Zacks Small-Cap Research

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MethylGene Inc.

(MYG-TO, MYLGF-OTC)

T.MYG: MGCD290 Phase II failed, focus shifted to oncology assets--Neutral

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	03/18/2013
Current Price (03/18/2013)	$0.15
Twelve- Month Target Price	**$0.45**

OUTLOOK

MethylGene is a development stage biotech company. The Company's two lead drug candidates MGCD290 and MGCD265 are differentiated agents targeting the fungal and cancer market respectively. The Company just announced the failure of MGCD290 Phase II program and will shift focus to oncology assets. MGCD265 is in Phase I/II clinical trials.

MethylGene also has established an impressive pipeline with diversified candidates, with some under development by its collaborators. It's also well capitalized with a strong balance sheet.

With the most advanced program gone, we rate the Company shares Neutral.

SUMMARY DATA

52-Week High	**$0.50**
52-Week Low	**$0.19**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**69,938**
Shares Outstanding (mil)	**497.8**
Market Capitalization ($mil)	**$75**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**71**
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 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	1.28 A	1.27 A	0.07 A	0.47 A	3.09 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	0.00	0.00 E
2014					0.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.04 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.04 A
2012	-$0.01 A	-$0.01 A	-$0.02 A	-$0.02 A	-$0.06 A
2013	-$0.01 E	-$0.01 e	-$0.01 E	-$0.01 E	-$0.03 E
2014					-$0.03 E

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

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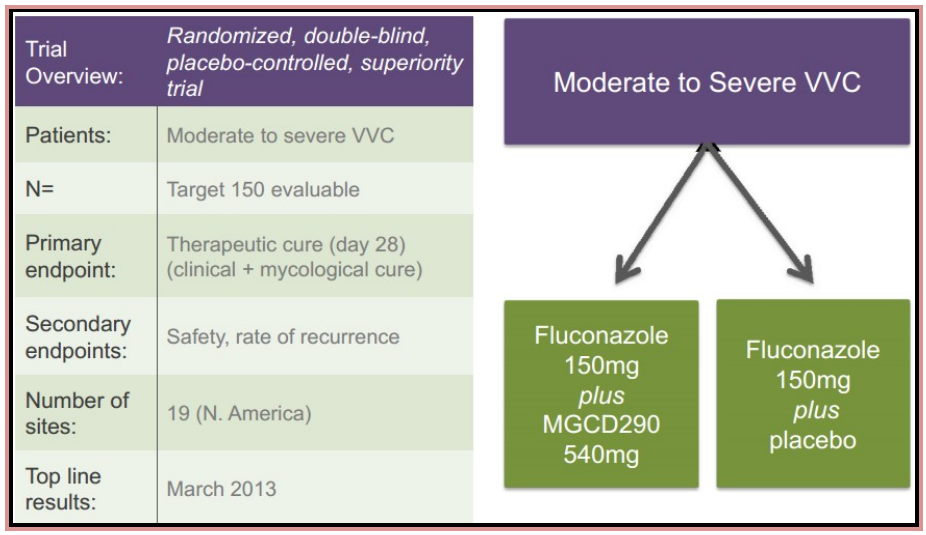
WHAT'S NEW

MGCD290 Phase II Failed, Focus Shifted to Oncology Assets

On March 18, 2013, MethylGene Inc. (MYG.TO) reported topline results from its **Phase II** human efficacy trial (Trial 290-005) with MGCD290. Trial 290-005 was a randomized, multicenter, double-blind, placebo-controlled trial designed to test whether MGCD290, in combination with fluconazole, was superior to fluconazole alone in patients with moderate-to-severe vulvovaginal candidiasis (**VVC**).

As a reminder, Trial 290-005 was initiated in October 2011 and completed enrollment in December 2012. Over 200 patients were enrolled at 19 sites in North America.



