or exemption from the Securities Act and any applicable state securities laws. The securities were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act based on the following facts: Acorn has represented that it is an accredited investor as defined in Regulation D promulgated under the Securities Act, that it is acquiring the securities for investment only and not with a view towards, or for resale in connection with, a distribution thereof in violation of applicable securities laws; that it understood that the securities would be issued as restricted securities and as a result, it must bear the economic risk of its investment in the securities for an indefinite period of time.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

The following discussion and analysis should be read in conjunction with our consolidated financial statements and notes thereto included elsewhere in this Form 10-K. This discussion and analysis contains forward looking statements. We make forward-looking statements, as defined by the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, and in some cases, you can identify these statements by forward-looking words such as "if," "will," "may," "might," "will likely result," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "goal," "predict," "potential" or "continue," or the negative of these terms and other comparable terminology. These forward-looking statements are based on various underlying assumptions and expectations and are subject to risks, uncertainties and other unknown factors, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business and include risks and uncertainties relating to Arch's current cash position and its need to raise additional capital in order to be able to continue to fund its operations; the stockholder dilution that may result from future capital raising efforts and the exercise or conversion, as applicable of Arch's outstanding options, warrants and convertible notes; Arch's limited operating history which may make it difficult to evaluate Arch's business and future viability; Arch's ability to timely commercialize and generate revenues or profits from our anticipated products; Arch's ability to achieve the desired regulatory approvals in the United States or elsewhere; Arch's ability to retain its managerial personnel and to attract additional personnel; the strength of Arch's intellectual property, the intellectual property of others and any asserted claims of infringement; and other risk factors identified under the caption " **Risk Factors** " in this Form 10-K and in the documents Arch has filed, or will file with the SEC. We undertake no duty to update any of these forward-looking statements after the date of filing of this Form 10-K to conform such forward-looking statements to actual results or revised expectations, except as otherwise required by law.

Corporate Overview

Arch Therapeutics, Inc. was incorporated under the laws of the State of Nevada on September 16, 2009 with the name "Almah, Inc.". Effective June 26, 2013, Arch completed a merger (the "**Merger**") with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation ("**ABS**"), and Arch Acquisition Corporation ("**Merger Sub**"), Arch's wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of Arch. Prior to the completion of the Merger, Arch was a "shell company" under applicable rules of the SEC and had no or nominal assets or operations. As part of the acquisition, Almah management resigned and was replaced with ABS management. Upon its acquisition of ABS, Arch abandoned its prior business plan and changed its operations to the business of a biotechnology company.

For financial reporting purposes, the Merger represented a "reverse merger". ABS was deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the assets, liabilities, accumulated deficit and the historical operations that are reflected in the Company's consolidated financial statements are those of ABS. All share information has been restated to reflect the effects of the Merger. The Company's financial information was consolidated with that of ABS after consummation of the Merger on June 26, 2013, and the historical financial statements of the Company before the Merger have been replaced with the historical financial statements of ABS before the Merger in this Annual Report on Form 10-K.

ABS was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc., changed its name to Arch Therapeutics, Inc. on April 7, 2008, and changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc. upon the closing of the Merger on June 26, 2013.

Liquidity

We are in the development stage and have generated no operating revenues to date and do not expect to do so in the foreseeable future due to the early stage nature of our current product candidates. We currently do not have any products that have obtained marketing approval in any jurisdiction. For the year ended September 30, 2016, we have a net loss of $5,992,370 versus a net loss of $2,947,526 in the comparable period in the prior year. We devote a significant amount of our efforts towards fundraising, clinical trials, and product research. The loss for the year ended September 30, 2016 is attributable to general and administrative costs, primarily relating to legal costs associated with intellectual property, patent application and prosecution costs, and general corporate legal expenses and research and development expenses, including clinical trials, all of which were partially offset by adjustments to the derivative liabilities. The loss for the year ended September 30, 2015 is attributable to general and administrative costs, primarily relating to legal costs associated with intellectual property, patent application and prosecution costs, and general corporate legal expenses and research and development expenses all of which were partially offset by adjustments to the derivative liabilities. Cash used in operating activities increased $507,641 during the year ended September 30, 2016 to $4,747,027, compared to $4,239,386 for the year ended September 30, 2015. Cash at September 30, 2016 increased by $1,076,376 to $5,036,476 compared to $3,960,100 for the year ended September 30, 2015.

Business Overview

We are a biotechnology company in the development stage. We have generated no revenues to date and are devoting substantially all of our operational efforts to the development of our core technology. We aim to develop products that make surgery and interventional care faster and safer by using a novel approach to stop bleeding (referenced as “hemostatic” or “hemostasis”), control leaking (referenced as “sealant” or “sealing”), and provide other advantages during surgery and trauma care. Our core technology is based on self-assembling peptides that creates a physical, mechanical barrier, which could be applied to seal organs or wounds that are leaking blood and other fluids. We believe our technology could support an innovative platform of potential products in the field of stasis and barrier applications. Our plan and business model is to develop products that apply that core technology for use with bodily fluids and tissues.

Our primary product candidates, known collectively as the AC5 Devices™ (which we sometimes refer to as “**AC5™**”, “**AC5 Surgical Hemostatic Device™**”, “**AC5 Surgical Hemostat™**”, “**AC5 Topical Hemostatic Device™**”, or “**AC5 Topical Hemostat™**”), are being designed to achieve hemostasis in surgical procedures. They rely on our self-assembling peptide technology and are being designed to achieve hemostasis in skin wounds and in minimally invasive and open surgical procedures. We intend to develop other product candidates based on our technology platform for use in a range of indications.

AC5 is being designed as a product containing synthetic biocompatible peptides comprising L amino acids, commonly referred to as naturally occurring amino acids. When applied to a wound, AC5 intercalates into the interstices of the connective tissue where it self-assembles into a physical, mechanical nanoscale structure that provides a barrier to leaking substances, such as blood. AC5 may be applied directly as a liquid, which we believe will make it user-friendly and able to conform to irregular wound geometry. Additionally, AC5 does not possess sticky or glue-like handling characteristics, which we believe will enhance its utility in several settings, including minimally invasive surgical procedures. Further, in certain settings, AC5 lends itself to a concept that we call Crystal Clear Surgery™; the transparency and physical properties of AC5 may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as it starts.

We believe that the results of early data from preclinical tests have shown quick and effective hemostasis with the use of AC5 relative to that reported with other types of hemostatic agents, and that time to hemostasis is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called “blood thinners”. Based on testing results to date, we believe that AC5 is biocompatible.

We have devoted much of our operational effort to date to the research and development of our core technology, including selecting our initial product composition, conducting initial safety and other related tests, conducting an initial human trial for safety and performance of AC5, developing methods for scale-up, reproducibility, manufacturing and formulation, and developing and protecting the intellectual property rights underlying our technology platform. Manufacturing method and formulation optimization are important parts of peptide development. Manufacturing and formulation optimization for our product candidates has been and continues to be done with extensive collaboration among our team and partners. The processes are focused on optimizing traditional product parameters to target specifications covering performance, biocompatibility, physical appearance, stability, and handling characteristics, among others. We and our partners intend to monitor manufacturing processes and formulation methods closely, as success or failure in both setting and realizing appropriate specifications may directly impact our ability to conduct preclinical and clinical trials and our subsequent commercialization timelines.

Our long-term business plan includes the following goals:

- conducting required biocompatibility studies and additional clinical trials on AC5 and related products;
- expanding and maintaining protection of our intellectual property portfolio;
- developing appropriate third party relationships to manufacture, distribute, market and otherwise commercialize AC5;
- obtaining regulatory approval or certification of AC5 and related products in the EU, the U.S., and other jurisdictions as we may determine;
- continuing or developing academic, scientific and institutional relationships to collaborate on product research and development; and
- developing additional product candidates in the hemostatic, sealant, and/or other fields.

In furtherance of our long-term business goals, we expect to continue to focus on the following activities during the next twelve months:

- seek additional funding as required to support the milestones described previously and our operations generally;
- work with our large scale manufacturing partners to scale up production of product compliant with current good manufacturing practices (“**cGMP**”), which activities will be ongoing as we seek to advance toward, enter into, and, if successful, subsequently increase commercialization activities;
- further clinical development of our product platform;

- continue to expand and enhance our financial and operational reporting and controls;
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, which activities will be ongoing as we seek to expand our product candidate portfolio; and
- assess our self-assembling peptide platforms in order to identify and select product candidates for advancement into development.

We believe that the Company has cash and cash equivalents on hand to meet its anticipated cash requirements into the fourth quarter of Fiscal 2017. In addition to capital required for operating expenses, depending upon additional input form EU and US regulatory authorities, as well as the potential for more than one regulatory filing and approval in 2017, up to $5,000,000 may be required to complete an initial European CE Mark approval and an initial US regulatory clearance or approval. These estimated capital requirements potentially could increase significantly if a number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading "**RISK FACTORS**" in this filing.

Merger with ABS and Related Activities

As noted earlier in this document, on June 26, 2013, the Company completed the Merger with ABS, pursuant to which ABS became a wholly owned subsidiary of the Company. In contemplation of the Merger, effective May 24, 2013, the Company increased its authorized common stock, par value $0.001 per share ("**Common Stock**"), from 75,000,000 shares to 300,000,000 shares and effected a forward stock split, by way of a stock dividend, of its issued and outstanding shares of Common Stock at a ratio of 11 shares to each one issued and outstanding share. Also in contemplation of the Merger, effective June 5, 2013, the Company changed its name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which its Common Stock trades on the OTC Bulletin Board from "AACH" to "ARTH".

Recent Developments

On December 16, 2015, we announced that we had received clearance from a regulatory authority in Western Europe to initiate a human clinical trial to assess the safety and performance of AC5 in humans. The initial patient was treated in the first quarter of 2016 and on June 6, 2016, we announced we had completed patient enrollment in this study. On August 15, 2016, we announced that the AC5 Topical Hemostatic Device met its primary and secondary endpoints in our first clinical trial. On October 31, 2016, the Company further announced that additional analysis of the subgroup of 10 patients who were taking a prescribed antiplatelet medication, commonly known as a blood thinner, such as aspirin, indicated that AC5 had similar effects for this patient population.

The objectives of the study were to evaluate the safety and performance of AC5 in patients scheduled to undergo excision of skin lesions on their trunk or upper limbs. The primary endpoint was safety throughout the surgical procedure and until the end of a 30-day follow-up period post procedure. Safety of the clinical investigation device was determined by monitoring for treatment related adverse events. The primary objective was met, as the safety outcomes of both the AC5 treatment group and the control group were similar. No serious adverse events were reported.

A secondary endpoint was performance as assessed by time to hemostasis. The median time to hemostasis of wounds in the AC5 treatment group was 41% faster than for those in the control group. This result was statistically significant ($p < 0.001$, Wilcoxon signed rank test).

An additional secondary endpoint of healing of treated wounds was assessed as measured by the ASEPSIS wound score at Days 7 and 30. There was no evidence, at either follow-up day, of an adverse effect of AC5 treatment on the wound ASEPSIS score. The ASEPSIS score did not appear to be compromised, as the majority of patients had an ASEPSIS score of 0 in both wounds at Days 7 and 30. All AC5-treated wounds healed satisfactorily as per wound healing scoring criteria.

During the year ended September 30, 2016, we also announced that we had received an internationally recognized ISO quality certification, and obtained favorable results from a broad panel of preclinical biocompatibility tests that were performed on AC5 in support of Arch's planned filing of a CE Mark application that indicate that AC5's peptide structure and mechanism of action, which is based on the formation of a local physical-mechanical barrier at the wound site, does not promote toxicity to the overall biological system following exposure to AC5. In addition, on April 5, 2016, April 11, 2016, and May 16, 2016, the Company announced that notices of allowance from the U.S. Patent Office had been received on two broad composition-of-matter patents and a broad method of use patent that are assigned to the Massachusetts Institute of Technology (MIT) and Versitech Limited and which are exclusively licensed worldwide to Arch. The broad composition claims of the composition-of-matter patents cover Arch's present and proposed products, which contain peptides and peptidomimetics, respectively, that self-assemble into barrier structures on tissue and inhibit or prevent the passage of bodily fluids. The broad method claims of the method of use patent cover techniques for preventing the loss or unwanted movement of body fluids. Further, on May 10, 2016, the Company announced that a notice of allowance from the U.S. Patent Office had been received for a broad composition of matter and method of use patent that covers solid forms of the Company's self-assembling technology. In addition, the Company has initiated the FDA regulatory process.

From October 1, 2015 through April 2016, $605,000 of principal on the Company's outstanding convertible notes and $39,900 of associated accrued interest were converted into an aggregate of 3,224,494 shares of common stock. In addition, from October 1, 2015 through September 30, 2016, Series C Warrants had been exercised on a cash basis for an aggregate issuance of 3,400,000 shares of the Company's Common stock resulting in gross proceeds to the Company of $680,000, Series A Warrants had been exercised on a cash basis for an aggregate issuance of 4,300,000 shares of the Company's Common Stock resulting in gross proceeds to the Company of $860,000, Series D Warrants had been exercised on a cash basis for an aggregate issuance of 3,439,091 shares of the Company's Common Stock resulting in gross proceeds to the Company of $859,773 and Series E Warrants had been exercised on a cash basis for an aggregate issuance of 705,425 shares of the Company's Common Stock resulting in gross proceeds to the Company of $308,976. In addition, 3,925,000 of Series A Warrants had been exercised on a cashless basis for an aggregate of 2,333,559 shares of the Company's Common Stock.

On May 3, 2016, pursuant to the approval of our Board, we issued an aggregate of 2,000,000 shares of our Common Stock pursuant to restricted stock awards granted outside of our 2013 Stock Incentive Plan to (i) Dr. Avtar Dhillon, the Chairman of our Board (737,000 shares); (ii) James R. Sulat, a member of our Board (30,000 shares); (iii) Dr. Terrence W. Norchi, our President, Chief Executive Officer and a member of our Board (1,130,000 shares); and (iv) Richard Davis, our Chief Financial Officer (103,000 shares).

Beginning May 24, 2016 and through May 26, 2016, we entered into 2016 Subscription Agreements with 18 accredited investors providing for the issuance and sale by the Company to the investors in the 2016 Private Placement Financing (the "**2016 Investors**"), in a private placement, of an aggregate of 9,418,334 Units at a purchase price of $0.36 per Unit. Each Unit consisted of a share of Common Stock, and a Series E Warrant to purchase 0.75 shares of Common Stock at an exercise price of $0.4380 per share at any time prior to the fifth anniversary of the issuance date of the Series E Warrant. The issuance of the common stock resulted in gross proceeds to the company of $3,390,600.

On September 28, 2016, the Company and MLSC entered into that certain Amendment Agreement to Arch Therapeutics, Inc. Accelerator Funding Agreement (the "**Amendment**"). Under the terms of the Amendment, (i) interest on the MLSC Loan will decrease from 10% per annum to 7% per annum beginning October 3, 2016; and (ii) the MLSC Loan will now become due and payable on the earlier of October 3, 2017 (the "**Maturity Date**"), the occurrence of a Corporate Event (which is defined as the occurrence of either a Qualified Sale or Qualified Financing), or the occurrence of a Default (as defined in the Note). In addition, under the terms of the Amendment, (a) beginning October 3, 2016, the Company will pay the principal and accrued interest under the MLSC Loan by making 13 monthly payments of approximately $106,022, with the last payment scheduled to occur on the Maturity Date; and (b) the term "**Qualified Financing**" is now defined to mean one or more financing transactions in which we receive, in a single transaction or series of transactions, cumulative net proceeds of not less than five million dollars ($5,000,000) at any time after October 3, 2016. As a result of the Amendment, the Company expects to reduce interest expenses that would otherwise be incurred under the MLSC Loan Agreement by approximately $232,000 due to the effect of the amortization payments and the lower 7% per annum interest rate.

On September 30, 2016, the Company filed registration statement with the Securities and Exchange Commission (the "**SEC**") utilizing a "shelf" registration process. On October 20, 2016, the SEC declared the registration statement effective. Under this registration statement, we may offer and sell an indeterminate number of shares of our common stock, warrants, debt securities, subscription rights, and/or units. Under this shelf process, the Company may sell up to $50,000,000 of these securities separately or as units, which may include combinations of the securities. The Company may offer these securities in amounts, at prices and on terms determined at the time of offering. The net proceeds from the sale of the securities will be used for working capital and general corporate purposes, which may include acquisitions, retirement of debt and other business opportunities..

Results of Operations

The following discussion of our results of operations should be read together with the financial statements included in this Annual Report and the notes thereto. Our historical results of operations and the period-to-period comparisons of our results of operations that follow are not necessarily indicative of future results.

Year Ended September 30, 2016 Compared to Year Ended September 30, 2015

	September 30, 2016	September 30, 2015	Increase (Decrease)
Revenue	$-	$-	$-
Operating Expenses			
General and Administrative	4,367,476	3,700,477	666,999
Research and Development	1,683,299	1,760,037	(76,738)
Loss from Operations	6,050,775	5,460,514	590,261
Other Income (Expense)	58,405	2,512,988	(2,454,583)
Net Loss	$5,992,370	$2,947,526	$3,044,844

Revenue

We did not generate any revenue in either of the years ended September 30, 2016 or 2015.

General and Administrative Expense

General and administrative expenses during the fiscal year ended September 30, 2016 were $4,367,476, an increase of $666,999 compared to $3,700,477 for the fiscal year ended September 30, 2015. The increase in general and administrative expense is primarily attributable to increased legal costs associated with intellectual property, patent application and prosecution costs, and fundraising efforts. General and administrative expenses are generally expected to increase as a result of additional staffing, increased stock based compensation as well as increased costs associated with the company's continued fundraising efforts.

Research and Development Expense

Research and development expense during the fiscal year ended September 30, 2016 was $1,683,299**,** a decrease of $76,738 compared to $1,760,037 for the fiscal year ended September 30, 2015. The decrease in research and development expense is primarily attributable to a reduction in stock-based compensation, the timing of the preclinical studies, and reduced research and development staffing levels. These expenses were partially offset by increased clinical trial related expenses and quality management system related expenses. Research and development expenses are expected to increase as a result of our plans for additional product development, clinical and regulatory programs.

Other Income/(Expense)

Other income during the year ended September 30, 2016 was $58,405, a decrease of $2,454,583 compared to total other expense of $2,512,988 for the year ended September 30, 2015. The decrease in other income was the result of the change in derivative liabilities.

Liquidity and Capital Resources

Working Capital

At September 30, 2016, we had total current assets of $5,144,260 (including cash and cash equivalents of $5,036,476) and working capital of $3,265,480. Our working capital as of September 30, 2016 and September 30, 2015 is summarized as follows:

	September 30, 2016	September 30, 2015
Total Current Assets	$ 5,144,260	$ 4,003,019
Total Current Liabilities	1,878,780	1,286,078
Working Capital	$ 3,265,480	$ 2,716,941

Total current assets as of September 30, 2016 were $5,144,260, an increase of $1,141,241 compared to $4,003,019 as of September 30, 2015. The increase in current assets is primarily attributable to proceeds received from the 2016 Private Placement Financing and the exercise of Series A, Series C and Series D Warrants partially offset by general and administrative expenses resulting from intellectual property costs and research and development expenses incurred in connection with activities to develop our primary product candidate. Our total current assets as of September 30, 2016 and September 30, 2015 were comprised primarily of cash and cash equivalents, prepaid expenses and other current assets.

Total current liabilities as of September 30, 2016 were $1,878,780, an increase of $592,702 compared to $1,286,078 as of September 30, 2015. The increase is primarily due to $899,627 of the long-term note and $304,770 of the long-term accrued interest being classified as current, partially offset by the conversion of $605,000 of convertible notes into equity and an adjustment to the fair value of the derivative liabilities associated with these Notes. Our total current liabilities as of September 30, 2016 were comprised of accounts payable, accrued expenses and the current portion of the note payable and accrued interest. Our total current liabilities as of September 30, 2015 were comprised primarily of the current portion of the derivative liability, the Notes, accounts payable and accrued expenses.

Cash Flow

	September 30, 2016	September 30, 2015
Cash Used in Operating Activities	$ (4,747,027)	$ (4,239,386)
Cash Used in Investing Activities	-	-
Cash Provided by Financing Activities	5,823,403	7,365,966
Net increase in cash and cash equivalents	$ 1,076,376	$ 3,126,580

Cash Used in Operating Activities

Cash used in operating activities increased $507,641 during the year ended September 30, 2016 to $4,747,027, compared to $4,239,386 during the year ended September 30, 2015. The increase was primarily due to an increase in general and administrative expense primarily attributable to increased intellectual property costs and research and development expenses incurred in connection with activities to develop our primary product candidate.

Cash Used in Investing Activities

There was no cash used in investing activities during the years ended September 30, 2016 or 2015, respectively.

Cash Provided by Financing Activities

Cash provided by financing activities decreased $1,542,563 to $5,823,403 during the year ended September 30, 2016, compared to $7,365,966 during the year ended September 30, 2015. For the year ended September 30, 2016, the cash provided by financing resulted from net proceeds received of $3,114,654 from 2016 Private Placement Financing to purchase 9,418,334 shares of our common stock and Series E Warrants to purchase 7,063,748 shares of Common Stock, from the $860,000 in proceeds received from the exercise of Series A Warrants to purchase 4,300,000 shares of our Common Stock, proceeds received of $680,000 from the exercise of the Series C Warrants to purchase 3,400,000 shares of our Common Stock, proceeds received of $859,773 from the exercise of the Series D Warrants to purchase 3,439,091 shares of our Common Stock, and proceeds received of $308,976 from the exercise of the Series E Warrants to purchase 705,425 shares of our Common Stock. For the year ended September 30, 2015, the cash provided by financing resulted from to the financings conducted by the Company during this fiscal year, in combination with the conversion of a portion of the 2014 Warrants, as previously described in this document.

Cash Requirements

We anticipate that our operating and other expenses will increase significantly as we continue to implement our business plan and pursue our operational goals. As of December 2, 2016, we believe that our current cash and cash equivalents on hand will meet our anticipated cash requirements into the fourth quarter of Fiscal 2017. We will require additional financing to fund our planned future operations, including the continuation of our ongoing research and development efforts, seeking to license or acquire new assets, and researching and developing any potential patents, the related compounds and any further intellectual property that we may acquire. In addition, our estimates of the amount of cash necessary to operate our business may prove to be wrong and we could spend our available financial resources much faster than we currently expect. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties or other issues arise, in which case our current funds may not be sufficient to operate our business for the period we expect.

We do not presently have, nor do we expect in the near future to have, revenue to fund our business from our operations, and will need to obtain all of our necessary funding from external sources for the foreseeable future. We do not have any commitments for future capital. Significant additional financing will be required to fund our planned operations in the near term and in future periods, including research and development activities relating to our principal product candidate, seeking regulatory approval of that or any other product candidate we may choose to develop, commercializing any product candidate for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or businesses, and maintaining our intellectual property rights and pursuing rights to new technologies. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. We are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the MLSC Loan Agreement (i) restricting our ability to incur certain types of additional indebtedness, and (ii) that would cause all amounts under the MLSC Loan Agreement to become immediately due and payable if we receive cumulative net proceeds of $5,000,000 or more in one or more financing transactions at any time after October 3, 2016. These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of debt or through equity issuances. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail and our stockholders could lose all of their investments.

As previously noted, since inception we have funded our operations primarily through equity and debt financings and we expect to continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders' ownership will be diluted. Additionally, the terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors, and in particular may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. If we obtain additional financing by incurring debt, we may become subject to significant limitations and restrictions on our operations pursuant to the terms of any loan or credit agreement governing the debt, which would be in addition to those currently imposed by the MLSC Loan Agreement. Further, obtaining any loan, assuming a loan would be available when needed on acceptable terms, would increase our liabilities and future cash commitments. We may also seek funding from collaboration or licensing arrangements in the future, which may require that we relinquish potentially valuable rights to our product candidates or proprietary technologies or grant licenses on terms that are not favorable to us. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs. In addition, as described in greater detail under the Risk Factor entitled "***The terms of the 2016 Private Placement Financing could impose additional challenges on our ability to raise funding in the future***," included in this Annual Report on Form 10-K, the 2016 Subscription Agreements impose certain restrictions on our ability to issue equity or debt securities.

Going Concern

From inception, we have not earned operating revenues from sales of products or services, and have recurring losses from operations. The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of September 30, 2016, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements included in this Annual Report on Form 10-K do not include any adjustments that might be necessary should operations discontinue.

Critical Accounting Policies and Significant Judgments and Estimates

Pursuant to certain disclosure guidance issued by the SEC, the SEC defines "critical accounting policies" as those that require the application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our critical accounting policies that we anticipate will require the application of our most difficult, subjective or complex judgments are as follows:

Basis of Presentation

The consolidated financial statements presented with this Form 10-K include the accounts of Arch Therapeutics, Inc. and its wholly owned subsidiary, Arch Biosurgery, Inc. a life science medical device company. All intercompany accounts and transactions have been eliminated in consolidation.

The Company is in the development stage and is devoting substantially all of its efforts to developing technologies, raising capital, establishing customer and vendor relationships, and recruiting new employees.

Use of Estimates

Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment when circumstances indicate the carrying value of an asset may not be recoverable in accordance with ASC 360, Property, Plant and Equipment. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value.

Convertible Debt

We record a discount to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying preferred stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized to noncash interest expense using the effective interest rate method over the term of the related debt to their date of maturity. If a security or instrument becomes convertible only upon the occurrence of a future event outside of our control, or, is convertible from inception, but contains conversion terms that change upon the occurrence of a future event, then any contingent beneficial conversion feature is measured and recognized when the triggering event occurs and contingency has been resolved.

Research and Development

We expense internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred

Accounting for Stock-Based Compensation

The Company accounts for employee stock-based compensation in accordance with the guidance of FASB ASC Topic 718, Compensation-Stock Compensation (“FASB ASC Topic 718”), which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. We account for non-employee stock-based compensation in accordance with the guidance of FASB ASC Topic 505, Equity (“FASB ASC Topic 505”), which requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees. FASB ASC Topic 505 requires us to re-measure the fair value of stock options issued to non- employee at each reporting period during the vesting period or until services are complete.

