Zacks Small-Cap Research

January 23, 2014
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

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

# Cynapsus Therapeutics Inc. (V.CTH-TSX)

## *CYNAF – Insights From Meeting With management…*

| | |
|---|---|
| **Current Recommendation** | **Buy** |
| Prior Recommendation | N/A |
| Date of Last Change | 07/23/2012 |
| Current Price (01/22/14) | $0.73 |
| **Target Price** | **$1.75** |

## UPDATE

On Sunday, January 12, 2014, we arrived in San Francisco, CA for the annual JP Morgan Healthcare Conference, as well as the parallel Biotech showcase and OneMedForum Conferences. This was the eighth year in a row that we made the trip to San Francisco for these events, which are a must-attend for serious healthcare investors.

During my three days in San Francisco, I conducted 25 one-on-one meetings with various managements of small and mid-cap biotechnology and specialty pharmaceutical companies. Below are some "notes" from our meeting with Cynapsus Therapeutics Inc.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.93** |
| **52-Week Low** | **$0.29** |
| **One-Year Return (%)** | **N/A** |
| **Beta** | **N/A** |
| **Average Daily Volume (sh)** | **215,987** |
| **Shares Outstanding (mil)** | **39** |
| **Market Capitalization ($mil)** | **$30** |
| **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 2013 Estimate** | **N/A** |
| **P/E using 2014 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) |
|---|---|---|---|---|---|
| 2012 | 0 A | 0 A | 0 A | 0 A | 0 A |
| 2013 | 0 A | 0 A | 0 A | 0 E | 0 E |
| 2014 | | | | | 0 E |
| 2015 | | | | | 0 E |

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

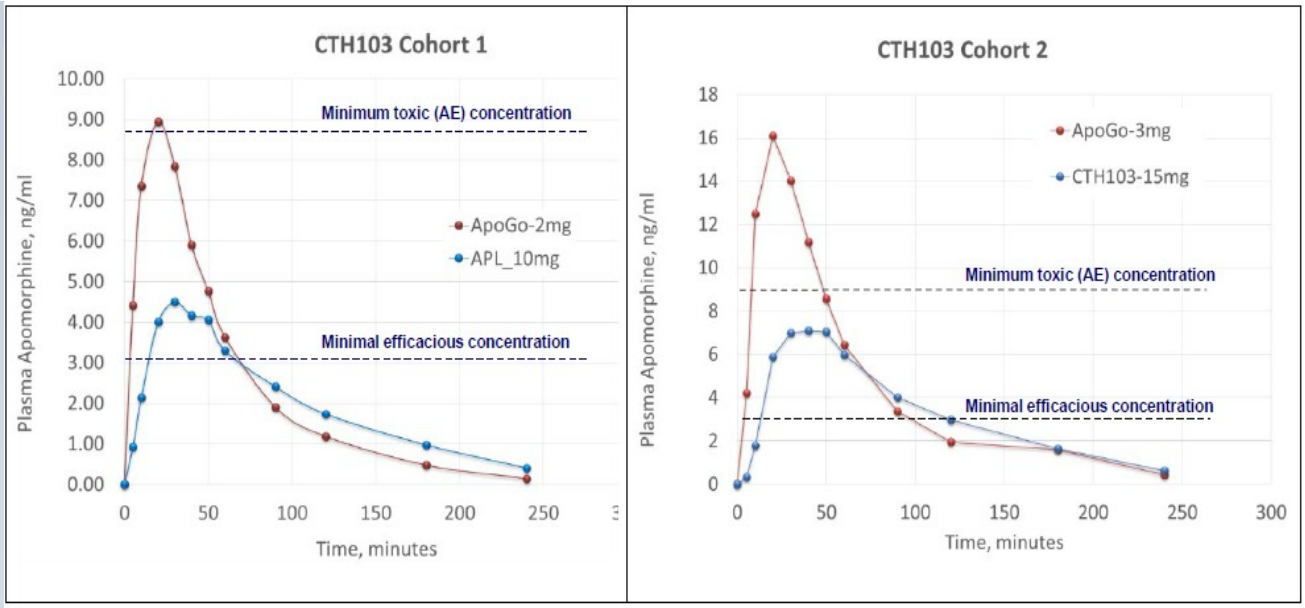
| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2012 | -$0.05 A | -$0.07 A | -$0.05 A | -$0.06 A | -$0.22 A |
| 2013 | -$0.07 A | -$0.03 A | -$0.03 A | -$0.03 E | -$0.14 E |
| 2014 | | | | | -$0.16 E |
| 2015 | | | | | -$0.07 E |