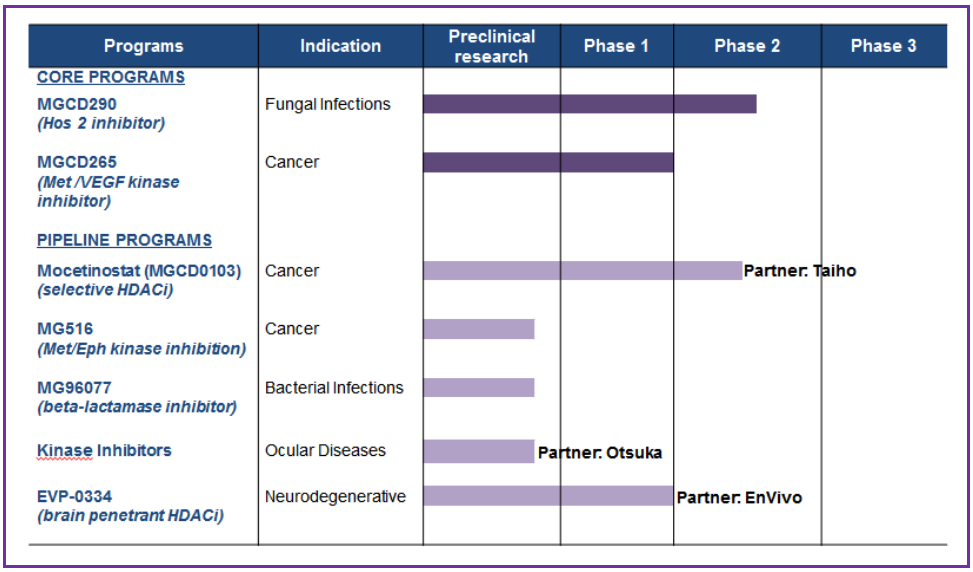
This study is a multicenter, randomized, double-blinded, placebo-controlled trial. This trial focuses on the most severe infections and therefore patients with mild disease are excluded. The purpose of the trial is to evaluate the safety and efficacy of fluconazole versus fluconazole + MGCD290.

- Subjects will be randomized in a 1:1 ratio to one of two arms of this study as follows: 150mg fluconazole + 540mg MGCD290, or 150mg fluconazole + placebo;
- 75 evaluable patients will be enrolled in each treatment arm; about 200 patients will be enrolled to get 150 evaluable patients in two arms;
- Subjects will be dosed on Day 1, and followed for one month after dosing;
- The **primary endpoint** for the study will be the **Therapeutic Cure Rate,** a composite endpoint of Clinical Cure (a resolution of clinical signs and symptoms) plus Mycologocial Cure (negative results on microscopy and culture) at Day 28;
- The primary endpoint population for this study will be based on the Modified Intent To Treat (MITT) population, which removes those patients who have been determined by screening not to have a fungal infection from analysis;
- Secondary endpoints will be:
    - Clinical Cure and Mycological Cure at 28 days;
    - Therapeutic Cure, Clinical Cure and Mycological Cure at 14 days;

- Time to Resolution of Symptoms;
- Safety of the combination of MGCD290 and fluconazole compared to fluconazole alone;

There were no serious treatment-related adverse events and non-serious adverse events were evenly distributed between treatment groups. However, the study showed no statistically significant benefit of MGCD290 plus fluconazole compared to fluconazole alone. Detailed data will be presented at a future meeting.

The failure of MGCD290 Phase II trial is a big setback for MethylGene in our view. Although the Company stated that they will review the data internally and with key opinion leaders to determine the next steps for the MGCD290 program, we think the MGCD290 program is likely dead. The Company has lost its most advanced asset in its pipeline. As a result, it will focus on its oncology programs and further update will be provided in 2H2013.



Focus will be Shifted to MGCD265

As a result of the MGCD290 Phase II failure, MethylGene has decided to shift its focus to its oncology programs. The most advanced oncology program in its pipeline is MGCD265.

MGCD265 is an oral, multi-targeted kinase inhibitor rationally designed to target the Met, VEGFR, RON, Tie-2 RTKs and Alx, key kinases involved in cancer and angiogenesis.

Enrollment is ongoing in the **Phase I/II** trials **MGCD265-101** (monotherapy) and **MGCD265-103** (combination therapy with docetaxel or erlotinib).

Interim data from the Phase I/II trials have been reported. In **monotherapy** studies, MGCD265 has been well tolerated with no grade 4 adverse events. Treatment-related grade 3-4 adverse events were infrequent. Long term stable disease (over 12 months in duration) has been observed in patients with bladder, renal cell and neuroendocrine cancer. One patient with squamous cell cancer achieved a partial response (PR), as determined by RECIST criteria, after ten cycles of monotherapy with MGCD265. The PR was based on one target axillary lesion, but the non-target bone lesions remained stable.

