Zacks Small-Cap Research

September 27, 2012
Grant Zeng, CFA
312-265-9466
gzeng@zacks.com

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

# CytoDyn Inc. (CYDY-OTC)

**CYDY: Acquisition of CCR5 antibody PRO140 boosts pipeline--Neutral**

| | |
|---|---|
| **Current Recommendation** | **Neutral** |
| Prior Recommendation | N/A |
| Date of Last Change | 01/12/2012 |
| Current Price (09/26/12) | $1.10 |
| **Twelve- Month Target Price** | **$1.50** |

## OUTLOOK

CytoDyn's lead candidate Cytolin represents a new class of compound for the treatment of HIV/AIDS. Cytolin targets CD11a, a cellular protein that is also expressed on the HIV virion. Its unique mechanism of action makes it an ideal candidate for an early HIV/AIDS treatment option. An ex-vivo study of Cytolin is underway and CytoDyn plans to bring a human version of Cytolin into clinic this year.

Recent acquisition of PRO 140 further boosts its pipeline.

Current risk/return profile is balanced at this point. We rate the Company's share a Neutral.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$3.15** |
| **52-Week Low** | **$0.65** |
| **One-Year Return (%)** | **N/A** |
| **Beta** | **0.13** |
| **Average Daily Volume (sh)** | **49,872** |
| **Shares Outstanding (mil)** | **29** |
| **Market Capitalization ($mil)** | **$32** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **0.01** |
| **Insider Ownership (%)** | **32** |
| **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 2012 Estimate** | **N/A** |
| **P/E using 2013 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **N/A** |
| **Type of Stock** | **N/A** |
| **Industry** | **Med-Biomed/Gene** |
| **Zacks Rank in Industry** | **N/A** |

## ZACKS ESTIMATES

**Revenue**
(in millions of $)

| | Q1 (Aug) | Q2 (Nov) | Q3 (Feb) | Q4 (May) | Year (May) |
|---|---|---|---|---|---|
| 2011 | 0.00 A | 0.00 A | 0.00 A | 0.00 A | 0.00 A |
| 2012 | 0.00 A | 0.00 A | 0.00 A | 0.00 A | 0.00 A |
| 2013 | 0.00 E | 0.00 E | 0.00 E | 0.00E | 0.00 E |
| 2014 | | | | | 0.00 E |

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

| | Q1 (Aug) | Q2 (Nov) | Q3 (Feb) | Q4 (May) | Year (May) |
|---|---|---|---|---|---|
| 2011 | -$0.03 A | -$0.05 A | -$0.05 A | -$0.05 A | -$0.18 A |
| 2012 | -$0.05 A | -$0.07 A | -$0.06 A | -$0.07 A | -$0.25 A |
| 2013 | -$0.05 E | -$0.05 E | -$0.05 E | -$0.04 E | -$0.19 E |
| 2014 | | | | | -$0.18 E |

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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## WHAT'S NEW

### *Management Change Will Not Affect Operations*

In recent 8-k filings, CytoDyn announced that Kenneth J. Van Ness stepped down as the President and Chief Executive Officer of the Company, effective immediately. Mr. Van Ness continues to serve as a member of the board of directors of the Company. In addition, Mr. Van Ness will serve as Senior Executive Advisor to the Company until October 16, 2012.

On September 10, 2012, the Board appointed Nader Pourhassan, Ph.D. to serve as the Company's interim CEO, effective immediately. The Board approved Dr. Pourhassan's title as interim President and CEO on September 13, 2012.

At the same time, CytoDyn appointed Dr. Richard Trauger as its new Chief Scientific Officer.

Dr. Pourhassan brings over 20 years of advanced engineering and mathematics expertise as well as strong business acumen, to his new role. Prior to his new position as CEO, Dr. Pourhassan served as the Company's Managing Director of Business Development, and before that, as its Chief Operating Officer. He received his Bachelor of Science degree from Utah State University in 1985, his Master of Science degree from Brigham Young University in 1990, and his Ph.D. in Mechanical Engineering from the University of Utah in 1998.

Dr. Trauger has over 20 years of experience in the HIV/AIDS space, working as head of the immunology research group for the Immune Response Corporation's Remune program and as the Senior Director of Cancer and Infectious Disease for Hollis-Eden Pharmaceuticals. He received his Ph.D. from the University of South Carolina School of Medicine in 1986 in biomedical science, specializing in retrovirology.

We believe the change of management will have limited impact on the Company's operations going forward. With the purchase of PRO 140, CytoDyn will be well positioned to enter into late stage of clinical development.

### *Acquisition of PRO 140 Boosts Pipeline*

In late July 30, CytoDyn and Progenics Pharmaceuticals, Inc. entered into an asset purchase agreement, effective as of July 25, 2012. Pursuant to the agreement, CytoDyn intends to acquire from Progenics its proprietary humanized monoclonal antibody HIV viral-entry inhibitor drug candidate, PRO 140.

