Cactus Ventures, Inc. Form 8-K/A January 04, 2013

#### **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 8-K/A (Amendment No. 1)

# CURRENT REPORT Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 28, 2012

#### CACTUS VENTURES, INC.

(Exact name of registrant as specified in its charter)

Nevada 000-52446 000-52446 (State or other jurisdiction of incorporation) 000-52446 (IRS Employer Identification No.)

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

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

123 W. Nye Lane, Suite 129 Carson City, NV 89706 (Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a -12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d -2(b))

0	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e -4(c))

Explanatory Note: This Form 8-K/A includes the exhibits that Cactus Ventures, Inc. was unable to include, due to size limitations. to the Form 8-K submitted to the Securities and Exchange Commission (SEC) on January 2, 2013. The Form 8-K/A also includes a revised Exhibit 99.3 "Unaudited pro forma combined financial information of Cactus Ventures, Inc. and Actinium Pharmaceuticals, Inc."

#### CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Current Report on Form 8-K (this "Report") contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Description of Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "seeks," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "would" and sim intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. These risks and uncertainties include, but are not limited to, the factors described in the section captioned "Risk Factors" below. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Such statements may include, but are not limited to, information related to: anticipated operating results; relationships with our merchants and subscribers; consumer demand; financial resources and condition; changes in revenues; changes in profitability; changes in accounting treatment; cost of sales; selling, general and administrative expenses; interest expense; the ability to produce the liquidity or enter into agreements to acquire the capital necessary to continue our operations and take advantage of opportunities; legal proceedings and claims.

Also, forward-looking statements represent our estimates and assumptions only as of the date of this Report. You should read this Report and the documents that we reference and file or furnish as exhibits to this Report completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.

#### USE OF CERTAIN DEFINED TERMS

Except as otherwise indicated by the context, references in this report to "we," "us," "our," "our Company," or "the Company" are to the combined business of Cactus Ventures, Inc. and its consolidated subsidiaries.

In addition, unless the context otherwise requires and for the purposes of this Report only:

- "Closing Date" means December 28, 2012;
- "Exchange Act" refers to the Securities Exchange Act of 1934, as amended;
- "Actinium" or "API" refers to Actinium Pharmaceuticals, Inc., a Delaware corporation;
- "Cactus" or "CTVN" refers to Cactus Ventures, Inc., a Nevada corporation;
- "SEC" or refers to the Securities and Exchange Commission; and
- "Securities Act" refers to the Securities Act of 1933, as amended.

#### INTRODUCTION

On December 28, 2012, Cactus entered into a transaction (the "Share Exchange"), pursuant to which Cactus acquired 21% of the issued and outstanding equity securities of Actinium, in exchange for the issuance of 4,309,015 shares of common stock, par value \$0.01 per share, of Cactus (the "Common Stock"), which were issued to the shareholders of Actinium. As a result of the Share Exchange, the former shareholders of Actinium became the controlling shareholders of Cactus. In connection with the Share Exchange, Diane S. Button, the former sole director and officer of Cactus submitted a resignation letter resigning from these positions, effective upon the closing of the Share Exchange, and the directors of Actinium were appointed to the Board of Directors of Cactus, and the officers of Actinium were appointed as the officers of Cactus. The Company intends to continue to exchange its shares of common stock for shares of Actinium held by the remaining Actinium shareholders.

The Share Exchange was accounted for as a reverse takeover/recapitalization effected by a share exchange, wherein Actinium is considered the acquirer for accounting and financial reporting purposes. For more information about the acquisition of Actinium, see "Item 1.01—Share Exchange" and "Item 2.01—Description of Business—Our Corporate History and Background" of this Report.

As a result of the Share Exchange, Cactus is now a holding company operating through Actinium, a clinical-stage biopharmaceutical company developing certain cancer treatments.

To the extent that we are deemed to be a shell company, and in accordance with the requirements of Item 2.01(a)(f) of Form 8-K, this Report sets forth information that would be required if the Cactus was required to file a general form for registration of securities on Form 10 under the Exchange Act with respect to the Common Stock (which is the only class of Cactus's securities subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act upon consummation of the Share Exchange).

