Zacks Small-Cap Research

August 13, 2014
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

Cynapsus Therapeutics Inc. (CYNAF-OTC)

CYNAF – Phase 2 Data From CTH-105 Expected Later This Quarter…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	07/23/2012
Current Price (08/13/14)	$0.56
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 $75 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	**$0.34**
One-Year Return (%)	**14.26**
Beta	**1.79**
Average Daily Volume (sh)	**76,041**
Shares Outstanding (mil)	**40**
Market Capitalization ($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 A	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	-$0.04 A	-$0.02 E	-$0.02 E	-$0.11 E
2015					-$0.07 E
2016					-$0.06 E

INVESTMENT THESIS

Financial Update

On August 13, 2014, Cynapsus Therapeutics (TSX:CTH.V) (OTC:CYNAF) reported financial results for the second quarter ended June 30, 2014. The company did not report any revenues in the quarter. This was in-line with expectations. Operating and net loss for the quarter totaled $2.8 million, or $0.04 per share. Loss was driven by $0.9 million in operating, general, and administrative costs, $1.16 million in research & development, and $0.40 million. Actual cash burn during the quarter was $2.0 million.

Cynapsus exited the second quarter with $20.7 million in cash and investments. The cash balance was recently 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. We remind investors that in July 2014, Cynapsus was awarded a second grant from the Michael J. Fox Foundation in the amount of $500,000.

…Clinical Program Moving Along…

Management is using the grant to fund the current Phase 2 CTH-105 study that began enrollment in July 2014. CTH-105 will study the use of APL-130277 in 16 patients with Parkinson's disease who are naïve to the use of 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 September or October 2014.

The next steps for the company after CTH-105 are a bioavailability study, dubbed CTH-200 to start in the fourth quarter 2014 and a Phase 3 efficacy study in apomorphine-naïve patients, dubbed CTH-300a, also to start in the first quarter 2015. We believe another Phase 3 study in apomorphine-experienced patients, to be called CTH-300b, will also initiate during the first half of 2015. Management continues to guide to the filing of the NDA in 2016. These timelines are consistent with previous guidance and our current financial model.

Outlining Our Thesis

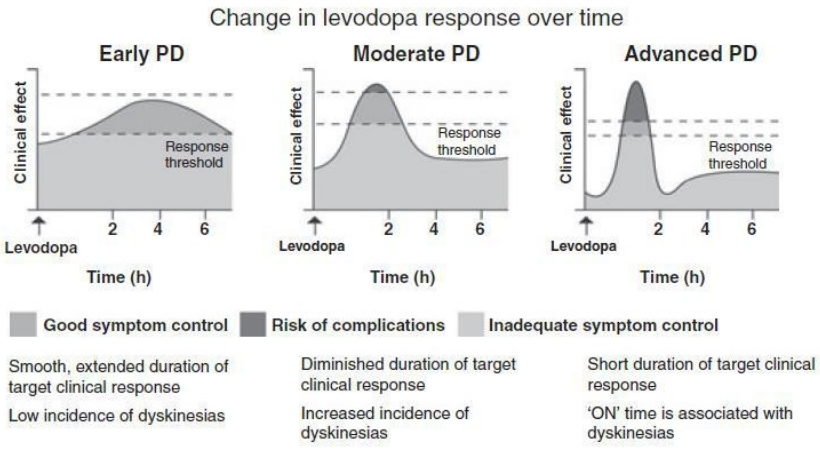
Cynapsus remains one of our best ideas for investment in the small-cap biotechnology sector. The company currently trades with a market capitalization of only $75 million on a fully diluted share count, yet sits on a potential $750 million drug for the treatment of Parkinson's disease. The company's 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 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).

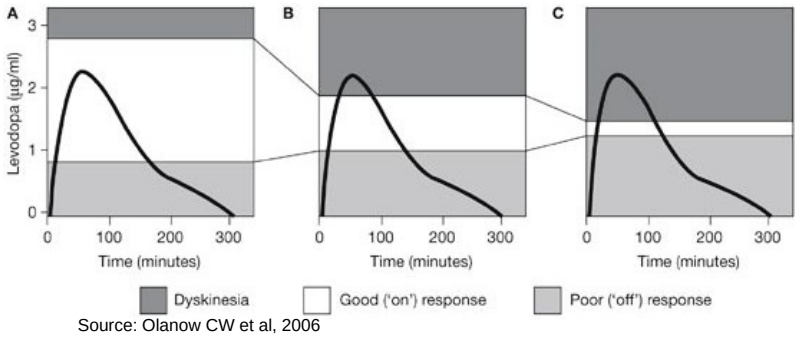
→ Dosing dynamics for Levodopa are challenging (Schapira et al, 2009). Too much drug (or too frequent dosing) leads to leads to dyskinesia and too little drug leads to increase "off" time (bradykinesia / akinesia).



