

Cactus Ventures, Inc.  
Form 10-K  
March 29, 2013

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

FORM 10-K

(Mark One)

Annual Report Under Section 13 Or 15(d) Of The Securities Exchange Act Of 1934

For the fiscal year ended December 31, 2012

or

Transition Report Under Section 13 Or 15(d) Of The Securities Exchange Act Of 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

COMMISSION FILE NUMBER: 000-52446

CACTUS VENTURES, INC.  
(Exact name of registrant as specified in its charter)

Nevada  
(State or other jurisdiction of  
organization)

000-52446  
(IRS Employer Identification  
#)

501 Fifth Avenue, 3rd Floor  
New York, NY, 10017  
(Address of principal executive offices)(Zip Code)

(212) 300-2131  
Registrant's telephone number, including area code

Action Stock Transfer Corporation  
2469 E. Fort Union Blvd., Suite 214  
Salt Lake City, UT 84121  
(801) 274-1088  
(Name, address, including zip code, and telephone number,  
including area code, of agent for service)

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. (Check one):

Large accelerated filer <input type="radio"/>	Accelerated filer <input type="radio"/>
Non-accelerated filer <input type="radio"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="radio"/>

Indicate by check mark whether the registrant is a shell company (as defined in Rule 126-2 of the act): Yes  No

There was no trading market for the Registrants voting stock on the last business day of the Registrant's most recently completed second fiscal quarter.

As of March 26, 2013, 12,053,405 shares of common stock, \$0.01 par value per share, were outstanding (excluding 9,338,260 shares of common stock the registrant is still in the process of exchanging certificates).

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this “Report”) contains forward looking statements that involve risks and uncertainties, principally in the sections entitled “Description of Business,” “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” All statements other than statements of historical fact contained in this prospectus, including statements regarding future events, our future financial performance, business strategy and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should,” or “will” or the negative of these terms or comparable terminology. Although we do not make forward looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under “Risk Factors” or elsewhere in this prospectus, which may cause our or our industry’s actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this prospectus. Before you invest in our securities, you should be aware that the occurrence of the events described in the section entitled “Risk Factors” and elsewhere in this prospectus could negatively affect our business, operating results, financial condition and stock price. Except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this prospectus to conform our statements to actual results or changed expectations.

## PART I

### Item 1. Business.

#### Business Overview

Cactus Ventures, Inc. (the “Company” or “Cactus”) is a biopharmaceutical company focused on the \$50 billion market for cancer drugs. Our most advanced products are Actimab™-A, an antibody-drug construct containing actinium 225 (Ac-225), currently in human clinical trials for acute myeloid leukemia (AML) and Iomab™-B, an antibody-drug construct containing iodine 131 (I-131), used in myeloconditioning for hematopoietic stem cells transplantation (HSCT) in various indications. The Company is currently designing a trial which the Company intends to submit for registration approval in HSCT in the settings of refractory and relapsed acute myeloid leukemia in older patients. The Company is developing its cancer drugs using its expertise in radioimmunotherapy. In addition, the Ac-225 based drugs development relies on the patented Alpha Particle Immunotherapy Technology (APIT) platform technology co-developed with Memorial Sloan-Kettering Cancer Center, a related institution. The APIT technology couples monoclonal antibodies (mAb) with extremely potent but comparatively safe alpha particle emitting radioactive isotopes, in particular actinium 225 and bismuth 213. The final drug construct is designed to specifically target and kill cancer cells while minimizing side effects. The Company intends to develop a number of products for different types of cancer and derive revenue from partnering relationships with large pharmaceutical companies and/or direct sales of its products in specialty markets in the U.S.



## Our Corporate History and Background

We were formed as a Nevada corporation on October 6, 1997, originally under the name Zurich U.S.A., Inc. On July 10, 2006, we changed our name to Cactus Ventures, Inc. and began pursuing our business of marketing sunglasses. The Company encountered numerous problems with various vendors and ceased its operations. The Company shifted its efforts to seeking a business combination opportunity with a business entity, and negotiated a merger of a target company into the Company. Upon ceasing its operations, the Company was considered a “blank check” or “Shell” company as such term is defined under the Securities Act.

Upon completing the Share Exchange (as defined below), the Company ceased being considered a “blank check” or “Shell” company and is now a clinical-stage biopharmaceutical company developing certain cancer treatments.

## Acquisition of Actinium

On December 28, 2012, the Company entered into a transaction (the “Share Exchange”), pursuant to which the Company will acquire 100% of the issued and outstanding equity securities of Actinium Pharmaceuticals, Inc. (“Actinium”), in exchange for the issuance of approximately 99% of the issued and outstanding common stock, par value \$0.01 per share, of the Company. The Share Exchange was closed on December 28, 2012. As a result of the Share Exchange, the former shareholders of Actinium became the controlling shareholders of the Company. At the closing, each Actinium shareholder received 0.333 shares (the “Exchange Ratio”) of Cactus common stock for each Actinium share exchanged. At the closing, all of the Actinium shareholders’ options and warrants to purchase Actinium common stock were exchanged at the Exchange Ratio for new options or warrants, as applicable, to purchase Cactus common stock.

Cactus has a class of securities registered under the Exchange Act of 1934, as amended (the “Exchange Act”) but its Common Stock is not registered under the Securities Act of 1933, as amended (the “Securities Act”). As part of the Share Exchange, Actinium paid \$250,000 to the shareholders of Cactus before the consummation of the Share Exchange.

The Share Exchange was treated as a recapitalization effected through a share exchange, with Actinium as the accounting acquirer and Cactus the accounting acquiree. Unless the context suggests otherwise, when we refer in this Report to business and financial information for periods prior to the consummation of the Share Exchange, we are referring to the business and financial information of Actinium.

Effective following the expiration of the ten day period following the mailing of the information statement required by Rule 14f-1 under the Exchange Act, Diane S. Button resigned from her position as member of the Board of Directors of the Company. Effective upon the closing of the Share Exchange, Diane S. Button resigned as an officer of the Company. Also effective upon the closing of the Share Exchange, Jack V. Talley was appointed to our Board of Directors. Effective as of the expiration of the ten day period following the mailing of the information statement required by Rule 14f-1 under the Exchange Act Dr. Rosemary Mazanet, David Nicholson, Sandesh Seth and Sergio Traversa were appointed to our Board of Directors. In addition, our Board of Directors appointed Jack V. Talley to serve as our President and Chief Executive Officer, Dragan Cicic to serve as our Chief Operating Officer and Chief Medical Officer, and Enza Guagenti to serve as our Chief Financial Officer, effective immediately upon the closing of the Share Exchange. On February 28, 2013, Mr. Talley resigned as the President and Chief Executive Officer, and Director of the Company and Actinium. On March 1, 2013, the Board of Directors of the Company unanimously approved the appointment of Sergio Traversa as the Company’s interim President and Chief Executive Officer. Dr. Traversa is also currently a member of the Board of the Company. On March 9, 2013, Ms. Guagenti resigned as the Chief Financial Officer of the Company and Actinium. On March 11, 2013, the Board of Directors of the Company unanimously approved the appointment of Sergio Traversa as the Company’s interim Chief Financial Officer. The

Board is actively looking for a candidate to fill the Chief Executive Officer and Chief Financial Officer positions of the Company. On March 13, 2013, the Board approved the appointment of Brio Financial Group as the Company's interim Controller, responsible for the Company's treasury and accounting functions.

As a result of the Share Exchange, the Company assumed the business and operations of Actinium. Cactus plans to change its name to more accurately reflect its new business operations. As Cactus is a "reporting company" under the Exchange Act of 1934, it is required to file periodic filings with the Securities and Exchange Commission (the "SEC"), which include Actinium's quarterly and annual financial information.

As of March 29, 2013, the Company has exchanged a total of 34,995,211, or approximately 57%, of the issued and outstanding equity securities of Actinium. The Company is continuing to exchange its shares of common stock for certificates of Actinium held by the remaining Actinium Shareholders.

## Corporate History of Actinium

Actinium was incorporated in 2000 in the state of Delaware. Until the Share Exchange, Actinium was a clinical-stage, privately held biopharmaceutical company with:

- Two clinical-stage products, Iomab-B and Actimab-A, in development for blood borne cancers;
- Preclinical data in additional cancer indications;
- A proprietary technology platform for novel radioimmunotherapy cancer treatments;
- and
- A proprietary process for manufacturing of the alpha particle emitting radioactive isotope actinium 225 (Ac-225).

