

Actinium Pharmaceuticals (ATNM - \$ 2.55)

KOL Breakfast Highlighted That Facilitated by Iomab-B, BMT Could Be a More Broadly Used Potential Curative Therapy

This morning, ATNM hosted a KOL breakfast to highlight that bone marrow transplant (BMT) could potential become more broadly applicable in difficult to treat elder r/r AML patients as a possible curative therapy, when facilitated by Iomab-B. Besides ATNM management, two invited speakers are Dr. Hillard M. Lazarus from Case Western Reserve University School of Medicine, and Dr. Roland U. Turck, an industry veteran with extensive experience in launching radiopharmaceuticals. Major takeaway from the meeting include:

- Iomab-B IND filing and Phase III commencement imminent.** ATNM management indicated that the IND filing for Iomab-B as a bone marrow transplant (BMT) conditioning regimen in r/r AML Phase III study is in preparation. They expect the trial to start later in 2015. We believe some of the ATNM shares overhang might due to the concern that it took a longer time for the company to start the Phase III study due to the transfer of manufacturing from the Fred Hutchinson Cancer Center to a commercial production setup. We doubt that ATNM would highlight the Iomab-B program advancements in this public forum if most of the issues have not already been resolved. As such, we believe the clinical advancement of Iomab-B is imminent and estimate the Phase III study could start in 2H15. ATNM suggested it could take ~2 years after trial start to complete the study before filing for approval.
- Iomab-B is a well differentiated treatment to potentially serve substantial unmet need.** Dr. Lazarus emphasized that BMT is likely to be the only potentially curative treatment for elder r/r AML patients given that all other therapies only have limited response rate and efficacy. Given the high comorbidities of elder patients, more demanding myeloablative conditioning treatments (high-dose chemo or whole body radiation) prior to BMT are not likely to be tolerated by most patients. Iomab-B conditioning could be a substantially better alternative if clinically successful and he did not see much competition in place.
- 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.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.09A	-0.21	-0.23	-0.23	-0.77	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

Healthcare/Biotechnology

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

Trading Data:

Last Price (05/12/2015)	\$ 2.55
52-Week High (6/2/2014)	\$ 13.70
52-Week Low (4/1/2015)	\$ 2.40
Market Cap. (MM)	\$ 91
Shares Out. (MM)	36

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- Iomab-B is well differentiated from other radiotherapeutics.** Dr. Turck provided a prospective on radiotherapeutics development, and on the commercial outlook of Iomab-B in treating r/r AML patients. He pointed out that BMT market is highly concentrated with top 15 transplant centers in the U.S. account for ~40% of AML transplant procedures. Given the Iomab-B Phase III study plans to engage 30 centers, it is possible that substantial mindshare about Iomab-B by physicians could be gained even prior to possible approval and launch. He also provided comparisons between various radiotherapeutics, which include Iomab-B and the more successful Xofigo, and the less successful, Zevalin and Bexxar (Figure 1).

Figure 1: Radiopharmaceuticals – a history of success and failure

	Zevalin, Bexxar	Xofigo	Iomab-B
Competition	Rituximab competition ** Abundance of data ** Ease of use ** Roche's marketing power	Unique positioning ** OS benefit in HRPC patients with symptomatic bone mets ** QoL endpoints Well tolerated SRE etc. benefit	Unique positioning, no alternative for curative approach ** Refractory, relapsed active AML in patients above 55 years of age ** QoL endpoints
RIT complexity	** Coordinate efforts of HemOnc and Nucl Med ** Logistical challenges, Y90 rarely used, short half-life (<3 days) ** Dosimetry (initially) with yet another radioisotope ** Quarantine	** Coordinate efforts of HemOnc and Nucl Med ** Long half-life (11 days) but single source for Ra223 ** No dosimetry ** No quarantine	** Coordinate efforts of HemOnc and Nucl Med ** Long half-life (8 days) and 131-I widely available ** Dosimetry with 131-I ** Quarantine (4-7 days)
OS benefit	No	Yes	Yes
Economics	** In-patient while competition as outpatient ** Economic incentive of infusion ** No outpatient option	** Outpatient ** Helps Urologists to keep patients longer vs. Oncologists	** In-patient - all patients are hospitalized anyhow ** Allows more HCT
Reimbursement	** Disadvantage vs. injectables ** Converts out-patients to in-patients	** New code required ** Unique	** PPS exempt hospitals represent large potential ** New DRG and NTAP code desirable ** Unique
2014 sales	50 Mio US\$	c 300 Mio US\$ (year 2 post launch)	

Source: TurckBio and Laidlaw and co equity research

Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
Iomab-B	Acute Myeloid Leukemia (AML) second line for conditioning for BMT	Potentially file IND for Phase III study	2H15	***
		Potentially enroll first patient for Phase III study	2H15	***
		Potentially report Phase III study top-line results	2017	****
		Potentially file for BLA	2H17	***
		Potential FDA decision	1H18	****
Actimab-A	Acute Myeloid Leukemia (AML) first line	Potentially complete the Phase I portion of the Phase I/II study	1H15	***
		Potentially start the the Phase II portion of the Phase I/II study	2H15	***
		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.

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 if it is approved, the commercial sales of any drug could be 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 may be 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.