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In accordance with FASB ASC Topic 718, we have elected to use the Black-Scholes option-pricing model to determine the fair value of options granted and we recognize the compensation cost of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the common stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. We do not have sufficient history of market prices of the Common Stock, and as such volatility is estimated in accordance with ASC 718-10-S99 Compensation-Stock Compensation ("ASC 718-10-S99"), using historical volatilities of similar public entities. The life term for awards uses the simplified method for all "plain vanilla" options, as defined in ASC 718-10-S99 and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense, when recognized in the financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

We measure both financial and nonfinancial assets and liabilities in accordance with FASB ASC Topic 820, Fair Value Measurements and Disclosures, except those that are recognized or disclosed in the financial statements at fair value on a recurring basis. The standard created a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect our own views about the assumptions market participants would use in pricing the asset or liability.

Our financial instruments include cash and cash equivalents. Because of their short maturity, the carrying amount of cash and cash equivalents are considered to approximate fair value.

Income Taxes

In accordance with FASB ASC 740, Income Taxes, we recognize deferred tax assets and liabilities for the expected future tax consequences or events that have been included in our financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

We provide reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is probable that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable. We have no reserves related to uncertain tax positions as of September 30, 2016 and September 30, 2015.

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with ASC 815, *Derivatives and Hedging*. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

Recent Accounting Guidance

Accounting Standards Update (ASU) 2016-15, "Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Payments" was issued by the Financial Accounting Standards Board (FASB) in August 2016. The purpose of this amendment is to address eight specific cash flow issues with the objective of reducing the existing diversity in practice. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2016-09, "Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting" was issued by the FASB in March 2016. The purpose of this amendment is to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2016-02, “Leases (Topic 842)” was issued by the FASB in February 2016. The purpose of this amendment requires the recognition of lease assets and lease liabilities by lessees for those leases previously classified as operating leases. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2015-17, “Income Taxes (Topic 740) – Balance Sheet Classification of Deferred Taxes” was issued by the FASB in November 2015. The purpose of this amendment requires deferred tax assets and liabilities to be classified as noncurrent in a classified statement of financial position. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted. The Company adopted ASU 2015-17 during our fourth quarter of fiscal year 2016, which had no impact on our financial statements, and will apply the new guidance in future periods.

ASU 2015-03, “Interest – Imputation of Interest (Subtopic 835-30) Simplifying the Presentation of Debt Issuance Costs” was issued by the FASB in April 2015. The purpose of this amendment requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company adopted ASU 2015-03 during our fourth quarter of fiscal year 2016, which had no impact on our financial statements, and will apply the new guidance in future periods.

ASU 2015-02, “Consolidation (Topic 810) – Amendments to the Consolidation Analysis”, was issued by the FASB in February 2015. The purpose of this amendment is to change the analysis that a reporting entity must perform to determine whether it should consolidate certain types of legal entities. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company adopted ASU 2015-02 during our fourth quarter of fiscal year 2016, which had no impact on our financial statements, and will apply the new guidance in future periods.

ASU 2014-16, “Derivatives and Hedging (Topic 815)” was issued by the FASB in November 2014. The primary purpose of the ASU is to determine whether the host contract in a Hybrid Financial Instrument issued in the form of a share is more akin to debt or equity. ASU 2014-16 is effective for public entities for the fiscal years and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company adopted ASU 2014-16 during our fourth quarter of fiscal year 2016, which had no impact on our financial statements, and will apply the new guidance in future periods.

ASU 2014-15, “Presentation of Financial Statements-Going Concern (Subtopic 205-40) – Disclosure of Uncertainties about an Entity’s Ability to ‘Continue as a Going Concern” was issued by the FASB in August 2014. The primary purpose of the ASU is to provide guidance in GAAP about management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. The amendments should reduce diversity in the timing and content of footnote disclosure. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for the annual periods and interim periods thereafter. Early adoption is permitted. The Company is currently assessing the impact of this guidance, but does not believe that it will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2014-12, “Compensation-Stock Compensation (Topic 718) – Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period” was issued by the FASB in June 2014. ASU 2014-12 requires that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. ASU 2014-12 is effective for public business entities for annual periods and interim periods within the annual periods beginning after December 15, 2015. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2014-09, “Revenue from Contracts with Customers (Topic 606)” was issued by the FASB in May 2014. The primary purpose of the ASU is to develop a common revenue standard for revenue recognition between the FASB and the International Accounting Standards Board (IASB). The ASU removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, and improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets, among other items. We are a development stage company and do not currently generate revenue. ASU 2014-09 is effective for public business entities for annual periods beginning after December 15, 2017. While we are a development stage company and do not currently generate revenue, we currently anticipate generating revenue by the effective date of this ASU and therefore will be subject to this guidance. The Company adopted ASU 2014-09 during our fourth quarter of fiscal year 2016, which had no impact on our financial statements, and will apply the new guidance in future periods.

Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth at the end of this Annual Report beginning on page F-1 and are incorporated herein by reference. We are not required to provide the supplementary data required by this item, as we are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer (who is our Principal Executive Officer) and our Chief Financial Officer (who is our Principal Financial

Officer and Principal Accounting Officer), of the effectiveness of the design of our disclosure controls and procedures (as defined by Exchange Act Rules 13a-15(e) or 15d-15(e)) as of September 30, 2016, pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2016 in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. This conclusion is based on the changes in internal controls over financial reporting implemented during the twelve month period ended September 30, 2016, which are discussed below under the heading "Remediation Efforts".

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, the Principal Executive Officer and Principal Financial Officer and effected by our Board of Directors, management and other personnel, 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. Under the supervision and with the participation of our Principal Executive Officer and Principal Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations (COSO). Based on such evaluation, management concluded that the Company's internal control over financial reporting was effective as of September 30, 2016. Such conclusion is based on the changes in internal controls over financial reporting that occurred during the twelve-month period ended September 30, 2016, and described below under the heading "Remediation Efforts".

Remediation Efforts

We have added certain members to our management team and staff who we believe have sufficient experience to review and design adequate internal control over financial reporting and the experience and formal training to properly analyze and record complex transactions in accordance with U.S. GAAP. As such, we concluded that we have remediated the associated material weakness previously reported

During the year ended September 30, 2016, the Company implemented the following to improve controls over segregation of duties and purchases:

- In October 2015, the controller position was converted into a full time position to improve the review and control over expenditures and disbursements;
- Implemented procedures that require expenditures and payments to be approved by the appropriate levels of management;
- Reviewed banking responsibilities to ensure appropriate access and restrict payment approval.

The current Board of Directors is comprised of three members; two independent members and the CEO. Since, the Company trades on the OTCQB, it is not required nor does it maintain a separate Audit Committee. However, as part of its responsibilities, the Board, in its entirety, provides oversight of the Company's accounting and financial reporting policies and procedures and the audit of the Company's financial statements. Therefore, the Board in its entirety fulfills the requirements of the Audit Committee. For the full year of 2016, their responsibilities included:

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- Overseeing the financial reporting and disclosure process;
- Monitoring and approving the Company’s accounting policies and procedures;
- Overseeing the selection, performance and independence of the external auditors; and
- Overseeing regulatory compliance and ethics.

During the year ended September 30, 2016, the Company performed an entity-level risk assessment to identify and evaluate risk, including fraud-related risks and risks related to unusual transactions.

During the year ended September 30, 2016, Company implemented the following to improve our budgeting process and milestone achievements:

- Prepared and presented quarterly high level operating budgets, cash forecast and operation milestones to the Board to provide them with sufficient information to determine cash requirements and timing of financings

Our management team will continue to monitor and evaluate the effectiveness of our disclosure controls and procedures and our internal control over financial reporting on an ongoing basis and is committed to taking further action and implementing additional enhancements or improvements as resources permit.

Changes in Internal Control Over Financial Reporting

Other than the ongoing remediation efforts identified above, there were no changes in our internal controls over financial reporting that occurred during the year ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Set forth below is certain information regarding our current directors and executive officers:

Name	Position	Age	Director/Officer Since
Dr. Avtar Dhillon	Chairman of the Board of Directors	55	April 2013
James R. Sulat	Director	66	August 2015
Dr. Terrence W. Norchi	President, Chief Executive Officer and Director	51	April 2013
Richard E. Davis	Chief Financial Officer	58	July 2014

Business Experience

The following is a brief account of the education and business experience of our current directors and executive officers during at least the past five years, indicating their principal occupation during the period, and the name and principal business of the organization by which they were employed:

Dr. Avtar Dhillon. Dr. Dhillon has served as the Chairman of our Board of Directors since April 2013 and has been on the Board of Directors of ABS since May 2011. Previously, Dr. Dhillon was the President and Chief Executive Officer of Inovio Pharmaceuticals, Inc. (formerly Inovio Biomedical Corporation) (NYSE Euronext: INO) from October 2001 to June 2009, as President and Chairman of Inovio from June 2009 until October 2009, as Executive Chairman until August 2011, and as Chairman from September 2011. During his tenure at Inovio, Dr. Dhillon led the successful turnaround of the company through a restructuring, acquisition of technology from several European and North American companies, and a merger with VGX Pharmaceuticals to develop a vertically integrated DNA vaccine development company with one of the strongest development pipelines in the industry. Dr. Dhillon led multiple successful financings for Inovio and concluded several licensing deals that included global giants, Merck and Wyeth (now Pfizer). Prior to joining Inovio, Dr. Dhillon was vice president of MDS Capital Corp. (now Lumira Capital Corp.), one of North America’s leading healthcare venture capital organizations. In July 1989, Dr. Dhillon started a medical clinic and subsequently practiced family medicine for over 12 years. Dr. Dhillon has been instrumental in successfully turning around struggling companies and influential as an active member in the biotech community. From March 1997 to July 1998, Dr. Dhillon was a consultant to Cardiome Pharma Corp. (NASDAQ: CRME), where he lead a turnaround based on three pivotal financings, establishing a clinical development strategy, and procuring a new management team. In his role as a founder and board member of companies, Dr. Dhillon has been involved in several early stage healthcare focused companies listed on U.S. or Canadian stock exchanges, which have successfully matured through advances in their development pipeline and subsequent M&A transactions. Most recently, he was a founding board member (May 2003) of Protox Therapeutics, Inc. (TSX-V: SHS) (now Sophiris Bio Inc.), a publicly traded specialty pharmaceutical company. Dr. Dhillon maintained his board position until the execution of a financing of up to $35 million with Warburg Pincus in November 2010. Dr. Dhillon currently sits on the Board of Directors of BC Advantage Funds, a Venture Capital Corporation in British Columbia, and since March 2012 has been the Chairman of the Board of Directors of Stevia First Corp. (OTCQB: STVF), an agricultural biotechnology company engaged in the cultivation and harvest of stevia leaf and the development of stevia products. Since March 2011, Dr. Dhillon has also served as the Chairman of the Board of Directors of OncoSec Medical, Inc. (OTCQB: ONCS), a company developing its advanced-stage ImmunoPulse DNA-based immunotherapy to treat solid tumor and metastatic cancers. Dr. Dhillon adds value to our Board of Directors with his extensive experience as a member of boards of directors and senior management of other public companies and with his experience in company building, financing, and licensing with large industry partners.

James R. Sulat. Mr. Sulat served as Chief Executive Officer and Chief Financial Officer of Maxygen Inc., a biopharmaceutical company focused on developing improved versions of protein drugs, from October 2009 to June 2013. Prior to this, he was Chief Executive Officer, Chief Financial Officer and a member of the Board of Directors at Memory Pharmaceuticals Corp., which developed innovative drug candidates for the treatment of debilitating central nervous system disorders, from 2005 to 2008. He previously served in senior executive roles for R.R. Donnelley & Sons, Co., Chiron Corporation, Stanford Health Services, Inc., and Esprit de Corp, Inc. He currently serves as Chairman of the Board of Directors of Momenta Pharmaceuticals, Inc., a biotechnology company focused on the analysis, characterization and design of complex pharmaceutical products. He also currently serves as a member of the Board of Directors of Valneva SE and AMAG Pharmaceuticals, Inc. Mr. Sulat received a BS in Administrative Sciences from Yale University and an MBA and MS in Health Services Administration from Stanford University. Mr. Sulat brings to our Board of Directors extensive experience with public and financial accounting matters, experience as a chief executive officer and chief financial officer, and experience serving on other boards of directors in the biopharmaceutical industry.

Dr. Terrence W. Norchi. Terrence W. Norchi, MD, our co-founder, serves as our President and Chief Executive Officer, and he is a director on our Board of Directors. Dr. Norchi also served as our Interim Chief Financial Officer through June 26, 2013. Dr. Norchi has served in similar positions since co-founding ABS, our predecessor company in 2006. Prior to ABS, Dr. Norchi was a portfolio manager of one of the world's largest healthcare mutual funds and a pharmaceutical analyst at Putnam Investments from April 2002 to September 2004. Prior to that, he served as the senior global biotech and international pharmaceutical equity analyst at Citigroup Asset Management, and as a sell-side analyst covering non-U.S. pharmaceutical equities at Sanford C. Bernstein in New York City. Dr. Norchi earned an M.B.A. from the Massachusetts Institute of Technology, Sloan School of Management in 1996. Dr. Norchi earned an M.D. degree in 1990 from Northeast Ohio Medical University and completed his internal medicine residency in 1994 at Baystate Medical Center, Tufts University School of Medicine, where he was selected to serve as the Chief Medical Resident. Dr. Norchi brings to our Board of Directors and management team invaluable experience and knowledge of our core technology and proposed product candidates as a result of his first-hand experience with the development of that technology, having ushered it from the research laboratory to its current stage of development. His investing experience as a former public company analyst and a portfolio manager provides further insights and value as the company advances toward commercialization. Dr. Norchi serves on the Board of Overseers of the Boston Museum of Science.

Richard E. Davis. Mr. Davis brings a proven and successful record of more than 25 years of progressive and diversified business, financial and operational leadership within both publicly traded and privately held, domestic and multinational companies. From July 2001 through July 2014, he has been an advisor to small and mid-size companies assisting them in their strategizing, accounting, financial reporting, and investor and banking needs. From February 2001 until June 2011, he was President, Chief Operating Officer and Chief Financial Officer at NMT Medical, Inc., a NASDAQ-traded medical device company. Mr. Davis also served on its Board of Directors. In this role he developed and executed strategic and operational plans that resulted in revenue growth of 35 percent, 13 consecutive quarters of profitability, increased stock price and analyst coverage from five major investment firms; directed the stabilization of a French subsidiary and led successful efforts in raising $6 million from institutional investors to fund ongoing FDA-approved clinical trials. Prior to that, he was Vice President and Chief Financial Officer at Q-Peak, Inc., where he oversaw all financial and administrative functions. Earlier, he worked in a variety of senior level positions at the Coleman Company, The TJX Companies, Inc. and Wang Laboratories. He holds a Master of Business Administration degree with a Finance concentration from Babson College and a Bachelor of Business Administration degree from the University of Massachusetts Amherst.

Term of Office of Directors

Our directors are elected at each annual meeting of stockholders and serve until the next annual meeting of stockholders or until their successor has been duly elected and qualified, or until the earlier of their death, resignation or removal.

Family Relationships

No family relationships exist between any of our current or former directors or executive officers.

Involvement in Certain Legal Proceedings

No director, executive officer or control person of the Company has been involved in any legal proceeding listed in Item 401(f) of Regulation S-K in the past 10 years.

Audit Committee

Our Board of Directors has not established a separate standing audit committee within the meaning of Section 3(a)(58)(A) of the Exchange Act. Instead, the entire Board of Directors presently acts as the audit committee within the meaning of that section and will continue to do so upon the appointment of any new directors until such time as a separate standing audit committee has been established. Our Board of Directors has determined that each member is an "audit committee financial expert" as defined by applicable SEC rules.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers, and stockholders beneficially owning more than 10% of our outstanding common stock to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Executive officers, directors, and persons who beneficially own more than 10% of our common stock are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file. Based solely on our review of the copies of such reports furnished to us, we believe that during the fiscal year ended September 30, 2016, all executive officers, directors and greater than 10% beneficial owners of our common stock complied with the reporting requirements of Section 16(a).

Code of Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, principal executive officer, principal financial officer, principal accounting officer and all of our other officers and employees and can be found on our website, http://www.archtherapeutics.com, on our "Corporate Governance" webpage, which can be accessed from the "Investors" tab of our website. We will also provide a copy of our code of business conduct and ethics to any person without charge upon his or her request. Any such request should be directed to our Chief Financial Officer at 235 Walnut Street, Suite 6, Framingham, Massachusetts 01702. We intend to make all required disclosures concerning any amendments to or waivers from our code of business conduct and ethics on our website.

ITEM 11. EXECUTIVE COMPENSATION

The following table summarizes all compensation recorded by us in each of the fiscal years ended September 30, 2016 and September 30, 2015 for (i) our principal executive officer; (ii) our two next most highly compensated executive officers whose total compensation exceeded $100,000 during our last completed fiscal year; and (iii) certain of our other executive officers, whose compensation is voluntarily provided.

Summary Compensation Table

Name	Fiscal Year	Salary ($)	Bonus $	Stock Awards ($) (1)	Option Awards ($) (2)	All other Compensation ($)	Total ($)
Dr. Terrence W. Norchi	2016	325,000	97,500	440,700	400,375		1,263,575
President and Chief Executive Officer	2015	325,000	77,000	—	138,865	—	540,865
Richard E. Davis	2016	265,625	62,500	40,170	48,045		416,340
Chief Financial Officer	2015	212,500	55,000	—	117,205	—	384,705

(1) Represents the aggregate grant date fair values of restricted stock awards granted during the fiscal year ended September 30, 2016.

(2) Represents the aggregate grant date fair values of awards granted during the fiscal years ended September 30, 2016 and 2015 under ASC Topic 718, which is calculated as of the grant date using a Black-Scholes option-pricing model. Accordingly, the dollar amounts listed do not necessarily reflect the dollar amount of compensation that may be realized by our executive officers. For information on the valuation assumptions with respect to option grants made during the fiscal years ended September 30, 2016 and 2015, refer to Note 9 “Stock-Based Compensation” in our consolidated financial statements included in this filing.

Employment Agreements with Named Executive Officers

Terrence W. Norchi

On June 25, 2013, we entered into an executive employment agreement with Dr. Terrence W. Norchi, our President and Chief Executive Officer and a member of our Board of Directors, which became effective as of June 26, 2013. Dr. Norchi’s employment agreement continues until terminated by Dr. Norchi, or us and provided for an initial annual base salary of $275,000 and eligibility to receive an annual cash bonus in an amount up to 30% of Dr. Norchi’s then-current annual base salary. Annual bonuses are awarded at the sole discretion of our Board of Directors. If Dr. Norchi’s employment is terminated by us (unless such termination is “For Cause” (as defined in his employment agreement)), or by Dr. Norchi for “Good Reason” (as defined in his employment agreement), then Dr. Norchi, upon signing a release in favor of the Company, will be entitled to severance in an amount equal to 12 months of Dr. Norchi’s then-current annual base salary, payable in the form of salary continuation, plus, if Dr. Norchi elects and subject to certain other conditions, payment of Dr. Norchi’s premiums to continue his group health coverage under COBRA until the earlier of (i) 12 months following the date of such termination; or (ii) the date Dr. Norchi becomes covered under another employer’s health plan. In addition, Dr. Norchi’s employment agreement provides that, in the event of a change of control of the Company, termination by Dr. Norchi for Good Reason, termination by the Company for any reason other than For Cause, or termination as a result of Dr. Norchi's death, all unvested shares under outstanding equity grants to Dr. Norchi, if any, shall automatically accelerate and become fully vested. On March 13, 2014, Mr. Norchi's employment agreement was amended to increase his annual base salary by $50,000 to $325,000, retroactively effective as of February 1, 2014, and increase his cash bonus eligibility from 30% of his annual base salary to 35% of his annual base salary.

Dr. Norchi's employment agreement provides the following definitions of "For Cause" and "Good Reason": (a) "For Cause" is (i) the commission by the executive of a crime involving dishonesty, breach of trust, or physical harm to any person, (ii) executive's engagement by the executive in conduct that is in bad faith and materially injurious to the Company, (iii) commission by the executive of a material breach of the employment agreement which is not cured within 20 days after the executive receives written notice of such breach, (iv) willful refusal by the executive to implement or follow a lawful policy or directive of the Company, which breach is not cured by the executive within 20 days after receiving written notice from the Company, (v) or executive's engagement in misfeasance or malfeasance demonstrated by a pattern of failure to perform job duties diligently and professionally (other than any such failure resulting from Executive's incapacity due to physical or mental illness); and (b) "Good Reason" is, without the executive's written consent, (1) a material reduction in executive's annual base salary, except for reductions that are comparable to reductions generally applicable to similarly-situated executives of the Company, (2) the relocation of executive to a facility or location that is more than 50 miles from his primary place of employment and such relocation results in an increase in executive's one-way driving distance by more than 50 miles, or (3) a material and adverse change in executive's authority, duties, or responsibilities with the Company or a material and adverse change in executive's reporting relationship within the Company.

In connection with our entry into the executive employment agreement with Dr. Norchi, effective on June 26, 2013, Dr. Norchi's former employment agreement with ABS was terminated pursuant to a termination agreement and release between Dr. Norchi and ABS.

Richard E. Davis

On July 7, 2014, we entered into an executive employment agreement with Mr. Davis, our Chief Financial Officer and Treasurer. The agreement continues until terminated by us or by Mr. Davis. Pursuant to the terms of the agreement, Mr. Davis is entitled to an initial annual base salary of $200,000 and is eligible to receive an annual cash bonus in an amount of up to 25% of Mr. Davis' then-current annual base salary. Annual bonuses are awarded at the sole discretion of our Board of Directors. If Mr. Davis' employment is terminated by us at any time after August 7, 2014 (unless such termination is "For Cause" (as defined in his employment agreement)), or by Mr. Davis for "Good Reason" (as defined in his employment agreement), then Mr. Davis, upon signing a release in favor of the Company, would be entitled to severance in an amount equal to six months of Mr. Davis' then-current annual base salary, payable in the form of salary continuation, plus, if Mr. Davis elects and subject to certain other conditions, payment of Mr. Davis' premiums to continue his group health coverage under COBRA until the earlier of (i) 12 months following the date of such termination; or (ii) the date Mr. Davis becomes covered under another employer's health plan. In addition, Mr. Davis' employment agreement provides that, in the event of a change of control of the Company or his employment is terminated by the Company for any reason other than For Cause, all unvested shares under outstanding equity grants to Mr. Davis, if any, shall automatically accelerate and become fully vested. On July 27, 2015, Mr. Davis's employment agreement was amended to increase his annual base salary by $50,000 to $250,000, retroactively effective as of July 1, 2015.

The agreement provides the following definitions of "For Cause" and "Good Reason": (a) "For Cause" is (i) the commission by the executive of a crime involving dishonesty, breach of trust, or physical harm to any person, (ii) executive's engagement by the executive in conduct that is in bad faith and materially injurious to the Company, (iii) commission by the executive of a material breach of the employment agreement which is not cured within 20 days after the executive receives written notice of such breach, (iv) willful refusal by the executive to implement or follow a lawful policy or directive of the Company, which breach is not cured by the executive within 20 days after receiving written notice from the Company, (v) or executive's engagement in misfeasance or malfeasance demonstrated by a pattern of failure to perform job duties diligently and professionally; and (b) "Good Reason" is, without the executive's written consent, (1) a reduction in the executive's annual base salary comparable to reductions generally applicable to similarly-situated executives of the Company if such reduction occurs during the first 365 days of employment and is greater than 15%, (2) a relocation of the executive to a facility or location that is more than 50 miles from his primary place of employment and results in an increase in one-way driving distance by more than 50 miles (provided that any such relocation shall not constitute Good Reason if the executive is permitted to perform his duties remotely from or near his home for two weeks per month), or (3) a material and adverse change in the executive's authority, duties, or responsibilities with the Company or reporting relationship within the Company.

Outstanding Equity Awards At Fiscal Year-End

The following table summarizes the aggregate number of option and stock awards held by our named executive officers at September 30, 2016:

Option Awards						Stock Awards		
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)		Market Value of Shares or Units of Stock That Have Not Vested ($)
Dr. Terrence W. Norchi	437,506	62,494	(1)	0.35	03/22/2024			
	266,664	133,336	(2)	0.19	01/21/2025			
	184,898	170,102	(3)	0.28	08/17/2025			
	416,668	833,332	(4)	0.39	05/02/2026			
						1,130,000	(5)	768,400
Richard E. Davis	359,375	140,625	(6)	0.22	07/06/2024			
	333,336	166,664	(7)	0.19	01/21/2025			
	91,148	83,852	(8)	0.28	08/17/2025			
	50,000	100,000	(9)	0.39	05/02/2026			
						103,000	(10)	70,040

(1) Represents an option to purchase 500,000 shares of Common Stock with a grant date of March 23, 2014. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing April 23, 2015.

(2) Represents an option to purchase 400,000 shares of Common Stock with a grant date of January 22, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing February 22, 2016.

(3) Represents an option to purchase 355,000 shares of Common Stock with a grant date of August 18, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing September 18, 2015.

(4) Represents an option to purchase 1,250,000 shares of Common Stock granted on May 3, 2016. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.

(5) Represents a stock award to receive 1,130,000 shares of Common Stock granted on May 3, 2016. 100% of the stock award becomes vested on May 3, 2018.

(6) Represents an option to purchase 500,000 shares of Common Stock with a grant date of July 7, 2014. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.

(7) Represents an option to purchase 500,000 shares of Common Stock with a grant date of January 22, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing February 22, 2015.

(8) Represents an option to purchase 175,000 shares of Common Stock with a grant date of August 18, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36 th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing September 18, 2015.

(9) Represents an option to purchase 150,000 shares of Common Stock granted on May 3, 2016. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.

(10) Represents a stock award to receive 103,000 shares of Common Stock granted on May 3, 2016. 100% of the stock award becomes vested on May 3, 2018.

Compensation of Directors

On March 23, 2014, our Board of Directors adopted a director compensation policy for non-employee directors. That policy provides that effective the first calendar quarter of 2014, the person serving as the Chairman of our Board of Directors receives an aggregate annual cash fee of $190,000 for that chairperson role, and all other non-employee directors receive an annual cash fee of $50,000. Prior to the adoption of the revised director compensation policy, the person serving as the Chairman of our Board of Directors received an aggregate annual cash fee of $110,000 for that chairperson role, and all other non-employee directors received an annual cash fee of $35,000.