Iomab-B has completed a Phase I/II design trial as a preparatory regimen in conjunction with fludarabine and reduced intensity radiation conditioning in patients who are ineligible for standard myeloablative conditioning for hematopoietic stem cell transplantation (HSCT) and the Company expects it to enter a regulatory approval trial in 2013, subject to input from the FDA concerning the design and conduct of a pivotal trial. Actimab-A is currently in a Phase I/II trial in newly diagnosed elderly acute myeloid leukemia (AML). In addition, using its patented Alpha Particle Immunotherapy Technology (APIT) platform and via its collaboration with the Memorial Sloan Kettering Cancer Center (MSKCC), the Company has preclinical data on potential drug candidates in several other cancer indications and expects to further develop these into clinical stage drug candidates.

Actinium has one wholly owned subsidiary, MedActinium, Inc., a Delaware corporation, which is party to certain isotope related licenses and contracts on which the Company relies.

Upon Actinium's formation in 2000, it acquired Pharmactinium, Inc. and MedActinium, Inc., and through Pharmactinium, Inc. acquired certain rights to the APIT platform. Core technology patents were in-licensed from N.V. Organon which also provided seed funding. Pharmactinium, Inc. was party to a research and development agreement with MSKCC beginning in 1996. In 2002, this agreement and relationship was significantly expanded and now includes research and development, preclinical development, clinical trials and commercial technology licenses. In 2007, Pharmactinium, Inc. was merged with and into the Company. In 2007, the Company also acquired its sister company, Actinium Pharmaceuticals, Limited (Bermuda) (the "Bermuda Company"), by a merger of the Bermuda Company into the Company and thereby also acquired certain patent licenses relating to APIT previously licensed by the Bermuda Company to the Company.

In 2000, the Company also began what has become a long term relationship with General Atlantic Investments Limited (GAIL), an entity which has provided most of the Company's investment capital since 2000, totaling \$50.7 million. In 2010, the parent of GAIL contributed and transferred its ownership of GAIL (now renamed Actinium Holdings, Limited), whose only asset at that time was the shares of API, to an indirect subsidiary of Memorial Sloan-Kettering Cancer Center. In January 2012, the Company closed on \$6,685,419 in net funding through the sale of the Company's stock and a Senior Convertible Note financing. On December 19, 2012, Actinium completed a private offering of units, consisting of common stock, Series A warrants and Series B warrants. The price per unit was \$1.65 for aggregate net proceeds of \$4,469,776.

Our executive office is located at 501 Fifth Avenue, 3rd Floor, New York, NY 10017 and our telephone number is (212) 300-2131. Our website address is <http://www.actiniumpharmaceuticals.com>. Except as set forth below, the information on our website is not part of this Report.





## Summary of Scientific and Business Achievements:

The Company's scientific and business achievements to date include:

- In-licensing a Phase II clinical stage monoclonal antibody, BC8, with safety and efficacy data in more than 250 patients in need of Hematopoietic Stem Cell Transplantation (HSCT), currently in 7 active Phase I and Phase II clinical trials;
- Commencing a Company sponsored multi-center Phase I/II clinical trial for Actimab-A in elderly Acute Myeloid Leukemia;
- Developing and organizing manufacturing of Actinium's lead drug candidate Actimab-A which was accepted by the FDA for multi-center human use;
- Supporting three physician sponsored clinical trials, including a Phase I and a Phase I/II trial with the alpha emitting radioactive isotope bismuth 213 (Bi-213) based AML drug and a Phase I clinical trial with the alpha emitting radioactive isotope actinium 225 (Ac-225) based AML drug;
- In-licensing the AML targeting monoclonal antibody known as HuM195 or Lintuzumab;
- Establishing clinical and preclinical development relationships with world-class institutions such as MSKCC, Fred Hutchinson Cancer Research Center (FHCRC) and University of Texas MD Anderson Cancer Center (the MD Anderson Cancer Center relationship includes clinical trials only), as well as leading clinical experts in the fields of AML and HSCT;
- Securing rights to an intellectual property estate that covers key aspects of the Company's proprietary technology platform;
- Supporting a number of pipeline projects, including preclinical experiments in metastatic prostate cancer, metastatic colon cancer, antiangiogenesis and breast cancer models;
- Maintaining contractual relationship with Oak Ridge National Laboratory (ORNL) of the Department of Energy (DOE) which gives API access to most of the current world supply of Ac-225; and
- Successfully developing commercial production methods for actinium 225.

## Business Strategy

API intends to potentially develop its most advanced clinical stage drug candidates through approval in the case of Iomab<sup>TM</sup>-B and up to and including a Phase II proof of concept human clinical trial (a trial designed to provide data on the drug's efficacy) in the case of Actimab<sup>TM</sup>-A. If these efforts are successful, API may elect to commercialize Iomab<sup>TM</sup>-B on its own or with a partner in the U.S. and/or outside of the U.S. to out-license the rights to develop and commercialize the product to a strategic partner. In the case of Actimab<sup>TM</sup>-A, API will most likely seek to enter into strategic partnerships whereby the strategic partner(s) co-fund(s) further human clinical trials of the drug that are needed to obtain regulatory approvals for commercial sale within and outside of the U.S. In parallel, the Company intends to identify and begin initial human trials with additional actinium-225 drug candidates in other cancer indications. API intends to retain marketing rights for its products in the U.S. whenever possible and outlicense marketing rights to its partners for the rest of the world.

## Market Opportunity

API is competing in the marketplace for cancer treatments estimated at over \$54 billion in 2011 sales per IMS Health and projected to exceed \$76 billion per year by 2015, according to the Global Academy for Medical Education. While

surgery, radiation and chemotherapy remain staple treatments for cancer, their use is limited by the fact that they often cause substantial damage to normal cells. On the other hand, targeted monoclonal antibody therapies exert most or all of their effect directly on cancer cells, but often lack sufficient killing power to eradicate all cancer cells with just the antibody. A new approach for treating cancer is to combine the precision of antibody-based targeting agents with the killing power of radiation or chemotherapy by attaching powerful killing agents to precise molecular carriers called monoclonal antibodies (mAb). The Company uses monoclonal antibodies labeled with radioisotopes to deliver potent doses of radiation directly to cancer cells while sparing healthy tissues. The radioisotopes we use are the alpha emitter Ac-225 and the beta emitter I-131. I-131 is among the best known and well characterized radioisotopes. It is used very successfully in treatment of papillary and follicular thyroid cancer as well as other thyroid conditions. It is also attached to a monoclonal antibody in treatment of Non-Hodgkin's Lymphoma (NHL). It is also used experimentally with different carriers in other cancers. Ac-225 has many unique properties and the Company is a leader in developing this alpha emitter for clinical applications using its proprietary APIT technology.

The Company's most advanced products are Actimab™-A, Ac-225 labeled mAb for treatment of newly diagnosed AML, a cancer of the blood, in patients ineligible for currently approved therapies, and Iomab™-B, I-131 labeled mAb for preparation of relapsed and refractory AML patients for hematopoietic stem cell transplantation (HSCT). Iomab™-B offers a potentially curative treatment for these patients most of whom do not survive beyond a year after being diagnosed with this condition. Iomab™-B has also demonstrated efficacy in HSCT preparation for other blood cancer indications, including Myelodysplastic Syndrome (MDS), acute lymphoblastic leukemia (ALL), Hodgkin's Lymphoma, and Non-Hodgkin's Lymphoma (NHL). These are all follow-on indications for which Iomab™-B can be developed and it is the Companies intention to explore these opportunities. In 2013, the Company intends to begin preclinical development of the mAb used in Iomab™-B by replacing I-131 with Ac-225. Such a follow-on product could have several advantages as a second generation product, including ease of transportation, minimal safety requirements for the centers using it, doses lower by orders of magnitude and significantly lower costs of manufacturing.

There are currently no FDA approved treatments for either Actimab™-A or Iomab™-B targeted patients.

Other potential product opportunities in which a significant amount of preclinical work is being undertaken include metastatic colorectal cancer, metastatic prostate cancer and antiangiogenesis which reduces the blood supply to solid tumors.

The Company believes that its biggest market opportunity lies in the applicability of the Company's APIT platform technology to a wide variety of cancers. A broad range of solid and blood borne cancers can be potentially targeted by monoclonal (mAbs) to enable treatment with its APIT technology. The APIT technology could potentially be applied to mAbs that are already FDA approved to create more efficacious and/or safer drugs ("biobetters").

#### Clinical Trials

The Company has completed a Phase I and Phase I/II physician trial in AML at MSKCC using Bismab®-A, The Company's first generation AML drug that consists of bismuth-213 attached to the antibody Lintuzumab™. The Phase II arm of the Bismab®-A drug study has shown signs of the drug's efficacy and safety, including reduction in peripheral blast counts and complete responses in some patients. Bi-213 is a daughter, i.e., product of the degradation of Ac-225, with cancer cell killing properties similar to Ac-225 but is less potent.