The terms of the Agreement provide for an initial payment by the Company to Progenics in the amount of $3.5 million and subsequent milestone payments conditioned on successful continued clinical development of PRO 140 and a royalty payment to Progenics based on net sales upon commercialization following final FDA approval. The closing of this transaction is expected to take place in late October 2012.

**PRO 140** is a humanized monoclonal antibody developed by Progenics that is directed at CCR5, a cell surface antigen that helps HIV gain entry to the immune cell for replication. PRO 140 has been shown in vitro to bind to CCR5 without interfering with normal cellular immune function and to block HIV entry into cells to which it is bound. Therefore, PRO 140 may have the potential to treat HIV.

Phase I and IIa clinical studies of PRO 140 have been substantially completed by Progenics.

The acquisition of PRO 140 will diversify CytoDyn's pipeline, which is relatively weak with only two early stage candidates. On the other hand, to complete the acquisition, the Company may need to raise new fund. Equity financing will dilute existing shareholder base.

### *CytoDyn is Moving Forward with the Development of CytoFeline*

Recently, CytoDyn (CYDY) completed production of a sufficient amount of CytoFeline, which will allow the Company to move forward with the next stage of the candidate's development.

CytoFeline is a monoclonal antibody developed by the Company for the treatment of Feline Immunodeficiency Virus (FIV). When purification of the antibody is completed, the Company will conduct in vivo efficacy tests in cats to determine the practicality of anti-LFA1 antibodies to lower viral loads in FIV infected cats.

CytoDyn has selected Colorado State University and Dr. Susan VandeWoude, DVM, Associate Dean for Research CVMBS, Professor of Comparative Medicine, DMIP, at Colorado State University to lead the continuing research of CytoFeline, and to conduct these additional efficacy tests.

Initial CytoFeline research was performed in the laboratory of Dr. John Elder, Ph.D, Professor in the Department of Immunology and Microbial Science at The Scripps Research Institute. The Company anticipates that Dr. Elder intends to publish a paper discussing the results of his research when the research is completed.

In addition to the domestic and feral cats, the Company intends to study whether CytoFeline may potentially benefit the large cat population, specifically lions, tigers and other big cats found in zoos.

CytoFeline is complementary to the Company's lead candidate Cytolin. The CytoFeline asset enhances the Company's intellectual property and diversifies its pipeline. Both Cytolin and CytoFeline will contribute to the growth of CytoDyn in the coming years.

## VALUATION AND RECOMMENDATION

We maintain our Neutral rating on CytoDyn shares. Our 12-month price target is $1.50 per share.

CytoDyn is an early stage development biotech company. The Company holds two unique drug discovery platform technologies: Cytolin monoclonal antibody targeting HIV and CytoFeline monoclonal antibody targeting cat FIV.

We are optimistic about the Company's lead drug candidate Cytolin. Uncontrolled clinical studies of mouse Cytolin have shown some promise for the treatment of HIV/AIDS, but we would like to see more data especially advanced clinical trial data of humanized Cytolin to confirm the results of mouse Cytolin studies. In this regard, we are pleased to learn that the Company plans to move humanized Cytolin into clinic this year.

Cytolin and CytoFeline target the large HIV and FIV market respectively.

We are very pleased to see that CytoDyn has acquired PRO 140, which boosts the Company's pipeline.

We think CytoDyn has entered into a transition period from a pure preclinical development stage company into a clinical stage biotech company. With an appropriate growth strategy in place, the Company is well positioned to deliver shareholder value in the next few years in our view.

Current risk/return profile is balanced for CytoDyn in our view based on the Company's fundamentals. We admit that it's always a pain to properly value a development stage biotech company, CytoDyn is no exception. We don't think absolute valuation such as free cash flow method is appropriate for CytoDyn

since generating positive cash flow is still many years away. Without revenue and operating income in the foreseeable future, it's also very difficult to come up with a value using a relative valuation metrics.

CytoDyn is still in an early development stage and pipeline is relatively weak. The Company's balance sheet is weak too. CytoDyn needs to tap the capital market soon and will continue to do so on a regular basis in our view. Our price target of $1.50 per share corresponds to a market cap of $44 million based on 29 million shares outstanding.

If the Company establishes a major partnership with a big pharma or biotech company for either of its development programs, the Company's share could shoot up beyond our price target. However if it proves to be difficult to get much needed cash, the Company's shares could suffer.

## RISKS

### *Cash Position Is Our Chief Concern*

Like most small cap biotech companies, CytoDyn has a relatively weak balance sheet.

As of May 31, 2012, the Company had only $0.28 million in cash. The Company completed a private placement on December 31, 2011 by selling 2 million shares at $1.50 per share. Total proceeds were about $3 million.

