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EQUITY RESEARCH
Company Report

November 11, 2013

Actinium Pharmaceuticals, Inc. (ATNM - $ 5.00)

Healthcare / Biotechnology

Iomab-B Phase III Trial Outlined, Study Smaller Than Expected

Ticker:	**ATNM**
Rating:	**Buy**
Price Target:	**$ 18.00**

Actinium Pharmaceuticals hosted a corporate update and virtual roadshow conference today. The company highlighted the strong results of its Iomab-B Phase I/II studies and outlined the design of its pivotal Phase III trial for bone marrow conditioning in relapsed and refractory AML patients.

- **Strong Data.** The initial indication for Actinium's lead product, Iomab-B, is bone marrow conditioning for bone marrow transplant (BMT) in refractory/relapsed older (55 years +) acute myeloid leukemia (AML) patients. Actinium has reviewed its data for safety and efficacy across multiple indications for Iomab-B with the FDA. Most notable were the results from Study 1432, in which patients had refractory/relapsed acute myeloid leukemia (AML)/ high-risk Myelodysplastic Syndromes (HR MDS) with active disease ineligible for standard BMT. There is no current alternative curative treatment for these patients. Median survival of this patient population is six weeks to six months with best supportive care. Of the 68 patients in dose escalation, 31 were treated at the maximum tolerated dose (MTD). The study reported complete response in all patients and approximately 40% one-year survival for all patients and 45% one-year survival for patients treated at the MTD. This proof of concept data is coupled with consistent safety results with over 250 patients receiving treatment in Phase I and II clinical trials.
- **Pivotal Phase III Trial Outlined.** Actinium announced it has completed the design of its pivotal Phase III trial in support of a Biologics License Application (BLA) submission. The Phase III trial will be a two arm, open label, randomized 1:1 study, with 150 patients age 55 or older. This is a smaller study size than our previously anticipated range of 150 patients – 250 patients. The primary endpoint is complete response lasting six months and the secondary endpoint is overall survival at one year. Management expects the first patient will be enrolled in 2014 and BLA submission is expected in 2H16.
- **Maintaining BUY Rating and Price Target.** We continue to believe that Iomab-B has blockbuster potential. The company has several expected near-term catalysts including first patient to enroll in Iomab-B Phase III and manufacturing and regulatory progress updates as well as the completion of Phase I/II trials for Actimab-A, all of which should be supportive for the stock, in our opinion. Our price target for Actinium is $18.00 is based on the NPV of our probability-adjusted forecasts for Iomab-B and Actimab-A plus a small value for the company's preclinical pipeline.

Trading Data:

Last Price (11/11/2013)	$ 5.00
52–Week High (3/21/2013)	$ 7.75
52–Week Low (12/17/2012)	$ 1.00
Market Cap. (MM)	$ 81
Shares Out. (MM)	16

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY_15E	NA	NA	NA	NA	-0.77	NM
FY_14E	NA	NA	NA	NA	-0.74	NM
FY_13E	-0.03A	-0.13A	-0.08	-0.08	-0.32	NM
FY_12A	-13.93	-24.65	0.00	0.00	-7.58	NM

Source: Laidlaw & Company estimates

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Trial Results/Expectations

In Phase I and Phase II trials, Iomab-B has led to effective cures in patients with no options left

In 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 older patients with refractory/relapsed AML or HR MDS patients with active disease is bone marrow transplantation (BMT), but the vast majority of patients over the age of 50 are either ineligible for myeloablative conditioning due to concomitant conditions or have a high burden and/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. In Phase I/II trials, all patients achieved Complete Response and one year survival was 30% in advanced AML patients with active disease at all does levels (see Figure 1). Historic survival in advanced active AML is 10% according to a 2009 article in *Biology of Blood and Marrow Transplantation*. Today, Actinium gave an update on its pivotal Phase III registration trial for bone marrow conditioning in relapsed and refractory AML patients over age 55. We believe this trial will allow for a relatively quick path to the market. Iomab-B provides a potentially curative treatment to patients who currently have little or no chance of achieving even a temporary remission, let alone a cure, in our opinion. We expect a BLA will be submitted in 2H16 and approval and launch will occur in 2H17.