The Company has commenced its first company sponsored Phase I/II multi-center trial with fractionated (two) doses of Actimab™-A, Actinium's lead product for treatment of elderly AML that consists of an AML specific monoclonal antibody (HuM195, also known as Lintuzumab™) and the actinium 225 radioactive isotope attached to it. The Company intends to conduct these trials at world-class cancer institutions such as MSKCC, Johns Hopkins Medicine, University of Pennsylvania Health System, Fred Hutchinson Cancer Center and MD Anderson Cancer Center.

The Company also continues to sponsor a Phase I AML trial at MSKCC with a single-dose administration of Actimab™-A. Initial data shows elimination of leukemia cells from blood in 67% of all evaluable patients who received a full dose and in 83% of those treated at dose levels above 0.5 microcuries (uCi/kg), and eradication of leukemia cells in both blood and bone marrow in 20% of all evaluable patients and 25% of those treated at dose levels above 0.5 uCi/kg. Dose levels in that trial have been reduced as we continue our work on establishing a maximum tolerated dose.

This Phase I trial builds on the experience with Company's first generation drug Bismab®-A that contains the same antibody used in Actimab™-A but labeled with bismuth 213, a less potent alpha emitting daughter of actinium 225 used in Actimab™-A. Bismab®-A trials and the Phase I Actimab™-A trial were focused on relapsed, refractory and other difficult to treat acute myeloid leukemia patients. The new multicenter Phase I/II trial is focused on newly diagnosed AML patients who have historically had better outcomes. In addition, the new trial includes low doses of

chemotherapy with the goal of further improving patient outcomes.

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## Operations

The Company's current operations are primarily focused on furthering the development of its lead clinical drug candidates Actimab™-A and Iomab™-B. In the case of Actimab™-A, key ongoing activities include progressing a multi-center Phase I/II trial, support for an ongoing Phase I clinical trial at Memorial Sloan Kettering Cancer Center in New York, managing isotope and other materials supply chain, and managing the manufacturing of the finished drug candidate product. The Company has secured access to much of the currently available world reserves of Ac-225 and Bi-213 through a renewable contractual arrangement with the U.S. Department of Energy (DOE). The Company projects that these quantities are sufficient to support early stages of commercialization of alpha isotopes based products. The Company has also developed its own proprietary process for industrial scale Ac-225 production in a cyclotron in quantities adequate to support full product commercialization.

Operations related to Iomab™-B include planning for a registration trial which will include development of commercial scale manufacturing to be suitable for an approval trial and preparation of appropriate regulatory submissions.

## Intellectual Property Portfolio

The Company's technology and products are protected by an extensive intellectual property estate in excess of 60 patents and patent applications, both in the U.S. and other countries. The cornerstones of the portfolio are patents and patent applications covering use of Ac-225 and Bi-213 for medical purposes and production of the Ac-225 isotope. Additional patents and applications relate to the Company's proprietary manufacturing and treatment processes. Additionally, the Company believes that several of its programs are likely eligible for "Orphan Drug Protection" including its products intended for AML as well as bone marrow transplants. Orphan Drug Protection in the United States refers to the protection provided by the 1983 Orphan Drug Act which provides seven years of market exclusivity to drugs developed to address diseases that affect fewer than 200,000 patients in the United States. Similar protection exists in Europe and provides for ten years of marketing exclusivity.

## Key Strengths

The Company believes that the key elements for its market success include:

Clinical results to date imply lower development risk for its lead drug candidates: The Company's lead drug candidates have been tested in over 300 patients and demonstrated favorable safety and efficacy profiles. Iomab™-B has been administered to more than 250 patients in a number of Phase I and Phase II trials and has shown a clear survival benefit in the indication for which it is being developed. Bismab®-A and Actimab™-A, drugs based on the APIT platform have so far been tested in over 60 patients in 3 clinical trials. In each trial they exhibited few side effects and have shown indications of efficacy. The current proof-of-concept Actimab™-A Phase I/II clinical trial is directed at a patient population that is generally easier to treat (newly diagnosed vs. relapsed/refractory in previous trials), and employs a more potent treatment regimen (low dose chemotherapy plus two doses of Actimab™-A plus low dose chemotherapy vs. a single dose of Actimab™-A in the physician sponsored trial).

Additional product opportunities from the APIT platform: The Company's Alpha Particle Immunotherapy technology has the potential for broad applicability for the treatment of many cancer types, which allows the Company to add new product candidates to its pipeline based on well-defined patent protected methods. The next

product from the platform is expected to be a second generation BC8 product linked to Ac-225, Actimab<sup>TM</sup>-B which could potentially significantly expand the market that is targeted by Iomab<sup>TM</sup>-B.

**Collaboration with Memorial Sloan-Kettering Cancer Center (MSKCC):** The Company's collaboration with MSKCC includes licensing, research and clinical trial arrangements involving MSKCC labs and clinicians and included financial support with respect to certain pre-2012 R&D-related expenses.

**Scientific backing of leading experts:** The Company's clinical advisory board and collaborators include some of the best recognized clinicians and scientists working at some of the highest regarded medical institutions in the U.S. and the world, including MSKCC, Johns Hopkins University, University of Pennsylvania, Fred Hutchinson Cancer Center and MD Anderson Cancer Center. This is expected to be beneficial to the Company both in clinical development and market acceptance assuming its drug candidates are approved.

**Isotope supply secured for clinical trials:** The Company has a contractual relationship with ORNL (Oak Ridge National Laboratory of the Department of Energy (DOE)) that provides the Company access to the largest known supply reserves of actinium 225. Iodine 131 is readily available from a number of qualified pharmaceutical supply vendors.

**Proprietary alpha emitting isotope manufacturing technology fully developed:** The Company has developed its own proprietary technology for commercial scale manufacturing of actinium 225. This is expected to ensure commercial supply of Ac-225 for Actimab™-A, Actimab™-B and other actinium-linked products should they be approved.

**cGMP Actimab™-A manufacturing developed:** The Company has developed at a contractor's site full cGMP (current good manufacturing practices) manufacturing processes for its drug candidate Actimab™-A.

**Substantial IP portfolio:** The Company has an intellectual property portfolio in excess of 60 patents and patent applications, both in the U.S. and other countries, which cover clinical applications of the APIT technology and methods of manufacturing actinium 225 thus giving the Company control over both the applications of its technology and a supply chain of its key ingredients, actinium 225 and bismuth 213 alpha emitting isotopes.

## Competition Overview

To the Company's knowledge, there are no other commercial entities that have significant programs in place for developing Ac-225- or Bi-213-based drugs. In the wider field of medical oncology, the Company faces competition from: developers of other alpha emitter based drug candidates, other radioimmunotherapy based technologies, technologies for labeling antibodies with toxic drugs (antibody-drug conjugates), and for each disease indication from all drugs available and/or in development.

For Company's lead indication, acute myeloid leukemia, there are a number of companies developing drugs for AML induction in the elderly. These drugs are most often small molecules. Until recently, our leukemia targeting monoclonal antibody HuM195 was under development as a native i.e. unconjugated mAb by Seattle Genetics, Inc., but its development has been discontinued due to lack of efficacy of the native mAb in that company's pivotal trial in



AML. To our knowledge, there are no clinical trials that have shown significant efficacy in this indication.

In the field of hematopoietic stem cell transplantation, pharmaceuticals currently used for bone marrow ablation/conditioning are generic drugs and to our knowledge there are no significant industry efforts to enter this area, especially not in older patients.

#### Government Regulation

Governmental authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of radioimmunotherapy pharmaceutical products such as those being developed by the Company. In the United States, the U.S. Food and Drug Administration (FDA) regulates such products under the Federal Food, Drug and Cosmetic Act (FDCA) and implements regulations. Failure to comply with applicable FDA requirements, both before and after approval, may subject us to administrative and judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

#### U.S. Food and Drug Administration Regulation

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the FDA as implemented and enforced by the FDA. Certain of our product candidates in the United States require FDA pre-marketing approval of a Biologics License Application (BLA) pursuant to 21 C.F.R. § 314. Foreign countries may require similar or more onerous approvals to manufacture or market these products.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA, the Nuclear Regulatory Commission or other regulatory authorities, which may result in sanctions, including but not limited to, untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; customer notifications or repair, replacement, refunds, recall, detention or seizure of our products; operating restrictions or partial suspension or total shutdown of production; refusing or delaying our requests for BLA premarket approval of new products or modified products; withdrawing BLA approvals that have already been granted; and refusal to grant export.

#### Employees

As of March 25, 2013, we have 3 full-time employees and 1 part-time employee. None of these employees are covered by a collective bargaining agreement, and we believe our relationship with our employees is good. We also engage consultants on an as-needed basis to supplement existing staff.

