Actinium Pharmaceuticals, Inc.

AMEX:ATNM

Analyst: Etienne Lehideux
Sector: Healthcare

BUY

Target Price: $12

Key Statistics as of 3/19/2015

Market Price:	$2.79
Industry:	Biotechnology
Market Cap:	$99.0 M
52-Week Range:	$15.00 – 2.40
Beta:	(0.56)

Thesis Points:

- Actinium offers an effective alternative for treating AML and BMT
- Proprietary technology platform that can lead to licensing opportunities and application to many types of cancers
- Two potentially breakthrough products in the pipeline

Company Description:

Actinium Pharmaceuticals, Inc., a biotechnology company, develops drugs for the treatment of cancer. The company develops therapies for life threatening diseases using its alpha particle immunotherapy (APIT) platform. Its products include Bismab-A for acute myeloid leukemia; Actimab-A, an antibody-drug construct that is in Phase I/II clinical trial for the treatment of acute myeloid leukemia; and Iomab-B, an antibody-drug construct used in myeloconditioning for hematopoietic stem cells transplantation in various indications. The company was formerly known as Cactus Ventures, Inc. and changed its name to Actinium Pharmaceuticals, Inc. in April 2013. Actinium Pharmaceuticals, Inc. was founded in 2000 and is based in New York, New York.

Thesis

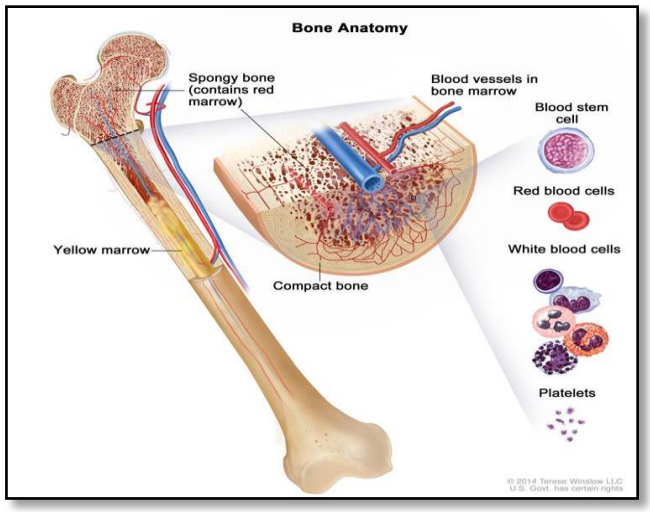
Actinium Pharmaceuticals, Inc. is an early stage biotech company that focuses on breakthrough cancer therapy, targeting Bone Marrow Transplant (BMT) and Acute Myeloid Leukemia (AML). Current treatments for both diseases are not effective, especially with patients older than 55. The company developed a proprietary platform in partnership with Memorial Sloan Kettering Cancer Center, which allows a precise targeting of cancer cells without killing other cells and that can be licensed for many other types of cancer. The company also has two products that are respectively in phase I/II and about to enter Phase III of clinical tests. Finally, the company is led by experienced healthcare executives and advised by reputed doctors. The company does not have direct competition, benefits from high barriers to entry, and its current valuation is cheap compared to Bayer's acquisition of similar company Algeta in 2014 for $2.9 billion.

Oncology and Acute Myeloid Leukemia

Actinium Pharmaceuticals, Inc. strives to research and develop breakthrough therapies against cancer. The two main products in the company's pipeline, Iomab-B and Actimab-A, respectively target Bone Marrow Transplant (BMT) and Acute Myeloid Leukemia (AML).

Bone Marrow Transplant represents a $1.3 billion market in the U.S. and is unaddressed by branded pharmaceutical companies. BMT is also a fast growing hospital procedure in the U.S., especially amongst patients over 50 years old (more than a third versus less than 10% in 2000). The issue that Actinium tries to solve with Iomab-B is the correct preparation of patients before the transplants. Indeed, certain blood cells have to be destroyed completely to avoid graft-versus-host disease after allogeneic transplants.