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

## WHAT'S NEW

**Cynapsus Therapeutics, Inc. (CYNAF)**
Meeting took place with Anthony Giovinazzo, CEO

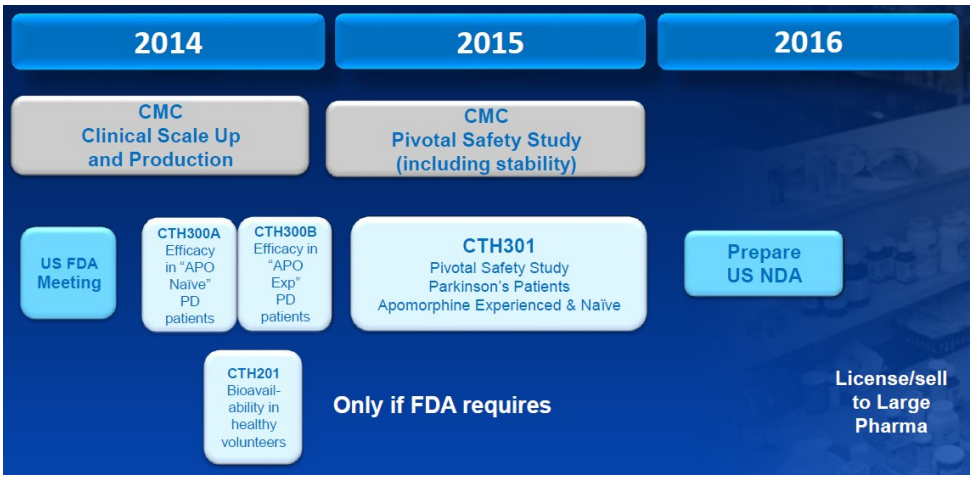
It was a good day to meet with Cynapsus because the company just put out a press release earlier that morning announcing the results from the CTH-103 pharmacokinetic pilot study. CTH-103 was designed to demonstrate dose proportionality between 10mg, 15mg, and 25mg of APL-130277, a sublingual film strip of apomorphine, and 2mg, 3mg, and 4mg of an injectable formulation of apomorphine solid outside the U.S. called ApoGo® in 30 healthy volunteers. We present the pk curves for the 10mg vs. 2mg and 15mg vs. 3mg arms below. The trial never progressed into the 25mg vs. 4mg cohort because patients on the 3mg ApoGo dose had too many adverse events, mostly vomiting and nausea, including one patient experiencing a seizure. We note that apomorphine is a notoriously difficult drug for volunteers with healthy and normal dopaminergic neurons to tolerate. In contrast, Parkinson's patients have fewer dopaminergic neurons and thus can tolerate much higher doses of a dopamine agonist like apomorphine.




On first glance, the results were mixed for the company, as the pk curves were far from identical. However, management noted the 10mg film was well tolerated and offered rapid dissolution of around two minutes with 10 minutes until "On" time. The 15mg film demonstrated a slower onset of action, with time until "On" at 13.6 minutes, but a longer duration of action due to a much smoother curve. The lack of initial drug burst also lead to meaningfully lower adverse events. Cynapsus is planning to conduct another quick study with the 25mg film alone (no crossover to the 4mg ApoGo dose) and will compare the pk curve to the curves for the 10mg and 15mg doses.

On deeper analysis of the CTH-103 data, we've come to the conclusion that Cynapsus is really sitting on a potential breakthrough here for Parkinson's patients. Not only does the data above confirm that APL-130277 can follow the 505(b)(2) pathway that allows for expedited clinical studies and reduced costs to develop, but the adverse event profile for (healthy) patients on APL-130277 was about half that for ApoGo®. That leads us to believe Cynapsus will be able to capture the ApoGo® / Apokyn® label with respect to efficacy, but also potentially include improved safety and tolerability (lower adverse event profile) on the label allowing for a dramatically improved marketing message to the neurologists or movement disorder doctor. Under that scenario, the drug may be positioned superior to generic subcutaneous apomorphine. This will lead to significant market share gains over the generic apomorphine and expansion into new a whole new prescribing base that was previously not amenable to Apokyn® due to the mode of administration or adverse event rate. We always suspected Cynapsus would capture a big piece of the apomorphine pie; what we now believe, however, is that the pie is three-to-four times the size that Apokyn sales suggest.

We expect that Cynapsus will present the results from the above CTH-103 study to the FDA in the next few months. The next steps after that for Cynapsus are to conduct two more pilot studies with APL-130277, but this time in Parkinson's patients instead of healthy volunteers; one study (CTH-300A) in apomorphine naïve patients and another (CTH-300B) in apomorphine experienced patients. There is still formulation and CMC work left to do, but nothing that prohibits Cynapsus from continuing down the 505(b)(2) pathway as noted above. The goal is to develop APL-130277 via the 505(b)(2) pathway, which would allow all the claims of Apokyn® in the product label, but also list a superior tolerability and adverse event profile to dramatically expand the market. We believe Cynapsus will be in position to begin the U.S. pivotal study with APL-130277 in early 2015. This should lead to a U.S. NDA filing in early 2016.