## ITEM 1A. RISK FACTORS.

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this Report, before making an investment decision. If any of the following risks actually occurs, our business, financial condition or results of operations could suffer. In that case, the trading price of our shares of common stock could decline and you may lose all or part of your investment. See “Cautionary Note Regarding Forward Looking Statements” above for a discussion of forward-looking statements and the significance of such statements in the context of this Report.

### Risks Related to Our Business

We have generated no revenue from commercial sales to date and our future profitability is uncertain.

We have a limited operating history and our business is subject to all of the risks inherent in the establishment of a new business enterprise. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with this development and expansion. Since we began our business, we have focused on research, development and clinical trials of product candidates, and have incurred losses since inception. As of December 31, 2012, we had a deficit accumulated during development stage of approximately \$55,743,463. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We expect to continue to operate at a net loss as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. There can be no assurance that the products under development by us will be approved for sale in the U.S. or elsewhere. Furthermore, there can be no assurance that if such products are approved they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain.

If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development and you will likely lose your entire investment.

We do not currently have sufficient capital for the development and commercialization of our lead product and we will need to continue to seek capital from time to time to continue development of our lead drug candidates and to acquire and develop other product candidates. Our first product is not expected to be commercialized until at least 2016 and we do not expect that the partnering revenues it will generate will be sufficient to fund our ongoing operations.

Our business or operations may change in a manner that would consume available funds more rapidly than anticipated and substantial additional funding may be required to maintain operations, fund expansion, develop new or enhanced products, acquire complementary products, business or technologies or otherwise respond to competitive pressures and opportunities, such as a change in the regulatory environment or a change in preferred cancer treatment modalities. However, we may not be able to secure funding when we need it or on favorable terms.

If we cannot raise adequate funds to satisfy our capital requirements, we will have to delay, scale-back or eliminate our research and development activities, clinical studies or future operations. We may also be required to obtain funds through arrangements with collaborators, which arrangements may require us to relinquish rights to certain technologies or products that we otherwise would not consider relinquishing, including rights to future product candidates or certain major geographic markets. We may further have to license our technology to others. This could result in sharing revenues which we might otherwise have retained for ourselves. Any of these actions may harm our business, financial condition and results of operations.

The amount of capital we may need depends on many factors, including the progress, timing and scope of our product development programs; the progress, timing and scope of our preclinical studies and clinical trials; the time and cost necessary to obtain regulatory approvals; the time and cost necessary to further develop manufacturing processes and arrange for contract manufacturing; our ability to enter into and maintain collaborative, licensing and other commercial relationships; and our partners' commitment of time and resources to the development and commercialization of our products.

We have limited access to the capital markets and even if we can raise additional funding, we may be required to do so on terms that are dilutive to you.

We have limited access to the capital markets to raise capital. The capital markets have been unpredictable in the recent past for radio-immunotherapy and other oncology companies and unprofitable companies such as ours. In addition, it is generally difficult for development stage companies to raise capital under current market conditions. The amount of capital that a company such as ours is able to raise often depends on variables that are beyond our control. As a result, we may not be able to secure financing on terms attractive to us, or at all. If we are able to consummate a financing arrangement, the amount raised may not be sufficient to meet our future needs. If adequate funds are not available on acceptable terms, or at all, our business, including our technology licenses, results of operations, financial condition and our continued viability will be materially adversely affected.

If we fail to obtain or maintain necessary U.S. Food and Drug Administration clearances for our radio-immunotherapy products, or if such clearances are delayed, we will be unable to commercially distribute and market our products.

Our products are subject to rigorous regulation by the U.S. Food and Drug Administration (FDA) and numerous other federal, state and foreign governmental authorities. The process of seeking regulatory clearance or approval to market a radio-immunotherapy product is expensive and time-consuming and, notwithstanding the effort and expense incurred, clearance or approval is never guaranteed. If we are not successful in obtaining timely clearance or approval of API products from the FDA, we may never be able to generate significant revenue and may be forced to cease operations. In particular, the FDA permits commercial distribution of a new radio-immunotherapy product only after the product has received approval of a Biologics License Application (“BLA”) filed with the U.S. Food and Drug Administration pursuant to 21 C.F.R. § 314, seeking permission to market the product in interstate commerce in the United States. The BLA process is costly, lengthy and uncertain. Any BLA application filed by the Company will have to be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA’s satisfaction the safety and efficacy of the product for its intended use.

Obtaining clearances or approvals from the FDA and from the regulatory agencies in other countries could result in unexpected and significant costs for us and consume management’s time and other resources. The FDA and other agencies could ask us to supplement our submissions, collect non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain a BLA approval or pre-market approvals in other countries, the approval could be revoked or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be materially adversely affected, and our ability to grow domestically and internationally may be limited. Additionally, even if cleared or approved, the Company’s products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

Our radio-immunotherapy product candidates are in the early stages of development; and we have not demonstrated that any of our products actually cure cancer.

Only two product candidates of the Company are currently in clinical development by the Company. There is an ongoing Phase I AML trial at MSKCC under physician IND with a single dose of Actimab™-A. The Company has also commenced a Phase I/II multi-center AML trial with fractionated doses of Actimab™-A. Additionally, there are a number of physician IND trials that have been conducted or are currently ongoing at FHCRC with single doses of Iomab™-B. Neither the Company nor any relevant collaborative partner(s) has yet undertaken any clinical assessment or investigation of Company radio-immunotherapy product candidates for other indications, including colon cancer or prostate cancer. Significant further investment may be required to acquire antibody rights and to undertake necessary

research and continued development. Further laboratory and specific clinical testing will be required prior to regulatory approval of any product candidates. Adverse or inconclusive results from pre-clinical testing or clinical trials of product candidates may substantially delay, or halt entirely, any further development of one or more of our products. The projected timetables for continued development of the technologies and related product candidates by us may otherwise be subject to delay or suspension.

Modifications to our product candidates may require new NDA approvals.

Once a particular Company product candidate receives FDA approval or clearance, expanded uses or uses in new indications of our products may require additional human clinical trials and new regulatory approvals or clearances, including additional IND and NDA submissions and premarket approvals before we can begin clinical development, and/or prior to marketing and sales. If the FDA requires new clearances or approvals for a particular use or indication, we may be required to conduct additional clinical studies, which would require additional expenditures and harm our operating results. If the products are already being used for these new indications, we may also be subject to significant enforcement actions.

Conducting clinical trials and obtaining clearances and approvals can be a time-consuming process, and delays in obtaining required future clearances or approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

There is no guarantee that the FDA will grant NDA approval of our future product candidates and failure to obtain necessary clearances or approvals for our future product candidates would adversely affect our ability to grow our business.

We have recently commenced a multi-center Phase I/II clinical trial for our lead drug candidate, Actimab<sup>TM</sup>-A, in AML and in the future expect to submit a NDA to the FDA for approval of this product. This drug candidate is also the subject of an ongoing human safety trial being conducted under a physician IND at Memorial Sloan Kettering Cancer Center in New York City. We are in the early stages of evaluating other drug candidates consisting of conjugates of Ac-225 with human or humanized antibodies for pre-clinical and clinical development in other types of cancer and the Company has recently acquired rights to Iomab<sup>TM</sup>, a Phase II clinical stage monoclonal antibody with safety and efficacy data in more than 250 patients in need of HSCT. Product candidates utilizing this antibody would also require FDA approval of a NDA. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for NDA market approval of new products, new intended uses or indications to existing or future product candidates. Failure to receive approval for our new products would have an adverse effect on our ability to expand our business.

Clinical trials necessary to support NDA approval of our future product candidates will be time consuming and expensive. Delays or failures in our clinical trials will prevent us from commercializing our product candidates and will adversely affect our business, operating results and prospects and could cause us to cease operations.

Initiating and completing clinical trials necessary to support NDA approval of Actimab<sup>TM</sup>-A and other product candidates, will be time-consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product candidate we advance into clinical trials may not have favorable results in later clinical trials. We have worked with the FDA to develop a clinical trial designed to support initial safety and efficacy of Actimab<sup>TM</sup>-A and on October 6, 2008, and January 5, 2009, we submitted IND amendments to the FDA for the conduct of a multi-center Phase I/II clinical trial for treatment of AML. The trial is now underway with the purpose of examining the use of Actimab-A in AML patients who are not eligible for approved forms of treatment with curative intent. The trial is not designed to support final NDA approval of the product candidate and one or more additional trials will have to be conducted in the future before we file a NDA. In addition, there can be no assurance that the data generated during the trial will meet our chosen safety and effectiveness endpoints or otherwise produce results that will eventually support the filing or approval of a BLA.

The issued patents, which are licensed by the Company for the HuM-195 antibody, our acute myeloid leukemia targeting antibody, will begin to expire before we have commercialized Actimab<sup>TM</sup>-A.