The following table summarizes all compensation paid to our non-employee directors during the fiscal year ended September 30, 2016:

Director Compensation Table

	Fees Earned or Paid In Cash ($)	Stock Awards ($)(1)	Option Awards ($)(2)	All other Compensation ($)	Total ($)
Dr. Avtar Dhillon (3)	190,000	287,430	265,849	—	743,279
James R. Sulat (4)	50,000	11,700	41,639	—	103,339

(1) The values listed represent the aggregate grant date fair values of restricted stock awards granted during the fiscal year ended September 30, 2016.

(2) Represents the aggregate grant date fair values of awards granted during the fiscal year ended September 30, 2016 under ASC Topic 718, which is calculated as of the grant date using a Black-Scholes option-pricing model. Accordingly, the dollar amounts listed do not necessarily reflect the dollar amount of compensation that may be realized by our non-employee directors. For information on the valuation assumptions with respect to option grants made during the fiscal years ended September 30, 2016, refer to Note 9 “Stock-Based Compensation” in our consolidated financial statements included in this filing.

(3) The aggregate number of shares of Common Stock underlying option awards and stock awards outstanding as of September 30, 2016 held by Mr. Dhillon was 1,785,000 and 737,000, respectively.

(4) Mr. Sulat was appointed as a member of the Board on August 19, 2015. The aggregate number of shares of Common Stock underlying option awards and stock awards outstanding as of September 30, 2016 held by Mr. Sulat was 360,000 and 30,000, respectively.

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

Securities Authorized for Issuance under Equity Compensation Plans

On June 18, 2013, our Board of Directors and the holders of a majority of our standing common stock approved and adopted the Arch Therapeutics, Inc. 2013 Stock Incentive Plan (the "Plan"). The Plan permits us to grant a variety of forms of awards, including stock options, stock appreciation rights, restricted stock, restricted stock units, and dividend equivalent rights, to allow us to adapt our incentive compensation program to meet our needs. As of September 30, 2016, the Plan has reserved 16,114,256 shares of our common stock for issuance thereunder in awards granted to employees, directors and/or consultants. The Plan provides that on the first business day of each fiscal year commencing with fiscal year 2013, the number of shares of our common stock reserved for issuance under the Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (i) 3,000,000 shares, (ii) 4% of the number of shares outstanding on the last day of our immediately preceding fiscal year, or (iii) such lesser number of shares as determined by the administrator of the Plan, which is currently our Board of Directors. As a result of that provision, as of October 1, 2016, the number of shares reserved for issuance under the Plan increased by 3,000,000 to 19,114,256. The following table provides information as of September 30, 2016 with respect to our equity compensation plans:

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	12,379,210	$ 0.33	2,447,527
Equity compensation plans not approved by security holders	—	—	—
Total	12,379,210	$ 0.33	2,447,527

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the beneficial ownership of our Common Stock by (i) each person who, to our knowledge, beneficially owns more than 5% of our Common Stock; (ii) each of our directors and named executive officers; and (iii) all of our directors and executive officers as a group. Unless otherwise indicated in the footnotes to the following table, the address of each person named in the table is: c/o Arch Therapeutics, Inc., 235 Walnut St., Suite #6, Framingham, Massachusetts 01702. The information set forth in the table below is based on 137,882,075 shares of our Common Stock outstanding on December 2, 2016. Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of December 2, 2016 are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person. The following table is presented after taking into account (a) the 4.9% ownership limitation (which may waived at the holder's discretion, provided that such waiver will not become effective until the 61st day after delivery of such waiver notice) to which Intracoastal and Tungsten III, LLC ("**Tungsten**"), an entity controlled by Michael Parker, is subject to under the terms of the Series D Warrants issued to Mr. Parker in the 2015 Private Placement Financing and subsequently transferred to Tungsten; and (b) the 4.99% ownership limitation (which may be increased to 9.99% at the holder's discretion, *provided that* such increase will not become effective until the 61st day after delivery of the notice in which the holder informs us of this increase) to which 2016 Investors and their assignees are subject under the terms of the Series E Warrants issued in the 2016 Private Placement Financing. As a result of the foregoing ownership limitations, the table below does not include any of the investors from the Private Placement Financings other than Mr. Parker.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned (1)	
5%+ Stockholders:			
Twelve Pins Partners (2)	10,000,000	7.25	%
Michael A. Parker (3)	9,911,667	7.19	%
Directors and Executive Officers			
Avtar Dhillon (4)	9,198,206	6.61	%
Terrence Norchi (5)	14,063,555	10.09	%
James R. Sulat (6)	1,660,980	1.20	%
Richard E. Davis (7)	1,068,104	0.77	%
Current Directors and Named Executive Officers as a Group (4 persons)	25,990,845	18.25	%

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Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of December 2, 2016, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person.

(1) Except as otherwise indicated, we believe that each of the beneficial owners of the Common Stock listed previously, based on information furnished by such owners, has sole investment and voting power with respect to the shares listed as beneficially owned by such owner, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities.

(2) Dr. Norchi is the sole member of Twelve Pins Partners, LLC and has sole voting and investment control with respect to the shares it holds. Dr. Norchi disclaims beneficial ownership of these securities except to the extent of his pecuniary interest therein.

(3) Represents (i) 5,000,000 shares of Common Stock originally issued to Mr. Parker, an investor in the 2015 Private Placement Financing, and assigned in March 2016 to Tungsten, an entity controlled by Mr. Parker; (ii) 2,222,223 shares of Common Stock issued to an IRA held by Ms. Parker, Mr. Parker's spouse with whom he resides, in connection with the 2016 Private Placement Financing and subsequently sold by the IRA to Ms. Parker in her personal capacity; (iii) 2,164,837 shares of Common Stock acquired by Mr. Parker in transactions unrelated to our private placement financings; and (iv) 524,607 shares of Common Stock acquired by Ms. Parker in transactions unrelated to our private placement financings. Excludes (a) 4,500,0000 shares of our Common Stock issuable upon the exercise of the Series D Warrant originally issued to Mr. Parker upon the Closing of the 2015 Private Placement Financing and subsequently assigned to Tungsten as a result of the ownership limitation that Tungsten is subject to under the terms of Tungsten's Series D Warrant; and (b) 1,666,667 shares of Common Stock issuable upon exercise of Series E Warrants issued to Ms. Parker's IRA in connection with the 2016 Private Placement Financing as a result of the ownership limitation that Ms. Parker's IRA is subject to under the terms of its Series E Warrant.

(4) Represents (a) 7,897,373 shares of our Common Stock; and (b) 1,300,833 shares subject to options exercisable within 60 days after December 2, 2016

(5) Represents (a) 10,000,000 shares of our Common Stock held by Twelve Pins Partners, LLC, with respect to which Dr. Norchi holds sole voting and investment control; (b) 1,419,076 shares issued to Dr. Norchi upon the closing of the Merger in exchange for the cancellation of shares of Common Stock and convertible notes of ABS owned by him immediately prior to the closing of the Merger; (c) 1,130,000 shares of restricted stock granted to Dr. Norchi on May 3, 2016; and (d) 1,514,479 shares subject to options exercisable within 60 days after December 2, 2016. Dr. Norchi disclaims beneficial ownership of the securities held by Twelve Pins Partners, LLC except to the extent of his pecuniary interest therein.

(6) Represents (a) 838,934 shares of our Common Stock, a Series D Warrant exercisable for 454,546 shares of our Common Stock, and a Series E Warrant exercisable for 83,333 shares of our Common Stock held by Keyes Sulat

Revocable Trust; (b) 30,000 shares of our Common Stock held directly by Mr. Sulat; and (c) 254,167 shares subject to options exercisable within 60 days after December 2, 2016. Excludes 30,000 shares subject to an option granted to Mr. Sulat in his capacity as a consultant on June 18, 2013 that can only be exercised upon the earlier of (i) calendar year 2018, or (ii) a corporate transaction or change of control which also constitutes a "change in the ownership or effective control, or in the ownership of a substantial portion of the assets" within the meaning of Section 409A. Mr. Sulat disclaims beneficial ownership of the securities held by Keyes Sulat Revocable Trust except to the extent of his pecuniary interest therein.

(7) Represents (a) 103,000 shares of our Common Stock; and (b) 965,104 shares subject to options exercisable within 60 days after December 2, 2016.

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

Related Party Transactions

During fiscal years 2015 and 2016, other than with respect to matters relating to the Company's compensation arrangements with its executive officers, there were no transactions between the Company or any of its subsidiaries and any "Related Person" (as that term is defined in Item 404 of Regulation S-K) that would be required to be reported pursuant to Item 404 of Regulation S-K other than the following:

James R. Sulat, who was appointed as a member of our Board of Directors on August 19, 2015, is a co-trustee of the Keyes Sulat Revocable Trust (the "**Trust**"). In exchange for a payment of (i) $100,000, the Trust received 454,546 shares of our Common Stock upon the Initial Closing of the 2015 Private Placement Financing on June 30, 2015, and a Series D Warrant exercisable for the same number of shares at an exercise price of $0.25; and (ii) $40,000, the Trust received 111,111 shares of our Common Stock upon the closing of the 2016 Private Placement Financing on May 26, 2016, and a Series E Warrant exercisable for 83,333 shares at an exercise price of $0.4380. Regarding the latter, Mr. Sulat disclosed his interest in the 2016 Private Placement Financing to the remaining members of the Board, all of whom were disinterested in the transaction (the "**Disinterested Directors**"), in accordance with the Company's policies governing related party transactions (which is described below), and recused himself from discussing or voting on matters related to the 2016 Private Placement Financing. The Disinterested Directors unanimously approved the 2016 Private Placement Financing.

Upon his resignation from our Board of Directors on May 28, 2015, the Company and Dr. Arthur Rosenthal entered into an oral agreement pursuant to which Dr. Rosenthal agreed to continue providing services to the Company as a scientific advisor. On October 15, 2015, the Company and Dr. Rosenthal entered into a written agreement to memorialize this agreement.

Review, Approval or Ratification of Transactions with Related Persons

Due to the small size of our Company, at this time we have determined to rely on our full Board of Directors to review related party transactions and identify and prevent conflicts of interest. Our Board of Directors reviews a transaction in light of the affiliations of the director, officer, employee or stockholder and the affiliations of such person's immediate family. Transactions are presented to our Board of Directors for approval before they are entered into or, if that is not possible, for ratification after the transaction has occurred. If our Board of Directors finds that a conflict of interest exists, then it will determine the appropriate remedial action, if any. Our Board of Directors approves or ratifies a transaction if it determines that the transaction is consistent with the best interests of the Company and its stockholders. The procedures described above have been approved by resolutions adopted by our Board of Directors.

Director Independence

Our Board of Directors has determined that Dr. Avtar Dhillon and Mr. James R. Sulat would qualify as "independent" as that term is defined by Nasdaq Listing Rule 5605(a)(2). Further, although we have not established separately designated audit, nominating or compensation board committees, Dr. Dhillon and Mr. Sulat would qualify as "independent" under Nasdaq Listing Rules applicable to all such board committees. Dr. Terrence W. Norchi would not qualify as "independent" under Nasdaq Listing Rules applicable to the Board of Directors generally or to separately designated board committees because he currently serves as our President and Chief Executive Officer.

Subject to some exceptions, Nasdaq Listing Rule 5605(a)(2) provides that an independent director is a person other than an executive officer or other employee of the Company or any other individual having a relationship which, in the opinion of our Board of Directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Under Nasdaq Listing Rule 5605(a)(2) and subject to certain exceptions, a director will not be deemed to be independent if (a) the director is, or at any time during the past three years was, an employee of ours; (b) the director or a member of the director's immediate family or a person living with such director (collectively, a "**Related Party**") has received more than $120,000 in compensation from us during any twelve-month period within the preceding three years, other than compensation for service as a director or as a non-executive employee (in the case of Related Party), benefits under a tax-qualified retirement plan or non-discretionary compensation; (c) a Related Party is, or in the past three years has been, an executive officer of ours; (d) the director or a Related Party is an executive officer, partner or controlling shareholder of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during our past three fiscal years, exceeds the greater of 5% of the recipient's consolidated gross revenues for that year or $200,000 (except for payments arising solely from investments in our securities or payments under non-discretionary charitable contribution matching programs); (e) the director or a Related Party is employed as an executive officer of another company where at any time during the preceding three years one of our executive officers served on the compensation committee of such company; and (f) the director or a Related Party is a current partner of our independent public accounting firm, or has worked for such firm in any capacity on our audit at any time during the past three years.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table presents the aggregate fees agreed to by the Company for the annual audits for the fiscal years ended September 30, 2016 and 2015 and all other fees paid by us for services rendered by Moody, Famiglietti & Andronico LLP, our current principal accountant, during the fiscal years ended September 30, 2016 and 2015:

	2016	2015
Audit Fees	$92,747	$100,000
Audit-Related Fees	-	-
Tax Fees	-	-
All Other Fees	22,683	29,650
Total	$115,430	$129,650

Audit Fees. The fees identified under this caption were for professional services rendered by Moody, Famiglietti & Andronico LLP for the audit of our annual financial statements. The fees identified under this caption also include fees for professional services rendered by Moody, Famiglietti & Andronico LLP for the review of the financial statements included in our quarterly reports on Forms 10-Q. In addition, the amounts include fees for services that are normally provided by the auditor in connection with regulatory filings and engagements for the years identified.

Audit-Related Fees. Audit-related fees consist principally of assurance and related services reasonably related to the performance of the audit or review of our financial statements that are not reported as audit fees.

Tax Fees. Tax fees consist principally of assistance related to tax compliance, tax advice, and tax planning. For the fiscal years ended September 30, 2016 and 2015 there were no tax fees paid to our principal accountant.

All Other Fees. These fees would consist of all fees paid to our principal accountant that are not reflected as audit, audit-related or tax fees such as fees incurred in connection with reviewing our registration statements and prospectus supplements.

Pre-Approval Policy

As our Board of Directors has not established a separate standing audit committee, all engagements of our independent registered public accounting firm for 2015 and 2014 were pre-approved by the full Board of Directors.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1). The following consolidated financial statements of Arch Therapeutics, Inc. and subsidiary, are found beginning on Page F-1 immediately following the signature page hereto, are incorporated by reference into Item 8 — Financial Statements and Supplementary Data:

(a)(2). Financial Statement Schedules

These schedules are omitted because they are not required, or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

(a)(3). Exhibits

The Exhibit Index attached to this Annual Report on Form 10-K is incorporated by reference herein.

SIGNATURES

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

	Arch Therapeutics, Inc.
By:	/s/ Terrence W. Norchi, MD
Date: December 5, 2016	Terrence W. Norchi, MD
	President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Terrence W. Norchi as his or her true and lawful attorney-in-fact and agent, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this report and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that such attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

SIGNATURE	**TITLE**	**DATE**
/s/ Terrence W. Norchi, MD Terrence W. Norchi, MD	President, Chief Executive Officer and Director (*Principal Executive Officer*)	December 5, 2016
/s/ Richard E. Davis Richard E. Davis	Chief Financial Officer (Principal *Financial and Accounting Officer*)	December 5, 2016
/s/ Avtar Dhillon, MD Avtar Dhillon, MD	Director	December 5, 2016
/s/ James R. Sulat James R. Sulat	Director	December 5, 2016

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ARCH THERAPEUTICS, INC.

CONSOLIDATED FINANCIAL STATEMENTS

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Arch Therapeutics, Inc.

Framingham, Massachusetts

We have audited the accompanying consolidated balance sheets of Arch Therapeutics, Inc. and subsidiary (the "Company") as of September 30, 2016 and 2015, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Arch Therapeutics, Inc. and subsidiary as of September 30, 2016 and 2015, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that Arch Therapeutics, Inc. and subsidiary will continue as a going concern. As discussed in Notes 1 and 2 to the consolidated financial statements, the Company has an accumulated deficit, has suffered significant net losses and negative cash flows from operations, and has limited working capital that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Notes 1 and 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Moody, Famiglietti & Andronico, LLP

Tewksbury, MA

December 5, 2016

Arch Therapeutics, Inc.
Consolidated Balance Sheets
As of September 30, 2016 and 2015

	September 30, 2016	September 30, 2015
ASSETS		
Current assets:		
Cash	$ 5,036,476	$ 3,960,100
Prepaid expenses and other current assets	107,784	42,919
Total current assets	5,144,260	4,003,019
Total assets	$ 5,144,260	$ 4,003,019
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 374,896	$ 231,761
Accrued expenses and other liabilities	299,487	245,478
Accrued Interest	304,770	-
Note Payable, net of unamortized discount	899,627	-
Convertible notes, net of unamortized discount	-	473,747
Current derivative liabilities	-	335,092
Total current liabilities	1,878,780	1,286,078
Long-term liabilities:		
Note payable, net of unamortized discount and current portion	78,255	966,824
Accrued interest, net of current portion	26,230	210,000
Total long-term liabilities	104,485	1,176,824
Total liabilities	1,983,265	2,462,902
Commitments and contingencies (see Note 12)		
Stockholders' equity:		
Common stock, $0.001 par value, 300,000,000 shares authorized, 136,657,075 and 107,592,205 shares issued and outstanding as of September 30, 2016 and September 30, 2015, respectively	134,432	107,392
Additional paid-in capital	24,741,153	17,154,945
Accumulated deficit	(21,714,590)	(15,722,220)
Total stockholders' equity	3,160,995	1,540,117
Total liabilities and stockholders' equity	$ 5,144,260	$ 4,003,019

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

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Arch Therapeutics, Inc.
Consolidated Statements of Operations
For the Years Ended September 30, 2016 and 2015

	Fiscal Year Ended September 30, 2016	Fiscal Year Ended September 30, 2015
Revenues	$ -	$ -
Operating expenses:		
General and administrative expenses	4,367,476	3,700,477
Research and development expenses	1,683,299	1,760,037
Total operating expenses	6,050,775	5,460,514
Operating loss	(6,050,775)	(5,460,514)
Other income (expense):		
Interest expense	(276,687)	(377,805)
Gain on exercise of warrants and conversion of debt	142,964	386,612
Loss on warrant derivative modification, net of inducement shares	-	(1,032,113)
Decrease to fair value of derivative	192,128	3,536,294
Total other income (expense)	58,405	2,512,988
Net loss	$ (5,992,370)	$ (2,947,526)
Earnings per share - basic and diluted		
Net loss per common share - basic and diluted	$ (0.05)	$ (0.04)
Weighted common shares - basic and diluted	121,462,897	81,394,873

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

Arch Therapeutics, Inc.
Consolidated Statements of Changes in Stockholders' Equity
For the Years Ended Septermber 30. 2016 and 2015

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at September 30, 2014	72,051,487	72,051	5,810,200	(12,774,694)	(6,892,443)
Net loss	-	-	-	(2,947,526)	(2,947,526)
Issuance of restricted stock for services	475,000	475	165,682	-	166,157
Reclassification of Series A and C Warrants	-	-	3,263,753	-	3,263,753
Shares issued for the exercise of warrants	18,686,801	18,687	3,581,313	-	3,600,000
Shares issued for the exercise of stock options	462,298	462	(462)	-	-
Shares issued in consideration for extending the Series C Warrants and eliminating the Ratchet Provision	570,000	570	134,782	-	135,352
Issuance of stock in private placement funding	14,390,754	14,391	3,001,575	-	3,015,966
Shares issued for the conversion of the convertible notes	755,865	756	150,417	-	151,173
Stock based compensation expense	-	-	1,047,685	-	1,047,685
Balance at September 30, 2015	107,392,205	107,392	17,154,945	(15,722,220)	1,540,117
Net loss	-	-	-	(5,992,370)	(5,992,370)
Issuance of restricted stock for services	150,000	150	52,350	-	52,500
Shares issued for the exercise of warrants	11,844,516	11,845	2,696,904	-	2,708,749
Shares issued for the exercise of stock options	68,967	69	(69)	-	-
Exercise of Series A Warrants Cashless	2,333,559	2,334	(2,334)	-	-

Issuance of stock in private placement funding, net of issuance costs	9,418,334	9,418	3,099,521	-	3,108,939
Shares issued for the conversion of the convertible notes	3,224,494	3,224	641,676	-	644,900
Stock based compensation expense	-	-	1,098,160	-	1,098,160
Balance at September 30, 2016	134,432,075	134,432	24,741,153	(21,714,590)	3,160,995

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

Arch Therapeutics, Inc.
Consolidated Statements of Cash Flows (Unaudited)
For the Years Ended September 30, 2016 and 2015

	Fiscal Year Ended September 30, 2016	
Cash flows from operating activities:		
Net loss	$	(5,992,3
Adjustments to reconcile net loss to cash used in operating activities:		
Stock-based compensation		1,098,16
Noncash interest expense on notes payable		276,687
Issuance of restricted stock for services		52,500
Gain on exercise of warrants and conversion of debt		(142,96
Loss on warrant derivative modification, net of inducement shares		-
Decrease to fair value of derivative		(192,12
Changes in operating		

assets and liabilities:	
(Increase) decrease in:	
Prepaid expenses and other current assets	(64,865
Increase (decrease) in:	
Accounts payable	137,420
Accrued expenses and other liabilities	80,533
Net cash used in operating activities	(4,747,0
Cash flows from financing activities:	
Proceeds from exercise of warrants	2,708,74
Proceeds from issuance of common stock and warrants	3,114,6
Proceeds from issuance of convertible notes	-
Net cash provided by financing activities	

The information set forth in the following table regarding the beneficial ownership after resale of securities assumes that the Selling Securityholder will purchase the maximum number of shares of Common Stock provided for by the Warrants and will sell all of the shares of Common Stock owned by that Selling Securityholder covered by this prospectus. There is no assurance that any of the Warrants will be exercised.

	Securities Beneficially Owned Prior to the Offering		Securities Offered Hereby		Securities Beneficially Owned After this Offering	
Name	**Common Stock**	**Warrants**	**Common Stock**	**Common Stock**	**Common Stock**	**Warrants**

				underlying Warrants		
AIGH Investment Partners LP	4,000,000	4,000,000	4,000,000	4,000,000	—	—
Dr. Joshua A. Hirsch	200,000	200,000	200,000	200,000	—	—
Perceptive Life Sciences Master Fund Ltd.	5,205,000	5,205,000	5,205,000	5,205,000	—	—
Titan Perc, Ltd.	795,000	795,000	795,000	795,000	—	—
HFR HE Sphera Global Healthcare Master Trust	252,000	252,000	252,000	252,000	—	—
Sphera Global Healthcare Master Fund	5,748,000	5,748,000	5,748,000	5,748,000	—	—
Sabby Healthcare Volatility Master Fund, Ltd.	12,000,000	12,000,000	12,000,000	12,000,000	—	—
Sabby Volatility Warrant Master Fund, Ltd.	10,000,000	10,000,000	10,000,000	10,000,000	—	—
Joann Mostovoy	1,000,000	1,000,000	1,000,000	1,000,000	—	—
Hewlett Fund	800,000	800,000	800,000	800,000	—	—
Brio Capital Master Fund Ltd.	2,000,000	2,000,000	2,000,000	2,000,000	—	—

LEGAL MATTERS

Validity of the securities offered by this prospectus will be passed upon for us by BRL Law Group LLC, Boston, Massachusetts. As of March 31, 2014, Thomas B. Rosedale, the Managing Member of BRL Law Group LLC, beneficially owned 545,042 shares of our Common Stock.

EXPERTS

The financial statements included in this Prospectus of the Company have been audited by Brightman Almagor Zohar & Co., a member of Deloitte Touche Tohmatsu, an independent registered public accounting firm, as stated in their report appearing herein (which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph regarding the Company's ability to continue as a going concern). Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports and other information with the SEC. These filings contain important information that does not appear in this prospectus. For further information about us, you may read and copy any reports, statements and other information filed by us at the SEC’s Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549-0102. You may obtain further information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our SEC filings are also available on the SEC Internet site at http://www.sec.gov, which contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2013

U.S. DOLLARS IN THOUSANDS

(Except share data)

INDEX

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

BRAINSTORM CELL THERAPEUTICS Inc. (A Development Stage Company)

We have audited the accompanying consolidated balance sheet of BRAINSTORM CELL THERAPEUTICS Inc. and subsidiary (a development stage company) (the “Company”) as of December 31, 2013 and 2012, and the related consolidated statement of income, stockholders' deficiency, and cash flows for each of the two years in the period ended December 31, 2013 and for the period from April 1, 2004 to December 31, 2013. These financial statements are the responsibility of the Company's Board of Directors and management. Our responsibility is to express an opinion on the financial statements based on our audits.

The financial statements for the period from April 1, 2004 through December 31, 2007, were audited by other auditors. The consolidated financial statements for the period from April 1, 2004 through December 31, 2007 included a net loss of $32,325,000. Our opinion on the consolidated statements of operations, changes in stockholders' deficiency and cash flows for the period from April 1, 2004 through December 31, 2013, insofar as it relates to amounts for prior periods through December 31, 2007, is based solely on the report of other auditors. The other auditors report dated April 13, 2008 expressed an unqualified opinion, and included an explanatory paragraph concerning an uncertainty about the Company's ability to continue as a going concern, and regarding the status of the Company research and development license agreement with Ramot.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditor, such consolidated financial statements present fairly, in all material respects, the financial position of BRAINSTORM CELL THERAPEUTICS Inc. and subsidiary as of December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2013 and for the period from April 1, 2004 to December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company is a development stage enterprise engaged in development innovative stem cell therapeutic products based on technologies enabling the *in-vitro* differentiation of bone marrow stem cells into neural-like cells, based on the acquired technology and research to be conducted and funded by the Company as discussed in Note 1 to the financial statements. The Company's working capital deficiency and operating losses since inception through December 31, 2013 raise substantial doubts about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of' these uncertainties.

/s/ Brightman Almagor Zohar & Co.

Brightman Almagor Zohar & Co.

Certified Public Accountants

A Member Firm of Deloitte Touche Tohmatsu Limited

Tel Aviv, Israel

March 27, 2014

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of

BRAINSTORM CELL THERAPEUTICS INC.

