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November 19, 2018

John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com **10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606**

Avenue Therapeutics, Inc. (ATXI - NASDAQ)

InvaGen Acquisition Spices Up Quarterly Report

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 (11/16/2018)	$5.52
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 mid-2019. 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.

With the capital infusion from InvaGen, ATXI holds sufficient funds to reach the anticipated target action date from the FDA.

SUMMARY DATA

52-Week High	**5.90**
52-Week Low	**2.08**
One-Year Return (%)	**29.6**
Beta	**-2.35**
Average Daily Volume (sh)	**83,709**
Shares Outstanding (mil)	**10.7**
Market Capitalization ($mil)	**58.8**
Short Interest Ratio (days)	**0.88**
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 2018 Estimate	**N/A**
P/E using 2019 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 A	$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	-$0.25 A	-$0.40 E	-$2.12 E
2019					-$1.78 E
2020					-$0.77 E

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WHAT'S NEW

Avenue Therapeutics (NASDAQ: ATXI) released third quarter 2018 financial results and submitted their Form 10-Q to the SEC on November 14. The day prior to the quarterly submission the company announced a transformative acquisition with Cipla subsidiary InvaGen Pharmaceuticals. The deal will provide sufficient capital to advance the company to its anticipated target action date for IV tramadol and a final buyout if IV tramadol is approved with its expected label. We see this transaction as favorable for shareholders as it allows the company to focus on its objective without the distractions or dilution risk of capital raises and also allows shareholders to participate in upside following the full acquisition of shares through contingent value rights tied to annual net sales and gross profit targets.

3Q:18 Financial Results

Avenue's third quarter expenses were $2.6 million, down 8% compared to the prior year's level. Research and development costs of $1.8 million slipped 11% on the completion of the bunionectomy study earlier in the year partially offset by an increase in spend on the advancement of the safety study. There were also new costs in the quarter related to preparation for the upcoming abdominoplasty study. General and administrative expenses were $0.8 million and fell 3% as higher marketing expenses were more than offset by lower legal expenses. Net loss was ($2.6) million or ($0.25) per share compared to ($2.9) million or ($0.30) per share in 3Q:17. No revenues were reported in the quarter.

Interest income in the quarter was $13 thousand. Cash balance stood at $4.8 million as of September 30, 2018 after 3Q:18 cash burn of ($4.1) million.

InvaGen Capital Raise and Acquisition

On November 13, 2018, Avenue announced an acquisition with InvaGen Pharmaceuticals which will initially provide $35 million in capital for a one-third stake in the company. Following FDA approval and the desired label, InvaGen will complete its acquisition of the company for an estimated $13.92 per share plus contingent rights to payments related to revenue and profit levels. Additional details will be available in a proxy that we anticipate will be available before year end. We discuss the deal in detail in our earlier article.

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
- Avenue & InvaGen Announce Transaction – 4Q:18
- Initiate Phase III Abdominoplasty Study – 4Q:18
- Close of Avenue & InvaGen Transaction – 1Q:18
- Topline readout of Safety & Abdominoplasty Study – mid-2019
- Submit NDA for IV tramadol – Year-end 2019
- Target action date for IV tramadol – 4Q:20
- Close of Avenue / InvaGen transaction – 2Q:21
- Potential contingent consideration for shareholders of record – 2021+

Summary

We update our model to reflect third quarter results and maintain our target price of $19.00 per share. We will adjust our target price to reflect the new capital contribution and the outstanding share count when it closes. The proposed transaction with InvaGen reduces the risk profile for Avenue by eliminating capital constraining delays in trial progress and shareholder dilution. We anticipate that the proposed timeline above will progress as expected with Phase III results available next summer and an FDA response by late 2020.

PROJECTED FINANCIALS

Avenue Therapeutics, Inc. - Income Statement

Avenue Therapeutics, Inc.	2017 A	Q1 A	Q2 A	Q3 A	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	$1.8	$3.0	$18.0	$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	$0.8	$1.2	$3.9	$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)	($4.7)	($2.6)	($4.2)	($21.9)	($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)	($2.6)	($4.2)	($21.8)	($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)	($4.7)	($2.6)	($4.2)	($21.8)	($29.5)	($13.0)
Reported EPS	**($1.85)**	**($1.03)**	**($0.45)**	**($0.25)**	**($0.40)**	**($2.12)**	**($1.78)**	**($0.77)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	6.6	10.1	10.3	10.3	10.6	10.3	16.6	16.8

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

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