Zacks Small-Cap Research

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Cynapsus Therapeutics Inc. (V.CTH-TSX)

CYNAF – Remains One Of Our Best Small-Cap Bio Ideas…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	07/23/2012
Current Price (05/08/14)	$0.58
Target Price	**$2.25**

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 $80 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 six-fold increase in returns.

SUMMARY DATA

52-Week High	**$1.26**
52-Week Low	**$0.29**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**230,650**
Shares Outstanding (mil)	**40**
Market Capitalization ($mil)	**$22**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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 E	0 E	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	-$0.02 E	-$0.02 E	-$0.02 E	-$0.09 E
2015					-$0.07 E
2016					-$0.06 E

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INVESTMENT THESIS

Canada-based Cynapsus Therapeutics (TSX:CTH.V) (OTC:CYNAF) remains one of our best ideas for investment in the small-cap biotechnology sector. The company currently trades with a market capitalization of only $80 million on a fully diluted share count, yet sits on a potential $750 million drug for the treatment of Parkinson's disease. The company's 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. Apomorphine is a highly effective drug, already approved in the U.S. and around the rest of the world in various injectable formulations.

Our research into apomorphine leaves little doubt that the drug works. Sales, however, are greatly limited because Parkinson's patients experiencing "off" time struggle immensely with delivering a subcutaneous injection. A rapidly dissolving sublingual formulation of this highly effective drug will dominate the market. Cynapsus' market research shows significant interest from neurologists and movement disorder doctors, as well as the patients they treat. 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 six-fold increase in returns.

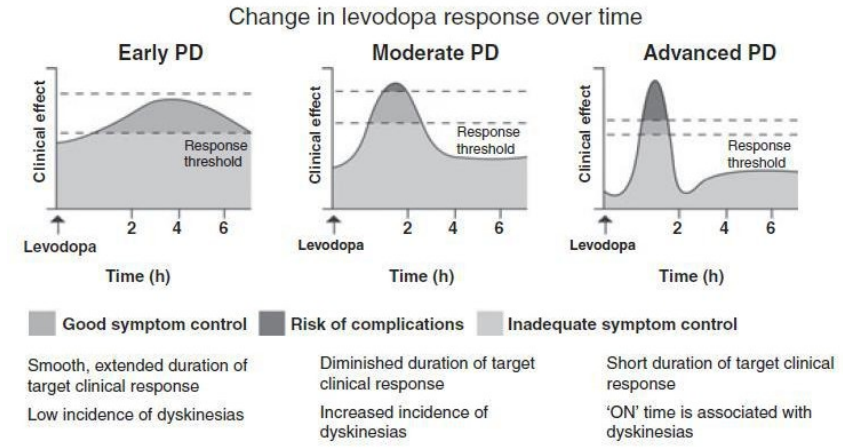
Outlining Our Thesis

Our work leads us to believe the global market opportunity for APL-130277 at around $750 million. We bullet-point some of the key findings from our research:

→ Treatment of Parkinson's disease represents a large and substantially unserved market. There are an estimated 1 million U.S. PD patients, 25-50% with significant "off" issues (PDF.org).

→ The current standard-of-care for PD is levodopa/carbidopa. Levodopa has a short half-life (60-90 minutes) even in the presence of carbidopa, and its effect begins to wane after 1.5 to 2.0 hours post dose (Brooks, D, 2008).

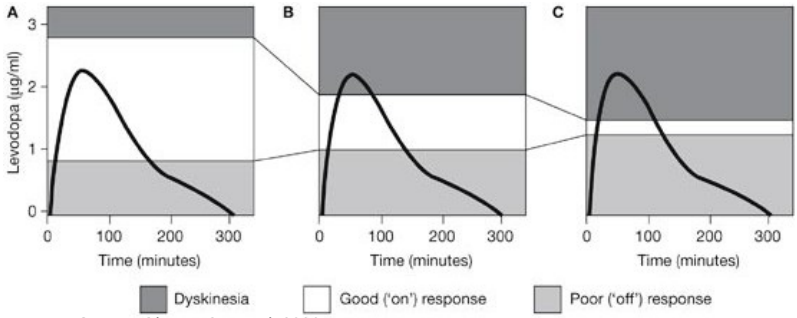
→ Dosing dynamics for Levodopa are challenging (Schapira et al, 2009). Too much drug (or too frequent dosing) leads to leads to dyskinesia and too little drug leads to increase "off" time (bradykinesia / akinesia).