(A development stage company)

We have audited the accompanying consolidated balance sheet of Brainstorm Cell Therapeutics Inc. (a development stage company) ("the Company") and its subsidiary as of December 31, 2007, and the related consolidated statements of operations, statements of changes in stockholders' equity (deficiency) and the consolidated statements of cash flows for the year ended December 31, 2007, for the nine months ended December 31, 2006 and 2005 and for the period from March 31, 2004 through December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits and the report of the other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its subsidiary as of December 31, 2007, and the consolidated results of their operations and cash flows for the year ended December 31, 2007, for the nine months ended December 31, 2006 and 2005 and for the period from March 31, 2004 through December 31, 2007, in conformity with U.S generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, in 2007, the Company adopted Financial Accounting Standard Board Statement No. 123(R), "Share-Based Payment".

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1h, the Company has incurred operating losses and has a negative cash flow from operating activities and has a working capital deficiency. As for the Company research and development license agreement with Ramot, see Note 3. These conditions raise substantial doubt about the Company's ability to continue to operate as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

	/s/ Kost Forer Gabbay & Kasierer
Tel-Aviv, Israel	KOST FORER GABBAY & KASIERER
April 13, 2008	A Member of Ernst & Young Global

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

(Except share data)

	December 31, 2013	2012
	U.S. $ in thousands	
ASSETS		
Current Assets:		
Cash and cash equivalents	3,503	1,317
Short-term deposit	-	2,769
Account receivable (Note 5)	910	742
Prepaid expenses	33	46
Total current assets	4,446	4,874
Long-Term Assets:		
Prepaid expenses	22	17
Total long-term assets	22	17
Property And Equipment, Net (Note 6)	258	247
Total assets	4,726	5,138
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Trade payables	228	358
Accrued expenses	877	605
Other accounts payable	227	193
Total current liabilities	1,332	1,156
Long-Term Liabilities:		
Warrants issued to investors	655	-
Total long-term liabilities	655	-
Total liabilities	1,987	1,156

Stockholders' Equity:		
Stock capital: (Note 8)	8	7
Common stock $0.00005 par value - Authorized: 800,000,000 shares at December 31, 2013 and December 31, 2012; Issued and outstanding: 176,263,587 and 150,085,035 shares, respectively.		
Additional paid-in-capital	55,138	51,483
Deficit accumulated during the development stage	(52,407)	(47,508)
Total stockholders' equity	2,739	3,982
Total liabilities and stockholders' Equity	4,726	5,138

The accompanying notes are an integral part of the consolidated financial statements.

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands

(Except share data)

	Year ended December 31,		Period from September 22, 2000 (inception date) through December 31, 2013(*)
	2013	2012	
	U.S. $ in thousands		
Operating costs and expenses:			
Research and development, net (Note 9)	2,917	1,770	29,106
General and administrative	2,101	1,748	20,852
Total operating costs and expenses	5,018	3,518	49,958
Financial expense (income), net	(144)	(93)	2,310
Other income	-	-	(132)
Operating loss	4,874	3,425	52,136
Taxes on income (Note 10)	25	5	107
Loss from continuing operations	4,899	3,430	52,243
Net loss from discontinued operations	-	-	164
Net loss	4,899	3,430	52,407
Basic and diluted net loss per share from continuing operations	0.03	0.02	-
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	161,071,968	137,596,391	-

(*) Out of which, $163, relating to the period from inception to March 31 2004, is unaudited.

The accompanying notes are an integral part of the consolidated financial statements

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity (deficiency)
	Number	Amount				
Balance as of September 22, 2000 (date of inception) (unaudited)	-	$ -	$ -	$ -	$ -	$ -
Stock issued on September 22, 2000 for cash at $0.00188 per share	8,500,000	1	16	-	-	17
Stock issued on June 30, 2001 for cash at $0.0375 per share	1,600,000	*	60	-	-	60
Contribution of capital	-	-	8	-	-	8
Net loss	-	-	-	-	(17)	(17)
Balance as of March 31, 2001 (unaudited)	10,100,000	$ 1	$ 84	$ -	$ (17)	$ 68
Contribution of capital	-	-	11	-	-	11
Net loss	-	-	-	-	(26)	(26)
Balance as of March 31, 2002 (unaudited)	10,100,000	$ 1	$ 95	$ -	$ (43)	$ 53
Contribution of capital	-	-	15	-	-	15
Net loss	-	-	-	-	(47)	(47)
Balance as of March 31, 2003 (unaudited)	10,100,000	$ 1	$ 110	$ -	$ (90)	$ 21
2-for-1 stock split	10,100,000	*	-	-	-	-
Stock issued on August 31, 2003 to purchase mineral option at $0.065	100,000	*	6	-	-	6

per share						
Cancellation of shares granted to Company's President	(10,062,000)	*	*	-	-	-
Contribution of capital	-	*	15	-	-	15
Net loss	-	-	-	-	(73)	(73)
Balance as of March 31, 2004 (unaudited)	10,238,000	$ 1	$ 131	$ -	$ (163)	$ (31)

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	Deferred Stock - based	Deficit accumulated during the development	Total stockholders' equity
	Number	Amount	capital	compensation	stage	(deficiency)
Balance as of March 31, 2004	10,238,000	$ 1	$ 131	$ -	$ (163)	$ (31)
Stock issued on June 24, 2004 for private placement at $0.01 per share, net of $25,000 issuance expenses	8,510,000	*	60	-	-	60
Contribution capital	-	-	7	-	-	7
Stock issued in 2004 for private placement at $0.75 per unit	1,894,808	*	1,418	-	-	1,418
Cancellation of shares granted to service providers	(1,800,000)	*		-	-	-
Deferred stock-based compensation related to options granted to employees	-	-	5,979	(5,979)	-	-
Amortization of deferred stock- based compensation related to shares and options granted to employees	-	-	-	584	-	584
Compensation related to shares and options granted to service providers	2,025,000	*	17,506	-	-	17,506
Net loss	-	-	-	-	(18,840)	(18,840)
	20,867,808	$ 1	$ 25,101	$ (5,395)	$ (19,003)	$ 704

Balance as of March 31,
2005

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDER' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	Deferred Stock - based	Deficit accumulated during the development	Total stockholders' equity
	Number	Amount	capital	compensation	stage	(deficiency)
Balance as of March 31, 2005	20,867,808	$ 1	$ 25,101	$ (5,395)	$ (19,003)	$ 704
Stock issued on May 12, 2005 for private placement at $0.80 per share	186,875	*	149	-	-	149
Stock issued on July 27, 2005 for private placement at $0.60 per share	165,000	*	99	-	-	99
Stock issued on September 30, 2005 for private placement at $0.80 per share	312,500	*	225	-	-	225
Stock issued on December 7, 2005 for private placement at $0.80 per share	187,500	*	135	-	-	135
Forfeiture of options granted to employees	-	-	(3,363)	3,363	-	-
Deferred stock-based compensation related to shares and options granted to directors and employees	200,000	*	486	(486)	-	-
Amortization of deferred stock- based compensation related to options and shares granted to employees and directors	-	-	51	1,123	-	1,174
Stock-based compensation related to options and shares	934,904	*	662	-	-	662

granted to service providers						
Reclassification due to application of ASC 815-40-25 (formerly EITF 00-19)	-	-	(7,906)			(7,906)
Beneficial conversion feature related to a convertible bridge loan	-	-	164	-	-	164
Net loss	-	-	-	-	(3,317)	(3,317)
Balance as of March 31, 2006	22,854,587	$ 1	$ 15,803	$ (1,395)	$ (22,320)	$ (7,911)

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity (deficiency)
	Number	Amount				
Balance as of March 31, 2006	22,854,587	$ 1	$ 15,803	$ (1,395)	$ (22,320)	$ (7,911)
Elimination of deferred stock compensation due to implementation of ASC 718-10 (formerly SFAS 123(R))	-	-	(1,395)	1,395	-	-
Stock-based compensation related to shares and options granted to directors and employees	200,000	*	1,168	-	-	1,168
Reclassification due to application of ASC 815-40-25 (formerly EITF 00-19)	-	-	7,191	-	-	7,191
Stock-based compensation related to options and shares granted to service providers	1,147,225	-	453	-	-	453
Warrants issued to convertible note holder	-	-	11	-	-	11
Warrants issued to loan holder	-	-	110	-	-	110
Beneficial conversion feature related to convertible bridge loans	-	-	1,086	-	-	1,086
Net loss	-	-	-	-	(3,924)	(3,924)
Balance as of December 31, 2006	24,201,812	$ 1	$ 24,427	$ -	$ (26,244)	$ (1,816)

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock Number	Common stock Amount	Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity (deficiency)
Balance as of December 31, 2006	24,201,812	$ 1	$ 24,427	$ -	$ (26,244)	$ (1,816)
Stock-based compensation related to options and shares granted to service providers	544,095		1,446	-	-	1,446
Warrants issued to convertible note holder	-	-	109	-	-	109
Stock-based compensation related to shares and options granted to directors and employees	200,000	*	1,232	-	-	1,232
Beneficial conversion feature related to convertible loans	-	-	407	-	-	407
Conversion of convertible loans	725,881	*	224	-	-	224
Exercise of warrants	3,832,621	*	214	-	-	214
Stock issued for private placement at $0.1818 per unit, net of finder's fee	11,500,000	1	1,999	-	-	2,000
Net loss	-	-	-	-	(6,244)	(6,244)
Balance as of December 31, 2007	41,004,409	$ 2	$ 30,058	$ -	$ (32,488)	$ (2,428)

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	Deferred Stock - based	Deficit accumulated during the development	Total stockholders' equity
	Number	Amount	capital	compensation	stage	(deficiency)
Balance as of December 31, 2007	41,004,409	$ 2	$ 30,058	$ -	$ (32,488)	$ (2,428)
Stock-based compensation related to options and stock granted to service providers	90,000	-	33	-	-	33
Stock-based compensation related to stock and options granted to directors and employees	-	-	731	-	-	731
Conversion of convertible loans	3,644,610	*	1,276	-	-	1,276
Exercise of warrants	1,860,000	*	-	-	-	-
Exercise of options	17,399	*	3	-	-	3
Stock issued for private placement at $0.1818 per unit, net of finder's fee	8,625,000	1	1,499	-	-	1,500
Subscription of shares for private placement at $0.1818 per unit	-	-	281	-	-	281
Net loss	-	-	-	-	(3,472)	(3,472)
Balance as of December 31, 2008	55,241,418	$ 3	$ 33,881	$ -	$ (35,960)	$ (2,076)

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock Number	Common stock Amount	Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity (deficiency)
Balance as of December 31, 2008	55,241,418	$ 3	$ 33,881	$ -	$ (35,960)	$ (2,076)
Stock-based compensation related to options and stock granted to service providers	5,284,284	*	775	-		775
Stock-based compensation related to stock and options granted to directors and employees	-	-	409	-		409
Conversion of convertible loans	2,500,000	*	200	-		200
Exercise of warrants	3,366,783	*	-	-		-
Stock issued for amendment of private placement	9,916,667	1	-	-		1
Subscription of shares	-	-	729	-		729
Net loss	-	-	-	-	(1,781)	(1,781)
Balance as of December 31, 2009	76,309,152	$ 4	$ 35,994	$ -	$ (37,741)	$ (1,743)

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	Deferred Stock - based	Deficit accumulated during the development	Total stockholders' equity
	Number	Amount	capital	compensation	stage	(deficiency)
Balance as of December 31, 2009	76,309,152	$ 4	$ 35,994	$ -	$ (37,741)	$ (1,743)
Stock-based compensation related to options and stock granted to service providers	443,333	*	96	-	-	96
Stock-based compensation related to stock and options granted to directors and employees	466,667	*	388	-	-	388
Stock issued for amendment of private placement	7,250,000	1	1,750	-	-	1,751
Conversion of convertible note	402,385	*	135	-	-	135
Conversion of convertible loans	1,016,109	*	189	-	-	189
Issuance of shares	2,475,000		400			400
Exercise of options	1,540,885	*	77	-	-	77
Exercise of warrants	3,929,446	*	11	-	-	11
Subscription of shares for private placement at $0.12 per unit			455	-	-	455
Conversion of trade payable to stock			201			201
Issuance of shares on account of previously subscribed shares	2,000,001	*	-	-	-	-
Net loss					(2,419)	(2,419)
	95,832,978	$ 5	$ 39,696	$ -	$ (40,160)	$ (459)

Balance as of December 31,
2010

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity (deficiency)
	Number	Amount				
Balance as of December 31, 2010	95,832,978	$ 5	$ 39,696	$ -	$ (40,160)	$ (459)
Stock-based compensation related to options and stock granted to service providers	474,203	-	449	-	-	449
Stock-based compensation related to stock and options granted to directors and employees	2,025,040	-	1,135	-	-	1,135
Conversion of convertible note	755,594	-	140	-	-	140
Exercise of options	1,648,728	-	243	-	-	243
Exercise of warrants	1,046,834	-	272	-	-	272
Issuance of shares for private placement	14,160,933	1	3,601	-	-	3,602
Issuance of shares on account of previously subscribed shares	10,499,999	-	24	-	-	24
Net loss	-	-	-	-	(3,918)	(3,918)
Balance as of December 31, 2011	126,444,309	$ 6	$ 45,560	$ -	$ (44,078)	$ 1,488

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

<u>STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)</u>

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	Deferred Stock - based	Deficit accumulated during the development	Total stockholders'
	Number	Amount	capital	compensation	stage	equity
Balance as of December 31, 2011	126,444,309	$ 6	$ 45,560	$ -	$ (44,078)	$ 1,488
Stock-based compensation related to options and stock granted to service providers	794,423		195	-	-	195
Stock-based compensation related to stock and options granted to directors and employees	885,000		560	-	-	560
Exercise of options	1,182,606	(*)	137	-	-	137
Exercise of warrants	959,729	(*)	9	-	-	9
Issuance of shares for private placement	19,818,968	1	5,022		-	5,023
Net loss	-	-	-	-	(3,430)	(3,430)
Balance as of December 31, 2012	150,085,035	$ 7	$ 51,483	$ -	$ (47,508)	$ 3,982

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

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STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	Deferred Stock - based	Deficit accumulated during the development	Total stockholders'
	Number	Amount	capital	compensation	stage	equity
Balance as of December 31, 2012	150,085,035	$ 7	$ 51,483	$ -	$ (47,508)	$ 3,982
Stock-based compensation related to options and stock granted to service providers	809,696		197	-	-	197
Stock-based compensation related to stock and options granted to directors and employees	760,000		674	-	-	674
Issuance of shares for public offering	23,529,411	1	2,496	-	-	2,497
Issuance of shares for private placement	833,334	(*)	250	-	-	250
Conversion of convertible loans	126,111	-	30	-	-	30
Exercise of options	120,000	(*)	8	-	-	8
Net loss	-	-	-	-	(4,899)	(4,899)
Balance as of December 31, 2013	176,263,587	$ 8	$ 55,138	-	$ (52,407)	$ 2,739

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31, 2013	Year ended December 31, 2012	Period from September 22, 2000 (inception date) through December 31, 2013*)
	U.S. $ in thousands		
Cash flows from operating activities:			
Net loss	$(4,899)	$(3,430)	$ (52,407)
Less - loss for the period from discontinued operations	-	-	164
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of deferred charges	97	157	1,255
Accrued interest on loans	-	-	451
Amortization of discount on short-term loans	-	-	1,864
Change in fair value of options and warrants	-	-	(795)
Expenses related to shares and options granted to service providers	227	195	21,908
Stock-based compensation related to options granted to employees	674	560	8,055
Increase in accounts receivable and prepaid expenses	(155)	(426)	(943)
Increase (decrease) in trade payables and convertible note	(130)	114	701
Increase (decrease) in other accounts payable and accrued expenses	306	(105)	1,610
Revaluation of warrants	(174)	-	(174)
Erosion of restricted cash	-	-	(6)
Net cash used in continuing operating activities	(4,054)	(2,935)	(18,317)
Net cash used in discontinued operating activities	-	-	(23)
Total net cash used in operating activities	(4,054)	(2,935)	(18,340)
Cash flows from investing activities:			
Purchase of property and equipment	(108)	(90)	(1,331)
Restricted cash	-	-	6
Changes in short-term deposit	2,769	(2,750)	-
Investment in lease deposit	(5)	-	(22)

Net cash provided by (used in) continuing investing activities	2,656	(2,840)	(1,347)
Net cash used in discontinued investing activities	-	-	(16)
Total net cash provided by (used in) investing activities	2,656	(2,840)	(1,363)
Cash flows from financing activities:			
Proceeds from issuance of Common stock and warrants, net	3,576	5,023	20,918
Proceeds from loans, notes and issuance of warrants, net	-		2,061
Proceeds from exercise of warrants and options	8	146	785
Repayment of short-term loans	-	-	(601)
Net cash provided by continuing financing activities	3,584	5,169	23,163
Net cash provided by discontinued financing activities	-	-	43
Total net cash provided by financing activities	3,584	5,169	23,206
Increase (decrease) in cash and cash equivalents	2,186	(606)	3,503
Cash and cash equivalents at the beginning of the period	1,317	1,923	-
Cash and cash equivalents at end of the period	$3,503	$1,317	$ 3,503

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 1 - GENERAL:

A. Brainstorm Cell Therapeutics Inc. (formerly: Golden Hand Resources Inc. - the "Company") was incorporated in the State of Washington on September 22, 2000.

B. On May 21, 2004, the former major stockholders of the Company entered into a purchase agreement with a group of private investors, who purchased from the former major stockholders 6,880,000 shares of the then issued and outstanding 10,238,000 shares of Common Stock.

C. On July 8, 2004, the Company entered into a licensing agreement with Ramot of Tel Aviv University Ltd. ("Ramot"), to acquire certain stem cell technology (see Note 3). Subsequent to this agreement, the Company decided to focus on the development of novel cell therapies for neurodegenerative diseases based on the acquired technology and research to be conducted and funded by the Company.

Following the licensing agreement dated July 8, 2004, the management of the Company decided to abandon all old activities related to the sale of the digital data recorder product. The discontinuation of this activity was accounted for under the provision of Statement of Financial Accounting Standard ASC 360-10, "Accounting for the Impairment or Disposal of Long-Lived Assets".

D. On October 25, 2004, the Company formed a wholly-owned subsidiary in Israel, Brainstorm Cell Therapeutics Ltd. ("BCT").

E. On November 22, 2004, the Company changed its name from Golden Hand Resources Inc. to Brainstorm Cell Therapeutics Inc. to better reflect its new line of business in the development of novel cell therapies for neurodegenerative diseases. BCT owns all operational property and equipment.

The Common Stock is registered and publicly traded on the OTC Markets Group service of the National Association of Securities Dealers, Inc. under the symbol BCLI.

F. On September 17, 2006, the Company changed the Company's fiscal year-end from March 31 to December 31.

G. In December 2006, the Company changed its state of incorporation from Washington to Delaware.

H. Since its inception, the Company has devoted substantially all of its efforts to research and development, recruiting management and technical staff, acquiring assets and raising capital. In addition, the Company has not generated revenues.

Accordingly, the Company is considered to be in the development stage, as defined in "Accounting and reporting by development Stage Enterprises" ASC 915-10.

I. In October 2010, the Israeli Ministry of Health ("MOH") granted clearance for a Phase I/II clinical trial using the Company's autologous NurOwn™ stem cell therapy in patients with amyotrophic lateral sclerosis (**"**ALS"), subject to some additional process specifications as well as completion of the sterility validation study for tests performed.

On February 23, 2011, the Company submitted, to the MOH, all the required documents. Following approval of the MOH, a Phase I/II clinical study for ALS patients using the Company's autologous NurOwn™ stem cell therapy (the "Clinical Trial") was initiated in June 2011.

J. In February 2011, the U.S. Food and Drug Administration ("FDA") granted orphan drug designation to the Company's NurOwn™ autologous adult stem cell product for the treatment of ALS.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 1 - GENERAL (Cont.):

K. On February 19, 2013, Brainstorm Ltd established a wholly-owned subsidiary, Brainstorm Cell Therapeutics UK Ltd. ("Brainstorm UK"). Brainstorm UK will act on behalf of the parent Company in the EU.

L. On February 21, 2013, Brainstorm UK filed a request for Orphan Medicinal Product Designation by the European Medicine Agency (EMA) for its Autologous Bone Marrow derived Mesenchymal Stromal cells Secreting Neurotropic factors (MSC-NTF, NurOwn).

M. On April 8, 2013, the Company entered into an agreement with Dana-Farber Cancer Institute ("Dana-Farber") to provide cGMP-compliant clean room facilities for production of the Company's NurOwn™ stem cell candidate during its upcoming Phase II ALS trial in the United States. The Company's Phase II trial, will be conducted at Massachusetts General Hospital ("MGH"), the University of Massachusetts ("UMass") Hospital and the Mayo Clinic. The Connell and O'Reilly Cell Manipulation Core Facility at Dana-Farber will produce NurOwn for the MGH and UMass Hospital clinical sites.

N. On April 18, 2013, the stockholders of the Company authorized the Board of Directors of the Company, in its discretion, should it deem it to be appropriate and in the best interests of the Company and its stockholders, to amend the Company's Certificate of Incorporation to effect a reverse stock split of the Company's issued and outstanding shares of common stock by a ratio of between 1-for-10 and 1-for-20, inclusive, without further approval or authorization of the Company's stockholders. As of December 31, 2013 a reverse stock split of the Company's shares wasn't performed.

O. On July 17, 2013, the European Commission granted Orphan Drug Designation to the Company's NurOwn autologous adult stem cell product for the treatment of ALS.

P. On September 27, 2013, the Company announced that it recently completed treatment of the 12 patients in its ALS Phase IIa dose-escalating clinical trial with the Company's NurOwn™ technology. The Company was informed that one patient in the study expired due to a medical condition unrelated to the Clinical Trial.

The Clinical Trial is being performed at Hadassah Medical Center in Jerusalem, Israel, under the direction of Prof. Dimitrios Karussis, M.D., Ph.D., head of Hadassah's Multiple Sclerosis Center and a member of the International Steering Committees for Bone Marrow and Mesenchymal Stem Cells Transplantation in Multiple Sclerosis (MS). The study is designed to establish the safety and preliminary efficacy of NurOwn at increasing dosages.

Q. In November 2013, the Company signed a definitive agreement with the Mayo Clinic in Rochester, Minnesota to conduct its Phase II clinical trial of NurOwn™ in amyotrophic lateral sclerosis (ALS), pending FDA approval. In addition, Mayo's Human Cell Therapy Laboratory will manufacture the NurOwn cells for their clinical trial participants.

R. On December 4, 2013, a Notice of Intention to Grant from the European Patent Office (EPO) was issued for the Company's patent application entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases" (European serial number EP06766101.7) . This patent relates to the production method for the company's proprietary stem cells induced to secrete large quantities of neurotrophic factors for the treatment of neurodegenerative diseases.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 1 - GENERAL (Cont.):

S. On December 9, 2013, a Notice of Allowance was issued from the U.S. Patent Office for the same patent application as above, U.S. serial number 11/727,583.

T. In March 2014, the Company signed a definitive agreement with the Massachusetts General Hospital (MGH) in Boston, MA to conduct a Phase II clinical trial of NurOwn™ in amyotrophic lateral sclerosis (ALS), pending FDA approval.

GOING CONCERN:

As reflected in the accompanying financial statements, the Company’s operations for the year ended December 31, 2013, resulted in a net loss of $5,073. The Company’s balance sheet reflects an accumulated deficit of $52,581. These conditions, together with the fact that the Company is a development stage Company and has no revenues nor are revenues expected in the near future, raise substantial doubt about the Company's ability to continue to operate as a going concern. The Company’s ability to continue operating as a “going concern” is dependent on several factors, among them is its ability to raise sufficient additional working capital.

In 2009, the Company decided to focus only on the effort to commence clinical trials for ALS and such trials did commence in 2011.

In July 2012, the Company raised $5.7 million, gross, in a public offering (See Note 8B 1 (i)). In August 2013, the Company raised $4 million, gross, in a public offering (See Note 8B 1 (j)). However, there can be no assurance that additional funds will be available on terms acceptable to the Company, or at all.

These financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

A. Basis of presentation:

The consolidated financial statements have been prepared in accordance with United States Generally Accepted Accounting Principles ("GAAP") applied on a consistent basis.

B. Use of estimates:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

C. Financial statement in U.S. dollars:

The functional currency of the Company is the U.S dollar ("dollar") since the dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future. Part of the transactions of BCT is recorded in new Israeli shekels ("NIS"); however, a substantial portion of BCT's costs are incurred in dollars or linked to the dollar. Accordingly, management has designated the dollar as the currency of BCT's primary economic environment and thus it is their functional and reporting currency.

Transactions and balances denominated in dollars are presented at their original amounts. Non-dollar transactions and balances have been re-measured to dollars in accordance with the provisions of ASC 830-10 (formerly Statement of Financial Accounting Standard 52), "Foreign Currency Translation". All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statement of operations as financial income or expenses, as appropriate.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.):

D. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, BCT and Brainstorm UK**.** Intercompany balances and transactions have been eliminated upon consolidation.

E. Cash and cash equivalents:

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with maturities of three months or less as of the date acquired.

F. Property and equipment:

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated by the straight-line method over the estimated useful lives of the assets.

The annual depreciation rates are as follows:

%

Office furniture and equipment	7
Computer software and electronic equipment	33
Laboratory equipment	15
Leasehold improvements	Over the shorter of the lease term (including the option) or useful life

G. Impairment of long-lived assets:

The Company’s and BCT’s long-lived assets are reviewed for impairment in accordance with ASC 360-10 (formerly Statement of Financial Accounting Standard 144), "Accounting for the Impairment or Disposal of Long-Lived Assets,” whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds their fair value. During 2012 and 2013, no impairment losses were identified.

H. Accrued post-employment benefit:

The majority of the Company's employees in Israel have agreed to Section 14 of Israel's Severance Pay Law, 5723-1963 (“Section 14”). Pursuant to Section 14, those of the Company's employees that are covered by this section are entitled only to an amount of severance pay equal to monthly deposits, at a rate of 8.33% of their monthly salary, made on their behalf by the Company. Payments in accordance with Section 14 release the Company from any future severance liabilities in respect of those employees. Neither severance pay liability nor severance pay funds under Section 14 for such employees is recorded on the Company's balance sheet.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.):

I. Fair value of financial instruments:

The carrying values of cash and cash equivalents, accounts receivable and prepaid expenses, trade payables and other accounts payable approximate their fair value due to the short-term maturity of these instruments.

