

## Actinium Pharmaceuticals (ATNM - \$ 3.94)

### ASCO Poster of Actimab-A in First-line Elderly AML Phase I/II Trial Data Well Received

Yesterday morning at the ASCO meeting, ATNM presented a poster for the interim results of the dose-finding portion of the Actimab-A in first-line elderly acute myeloid leukemia (AML) Phase I/II trial.

- Details.** The poster provided more details of the clinical data from the first three dose cohorts. The study is currently testing the 4<sup>th</sup> dose (2 µCi/kg) in order to identify dose limiting toxicities (DLT); which were not reached during the prior dose (1.5 µCi/kg with n=3) study. At the efficacy front, the 25% (3/12) overall response rate is comprised of CRi (CR with incomplete blood count recovery, n=2) and CRp (CR with incomplete platelet count recovery, with n=1). Further, response rate of 67% (2/3) were achieved in patients dosed at 1.5 µCi. As a reminder, the Phase I/II study is an open-label trial with two study portions: Phase I is a dose-escalating study (with n up to 21) designed to identify the MTD of Actimab-A plus low dose cytarabine (LDAC), while the Phase II portion is to treat AML patients at MTD with Actimab-A+LDAC with n~ 47.
- Implications.** We continue to have a positive outlook for Actimab-A as a first-line treatment in elderly AML therapy development. Although the patient size is small the efficacy results are very promising, in our opinion; since responses were only comprised of different CRs, not RP. Further, a higher 1.5 µCi dose so far has generated greater responses. The safety profile remains benign as most frequent SAEs are myelosuppressions, such as thrombocytopenia and neutropenia. These SAEs are caused by the underlying disease, not by the drug treatment. In the dose-finding study, DLT is defined as ≥33% patients of a specific dose experiencing drug-caused SAEs. Given the slightly reiterated process of identifying DLT and determining the MTD, ATNM should complete the Phase I portion of the study in 2H15 with commencement of Phase II study shortly thereafter. Although the data reported at the ASCO mostly reflected the information presented at an earlier published abstract, our due diligence suggested that the poster was well received and generated significant interest from attendees.
- 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
<b>FY-15E</b>	-0.09A	-0.21	-0.23	-0.23	-0.77	NM
<b>FY-14A</b>	-0.66	0.14	-0.21	-0.18	-0.90	NM
<b>FY-13A</b>	0.02	-0.10	-0.03	-0.25	-0.36	NM
<b>FY-12A</b>	NA	NA	NA	NA	-4.46	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	<b>ATNM</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$ 17.00</b>

#### Trading Data:

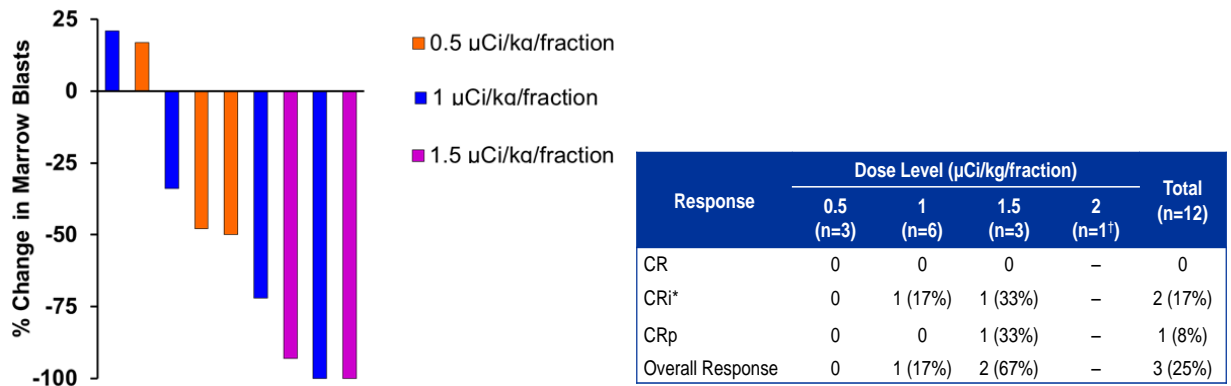
Last Price (05/29/2015)	\$ 3.94
52-Week High (6/2/2014)	\$ 13.70
52-Week Low (5/18/2015)	\$ 2.31
Market Cap. (MM)	\$ 141
Shares Out. (MM)	36

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**Figure 1: Water fall plot illustrates that bone marrow blast reduction in 7/9 treated patients**



Source: Jurcid, J.G., et. al.,2015 ASCO abstract No: 7050.

**Figure 2: SAEs profile of Actinomab-A in elderlyAML Phase I study**

Event	Dose Level (uCi/kg/fraction)			
	0.5 (n=3)	1 (n=6)	1.5 (n=3)	2 (n=1)
Neutropenia (grade 4)	2	1	0	0
Thrombocytopenia (grade 4)	0	3*	2	0
Febrile neutropenia (grade 3)	1	5	1	0
Pneumonia (grade 3)	0	2	1	0
Bacteremia (grade 3)	0	1	0	0
Cellulitis (grade 3)	0	1	0	0
Elevated creatinine (grade 3)	0	1†	0	0
Hypokalemia (grade 3)	0	1	0	0
Rectal hemorrhage (grade 3)	0	0	1	0
Generalized weakness (grade 3)	1	0	1	0

Source: Jurcid, J.G., et. al.,2015 ASCO abstract No: 7050.

**Figure 3: Patient characteristics of Actinomab-A in elderlyAML Phase I study**

Characteristic	No. of patients (n=13)	%
Median age (range), yrs	77 (68–87)	
Female	5	38
Antecedent hematologic disorders		
MDS	8	62
CML in molecular remission	1	8
Prior MDS therapy	6	75
Hypomethylating agent	5	63
Allogeneic HCT	1	12
Cytogenetics		
Intermediate-risk	9	69
High-risk	4	31
Median CD33 expression (range), %	76 (45-100)	

Source: Jurcid, J.G., et. al.,2015 ASCO abstract No: 7050.

## 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	2H15	***
		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

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**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
<b>Revenue</b>												
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
<b>Total Operating Expenses</b>	3,925	22,481	7,866	6,894	7,497	7,712	29,969	38,369	54,814	71,128	85,927	91,402
<b>Operating Incomes (losses)</b>	(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)
<b>Net Income (Loss)</b>	(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
<b>Margin Analysis (% of Sales/Revenue)</b>												
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%
<b>Financial Indicator Growth Analysis (YoY%)</b>												
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 &amp; Company estimates.

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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

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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	74.07%	29.63%	7.41%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	3.70%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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