Source: Schapira et al, 2009

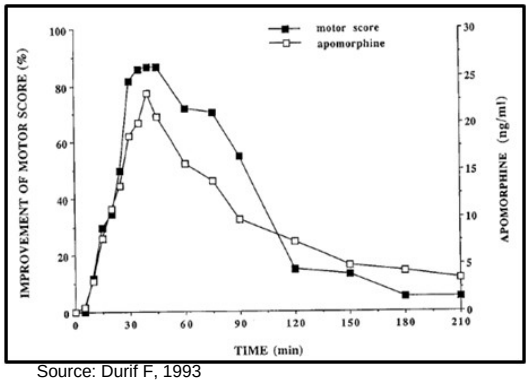
→ The range between the maximum tolerated concentration (MTC) and minimum effective concentration (MEC) defines the therapeutic window.

→ The therapeutic window for Parkinson's disease patients rapidly closes (narrows) as patients gain experience with Levodopa use (Olanow et al, 2006).



Source: Olanow CW et al, 2006

→ Apomorphine is a highly effective approved rescue medication for Levodopa "off" time in PD patients experiencing a narrowed therapeutic window to levodopa.



Source: Durif F, 1993

→ Subcutaneous injectable apomorphine, sold in the U.S. as Apokyn®, is a horrible impractical and inefficient drug, flawed by its delivery system and quick peak-to-trough pharmacokinetic profile.

→ For example, the Instructions For Use for Apokyn® is 27 pages long, and consists of steps that logically seem impossible for the frozen / rigid PD patient to complete. Self-administration of Apokyn® is nearly impossible, and thus places undue burden on the healthcare system.

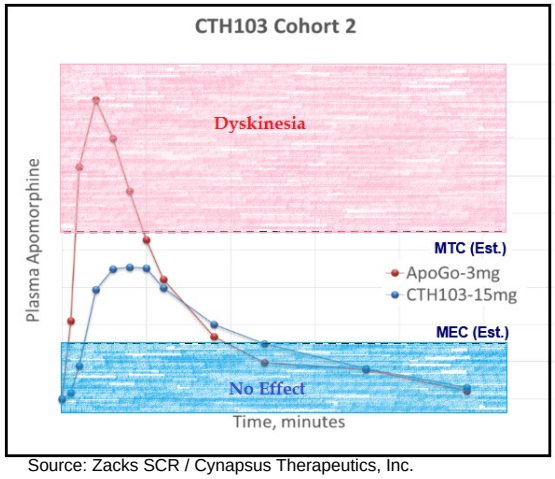


Source: U.S. WorldMeds, LLC 2014

→ As a result of the impracticality of subcutaneous apomorphine, sales are low at only around $70 million on a global basis. Patient and physician acceptance is poor.

→ Developing a sublingual formulation of apomorphine has a high chance of success given the excellent coverage of the therapeutic window seen in the CTH-103 and CTH-104 trial results.

→ Data from the CTH-103 study suggests that APL-130277 may offer a dramatically lower side effect profile and longer duration of action when compared to Apokyn®.



Source: Zacks SCR / Cynapsus Therapeutics, Inc.

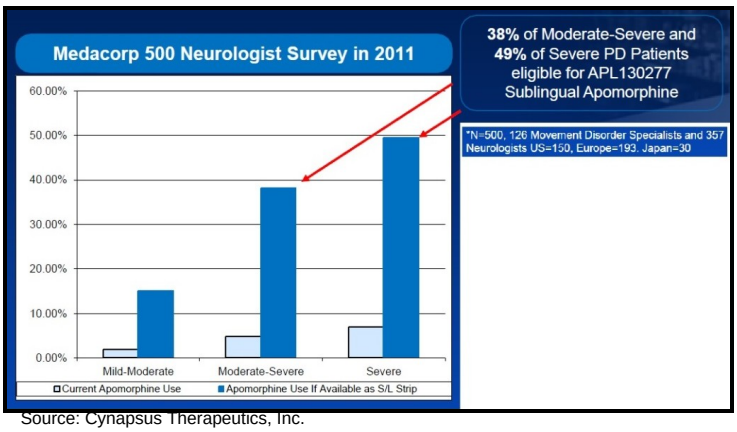
→ Data from the CTH-104 study suggest that 25 mg APL-130277 can provide apomorphine plasma concentrations above the MEC for roughly 2 hours, an estimated doubling of the therapeutic effect vs. approved formulations of subcutaneous apomorphine.

