

Actinium Pharmaceuticals (ATNM - \$ 2.50)

Pre-IND Meeting for Iomab-B Phase III Trial Requested

This morning, ATNM announced that it has requested the FDA to schedule a pre-IND meeting for discussing the advancement of Iomab-B in elderly acute myeloid leukemia (AML) Phase III trial.

- Details.** This morning, ATNM announced that it has requested the FDA to schedule a pre-IND meeting for discussing the advancement of Iomab-B in elderly AML Phase III trial. As a reminder, the reason why ATNM needs to file an IND for the pivotal study is due to fact that the Iomab-B manufacture has been moved to a different facility (Goodwin Biotechnology, Inc.) from Fred Hutchinson Cancer Research Center, which has provided material for earlier clinical studies.
- Implications.** We view this announcement a critical step for the company's execution in Iomab-B's clinical advancement – one of ATNM's two leading clinical assets. Based on the typical timeline needed for scheduling an FDA meeting and subsequent responses, we estimate the pre-IND meeting could take place in mid-September. Depending on the responses from the agency during the meeting, ATNM might be able to file an IND in October /November if the agency and the company agree on most of the study design and other issues. Under this scenario, the company could potentially start the Phase III study by year-end 2015 or early 2016. Given Iomab-B is clinically the most advanced program in ATNM's pipeline, having the Phase III pivotal trial take off would be an important milestone for ATNM shareholders. In addition, our discussion with management indicated that the dose-finding portion of the Actimab-A in first-line elderly AML Phase I/II trial is currently testing the 4th dose (2 µCi/kg) in order to identify dose limiting toxicities (DLT). Management is very encouraged for the progress of this program. We estimate data for this portion of the study could potentially be available in 4Q15. We also estimate that the Phase II portion of the study could start enrolling patient in early 2016. Phase II portion of the study is to treat AML patients at MTD with Actimab-A plus low dose cytarabine (LDAC), with n~47.
- 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 (07/15/2015)	\$ 2.50
52-Week High (10/16/2014)	\$ 8.12
52-Week Low (7/9/2015)	\$ 2.16
Market Cap. (MM)	\$ 96
Shares Out. (MM)	38

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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	2H15	***
		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	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	1H16	***
		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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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

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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%
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Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.57%	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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