MGCD265 **in combination with docetaxel** continues to be well tolerated. Non-hematologic grade 3-4 adverse events occurring in more than one patient were infrequent and hematologic toxicities of grade 3-4 were as expected with docetaxel therapy. Objective responses have been observed in NSCLC,

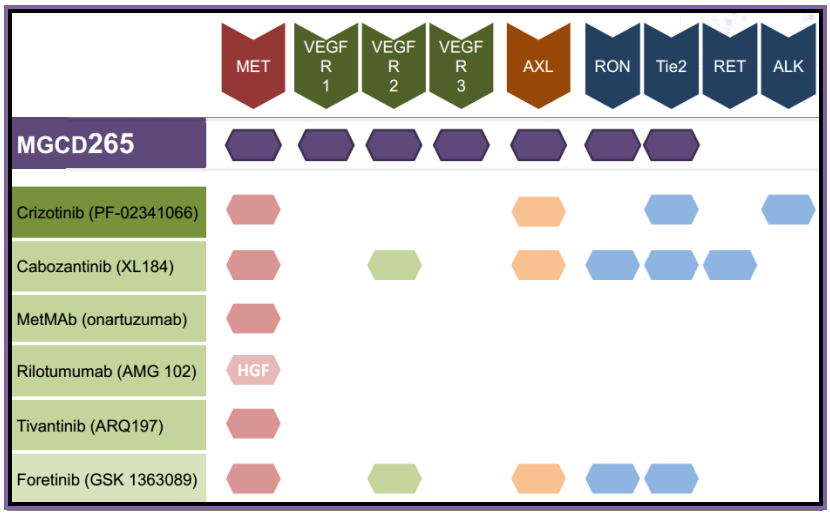
prostate cancer and endometrial cancer patients. Of twelve evaluable NSCLC patients, two achieved partial remission and eleven achieved disease control (partial remission or stable disease) at the first tumor assessment.

In the **MGCD265 plus erlotinib combination** studies there were no grade 4 toxicities and grade 3-4 adverse events were infrequent. Five of nine gastro-esophageal (GE) patients achieved stable disease at the first scan (disease control rate of 56%). Of these four patients remained stable for greater than 4 months and two remained stable for greater than 1 year.

The product has moved into multiple Phase I/II expansion cohorts including indications of renal cell, gastric, NSCLC and hepatocellular cancer patients who are c-Met positive. Enrollment is continuing in the 265-101 monotherapy and 265-103 combination trials with until a maximum tolerated dose (MTD) is reached. Once the MTD is reached, the Company will define the optimal dose for **Phase II studies**.

Milestones	2013				2014			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Expansion Cohorts (Single Arm) in Ongoing Phase I/II Trials								
- 3rd Line RCC; MET+		→	→	→	→	→		
- NSCLC; AXL+, MET+		→	→	→	→	→		
- 2nd Line HCC; MET+		→	→	→	→	→		
- 2nd Line Gastric; MET+		→	→	→	→	→		
Randomized Controlled Combination Trials								
- 2nd Line Gastric; MET+				→	→	→	→	→
- 2nd Line NSCLC; MET+ and/or AXL+				→	→	→	→	→

MethylGene has been talking about the kinase **Axl** as a potential differentiator based on potent inhibition of Axl by MGCD265. Plans are underway to initiate a study in NSCLC patients who express Axl.



We think the decision to shift focus to oncology programs after the MGCD290 failure is prudent. In addition to its lead cancer program MGCD265, MethylGene also has MGCD516 in preclinical studies as well as MGCD0103 which is partnered with Taiho, and is in Phase II clinical studies. Together, these cancer programs constitute the major assets post MGCD290, and will build up shareholder value in the years ahead.

Balance Sheet Boosted by Recent Financing

On November 21, 2012, MethylGene Inc. completed a private placement of 179,690,970 units at a subscription price per unit of Cdn $0.145. Each unit consisting of one common share and thirty one-hundredths (0.30) of a common share purchase warrant, exercisable until November 19, 2017 at an exercise price of Cdn.$0.174 (being 120% of the Subscription Price), for gross proceeds to MethylGene of approximately Cdn $26.1 million.