Source: Schapira et al, 2009

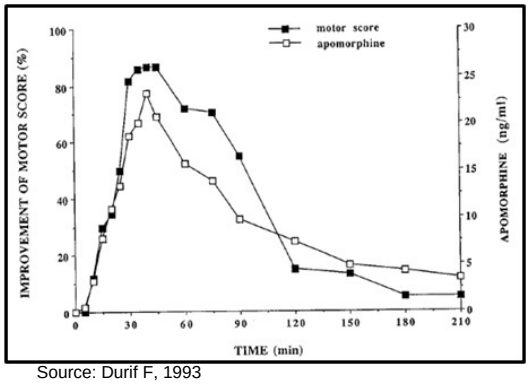
→ The range between the maximum tolerated concentration (MTC) and minimum effective concentration (MEC) defines the therapeutic window.

→ The therapeutic window for Parkinson's disease patients rapidly closes (narrows) as patients gain experience with Levodopa use (Olanow et al, 2006). It is for this reason we believe potential competing therapies such as inhaled levodopa do not offer effective alternatives to apomorphine. Our research concludes that physicians are seeking alternatives to levodopa for the treatment of "off" episodes, not a new levodopa formulation.



Source: Olanow CW et al, 2006

→ We believe apomorphine is the ideal drug to treat "off" episodes. It 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.

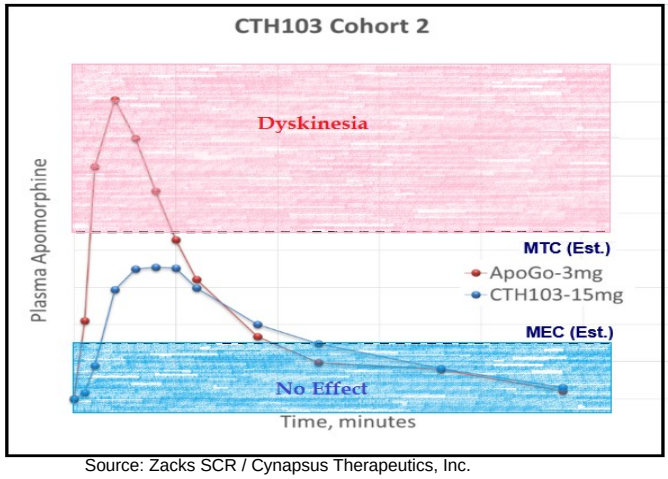
Source: U.S. WorldMeds, LLC 2014

→ 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.

→ Intravenous administration of apomorphine has been shown to cause pulmonary embolism and other serious events due to crystallization. Inhaled apomorphine has been shown to cause severe lung irritation and allergic reactions, including anaphylactic symptoms and life-threatening asthmatic episodes (DoubleCheckMD)

→ 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. Initial clinical work was hampered by buccal irritation (formulation was highly acidic), but new data from May 2014 points to this hurdle being overcome by new formulations of the thin film strip.

→ Data from the CTH-103 and CTH-104 studies 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.

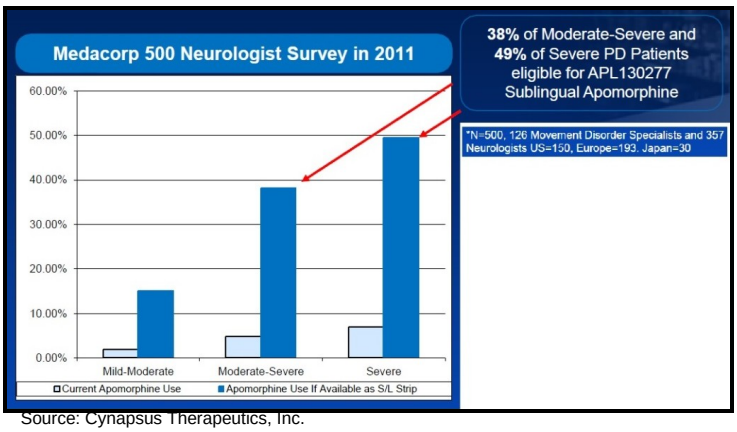
→ Data from the CTH-104 study suggest that 25 mg APL-130277 can provide apomorphine plasma concentrations above the MEC for roughly 2 hours, an estimated doubling of the therapeutic effect vs. approved formulations of subcutaneous apomorphine.

→ 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 at around $10 per dose, 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 from this point to the NDA filing are estimated at around $20 million. Cynapsus has a current market capitalization of only $75 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 do not believe the market is aware that Cynapsus is now fully-funded with limited future dilution expected over the next two years.

