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EQUITY RESEARCH
Company Report

November 18, 2015

Actinium Pharmaceuticals (ATNM - $ 2.20)

IND Filing For Iomab-B Submitted with Phase III Trial Expected to Commence in 1H16

Healthcare/Biotechnology

Ticker:	**ATNM**
Rating:	**Buy**
Price Target:	**$ 17.00**

This morning, ATNM announced that it has submitted an IND application to the FDA for Iomab-B in refractory and relapsed AML Phase III trial.

- **Details.** After the recent successful pre-IND meeting with the FDA, ATNM submitted an IND to start a Phase III trial evaluating Iomab-B in elderly refractory and relapsed AML patients. Should the agency agree with the study design, the company could potentially start the study in December 2015. Given the needs for gaining IRB approvals from each clinical site, we estimate patient recruitment could start in 1H16.
- **Implications.** We view today's news as an important positive for the Iomab-B clinical program as it positions ANTM to begin the pivotal trial for their clinically most advanced program. We will project the time for completing the study later, once we gain more insights on the pace of patient recruitment. Our discussion with management indicated that patient recruitment will commence in 1H16 based on IRB approvals by clinical sites. They also confirmed that the trial design is consistent with the prior guidance: a two-armed, randomized, open-label study in refractory and relapsed AML patients over the age of 55. The patient size is 150 and evenly randomized between the Iomab-B followed by HSCT arm and the control treatment arm. The primary endpoint is durable, complete remission (CR) defined as a CR lasting at least 6 months. The secondary endpoint is overall survival at one year. Patients in the treatment arm who achieve CR will be counted as a success. The control arm is the physician's choice of conventional care with curative intent. Patients who achieve a CR in the chemotherapy control arm will undertake RIC followed by HSCT or other treatment modalities. Patients in the control arm who fail to achieve CR will crossover to the Iomab-B treatment followed by the HSCT arm, and their clinical outcome would not be counted. Management also indicated that the Actimab-A Phase I dose finding study is still testing the potential final dose with additional data to be presented at the ASH meeting this December.
- **Action.** We are reiterating our Buy rating and $17 target price to reflect the company's continued advancements of the two leading products. Our target price is supported by peer comparable and probability-adjusted-NPV-driven sum-of-the-parts analyses.

Trading Data:

Last Price (11/17/2015)	$ 2.20
52–Week High (11/21/2014)	$ 6.65
52–Week Low (8/3/2015)	$ 1.52
Market Cap. (MM)	$ 92
Shares Out. (MM)	42

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.09A	-0.20A	-0.11A	-0.13	-0.56	NM
FY-14A	-0.66	0.14	-0.21	-0.18	-0.90	NM
FY-13A	0.02	-0.10	-0.03	-0.25	-0.36	NM
FY-12A	NA	NA	NA	NA	-4.46	NM

Source: Laidlaw & Company estimates

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Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
Iomab-B	Acute Myeloid Leukemia (AML) second line for conditioning for BMT	Potentially enroll first patient for Phase III study	**1H16**	***
		Potentially report Phase III study top-line results	**2017**	****
		Potentially file for BLA	**2H17**	***
		Potential FDA decision	**2018**	****
Actimab-A	Acute Myeloid Leukemia (AML) first line	Presentation at the ASH	**Dec. 5-8, 2015**	***
		Potentially complete the Phase I portion of the Phase I/II study	**4Q15**	***
		Potentially start the the Phase II portion of the Phase I/II study	**1Q16**	***
		Potentially report Phase II study top-line results	**2H16**	****

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company estimates and company presentation.

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Major Risks

Risks of clinical study failure could have significant impacts on ATNM share value. Although the prior and ongoing studies have provided encouraging clinical outcomes, risks remain that some current trials might not meet study endpoints. As such, the value of the clinical assets could be significantly impaired and, therefore, ATNM shareholder value could diminish. Such a negative impact could be more pronounced if the clinical program is in very advanced development stages, such as Iomab-B in r/r AML or with high investor expectations. Regulatory risks are part of the clinical risks as even if a drug meets its' endpoints for pivotal studies, regulatory agencies might not grant approval.

Commercial risk even with approval, sales could be substantially below expectations. Even it is approved, the commercial sales of any drug could below expectations, resulting in diminished ATNM shareholder value. Factors that could impact the commercial outlook of a drug could include execution of marketing and sales, competition from other drugs, potential change of the treatment paradigm, and unrealistic expectations or projections.

Future capital raises could potentially dilute value of current shareholders. ATNM is still in the product development stage and additional financial resources maybe needed for further advancement of their product pipeline. The company may need to raise capital from financial markets to support its operations even if the company already has partners to provide milestone and other types of payments and/or product revenue. The company might not always be able to raise capital from financial markets at favorable terms. Share dilution under this scenario could reduce the value of the investment to current shareholders of the company.

Other radiotherapeutics have been approved but failed commercially, and this modality might not be broadly accepted and therefore limit its commercial potential. Although two radiotherapeutic drugs have already been approved and commercialized in the U.S. and other parts of the world, their revenue has been a disappointment. Nevertheless, we believe the market and unmet medical need for ATNM's products is different from that of the two prior radiotherapeutics. It is possible that going forward, radiotherapeutics-based medication could have limited use due to market acceptance. Such a scenario could reduce the market potential of radiotherapeutic drugs and have negative impact on ATNM shareholder value.