The Company utilized the Black Scholes Merton formula to measure the fair value of the warrants issued in the 2013 public offering (refer to note B.1.(J)). The assumptions included in the Black-Scholes model were: (i) the market price of the Company's shares; (ii) the exercise price of the warrant; (iii) risk-free interest; (iv) term available to exercise or redeem the security and (v) the volatility of the share during the relevant term. The Company determines the volatility of its share using daily historical quotes of the share. The risk free interest rate is determined as the interest rate on governmental bonds with maturity commensurate with the term of the warrant.

J. Accounting for stock-based compensation:

Effective April 1, 2006, the Company adopted ASC 718-10 (formerly Statement of Financial Accounting Standards 123 (Revised 2004)), "Share-Based Payment," which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options under the Company's stock plans based on estimated fair values. ASC 718-10 supersedes the Company's previous accounting under Accounting Principles Board Opinion 25, "Accounting for Stock Issued to Employees" ("APB 25"). In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin 107 ("SAB 107") relating to ASC 718-10. The Company has applied the provisions of SAB 107 in its adoption of ASC 718-10.

ASC 718-10 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's consolidated statement of operations.

The Company recognizes compensation expense for the value of non-employee awards, which have graded vesting, based on the accelerated attribution method over the requisite service period of each award, net of estimated forfeitures.

The Company recognizes compensation expense for the value of employee awards that have graded vesting, based on the straight-line method over the requisite service period of each of the awards, net of estimated forfeitures.

J. Accounting for stock-based compensation (Cont.):

The Company estimates the fair value of restricted shares based on the market price of the shares at the grant date and estimates the fair value of stock options granted using a Black-Scholes options pricing model. The option-pricing model requires a number of assumptions, of which the most significant are, expected stock price volatility and the expected option term (the time from the grant date until the options are exercised or expire). Expected volatility was calculated based upon actual historical stock price movements over the period, equal to the expected option term. The expected option term was calculated for options granted to employees and directors in accordance with SAB 107 and SAB 110, using the "simplified" method. Grants to non-employees are based on the contractual term. The Company has historically not paid dividends and has no foreseeable plans to issue dividends. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent term.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.):

K. Basic and diluted net loss per share:

Basic net loss per share is computed based on the weighted average number of shares outstanding during each year. Diluted net loss per share is computed based on the weighted average number of shares outstanding during each year, plus the dilutive potential of the Common Stock considered outstanding during the year, in accordance with ASC 260-10 (formerly Statement of Financial Accounting Standard 128), "Earnings per Share".

All outstanding stock options and warrants have been excluded from the calculation of the diluted loss per share for the year ended December 31, 2013 and December 31, 2012, since all such securities have an anti-dilutive effect.

L. Research and development expenses, net:

Research and development expenses, are charged to the statement of operations as incurred.

Royalty-bearing grants from the Government of Israel for funding approved research and development projects are recognized at the time the Company is entitled to such grants, on the basis of the costs incurred and applied as a deduction from research and development expenses. Such grants are included as a deduction of research and development costs since at the time received it is not probable the Company will generate sales from these projects and pay the royalties resulting from such sales.

M. Income taxes:

The Company and BCT account for income taxes in accordance with ASC 740-10 (formerly Statement of Financial Accounting Standard 109), "Accounting for Income Taxes." This Statement requires the use of the liability method of accounting for income taxes, whereby deferred tax asset and liability account balances are determined based on the differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company and BCT provide a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value.

In September 2006, the Financial Accounting Standards Board ("FASB") issued ASC 740-10 (formerly FASB interpretation ("FIN") 48), "Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement 109". ASC 740-10 establishes a single model to address accounting for uncertain tax positions. ASC 740-10 clarified the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. ASC 740-10 also provides guidance on recognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of the provisions of ASC 740-10 did not have an impact on the Company's consolidated financial position and results of operations.

NOTE 3 - RESEARCH AND LICENSE AGREEMENT

The Company has a Research and License Agreement, as amended and restated, with Ramot. The Company obtained a waiver and release from Ramot pursuant to which Ramot agreed to an amended payment schedule regarding the Company's payment obligations under the Research and License Agreement and waived all claims against the Company resulting from the Company's previous defaults and non-payment under the Research and License Agreement. The waiver and release amended and restated the original payment schedule under the original agreement providing for payments during the initial research period and additional payments for any extended research period.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 3 - RESEARCH AND LICENSE AGREEMENT (Cont.):

The Company is to pay Ramot royalties on Net Sales on a Licensed Product by Licensed Product and jurisdiction by jurisdiction basis as follow:

a) So long as the making, producing, manufacturing, using, marketing, selling, importing or exporting of such Licensed Product is covered by a Valid Claim or is covered by Orphan Drug Status in such jurisdiction – 5% of all Net Sales.

b) In the event the making, producing, manufacturing, using, marketing, selling, importing or exporting of such Licensed Product is not covered by a Valid Claim and not covered by Orphan Drug status in such jurisdiction – 3% of all Net Sales until the expiration of 15 years from the date of the First Commercial Sale of such Licensed Product in such jurisdiction.

NOTE 4 - CONSULTING AGREEMENTS

A. On July 8, 2004, the Company entered into two consulting agreements with Prof. Eldad Melamed and Dr. Daniel Offen (together, the "Consultants"), under which the Consultants provide the Company scientific and medical consulting services in consideration for a monthly payment of $6 each. In addition, the Company granted each of the Consultants, a fully vested warrant to purchase 1,097,215 shares of Common Stock at an exercise price of $0.01 per share. The warrants issued pursuant to the agreement were issued to the Consultants effective as of November 4, 2004. Each of the warrants is exercisable for a seven-year period beginning on November 4, 2005. As of September 2010, all the above warrants had been exercised. In June 2012 an amendment was signed with Dr. Daniel Offen, according to which the company will pay Daniel Offen a monthly payment of $6, out of which $3 in cash and $3 by grant of Company stock.

B. On December 16, 2010, the Company approved a grant of 1,100,000 shares of the Company's Common Stock to the two Consultants, for services rendered through December 31, 2010. Related compensation in the amount of $220 was recorded as research and development expense. A sum of $487 was cancelled concurrently with the issuance of the 1,100,000 shares of Common Stock of the Company.

C. On June 27, 2011, the Company approved an additional grant of 400,000 shares of the Company's Common Stock to Prof. Daniel Offen, for services rendered through December 31, 2009. Related compensation in the amount of $192 is recorded as research and development expense.

D. On August 1, 2012, the Company approved an additional grant of 623,077 shares of the Company's Common Stock to the Consultants, for services rendered during January 1, 2011 through June 30, 2012. Related compensation in the amount of $162 was recorded as research and development expense.

E. On January 16, 2013, the Company granted the Consultants an aggregate of 216,000 shares of Common Stock for their services from January 1, 2012 through December 31, 2012. Related compensation in the amount of $54 was recorded as research and development expense.

F. On November 13, 2013, the Company approved a grant of 450,000 shares of the Company's Common Stock to the Consultants, for services rendered during January 1, 2013 through September 30, 2013.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 5 - ACCOUNTS RECEIVABLE

	December 31, 2013	December 31, 2012
	U.S. $ in thousands	
Government institutions	60	108
Grants receivable from the CSO	850	634
	910	742

NOTE 6 - PROPERTY AND EQUIPMENT

	December 31, 2013	December 31, 2012
	U.S. $ in thousands	
Cost:		
Office furniture and equipment	18	9
Computer software and electronic equipment	149	120
Laboratory equipment	482	437
Leasehold improvements	716	690
	1,365	1,256
Accumulated depreciation:		
Office furniture and equipment	5	4
Computer software and electronic equipment	116	106
Laboratory equipment	350	306
Leasehold improvements	636	593
	1,107	1,009
Depreciated cost	258	247

Depreciation expenses for the year ended December 31, 2013 and December 31, 2012 were $97, and $157, respectively.

NOTE 7 - COMMITMENTS AND CONTINGENCIES

A. On November, 2012, BCT entered into an amended lease agreement for the lease of its facilities. The term of the lease is 60 months, with an option to terminate the agreement with 6 month pre-notice, after 36 months. Rent is paid on a monthly basis in the amount of NIS 40,000 (approximately $11) per month.

The facilities and vehicles of the Company and BCT are rented under operating leases that expire on various dates. Aggregate minimum rental commitments under non-cancelable leases as of December 31, 2013 are as follows:

Period ending December 31, 2013	Facilities	Vehicles	Total
2014	121	5	126
2015	121	-	121
2016	90	-	90
	332	5	337

Total facilities rent expenses for the year ended December 31, 2013 and 2012 were $129 and $106, respectively.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 7 - COMMITMENTS AND CONTINGENCIES (Cont.):

B. Commitments to pay royalties to the Chief Scientist:

BCT obtained from the Chief Scientist of the State of Israel grants for participation in research and development for the years 2007 through 2013, and, in return, BCT is obligated to pay royalties amounting to 3%-3.5% of its future sales up to the amount of the grant. The grant is linked to the exchange rate of the dollar and bears interest of Libor per annum.

Through the year ended December 31, 2013, total grants obtained amounted to $942**.** After balance sheet date 2014 the Company received approximately $380.

C. On February 17, 2010, BCT entered into an agreement with Hadasit Medical Research Services and Development Ltd ("Hadasit") to conduct clinical trials in ALS patients. The agreement was revised in June 2011 according to which, in connection with the trials BCT will pay Hadasit $32 per patient totaling up to $773, as well as $65 per month for rental and operation of two clean rooms. The Company has the right to cease the rental of the clean rooms at any time upon 30 days prior notice.

D. In April 2008, Chapman, Spira & Carson, LLC (“CSC”) filed a breach of contract complaint in the Supreme Court of the State of New York (the “Court”) against the Company. The complaint alleges that the Company improperly terminated its contract with CSC. The complaint seeks, among other things, the following relief: (i) 400,000 shares of the common stock of the Company and (ii) warrants to purchase 250,000 shares of the common stock of the Company at an exercise price of $0.30 per share. Further, the complaint alleges that CSC performed its obligations under the contract and has suffered compensatory damages in an amount up to approximately $672. CSC also seeks costs and attorneys’ fees.

On October 24, 2012, the Company reached an understanding with CSC according to which the Company paid CSC $125 in full satisfaction of CSC's claims against the Company.

NOTE 8 - STOCK CAPITAL

A. The rights of Common Stock are as follows:

Holders of Common Stock have the right to receive notice to participate and vote in general meetings of the Company, the right to a share in the excess of assets upon liquidation of the Company and the right to receive dividends, if declared.

The Common Stock is registered and publicly traded on the OTC Markets Group service of the National Association of Securities Dealers, Inc. under the symbol BCLI.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares warrants and options:

1. Private placements and public offering:

(a) During 2004 and 2005 the Company issued, in separate transactions, 8,861,875 shares of Common Stock of the Company for total proceeds of $308

(b) On February 23, 2005, the Company completed a private placement for sale of 1,894,808 units for total proceeds of $1,418. Each unit consisted of one share of Common Stock and a three-year warrant to purchase one share of Common Stock at $2.50 per share. This private placement was consummated in three tranches which closed in October 2004, November 2004 and February 2005. All warrants are no longer valid.

(c) On August 11, 2005, the Company signed a private placement agreement with investors for the sale of up to 1,250,000 units at a price of $0.80 per unit. Each unit consisted of one share of Common Stock and one warrant to purchase one share of Common Stock at $1.00 per share. The warrants were exercisable for a period of three years from issuance. On September 30, 2005, the Company sold 312,500 units for total net proceeds of $225. On December 7, 2005, the Company sold 187,500 units for total net proceeds of $135. All warrants are no longer valid.

(d) In July 2007, the Company entered into an investment agreement, that was amended in August 2009, according to which for an aggregate subscription price of up to $5 million, the Company issued 41,666,667 shares of Common Stock and a warrant to purchase 10,083,333 shares of the Company's common stock at an exercise price of $0.20 per share and a warrant to purchase 20,166,667 shares of common stock at an exercise price of $0.29 per share. The warrants may be exercised at any time and expire on November 5, 2013. . In May 2012 the warrants were extended by additional 18 months, through May 5, 2015.

In January 2011, the Company and an investor signed an agreement to balance the remaining amount due to the investor, totaling $20, against the remaining balance of the investment and the Company issued the above shares and warrants.

In addition, the Company issued an aggregate of 1,250,000 shares of Common Stock to a related party as an introduction fee for the investment. As of balance sheet date no warrants have been exercised.

(e) In January 2010, the Company issued 1,250,000 units to a private investor for total proceeds of $250. Each unit consisted of one share of Common Stock and a two-year warrant to purchase one share of Common Stock at $0.50 per share. All warrants are no longer valid.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

1. Private placements and public offering: (Cont.):

(f) In February 2010, the Company issued 6,000,000 shares of Common Stock to three investors (2,000,000 to each investor) and warrants to purchase an aggregate of 3,000,000 shares of Common Stock (1,000,000 to each investor) with an exercise price of $0.50 for aggregate proceeds of $1,500 ($500 each).

(g) In February 2011, the Company issued 833,333 shares of Common Stock, at a price of $0.30 per share, and a warrant to purchase 641,026 shares of the Company's Common Stock at an exercise price of $0.39 per share exercisable for one year for total proceeds of $250. The warrants are no longer valid.

(h) On February 23, 2011, the Company entered into an investment agreement, pursuant to which the Company agreed to sell up to 12,815,000 shares of Common Stock, for an aggregate subscription price of up to $3.6 million and warrants to purchase up to 19,222,500 shares of Common Stock as follows: warrant to purchase 12,815,000 shares of Common Stock at $0.5 for two years, and warrants to purchase 6,407,500 shares of Common Stock at $0.28 for one year, out of which 946,834 were exercised, and 5,460,666 were cancelled.

In addition, the Company agreed to pay 10% of the funds received for the distribution services received, out of this amount, 4% was be paid in stock and the remaining 6% in cash. Accordingly, in March 2011, the Company issued 512,600 shares of Common Stock and paid $231.

I) On July 17, 2012, the Company raised a $5.7 million gross proceeds through a public offering ("2012 Public Offering") of its common stock. The Company issued a total of 19,818,968 common stock of $0.00005 par value, ($0.29 per share) and 14,864,228 warrants to purchase 0.75 shares of Common Stock for every share purchased in the Public Offering, at an exercise price of $0.29 per share. The Warrants are exercisable until the 30 month anniversary of the date of issuance. After deducting closing costs and fees, the Company received net proceeds of approximately $4.9 million.

The Company paid to the Placement Agency, Maxim Group LLC (the "Placement Agent"), a cash fee and a corporate finance fee equal to 7% of the gross proceeds of the Public Offering. In addition, the Company issued to the Placement Agent a two year warrant to purchase up to 493,966 shares of Common Stock (equal to 3% of the number of shares sold in the Public Offering), with an exercise price equal to $0.348 (120% of the Public offering price). The Warrants are exercisable until the 30 month anniversary of the date of issuance. In addition, the Company issued to Leader Underwriters (1993) Ltd, warrants to purchase 232,758 shares of Common stock, at an exercise price of $0.29 per share. The warrants are exercisable until the 30 month anniversary of the date of issuance.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

1. Private placements and public offering: (Cont.):

(j) On August 16, 2013, the Company raised $4 million (gross) through a registered public offering ("2013 Public Offering") of its common stock. The Company issued a total of 23,529,411 common stock of $0.00005 par value, ($0.17 per share) and 17,647,058 warrants to purchase 0.75 shares of Common Stock for every share purchased in the Public Offering, at an exercise price of $0.25 per share. The Warrants are exercisable until the 36 month anniversary of the date of issuance. The Warrants also include, subject to certain exceptions, full ratchet anti-dilution protection in the event of the issuance of any common stock, securities convertible into common stock, or certain other issuances at a price below the then-current exercise price of the Warrants, which would result in an adjustment to the exercise price of the Warrants. In the event of a sale of the Company, each holder of Warrants has the right, exercisable at its option, to require the Company to purchase such holder's Warrants at a price determined using a Black-Scholes option pricing model as described in the Warrants. After deducting closing costs and fees, the Company received net proceeds of approximately $3.3 million. In accordance with the provisions of ASC 815 (formerly FAS 133) the proceeds related to the warrants at the amount of $829 were recorded to liabilities at the fair value of such warrants as of the date of issuance, and the proceeds related to common stocks of 2,496 were recorded to equity. As of December 31, 2013, the fair value of such warrants was presented as a liability at its fair value $655 as of such date (Also see note 2(i)).

(k) On February 7, 2013, the Company issued 833,334 units to a private investor for total proceeds of $250. Each unit consisted of one share of Common Stock and a warrant to purchase one share of Common Stock at $0.50 per share exercisable for 32 months.

On November 25, 2004, the Company's stockholders approved the 2004 Global Stock Option Plan and the Israeli Appendix thereto (which applies solely to participants who are residents of Israel) and on March 28, 2005, the Company's stockholders approved the 2005 U.S. Stock Option and Incentive Plan, and the reservation of 9,143,462 shares of Common Stock for issuance in the aggregate under these stock plans.

Each option granted under the plans is exercisable until the earlier of ten years from the date of grant of the option or the expiration dates of the respective option plans. The 2004 and 2005 options plans will expire on November 25, 2014 and March 28, 2015, respectively. The exercise price of the options granted under the plans may not be less than the nominal value of the shares into which such options are exercised. The options vest primarily over three years. Any options that are canceled or forfeited before expiration become available for future grants.

In June 2008, June 2011 and in June 2012, the Company's stockholders approved increases in the number of shares of common stock available for issuance under these stock option plans by 5,000,000, 5,000,000 and 9,000,000 shares, respectively.

From 2005 through 2009, the Company granted its directors options to purchase 800,000 (in total) shares of Common Stock of the Company at an exercise price of $0.15 per share. The options are fully vested and will expire after 10 years.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.)

2. Share-based compensation to employees and to directors:

(a) Options to employees and directors:

As of December 31, 2013, 8,310,937 options are available for future grants.

On June 22, 2006, the Company entered into an amendment to the Company's option agreement with two of its employees. The amendment changed the exercise price of 270,000 options granted to them from $0.75 to $0.15 per share. The excess of the fair value resulting from the modification, in the amount of $2, was recorded as general and administration expense over the remaining vesting period of the options.

On October 23, 2007, the Company granted to its Chief Executive Officer an option to purchase 1,000,000 shares of Common Stock at an exercise price of $0.87 per share. On November 5, 2008, the Company amended the exercise price to $0.15 per share. The option is fully vested and expires after 10 years. The total compensation related to the option is $737, which was recorded as general and administrative expense. The options were all exercised for $150.

On June 29, 2009, the Company granted to its former Chief Executive Officer and director an option to purchase 1,000,000 shares of Common Stock at an exercise price of $0.067 per share. The option vests with respect to 1/3 of the shares subject to the option on each anniversary of the date of grant and expires after 10 years. Out of which 483,333 were exercised for $32 and 516,667 were cancelled.

The total compensation related to the option is $68, which is amortized over the vesting period as general and administrative expense. In February 2011, the former CEO resigned. On July 25, 2011, the Company signed a settlement agreement with the former CEO under which 483,333 shares out of the above grant became fully vested and exercisable through April 30, 2012. An additional $30 was written as compensation in general and administrative expense. In April 2012, the former CEO exercised the option to 483,333 shares of Common Stock for an exercise price of $32.

In the year ended December 31, 2012, 1,182,606 options were exercised by the former CEO of the Company for $137.

On June 29, 2009, the Company granted to its former Chief Financial Officer an option to purchase 200,000 shares of Common Stock at an exercise price of $0.067 per share. The option vested with respect to 1/3 of the shares subject to the option. In connection with the former Chief Financial Officer’s resignation, 2/3 of the above shares were cancelled and the remaining 66,667 were exercised for $4.

On April 13, 2010, the Company, Abraham Israeli and Hadasit Medical Research Services and Development Ltd. (“Hadasit”) entered into an Agreement (the “Agreement”) pursuant to which Prof. Israeli agreed, during the term of the Agreement, to serve as (i) the Company’s Clinical Trials Advisor and (ii) a member of the Company’s Board of Directors.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

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Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

2. Share-based compensation to employees and to directors: (Cont.):

a) Options to employees and directors: (Cont.):

In consideration of the services to be provided by Prof. Israeli to the Company under the Agreement, the Company agreed to grant options annually during the term of the Agreement for the purchase of its Common Stock, as follows:

- An option for the purchase of 166,666 shares of Common Stock at an exercise price equal to $0.00005 per share to Prof. Israeli; and

- A warrant for the purchase of 33,334 shares of Common Stock at an exercise price equal to $0.00005 per share to Hadasit.

Such options will vest and become exercisable in twelve (12) consecutive equal monthly amounts.

Accordingly, the Company granted to Prof. Israeli in each of April 2010, in June 2011, in April 2012 and April 2013, an option to purchase 166,666 shares of Common Stock at an exercise price equal to $0.00005 per share.

The aggregated compensation related to such warrants recorded as of December 31, 2013 is $166 was classified as general and administrative expense.

Accordingly, the Company also granted Hadasit, in each of April 2010, in June 2011, in April 2012 and April 2013, a warrant to purchase 33,334 shares of Common Stock at an exercise price equal to $0.00005 per share. The aggregated compensation related to the options recorded as of December 31, 2013 is $31 was classified as research and development expense.

In December 2013, the Board of the Company agreed to amend the agreement with Prof. Israeli and Hadasit and the yearly grant, starting April 2014, will be 360,000 options annually out of which Prof. Israeli will receive an option to purchase 300,000 shares of Common Stock and Hadasit will receive 60,000 shares of Common Stock.

On December 16, 2010, the Company granted to two of its directors an option to purchase 400,000 shares of Common Stock at an exercise price of $0.15 per share. The options are fully vested and are exercisable for a period of 10 years. The compensation related to the option, in the amount of $78, was recorded as general and administrative expense.

On December 16, 2010, the Company approved the grant to its three Scientific Board members 300,000 shares of Common Stock of the Company. The compensation related to the option, in the amount of $60, was recorded as research and development expense.

In January 2011, the Company granted to its former CEO, an option to purchase 450,000 shares of Common Stock of the Company at $0.20. The total compensation related to the option is $177, which is amortized over the vesting period as general and administrative expense.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

2. Share-based compensation to employees and to directors: (Cont.):

a) Options to employees and directors: (Cont.)

On June 27, 2011, the Company granted to four of its directors options to purchase an aggregate of 634,999 shares of Common Stock of the Company at $0.15. The total compensation related to the option was $287, which is amortized over the vesting period as general and administrative expense.

On August 10, 2011, the Company granted to its former CEO, an option to purchase 70,000 shares of Common Stock of the Company at $0.20. The total compensation related to the option was $26, which was amortized as general and administrative expense.

On August 1, 2012, the Company granted to three of its directors options to purchase an aggregate of 460,000 shares of Common Stock of the Company at $0.15 per share. The total compensation related to the option was $105, which is amortized over the vesting period as general and administrative expense.

On August 1, 2012, the Company granted to its former CEO, an option to purchase 70,000 shares of Common Stock of the Company at $0.26 per share. The total compensation expense related to the option was $16, which was amortized as general and administrative expense.

On February 1, 2013, the Company granted its former Chief Executive Officer an option to purchase 4,000,000 shares of Common Stock at an exercise price of $0.29 per share. The option would have vested as to 1/3 of the shares subject thereto on January 24, 2014 and the remainder would have vested over the subsequent 36 consecutive months. On July 28, 2013, the former CEO informed the Company of his resignation from his position with the Company effective October 28, 2013. In connection with the former CEO's resignation on October 28, 2013, the above options were cancelled and the total compensation expense related to the option that was recorded as general and administrative expense was cancelled.

On April 19, 2013, the Company granted to three of its directors options to purchase an aggregate of 460,000 shares of Common Stock of the Company at $0.15 per share. The total compensation expense related to the options will be recorded as general and administrative expense.

As of December 31, 2013, 8,310,937 options are available for future grants.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

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Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.)

2. Share-based compensation to employees and to directors: (Cont.)

a) Options to employees and directors: (Cont.)

A summary of the Company's option activity related to options to employees and directors, and related information is as follows:

	For the year ended December 31, 2013		
	Amount of options	Weighted average exercise price $	Aggregate intrinsic value $
Outstanding at beginning of period	4,751,665	0.1803	
Granted	5,726,666	0.2492	
Exercised	(20,000)	0.0670	
Cancelled	(4,272,500)	0.2873	
Outstanding at end of period	6,185,831	0.1705	58,765
Vested and expected-to-vest at end of period	5,036,942	0.1712	44,325

The aggregate intrinsic value in the table above represents the difference between the fair market value of the Company's shares on December 31, 2013 and 2012 and the exercise price, multiplied by the number of in-the-money options that would have been received by the option holders had all option holders exercised their options on December 31, 2013 and 2012.

The options outstanding as of December 31, 2013, have been separated into exercise prices, as follows:

Exercise price $	Options outstanding as of December 31, 2013	Weighted average remaining contractual Life Years	Options exercisable as of December 31, 2013
0.00005	666,664	7.29	611,109
0.067	96,668	5.50	96,668
0.15	2,604,999	6.86	2,451,666
0.18	1,580,000	8.57	640,000
0.2	507,500	7.51	507,500
0.26	355,000	8.59	355,000
0.32	30,000	6.12	30,000
0.39	90,000	3.50	90,000
0.4	90,000	2.47	90,000
0.47	90,000	3.22	90,000
0.75	75,000	1.16	75,000
	6,185,831	7.23	5,036,942

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

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Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.)

2. Share-based compensation to employees and to directors: (Cont.)

a) Options to employees and directors: (Cont.)

Compensation expense recorded by the Company in respect of its stock-based employee compensation award in accordance with ASC 718-10 for the year ended December 31, 2013 and 2012 amounted to $674 and $560, respectively.

The fair value of the options is estimated at the date of grant using Black-Scholes options pricing model with the following assumptions used in the calculation:

	Year ended December 31,			
	2013		2012	
Expected volatility	121	%	132	%
Risk-free interest	0.86	%	0.63	%
Dividend yield	0	%	0	%
Expected life of up to (years)	5.4		5.5	
Forfeiture rate	0	%	0	%

b) Restricted shares to directors:

During May 2006 through April 2007, the Company issued to its directors 400,000 restricted shares of Common Stock (100,000 each). The restrictions on the shares have fully lapsed. The compensation related to the stocks issued amounted to $198, which was amortized over the vesting period as general and administrative expenses.

