Zacks Small-Cap Research

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Cynapsus Therapeutics Inc. (CYNAF-OTC)

CYNAF – Q3 Financials – Quick Take

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	07/23/2012
Current Price (11/11/14)	$0.56
Target Price	**$2.75**

UPDATE

Little known Toronto, Canada-based Cynapsus Therapeutics is one of our best ideas for investment in the small-cap biotechnology sector. The company currently trades with a market capitalization of only $63 million, yet sits on a potential $750 million drug for the treatment of Parkinson's disease. The leading drug is APL-130277, a sublingual formulation of apomorphine, designed as a rescue medication for patients experiencing "off" time in-between their daily levodopa dosing. We like Cynapsus because the costs and risks to develop APL-130277 are low, and the exit strategy is clear – develop APL-130277 to the point where a new drug application (NDA) can be filed, and then sell the company to a larger pharmaceutical looking to commercial. Based on the data and market research that we have seen, Cynapsus shares offer a potential four-fold increase in returns.

SUMMARY DATA

52-Week High	**$1.26**
52-Week Low	**$0.34**
One-Year Return (%)	**87.57**
Beta	**1.31**
Average Daily Volume (sh)	**142,396**
Shares Outstanding (mil)	**79**
Market Capitalization ($mil)	**$57**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**12**
Insider Ownership (%)	**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 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**

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

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0 A	0 A	0 A	0 A	0 A
2014	0 A	0 A	0 A	0 E	0 E
2015					0 E
2016					0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.07 A	-$0.03 A	-$0.03 A	-$0.02 A	-$0.13 A
2014	-$0.03 A	-$0.04 A	-$0.02 A	-$0.02 E	-$0.11 E
2015					-$0.07 E
2016					-$0.06 E

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INVESTMENT THESIS

Financial Update

On November 12, 2014, Cynapsus Therapeutics (TSX:CTH.V) (OTC:CYNAF) reported financial results for the third quarter ended September 30, 2014. The company did not report any revenues in the quarter. This was in-line with expectations. Operating expenses in the quarter totaled CAD$1.82 million, which included mainly of CAD$1.01 million in general and administrative costs and CAD$1.16 million in research and development costs, offset by CAD$0.64 in foreign exchange gains. Net loss for the quarter totaled CAD$1.69 million, or CAD$0.02 per share. This was within our expectations and in-line with our financial model. Actual cash burn during the quarter was CAD$1.79 million.

We note that on July 3, 2014, Cynapsus was awarded a new grant of US$0.5 million from MJFF to support clinical studies to develop APL-130277. This second MJFF grant is being used to fund the company's ongoing CTH-105 clinical study. As part of the MJFF grant agreement, Cynapsus has made a commitment to support further Parkinson's research by making up to US$1.0 million in contributions to MJFF based on future sales of APL-130277. The first milestone payment of US$0.1 million (CAD$112,000) was received on September 4, 2014 and was recognized as research grant income in the third quarter of 2014.

In October 2014, Cynapsus announced Thierry Bilbault, Ph.D., has been named Chief Scientific Officer (CSO) and Executive Vice President of Chemistry, Manufacturing and Controls (CMC). Dr. Bilbault will lead the strategic chemistry, manufacturing and controls (CMC) activities related to the company's APL-130277 drug candidate.

Cynapsus exited the third quarter with CAD$19.6 million in cash and investments. The cash balance was strengthened by a net $23 million public offering that took place in April 2014. We believe the current cash balance is sufficient to fund all clinical development of APL-130277 and do not see a need for new dilutive capital prior to the potential filing of a New Drug Application (NDA) with the U.S. FDA on APL-130277.

As of September 30, 2014, the basic share count stood at 79.0 million. We note that there are approximately 61.4 million warrants outstanding, all with a strike price of $1.00 or less. Based on today's stock price of $0.80 per share for CTH.V, 20.1 million of these warrants are currently in-the-money and would contribute CAD$11.6 million in new cash if exercised. Approximately 41.1 million of these warrants have an exercise price of $0.81 per share and would contribute CAD$33.3 million in new cash to the company if exercised. The company also has approximately 2.7 million stock options vested and exercisable at September 30, 2014. All are at $1.00 or less. Based on today's stock price, we believe Cynapsus has reasonable access to nearly CAD$45 million in cash through warrant and stock option exercising. Many of the outstanding warrants have call provisions, which can be found in the company's interim consolidated financial statements for September 30, 2014.