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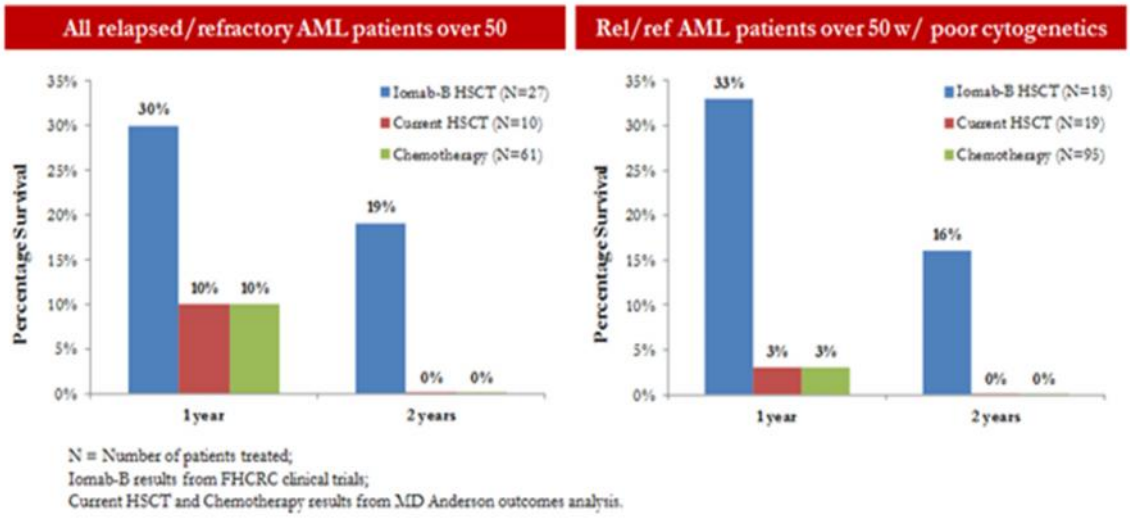
Figure 1: Iomab-B Clinical Trial Data



Source: Company reports

The pivotal Phase III trial will include 150 patients, with 75 patients in each study arm

The pivotal Phase III trial will include 150 patients, with 75 patients in each study arm. We had been expecting that a Phase III trial would require approximately 150 patients – 250 patients. We believe this will result in lower costs to execute the study, allowing the firm to allocate additional capital to the

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The primary endpoint is complete response lasting six months and the secondary endpoint is overall survival at one year

manufacturing and development efforts of Iomab-B, as well as additional pipeline products. The Phase III trial is a multicenter, open label, randomized study with two arms. The study will include the Iomab-B treatment arm and a control arm using the method of care chosen by the investigator for bone marrow transplant conditioning in relapsed and refractory AML patients. The primary endpoint is complete response lasting six months and the secondary endpoint is overall survival at one year.

We expect the first patient will be enrolled in 2H14

Management expects several Iomab-B developments in 2014 in both the manufacturing and regulatory settings. Actinium expects enrollment of the first clinical patient in the Phase III trial in 2014. We expect the first patient will be enrolled in 2H14. BLA submission is projected by management to occur in 2H16, which is consistent with what we have in our NPV valuation model. The positive efficacy and safety data for the drug continues to attract the attention of leading bone marrow transplant medical professionals. The highly concentrated volume of bone marrow transplant procedures at top centers and continued recognition as a potential curative option by opinion leaders will likely be highly supportive of the marketing effort, reducing sales force and physician education costs. The top ten centers perform about 40% of allogeneic BMTs and the top 50 centers have about 80% of the volume in the U.S.

There are seven ongoing physician trials with BC8 monoclonal antibody (mAb), the antibody used in Iomab-B, for other indications. The detailed efficacy results of the Iomab-B Phase II trial reinforce our continued expectation that the drug will be approved for its initial indication, leading the way for multiple additional indications including Myeolodysplastic Syndrome (MDS), Acute Lymphoblastic Leukemia (ALL), Non-Hodgkin's Lymphoma and Hodgkin's Disease, and Multiple Myeloma. The lack of available treatment options for these intended indications makes a strong case for Iomab-B being a potential blockbuster drug.