This Current Report contains summaries of the material terms of various agreements executed in connection with the transactions described herein. The summaries of these agreements are subject to, and are qualified in their entirety by, reference to these agreements, all of which are incorporated herein by reference.

This Current Report is being filed in connection with a series of transactions consummated by the Company and certain related events and actions taken by the Company.

This Current Report responds to the following items on Form 8-K:

Item 1.01 Entry into a Material Definitive Agreement

Item 2.01 Completion of Acquisition or Disposition of Assets

Item 3.02 Unregistered Sales of Equity Securities

Item 4.01 Changes in Registrant's Certifying Accountant

Item 5.01 Changes in Control of Registrant

Item 5.02 Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers; Compensatory Arrangements of Certain Officers

Amendments to the Registrant's Code of Ethics, Waiver of the Code of Ethics

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Item 5.06 Change in Shell Company Status

Item 9.01 Financial Statements and Exhibits

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Item Entry into a Material Definitive Agreement. 1.01

# ACQUISITION OF ACTINIUM AND RELATED TRANSACTIONS

#### Acquisition of Actinium

On the Closing Date, Cactus entered into a Share Exchange Agreement (the "Exchange Agreement") with (i) Actinium and (ii) the former shareholders of Actinium (the "Actinium Shareholders") pursuant to which we acquired 12,939,986 shares of capital stock of Actinium from the Actinium Shareholders in exchange for the issuance of 4,309,015 shares of Common Stock to the Actinium Shareholders (the "Share Exchange"). As part of the Share Exchange, Actinium paid \$250,000 to the shareholders of Cactus before the consummation of the Share Exchange. As a result of the Share Exchange, the Actinium Shareholders became the principal shareholders of Cactus.

The foregoing description of the Exchange Agreement is qualified in its entirety by reference to the provisions of the Exchange Agreement filed as Exhibit 2.1 to this Report, which is incorporated by reference herein.

#### The Offering

On October 1, 2012, prior to the closing of the Share Exchange Agreement, Actinium commenced an offering (the "Offering") of units (the "Units") each Unit consisting of an aggregate of (i) 181,818 shares of common stock of Actinium (the "Actinium Stock"); (ii) an "A" warrant to purchase 181,818 shares of Actinium Stock, exercisable at a price of \$0.55 per share for a period of one hundred and twenty (120) days from the date of the final closing of the Offering (the "A Warrant"); and (iii) a "B" warrant to purchase 90,909 shares of Actinium Stock, exercisable at a price of \$0.825 per share for a period of five (5) years from the date of the final closing (the "B Warrant") (collectively, with the A Warrant, the "Investor Warrants"). The Units were offered to Accredited Investors (as such term is defined in Rule 501 under the Securities Act) for \$100,000 each. Laidlaw & Company (UK) Ltd. was engaged by Actinium as its exclusive agent (the "Placement Agent") to assist in placing the Units. The minimum offering amount is \$5,000,000 (the "Minimum Offering Amount") and the maximum offering amount is \$15,000,000 (the "Maximum Offering Amount"). Actinium also granted the Placement Agent an option (the "Greenshoe Option") to increase the Offering through the sale, in whole or in part, of an amount of Units equal to \$5,000,000.

On December 19, 2012 and in contemplation of the closing of the Share Exchange, Actinium closed on the Minimum Offering Amount selling an aggregate of 9,366,273 Units (prior to the Share Exchange) to investors (the "Investors"), pursuant to subscription agreement (the "Subscription Agreements") and Unit Purchase Agreements (the "Unit Purchase Agreements") for gross proceeds in the amount of \$5,151,450, and net proceeds in the amount of \$4,469,776 after legal and other fees and expenses remitted to the Placement Agent. Post the closing of the Share Exchange, the Offering will continue on the same terms on a pro-forma basis with the common shares offered at \$1.65 per share, the 120 day warrants exercise price at \$1.65 per share and the 5 year warrants exercise price at \$2.48 per share.