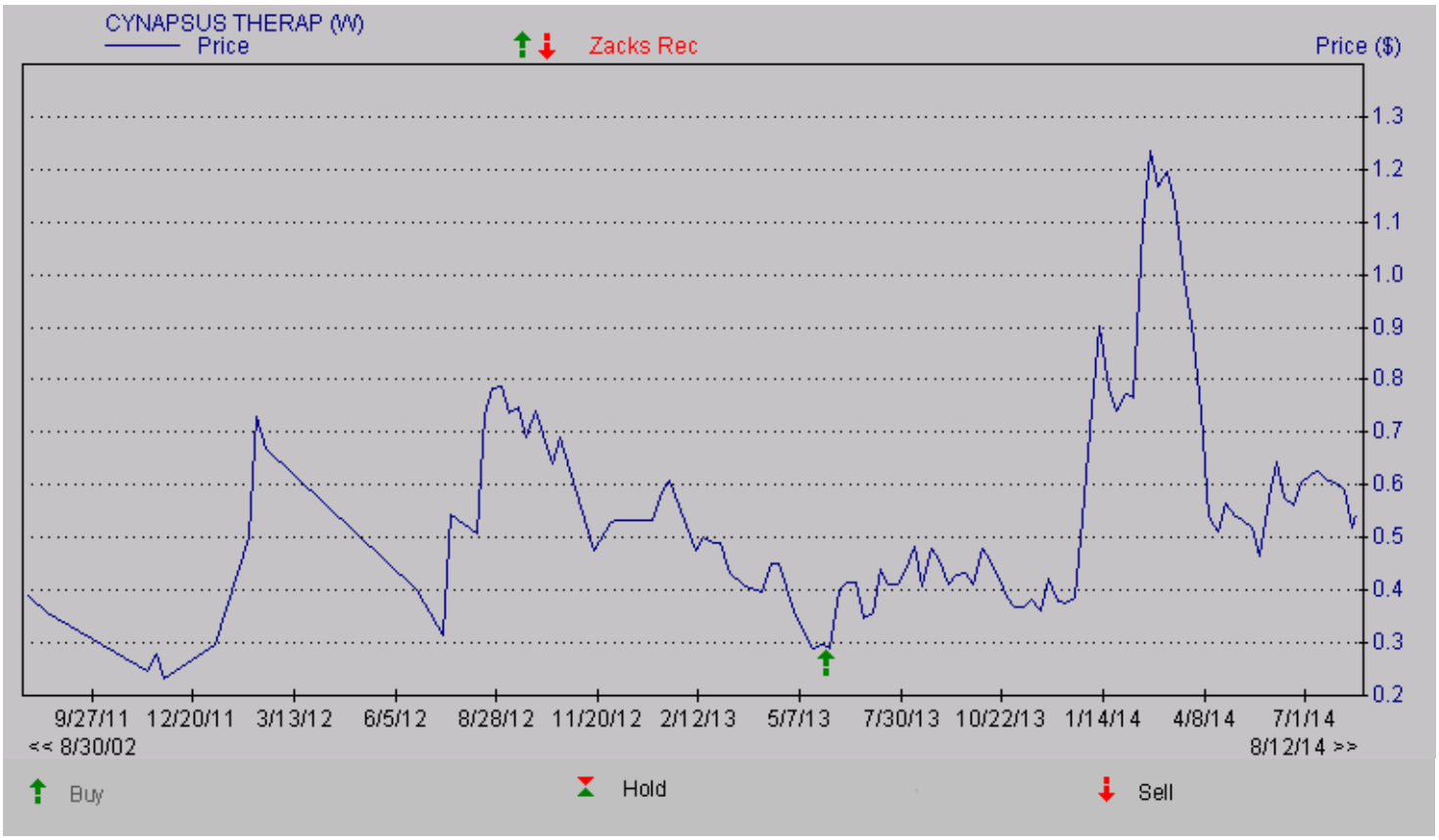
We have conducted two separate valuation methods to value shares of Cynapsus Therapeutics. Applying a modest 4x sales multiple on our peak 2024 revenue assumption, and discounting back to present day at 25%, we calculate a potential take-out price of $382 million. We have also incorporated these forecasts 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 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 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.

PROJECTED FINANCIALS

Cynapsus Therapeutics – Income Statement

Cynapsus Therapeutics, Inc.	2012 A	2013 A	Q1 A	Q2 A	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	$0.89	$0.90	$0.90	$3.65	$3.00	$3.00
Research & Development	$0.81	$1.63	$0.45	$1.16	$0.75	$1.10	$3.46	$4.00	$5.00
Share-Based Comp	$0.34	$0.52	$0.02	$0.40	$0.10	$0.10	$0.62	$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	$0.01	$0.01	$0.41	$0.00	$0.00
Other Expenses	($0.09)	($0.04)	($0.01)	($0.01)	($0.05)	($0.05)	($0.12)	($0.02)	($0.02)
Operating Income	($2.49)	($4.85)	($1.45)	($2.83)	($1.73)	($2.08)	($8.09)	($7.60)	($8.60)
Operating Margin	-	-	-	-	-	-	-	-	-
Grants & Other Income	$0.30	$0.43	$0.24	$0.00	$0.15	$0.15	$0.54	$0.75	$0.75
Interest / Financing Net	($0.88)	$0.01	$0.00	$0.02	$0.00	$0.00	$0.00	$0.00	$0.00
Pre-Tax Income	($3.06)	($4.43)	($1.21)	($2.82)	($1.58)	($1.93)	($7.55)	($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)	($1.58)	($1.93)	($7.55)	($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)*	-	-	-	-	*($0.14)*	*($0.41)*	*($0.04)*
Basic Shares Outstanding	13.65	34.67	39.46	72.39	80.00	82.00	68.46	105.00	125.00

HISTORICAL ZACKS RECOMMENDATIONS



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