The humanized antibody which we use in the conjugated Actimab™-A product candidate is covered by the claims of issued patents that we license from Facet Biotech Corporation, a wholly-owned subsidiary of Abbott Laboratories (“Facet”). Some of those patents will begin to expire in 2013. After these patents expire, others may be eventually able to use an antibody with the same sequence in alpha particle drug products based on alpha particle emitters other than actinium 225 and bismuth 213. Any process that would enable such a competition as described above is likely to require several years of development before achieving our product candidate’s current status and may be subject to significant regulatory hurdles, but is nevertheless a possibility that can affect the Company’s business in the future.



Additionally, because we expect that certain of these patents will expire prior to commercialization of Actimab™-A, the Company expects that in order to attract a commercialization partner for that product candidate, it will may need to reach an agreement with Facet to reduce the milestone payments and royalties currently required to be paid under our license agreement for HuM-195. There can be no assurance that the parties will be able to agree on an amendment to the terms of the license. Failure to reach such an agreement could materially adversely affect the Company's ability to find a commercialization partner for Actimab™-A which may materially harm our business.

The BC8 antibody utilized in Iomab™-B is not patent protected.

The antibody we use in the conjugated Iomab™ product candidate is not covered by the claims of any issued or pending patents. Accordingly, others may be eventually able to use an antibody with the same sequence in alpha particle drug products based on alpha particle emitters. Any process that would enable such a competition as described above is likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles, but is nevertheless a possibility that could negatively impact the Company's business in the future.

We may be unable to obtain a sufficient supply of Ac-225 medical grade isotope in order to continue clinical trials and to allow for the manufacture of commercial quantities of Actimab-A

There are limited quantities of Ac-225 available today. The existing supplier of Ac-225 to the Company is Oak Ridge National Laboratory (ORNL). It manufactures Ac-225 by eluting it from its supply of Thorium-229. Although this has proven to be a very reliable source of production for a number of years, it is limited by the quantity of Thorium-229 at ORNL. We believe that the current approximate maximum of Ac-225 production from this source is sufficient for approximately 1,000 - 2,000 patient treatments per year. Since our needs are significantly below that amount at this time, and will continue to be below that for as long as we do not have a commercial product with a potential of selling more than 2,000 patient doses per year, we believe that this supply will be sufficient for completion of clinical trials and early commercialization. To secure supplies beyond this amount, the Company has developed what it believes to be a scalable cost-effective process for manufacturing Ac-225 in a cyclotron at an estimated cost in excess of \$5 million. This work has been conducted at Technical University Munich (TUM) in Germany. The Company is now in possession of detailed descriptions of all the developed manufacturing procedures and has rights to all relevant patent applications and other intellectual property. However, we do not currently have access to a commercial cyclotron capable of producing medical grade Ac-225. Although beam time on such cyclotrons is commercially available, the Company does not currently have a relationship with any entity that owns or controls a suitable cyclotron. It has identified possible sources and estimates that it could secure the necessary beam time when needed at a cost of approximately \$2 million per year. The Company's contract for supply of this isotope from ORNL extends through the end of 2012, is renewable for future years, and has already been renewed for several consecutive years. However, there can be no assurance that ORNL will decide to renew the contract or that the U.S. Department of Energy will not change its policies that allow for the sale of isotope to the Company. Failure to acquire sufficient quantities of medical grade Ac-225 would make it impossible to effectively complete clinical trials and to commercialize Actimab™-A and would materially harm our business.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be

discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive product candidates. In addition, patients participating in refractory AML clinical trials are seriously and often terminally ill and therefore may not complete the clinical trial due to reasons including comorbid conditions or occurrence of adverse medical events related or unrelated to the investigational products, or death.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval.

The FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. They may also require additional data on certain categories of patients, should it emerge during the conduct of our clinical trials that certain categories of patients are likely to be affected in different and/or additional manner than most of the patients. In addition to FDA requirements, our clinical trial requires the approval of the institutional review board, or IRB, at each site selected for participation in our current Actimab<sup>TM</sup>-A clinical trial. We have submitted our clinical trial to the IRBs at participating sites for approval and we have thus far obtained approval from two IRBs, and are engaged in discussions with investigators at other sites to in order to complete the approval process with their respective hospital centers. The Company's clinical trial protocols have not been rejected by any IRB.

Additional delays to the completion of clinical studies may result from modifications being made to the protocol during the clinical trial, if such modifications are warranted and/or required by the occurrences in the given trial.

Each such modification has to be submitted to the FDA. This could result in the delay or halt of a clinical trial while the modification is evaluated. In addition, depending on the quantity and nature of the changes made, FDA could take the position that some or all of the data generated by the clinical trial is not usable because the same protocol was not used throughout the trial. This might require the enrollment of additional subjects, which could result in the extension of the clinical trial and the FDA delaying clearance or approval of a product candidate.

There can be no assurance that the data generated using modified protocols will be acceptable to FDA.

There can be no assurance that the data generated using modified protocols will be acceptable to FDA or that if future modifications during the trial are necessary, that any such modifications will be acceptable to FDA. If the FDA believes that its prior approval is required for a particular modification, it can delay or halt a clinical trial while it evaluates additional information regarding the change.

Serious injury or death resulting from a failure of one of our drug candidates during current or future clinical trials could also result in the FDA delaying our clinical trials or denying or delaying clearance or approval of a product.

The ongoing Phase I clinical trial for Actimab<sup>TM</sup>-A conducted at MSKCC was designed to establish the maximum tolerated dose of the product. As the Company expected, patients receiving highest dose of the drug administered in the trial so far had prolonged bone marrow suppression which could lead to fatal infections and other severe consequences. Consequently, the dose levels of our drug in that trial were reduced as we continue our work on establishing maximum tolerated dose.

Even though an adverse event may not be the result of the failure of our drug candidate, FDA or an IRB could delay or halt a clinical trial for an indefinite period of time while an adverse event is reviewed, and likely would do so in the event of multiple such events.

Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse events during the trials, may cause an increase in costs and delays in the filing of any submissions with the FDA, delay the approval and commercialization of our product candidates or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects. Lengthy delays in the completion of our Actimab<sup>TM</sup>-A clinical trials would adversely affect our business and prospects and could cause us to

cease operations.

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If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We do not have the ability to independently conduct our pre-clinical and clinical trials for our product candidates and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

The future results of our current or future clinical trials may not support our product candidate claims or may result in the discovery of unexpected adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses. If FDA concludes that the clinical trials for Actimab™-A, or any other product candidate for which we might seek clearance, have failed to demonstrate safety and effectiveness, we would not receive FDA clearance to market that product candidate in the United States for the indications sought. In addition, such an outcome could cause us to abandon the product candidate and might delay development of others. Any delay or termination of our clinical trials will delay the filing of any submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of a product candidate's profile. In addition, our clinical trials for Actimab™-A involve a relatively small patient population. Because of the small sample size, their results may not be indicative of future results.

Actimab™-A and future product candidates may never achieve market acceptance.

Actimab™-A and future product candidates that we may develop may never gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of any of product will depend on a number of factors, including the actual and perceived effectiveness and reliability of the product; the results of any long-term clinical trials relating to use of the product; the availability, relative cost and perceived advantages and disadvantages of alternative technologies; the degree to which treatments using the product are approved for reimbursement by public and private insurers; the strength of our marketing and distribution infrastructure; and the level of education and awareness among physicians and hospitals concerning the product.

Failure of Actimab™-A or any of our other product candidates to significantly penetrate current or new markets would negatively impact our business, financial condition and results of operations.

To be commercially successful, physicians must be persuaded that using our product candidates for treatment of AML and other cancers are effective alternatives to existing therapies and treatments.

We believe that oncologists and other physicians will not widely adopt a product candidate unless they determine, based on experience, clinical data, and published peer-reviewed journal articles, that the use of that product candidate provides an effective alternative to other means of treating specific cancers. Patient studies or clinical experience may indicate that treatment with our product candidates does not provide patients with sufficient benefits in extension of life or quality of life. We believe that recommendations and support for the use of each product candidate from influential physicians will be essential for widespread market acceptance. Our product candidates are still in the development stage and it is premature to attempt to gain support from physicians at this time. We can provide no assurance that such support will ever be obtained. If our product candidates do not receive such support from these physicians and from long-term data, physicians may not use or continue to use, and hospitals may not purchase or continue to purchase, them.

