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Avenue Therapeutics, Inc. (ATXI - NASDAQ)

Bunionectomy Results Announced

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 (5/21/2018)	$4.09
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 currently completed a Ph 3 orthopedic surgery study that provided topline data in May 2018.

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)	**38,146**
Shares Outstanding (mil)	**10.6**
Market Capitalization ($mil)	**43.4**
Short Interest Ratio (days)	**0.11**
Institutional Ownership (%)	**1.9**
Insider Ownership (%)	**36.4**
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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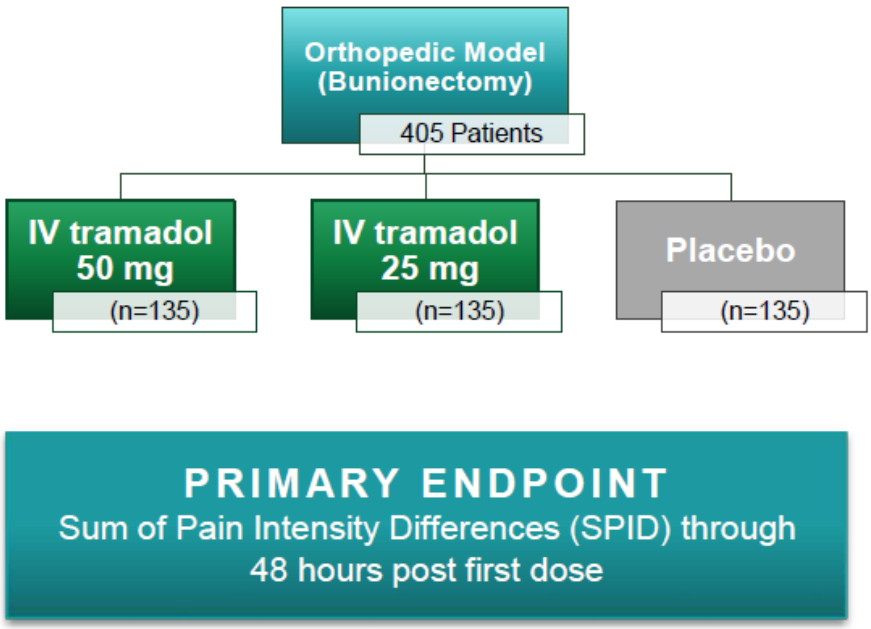
WHAT'S NEW

Avenue Therapeutics (NASDAQ: ATXI) reported topline results from their Phase III trial for intravenous tramadol in the management of postoperative pain. The results were favorable with both primary and secondary endpoints met as well as incidence of only low-intensity side effects and no reports of drug-related serious adverse events. A clear dose response was observed. This clears the path for the launch of the Phase III soft tissue study which is slated to begin in 3Q:18.

The trial titled Tramadol Versus Placebo in the Management of Postoperative Pain Following Bunionectomy was launched in September 2017 as a Phase III, multicenter, randomized, double blind, three arm study. The investigational drug is identified as tramadol infusion (AVE-901) for the management of post-operative pain following bunionectomy. The study enrolled 409 patients and was separated into three arms which include 1:1:1 split between IV tramadol at 50 mg, IV tramadol at 25 mg and placebo.

The drug was infused intravenously over 15 minutes at hours 0, 2, 4 and every subsequent four hours. The primary endpoint for the study was the sum of pain intensity differences (SPID) for the first 48 hours after the initial dose. SPID is a metric that evaluates a treatment response over a defined period of time. It accounts for the level of pain relief and weights it over time providing a single quantitative output. Secondary endpoints were SPID at 24 hours, use of rescue medications and Patient Global Assessment, which patient's perception of the treatment.

Exhibit I – Phase III Orthopedic Model Trial Design



The trial showed statistically significant outcomes on the primary and secondary endpoints compared to placebo and a strong safety profile. SPID48 using the 50 mg dose achieved a statistically significant result ($p = 0.005$) compared to the placebo arm which began to be evident within 30 minutes of the start of treatment. The results for the 25 mg arm fell in between the placebo and 50 mg dose.

Adverse events were minimal, and no drug-related serious adverse events were reported. One patient in the IV tramadol arm discontinued use due to an adverse event (vomiting). Other drop-outs occurred due to efficacy, one in the 50 mg arm and ten in the placebo arm. Adverse events that were experienced in excess of 5% of patients in the 50 mg arm included nausea, vomiting, dizziness and somnolence. The majority of these were mild or moderate (Grade 1 or 2) in severity and only 4 (3%) patients experienced a Grade 3 event (vomiting). No Grade 4 events were observed in the IV tramadol 50 mg group.

As the topline results of the study were only recently available, detailed results will be provided at a later date in conjunction with a scientific conference or journal publication. We do not expect this to occur before the start of the soft tissue trial. Our analysis of the topline results is favorable. Endpoints have been met with minimal dropouts

from the 50 mg study and only minor side effects. The rapid (within 30 minutes) onset of action and statistically significant difference between the 50 mg arm and the placebo arm are supportive of efficacy and we believe that the current hesitancy to prescribe Schedule II narcotics will provide demand for alternatives that are safer.

Avenue is on track for the launch of their Phase III soft tissue study in 3Q:18. There are a number of items that need to be done prior to first enrollment in the trial. Avenue expects to submit another round of protocol to FDA, sign up all of the vendors, and set up the CRO to commence the trial. Additionally, site initiation visits, site qualification visits need to be performed along with help from the Fortress team. We anticipate this will take at least three months, which places the start date in the August or September timeframe.

Market Size

As we discussed in our initiation, the market opportunity for IV tramadol is substantial. IV tramadol has been available in Europe for some time now and the product has achieved 10% unit penetration according to IMS health data without a substantial marketing push. Europe has provided a benchmark for IV tramadol as the drug has been used there for many years in a surgical setting as a generic. If this penetration rate is applied to the United States, this suggests sales of 30+ million units could be achieved. We take a more conservative view in our estimates and assume a 4 to 5% penetration rate until we see evidence that higher levels can be achieved.

Key Events

- Initiated Phase III Bunionectomy Study – 3Q:17
- Initiated Safety Study – 4Q:17
- Topline Readout from Phase III Bunionectomy Study – May 2018
- Begin Process for Initiating Phase III Soft Tissue Study
- 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. The topline readout is an important milestone in the development of IV tramadol. We anticipate raising our target price upon the start of the Phase III soft tissue study as we will increase the probability of success. There are other alternatives in the market that may compete with IV tramadol, such as IV meloxicam which is expected to see a response from the FDA by the end of the week. 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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