We believe the potential addressable BMT market in AML for Iomab-B in the U.S. is about $500 million and the total worldwide market is about $800 million - $1 billion

We continue to estimate that Iomab-B has blockbuster potential for BMT conditioning, especially for elderly, very sick patients with no curative treatment options. We believe Iomab-B will expand the patient population eligible for BMT while minimizing transplant related mortality and increasing curative outcomes. Iomab-B provides a faster, safer way of performing bone marrow transplant, in our opinion. We project the potential addressable BMT market in AML for Iomab-B in the U.S. is about $500 million and the total worldwide market is about $800 million - $1 billion.

Actinium has commenced a Phase I/II multi-center AML trial with fractionated doses of Actimab-A that will target newly diagnosed AML patients… the company hopes to have interim results by the 2014 ASH Conference

In addition to Iomab-B, Actinium management discussed another pipeline product, Actimab-A. Actinium has commenced a Phase I/II multi-center AML trial with fractionated doses of Actimab-A that will target newly diagnosed AML patients. Patients are eligible if they have previously untreated newly diagnosed acute myeloid leukemia, are age 60 years or older and are unfit for or decline intensive chemotherapy, or are 70 years or older with newly diagnosed AML. This target population has had better outcomes than relapsed and refractory patients who have been most of the patients in Actinium's previous trials. In addition, the new trial includes low doses of chemotherapy with the goal of further improving patient outcomes. The trial is projected to be completed within 12 – 18 months and the company hopes to have interim results by the 2014 American Society of Hematology (ASH) Conference (held each year in December). A Phase III trial could potentially start in 2015 and would need about 200 patients, in our opinion. We believe Actinium could file a BLA with the FDA for Actimab-A in 2018. A launch could occur in 2019. No new

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AML drugs have been approved in over a decade. We forecast the potential U.S. market for Actimab-A is about $450 million and the total worldwide market is $900 million - $1 billion.

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Risks to Owning the Stock

There are many standard risks for development stage biotechnology companies that hold true for the entire industry. There are development risks associated with preclinical and clinical studies, and potential delays in the start of trials. There is regulatory risk that the company will be unable to receive regulatory approvals for drugs or that regulatory approval may be delayed. Manufacturing risks are associated with the upgrading of facilities from clinical study production to commercial production. There is also commercial risk for a company to successfully market and sell its drug or drugs. Other risks include financing risk, currency risk, potential governmental price controls, and IP (generic) risks. The stock of biotechnology companies, like all publically traded companies, is subject to market volatility and liquidity risks if there are small trading floats. Actinium is susceptible to all of these risks.

Downside risks specific to Actinium include the likelihood of the need to sell more stock to raise capital for the continuation of the company's clinical trials. However, we believe investors already assume that the company will have to raise funds for the continued development of the company's products. We expect the company will have to raise capital in each of the next two years and have included those assumptions in our models. The near-term value of the stock is hinged on binary events, including the success of the Phase I/II trial for Actimab-A in AML and the start of the Phase III trial for Iomab-B HSCT in refractory/relapsed older AML patients in 2014. The longer-term value for the company is based on the timing of regulatory submission and approval, the ultimate market potential and expectations for the company's drugs, and the successful commercialization of these drugs.