Since inception, CytoDyn has financed its activities principally from the sale of public and private equity securities and proceeds from notes payable. The Company intends to finance future development activities and working capital needs largely from the sale of equity securities with some additional funding from other traditional financing sources.

As the Company prepares to bring Cytolin into clinic and continues the development of PRO 140, R&D costs will increase dramatically.

We believe CytoDyn needs to tap the capital market soon and will continue to do so on a regular basis before the Company achieves revenue from product sales or establish any partnership with major pharma or biotech companies.

We remind investors that equity financing will dilute existing shareholder base.

### *Early Stage Of Development Poses Higher Risks*

CytoDyn has two drug candidates Cytolin and CytoFeline. Both are in the early stage of development (pre-clinical) at this point.

Early stage of development poses greater risks as the drug candidate must navigate through the long clinical trials and regulatory review process in order to get into market.

We would like to see more data especially clinical data for the Company's drug candidates before we are bullish about the Company's stocks. We will update investors on this matter once the data are available.

## PROJECTED INCOME STATEMENT

| | 2012E (May) | | | | | 2013E (May) | | | | | 2014E (May) | 2015E (May) | 2016E (May) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| $ in million except per share data | Q1A | Q2A | Q3A | Q4A | FYA | Q1E | Q2E | Q3E | Q4E | FYE | FYE | FYE | FYE |
| *R&D* | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| *Grants and Others* | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| **Total Revenues** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| *CoGS* | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Gross Income** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** | **$0.00** |
| *Gross Margin* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| R&D | $0.17 | $0.17 | $0.07 | $0.12 | $0.53 | $0.15 | $0.17 | $0.20 | $0.25 | $0.77 | $1.50 | $3.00 | $4.50 |
| *% R&D* | - | - | - | - | - | | | | | - | - | - | - |
| SG&A | $0.64 | $1.01 | $1.07 | $2.73 | $5.45 | $1.09 | $1.12 | $1.20 | $1.25 | $4.66 | $5.00 | $5.50 | $6.00 |
| *% SG&A* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Other expenses | $0.34 | $0.31 | $0.27 | $0.55 | $1.47 | $0.15 | $0.18 | $0.18 | $0.20 | $0.71 | $1.00 | $1.20 | $1.50 |
| *% Other* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| **Operating Income** | **($1.2)** | **($1.5)** | **($1.4)** | **($3.4)** | **($7.5)** | **($1.4)** | **($1.5)** | **($1.6)** | **($1.7)** | **($6.1)** | **($7.5)** | **($9.7)** | **($12.0)** |
| *Operating Margin* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Other Net | ($0.0) | $0.0 | ($0.0) | ($0.1) | ($0.1) | ($0.0) | ($0.0) | ($0.1) | ($0.1) | ($0.2) | ($0.1) | ($0.1) | ($0.1) |
| **Pre-Tax Income** | **($1.2)** | **($1.5)** | **($1.4)** | **($3.5)** | **($7.6)** | **($1.4)** | **($1.5)** | **($1.6)** | **($1.8)** | **($6.3)** | **($7.6)** | **($9.8)** | **($12.1)** |
| Income taxes(benefit) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *Tax Rate* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| **Reported Net Income** | **($1.2)** | **($1.5)** | **($1.4)** | **($3.5)** | **($7.6)** | **($1.4)** | **($1.5)** | **($1.6)** | **($1.8)** | **($6.3)** | **($7.6)** | **($9.8)** | **($12.1)** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| *Net Margin* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| *Shares Out* | *22.3* | *22.3* | *25.5* | *28.4* | *24.6* | *28.8* | *30.0* | *32.0* | *40.0* | *32.7* | *42.0* | *50.0* | *60.0* |
| **Reported EPS** | **($0.05)** | **($0.07)** | **($0.06)** | **($0.12)** | **($0.31)** | **($0.05)** | **($0.05)** | **($0.05)** | **($0.04)** | **($0.19)** | **($0.18)** | **($0.20)** | **($0.20)** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| One time charge | *$0.00* | *$0.00* | *$0.00* | *$1.47* | *$1.47* | *$0.00* | *$0.00* | *$0.00* | *$0.00* | *$0.00* | *$0.00* | *$0.00* | *$0.00* |
| **Non GAAP Net Income** | **($1.2)** | **($1.5)** | **($1.4)** | **($2.0)** | **($6.1)** | **($1.4)** | **($1.5)** | **($1.6)** | **($1.8)** | **($6.3)** | **($7.6)** | **($9.8)** | **($12.1)** |
| **Non GAAP EPS** | **($0.05)** | **($0.07)** | **($0.06)** | **($0.07)** | **($0.25)** | **($0.05)** | **($0.05)** | **($0.05)** | **($0.04)** | **($0.19)** | **($0.18)** | **($0.20)** | **($0.20)** |

*Source: Company filings and Zacks Investment Research*

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## HISTORICAL ZACKS RECOMMENDATIONS




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