Acute Myeloid Leukemia, or AML, is a cancer of the blood and bone marrow. Referred to as the most common type of leukemia amongst adults, this cancer alters the normal development of blood stem cells generated by the bone marrow. Instead of maturing to become red blood cells, platelets, or white blood cells, the myeloid stem cells evolve into abnormal, unhealthy cells (also called leukemia cells, or blasts). The accumulation of these cells in the bone marrow avoids normal cell generation and causes infection or anemia.



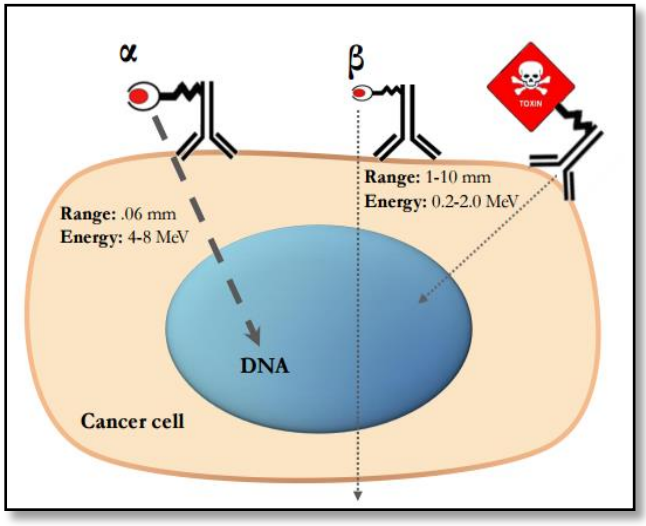
Source: Cancer.gov

There are two main types of treatment used against AML.

First, chemotherapy consists of drugs, ingested or injected, designed to kill cancer cells by targeting the cells that are dividing rapidly. These drugs also kill non-cancerous cells, which results in side effects such as hair loss.

Next, radiation therapy is an alternative used by approximately 50% of cancer patients. It consists of using *"high-energy x-rays or other types of radiation to kill cancer cells or keep them from growing" (Cancer.gov)*. The radiation can be either external, using a machine outside the body, or internal, where radioactive substances are injected into or near the cancer. The side effects associated with radiotherapy are often limited to the areas of the body around the tumors that receive the treatment, and other common side effects include fatigue and skin irritation. The most commonly used radiotherapy is Beta radiation, which has two major shortfalls. The treatment kills all the cells that they interact with, which can include cells that are not affected by the cancer. Also, certain cancer cells can resist radiation and grow back after remission.

Another type of radiation therapy uses alpha emitting radioisotopes, which generate more energy than Beta emitting radioisotopes but have a shorter range. It should be noted that the killing power of radioactive particles is proportional to its energy and inversely proportional to its range. Alpha particle carries the most energy but travels the shortest path, while beta particle has less energy but goes farther in the body.



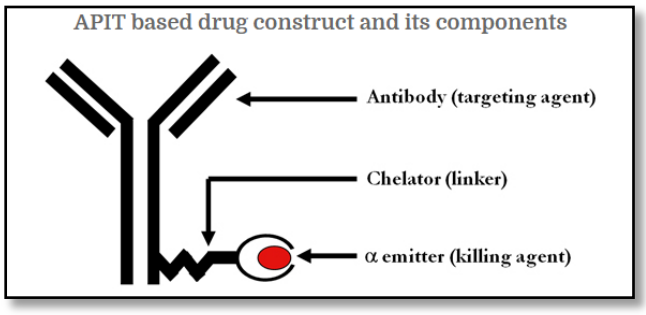
Source: Actinium's Investor Presentation

Acute Myeloid Leukemia is the deadliest form of leukemia and 55% of AML patients are over 65 years old. Insufficient treatment options are available in the marketplace, and the current treatments kill as many patients as it helps due to toxicity, offering no significant survival benefits.