- ⇨ The basic market capitalization is $63.2 million.
- ⇨ The fully-diluted market capitalization is $116.0 million (but would include +$45 million in new cash)

…Clinical Program Moving Along…

Enrollment began in the Phase 2 CTH-105 study in July 2014. CTH-105 (NCT02228590) is designed to study the use of APL-130277 in 16 patients with Parkinson's disease who are naïve to or not current using apomorphine and who experience at least one daily "off" episode, with a total duration of "off" in any 24-hour period of at least 2 hours. The study is an open-label design and will examine the effect of APL-130277 on relieving "off" episodes over a single day, with dose-titration used to determine dose strengths necessary for future clinical development. We anticipate results from CTH-105 in November 2014.

The next step for the company after CTH-105, assuming positive results, is a comparative bioavailability and pharmacokinetic study in healthy volunteers, dubbed CTH-200, to start in the fourth quarter 2014. This study is designed to provide the clinical "bridge" to the FDA's finding of safety and efficacy for the Reference Listed Drug (i.e. subcutaneous apomorphine sold in the U.S. as Apokyn®).

In early 2015, we expect that the company will initiate the Phase 3 program on APL-130277. CTH-300 is designed to be the "efficacy study". CTH-300 is a double-blind, placebo-controlled, parallel-design study with Parkinson's patients who have at least one "off" episode every 24 hours, with total "off" time of at least 2 hours. The primary end point will be the change in the UPDRS III score. A long-term "safety study", dubbed CTH-301, will also be necessary for approval of APl-130277. Current guidance is that this study will take place in apomorphine naïve Parkinson's patients who have at least one "off" episode every 24 hours, with total "off" time of at least 2 hours; however, the protocol might be expanded to include apomorphine experienced patients who have not previously failed subcutaneous apomorphine. Regardless, the study will specifically look at the safety and tolerability of the new delivery route over a minimum period of 16 weeks. Management continues to guide to the filing of the NDA in 2016. These timelines are consistent with previous guidance and our current financial model.

Conclusion

We continue to be optimistic on Cynapsus Therapeutics. We believe the company has a clearly defined exit strategy for shareholders. The plan is to develop the drug to the completion of the NDA and then sell the company. We think all-in costs to develop APL-130277 from this point to the NDA filing are estimated at around $18 million. Cynapsus has a current market capitalization of only $63 million on a basic share count basis.

We have conducted two separate valuation methods to value shares of Cynapsus Therapeutics. Applying a modest 4x sales multiple on our peak 2024 revenue assumption of $728 million and discounting back to present day at 25%, we calculate a potential take-out price of $387 million. We have also incorporated these forecasts into a 10-year DCF model with first sales posted in 2017, peak sales in 2024, 2% terminal growth rate, 10% cost of goods sold, 10% marketing costs, 25% effective tax rate after approximately $18 million in NOL s, and a similar 20% discount rate. Our DCF analysis yields a fair-value of $394 million. Based on 145.0 million shares (current fully-diluted), we believe Cynapsus shares are fairly-valued today (average of our two methods) at $2.75 per share with 75% probability of approval in 2017. We continue to view the stock as one of our best small-cap ideas for a two-year holding period. Data from CTH-105 in the next 1-2 weeks will confirm or refute this belief.

Cynapsus Therapeutics – Income Statement

Cynapsus Therapeutics, Inc.	2012 A	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 E
APL-130277 WW Sales	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Royalty Payments	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Licensing & Collaborative	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-	-
Operating, General & Admin	$1.37	$2.64	$0.96	$0.89	$1.01	$0.90	$3.76	$3.00	$3.00
Research & Development	$0.81	$1.63	$0.45	$1.16	$1.25	$1.10	$3.96	$4.00	$5.00
Share-Based Comp	$0.34	$0.52	$0.02	$0.40	$0.21	$0.10	$0.73	$0.55	$0.55
Amortization & Depreciation	$0.06	$0.06	$0.02	$0.02	$0.02	$0.02	$0.06	$0.07	$0.07
Foreign Exchange	($0.01)	$0.04	$0.02	$0.37	($0.64)	$0.01	($0.24)	$0.00	$0.00
Other Expenses	($0.09)	($0.04)	($0.01)	($0.01)	($0.02)	($0.05)	($0.09)	($0.02)	($0.02)
Operating Income	($2.49)	($4.85)	($1.45)	($2.83)	($1.82)	($2.08)	($8.18)	($7.60)	($8.60)
Operating Margin	-	-	-	-	-	-	-	-	-
Grants & Other Income	$0.30	$0.43	$0.24	$0.00	$0.11	$0.15	$0.50	$0.75	$0.75
Interest / Financing Net	($0.88)	$0.01	$0.00	$0.02	$0.01	$0.00	$0.00	$0.00	$0.00
Pre-Tax Income	($3.06)	($4.43)	($1.21)	($2.82)	($1.69)	($1.93)	($7.68)	($6.85)	($7.85)
Income Taxes Paid	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	($3.06)	($4.43)	($1.21)	($2.82)	($1.69)	($1.93)	($7.68)	($6.85)	($7.85)
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.22)**	**($0.13)**	**($0.03)**	**($0.04)**	**($0.02)**	**($0.02)**	**($0.11)**	**($0.07)**	**($0.06)**
YOY Growth	*($0.20)*	*($0.43)*	-	-	-	-	*($0.11)*	*($0.42)*	*($0.04)*
Basic Shares Outstanding	13.65	34.67	39.46	72.39	78.97	80.00	67.70	105.00	125.00