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Actinium Pharmaceuticals – Income Statement

($'000)	2013	2014	1Q15	2Q15	3Q15	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue												
Product revenue	0	0	-	-	-	-	0	0	0	15,970	53,768	180,276
Other revenue	0	0	-	-	-	-	0	0	0	0	0	0
Total revenue	0	0	-	-	-	-	0	0	0	15,970	53,768	180,276
Costs of goods									0	2,555	8,603	28,844
Gross sales									0	13,415	45,165	151,432
Research and development	2,667	12,267	4,049	3,838	2,828	2,941	13,656	19,664	25,564	27,864	30,372	32,802
General and administrative	3,919	10,175	3,806	3,550	1,795	1,813	10,965	11,513	13,125	13,781	14,470	15,194
Marketing and sales	0								7,000	19,600	30,380	31,899
Depreciation and amortization	2	38	10	16	17	17	61	61	61	61	61	61
Loss on disposition of equipment	4	0	-	-	-	-	0	0	0	0	0	0
Total Operating Expenses	3,925	22,481	7,866	7,405	4,640	4,771	24,681	31,238	45,749	61,306	75,283	79,955
Operating Incomes (losses)	(3,925)	(22,481)	(7,866)	(7,405)	(4,640)	(4,771)	(24,681)	(31,238)	(45,749)	(47,891)	(30,117)	71,476
Interest income (expense)	(3)	(1)	(6)	(2)	1	1	(5)	0	0	0	0	0
Gain on change in fair value of derivative liabilities	(4,179)	(2,206)	4,796	(58)	(200)	(200)	4,339	4,773	5,250	5,775	6,352	6,988
Total Other Income (Expense)	(4,182)	(2,207)	4,791	(59)	(199)	(199)	4,339	4,773	5,250	5,775	6,352	6,988
Net loss and comprehensive loss	(8,107)	(24,688)	(3,075)	(7,464)	(3,946)	(4,970)	(20,342)	(26,465)	(40,499)	(42,116)	(23,765)	78,464
Tax	0	0	-	-	-	-	0	0	0	0	0	(29,032)
Net Income (Loss)	(8,107)	(24,688)	(3,075)	(7,464)	(3,946)	(4,970)	(20,342)	(26,465)	(40,499)	(42,116)	(23,765)	49,432
Net Income (Loss) Applicable to Common Shareholders	(8,107)	(24,688)	(3,075)	(7,464)	(3,946)	(4,970)	(20,342)	(26,465)	(40,499)	(42,116)	(23,765)	49,432
Net Earnings (Losses) Per Share—Basic	($0.36)	($0.90)	($0.09)	($0.20)	($0.11)	($0.13)	($0.56)	($0.70)	($1.04)	($1.05)	($0.58)	$1.17
Net Earnings (Losses) Per Share—Diluted	($0.36)	($0.90)	($0.09)	($0.20)	($0.11)	($0.13)	($0.56)	($0.70)	($1.04)	($1.05)	($0.58)	$1.17
Shares outstanding—basic	22,753	27,364	33,256	36,651	36,951	37,451	36,077	38,077	39,077	40,077	41,077	42,077
Shares outstanding—diluted	22,753	27,364	33,256	36,651	36,951	37,451	36,077	38,077	39,077	40,077	41,077	42,077
Margin Analysis (% of Sales/Revenue)												
Costs of goods										16%	16%	16%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	174%	56%	18%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	86%	27%	8%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-300%	-56%	40%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-264%	-44%	27%
Financial Indicator Growth Analysis (YoY%)												
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	237%	235%
R&D	-22%	360%	142%	92%	-25%	-39%	11%	44%	30%	9%	9%	8%
SG&A	-13%	160%	55%	47%	-45%	-11%	8%	5%	14%	5%	5%	5%
Marketing and sales										180%	55%	5%
Operating Income (Losses)	-13%	473%	90%	67%	-34%	-31%	10%	27%	46%	5%	-37%	-337%
Pretax Income	65%	205%	-82%	-312%	-35%	-8%	-18%	30%	53%	4%	-44%	-430%
Net Income	65%	205%	-82%	-312%	-35%	-8%	-18%	30%	53%	4%	-44%	-308%
EPS	-92%	153%	-86%	-249%	-50%	-27%	-38%	23%	49%	1%	-45%	-303%

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

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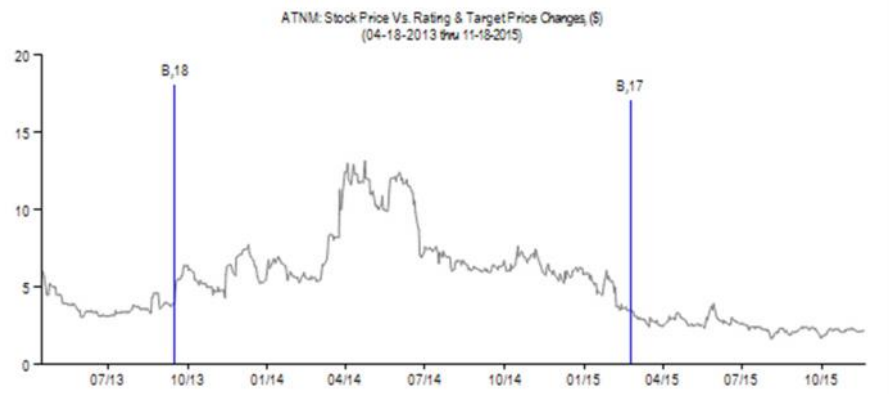

3 Year Rating Change History

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
02/23/2015	17.00	3.50

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

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			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.	71.88%	25.00%	6.25%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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