Competitive Advantage and Industry

APIT Platform

ANTM's main competitive advantage is their proprietary "Alpha Particle Immunotherapy (APIT) platform". It is a highly potent and selective form of targeted radiotherapy, based on attaching alpha emitting radioisotopes (Actinium 225 or Bismuth 213) to monoclonal antibodies (mAbs), which are large molecules capable of binding specifically to cancer cells. By virtue of carrying alpha emitters, mAbs bring them directly to cancer cells where alpha emitters can selectively kill the targeted cell. As the below figure shows, the proprietary platform allows ATNM to "lead" alpha particles directly to cancerous cells, hence avoiding the destruction of unaffected cells.



Source: Actinium's website

Currently, ANTM's focus is on the clinical testing of their two main products, which are described in the "Pipeline" part later in this report. Although, the company believes that its biggest market opportunity lies in the applicability of the APIT platform technology to a wide variety of cancers.

Their first strategy with this platform is to create other monoclonal antibodies (mAbs) "combos" with proven safety and cancer binding capabilities. The company focuses on unmet needs in the market, where no other treatments are available. Currently, three mAbs are under consideration (Antiangiogenesis, Prostate Cancer, Colorectal Cancer).

The second potential use of their proprietary platform is the development of "Biobetters". It consists of improving the already existing biotech drugs with proven safety and efficacy by applying the APIT technology and creating more efficient "combos".

Intelectual Property

ATNM also have an important intellectual property portfolio that should certainly help the company's success. ATNM's IP estate includes 17 U.S. and 51 international both issued and pending patents. Internally generated patents and in-licensed patents include protection for their Platform Technology, their drug preparation methods, their Isotope production methods, and mAb composition and production, as shown in the table below.

Area	Claim
Methods of treatment (multiple patents)	Protection from toxicity
Platform Technology	Medical Treatment w/α emitters Ac-225 and Bi-213, Treatment of cancer metastases larger than 1mm, DOTA based Ac-225 constructs
Drug Preparation Methods	Ac-225 labeling , Bi-213 labeling
Isotope production methods (multiple patents)	Ac-225 cyclotron production
mAb composition and production (multiple patents)	Production of an ti-leukemia antibody

Radioisotopes

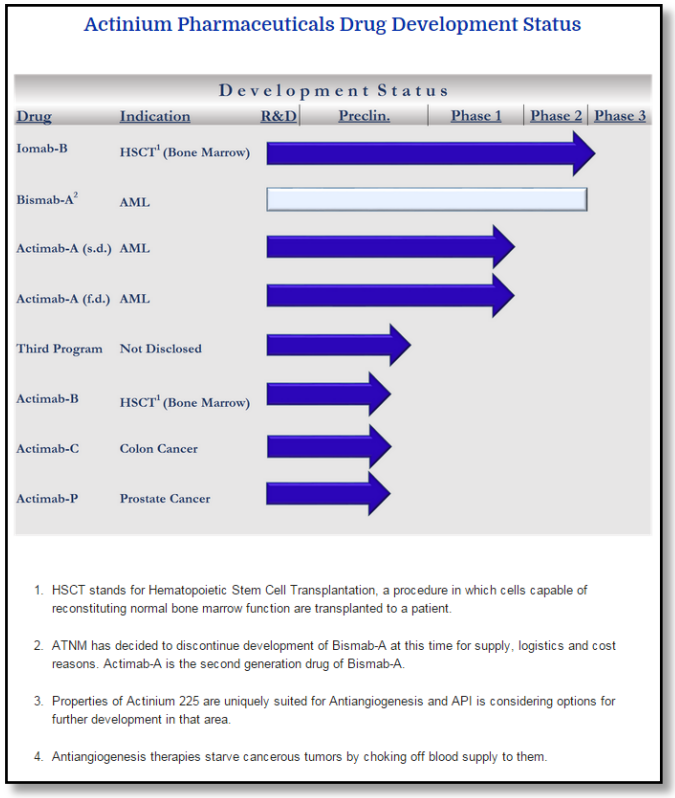
The radioisotopes that ATNM uses are the alpha emitter Ac-225 and the beta emitter I-131. I-131 is among the best known and well characterized radioisotopes, and is used very successfully in treatment of papillary and follicular thyroid cancer as well as other thyroid conditions. Ac-225 has many unique properties and