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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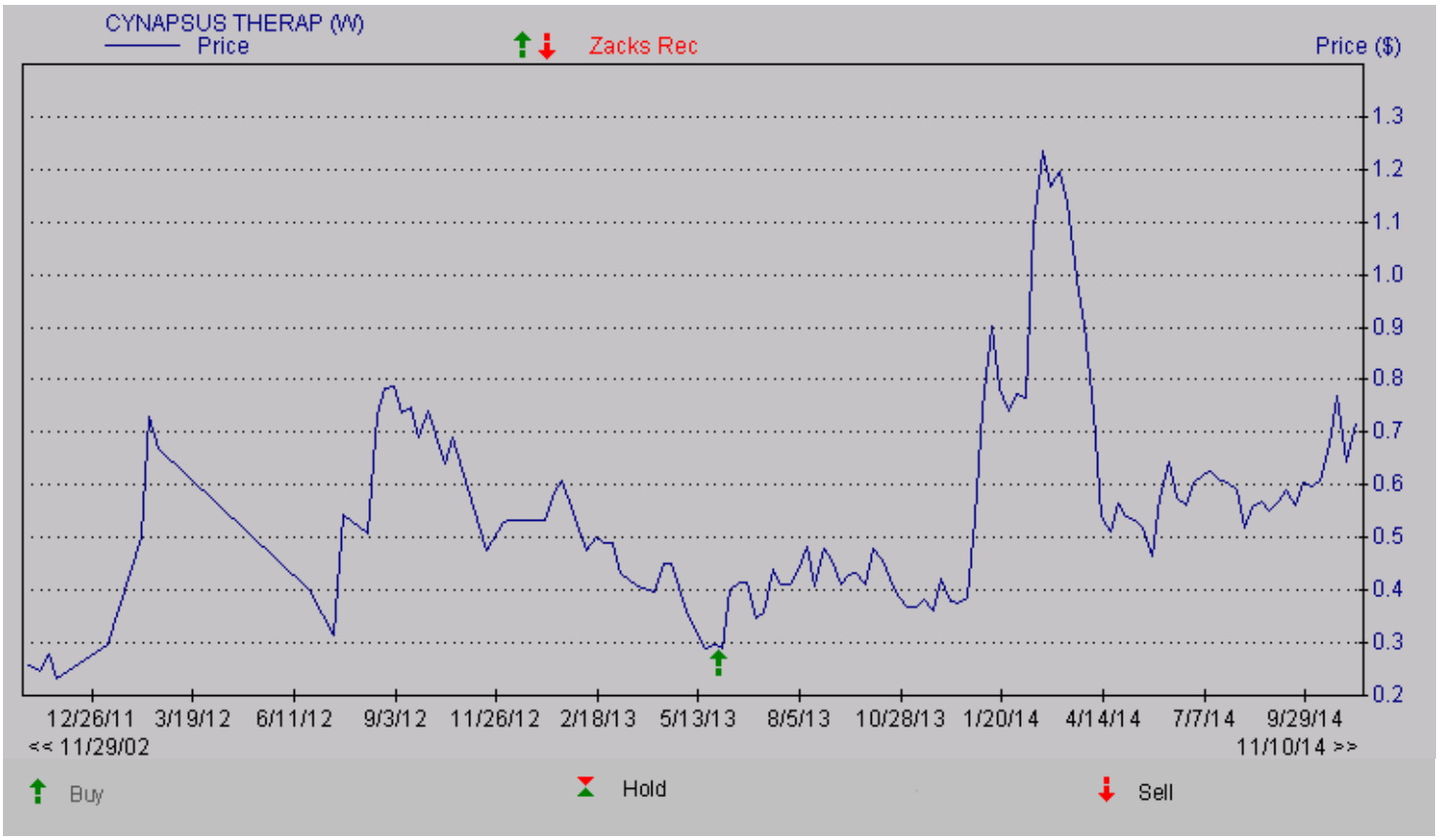

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