

Avenue Therapeutics, Inc.

(ATXI - NASDAQ)

How Much are the CVRs Worth?

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 (1/18/2019) **\$6.59**
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 and safety study are underway, 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.

In November 2018 InvaGen agreed to acquire ATXI and provide funding under an agreement with defined milestones, including FDA approval by 2021. 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 **6.62**
 52-Week Low **2.08**
 One-Year Return (%) **75.7**
 Beta **-1.35**
 Average Daily Volume (sh) **78,162**

Shares Outstanding (mil) **10.7**
 Market Capitalization (\$mil) **70.5**
 Short Interest Ratio (days) **0.66**
 Institutional Ownership (%) **2.1**
 Insider Ownership (%) **40.7**

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	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(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	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(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

WHAT'S NEW

Avenue Therapeutics (NASDAQ: ATXI) will hold its special meeting of shareholders on February 6, 2019 to consider the stock purchase and merger agreement proposed by InvaGen Pharmaceuticals. 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. We have outlined many of the details of the transaction in an earlier [article](#); however the specifics regarding the contingent value rights (CVRs) were provided along with the recently filed [proxy](#) allowing us to estimate their value.

We use our IV tramadol sales estimates to value the CVR portion of the transaction compensation by applying the thresholds provides to calculate profit sharing with current shareholders if the deal is consummated. CVRs will receive cash flows based on revenues achieving certain thresholds and will be calculated as a percentage of gross margin. From first sales to December 31, 2028, there will be multiple tiers with increasing proportions of profit sharing with CVR holders. After 2028, assuming total sales of IV tramadol have exceeded \$1.5 billion, 20% of gross profits on sales above \$100 million will be allocated to CVR holders.

Below we summarize the details of the profit sharing arrangement:

Exhibit I – Entitlement to Payments for CVR Holders

Period	Threshold	Profit Sharing % Above Threshold Levels
Present - 2028	\$325-\$400 MM	10% of gross profits
Present - 2028	\$400-\$500 MM	12.5% of gross profits
Present - 2028	\$500 MM +	15% of gross profits
2029 & Beyond	\$100 MM	20% of gross profits after total sales of \$1.5 billion

Based on our revenue estimates, IV tramadol sales will not exceed the annual \$325 million threshold until 2028 when they reach \$326 million. This coincides with the end of the initial period.¹ In 2029, which begins the subsequent period,² the payment structure to Avenue improves as the revenue threshold declines to a single \$100 million tier and the profit sharing moves to 20% of gross profits. Total cumulative revenues for IV tramadol are forecast to exceed \$1.5 billion in 2028 in our model, achieving the hurdle required for payment of the subsequent period profit sharing arrangement. Based on our forecasts, all of the revenues qualifying for CVR payments occur in 2028 and after.

The merger agreement calculates the value of the CVRs as a percentage of gross profits. During the initial period, total IV tramadol sales only exceed the base threshold in one year and qualify for the 10% of gross profits allocation. In 2029 and beyond, forecasted sales exceed the threshold every year, qualifying for the higher 20% of gross profit rate.

As part of the acquisition agreement, Avenue's parent, Fortress Biotech (NASDAQ: FBIO) waived the 4.5% royalty based on net sales as part of the agreement. Based on our estimates this provides for a modified gross margin of approximately 78.5%. We apply this to our revenue estimates over the forecast period and discount it back to present using a 15% rate. This methodology generates a present value of approximately \$42 million.

Approximate shares estimated to be outstanding at the time of the second stage closing will be 12 million, which we anticipate will reflect annual awards of non-cash compensation over the balance at the date of the first closing. This total excludes the previously required 2.5% share dividend payment in kind to Fortress Biotech, which was included in the original Founder's Agreement, but waived as part of the transaction with InvaGen. Our estimates call for approximately 12 million shares to be outstanding by the second stage closing date, excluding the ~5.8 million shares owned by InvaGen which do not qualify for the payment. These 12 million units will divide the CVR payments. Based on our estimate of a present value of \$42 million and 12 million shares outstanding, this yields a \$3.50 per share value for the CVRs.

¹ The initial period is defined as starting the day following the deal closing date and ending on December 31, 2028.

² The subsequent period is defined as starting January 1, 2029 and ending on December 31, 2036, or on the date a generic competitor is approved, whichever is earlier.

We note that the payoff for CVR holders is favorably asymmetric. If sales are much lower in the early period, there is little downside for this class; however, if sales move into the first or second tier, the value of the CVRs could double. Under a favorable scenario where IV tramadol penetration achieved 10% share of the market, the present value of the CVRs could be worth around \$10 per share.

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:19
- **Special meeting to approve merger agreement – February 6, 2019**
- 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

Based on the additional detail provided in the proxy relating to the calculation of the contingent value rights (CVRs), we determine value of the profit sharing. The payment is determined as a proportion of gross margin in a tiered structure until the end of the initial period at which time it moves to a single tier. The result of this effort generates a value of approximately \$42 million or \$3.50 per share. Avenue has estimated the per share value of the merger consideration to be \$13.92 at the second close, or \$180 million in the aggregate, based on the estimated share issuances, and future expenses. Summing our calculation of the present value of the CVR and the anticipated share price yields a current value of approximately \$17.50 per share. While it is lower than our target price, we feel that this agreement reduces the risk substantially of a profitable exit and raising sufficient capital to advance IV tramadol forward. There is upside to this target if IV tramadol sales exceed our conservative estimates. We note that if approval of IV tramadol is delayed beyond April 30, 2021, rights to develop IV tramadol could revert to Avenue, at which time a revaluation would be necessary. We will update our official target valuation to reflect the calculations and discussions herein following a favorable shareholder vote next month.

The proposed transaction with InvaGen reduces the risk profile for Avenue by eliminating capital constraining delays in trial progress and shareholder dilution and provides an exit and commercialization strategy that de-risks the endeavor. Shareholders can also share in post-transaction payments based on our base case revenue estimates. We anticipate that the proposed timeline above will progress as expected with Phase III results available next summer and an FDA response forthcoming in 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&DLicenses	\$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)
<i>Operating Margin</i>	-	-	-	-	-	-	-	# 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
<i>Tax Rate</i>	\$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)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
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

HISTORICAL STOCK PRICE

Avenue Therapeutics, Inc. – Share Price History



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