ATNM is a leader in developing this alpha emitter for clinical applications. According to the company's latest 10-K, there are no other commercial entities that have significant programs in place for developing Ac-225- or Bi-213-based drugs. In the field of hematopoietic stem cell transplantation, pharmaceuticals currently used for bone marrow ablation/conditioning are generic drugs and ATNM does not recognize any significant industry efforts to enter this area, especially in older patients.

Algeta ASA and Dr. Turck

The only other company working in the field of alpha-particle emitting radioisotopes was Algeta ASA. Founded in 1997 in Norway, it was acquired in 2014 by giant pharmaceutical group Bayer for $2.9 billion.
Former Algeta's lead product Xofigo is a radiotherapeuthic drug prescribed against castration-resistant prostate cancer and symptomatic bone metastases. According to its phase III clinical tests results, the drug improved overall survival rate from 11.2 to 14 months. A recent development that will play in favor of ATNM is that the company's board has retained Roland Turck, MD, former President, Global Specialty Medicine, Bayer Healthcare to provide strategic advice. At Bayer, Dr. Turck played a leadership role in the commercialization of Xofigo. Dr. Turck will provide guidance on the ongoing clinical development, pre-commercialization, and licensing activities for Iomab-B and clinical development and licensing activities for Actimab-A.

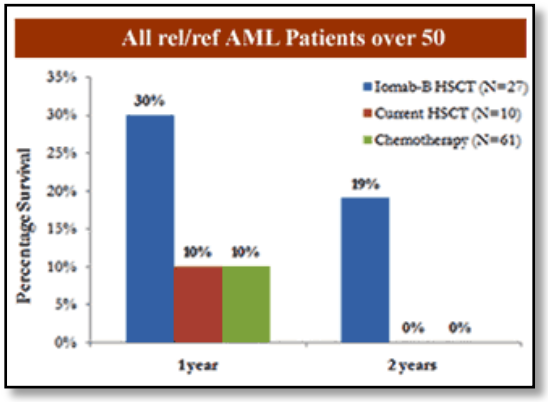
Pipeline



ATNM currently has two main products in clinical testing:

Iomab-B

Iomab-B for Hematopoietic Stem Cells Transplantion has already been successfully used in over 250 patients with incurable blood cancers. In both Phase I and Phase II trials, Iomab-B has led to effective cures in patients with no options left. The only potentially curative treatment option for those patients is bone marrow transplantation (BMT), also known as a hematopoietic stem cell transplant (HSCT), but vast majority of patients over the age of 50 are either ineligible or have a high burden or very resistant disease that makes reduced dose conditioning futile. Iomab-B has demonstrated ability to successfully prepare such patients for bone marrow transplants when no other treatment was indicated. ATNM intends to develop Iomab-B through a regulatory approval via a pivotal registration trial in AML refractory/relapsing patients. That would allow for a relatively quick path to the market and provide a potentially curative treatment to patients who currently have little or no chance of achieving even a temporary remission.



Actimab-A

Actimab-A is the second generation of Bismab-B (which had been discontinued due to high costs), with 500x better potency and 10x lower COGS. It is a radiolabeled antibody being developed for newly diagnosed AML in patients over 60, and is currently in a multicenter Phase 1/2 clinical trial. The preliminary results are positive with no dose limiting toxicities in patients older than 60 and up to 87 years of age who were not eligible for currently approved therapies. Two out of three Actimab-A treated patients achieved complete remission with different degrees of hematological recovery (CRi). These responses were documented in the settings of high pre-treatment leukemia burdens of up to 88% in the bone marrow. In the previous cohort treated at a lower dose level of Actimab-A, one patient achieved CRi.