On August 27, 2008, the Company issued to its director 960,000 shares of Common Stock upon a cashless exercise by a shareholder of a warrant to purchase 1,000,000 shares of Common Stock at an exercise price of $.01 per share that was acquired by the shareholder from Ramot. The shares were allocated to the director by the shareholder.

In May and June 2010, based on a board resolution dated June 29, 2009, the Company issued to three directors, three of its Scientific Advisory Board members and two of its Advisory Board members 800,000 restricted shares of Common Stock. The shares will vest in three annual and equal portions commencing with the grant date.

On December 16, 2010, the Company approved a grant to two of its directors of 400,000 (total) shares of Common Stock. Related compensation in the amount of $80 was recorded as general and administrative cost in 2010. These shares were actually granted in June 2011, and an additional related compensation in the amount of $112 was recorded as general and administrative expense.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

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Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.)

2. Share-based compensation to employees and to directors: (Cont.)

b) Restricted shares to directors: (Cont.)

On June 27, 2011, the Company granted to two of its directors 476,666 (total) shares of Common Stock, out of which 216,666 shares are fully vested and 260,000 shares will vest in 12 equal monthly installments through June 2012. Related compensation in the amount of $229 will be recorded as general and administrative expense.

On August 22, 2011, the Company entered into an agreement with Chen Schor (the "Executive Director Agreement") pursuant to which the Company granted to Mr. Schor 923,374 shares of restricted Common Stock of the Company. The shares will vest over 3 years - 1/3 upon each anniversary of the Grant Date. In addition, the Company will pay $15 per quarter to Mr. Schor for his services as an Executive Board Member.

In August 2011, the Company issued to three of its Scientific Advisory Board members and three of its Advisory Board members a total of 300,000 restricted shares of Common Stock. The restrictions of the shares shall lapse in equal monthly portions over the service period.

In November 2011, the Company issued to four of its Advisory Board members a total of 500,000 restricted shares of Common Stock.

The shares will vest in equal monthly portions over the service period.

In addition, in November 2011, the Company issued to a former director 250,000 shares of Common Stock. Related compensation in the amount of $70 was recorded as general and administrative expense.

In August 2012, the Company issued to two directors, four of its Scientific Advisory Board members and three of its Advisory Board members a total of 885,000 restricted shares of Common Stock. The shares will vest in 12 equal monthly portions over the service period. Related compensation in the amount of $198 was recorded as general and administrative expense.

On April 19, 2013, the Company issued to two of its directors and four of its Advisory Board members a total of 760,000 restricted shares of Common Stock. The shares will vest in 12 equal monthly portions until fully vested on the anniversary of grant. Related compensation expense in the amount of $175 will be recorded as general and administrative expense.

3. Shares and warrants to service providers:

The Company accounts for shares and warrant grants issued to non-employees using the guidance of ASC 505-50, "Equity-Based Payments to Non-Employees" (EITTF 96-18, "Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services"), whereby the fair value of such option and warrant grants is determined using a Black-Scholes options pricing model at the earlier of the date at which the non-employee's performance is completed or a performance commitment is reached.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

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Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.)

B. Issuance of shares, warrants and options: (Cont.)

3. Shares and warrants to service providers: (Cont.)

a) Warrants to investors and service providers:

Issuance date	Number of warrants issued	Exercised	Forfeited	Outstanding	Exercise Price $	Warrants exercisable	E th
November-December 2004	14,600,845	14,396,010	204,835	-	0.00005 - 0.01	-	-
February-December 2005	3,058,471	173,000	2,548,308	337,163	0.15 - 2.5	337,163	Ju
February-December 2006	1,686,355	727,696	478,659	480,000	0.005 – 1.5	480,000	F
March 2007	14,803,300		1,003,300	13,800,000	0.15 - 0.47	13,800,000	M
April 2008	9,175,000			9,175,000	0.15 - 0.29	9,175,000	M
Apr-Oct 2009	4,937,500	100,000		4,837,500	0.067 – 0.29	4,837,500	M
January 2010	1,250,000		1,250,000	-	0.5	-	-
February 2010	125,000	125,000		-	0.01	-	-
February 2010	3,000,000		3,000,000	-	0.5	-	-
February 2010	1,500,000			1,500,000	0.001	500,000	F
April 2010	33,334			33,334	0.00005	33,334	A
January 2011	4,537,500			4,537,500	0.29	4,537,500	M
February 2011	641,026		641,026	-	0.39	-	-
February 2011	6,407,500	946,834	5,460,666	-	0.28	-	-
February 2011	12,815,000		12,815,000	-	0.5	-	-
April 2011	33,334			33,334	0.00005	33,334	A
April 2012	33,334			33,334	0.00005	33,334	A
July 2012	493,966			493,966	0.348	493,966	Ju
July 2012	232,758			232,758	0.29	232,758	Ja
July 2012	14,864,228			14,864,228	0.29	14,864,228	Ja

Feb 2013	833,334			833,334	0.5	833,334	C
April 2013	33,334			33,334	0.00005	13,889	A
August 2013	17,647,058			17,647,058	0.25	17,647,058	A
	112,742,177	16,468,540	27,401,794	68,871,843		67,852,398	

The fair value for the warrants to service providers was estimated on the date of grant using a Black-Scholes option pricing model, with the following weighted-average assumptions for the year ended December 31, 2010; weighted average volatility of 140%, risk free interest rates of 2.39%-3.14%, dividend yields of 0% and a weighted average life of the options of 5-5.5 and 1-9 years. There were no grants to service providers during 2013 and 2012 using Black-Scholes calculation.

b) Shares:

In June, 2004, the Company issued 40,000 and 150,000 shares of Common Stock for 12 months of filing services and legal and due-diligence services, respectively, with respect to a private placement. Compensation expense related to filing services, totaling $26, was amortized over a 12-month period. Compensation related to legal services, totaling $105 was recorded as equity issuance cost and had no effect on the statement of operations.

On February 10, 2005, the Company signed an agreement with one of its service providers under which the Company issued to the service provider 100,000 restricted shares at a purchase price of $0.00005 par value under the U.S. Stock Option and Incentive Plan of the Company. All restrictions on these shares have lapsed.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.)

3. Shares and warrants to service providers: (Cont.)

b) Shares: (Cont.)

In March and in April 2005, the Company signed an agreement with four members of its Scientific Advisory Board under which the Company issued to the members of the Scientific Advisory Board 400,000 restricted shares at a purchase price of $0.00005 par value under the U.S. Stock Option and Incentive Plan (100,000 each). All restrictions on these shares have lapsed.

Between the years 2004 through 2009, the Company issued to several services providers, in separate transactions, 3,045,508 shares of Common Stock in total. The total related compensation, in the amount of $758, was recorded as general and administrative expense.

On March 5, 2007, the Company issued a $150 Convertible Promissory Note to a third party. Interest on the note accrued at the rate of 8% per annum for the first year and 10% per annum after the first year. On January 27, 2010, the third party converted the entire accrued principle and interest outstanding under the note, amounting to $189, into 1,016,109 shares of Common Stock.

On October 29, 2007, the Company issued to a Scientific Advisory Board member 80,000 shares of the Company's Common Stock for scientific services. Compensation of $67 was recorded as research and development expense.

On May 20, 2008, the Company issued to its finance advisor 90,000 shares of the Company's common stock. The shares are for $35 payable to the finance advisor for introduction fee of past convertible loans. Related compensation in the amount of $36 is recorded as finance expenses.

On April 5, 2009, the Company issued to its Chief Technology Advisor 1,800,000 shares of Common Stock. The shares are for $180 payable to the advisor. Related compensation in the amount of $144 was recorded as research and development expense.

On October 1, 2009, the Company issued to its service provider 150,000 shares of the Company's Common Stock. The shares are for financial and investor relation services done by the provider. Related compensation in the amount of $51 is recorded as general and administrative expense.

On October 2, 2009, the Company issued to its service provider 1,250,000 shares of the Company's Common Stock. The shares are for investor and public relation services. Related compensation in the amount of $400 is recorded as general and administrative expense.

On December 30, 2009, the Company issued to Ramot 1,120,000 shares of the Company's Common Stock (See note 3).

On December 13, 2009, the Company issued a $135 Convertible Promissory Note to it legal advisor for $217 in legal fees accrued through October 31, 2009. Interest on the note accrued at the rate of 4%.

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(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.)

3. Shares and warrants to service providers: (Cont.)

b) Shares: (Cont.)

On January 5, 2010, the Company issued to its public relations advisor 50,000 shares of the Company's Common Stock for six months service. The issuance of the shares is part of the agreement with the public relations advisor that entitles it to a monthly grant of 8,333 shares of the Company's Common Stock. Related compensation in the amount of $12 was recorded as general and administrative expense.

On January 6, 2010, the Company issued to its service provider 60,000 shares of the Company's Common Stock. The shares are for $15 payable to the service provider for insurance and risk management consulting and agency services for three years. Related compensation in the amount of $16 was recorded as general and administrative expense.

On February 19, 2010, the Company's legal advisor converted the entire accrued principal and interest amount outstanding under the note into 402,385 shares of Common Stock.

On April 6, 2010, Prof. Melamed fully exercised his warrant to purchase 1,097,215 shares of the Company’s Common Stock. The warrant was issued to him pursuant to the agreement with the Consultants effective as of November 4, 2004 (See Note 4a).

In May 2010, based on a board resolution dated June 29, 2009, the Company issued to one of its public relations advisors 100,000 restricted shares of Common Stock. The shares will vest in three annual and equal portions commencing with the grant date.

On December 16, 2010, the Company granted to its service provider 200,000 shares of the Company's Common Stock. The shares are for investor and public relations services. Related compensation in the amount of $40 is recorded as general and administrative expense.

On December 16, 2010, the Company granted to its two consultants 1,100,000 shares of the Company's Common Stock (See Note 4B).

On February 18, 2011, the Company's legal advisor converted the entire accrued principal and interest of the Convertible Promissory Note granted on September 15, 2010, totaling $137, into 445,617 shares of Common Stock.

On June 27, 2011, the Company granted to its legal advisor 180,000 shares of Common Stock for 2011 legal services. Related compensation in the amount of $86 was recorded as general and administrative expense.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.)

3. Shares and warrants to service providers: (Cont.)

b) Shares: (Cont.)

On June 27, 2011, the Company granted to its consultant 400,000 shares of the Company's Common Stock, for services rendered through December 31, 2009 (See note 4c).

Related compensation in the amount of $192 was recorded as research and development expense.

On June 27, 2011, the Company granted to a service provider 10,870 shares of the Company's Common Stock. Related compensation in the amount of $5 is recorded as general and administrative expense.

On December 31, 2011, the Company issued to Hadasit warrants to purchase up to 1,500,000 restricted shares of the Company's Common Stock at an exercise price of $0.001 per share, exercisable for a period of 5 years. The warrants shall vest over the course of the trials as follows: 500,000 upon enrollment of 1/3 of the patients; an additional 500,000 upon enrollment of all the patients and the final 500,000 upon completion of the study.

On August 1, 2012, the Company approved an additional grant of 623,077 shares of the Company's Common Stock to the Consultants, for services rendered from January 1, 2011 through June 30, 2012. Related compensation in the amount of $162 was recorded as research and development expense.

On January 16, 2013, the Company granted an aggregate of 216,000 shares of Common Stock of the Company to two consultants, for services rendered through December 31, 2012. Related compensation expense in the amount of $54 was recorded as research and development expense(See note 4E).

On February 4, 2013, the Company issued 126,111 shares of Common Stock to an investor, according to a settlement agreement, for the correction of the conversion rate of a $200 convertible loan. The convertible loan was issued in 2006 and converted in 2010.

On March 11, 2013, the Company granted to its legal advisor 193,696 shares of Common Stock for 2013 legal services. As of June 30, 2013, related compensation expense in the amount of $22 was recorded as general and administrative expense.

On November 13, 2013, the Company approved a grant of 450,000 shares of the Company's Common Stock to the Consultants, for services rendered during January 1, 2013 through September 30, 2013.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 8 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.)

3. Shares and warrants to service providers: (Cont.)

(a) Shares: (Cont.)

On March 11, 2013, the Company granted to two of its service providers an aggregate of 400,000 shares of the Company's Common Stock. The shares are public relations services. As of December 31, 2013, related compensation expense in the amount of $92 was recorded as general and administrative expense.

A summary of the Company's stock awards activity related to shares issued to service providers and related information is as follows:

	Year ended December 31, 2013		Year ended December 31, 2012	
	Amount of shares	Weighted average issue price $	Amount of shares	Weighted average issue price $
Outstanding at beginning of period	11,795,801	0.27	11,001,378	0.27
Issued	809,696	0.24	794,423	0.26
Outstanding at end of period	12,605,497	0.27	11,795,801	0.27

Stock-based compensation and issuance of shares recorded by the Company in respect of shares and warrants granted to service providers amounted to $197 and $195 for the year ended December 31, 2013 and 2012, respectively.

The total stock-based compensation expense, related to shares, options and warrants granted to employees and service providers, was comprised, at each period, as follows:

	Year ended December 31,		Period from September 22, 2000 (inception date) through December 31,
	2013	2012	2013
	U.S. $ in thousands		
Research and development	105	236	17,871
General and administrative	767	545	11,425
Financial expenses, net	-	-	248
Total stock-based compensation expense	872	781	29,544

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 9 - RESEARCH AND DEVELOPMENT, NET

	Year ended December 31,		Period from September 22, 2000 (inception date) through December 31,
	2013	2012	2013
	U.S. $ in thousands		
Research and development	4,030	2,688	33,551
Less : Ramot reverse accruals (See Note 3)	-	-	(760)
Less : Participation by the Israeli Office of the Chief Scientist	(1,113)	(918)	(3,685)
	2,917	1,770	29,106

NOTE 10 - TAXES ON INCOME

A. Tax rates applicable to the income of the subsidiary:

The corporate tax rate in Israel for 2010 was 25%. In 2011, following the Amended Legislation for Implementing the Economic Plan for 2009 and 2010, the corporate tax rate in Israel was 24%.

The Tax Burden Distribution Law of 2011 set the corporate tax rate at 25% for 2012 and 2013. In August 2013, the Israeli Knesset (Israeli parliament) approved an increase in the corporate tax rate to 26.5% for 2014 and thereafter.

Such tax rate changes have no significant impact on the Company's financial statements.

B. Tax laws applicable to the income of the Subsidiary:

Income Tax (Inflationary Adjustments) Law, 1985:

Under Israeli law (the Income Tax (Inflationary Adjustments) Law, 1985), until 2007, the Company's results for tax purposes were adjusted annually as a result of changes in the Israeli Consumer Price Index (CPI)

In February 2008, the “Knesset” passed an amendment to such law that limits its scope starting in 2008, and thereafter. Starting in 2008, the Company's results for tax purposes are measured in nominal values. The amendment to the law includes, inter alia, the elimination of the inflationary additions and deductions and the additional deduction for depreciation starting in 2008.

The Law for the Encouragement of Capital Investments, 1959 ("the Law"):

According to the Law, BCT is entitled to various tax benefits by virtue of "beneficiary enterprise" status granted, as defined by this Law.

In March 2005, the Knesset passed the Arrangements Law for fiscal year 2005, which includes a broad and comprehensive amendment to the provisions of the Law ("Amendment No. 60 to the Law").

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 10 - TAXES ON INCOME (Cont.):

B. Tax laws applicable to the income of the Subsidiary: (Cont.)

The principal benefits by virtue of the Law are:

Tax benefits and reduced tax rates under the Alternative Track of Benefits:

The Company is tax exempt for a benefit period of two years and in the five/eight subsequent years of the benefit period is subject to a reduced tax rate of 10%-25%.

In December 2010, the Knesset passed the Law for Economic Policy for 2011 and 2012 (Amended Legislation), 2011, which prescribes, among others, amendments to the Law for the Encouragement of Capital Investments, 1959 (the “Investment Law”). The amendment was enacted as of January 1, 2011. Under the amendment, the benefit tracks in the Investment Law were modified and a flat tax rate applies to the Company's entire “Preferred Income”. The Company will be able to opt to apply (the waiver is non-recourse) the amendment and from then on it will be subject to the amended tax rates that are: 2011 and 2012 - 15% (in development area A - 10%), 2013 and 2014 - 12.5% (in development area A - 7%) and in 2015 and thereafter - 12% (in development area A - 6%).

On July 30, 2013 the Knesset passed the Law for the change in the order of National Priorities (Legislative amendments to achieve budget objectives for 2013 and 2014) - 2013. As part of the legislation, the Law for the Encouragement of Capital Investments was amended so that the tax rate applicable to a preferred enterprise in this period in Development Area A will be 9% and the tax rate in other parts of the country will be 16%.

C. Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	December 31,	
	2013	2012
	U.S. $ in thousands	
Operating loss carryforward	25,156	22,067
Net deferred tax asset before valuation allowance	8,961	8,340
Valuation allowance	(8,961)	(8,340)
Net deferred tax asset	-	-

As of December 31, 2013, the Company has provided valuation allowances of $8,961 in respect of deferred tax assets resulting from tax loss carryforward and other temporary differences. Management currently believes that because the Company has a history of losses, it is more likely than not that the deferred tax regarding the loss carryforward and other temporary differences will not be realized in the foreseeable future.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

Notes to the financial statements

U.S. dollars in thousands

NOTE 10 - TAXES ON INCOME (Cont.):

D. Available carryforward tax losses:

As of December 31, 2013, the Company has an accumulated tax loss carryforward of approximately $25,156. Carryforward tax losses in Israel are unlimited duration and carryforward tax losses in the U.S. can be carried forward and offset against taxable income in the future for a period of 20 years. Utilization of U.S. net operating losses may be subject to substantial annual limitations due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization.

E. Loss from continuing operations, before taxes on income, consists of the following:

	Year ended December 31, 2013	2012
	U.S. $ in thousands	
United States	(1,379)	(1,197)
Israel	(3,694)	(2,233)
	(5,073)	(3,430)

F. Due to the Company's cumulative losses, the effect of ASC 740 as codified from ASC 740-10 (formerly FIN 48) is not material.

NOTE 11 - TRANSACTIONS WITH RELATED PARTIES

		Year ended December 31, 2013	2012
		U.S. $ in thousands	
A.	Fees and related benefits and compensation expenses in respect of options granted to a member of the Board who is a related party	248	239

B. As for transactions with Ramot, see Note 3.

NOTE 12 - SUBSEQUENT EVENTS

A. Through January and February, 2014 the Company received approximately $380 from the Chief Scientist of the State of Israel for participation in research and development.

B. In March 2014, the Company signed a definitive agreement with the Massachusetts General Hospital (MGH) in Boston, MA to conduct a Phase II clinical trial of NurOwn™ in amyotrophic lateral sclerosis (ALS), pending FDA approval.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

(Except share data)

	March 31, 2014 Unaudited	December 31, 2013 Audited
ASSETS		
Current Assets:		
Cash and cash equivalents	3,027	3,503
Account receivable	792	910
Prepaid expenses	34	33
Total current assets	3,853	4,446
Long-Term Assets:		
Prepaid expenses	13	22
Total long-term investments	13	22
Property and Equipment, Net	327	258
Total assets	4,193	4,726
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Trade payables	326	228
Accrued expenses	1,034	877
Other accounts payable	247	227
Total current liabilities	1,607	1,332
Long-Term Liabilities:		
Warrants issued to investors	1,726	655
Total long-term liabilities	1,726	655
Total liabilities	3,333	1,987

Stockholders' Equity:		
Stock capital: (Note 6)	8	8
Common stock of $0.00005 par value - Authorized: 800,000,000 shares at March 31, 2014 and December 31, 2013; Issued and outstanding: 176,803,587 and 176,263,587 shares at March 31, 2014 and December 31, 2013 respectively.		
Additional paid-in-capital	55,370	55,138
Deficit accumulated during the development stage	(54,518)	(52,407)
Total stockholders' equity	860	2,739
Total liabilities and stockholders' equity	4,193	4,726

The accompanying notes are an integral part of the consolidated financial statements.

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands

(Except share data)

	Three months ended March 31,		Period from September 22, 2000 (inception date) through March 31,
	2014	2013	2014
	Unaudited		Unaudited
Operating costs and expenses:			
Research and development, net	680	522	29,786
General and administrative	351	559	21,203
Total operating costs and expenses	1,031	1,081	50,989
Financial expenses (income), net	1,080	1	3,390
Other income	-	-	(132)
Operating loss	2,111	1,082	54,247
Taxes on income	-	-	107
Loss from continuing operations	2,111	1,082	54,354
Net loss from discontinued operations	-	-	164
Net loss	2,111	1,082	54,518
Basic and diluted net loss per share from continuing operations	0.01	0.01	
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	176,305,587	150,953,117	

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock Number	Common stock Amount	Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity (deficiency)
Balance as of September 22, 2000 (date of inception) (unaudited)	-	$ -	$ -	$ -	$ -	$ -
Stock issued on September 22, 2000 for cash at $0.00188 per share	8,500,000	1	16	-	-	17
Stock issued on March 31, 2001 for cash at $0.0375 per share	1,600,000	* -	60	-	-	60
Contribution of capital	-	-	8	-	-	8
Net loss	-	-	-	-	(17)	(17)
Balance as of March 31, 2001 (unaudited)	10,100,000	1	84	-	(17)	68
Contribution of capital	-	-	11	-	-	11
Net loss	-	-	-	-	(26)	(26)
Balance as of March 31, 2002 (unaudited)	10,100,000	1	95	-	(43)	53
Contribution of capital	-	-	15	-	-	15
Net loss	-	-	-	-	(47)	(47)
Balance as of March 31, 2003 (unaudited)	10,100,000	1	110	-	(90)	21
2-for-1 stock split	10,100,000	* -	-	-	-	-
Stock issued on August 31, 2003 to purchase mineral option at $0.065 per share	100,000	* -	6	-	-	6

Cancellation of shares granted to Company's President	(10,062,000)	* -	* -	-	-	-
Contribution of capital	-	* -	15	-	-	15
Net loss	-	-	-	-	(73)	(73)
Balance as of March 31, 2004 (unaudited)	10,238,000	$ 1	$ 131	$ -	$ (163)	$ (31)

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock Number	Common stock Amount	Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity (deficiency)
Balance as of March 31, 2004	10,238,000	$ 1	$ 131	$ -	$ (163)	$ (31)
Stock issued on June 24, 2004 for private placement at $0.01 per share, net of $25,000 issuance expenses	8,510,000	* -	60	-	-	60
Contribution capital	-	-	7	-	-	7
Stock issued in 2004 for private placement at $0.75 per unit	1,894,808	* -	1,418	-	-	1,418
Cancellation of shares granted to service providers	(1,800,000)	* -		-	-	-
Deferred stock-based compensation related to options granted to employees	-	-	5,979	(5,979)	-	-
Amortization of deferred stock-based compensation related to shares and options granted to employees	-	-	-	584	-	584
Compensation related to shares and options granted to service providers	2,025,000	* -	17,506	-	-	17,506
Net loss	-	-	-	-	(18,840)	(18,840)
Balance as of March 31, 2005	20,867,808	$ 1	$ 25,101	$ (5,395)	$ (19,003)	$ 704

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock Number	Amount	Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity (deficiency)
Balance as of March 31, 2005	20,867,808	$ 1	$ 25,101	$ (5,395)	$ (19,003)	$ 704
Stock issued on May 12, 2005 for private placement at $0.8 per share	186,875	* -	149	-	-	149
Stock issued on July 27, 2005 for private placement at $0.6 per share	165,000	* -	99	-	-	99
Stock issued on September 30, 2005 for private placement at $0.8 per share	312,500	* -	225	-	-	225
Stock issued on December 7, 2005 for private placement at $0.8 per share	187,500	* -	135	-	-	135
Forfeiture of options granted to employees	-	-	(3,363)	3,363	-	-
Deferred stock-based compensation related to shares and options granted to directors and employees	200,000	* -	486	(486)	-	-
Amortization of deferred stock-based compensation related to options and shares granted to employees and directors	-	-	51	1,123	-	1,174
Stock-based compensation related to options and shares granted to service providers	934,904	* -	662	-	-	662
Reclassification due to application of ASC	-	-	(7,906)			(7,906)

815-40-25 (formerly EITF 00-19)						
Beneficial conversion feature related to a convertible bridge loan	-	-	164	-	-	164
Net loss	-	-	-	-	(3,317)	(3,317)
Balance as of March 31, 2006	22,854,587	$ 1	$ 15,803	$ (1,395)	$ (22,320)	$ (7,911)
Elimination of deferred stock compensation due to implementation of ASC 718-10 (formerly SFAS 123(R))	-	-	(1,395)	1,395	-	-
Stock-based compensation related to shares and options granted to directors and employees	200,000	* -	1,168	-	-	1,168
Reclassification due to application of ASC 815-40-25 (formerly EITF 00-19)	-	-	7,191	-	-	7,191
Stock-based compensation related to options and shares granted to service providers	1,147,225	-	453	-	-	453
Warrants issued to convertible note holder	-	-	11	-	-	11
Warrants issued to loan holder	-	-	110	-	-	110
Beneficial conversion feature related to convertible bridge loans	-	-	1,086	-	-	1,086
Net loss	-	-	-	-	(3,924)	(3,924)
Balance as of December 31, 2006	24,201,812	$ 1	$ 24,427	$ -	$ (26,244)	$ (1,816)

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock Number	Capital	Additional paid-in compensation	Deferred Stock - based stage	Deficit accumulated during the development stage	Total stockholders' equity (deficiency)
Balance as of December 31, 2006	24,201,812	$ 1	$ 24,427	$ -	$ (26,244)	$ (1,816)
Stock-based compensation related to options and shares granted to service providers	544,095		1,446	-	-	1,446
Warrants issued to convertible note holder	-	-	109	-	-	109
Stock-based compensation related to shares and options granted to directors and employees	200,000	* -	1,232	-	-	1,232
Beneficial conversion feature related to convertible loans	-	-	407	-	-	407
Conversion of convertible loans	725,881	* -	224	-	-	224
Exercise of warrants	3,832,621	* -	214	-	-	214
Stock issued for private placement at $0.1818 per unit, net of finder's fee	11,500,000	1	1,999	-	-	2,000
Net loss	-	-	-	-	(6,244)	(6,244)
Balance as of December 31, 2007	41,004,409	$ 2	$ 30,058	$ -	$ (32,488)	$ (2,428)
Stock-based compensation related to options and stock granted to service providers	90,000	-	33	-	-	33
Stock-based compensation related to stock and options granted to directors and employees	-	-	731	-	-	731
	3,644,610	* -	1,276	-	-	1,276

