Zacks Small-Cap Research

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Avenue Therapeutics, Inc. (ATXI - NASDAQ)

2H:18 Soft Tissue Study Launch

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 (8/21/2018)	$3.71
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 has completed a Ph 3 orthopedic surgery study which provided a favorable readout in May 2018.

A Ph 3 soft tissue surgery study is planned for 2H: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	**6.90**
52-Week Low	**3.06**
One-Year Return (%)	**-42.2**
Beta	**N/A**
Average Daily Volume (sh)	**28,081**
Shares Outstanding (mil)	**10.6**
Market Capitalization ($mil)	**39.3**
Short Interest Ratio (days)	**0.58**
Institutional Ownership (%)	**2.1**
Insider Ownership (%)	**43.1**
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 A	$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	-$0.45 A	-$0.39 E	-$0.40 E	-$2.25 E
2019					-$2.72 E
2020					-$1.13 E

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WHAT'S NEW

Avenue Therapeutics (NASDAQ: ATXI) provided their press release and their form 10-K including second quarter 2018 financial results for investor review. Total expenses for the second quarter were $4.7 million, comprised of research and development expense of $3.8 million and general and administrative expense of $0.9 million. No revenues were reported. Net loss was ($4.7) million or ($0.45) per share.

R&D expense was $3.8 million in 2Q:18, rising from $0.4 million in 2Q:17 as the company ramped up its two Phase III studies for IV tramadol. The amount was lower than our expectation due to an effort to conserve cash and delay some non-critical activities in order to focus on the abdominoplasty trial which is targeted for 2H:18.

G&A expenses were $927 thousand in the quarter, down from $1.3 million in the same period last year on account of lower levels of stock compensation. This was partially offset by increases in increases personnel costs, market research costs and other general expenses. This compares to our estimate of $1.5 million.

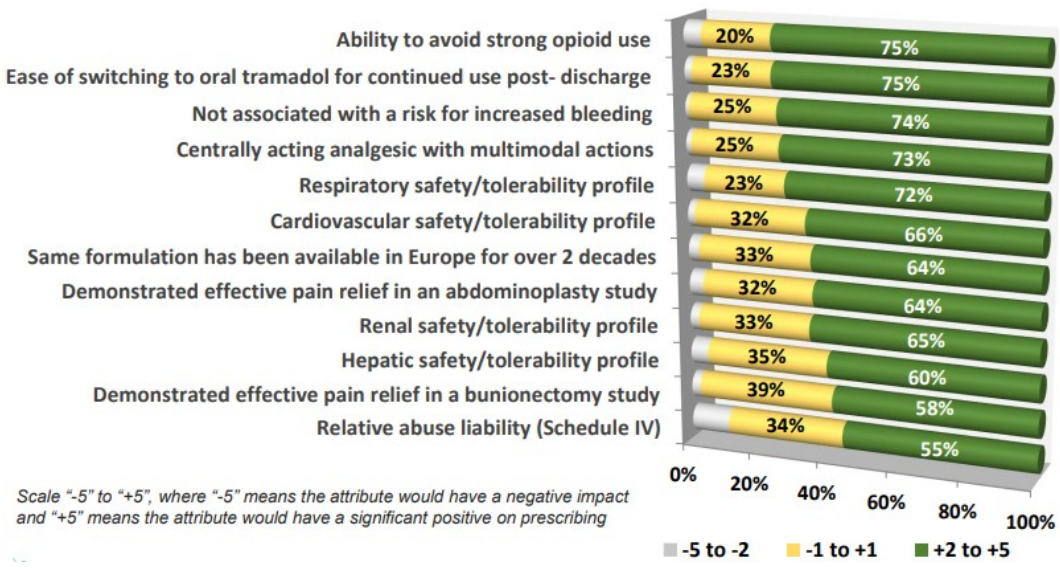
Interest income in the quarter was $24 thousand. Cash balance stood at $8.9 million as of June 30, 2018 after 2Q:18 cash burn of ($6.0) million.

Following the favorable safety and efficacy results from the bunionectomy study, and in preparation for the soft tissue study, Avenue has been developing the protocol, preparing contracts, initiating the data monitoring and management with the CROs and other activities that will allow for an immediate start to the final Phase III study. Other activities during the quarter include the key opinion leader (KOL) call on June 11 which discussed trends in surgical pain management. We provided a review of the discussion here.

We reduce our estimates for cash burn in 2018 to reflect the company's sharpened focus on critical efforts. Avenue is seeking non-dilutive forms of capital to obtain sufficient cash to complete the soft tissue (abdominoplasty) study. Management guidance anticipates sufficient liquidity to support operations until August 2019 and they believe there are opportunities for non-dilutive financing. We anticipate that there will be an announcement regarding financing prior to the start of the remaining study.

Avenue commissioned a survey that was performed in March and April of 2018, measuring the perceptions of practitioners on the use of IV tramadol as an alternative to Schedule II opioids. The surveyed practitioners were evenly split among orthopedic surgeons, general surgeons, anesthesiologists and emergency medicine physicians. The data was gathered prior to any results from Avenue's bunionectomy study, which confirmed safe and effective use. Below, the graphic highlights the key rationales for IV tramadol use. Ability to avoid strong opioids had the strongest support, which is understandable given the national crisis we are suffering in the United States in this class of drug.

Exhibit I – Survey Results



Key Events

- Initiated Phase III Bunionectomy Study – 3Q:17
- Initiated Safety Study – 4Q:17
- Topline Readout from Phase III Bunionectomy Study – 2Q:18
- KOL call for Intravenous Tramadol – 2Q:18
- Initiate Phase III Abdominoplasty Study – 2H:18
- Topline readout of Safety & Abdominoplasty Study – mid-2019
- Submit NDA for IV tramadol – Year-end 2019

Summary

We update our model to reflect second quarter actuals and maintain our target price of $19.00 per share. Avenue anticipates a 2H:18 launch of the abdominoplasty study which we anticipate will yield results in 2019.

PROJECTED FINANCIALS

Avenue Therapeutics, Inc. - Income Statement

Avenue Therapeutics, Inc.	2017 A	Q1 A	Q2 A	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	$3.8	$3.0	$3.0	$19.2	$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	$0.9	$1.1	$1.2	$4.2	$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)	($4.7)	($4.1)	($4.2)	($23.4)	($29.5)	($13.0)
Operating Margin	-	-	-	-	-	-	-	*# DIV/0!*
Interest Expense	$0.3	($0.0)	($0.0)	$0.0	$0.0	($0.1)	$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)	($4.7)	($4.1)	($4.2)	($23.3)	($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)	($4.7)	($4.1)	($4.2)	($23.3)	($29.5)	($13.0)
Reported EPS	**($1.85)**	**($1.03)**	**($0.45)**	**($0.39)**	**($0.40)**	**($2.25)**	**($2.72)**	**($1.13)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	6.6	10.1	10.3	10.5	10.6	10.4	10.9	11.5

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

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