→ Data from the CTH-103 and CTH-104 study suggest safety and tolerability consistent with limited exposure above the MTC.

	S.C 2mg (n=15)	APL 10mg (n=15)	S.C 3mg (n=14)	APL 15mg (n=14)
# of subjects with AEs	9	5	14	7
# of subjects with Moderate AEs	5	2	10	3

Source: Cynapsus Therapeutics, Inc.

→ This improved profile should lead to a dramatic increase in market penetration. Company sponsored neurologist surgery (n=500) suggests 7.5-fold increase in penetration.



Source: Cynapsus Therapeutics, Inc.

→ For the purpose of our financial model, we assume only a 2.5-fold increase in penetration.

→ Priced at only a modest premium to the injectable formulation, APL-130277 is a ~$400 million U.S. revenue opportunity at peak.

~1.25 Million U.S. Parkinson's Disease Patients by 2024	Percent of PD Patients	Current Penetration Apokyn®	Estimated Penetration APL-130277	Fold Increase	U.S. PD Patients On APL-130277	Strips Needed Per Day	APL-130277 Strips
- Estimated 35% with "OFF" Issues -							
Mild Disease	35%	2.0%	5.0%	2.5	7,656	1	7,656
Moderate Disease	50%	5.0%	13.5%	2.7	29,531	2	59,063
Severe Disease	15%	7.0%	20.0%	2.9	13,125	3	39,375
						Total APL-130277 Strips Sold (at Peak)	106,094
						Price Per Strip Per Day (at Peak)	$10
						Peak U.S. Sales (Millions)	**$387**

Source: Zacks SCR / Jason Napodano, CFA

→ Global peak sales could hit $750 million.

Cynapsus has defined a clear exit strategy for shareholders. Develop the drug to the completion of the NDA and then sell the company. All-in costs to develop APL-130277 to this stage are estimated at around $25 million. Cynapsus has a current market capitalization of only $80 million on a fully-diluted basis. Fully-diluted share count would include cash in-flow of approximately $45.1 million from exercised warrants and $1.3 million in stock options.

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, and discounting back to present day at 25%, we calculate a potential take-out price of $432 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, 35% effective tax rate after approximately $16.6 million in NOL's, and a similar 25% discount rate and 50% probability of approval. Our DCF analysis yields a fair-value of $393 million. Based on 142.6 million shares (current fully-diluted), we believe Cynapsus shares are fairly-valued today (average of our two methods) at $2.25 per share.

PROJECTED FINANCIALS

Cynapsus Therapeutics – Income Statement

Cynapsus Therapeutics, Inc.	2012 A	2013 A	Q1 A	Q2 E	Q3 E	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	$0.85	$0.90	$0.90	$3.61	$3.00	$3.00
Research & Development	$0.81	$1.63	$0.45	$0.55	$0.75	$1.10	$2.85	$4.00	$5.00
Share-Based Comp	$0.34	$0.52	$0.02	$0.20	$0.10	$0.10	$0.42	$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	$0.01	$0.01	$0.01	$0.05	$0.00	$0.00
Other Expenses	($0.09)	($0.04)	($0.01)	($0.05)	($0.05)	($0.05)	($0.16)	($0.02)	($0.02)
Operating Income	($2.49)	($4.85)	($1.45)	($1.58)	($1.73)	($2.08)	($6.83)	($7.60)	($8.60)
Operating Margin	-	-	-	-	-	-	-	-	-
Grants & Other Income	$0.30	$0.43	$0.24	$0.15	$0.15	$0.15	$0.69	$0.75	$0.75
Interest / Financing Net	($0.88)	$0.01	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Pre-Tax Income	($3.06)	($4.43)	($1.21)	($1.43)	($1.58)	($1.93)	($6.14)	($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)	($1.43)	($1.58)	($1.93)	($6.14)	($6.85)	($7.85)
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	($0.22)	($0.13)	($0.03)	($0.02)	($0.02)	($0.02)	($0.09)	($0.07)	($0.06)
YOY Growth	*($0.20)*	*($0.43)*	-	-	-	-	*($0.28)*	*($0.29)*	*($0.04)*
Basic Shares Outstanding	13.65	34.67	39.46	65.00	80.00	82.00	66.61	105.00	125.00

