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Avenue Therapeutics, Inc. (ATXI - NASDAQ)

1Q:18 Update Confirms Timeline

Based on our DCF model and a 15% discount rate, ATXI is valued at approximately $19.00 per share. Our model applies a 50% probability of eventual IV tramadol sales for operative pain based on historical Phase 3 success ratios. Our valuation includes geographic contributions from the US only.

Current Price (5/3/2018)	$3.75
Valuation	**$19.00**

OUTLOOK

Avenue Therapeutics is developing IV tramadol for use in a hospital setting where moderate to moderately severe pain relief is required. The candidate is currently in a Ph 3 orthopedic surgery study which is expected to read out in 2Q:18.

A Ph 3 soft tissue surgery study is planned for 3Q:18 concurrent with the ongoing safety study, both of which should provide data by 2Q:19. The company's trials are centered on bunionectomy, abdominoplasty and safety which are to be included in an NDA submission targeted for 2019.

IV tramadol may fill a void in the pain continuum with multi-modal benefits potentially reducing the need for schedule II opioids and addressing the associated side effects of both opioids and NSAIDs. There are ~50 million surgeries and 300 million pain prescriptions written providing a large end market with an unmet need.

ATXI holds sufficient capital to complete the currently active studies. Based on our assessment of market penetration, we initiate with a target price of $19.00 per share.

SUMMARY DATA

52-Week High	**8.58**
52-Week Low	**3.40**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**24,991**
Shares Outstanding (mil)	**10.6**
Market Capitalization ($mil)	**39.6**
Short Interest Ratio (days)	**0.11**
Institutional Ownership (%)	**1.4**
Insider Ownership (%)	**37.3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2018	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2019					$0.0 E
2020					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.07 A	-$0.70 A	-$0.30 A	-$0.50 A	-$1.85 A
2018	-$1.03 A	-$0.77 E	-$0.50 E	-$0.49 E	-$2.77 E
2019					-$2.72 E
2020					-$1.13 E

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WHAT'S NEW

Avenue Therapeutics (NASDAQ: ATXI) circulated a press release and their form 10-K with their first quarter 2018 financial results today. Total expenses for the first quarter were $10.4 million, comprised of research and development expense of $9.4 million and general and administrative expense of $1.0 million. No revenues were reported. Net loss was ($10.4) million or ($1.03) per share.

R&D expense was $9.4 million in 1Q:18, a large increase from the $0.1 million in 1Q:17. The increase was due to the launch of the Phase III safety trial and orthopedic study last year. The amount was higher than our estimates of $4.8 million; however, we did anticipate a lot of variability in costs related to timing of payables and the cadence of the trial. Costs were ahead of the run rate due to a faster pace of surgeries in the existing trials.

G&A expenses were $986 thousand in the quarter, up from $371 thousand in the same quarter last year. The increase represents the addition of full time employees to the corporate roster, higher stock compensation costs, greater market research costs and expanded other expenses. This compares to our estimate of $2.2 million.

Interest income in the quarter was $48 thousand.

Cash balance stood at $15.0 million as of March 31, 2018 after 1Q:18 cash burn of ($6.8) million.

Avenue has maintained its timeline and continues to expect the bunionectomy study to report topline data in 2Q:18. If results from this study are favorable, the soft tissue study will be launched in the third quarter as previously expected.

Our estimates for cash burn in 2018 were approximately $28.5 million which we maintain despite a higher first quarter run rate. A variety of factors including a faster pace of surgeries and timing of payables contributed to the higher than forecast 1Q:18 result. This was partially offset by lower than expected G&A cost. Since our initial estimates, there has been additional clarity on the timing of expenses throughout the year and we raise our cost estimates for the second quarter and lower them for the third and fourth quarters, maintaining the overall expense rate for 2018.

Key Events

- Initiated Phase III Bunionectomy Study – 3Q:17
- Initiated Safety Study – 4Q:17
- Topline Readout from Phase III Bunionectomy Study – 2Q:18
- Initiate Phase III Abdominoplasty Study – 3Q:18

Summary

We update our model to reflect financial results for the first quarter and maintain our target price of $19.00 per share. Avenue maintains timing for the readout for the bunionectomy study and the start of its abdominoplasty study, both positives indicating the ship is on course.

PROJECTED FINANCIALS

Avenue Therapeutics, Inc. - Income Statement

Avenue Therapeutics, Inc.	2017 A	Q1 A	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
	-					-	-	-
R&D	$6.7	$9.4	$6.5	$3.5	$3.5	$22.9	$21.5	$1.0
R&D Licenses	$1.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
G&A	$3.6	$1.0	$1.5	$1.7	$1.7	$5.9	$8.0	$12.0
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($11.4)	($10.4)	($8.0)	($5.2)	($5.2)	($28.8)	($29.5)	($13.0)
Operating Margin	-	-	-	-	-	-	-	*#DIV/0!*
Interest Expense	$0.3	($0.0)	$0.0	$0.0	$0.0	($0.0)	$0.0	$0.0
Total Other Income	$0.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($12.3)	($10.4)	($8.0)	($5.2)	($5.2)	($28.8)	($29.5)	($13.0)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*$0.0*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($12.3)	($10.4)	($8.0)	($5.2)	($5.2)	($28.8)	($29.5)	($13.0)
Reported EPS	**($1.85)**	**($1.03)**	**($0.77)**	**($0.50)**	**($0.49)**	**($2.77)**	**($2.72)**	**($1.13)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	6.6	10.1	10.4	10.5	10.6	10.4	10.9	11.5

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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