According to Dragan Cicic, MD, Chief Medical Officer of Actinium, *"We believe the responses observed for Actimab-A, with minimal toxicity being reported, are impressive in this disease setting. These findings build upon those presented and published over the past year which demonstrated a clear survival benefit in secondary AML patients. We remain steadfast in our belief that Actimab-A could play an important role in the treatment regimen for newly diagnosed elderly secondary AML patients who currently have limited treatment options, and have historically achieved overall survival of only 2 to 5 months, depending on treatment modality."* The press release is available here.

Management & Strategy

Dr. Kaushik J. Dave, Ph.D, R.Ph, MBA has been the Chief Executive Officer and President of Actinium Pharmaceuticals, Inc. since September 16, 2013. He also serves as Interim Chief Financial Officer and Principal Accounting Officer. Dr. Dave has more than 17 years in the pharmaceutical industry, serves as a consultant for investment banks and venture capital firms, and as an advisor to several startup pharmaceutical companies. His broad experience includes securing multiple product approvals from the US Food and Drug Administration (FDA), European Medicines Agency (EMEA) and the Medicines Control Agency (MCA). Dr. Dave obtained his Pharmacy degree from University of Bath, UK, a Ph.D in Pharmaceutical Chemistry from the University of Kansas, and an MBA from the Wharton School, University of Pennsylvania.

Dr. Dave's leadership is focused on the development of Actinium's breakthrough therapy products and the FDA application processes. His experience in clinical testing provides him with credibility in terms of drugs application. If the clinical tests and FDA application are are successful, Actinium may elect to commercialize Iomab-B on its own or with a partner in the United States and/or outside of the United States to out-license the rights to develop and commercialize the product to a strategic partner. In the case of Actimab-A, the company will most likely seek to enter into strategic partnerships whereby the strategic partners co-funds further human clinical trials of the drug that are needed to obtain regulatory approvals for commercial sale within and outside of the United States. In parallel, Actinium intends to identify and begin initial human trials with additional actinium-225 product candidates in other cancer indications. The company intends to retain marketing rights for its products in the United States whenever possible and out-license marketing rights to our partners for the rest of the world.

To assist the company's management in their research and development, a Clinical Advisory Board and a Scientific Advisory Board are in place. The former is focused on Hematology and Actimab-A related issues while the latter focuses on Bone Marrow Transplant and Iomab-B related issues. Members of these boards include experienced researchers from different cancer research centers, such as Fred Hutchinson Cancer Research Center, Seattle, WA, Memorial Sloan Kettering Cancer Center, New York, NY, or MD Anderson Cancer Center.

Actinium Pharmaceuticals, Inc.'s majority shareholder is AHLB Holdings, LLC, with approximately 16% and is wholly owned by Memorial Sloan Kettering Cancer Center. ATNM's second largest shareholder is a subsidiary of Merck and Co. As of the end of 2014, management's ownership was approximately 2%.

Financials and Valuation

Because ATNM is still at an early stage and does not sell any of its products, it is difficult to proceed to a financial analysis and valuation for the company without using guesstimates. The 2014 transaction between acquirer Bayer and target company Algeta set a precedent with a $2.9 billion valuation and revealed significant potential for ATNM. Analysts estimate that clinical tests will be done and FGDA approval granted by 2018, where ATNM could start generating revenues. It must not be forgotten that key player Dr. Tuck just joined Actinium's advising team. Another scenario for Actinium would be to get acquired.2015 developments should also impact ATNM stock prices. With Iomab-B entering phase III, both professionals and investors will increase their interests for the product and for the company. ATNM is currently trading near its 52 weeks low of $2.4, and the downside is limited considering that the company manages to raise approximately $20 million a year from shareholders.

Unlike most other biotech companies, the success of this investment does not only rely on FDA approval of the current pipeline's products. Actinium's competitive advantage lays in its proprietary APIT platform, that could be used with the right partners and generate significant licensing revenues.

My DCF analysis implied a Terminal Value approximately $1 Billion by 2022 and a price per share of $11.7. The terminal growth used was 5% and the discount rate 14%.