We remind investors that Apokyn® (subcutaneous apomorphine) is generic in the U.S., and over the last few years several attempts to develop alternative formulations including oral tablets, buccal wafers, intranasal sprays, and pulmonary inhalations have all failed. Cynapsus has been able to secure the intellectual property to a sublingual film formulation and so far the results look very promising. With similar efficacy and the meaningful reduction in adverse events seen in the CTH-103 study, APL-130277 should be a highly coveted asset by big pharma once approved. Management has conducted some initial market research and product positioning studies they have shared with us. It's impressive. We expect to share this information with investors in the next few weeks.

We have looked in detail at the sales opportunity for APL-130277. In the U.S., there are around one million Parkinson's disease patients, about half of who have significant "Off" episode issues. According to management's survey of over 500 neurologists and movement disorder specialists, the market breaks down as: ~40% with mild Parkinson's disease (might require 1 SL film per day), ~45% with moderate Parkinson's disease (might require 2 SL films per day), and ~15% with severe Parkinson's disease (might require 3 SL films per day). We estimate 2022 market penetration of 5% among patients with mild disease, 10% among those with moderate disease, and 15% among those with severe disease, for a total of around 35 million sublingual strips per year in 2022. Assuming reimbursement at $10 per strip (inflation-adjusted price of Apokyn), we estimate U.S. sales at roughly $350 million. Assuming RoW sales of a similar level, and we estimate 2022 global sales at $700M. Our financial modeling for Cynapsus tells us the stock is worth, conservatively, $1.75 per share. In the hands of big pharma, it could be worth a whole lot more.