### Registration Rights

In connection with the Offering, Actinium entered into a 2012 investor rights agreement (the "Investor Rights Agreement") with each of the Investors, under which it would be required, within 45 days after the final closing of the Offering (the "Filing Deadline"), to file a registration statement (the "Registration Statement") registering for resale (i) all Common Stock issued to the Investors pursuant to the Share Exchange Agreement, in exchange for the Actinium Stock issued as part of the Units, and (ii) all shares of Common Stock issuable upon exercise of the warrants issued pursuant to the Share Exchange Agreement in exchange for the Investor Warrants (collectively, the "Registrable Shares"). The holders of any Registrable Shares removed from the Registration Statement as a result of a Rule 415 or

other comment from the SEC shall have "piggyback" registration rights for such Registrable Shares with respect to any registration statement filed by Cactus following the effectiveness of the Registration Statement which would permit the inclusion of such Registrable Shares. Actinium has agreed to use its reasonable best efforts to have the Registration Statement declared effective within 30 days of being notified by the SEC that the Registration Statement will not be reviewed by the SEC (and in such case of no SEC review, not later than 60 days after the Filing Deadline) or within 180 days after the Filing Deadline in the event the SEC provides comments to the Registration Statement (the "Effectiveness Deadline"). In addition, certain other holders of the Company's common stock have demand registration rights at any time after the earlier of (i) October 2014, or (ii) three (3) months after API's common stock becomes publicly traded.

#### Lock-Up Agreement

On the Closing Date and in connection with the Offering, we entered into lock-up agreements (collectively, the "Lock-Up Agreements") with each of the officers, and directors, as well as the Placement Agent and any other controlling persons, under which they agreed to not sell or otherwise transfer any securities of Actinium or Cactus owned by them until the date that is the earlier of (i) twelve (12) months from the Closing Date; or (ii) six (6) months following the effective date of the Registration Statement. On December 31, 2012, Actinium Holdings Ltd. (AHL) agreed not to transfer its shares of Common Stock, subject to exceptions for certain related-party transfers, transfers to trusts and other private transfers, until, in general, the earlier of (i) twelve (12) months from the Closing Date; or (ii) six (6) months following the effective date of the Registration Statement; however, the AHL "lock-up" agreement has not been finalized as of the date of this filing.

In addition, on the Closing Date and in connection with the Share Exchange, we also entered into a lock-up agreement with our former principal shareholder, Diane Button, under which she agreed to not sell or otherwise transfer any securities of Cactus owned by her until the date that is the earlier of (i) the final closing of the Offering, or (ii) February 28, 2013.

The foregoing description of the Subscription Agreements, Unit Purchase Agreement, A Warrant, B Warrant, Investor Rights Agreement, and Lock-Up Agreements are qualified in its entirety by reference to the provisions of the Forms of Subscription Agreement, Unit Purchase Agreement, A Warrant, B Warrant, Investor Rights Agreement and Lock-Up Agreement filed as Exhibits 10.6, 10.7, 4.1, 4.2, 10.20 and 4.3, respectively, to this Report, which are incorporated by reference herein.

Item Completion of Acquisition or Disposition of Assets. 2.01

The disclosure in Item 1.01 of this Report regarding the Share Exchange is incorporated herein by reference in its entirety.

#### FORM 10 DISCLOSURE

As disclosed elsewhere in this Report, we acquired Actinium on the Closing Date pursuant to the Share Exchange, which was accounted for as a recapitalization effected by a share exchange. Item 2.01(f) of Form 8-K provides that if the Company was a shell company, other than a business combination related shell company (as those terms are defined in Rule 12b-2 under the Exchange Act) immediately before the Share Exchange, then the Company must disclose the information that would be required if the Company were filing a general form for registration of securities on Form 10 under the Exchange Act reflecting all classes of the Company's securities subject to the reporting requirements of Section 13 of the Exchange Act upon consummation of the Share Exchange.

To the extent that the Company might have been considered to be a shell company immediately before the Share Exchange, we are providing below the information that we would be required to disclose on Form 10 under the Exchange Act if we were to file such form. Please note that the information provided below relates to the combined Company after the acquisition of Actinium, except that information relating to periods prior to the date of the Share Exchange relate only to Actinium unless otherwise specifically indicated.