Even if our product candidates are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA regulation or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product candidate for which we obtain FDA clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product candidate, will be subject to continued regulatory review, oversight and periodic inspections by the FDA. In particular, we and our suppliers are required to comply with FDA's Quality System Regulations, or QSR, and International Standards Organization, or ISO, regulations for the manufacture of products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product candidate for which we obtain clearance or approval. Additionally, because our product candidates include radio-active isotopes, they will be subject to additional regulation and oversight from the United States Nuclear Regulatory Commission (NRC) and similar bodies in other jurisdictions. Regulatory bodies, such as the FDA, enforce these regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or safety issues, could result in, among other things, enforcement actions by the FDA and/or other regulatory bodies.

If any of these actions were to occur, it would harm our reputation and cause our future product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our product candidates on a timely basis and in the required quantities, if at all.

Even if regulatory clearance or approval of a product candidate is granted, such clearance or approval may be subject to limitations on the intended uses for which a product may be marketed and reduce the potential to successfully commercialize that product and generate revenue from that product. If the FDA determines that the product promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we or our commercialization partners cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider such training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with adverse event and pharmacovigilance reporting requirements, including the reporting of adverse events which occur in connection with, and whether or not directly related to, our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to recall, replace or refund the cost of any product we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Our revenue stream will depend upon third party reimbursement.

The commercial success of our product candidates in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for patients that use our products. However, the availability of insurance coverage and reimbursement for newly approved cancer therapies is

uncertain, and therefore, third-party coverage may be particularly difficult to obtain even if our products are approved by the FDA as safe and efficacious. Patients using existing approved therapies are generally reimbursed all or part of the product cost by Medicare or other third-party payors. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs, and, as a result, they may not cover or provide adequate payment for these products. Submission of applications for reimbursement approval generally does not occur prior to the filing of an NDA for that product and may not be granted until many months after NDA approval. In order to obtain reimbursement arrangements for these products, we or our commercialization partners may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Initial dependence on the commercial success of our products may make our revenues particularly susceptible to any cost containment or reduction efforts.



### Our Business as a “Going Concern”

In expressing an opinion on our financial statements, our auditor has expressed its opinion as to our business being a “going concern”. Such an opinion indicates that the business lacks sufficient liquidity to remain operating as a business entity for the next 12 months. Our ability to continue operations is dependent on the successful execution of our plans, which include the expectation of raising debt or equity based capital, with some additional funding from other traditional financing sources, including term notes, until such time that funds provided by operations are sufficient to fund working capital requirements. We may need to issue additional equity and incur additional liabilities with related parties to sustain our existence although no commitments for funding have been made and no assurance can be made that such commitments will be available.

We are dependent on third parties for manufacturing and marketing of our proposed proprietary products. If we are not able to secure favorable arrangements with such third parties, our business and financial condition would be harmed.

We will not manufacture any of our proposed proprietary products for commercial sale nor do we have the resources necessary to do so. In addition, we currently do not have the capability to market drug products ourselves. We intend to contract with specialized manufacturing companies to manufacture our proposed proprietary products and partner with larger pharmaceutical companies for their commercialization. In connection with our efforts to commercialize our proposed proprietary products, we will seek to secure favorable arrangements with third parties to distribute, promote, market and sell them. If we are not able to secure favorable commercial terms or arrangements with third parties for distribution, marketing, promotion and sales of our proposed proprietary products, we may have to retain promotional and marketing rights and seek to develop the commercial resources necessary to promote or co-promote or co-market certain or all of our proprietary product candidates to the appropriate channels of distribution in order to reach the specific medical market that we are targeting. We may not be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure favorable partnering arrangements, or are unable to develop the appropriate resources necessary for the commercialization of our proposed proprietary products, our business and financial condition could be harmed. In addition, we will have to hire additional employees or consultants, since our current employees have limited experience in these areas. Sufficient employees with relevant skills may not be available to us. Any increase in the number of our employees would increase our expense level, and could have an adverse effect on our financial position.

In addition, we, or our potential commercial partners, may not successfully introduce our proposed proprietary products or they may not achieve acceptance by patients, health care providers and insurance companies. Further, it is possible that we may not be able to secure arrangements to manufacture, market, distribute, promote and sell our proposed proprietary products at favorable commercial terms that would permit us to make a profit. To the extent that corporate partners conduct clinical trials, we may not be able to control the design and conduct of these clinical trials.

We may have conflicts with our partners that could delay or prevent the development or commercialization of our product candidates.

We may have conflicts with our partners, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due under a collaboration; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

Upon commercialization of our product candidates, we may be dependent on third parties to market, distribute and sell them.

Our ability to receive revenues may be dependent upon the sales and marketing efforts of any future co-marketing partners and third-party distributors. At this time, we have not entered into an agreement with any commercialization partner and only plan to do so after the successful completion of Phase II clinical trials and prior to commercialization. If we fail to reach an agreement with any commercialization partner, or if upon reaching such an agreement that partner fails to sell a large volume of our products, it may have a negative impact on our business, financial condition and results of operations.

Our product candidates will face significant competition in the markets for them, and if they are unable to compete successfully, our business will suffer.

Our product candidates face, and will continue to face, intense competition from large pharmaceutical companies, as well as academic and research institutions. We compete in an industry that is characterized by (i) rapid technological change, (ii) evolving industry standards, (iii) emerging competition and (iv) new product introductions. Our competitors have existing products and technologies that will compete with our product candidates and technologies and may develop and commercialize additional products and technologies that will compete with our product candidates and technologies. Because several competing companies and institutions have greater financial resources than us, they may be able to (i) provide broader services and product lines, (ii) make greater investments in research and development, or R&D, and (iii) carry on broader R&D initiatives. Our competitors also have greater development capabilities than we do and have substantially greater experience in undertaking preclinical and clinical testing of product candidates, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. They also have greater name recognition and better access to customers than us. Our chief competitors include companies such as Bayer Schering Pharma AG, GlaxoSmithKline Plc, Spectrum Pharmaceuticals, Inc. and Algeta ASA.

Adverse events involving our products may lead the FDA to delay or deny clearance for our product candidates or result in product recalls that could harm our reputation, business and financial results.

Once a product candidate receives FDA clearance or approval, the agency has the authority to require the recall of commercialized products in the event of adverse side effects, material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is a reasonable probability

that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of adverse side effects, impurities or other product contamination, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

Our business depends upon securing and protecting critical intellectual property.

Our commercial success will depend in part on our obtaining and maintaining patent, trade secret, copyright and trademark protection of our technologies in the United States and other jurisdictions, as well as successfully enforcing this intellectual property and defending this intellectual property against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable intellectual property protection, such as patents or trade secrets law, cover them. In particular, we place considerable emphasis on obtaining patent and trade secret protection for significant new technologies, products and processes. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Moreover, the degree of future protection of our proprietary rights is uncertain for product candidates that are currently in the early stages of development because we cannot predict which of these product candidates will ultimately reach the commercial market or whether the commercial versions of these product candidates will incorporate proprietary technologies.

Our patent position is highly uncertain and involves complex legal and factual questions.

Accordingly, we cannot predict the breadth of claims that may be allowed or enforced under our patents or in third-party patents. For example, we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents; we or our licensors might not have been the first to file patent applications for these inventions; others may independently develop similar or alternative technologies or duplicate any of our technologies; it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents; our issued patents and issued patents of our licensors may not provide a basis for commercially viable technologies, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties; and, we may not develop additional proprietary technologies that are patentable.

As a result, our owned and licensed patents may not be valid and we may not be able to obtain and enforce patents and to maintain trade secret protection for the full commercial extent of our technology. The extent to which we are unable to do so could materially harm our business.

We or our licensors have applied for and will continue to apply for patents for certain products. Such applications may not result in the issuance of any patents, and any patents now held or that may be issued may not provide us with adequate protection from competition. Furthermore, it is possible that patents issued or licensed to us may be challenged successfully. In that event, if we have a preferred competitive position because of such patents, such preferred position would be lost. If we are unable to secure or to continue to maintain a preferred position, we could become subject to competition from the sale of generic products. Failure to receive, inability to protect, or expiration of our patents for medical use, manufacture, conjugation and labeling of Ac-225, the antibodies that we license from third parties, or subsequent related filings, would adversely affect our business and operations.

Patents issued or licensed to us may be infringed by the products or processes of others. The cost of enforcing our patent rights against infringers, if such enforcement is required, could be significant, and the Company does not currently have the financial resources to fund such litigation. Further, such litigation can go on for years and the time demands could interfere with our normal operations. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. We may become a party to patent litigation and other proceedings. The cost to us of any patent litigation, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation more effectively than we can because of their substantially greater financial resources. Litigation may also absorb significant management time.



Unpatented trade secrets, improvements, confidential know-how and continuing technological innovation are important to our scientific and commercial success. Although we attempt to and will continue to attempt to protect our proprietary information through reliance on trade secret laws and the use of confidentiality agreements with our partners, collaborators, employees and consultants and other appropriate means, these measures may not effectively prevent disclosure of our proprietary information, and, in any event, others may develop independently, or obtain access to, the same or similar information.