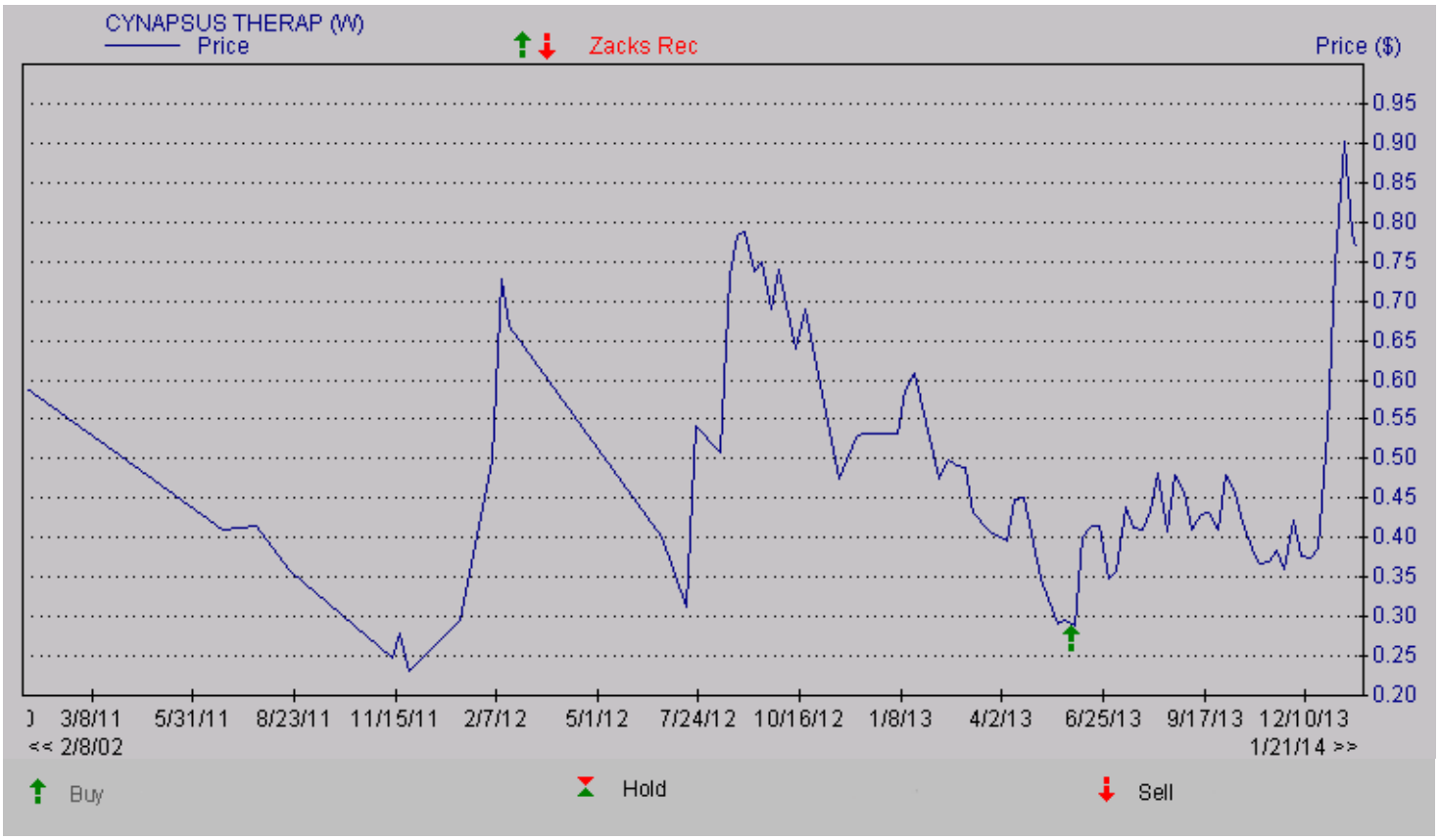
## PROJECTED FINANCIALS

### Cynapsus Therapeutics – Income Statement

| Cynapsus Therapeutics, Inc. | 2012 A | Q1 A | Q2 A | Q3 A | Q4 E | 2013 E | 2014 E | 2015 E |
|---|---|---|---|---|---|---|---|---|
| **APL-130277 WW Sales** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| **Royalty Payments** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| **Licensing & Collaborative** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$5.00** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| **Total Revenues** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$5.00** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Cost of Sales | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| *Product Gross Margin* | - | - | - | - | - | - | - | - |
| Operating, General & Admin | $1.37 | $0.39 | $0.66 | $0.74 | $0.70 | $2.49 | $2.20 | $3.00 |
| Research & Development | $0.81 | $0.14 | $0.17 | $0.40 | $0.35 | $1.07 | $4.00 | $5.00 |
| Share-Based Comp | $0.34 | $0.12 | $0.22 | $0.11 | $0.10 | $0.55 | $0.50 | $0.50 |
| Amortization & Depreciation | $0.06 | $0.02 | $0.02 | $0.02 | $0.02 | $0.06 | $0.06 | $0.06 |
| Foreign Exchange | ($0.01) | $0.01 | $0.01 | $0.01 | $0.01 | $0.04 | $0.00 | $0.00 |
| Other Expenses | ($0.09) | $0.76 | ($0.01) | ($0.02) | $0.00 | $0.73 | $0.00 | $0.00 |
| Operating Income | ($2.49) | ($1.44) | ($1.06) | ($1.26) | ($1.18) | ($4.93) | ($6.76) | ($3.56) |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| Grants & Other Income | $0.30 | $0.12 | $0.09 | $0.00 | $0.10 | $0.31 | $0.50 | $0.25 |
| Interest / Financing Net | ($0.88) | ($0.19) | ($0.00) | ($0.00) | ($0.10) | ($0.29) | ($1.50) | ($1.00) |
| Pre-Tax Income | ($3.06) | ($1.51) | ($0.97) | ($1.26) | ($1.18) | ($4.91) | ($7.76) | ($4.31) |
| Income Taxes Paid | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| *Tax Rate* | *$0.00* | *$0.00* | *$0.00* | *$0.00* | *$0.00* | *$0.00* | *$0.00* | *$0.00* |
| Net Income | ($3.06) | ($1.51) | ($0.97) | ($1.26) | ($1.18) | ($4.91) | ($7.76) | ($4.31) |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($0.22)** | **($0.07)** | **($0.03)** | **($0.03)** | **($0.03)** | **($0.14)** | **($0.16)** | **($0.07)** |
| *YOY Growth* | *($0.20)* | - | - | - | - | *($0.37)* | *$0.09* | *($0.54)* |
| Basic Shares Outstanding | 13.65 | 20.49 | 38.88 | 38.88 | 40.00 | 34.56 | 50.00 | 60.00 |

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

## HISTORICAL ZACKS RECOMMENDATIONS



## DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Jason Napodano, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

Zacks SCR has received compensation for non-investment banking services on the Small-Cap Universe, and expects to receive additional compensation for non-investment banking services on the Small-Cap Universe, paid by issuers of securities covered by Zacks SCR Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, investment management, non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per client basis and are subject to the number of services contracted. Fees typically range between ten thousand and fifty thousand per annum.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities in the issuers which they cover. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but are not guaranteed as to be accurate nor do we purport to be complete. Because of individual objectives, this report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1047 companies whose securities it covers, including securities covered by Zacks SCR:
Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 16.5%, Hold/Neutral- 77.7%, Sell/Underperform – 5.1%. Data is as of midnight on the business day immediately prior to this publication.