Income Statement

Actinium Pharmaceuticals – Income Statement												
(\$'000)	2013	2014	1Q15	2Q15E	3Q15E	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	4,105	4,680	4,867	17,702	25,490	33,137	36,120	39,371	42,520
General and administrative	3,919	10,175	3,806	2,779	2,806	2,835	12,226	12,837	14,635	15,366	16,135	16,941
Marketing and sales	0								7,000	19,600	30,380	31,899
Depreciation and amortization	2	38	10	10	10	10	42	42	42	42	42	42
Loss on disposition of equipment	4	0	-	-	-	-	0	0	0	0	0	0
Total Operating Expenses	3,925	22,481	7,866	6,894	7,497	7,712	29,969	38,369	54,814	71,128	85,927	91,402
Operating Incomes (losses)	(3,925)	(22,481)	(7,866)	(6,894)	(7,497)	(7,712)	(29,969)	(38,369)	(54,814)	(57,713)	(40,761)	60,029
Interest income (expense)	(3)	(1)	(6)	(6)	(6)	(6)	(23)	0	0	0	0	0
Gain on change in fair value of derivative liabilities	(4,179)	(2,206)	4,796	(200)	(200)	(200)	4,196	4,616	5,078	5,585	6,144	6,758
Total Other Income (Expense)	(4,182)	(2,207)	4,791	(206)	(206)	(206)	4,196	4,616	5,078	5,585	6,144	6,758
Net loss and comprehensive loss	(8,107)	(24,688)	(3,075)	(7,100)	(7,703)	(7,918)	(25,773)	(33,753)	(49,736)	(52,127)	(34,617)	66,788
Tax	0	0	-	-	-	-	0	0	0	0	0	(24,711)
Net Income (Loss)	(8,107)	(24,688)	(3,075)	(7,100)	(7,703)	(7,918)	(25,773)	(33,753)	(49,736)	(52,127)	(34,617)	42,076
Net Income (Loss) Applicable to Common Shareholders	(8,107)	(24,688)	(3,075)	(7,100)	(7,703)	(7,918)	(25,773)	(33,753)	(49,736)	(52,127)	(34,617)	42,076
Net Earnings (Losses) Per Share—Basic	(\$0.36)	(\$0.90)	(\$0.09)	(\$0.21)	(\$0.23)	(\$0.23)	(\$0.77)	(\$0.95)	(\$1.36)	(\$1.39)	(\$0.90)	\$1.06
Net Earnings (Losses) Per Share—Diluted	(\$0.36)	(\$0.90)	(\$0.09)	(\$0.21)	(\$0.23)	(\$0.23)	(\$0.77)	(\$0.95)	(\$1.36)	(\$1.39)	(\$0.90)	\$1.06
Shares outstanding—basic	22,753	27,364	33,256	33,356	33,656	34,156	33,606	35,606	36,606	37,606	38,606	39,606
Shares outstanding—diluted	22,753	27,364	33,256	33,356	33,656	34,156	33,606	35,606	36,606	37,606	38,606	39,606
Margin Analysis (% of Sales/Revenue)												
Costs of goods										16%	16%	16%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	226%	73%	24%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	96%	30%	9%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-361%	-76%	33%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-326%	-64%	23%
Financial Indicator Growth Analysis (YoY%)												
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	237%	235%
R&D	-22%	360%	142%	105%	24%	1%	44%	44%	30%	9%	9%	8%
SG&A	-13%	160%	55%	15%	-14%	39%	20%	5%	14%	5%	5%	5%
Marketing and sales										180%	55%	5%
Operating Income (Losses)	-13%	473%	90%	56%	6%	12%	33%	28%	43%	5%	-29%	-247%
Pretax Income	65%	205%	-82%	-302%	27%	46%	4%	31%	47%	5%	-34%	-293%
Net Income	65%	205%	-82%	-302%	27%	46%	4%	31%	47%	5%	-34%	-222%
EPS	-92%	153%	-86%	-256%	7%	28%	-15%	24%	43%	2%	-35%	-218%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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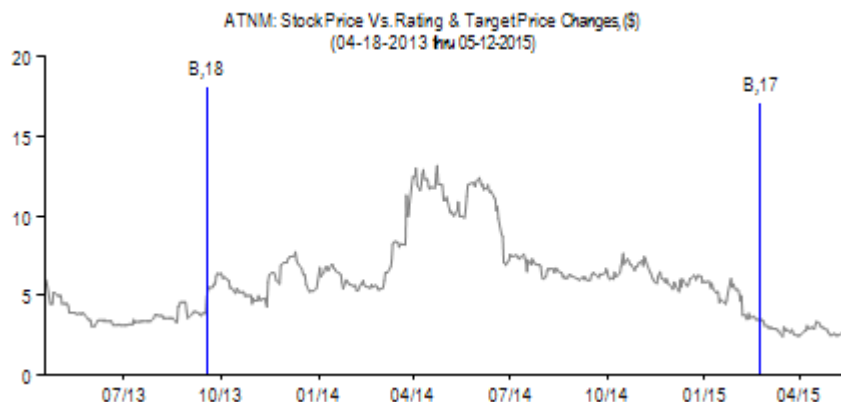
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Date	Rating	Closing Price (\$)
09/17/2013	Buy (B)	4.90

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

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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.	73.08%	30.77%	7.69%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.85%	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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