Certain of our patent rights are licensed to us by third parties. If we fail to comply with the terms of these license agreements, our rights to those patents may be terminated, and we will be unable to conduct our business.

If we are found to be infringing on patents or trade secrets owned by others, we may be forced to cease or alter our product development efforts, obtain a license to continue the development or sale of our products, and/or pay damages.

Our manufacturing processes and potential products may violate proprietary rights of patents that have been or may be granted to competitors, universities or others, or the trade secrets of those persons and entities. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to claims that they infringe the patents or trade secrets of others. These other persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or process. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to conduct clinical tests, manufacture or market the affected product or use the affected process. Required licenses may not be available on acceptable terms, if at all, and the results of litigation are uncertain. If we become involved in litigation or other proceedings, it could consume a substantial portion of our financial resources and the efforts of our personnel.

Our ability to protect and enforce our patents does not guaranty that we will secure the right to commercialize our patents.

A patent is a limited monopoly right conferred upon an inventor, and his successors in title, in return for the making and disclosing of a new and non-obvious invention. This monopoly is of limited duration but, while in force, allows the patent holder to prevent others from making and/or using its invention. While a patent gives the holder this right to exclude others, it is not a license to commercialize the invention where other permissions may be required for commercialization to occur. For example, a drug cannot be marketed without the appropriate authorization from the FDA, regardless of the existence of a patent covering the product. Further, the invention, even if patented itself, cannot be commercialized if it infringes the valid patent rights of another party.

We rely on confidentiality agreements to protect our trade secrets. If these agreements are breached by our employees or other parties, our trade secrets may become known to our competitors.

We rely on trade secrets that we seek to protect through confidentiality agreements with our employees and other parties. If these agreements are breached, our competitors may obtain and use our trade secrets to gain a competitive advantage over us. We may not have any remedies against our competitors and any remedies that may be available to us may not be adequate to protect our business or compensate us for the damaging disclosure. In addition, we may have to expend resources to protect our interests from possible infringement by others.

We may undertake international operations, which will subject us to risks inherent with operations outside of the United States.

Although we do not have any foreign operations at this time, we intend to seek market clearances in foreign markets that we believe will generate significant opportunities. However, even with the cooperating of a commercialization partner, conducting drug development in foreign countries involves inherent risks, including, but not limited to difficulties in staffing, funding and managing foreign operations; unexpected changes in regulatory requirements; export restrictions; tariffs and other trade barriers; difficulties in protecting, acquiring, enforcing and litigating intellectual property rights; fluctuations in currency exchange rates; and potentially adverse tax consequences.

If we were to experience any of the difficulties listed above, or any other difficulties, any international development activities and our overall financial condition may suffer and cause us to reduce or discontinue our international development and registration efforts.

We may not be successful in hiring and retaining key employees.

Our future operations and successes depend in large part upon the continued service of key members of our senior management team whom we are highly dependent upon to manage our business, in particular, Dr. Dragan Cicic, our Chief Operating Officer and Chief Medical Officer. If any member of our current senior management terminates his or her employment with us, such a departure may have a material adverse effect on our business.

Our future success also depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified managerial, technical, clinical and regulatory personnel. There can be no assurance that such professionals will be available in the market, or that we will be able to retain existing professionals or meet or continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow and manage our business.

We do not yet know what the consequences may be on our business of the Patient Protection and Affordable Care Act.

In March 2010, President Obama signed the Patient Protection and Affordable Care Act ("PPACA"), which makes changes that are expected to significantly impact the pharmaceutical industries. One of the principal aims of the PPACA as currently enacted is to expand health insurance coverage to approximately 32 million Americans who are currently uninsured. The consequences of this significant coverage expansion on the sales of our products, once they are developed, are unknown and speculative at this point.

The PPACA contains a number of provisions designed to generate the revenues necessary to fund the coverage expansions among other things. This includes new fees or taxes on certain health-related industries.

The PPACA provisions on comparative clinical effectiveness research extend the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which included \$1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. This stimulus funding was designated for, among other things, conducting, supporting or synthesizing research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The PPACA appropriates additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. Most recently, on August 2, 2011, the President Obama signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, which threatened to trigger the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. Congress passed and President Obama signed, however, the American Taxpayer Relief Act of 2012 which delays these required cuts for one year. We expect that the PPACA, as well as other federal or state health care reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on certain development



projects. The taxes imposed by the PPACA and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for our products, and/or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

Managing our growth as we expand operations may strain our resources.

We expect to need to grow rapidly in order to support additional, larger, and potentially international, pivotal clinical trials of our drug candidates, which will place a significant strain on our financial, managerial and operational resources. In order to achieve and manage growth effectively, we must continue to improve and expand our operational and financial management capabilities. Moreover, we will need to increase staffing and to train, motivate and manage our employees. All of these activities will increase our expenses and may require us to raise additional capital sooner than expected. Failure to manage growth effectively could materially harm our business, financial condition or results of operations.

We may expand our business through the acquisition of rights to new product candidates that could disrupt our business, harm our financial condition and may also dilute current stockholders' ownership interests in our company.

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions of drug candidates, antibodies or technologies to do so. Acquisitions involve numerous risks, including substantial cash expenditures; potentially dilutive issuance of equity securities; incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition; difficulties in assimilating acquired technologies or the operations of the acquired companies; diverting our management's attention away from other business concerns; risks of entering markets in which we have limited or no direct experience; and the potential loss of our key employees or key employees of the acquired companies.

We can make no assurances that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired product, company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure that we will be able to make the combination of our business with that of acquired products, businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired products, business or companies may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our preferred or common stock, which could dilute each current stockholder's ownership interest in the Company.

#### Risks Related to Ownership of Our Common Stock

Shares of our capital stock are not registered under the Securities Act of 1933 and there is a lack of liquidity for our securities.

Though our Common Stock is listed on the OTCBB and OTCQB, there is little to no market for our Common Stock. Investors may have to bear the economic risk of an investment in the Company for an indefinite period of time. At this time, the offer and sale of our securities will not be registered under the Securities Act or any state securities laws. Each purchaser of Common Stock will be required to represent that it is purchasing such stock for its own account for investment purposes and not with a view to resale or distribution. No transfer of Common Stock issued may be made unless such transfer is registered under the Securities Act and applicable state securities laws, or an exemption therefrom is available, which will be noted on a restrictive legend placed on each Common Stock certificate. In connection with any such transfer, we may require the transferor to provide us with an opinion of legal counsel stating that the transfer complies with such securities laws and to pay any costs we incur in connection with such transfer and our review thereof as a precondition to the effectiveness of the transfer. There is no public trading market for our warrants and such trading market may never exist.

Resale of our securities is subject to significant restrictions.

Any of our securities that are sold are under exemptions from registration under applicable federal and state securities laws, as none of our securities have been registered under the Securities Act or any state securities laws. Until our securities have been registered, they may not be transferred or resold except in a transaction exempt from or not subject to the registration requirements of the Securities Act and applicable state securities laws. The SEC has broad discretion to determine whether any registration statement will be declared effective and may delay or deny the effectiveness of any registration statement filed by us for a variety of reasons. In the event that the effectiveness of any registration statement relating to resales of the shares of our securities is delayed or denied, or the registration statement, once effective, becomes unavailable for use by selling security holders, the transferability of the shares of Common Stock may be restricted and the value of such securities could be materially adversely affected.

If our ability to register our shares is limited, the ability of holders of our shares to sell them may be subject to substantial restrictions, and you may be required to hold such securities for a period of time prior to sale, in which case you could suffer a substantial loss on such shares.

If our ability to register the resale of shares of our Common Stock is limited, you may not be able to exercise all or some of your Warrants for shares of our Common Stock that are registered for resale. There will be substantial restrictions on your ability to transfer any shares which are not registered for resale, and you may be required to hold the shares you receive upon exercise of your Warrants for some period of time after exercise. During such time, the market price of our Common Stock may fluctuate and you could suffer a substantial or total loss with respect to such shares.

Because we became public by means of a “reverse merger,” we may not be able to attract the attention of major brokerage firms.

Additional risks may exist since we became public through a “reverse merger.” Securities analysts of major brokerage firms may not provide coverage of us since there is little incentive to brokerage firms to recommend the purchase of our common stock. We cannot assure you that brokerage firms will want to conduct any secondary offerings on behalf of our company in the future.

Because we were formerly an SEC-reporting shell company, we are subject to SEC rules on seasoning requirements.