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

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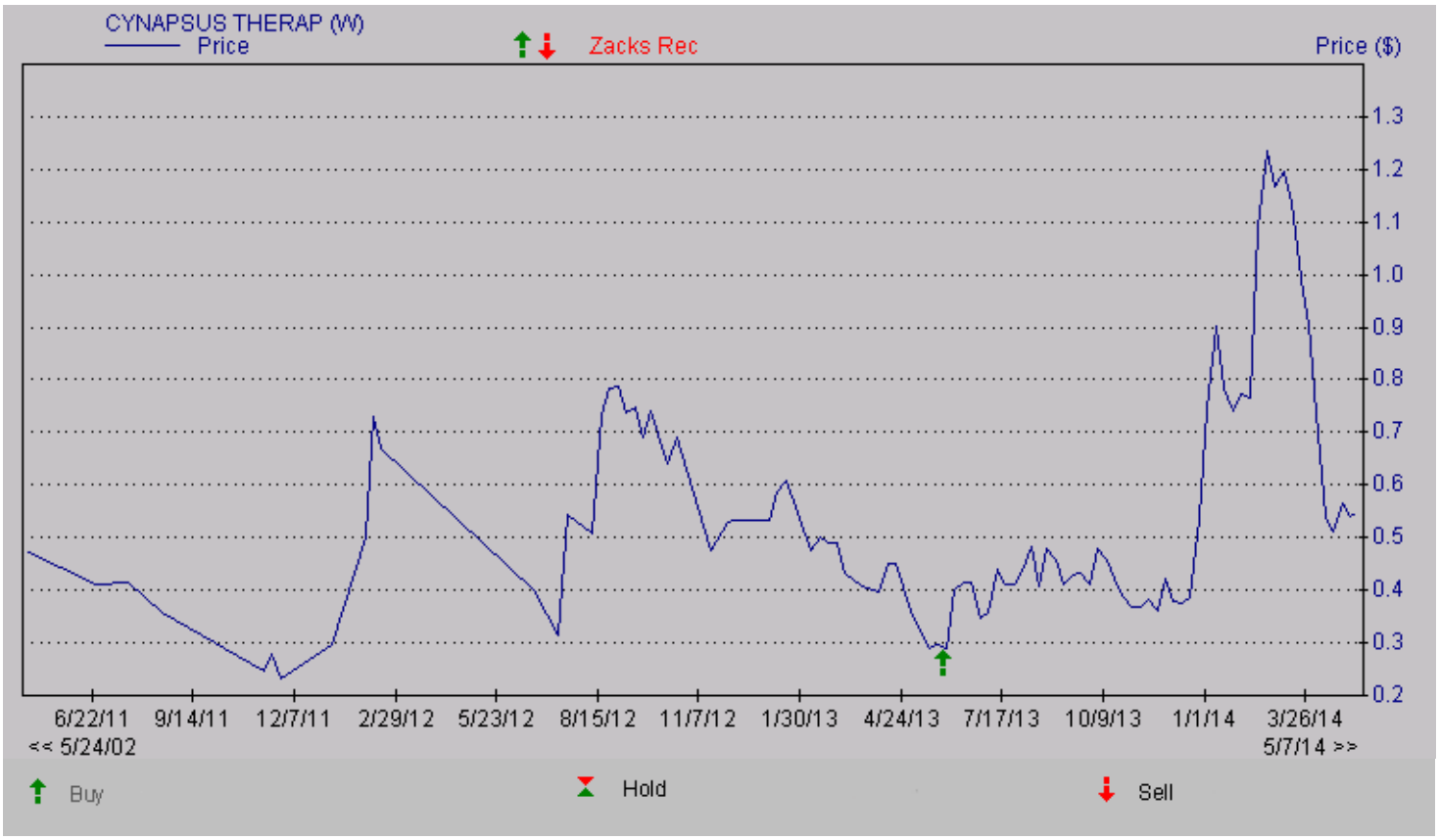

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