#### **DESCRIPTION OF BUSINESS**

**Business Overview** 

We are a biopharmaceutical company focused on the \$50 billion market for cancer drugs. Our most advanced products are Actimab<sup>TM</sup>-A, an antibody-drug construct containing actinium 225 (Ac-225), currently in human clinical trials for acute myeloid leukemia (AML) and Iomab<sup>TM</sup>-B, an antibody-drug construct containing iodine 131 (I-131), used in myeloconditioning for hematopoietic stem cells transplantation (HSCT) in various indications. API 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, and 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" company as such term is defined under the Securities Act.

Upon completing the Share Exchange, the Company ceased being considered a "blank check" company and is now a clinical-stage biopharmaceutical company developing certain cancer treatments.

#### Acquisition of Actinium

On the Closing Date, Actinium completed a Share Exchange with Cactus, whereby Cactus acquired 21% of the issued and outstanding capital stock of Actinium from the Actinium Shareholders in exchange for the issuance of 4,309,015 shares of Common Stock to the Actinium Shareholders (the "Share Exchange"). Cactus has a class of securities registered under the Exchange Act of 1934 but its Common Stock is not registered under the Securities Act of 1933. As part of the Share Exchange, Actinium paid \$250,000 to the shareholders of Cactus before the consummation of the Share Exchange. As a result of the Share Exchange, Actinium became the wholly owned subsidiary of Cactus and the Actinium Shareholders became the principal shareholders of Cactus.

The Share Exchange was treated as a recapitalization effected through a share exchange, with Actinium as the accounting acquirer and the 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 has 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.

As a result of the Share Exchange, Actinium became a subsidiary of Cactus and Cactus 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, and it is required to file periodic filings with the SEC, which include Actinium's quarterly and annual financial statements.

#### 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 Phase I and Phase II trials as a preparatory regimen in conjunction with fludarabine and reduced intensity radiation conditioning in patients who are otherwise ineligible 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.

The 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 API and thereby also acquired certain patent licenses relating to APIT previously licensed by the Bermuda Company to API.

In 2000, API 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 \$7,844,268 in gross funding through the sale of Series E Preferred Stock and a Senior Convertible Note financing. 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 the Form 10 information for Actinium.

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 Hematotoietic (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 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 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). API 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.

API's most advanced products are Actimab<sup>TM</sup>-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<sup>TM</sup>-B, I-131 labeled mAb for preparation of relapsed and refractory AML patients for hematopoietic stem cell transplantation (HSCT). Iomab<sup>TM</sup>-B offers the only potentially curative treatment for these patients most of whom do not survive beyond a year after being diagnosed with this condition. Iomab<sup>TM</sup>-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<sup>TM</sup>-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<sup>TM</sup>-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 approved treatments for either Actimab<sup>TM</sup>-A or Iomab<sup>TM</sup>-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

API has completed a Phase I and Phase I/II physician trial in AML at MSKCC using Bismab®-A, API'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.

API has commenced its first company sponsored Phase I/II multi-center trial with fractionated (two) doses of Actimab<sup>TM</sup>-A, Actinium's lead product for treatment of elderly AML that consists of an AML specific monoclonal antibody (HuM195, also known as Lintuzumab<sup>TM</sup>) 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<sup>TM</sup>-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<sup>TM</sup>-A but labeled with bismuth 213, a less potent alpha emitting daughter of actinium 225 used in Actimab<sup>TM</sup>-A. Bismab®-A trials and the Phase I Actimab<sup>TM</sup>-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.

#### Operations

The Company's current operations are primarily focused on furthering the development of its lead clinical drug candidates Actimab<sup>TM</sup>-A and Iomab<sup>TM</sup>-B. In the case of Actimab<sup>TM</sup>-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. API 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. API 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<sup>TM</sup>-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

API'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 API'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**

API believes that the key elements for its market success include:

Clinical results to date imply lower development risk for its lead drug candidates: API's lead drug candidates have been tested in over 300 patients and demonstrated favorable safety and efficacy profiles. Iomab<sup>TM</sup>-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<sup>TM</sup>-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<sup>TM</sup>-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 ActimabTM-A plus low dose chemotherapy vs. a single dose of ActimabTM-A in the physician sponsored trial).

Additional product opportunities from the APIT platform: API'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): API'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: API'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 API both in clinical development and market acceptance assuming its drug candidates are approved.

Isotope supply secured for clinical trials: API 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.