The Company, since it was formerly an SEC-reporting shell company, is also subject to SEC rules which require such companies to trade in the over-the-counter markets (or some other national exchanges) for one full fiscal year and to file all periodic reports with the SEC before seeking to “uplist” to a national securities exchange like NASDAQ or NYSE MKT. The Company can only bypass the one year over-the-counter trading requirement if it can complete a firm commitment underwritten public offering with gross proceeds of at least \$40 million. As a result, our stockholders may find it more difficult to dispose of shares or obtain accurate quotations as to the market value of our common stock.

The sale of securities by us in any equity or debt financing could result in dilution to our existing stockholders and have a material adverse effect on our earnings.

Any sale of common stock by us in a future private placement offering could result in dilution to the existing stockholders as a direct result of our issuance of additional shares of our capital stock. In addition, our business strategy may include expansion through internal growth, by acquiring subscribers email lists, or by establishing strategic relationships with targeted customers and vendor. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could dilute our stockholders’ stock ownership. We may also assume additional debt and incur impairment losses related to goodwill and other tangible assets if we acquire another company and this could negatively impact our earnings and results of operations.

Future sales of our common stock in the public market could lower the price of our common stock and impair our ability to raise funds in future securities offerings.

Future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then prevailing market price of our common stock and could make it more difficult for us to raise funds in the future through a public offering of our securities.



Our Common Stock is quoted on the OTCBB and OTCQB which may have an unfavorable impact on our stock price and liquidity.

Our common stock is quoted on the OTCBB and OTCQB, which is a significantly more limited trading market than the New York Stock Exchange or The NASDAQ Stock Market. The quotation of the Company's shares on the OTCBB and OTCQB may result in a less liquid market available for existing and potential stockholders to trade shares of our common stock, could depress the trading price of our common stock and could have a long-term adverse impact on our ability to raise capital in the future.

There is limited liquidity on the OTCBB and OTCQB which may result in stock price volatility and inaccurate quote information.

When fewer shares of a security are being traded on the OTCBB and OTCQB, volatility of prices may increase and price movement may outpace the ability to deliver accurate quote information. Due to lower trading volumes in shares of our common stock, there may be a lower likelihood of one's orders for shares of our common stock being executed, and current prices may differ significantly from the price one was quoted at the time of one's order entry.

Our common stock is extremely thinly traded, so you may be unable to sell at or near asking prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.

Currently, the Company's common stock is quoted in the OTCBB and OTCQB and future trading volume may be limited by the fact that many major institutional investment funds, including mutual funds, as well as individual investors follow a policy of not investing in OTCBB and OTCQB stocks and certain major brokerage firms restrict their brokers from recommending OTCBB and OTCQB stocks because they are considered speculative, volatile and thinly traded. The OTCBB and OTCQB market is an inter-dealer market much less regulated than the major exchanges and our common stock is subject to abuses, volatility and shorting. Thus, there is currently no broadly followed and established trading market for the Company's common stock. An established trading market may never develop or be maintained. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders. Absence of an active trading market reduces the liquidity of the shares traded there.

Our Common Stock is subject to price volatility unrelated to our operations.

The trading volume of our common stock has been and may continue to be extremely limited and sporadic. As a result of such trading activity, the quoted price for the Company's common stock on the OTCBB and OTCQB may not necessarily be a reliable indicator of its fair market value. Further, if we cease to be quoted, holders would find it more difficult to dispose of our common stock or to obtain accurate quotations as to the market value of the Company's common stock and as a result, the market value of our common stock likely would decline.

We expect the market price of our Common Stock to fluctuate substantially due to a variety of factors, including market perception of our ability to achieve our planned growth, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting the Company's competitors or the Company itself. In addition, the OTCBB is subject to extreme price and volume fluctuations in general. This volatility has had a significant effect on the market price of securities issued by many companies for reasons unrelated to their operating performance and could have the same effect on our common stock.

We are an "emerging growth company" under the JOBS Act of 2012 and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company”, as defined in the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to take advantage of the extended transition period for complying with new or revised accounting standards.

We will remain an “emerging growth company” for up to five years, although we will lose that status sooner if our revenues exceed \$1 billion, if we issue more than \$1 billion in non-convertible debt in a three year period, or if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30.

Our status as an “emerging growth company” under the JOBS Act of 2012 may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements provided to us as an “emerging growth company” and because we will have an extended transition period for complying with new or revised financial accounting standards, we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

We are subject to penny stock regulations and restrictions and you may have difficulty selling shares of our common stock.

We are subject to the provisions of Section 15(g) and Rule 15g-9 of the Exchange Act, commonly referred to as the “penny stock rule.” Section 15(g) sets forth certain requirements for transactions in penny stock, and Rule 15g-9(d) incorporates the definition of “penny stock” that is found in Rule 3a51-1 of the Exchange Act. The SEC generally defines a penny stock to be any equity security that has a market price less than \$5.00 per share, subject to certain exceptions. We will be subject to the SEC’s penny stock rules.

Since our Common Stock is deemed to be penny stock, trading in the shares of our common stock is subject to additional sales practice requirements on broker-dealers who sell penny stock to persons other than established customers and accredited investors. “Accredited investors” are persons with assets in excess of \$1,000,000 (excluding the value of such person’s primary residence) or annual income exceeding \$200,000 or \$300,000 together with their spouse. For transactions covered by these rules, broker-dealers must make a special suitability determination for the purchase of such security and must have the purchaser’s written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt the rules require the delivery, prior to the first transaction of a risk disclosure document, prepared by the SEC, relating to the penny stock market. A broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information for the penny stocks held in an account and information to the limited market in penny stocks. Consequently, these rules may restrict the ability of broker-dealer to trade and/or maintain a market in our common stock and may affect the ability of the Company’s stockholders to sell their shares of common stock.

There can be no assurance that our shares of common stock will qualify for exemption from the Penny Stock Rule. In any event, even if our common stock was exempt from the Penny Stock Rule, we would remain subject to Section 15(b)(6) of the Exchange Act, which gives the SEC the authority to restrict any person from participating in a distribution of penny stock if the SEC finds that such a restriction would be in the public interest.



Because we do not intend to pay dividends, stockholders will benefit from an investment in our Common Stock only if it appreciates in value.

We have never declared or paid any cash dividends on our Preferred Stock or Common Stock. For the foreseeable future, it is expected that earnings, if any, generated from our operations will be used to finance the growth of our business, and that no dividends will be paid to holders of the Company's Preferred Stock or Common Stock. As a result, the success of an investment in our Preferred Stock or Common Stock will depend upon any future appreciation in its value. There is no guarantee that our Preferred Stock or Common Stock will appreciate in value.

Certain provisions of our Articles of Incorporation and Bylaws and Nevada law make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in the stockholders' interest.

Our Articles of Incorporation and Bylaws and certain provisions of Nevada State law could have the effect of making it more difficult or more expensive for a third party to acquire, or from discouraging a third party from attempting to acquire, control of the Company, even when these attempts may be in the best interests of our stockholders. For example, Nevada law provides that approval of a majority of the stockholders is required to remove a director, which may make it more difficult for a third party to gain control of the Company. This concentration of ownership limits the power to exercise control by the minority shareholders.

Compliance with the reporting requirements of federal securities laws can be expensive.

We are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, and the compliance obligations of the Sarbanes-Oxley Act. The costs of preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders are substantial. In addition, we will incur substantial expenses in connection with the preparation of registration statements and related documents with respect to the registration of resale of the Common Stock.

Applicable regulatory requirements, including those contained in and issued under the Sarbanes-Oxley Act, may make it difficult for us to retain or attract qualified officers and directors, which could adversely affect the management of its business and its ability to obtain or retain listing of our Common Stock.

We may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management because of the rules and regulations that govern publicly held companies, including, but not limited to, certifications required by principal executive officers. The enactment of the Sarbanes-Oxley Act has resulted in the issuance of a series of related rules and regulations and the strengthening of existing rules and regulations by the SEC, as well as the adoption of new and more stringent rules by the stock exchanges. The perceived increased personal risk associated with these changes may deter qualified individuals from accepting roles as directors and executive officers.

Further, some of these changes heighten the requirements for board or committee membership, particularly with respect to an individual's independence from the corporation and level of experience in finance and accounting matters. We may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified officers and directors, the management of our business and our ability to obtain or retain listing of our shares of Common Stock on any stock exchange (assuming we elect to seek and are successful in obtaining such listing) could be adversely affected.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Investors could lose confidence in our financial reporting and this may decrease the trading price of our Common Stock.

We must maintain effective internal controls to provide reliable financial reports and detect fraud. We have been assessing our internal controls to identify areas that need improvement. Failure to maintain an effective system of internal controls could harm our operating results and cause investors to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our Common Stock.



The price of our common stock may become volatile, which could lead to losses by investors and costly securities litigation.