

Actinium Pharmaceuticals (ATNM - \$ 2.00)

IND Filing For Iomab-B Phase III Trial Expected in 4Q15, Study Potentially Will Start in 1H16

This morning, ATNM announced that after the completion of a pre-IND meeting with the FDA for Iomab-B PIII trial in elderly acute myeloid leukemia (AML) patients, the company is schedule to file an IND in 4Q15.

- Details.** ATNM indicated that they were pleased with the discussion with the FDA and anticipated “a straightforward path to IND designation.” Based on this timeline and the assumption that the agency accepts the application, ATNM could commence the Phase III study in 1H16.
- Implications.** We view today’s news as a positive development for ATNM shares and removes an overhang for the shares. With a positive outcome, ATNM could advance the Iomab-B program forward into the pivotal study. Although the final study design is not available, earlier ATNM guidance suggested that the Phase III study would be a randomized, 150-patient, multicenter, open-label, controlled trial. Eligible patients are those over the age of 55 with refractory AML. Patients will be randomized to receive either Iomab-B followed by HSCT or the control arm treatment. The primary endpoint is durable complete response lasting at least 6 months. Patients in the treatment arm who achieve CR will be counted as success. The control arm is the physician’s choice of conventional care with curative intent. Patients who achieve CR in chemotherapy control arm will undertake RIC followed by HSCT or other treatment modalities. Patients 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. In addition, our discussions with management indicated that the Actimab-A Phase I dose finding study is currently testing the possible final dose. As such, we believe this portion of the study could be complete in late 2015/early 2016 with the Phase II portion of the study potentially starting in early 2016.
- 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.

Healthcare/Biotechnology

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

Trading Data:

Last Price (10/06/2015)	\$ 2.00
52-Week High (10/16/2014)	\$ 8.12
52-Week Low (8/3/2015)	\$ 1.52
Market Cap. (MM)	\$ 81
Shares Out. (MM)	41

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.09A	-0.20A	-0.22	-0.22	-0.74	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

Yale Jen, Ph.D.

Managing Director /
Senior Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

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 file IND for Phase III study	4Q15	***
		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	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

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	2Q15	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	3,838	4,222	4,391	16,499	23,759	30,886	33,666	36,696	39,632
General and administrative	3,919	10,175	3,806	3,550	3,586	3,622	14,564	15,293	17,434	18,305	19,220	20,181
Marketing and sales	0								7,000	19,600	30,380	31,899
Depreciation and amortization	2	38	10	16	16	16	59	59	59	59	59	59
Loss on disposition of equipment	4	0	-	-	-	-	0	0	0	0	0	0
Total Operating Expenses	3,925	22,481	7,866	7,405	7,824	8,029	31,122	39,110	55,379	71,630	86,355	91,771
Operating Incomes (Losses)	(3,925)	(22,481)	(7,866)	(7,405)	(7,824)	(8,029)	(31,122)	(39,110)	(55,379)	(58,215)	(41,190)	59,661
Interest income (expense)	(3)	(1)	(6)	(2)	(2)	(2)	(10)	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)	(202)	(202)	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)	(8,025)	(8,230)	(26,784)	(34,338)	(50,129)	(52,440)	(34,838)	66,648
Tax	0	0	-	-	-	-	0	0	0	0	0	(24,660)
Net Income (Loss)	(8,107)	(24,688)	(3,075)	(7,464)	(8,025)	(8,230)	(26,784)	(34,338)	(50,129)	(52,440)	(34,838)	41,988
Net Income (Loss) Applicable to Common Shareholders	(8,107)	(24,688)	(3,075)	(7,464)	(8,025)	(8,230)	(26,784)	(34,338)	(50,129)	(52,440)	(34,838)	41,988
Net Earnings (Losses) Per Share—Basic	(\$0.36)	(\$0.90)	(\$0.09)	(\$0.20)	(\$0.22)	(\$0.22)	(\$0.74)	(\$0.90)	(\$1.28)	(\$1.31)	(\$0.85)	\$1.00
Net Earnings (Losses) Per Share—Diluted	(\$0.36)	(\$0.90)	(\$0.09)	(\$0.20)	(\$0.22)	(\$0.22)	(\$0.74)	(\$0.90)	(\$1.28)	(\$1.31)	(\$0.85)	\$1.00
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	211%	68%	22%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	115%	36%	11%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-365%	-77%	33%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-328%	-65%	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%	92%	12%	-9%	34%	44%	30%	9%	9%	8%
SG&A	-13%	160%	55%	47%	10%	77%	43%	5%	14%	5%	5%	5%
Marketing and sales										180%	55%	5%
Operating Income (Losses)	-13%	473%	90%	67%	11%	17%	38%	26%	42%	5%	-29%	-245%
Pretax Income	65%	205%	-82%	-312%	32%	52%	8%	28%	46%	5%	-34%	-291%
Net Income	65%	205%	-82%	-312%	32%	52%	8%	28%	46%	5%	-34%	-221%
EPS	-92%	153%	-86%	-249%	2%	21%	-18%	21%	42%	2%	-35%	-218%

Yale Jen, Ph.D. 212-953-4978

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

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Rating and Price Target Change History



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.	74.19%	25.81%	6.45%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.23%	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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