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Figure 2: Income Statement

Actinium Pharmaceuticals *Income Statement (000s, except per share data)*	FY 2013E Q1_13 Mar	 Q2_13 Jun	 Q3_13E Sept	 Q4_13E Dec	FY 2014E Q1_14E Mar	 Q2_14E Jun	 Q3_14E Sept	 Q4_14E Dec	FY_11 Dec	FY_12 Dec	FY_13E Dec	FY_14E Dec	FY_15E Dec
Revenue	-								-				
									-	-	-	-	-
Cost of sales	-	-	-	-	-	-	-	-	-	-	-	-	-
Gross Profit	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating expenses:													
Selling, general and administrative	933.1	966.4	1,034.0	1,156.4	1,229.8	1,314.7	1,415.0	1,591.1	2,959.2	4,506.2	4,089.9	5,550.6	6,661.6
Research and development	1,085.7	509.3	662.0	960.7	3,000.0	3,200.0	3,500.0	3,700.0	323.8	3,440.5	3,217.7	13,400.0	14,500.0
Depreciation and amortization	-	-	-	-	-	-	-	-	0.6	0.6	-	-	-
Loss on disposition of equipment	4.1	-	-	-	-	-	-		-	-	4.1	-	-
Other	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	**2,023.0**	**1,475.6**	**1,696.1**	**2,117.0**	**4,229.8**	**4,514.7**	**4,915.0**	**5,291.1**	**3,283.7**	**7,947.3**	**7,307.6**	**18,950.6**	**21,161.6**
Operating Income/(loss)	**(2,023.0)**	**(1,475.6)**	**(1,696.1)**	**(2,117.0)**	**(4,229.8)**	**(4,514.7)**	**(4,915.0)**	**(5,291.1)**	**(3,283.7)**	**(7,947.3)**	**(7,307.6)**	**(18,950.6)**	**(21,161.6)**
Other Income:													
Interest income (expense)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(175.1)	(1,099.3)	(2.5)	(2.5)	(2.5)
Gain on change in fair value of derivative liabilities	1,334.5	(1,307.7)	-	-	-	-	-	-	14.0	685.4	26.8	-	-
Income (loss) before provision for income taxes	**(689.0)**	**(2,784.0)**	**(1,696.7)**	**(2,117.7)**	**(4,230.4)**	**(4,515.3)**	**(4,915.7)**	**(5,291.7)**	**(3,444.8)**	**(8,361.2)**	**(7,283.3)**	**(18,953.1)**	**(21,164.1)**
Tax: (%) non-GAAP	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Income tax	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss)	**(689.0)**	**(2,784.0)**	**(1,696.7)**	**(2,117.7)**	**(4,230.4)**	**(4,515.3)**	**(4,915.7)**	**(5,291.7)**	**(3,444.8)**	**(8,361.2)**	**(7,283.3)**	**(18,953.1)**	**(21,164.1)**
Diluted EPS (GAAP)	**(0.03)**	**(0.13)**	**(0.08)**	**(0.08)**	**(0.16)**	**(0.18)**	**(0.19)**	**(0.18)**	**(4.30)**	**(7.58)**	**(0.32)**	**(0.74)**	**(0.77)**
Weighted Diluted Shares outstanding	21,391.7	22,178.6	22,178.6	25,735.5	25,735.5	25,735.5	25,735.5	29,068.8	801.8	1,103.5	22,871.1	25,761.2	27,427.9
Weighted Diluted Shares YOY change (%)	*56.1%*	*30.3%*	*NA*	*NA*	*20.3%*	*16.0%*	*16.0%*	*13.0%*		*37.6%*	*NM*	*12.6%*	*6.5%*

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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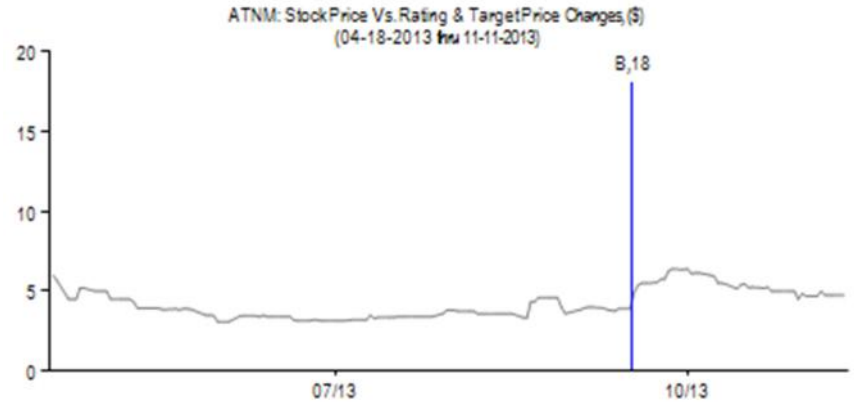

3 Year Rating Change History

Date	Rating	Closing Price ($)
09/17/2013	Buy (B)	4.90

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
09/17/2013	18.00	4.90

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	85.71%	42.86%	0.00%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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