Conversion of convertible loans						
Exercise of warrants	1,860,000	*	-	-	-	-
Exercise of options	17,399	*	3	-	-	3
Stock issued for private placement at $0.1818 per unit, net of finder's fee	8,625,000	1	1,499	-	-	1,500
Subscription of shares for private placement at $0.1818 per unit	-	-	281	-	-	281
Net loss	-	-	-	-	(3,472)	(3,472)
Balance as of December 31, 2008	55,241,418	$ 3	$ 33,881	$ -	$ (35,960)	$ (2,076)

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	Deferred stock - based	Deficit accumulated during the development	Total stockholders' equity
	Number	Amount	capital	compensation	stage	(deficiency)
Balance as of December 31, 2008	55,241,418	$ 3	$ 33,881	$ -	$ (35,960)	$ (2,076)
Stock-based compensation related to options and stock granted to service providers	5,284,284	(*)	775	-	-	775
Stock-based compensation related to stock and options granted to directors and employees	-	-	409	-	-	409
Conversion of convertible loans	2,500,000	(*)	200	-	-	200
Exercise of warrants	3,366,783	(*)	-	-	-	-
Stock issued for amendment of private placement	9,916,667	1	-	-	-	1
Subscription of shares	-	-	729	-	-	729
Net loss	-	-	-	-	$ (1,781)	(1,781)
Balance as of December 31, 2009	76,309,152	$ 4	$ 35,994	$ -	$ (37,741)	$ (1,743)

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock Number	Common stock Amount	Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity (deficiency)
Balance as of December 31, 2009	76,309,152	$ 4	$ 35,994	$ -	$ (37,741)	$ (1,743)
Stock-based compensation related to options and stock granted to service providers	443,333	* -	96	-	-	96
Stock-based compensation related to stock and options granted to directors and employees	466,667	* -	388	-	-	388
Stock issued for amendment of private placement	7,250,000	1	1,750	-	-	1,751
Conversion of convertible note	402,385	* -	135	-	-	135
Conversion of convertible loans	1,016,109	* -	189	-	-	189
Issuance of shares	2,475,000		400			400
Exercise of options	1,540,885	* -	77	-	-	77
Exercise of warrants	3,929,446	* -	11	-	-	11
Subscription of shares for private placement at $0.12 per unit		-	455	-	-	455
Conversion of trade payable to stock		-	201	-	-	201
Issuance of shares on account of previously subscribed shares	2,000,001	* -	-	-	-	-
Net loss					(2,419)	(2,419)
	95,832,978	$ 5	$ 39,696	$ -	$ (40,160)	$ (459)

Balance as of December 31,
2010

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in	Deferred Stock - based	Deficit Accumulated during the development	Total stockholders' equity
	Number	Amount	capital	compensation	Stage	(deficiency)
Balance as of December 31, 2010	95,832,978	$ 5	$ 39,696	$ -	$ (40,160)	$ (459)
Stock-based compensation related to options and stock granted to service providers	474,203	-	449	-	-	449
Stock-based compensation related to stock and options granted to directors and employees	2,025,040	-	1,135	-	-	1,135
Conversion of convertible note	755,594	-	140	-	-	140
Exercise of options	1,648,728	-	243	-	-	243
Exercise of warrants	1,046,834	-	272	-	-	272
Issuance of shares for private placement	14,160,933	1	3,601	-	-	3,602
Issuance of shares on account of previously subscribed shares	10,499,999	-	24	-	-	24
Net loss	-	-	-	-	(3,918)	(3,918)
Balance as of December 31, 2011	126,444,309	$ 6	$ 45,560	$ -	$ (44,078)	$ 1,488

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

U.S. dollars in thousands

(Except share data)

	Common stock Number	Common stock Amount	Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity
Balance as of December 31, 2011	126,444,309	$ 6	$ 45,560	$ -	$ (44,078)	$ 1,488
Stock-based compensation related to options and stock granted to service providers	794,423	-	195	-	-	195
Stock-based compensation related to stock and options granted to directors and employees	885,000	-	560	-	-	560
Exercise of options	1,182,606	(*)	137	-	-	137
Exercise of warrants	959,729	(*)	9	-	-	9
Issuance of shares for private placement	19,818,968	1	5,022		-	5,023
Net loss	-	-	-	-	(3,430)	(3,430)
Balance as of December 31, 2012	150,085,035	$ 7	$ 51,483	$ -	$ (47,508)	$ 3,982

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands

(Except share data)

	Common stock Number	Amount	Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity
Balance as of December 31, 2012	150,085,035	$ 7	$ 51,483	$ -	$ (47,508)	$ 3,982
Stock-based compensation related to options and stock granted to service providers	809,696		197	-	-	197
Stock-based compensation related to stock and options granted to directors and employees	760,000		674	-	-	674
Issuance of shares for public offering	23,529,411	1	2,496	-	-	2,497
Issuance of shares for private placement	833,334	(*)	250	-	-	250
Conversion of convertible loans	126,111	-	30	-	-	30
Exercise of options	120,000	(*)	8	-	-	8
Net loss	-	-	-	-	(4,899)	(4,899)
Balance as of December 31, 2013	176,263,587	$ 8	$ 55,138	-	$ (52,407)	$ 2,739

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

U.S. dollars in thousands

(Except share data)

	Common stock		Additional paid-in capital	Deferred Stock - based compensation	Deficit accumulated during the development stage	Total stockholders' equity
	Number	Amount				
Balance as of December 31, 2013	176,263,587	$ 8	$ 55,138	-	$ (52,407)	$ 2,739
Stock-based compensation related to options and stock granted to service providers	540,000	-	110	-	-	110
Stock-based compensation related to stock and options granted to directors and employees	-	-	122	-	-	122
Net loss	-	-	-	-	(2,111)	(2,111)
Balance as of March 31, 2014	176,803,587	$ 8	$ 55,370	-	$ (54,518)	$ 860

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

(Except share data)

	Three months ended March 31, 2014 Unaudited	2013	Period from September 22, 2000 (inception date) through March 31, 2014(*) Unaudited
Cash flows from operating activities:			
Net loss	(2,111)	(1,082)	(54,518)
Less - loss for the period from discontinued operations	-	-	164
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of deferred charges	25	33	1,280
Accrued interest on loans	-	-	451
Amortization of discount on short-term loans	-	-	1,864
Change in fair value of options and warrants		-	(795)
Expenses related to shares and options granted to service providers	110	128	22,018
Amortization of deferred stock-based compensation related to options granted to employees	122	203	8,177
Decrease (increase) in accounts receivable and prepaid expenses	117	128	(826)
Increase (decrease) in trade payables and convertible note	98	(112)	799
Increase in other accounts payable and accrued expenses	177	32	1,787
Revaluation of warrants	1,071	-	897
Erosion of restricted cash	-	-	(6)
Net cash used in continuing operating activities	(391)	(670)	(18,708)
Net cash used in discontinued operating activities	-	-	(23)
Total net cash used in operating activities	(391)	(670)	(18,731)
Cash flows from investing activities:			
Purchase of property and equipment	(94)	(20)	(1,425)
Restricted cash	-	-	6
Changes in short-term deposit	-	997	-
Investment in lease deposit	9	(6)	(13)

Net cash (used in) provided by continuing investing activities	(85)	971	(1,432)
Net cash used in discontinued investing activities	-	-	(16)
Total net cash (used in) provided by investing activities	(85)	971	(1,448)
Cash flows from financing activities:			
Proceeds from issuance of Common stock, net	-	250	20,918
Proceeds from loans, notes and issuance of warrants, net	-	-	2,061
Proceeds from exercise of warrants and options	-	-	785
Repayment of short-term loans	-	-	(601)
Net cash provided by continuing financing activities	-	250	23,163
Net cash provided by discontinued financing activities	-	-	43
Total net cash provided by financing activities	-	250	23,206
Increase (decrease) in cash and cash equivalents	(476)	551	3,027
Cash and cash equivalents at the beginning of the period	3,503	1,317	-
Cash and cash equivalents at end of the period	3,027	1,868	3,027

(*) **Out of the which, cash flows used in discontinued operating activities of $36, cash flows used in discontinued investing activities of $16 and cash flows provided in discontinued financing activities of $57, relating to the period from inception to March 31, 2004, is unaudited.**

The accompanying notes are an integral part of the consolidated financial statements.

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 1 - GENERAL

A. Brainstorm Cell Therapeutics Inc. (formerly: Golden Hand Resources Inc. - the "Company") was incorporated in the State of Washington on September 22, 2000.

B. On May 21, 2004, the former major stockholders of the Company entered into a purchase agreement with a group of private investors, who purchased from the former major stockholders 6,880,000 shares of the then issued and outstanding 10,238,000 shares of the Company's Common Stock, $0.00005 par value (the "Common Stock").

C. On July 8, 2004, the Company entered into a licensing agreement with Ramot of Tel Aviv University Ltd. ("Ramot"), to acquire certain stem cell technology (see Note 4). Subsequent to this agreement, the Company decided to focus on the development of novel cell therapies for neurodegenerative diseases based on the acquired technology and research to be conducted and funded by the Company.

Following the licensing agreement dated July 8, 2004, the management of the Company decided to abandon all old activities related to the sale of the digital data recorder product. The discontinuation of this activity was accounted for under the provision of Statement of Financial Accounting Standard ASC 360-10, "Accounting for the Impairment or Disposal of Long-Lived Assets".

D. On October 25, 2004, the Company formed a wholly-owned subsidiary in Israel, Brainstorm Cell Therapeutics Ltd. ("BCT").

E. On November 18, 2004, the Company changed its name from Golden Hand Resources Inc. to Brainstorm Cell Therapeutics Inc. to better reflect its new line of business in the development of novel cell therapies for neurodegenerative diseases. BCT, as defined above, owns all operational property and equipment.

The Common Stock is registered and publicly traded on the OTC Markets Group service of the National Association of Securities Dealers, Inc. under the symbol BCLI.

F. On September 17, 2006, the Company changed the Company's fiscal year-end from March 31 to December 31.

G. In December 2006, the Company changed its state of incorporation from Washington to Delaware.

H. Since its inception, the Company has devoted substantially all of its efforts to research and development, recruiting management and technical staff, acquiring assets and raising capital. In addition, the Company has not generated revenues. Accordingly, the Company is considered to be in the development stage, as defined in "Accounting and reporting by development Stage Enterprises" ASC 915-10.

I. In October 2010, the Israeli Ministry of Health ("MOH") granted clearance for a Phase I/II clinical trial using the Company's autologous NurOwn stem cell therapy in patients with amyotrophic lateral sclerosis ("ALS"), subject to some additional process specifications as well as completion of the sterility validation study for tests performed.

On February 23, 2011, the Company submitted, to the MOH, all the required documents. Following approval of the MOH, a Phase I/II clinical study for ALS patients using the Company's autologous NurOwn stem cell therapy (the "Clinical Trial") was initiated in June 2011.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 1 - GENERAL (Cont.):

J. In February 2011, the U.S. Food and Drug Administration ("FDA") granted orphan drug designation to the Company's NurOwn autologous adult stem cell product for the treatment of ALS.

K. On February 19, 2013, Brainstorm Ltd established a wholly-owned subsidiary, Brainstorm Cell Therapeutics UK Ltd. ("Brainstorm UK"). Brainstorm UK will act on behalf of the parent Company in the EU.

L. On February 21, 2013, Brainstorm UK filed a request for Orphan Medicinal Product Designation by the European Medicine Agency (EMA) for its Autologous Bone Marrow derived Mesenchyme Stromal cells Secreting Neurotropic factors (MSC-NTF, NurOwn).

M. Effective April 3, 2013, BCT entered into an agreement with Dana-Farber Cancer Institute ("Dana-Farber") to provide cGMP-compliant clean room facilities for production of the Company's NurOwn™ stem cell candidate during its upcoming Phase II ALS trial in the United States. The Company's Phase II trial, will be conducted at Massachusetts General Hospital ("MGH"), the University of Massachusetts ("UMass") Hospital and the Mayo Clinic. The Connell and O'Reilly Cell Manipulation Core Facility at Dana-Farber will produce NurOwn for the MGH and UMass Hospital clinical sites.

N. On April 18, 2013, the stockholders of the Company authorized the Board of Directors of the Company, in its discretion, should it deem it to be appropriate and in the best interests of the Company and its stockholders, to amend the Company's Certificate of Incorporation to effect a reverse stock split of the Company's issued and outstanding shares of common stock by a ratio of between 1-for-10 and 1-for-20, inclusive, without further approval or authorization of the Company's stockholders. A reverse stock split of the Company's shares wasn't performed and this authorization expired April 18, 2014.

O. On July 17, 2013, the European Commission granted Orphan Drug Designation to the Company's NurOwn autologous adult stem cell product for the treatment of ALS.

P. On September 27, 2013, the Company announced that it recently completed treatment of the 12 patients in its ALS Phase IIa dose-escalating clinical trial with the Company's NurOwn™ technology. The Company was informed that one patient in the study expired due to a medical condition unrelated to the Clinical Trial.

The Clinical Trial is being performed at Hadassah Medical Center in Jerusalem, Israel, under the direction of Prof. Dimitrios Karussis, M.D., Ph.D., head of Hadassah's Multiple Sclerosis Center and a member of the International Steering Committees for Bone Marrow and Mesenchymal Stem Cells Transplantation in Multiple Sclerosis (MS). The study is designed to establish the safety and preliminary efficacy of NurOwn at increasing dosages.

Q. On December 4, 2013, a Notice of Intention to Grant from the European Patent Office (EPO) was issued for the Company's patent application entitled "Isolated Cells and Populations Comprising Same for the Treatment of CNS Diseases" (European serial number EP06766101.7) . This patent relates to the production method for the company's proprietary stem cells induced to secrete large quantities of neurotrophic factors for the treatment of neurodegenerative diseases.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 1 - GENERAL (Cont.):

R. On February 11, 2014, a Notice of Allowance was issued from the U.S. Patent Office for the same patent application as above, U.S. serial number 11/727,583.

S. On March 4, 2014, a Notice of Allowance was issued from the U.S. Patent Office for the same patent application as above, U.S. serial number 12/994,761.

T. On March 14, 2013, the Company signed a definitive agreement with the Mayo Clinic in Rochester, Minnesota to conduct its Phase II clinical trial of NurOwn™ in amyotrophic lateral sclerosis (ALS), pending FDA approval. In addition, Mayo's Human Cell Therapy Laboratory will manufacture the NurOwn cells for their clinical trial participants.

U. On March 24, 2014, BCT signed a definitive agreement with the Massachusetts General Hospital (MGH) in Boston, MA to conduct a Phase II clinical trial of NurOwn™ in amyotrophic lateral sclerosis (ALS), pending FDA approval.

V. On April 28, 2014 the Company announced that the US Food and Drug Administration (FDA) has approved commencement of its Phase II clinical trial with NurOwn™ in patients with Amyotrophic Lateral Sclerosis (ALS). The trial will be launched initially at the Massachusetts General Hospital (MGH) in Boston, MA and the University of Massachusetts Memorial (UMass) Hospital in Worcester, MA following Institutional Review Board (IRB) approvals. Dana-Farber Cancer Institute's Connell O'Reilly Cell Manipulation Core Facility will manufacture the NurOwn™ cells for these two clinical sites. The trial will also be conducted at the Mayo Clinic in Rochester, Minnesota. (See Note 7E).

GOING CONCERN:

As reflected in the accompanying financial statements, the Company's operations for the three months ended March 31, 2014, resulted in a net loss of $2,111. The Company's balance sheet reflects an accumulated deficit of $54,518. These conditions, together with the fact that the Company is a development stage Company and has no revenues nor are revenues expected in the near future, raise substantial doubt about the Company's ability to continue to operate as a going concern. The Company's ability to continue operating as a "going concern" is dependent on several factors, among them is its ability to raise sufficient additional working capital.

In 2009, the Company decided to focus only on the effort to commence clinical trials for ALS and such trials did commence in 2011.

In July 2012, the Company raised $5.7 million, gross, in a public offering (See Note 6B 1 (i)). In August 2013, the Company raised $4 million, gross, in a public offering (See Note 6B 1 (l)). However, there can be no assurance that additional funds will be available on terms acceptable to the Company, or at all.

These financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies applied in the annual financial statements of the Company as of December 31, 2013 are applied consistently in these financial statements.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 3 - UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

The accompanying unaudited interim financial statements have been prepared in a condensed format and include the consolidated financial operations of the Company and its wholly-owned subsidiary as of March 31, 2014 and for the three months then ended, in accordance with accounting principles generally accepted in the United States relating to the preparation of financial statements for interim periods. Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2014, are not necessarily indicative of the results that may be expected for the year ended December 31, 2014.

NOTE 4 - RESEARCH AND LICENSE AGREEMENT

The Company has a Research and License Agreement, as amended and restated, with Ramot. The Company obtained a waiver and release from Ramot pursuant to which Ramot agreed to an amended payment schedule regarding the Company's payment obligations under the Research and License Agreement and waived all claims against the Company resulting from the Company's previous defaults and non-payment under the Research and License Agreement. The waiver and release amended and restated the original payment schedule under the original agreement providing for payments during the initial research period and additional payments for any extended research period.

The Company is to pay Ramot royalties on Net Sales on a Licensed Product by Licensed Product and jurisdiction by jurisdiction basis as follow:

a) So long as the making, producing, manufacturing, using, marketing, selling, importing or exporting of such Licensed Product is covered by a Valid Claim or is covered by Orphan Drug Status in such jurisdiction – 5% of all Net Sales.

b) In the event the making, producing, manufacturing, using, marketing, selling, importing or exporting of such Licensed Product is not covered by a Valid Claim and not covered by Orphan Drug status in such jurisdiction – 3% of all Net Sales until the expiration of 15 years from the date of the First Commercial Sale of such Licensed Product in such jurisdiction.

NOTE 5 - CONSULTING AGREEMENTS

A. On July 8, 2004, the Company entered into two consulting agreements with Prof. Eldad Melamed and Dr. Daniel Offen (together, the "Consultants"), under which the Consultants provide the Company scientific and medical consulting services in consideration for a monthly payment of $6 each. In addition, the Company granted each of the Consultants, a fully vested warrant to purchase 1,097,215 shares of Common Stock at an exercise price of $0.01 per share. The warrants issued pursuant to the agreement were issued to the Consultants effective as of November 4, 2004. Each of the warrants is exercisable for a seven-year period beginning on November 4, 2005. As of September 2010, all the above warrants had been exercised. In June 2012 an amendment was signed with Dr. Daniel Offen, according to which the company pays Daniel Offen a monthly payment of $6, out of which $3 in cash and $3 by grant of Company stock.

B. On December 16, 2010, the Company approved grants of an aggregate 1,100,000 shares of Common Stock to the two Consultants, for services rendered through December 31, 2010. Related compensation in the amount of $220 was recorded as research and development expense. A sum of $487 was cancelled concurrently with the issuance of the 1,100,000 shares of Common Stock of the Company.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 5 - CONSULTING AGREEMENTS (Cont.):

C. On June 27, 2011, the Company approved an additional grant of 400,000 shares of Common Stock to Prof. Daniel Offen, for services rendered through December 31, 2009. Related compensation in the amount of $192 was recorded as research and development expense.

D. On August 1, 2012, the Company approved additional grants of an aggregate 623,077 shares of Common Stock to the Consultants, for services rendered from January 1, 2011 through June 30, 2012. Related compensation in the amount of $162 was recorded as research and development expense.

E. On January 16, 2013, the Company granted the Consultants an aggregate of 216,000 shares of Common Stock for their services from January 1, 2012 through December 31, 2012. Related compensation in the amount of $54 was recorded as research and development expense.

F. On November 13, 2013, the Company approved grants of an aggregate 450,000 shares of Common Stock to the Consultants, for services rendered during January 1, 2013 through September 30, 2013 (the "2013 Shares").

G. On March 24, 2014, the Company approved grants of an aggregate 90,000 shares of Common Stock to the Consultants for services rendered in 2014, and issued such shares together with the 2013 Shares.

NOTE 6 - STOCK CAPITAL

A. The rights of Common Stock are as follows:

Holders of Common Stock have the right to receive notice to participate and vote in general meetings of the Company, the right to a share in the excess of assets upon liquidation of the Company and the right to receive dividends, if declared.

The Common Stock is registered and publicly traded on the OTC Markets Group service of the National Association of Securities Dealers, Inc. under the symbol BCLI.

B. Issuance of shares, warrants and options:

1. Private placements and public offering:

(a) During 2004 and 2005 the Company issued, in separate transactions, 8,861,875 shares of Common Stock of the Company for total proceeds of $308

(b) On February 23, 2005, the Company completed a private placement for sale of 1,894,808 units for total proceeds of $1,418. Each unit consisted of one share of Common Stock and a three-year warrant to purchase one share of Common Stock at $2.50 per share. This private placement was consummated in three tranches which closed in October 2004, November 2004 and February 2005. All warrants are no longer valid

(c) On August 11, 2005, the Company signed a private placement agreement with investors for the sale of up to 1,250,000 units at a price of $0.80 per unit. Each unit consisted of one share of Common Stock and one warrant to purchase one share of Common Stock at $1.00 per share. The warrants were exercisable for a period of three years from issuance. On September 30, 2005, the Company sold 312,500 units for total net proceeds of $225. On December 7, 2005, the Company sold 187,500 units for total net proceeds of $135. All warrants are no longer valid.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

1. Private placements and public offering: (Cont.):

(d) In July 2007, the Company entered into an investment agreement, that was amended in August 2009, according to which for an aggregate subscription price of up to $5 million, the Company issued 41,666,667 shares of Common Stock and a warrant to purchase 10,083,333 shares of Common Stock at an exercise price of $0.20 per share and a warrant to purchase 20,166,667 shares of common stock at an exercise price of $0.29 per share. The warrants may be exercised at any time and expire on November 5, 2013. In May 2012 the warrants were extended by additional 18 months, through May 5, 2015.

In January 2011, the Company and an investor signed an agreement to balance the remaining amount due to the investor, totaling $20, against the remaining balance of the investment and the Company issued the above shares and warrants.

In addition, the Company issued an aggregate of 1,250,000 shares of Common Stock to a related party as an introduction fee for the investment. As of the balance sheet date, no warrants have been exercised.

(e) In January 2010, the Company issued 1,250,000 units to a private investor for total proceeds of $250. Each unit consisted of one share of Common Stock and a two-year warrant to purchase one share of Common Stock at $0.50 per share. All warrants are no longer valid.

(f) In February 2010, the Company issued 6,000,000 shares of Common Stock to three investors (2,000,000 to each investor) and warrants to purchase an aggregate of 3,000,000 shares of Common Stock (1,000,000 to each investor) with an exercise price of $0.50 for aggregate proceeds of $1,500 ($500 each).

(g) In February 2011, the Company issued 833,333 shares of Common Stock, at a price of $0.30 per share, and a warrant to purchase 641,026 shares of Common Stock at an exercise price of $0.39 per share exercisable for one year for total proceeds of $250. The warrants are no longer valid.

(h) On February 23, 2011, the Company entered into an investment agreement, pursuant to which the Company agreed to sell up to 12,815,000 shares of Common Stock, for an aggregate subscription price of up to $3.6 million and warrants to purchase up to 19,222,500 shares of Common Stock as follows: warrant to purchase 12,815,000 shares of Common Stock at $0.5 per share for two years, and warrants to purchase 6,407,500 shares of Common Stock at $0.28 per share for one year, out of which 946,834 were exercised, and 5,460,666 were cancelled.

In addition, the Company agreed to pay 10% of the funds received for the distribution services received, out of this amount, 4% was be paid in stock and the remaining 6% in cash. Accordingly, in March 2011, the Company issued 512,600 shares of Common Stock and paid $231.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

1. Private placements and public offering: (Cont.):

(i) On July 17, 2012, the Company raised a $5.7 million gross proceeds through a public offering ("2012 Public Offering") of its common stock. The Company issued a total of 19,818,968 common stock of $0.00005 par value, ($0.29 per share) and 14,864,228 warrants to purchase 0.75 shares of Common Stock for every share purchased in the Public Offering, at an exercise price of $0.29 per share. The Warrants are exercisable until the 30 month anniversary of the date of issuance. After deducting closing costs and fees, the Company received net proceeds of approximately $4.9 million.

The Company paid to the Placement Agency, Maxim Group LLC (the "Placement Agent"), a cash fee and a corporate finance fee equal to 7% of the gross proceeds of the Public Offering. In addition, the Company issued to the Placement Agent a two year warrant to purchase up to 493,966 shares of Common Stock (equal to 3% of the number of shares sold in the Public Offering), with an exercise price equal to $0.348 (120% of the Public offering price). The Warrants are exercisable until the 30 month anniversary of the date of issuance. In addition, the Company issued to Leader Underwriters (1993) Ltd, warrants to purchase 232,758 shares of Common stock, at an exercise price of $0.29 per share. The warrants are exercisable until the 30 month anniversary of the date of issuance.

(j) On February 4, 2013, the Company issued 126,111 shares of Common Stock to an investor, according to a settlement agreement, for the correction of the conversion rate of a $200 convertible loan. The convertible loan was issued in 2006 and converted in 2010.

(k) On February 7, 2013, the Company issued 833,334 units to a private investor for total proceeds of $250. Each unit consisted of one share of Common Stock and a warrant to purchase one share of Common Stock at $0.50 per share exercisable for 32 months.

(l) On August 16, 2013, the Company raised $4 million (gross) through a registered public offering ("2013 Public Offering") of its common stock. The Company issued a total of 23,529,411 common stock of $0.00005 par value, ($0.17 per share) and 17,647,058 warrants to purchase 0.75 shares of Common Stock for every share purchased in the Public Offering, at an exercise price of $0.25 per share. The Warrants are exercisable until the 36 month anniversary of the date of issuance. The Warrants also include, subject to certain exceptions, full ratchet anti-dilution protection in the event of the issuance of any common stock, securities convertible into common stock, or certain other issuances at a price below the then-current exercise price of the Warrants, which would result in an adjustment to the exercise price of the Warrants. In the event of a sale of the Company, each holder of Warrants has the right, exercisable at its option, to require the Company to purchase such holder's Warrants at a price determined using a Black-Scholes option pricing model as described in the Warrants. After deducting closing costs and fees, the Company received net proceeds of approximately $3.3 million.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

1. Private placements and public offering: (Cont.):

In accordance with the provisions of ASC 815 (formerly FAS 133) the proceeds related to the warrants at the amount of $829 were recorded to liabilities at the fair value of such warrants as of the date of issuance, and the proceeds related to common stocks of 2,496 were recorded to equity.

As of March 31, 2014, the fair value of such warrants was presented as a liability at its fair value $1,726 as of such date.

After the balance sheet date, on April 25, 2014, the Company entered into agreements with holders of warrants originally issued in the Company's August 16, 2013 public offering (the "2013 Warrants") to exchange outstanding 2013 Warrants entitling the holders to purchase an aggregate of 11,662,059 shares of Company common stock, $0.00005 par value for an aggregate of 5,831,031 unregistered shares of Common Stock. After the exchange, the 2013 Warrants were cancelled and of no further force and effect. (See Note 7D).

2. Share-based compensation to employees and to directors:

(a) Options to employees and directors:

On November 25, 2004, the Company's stockholders approved the 2004 Global Stock Option Plan and the Israeli Appendix thereto (which applies solely to participants who are residents of Israel) and on March 28, 2005, the Company's stockholders approved the 2005 U.S. Stock Option and Incentive Plan, and the reservation of 9,143,462 shares of Common Stock for issuance in the aggregate under these stock plans.

Each option granted under the plans is exercisable until the earlier of ten years from the date of grant of the option or the expiration dates of the respective option

plans. The 2004 and 2005 options plans will expire on November 25, 2014 and March 28, 2015, respectively. Brainstorm plans to adopt new plans at the upcoming stockholders meeting. The exercise price of the options granted under the plans may not be less than the nominal value of the shares into which such options are exercised. The options vest primarily over three years. Any options that are canceled or forfeited before expiration become available for future grants.

In June 2008, June 2011 and in June 2012, the Company's stockholders approved increases in the number of shares of common stock available for issuance under these stock option plans by 5,000,000, 5,000,000 and 9,000,000 shares, respectively.

From 2005 through 2009, the Company granted its directors options to purchase 800,000 (in total) shares of Common Stock of the Company at an exercise price of $0.15 per share. The options are fully vested and will expire after 10 years.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

2. Share-based compensation to employees and to directors: (Cont.):

(a) Options to employees and directors: (Cont.):

On June 22, 2006, the Company entered into an amendment to the Company's option agreement with two of its employees. The amendment changed the exercise price of 270,000 options granted to them from $0.75 to $0.15 per share. The excess of the fair value resulting from the modification, in the amount of $2, was recorded as general and administration expense over the remaining vesting period of the options.

On October 23, 2007, the Company granted to its former Chief Executive Officer an option to purchase 1,000,000 shares of Common Stock at an exercise price of $0.87 per share. On November 5, 2008, the Company amended the exercise price to $0.15 per share. The option is fully vested and expires after 10 years. The total compensation related to the option is $737, which was recorded as general and administrative expense. The options were all exercised for $150.

On June 29, 2009, the Company granted to its former Chief Executive Officer and director an option to purchase 1,000,000 shares of Common Stock at an exercise price of $0.067 per share. The option vests with respect to 1/3 of the shares subject to the option on each anniversary of the date of grant and expires after 10 years. Out of which 483,333 were exercised for $32 and 516,667 were cancelled.

The total compensation related to the option is $68, which is amortized over the vesting period as general and administrative expense. In February 2011, the former CEO resigned. On July 25, 2011, the Company signed a settlement agreement with the former CEO under which 483,333 shares out of the above grant became fully vested and exercisable through April 30, 2012. An additional $30 was written as compensation in general and administrative expense.

In April 2012, the former CEO exercised the option to 483,333 shares of Common Stock for an exercise price of $32.

On June 29, 2009, the Company granted to its former Chief Financial Officer an option to purchase 200,000 shares of Common Stock at an exercise price of $0.067 per share. The option vested with respect to 1/3 of the shares subject to the option. In connection with the former Chief Financial Officer's resignation, 2/3 of the above shares were cancelled and the remaining 66,667 were exercised for $4.

On April 13, 2010, the Company, Abraham Israeli and Hadasit Medical Research Services and Development Ltd. ("Hadasit") entered into an Agreement (as amended, the "Hadasit Agreement") pursuant to which Prof. Israeli agreed, during the term of the Hadasit Agreement, to serve as (i) the Company's Clinical Trials Advisor and (ii) a member of the Company's Board of Directors.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

2. Share-based compensation to employees and to directors: (Cont.):

(a) Options to employees and directors: (Cont.):

In consideration of the services to be provided by Prof. Israeli to the Company under the Hadasit Agreement, the Company agreed to grant equity annually during the term of the Hadasit Agreement for the purchase of its Common Stock, as follows:

- An option for the purchase of 166,666 shares of Common Stock at an exercise price equal to $0.00005 per share to Prof. Israeli; and
- A warrant for the purchase of 33,334 shares of Common Stock at an exercise price equal to $0.00005 per share to Hadasit,

Such options and warrants will vest and become exercisable in twelve (12) consecutive equal monthly amounts.

Accordingly, the Company granted to Prof. Israeli in each of April 2010, June 2011, April 2012 and April 2013, an option to purchase 166,666 shares of Common Stock at an exercise price equal to $0.00005 per share. The aggregated compensation related to such warrants recorded as of December 31, 2012 is $126 was classified as general and administrative expense.

In addition, the Company granted Hadasit, in each of April 2010, June 2011, April 2012, and April 2013, a warrant to purchase 33,334 shares of Common Stock at an exercise price equal to $0.00005 per share. The aggregated compensation related to the options recorded as of December 31, 2012 is $24 was classified as general and administrative expense.

In December 2013, the Board of the Company agreed to grant to Prof. Israeli additional options in connection with the yearly grant under the Hadasit Agreement. Starting April 2014, the Company will grant a total of 360,000 options annually out of which Prof. Israeli will receive options to purchase up to 300,000 shares of Common Stock and Hadasit will receive options and warrants to purchase up to 60,000 shares of Common Stock.

Accordingly, on April 13, 2014, the Company granted to Hadasit an option to purchase 60,000 shares of Common Stock at an exercise price of $0.00005 per share. (See Note 7A)

In addition, on April 13, 2014, the Company granted to Prof. Israeli options to purchase up to an aggregate of 300,000 shares of Common Stock at an exercise price equal to $0.00005 per share. (See Note 7B)

On April 25, 2014 the Hadasit Agreement was terminated pursuant to notice given by Hadasit and Prof. Israeli, in connection with Prof. Israeli's resignation from the Company. The Hadasit Agreement provided terms for Prof. Israeli's service as the Company's Clinical Trials Advisor and a member of the Company's Board of Directors, both of which ceased on April 25, 2014.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

2. Share-based compensation to employees and to directors: (Cont.):

(a) Options to employees and directors: (Cont.):

As a result of the termination of the Hadasit Agreement Prof. Israeli and Hadasit will no longer receive annual grants to purchase shares of Common Stock, and any outstanding and unvested grants made pursuant to the Hadasit Agreement will cease to vest, and the grants shall be valid until and may be exercised only on or before October 25, 2014. (See Note 7C).

On December 16, 2010, the Company granted to two of its directors an option to purchase 400,000 shares of Common Stock at an exercise price of $0.15 per share. The options are fully vested and are exercisable for a period of 10 years. The compensation related to the option, in the amount of $78, was recorded as general and administrative expense.

On December 16, 2010, the Company approved the grant to its three Scientific Board members 300,000 shares of Common Stock of the Company. The compensation related to the option, in the amount of $60, was recorded as research and development expense.

In January 2011, the Company granted to its former CEO, an option to purchase 450,000 shares of Common Stock of the Company at $0.20 per share. The total compensation related to the option is $177, which is amortized over the vesting period as general and administrative expense.

On June 27, 2011, the Company granted to three of its directors options to purchase an aggregate of 634,999 shares of Common Stock of the Company at $0.15 per share. The total compensation related to the option was $287, which is amortized over the vesting period as general and administrative expense.

On August 10, 2011, the Company granted to its CEO, an option to purchase 70,000 shares of Common Stock of the Company at $0.20 per share. The total compensation related to the option was $26, which was amortized as general and administrative expense.

On August 1, 2012, the Company granted to three of its directors options to purchase an aggregate of 460,000 shares of Common Stock of the Company at $0.15 per share. The total compensation related to the option was $105, which is amortized over the vesting period as general and administrative expense.

On August 1, 2012, the Company granted to its former CEO, an option to purchase 70,000 shares of Common Stock of the Company at $0.26 per share. The total compensation expense related to the option was $16, which was amortized as general and administrative expense.

On February 1, 2013, the Company granted its former Chief Executive Officer an option to purchase 4,000,000 shares of Common Stock at an exercise price of $0.29 per share.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

2. Share-based compensation to employees and to directors: (Cont.):

(a) Options to employees and directors: (Cont.):

The option would have vested as to 1/3 of the shares subject thereto on January 24, 2014 and the remainder would have vested over the subsequent 36 consecutive months. On July 28, 2013, the former CEO informed the Company of his resignation from his position with the Company effective October 28, 2013. In connection with the former CEO's resignation on October 28, 2013, the above options were cancelled and the total compensation expense related to the option that was recorded as general and administrative expense was cancelled.

On April 19, 2013, the Company granted to three of its directors options to purchase an aggregate of 460,000 shares of Common Stock of the Company at $0.15 per share. The total compensation expense related to the options will be recorded as general and administrative expense.

A summary of the Company's option activity related to options to employees and directors, and related information is as follows:

For the three months ended
March 31, 2014

	Amount of options	Weighted average exercise price $	Aggregate intrinsic value $
Outstanding at beginning of period	6,185,831	0.1705	
Granted	-	-	
Exercised	-	-	
Cancelled	-	-	
Outstanding at end of period	6,185,831	0.1705	677,348
Vested and expected-to-vest at end of period	5,193,609	0.1694	574,413

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the fair market value of the Company's shares on March 31, 2014 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on March 31, 2014.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

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U.S. dollars in thousands

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Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

2. Share-based compensation to employees and to directors: (Cont.):

(b) Restricted shares to directors:

During May 2006 through April 2007, the Company issued to its directors 400,000 restricted shares of Common Stock (100,000 each). The restrictions on the shares have fully lapsed. The compensation related to the stocks issued amounted to $198, which was amortized over the vesting period as general and administrative expenses.

On August 27, 2008, the Company issued to its director 960,000 shares of Common Stock upon a cashless exercise by a shareholder of a warrant to purchase 1,000,000 shares of Common Stock at an exercise price of $.01 per share that was acquired by the shareholder from Ramot. The shares were allocated to the director by the shareholder.

In May and June 2010, based on a board resolution dated June 29, 2009, the Company issued to three directors, three of its Scientific Advisory Board members and two of its Advisory Board members 800,000 restricted shares of Common Stock. The shares will vest in three annual and equal portions commencing with the grant date.

On December 16, 2010, the Company approved a grant to two of its directors 400,000 (total) shares of Common Stock. Related compensation in the amount of $80 was recorded as general and administrative costs in 2010. These shares were actually granted in June 2011, and an additional related compensation in the amount of $112 was recorded as general and administrative expense.

On June 27, 2011, the Company granted to two of its directors 476,666 (total) shares of Common Stock, which shares are fully vested as of March 31, 2013. Related compensation in the amount of $229 will be recorded as general and administrative expense.

On August 22, 2011, the Company entered into an agreement with Chen Schor (the "Executive Director Agreement") pursuant to which the Company granted to Mr. Schor 923,374 shares of restricted Common Stock of the Company. The shares will vest over 3 years - 1/3 upon each anniversary of the Grant Date. In addition, the Company will pay $15 per quarter to Mr. Schor for his services as an Executive Board Member.

In August 2011, the Company issued to three of its Scientific Advisory Board members and three of its Advisory Board members a total of 300,000 restricted shares of Common Stock. The shares will vest in equal monthly portions over the service period.

In November 2011, the Company issued to four of its Advisory Board members a total of 500,000 restricted shares of Common Stock. The shares will vest in equal monthly portions over the service period.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

C. Issuance of shares, warrants and options: (Cont.):

2. Share-based compensation to employees and to directors: (Cont.):

(a) Restricted shares to directors: (Cont.):

In addition, in November 2011, the Company issued to a former director 250,000 shares of Common Stock. Related compensation in the amount of $70 was recorded as general and administrative expense.

In August 2012, the Company issued to two directors, four of its Scientific Advisory Board members and three of its Advisory Board members a total of 885,000 restricted shares of Common Stock.

The shares will vest in 12 equal monthly portions over the service period. Related compensation in the amount of $198 was recorded as general and administrative expense.

On April 19, 2013, the Company issued to two of its directors and four of its Advisory Board members a total of 760,000 restricted shares of Common Stock. The shares will vest in 12 equal monthly portions until fully vested on the anniversary of grant. Related compensation expense in the amount of $175 will be recorded as general and administrative expense.

3. Shares and warrants to investors and service providers:

The Company accounts for shares and warrant grants issued to non-employees using the guidance of ASC 505-50, "Equity-Based Payments to Non-Employees" (EITTF 96-18, "Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services"), whereby the fair value of such option and warrant grants is determined using a Black-Scholes options pricing model at the earlier of the date at which the non-employee's performance is completed or a performance commitment is reached.

a) Warrants to investors and service providers and investors:

The fair value for the warrants to service providers was estimated on the measurement date determined using a Black-Scholes option pricing model, with the following weighted-average assumptions for the year ended December 31, 2010; weighted average volatility of 140%, risk free interest rates of 2.39%-3.14%, dividend yields of 0% and a weighted average life of the options of 5-5.5 and 1-9 years. There were no grants to service providers during 2012 and 2013 using Black-Scholes calculation.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

3. Shares and warrants to service providers: (Cont.):

(a) Warrants to investors and service providers and investors: (Cont.):

Issuance date	Number of warrants issued	Exercised	Forfeited	Outstanding	Exercise Price $	Warrants exercisable	Exerci throug
November-December 2004	14,600,845	14,396,010	204,835	-	0.00005 - 0.01	-	-
February-December 2005	3,058,471	173,000	2,548,308	337,163	0.15 - 2.5	337,163	Jun - D 2015
February-December 2006	1,686,355	727,696	478,659	480,000	0.005 – 1.5	480,000	Feb - M 2016
March 2007	14,803,300		1,003,300	13,800,000	0.15 - 0.47	13,800,000	May 2 Oct 20
April 2008	9,175,000			9,175,000	0.15 - 0.29	9,175,000	May 2 Sep 20
Apr-Oct 2009	4,937,500	100,000		4,837,500	0.067 – 0.29	4,837,500	May 2 Oct 20
January 2010	1,250,000		1,250,000	-	0.5	-	-
February 2010	125,000	125,000		-	0.01	-	-
February 2010	3,000,000		3,000,000	-	0.5	-	-
February 2010	1,500,000			1,500,000	0.001	1,000,000	Feb 20
April 2010	33,334			33,334	0.00005	33,334	Apr 20
January 2011	4,537,500			4,537,500	0.29	4,537,500	May 2
February 2011	641,026		641,026	-	0.39	-	-

February 2011	6,407,500	946,834	5,460,666	-	0.28	-	-
February 2011	12,815,000		12,815,000	-	0.5	-	-
April 2011	33,334			33,334	0.00005	33,334	Apr 20
April 2012	33,334			33,334	0.00005	33,334	Apr 20
July 2012	493,966			493,966	0.348	493,966	Jul 201
July 2012	232,758			232,758	0.29	232,758	Jan 20
July 2012	14,864,228			14,864,228	0.29	14,864,228	Jan 20
Feb 2013	833,334			833,334	0.5	833,334	Oct 20
April 2013	33,334			33,334	0.00005	30,556	April 2
August 2013	17,647,058			17,647,058	0.25	17,647,058	Augus 2016
	112,742,177	16,468,540	27,401,794	68,871,843		68,369,065	

(b) Shares:

On June 1 and June 4, 2004, the Company issued 40,000 and 150,000 shares of Common Stock for 12 months of filing services and legal and due-diligence services, respectively, with respect to a private placement. Compensation expense related to filing services, totaling $26, was amortized over a 12-month period. Compensation related to legal services, totaling $105 was recorded as equity issuance cost and had no effect on the statement of operations.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

3. Shares and warrants to service providers: (Cont.):

(b) Shares: (Cont.):

On February 10, 2005, the Company signed an agreement with one of its service providers under which the Company issued to the service provider 100,000 restricted shares at a purchase price of $0.00005 par value under the U.S. Stock Option and Incentive Plan of the Company. All restrictions on these shares have lapsed.

In March and in April 2005, the Company signed an agreement with four members of its Scientific Advisory Board under which the Company issued to the members of the Scientific Advisory Board 400,000 restricted shares at a purchase price of $0.00005 par value under the U.S. Stock Option and Incentive Plan (100,000 each). All restrictions on these shares have lapsed.

Between the years 2004 through 2009, the Company issued to several services providers, in separate transactions, 3,045,508 shares of Common Stock in total. The total related compensation, in the amount of $758, was recorded as general and administrative expense.

On March 5, 2007, the Company issued a $150 Convertible Promissory Note to a third party. Interest on the note accrued at the rate of 8% per annum for the first year and 10% per annum after the first year. On January 27, 2010, the third party converted the entire accrued principle and interest outstanding under the note, amounting to $189, into 1,016,109 shares of Common Stock.

On October 29, 2007, the Company issued to a Scientific Advisory Board member 80,000 shares of Common Stock for scientific services. Compensation of $67 was recorded as research and development expense.

On May 20, 2008, the Company issued to its finance advisor 90,000 shares Common Stock. The shares are for $35 payable to the finance advisor for introduction fee of past convertible loans. Related compensation in the amount of $36 is recorded as finance expenses.

On April 5, 2009, the Company issued to its Chief Technology Advisor 1,800,000 shares of Common Stock. The shares are for $180 payable to the advisor. Related compensation in the amount of $144 was recorded as research and development expense.

On October 1, 2009, the Company issued to its service provider 150,000 shares of Common Stock. The shares are for financial and investor relation services done by the provider. Related compensation in the amount of $51 is recorded as general and administrative expense.

On October 2, 2009, the Company issued to its service provider 1,250,000 shares of Common Stock. The shares are for investor and public relation services.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

3. Shares and warrants to service providers: (Cont.):

(b) Shares: (Cont.):

Related compensation in the amount of $400 was recorded as general and administrative expense.

On December 30, 2009, the Company issued to Ramot 1,120,000 shares of Common Stock (See Note 4).

On December 13, 2009, the Company issued a $135 Convertible Promissory Note to it legal advisor for $217 in legal fees accrued through October 31, 2009. Interest on the note accrued at the rate of 4%.

On January 5, 2010, the Company issued to its public relations advisor 50,000 shares of Common Stock for six months service. The issuance of the shares is part of the agreement with the public relations advisor that entitles it to a monthly grant of 8,333 shares of Common Stock. Related compensation in the amount of $12 was recorded as general and administrative expense.

On January 6, 2010, the Company issued to its service provider 60,000 shares of Common Stock. The shares are for $15 payable to the service provider for insurance and risk management consulting and agency services for three years. Related compensation in the amount of $16 was recorded as general and administrative expense.

On February 19, 2010, the Company's legal advisor converted the entire accrued principal and interest amount outstanding under the note into 402,385 shares of Common Stock.

On April 6, 2010, Prof. Melamed fully exercised his warrant to purchase 1,097,215 shares of Common Stock. The warrant was issued to him pursuant to the agreement with the Consultants effective as of November 4, 2004 (See Note 5a).

In May 2010, based on a board resolution dated June 29, 2009, the Company issued to one of its public relations advisors 100,000 restricted shares of Common Stock. The shares will vest in three annual and equal portions commencing with the grant date.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

3. Shares and warrants to service providers: (Cont.):

(b) Shares: (Cont.):

On December 16, 2010, the Company granted to its service provider 200,000 shares of Common Stock. The shares are for investor and public relations services. Related compensation in the amount of $40 was recorded as general and administrative expense.

On December 16, 2010, the Company granted to its two consultants 1,100,000 shares of Common Stock (See Note 5B).

On February 18, 2011, the Company's legal advisor converted the entire accrued principal and interest of the Convertible Promissory Note granted on September 15, 2010, totaling $137, into 445,617 shares of Common Stock.

On June 27, 2011, the Company granted to its legal advisor 180,000 shares of Common Stock for 2011 legal services. Related compensation in the amount of $86 was recorded as general and administrative expense.

On June 27, 2011, the Company granted to its consultant 400,000 shares of Common Stock, for services rendered through December 31, 2009.

Related compensation in the amount of $192 was recorded as research and development expense.

On June 27, 2011, the Company granted to a service provider 10,870 shares of Common Stock. Related compensation in the amount of $5 was recorded as general and administrative expense.

On December 31, 2011, the Company issued to Hadasit warrants to purchase up to 1,500,000 restricted shares of Common Stock at an exercise price of $0.001 per share, exercisable for a period of 5 years. The warrants shall vest over the course of the trials as follows: 500,000 upon enrollment of 1/3 of the patients; an additional 500,000 upon enrollment of all the patients and the final 500,000 upon completion of the study.

On August 1, 2012, the Company approved an additional grant of 623,077 shares of Common Stock to the Consultants, for services rendered from January 1, 2011 through June 30, 2012. Related compensation in the amount of $162 was recorded as research and development expense.

On January 16, 2013, the Company granted an aggregate of 216,000 shares of Common Stock of the Company to two consultants, for services rendered through December 31, 2012. Related compensation expense in the amount of $54 was recorded as research and development expense.

BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 6 - STOCK CAPITAL (Cont.):

B. Issuance of shares, warrants and options: (Cont.):

3. Shares and warrants to service providers: (Cont.):

(b) Shares: (Cont.):

On February 4, 2013, the Company issued 126,111 shares of Common Stock to an investor, according to a settlement agreement, for the correction of the conversion

rate of a $200 convertible loan. The convertible loan was issued in 2006 and converted in 2010.

On March 11, 2013, the Company granted to its legal advisor 193,696 shares of Common Stock for 2013 legal services. As of December 31, 2013, related compensation expense in the amount of $22 was recorded as general and administrative expense.

On November 13, 2013, the Company approved a grant of 450,000 shares of Common Stock to the Consultants, for services rendered during January 1, 2013 through September 30, 2013 (the “2013 Shares”). On March 24, 2014, the Company approved grants of an aggregate of 90,000 shares of Common Stock to the Consultants for services rendered in 2014, and issued such shares together with the 2013 Shares.

On March 11, 2013, the Company granted to two of its service providers an aggregate of 400,000 shares of Common Stock. The shares are public relations services. As of December 31, 2013, related compensation expense in the amount of $92 was recorded as general and administrative expense.

The total stock-based compensation expense, related to shares, options and warrants granted to employees, directors and service providers, was comprised, at each period, as follows:

	Three months ended March 31,		Period from September 22, 2000 (inception date) through March 31,
	2014	2013	2014
	U.S. $ in thousands		
Research and development	128	75	17,999
General and administrative	104	226	11,529
Financial expenses, net	-	-	248
Total stock-based compensation expense	232	301	29,776

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BRAINSTORM CELL THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

U.S. dollars in thousands

(Except share data)

Notes to Consolidated Financial Statements

NOTE 7 - SUBSEQUENT EVENTS

A. On April 13, 2014, pursuant to the Hadasit Agreement, and pursuant to the December 2013 letter from the Company to Prof. Israeli, the Company issued to Hadasit a warrant to purchase 60,000 shares of its Common Stock at an exercise price of $0.00005 per share.

B. In addition, on April 13, 2014, pursuant to the Hadasit Agreement, and pursuant to the December 2013 letter from the Company to Prof. Israeli, the Company issued to Prof. Israeli, a warrant to purchase 300,000 shares of its Common Stock at an exercise price of $0.00005 per share.

C. On April 25, 2014 the Agreement by and among the Company, Prof. Abraham Israeli and Hadasit Medical Research Services and Development Ltd. ("Hadasit"), dated April 13, 2010 and amended December 31, 2011 (as amended, the "Agreement") was terminated pursuant to notice given by Hadasit and Prof. Israeli, in connection with Prof. Israeli's resignation from the Company. The Agreement provided terms for Prof. Israeli's service as the Company's Clinical Trials Advisor and a member of the Company's Board of Directors, both of which ceased on April 25, 2014. As a result of the termination of the Agreement Prof. Israeli and Hadasit will no longer receive annual grants to purchase shares of Common Stock, and any outstanding and unvested grants made pursuant to the Agreement will cease to vest, and the grants shall be valid until and may be exercised only on or before October 25, 2014.

D. On April 25, 2014, the Company entered into agreements with holders of warrants originally issued in the Company's August 16, 2013 public offering (the "2013 Warrants") to exchange outstanding 2013 Warrants entitling the holders to purchase an aggregate of 11,662,059 shares of Company common stock, $0.00005 par value for an aggregate of 5,831,031 unregistered shares of Common Stock. After the exchange, the 2013 Warrants were cancelled and of no further force and effect.

E. On April 28, 2014, the Company announced that the US Food and Drug Administration (FDA) has approved commencement of its Phase II clinical trial with NurOwn™ in patients with Amyotrophic Lateral Sclerosis (ALS). The trial will be launched initially at the Massachusetts General Hospital (MGH) in Boston, MA and the University of Massachusetts Memorial (UMass) Hospital in Worcester, MA following Institutional Review Board (IRB) approvals. Dana-Farber Cancer Institute's Connell O'Reilly Cell Manipulation Core Facility will manufacture the NurOwn™ cells for these two clinical sites. The trial will also be conducted at the Mayo Clinic in Rochester, Minnesota.

BRAINSTORM CELL THERAPEUTICS INC.

84,000,000 Shares of Common Stock

Prospectus dated July 24, 2014