The lead investor in the Offering was Tavistock Life Sciences, an insider of the Company, and other insiders participating in the Offering included funds managed by Baker Bros. Advisors, LLC, a fund managed by OrbiMed Advisors LLC, and Tang Capital Partners, LP. Other investors participating in the Offering included RA Capital Management and BVF Partners L.P.

This financing not only provides much needed cash for the Company, but also validates the Company's technology and clinical programs. We think the net proceeds from the Offering will enable the Company to accelerate advancing its oncology programs including its lead cancer program MGCD265.

As a result of the financing, cash, cash equivalents, marketable securities and restricted cash totaled $37.2 million as at December 31, 2012. Current cash is sufficient to last through the second half of 2014 according to our long term financial model.

Management Change May Facilitate the Execution of Growth Strategy Post MGCD290

MethylGene has a series of management changes in recent months.

On November 12, 2012, MethylGene appointed Charles M. Baum, MD, PhD, as President and Chief Executive Officer as well as the Company's Board of Directors.

Dr. Baum was most recently Senior Vice President for Clinical Research within Pfizer's Worldwide Research & Development division. He has worked at Pfizer since 2003, taking on roles of increasing responsibility, including Vice President and Head of Oncology Development and Chief Medical Officer for Pfizer's Biotherapeutics and Bioinnovation Center, a Pfizer division comprised of small biotech research units. During his tenure at Pfizer he was responsible for the development of the oncology portfolio, including the tyrosine kinase inhibitors sunitinib (Sutent®), axitinib (Inlyta®) and crizotinib (Xalkori®). Prior to joining Pfizer Dr. Baum was responsible for the Phase I-IV development of several oncology compounds at Schering-Plough, including temozolomide (Temodar®). His career also includes academic and hospital positions at Stanford and Emory Universities, as well as positions of increasing responsibility within the pharmaceutical industry (Systemix, Searle, Schering-Plough and Pfizer).

Dr. Baum received his M.D. and Ph.D. (Immunology) degrees from the Washington University School of Medicine and did his post-graduate work at Stanford University, where he completed his medical training and conducted research on human bone marrow stem cells with Dr. Irving Weissman. Dr. Baum was granted research support by the National Institutes of Health and the American Cancer Society, published more than 50 peer-reviewed manuscripts, and holds a number of patents and patent applications.

On March 14, 2013, MethylGene announced that Messrs. Jeffrey M. Besterman, PhD, Executive Vice President Research and Development and Chief Scientific Officer, Joe Walewicz, Vice President of Business and Corporate Development and Klaus B. Kepper, Vice President Finance and Chief Financial Officer, will be leaving the company to pursue other interests.

Effective immediately, the responsibilities of Dr. Besterman have been assumed by Charles Baum, MD PhD, CEO, and the responsibilities of Mr. Kepper and Mr. Walewicz have been assumed by Mark Gergen, COO. Each of the executives will depart following a brief transition period.

It's our belief that the management change won't affect MethylGene's operation, and instead, it may facilitate the execution of growth strategy post MGCD290. We believe the new CEO **Dr. Baum's** exceptional experience in drug development will be of great value to the advancement of MethylGene's oncology programs which is the Company's current focus after the MGCD290 failure.

VALUATION AND RECOMMENDATION

We move to Neutral on MethylGene (MYLGF) following the announcement of MGCD290 Phase II failure. Our new 12-month price target is $0.45 per share.

MethylGene is a development stage development biotech company focused on development and commercialization of pharmaceuticals for the treatment of fungal infection and cancer. Based on its extensive knowledge and expertise in molecular biology and chemistry, the Company has built up an impressive pipeline with candidates in different development stages.

With the failure of its lead **Phase II** anti-fungal program MGCD290, MethylGene has lost its most advanced clinical asset. This is certainly a big setback for the Company and for investors in general.

With MGCD290 gone, the Company has shifted its focus to its oncology assets. We think the decision is prudent. Among its oncology assets is its lead cancer program MGCD265, which is already in Phase I/II clinical study, and MGCD516 in preclinical studies as well as MGCD0103 which is partnered with Taiho, and is in Phase II clinical studies. Together, these cancer programs constitute the Company's major assets post MGCD290, and will build up shareholder value in the coming years.

MGCD265 is a highly promising drug candidate, which is differentiated from other kinase inhibitors either in development or on the market. MGCD265 is a multi-targeted kinase inhibitor, which has shown favorable safety profile and clinical activities. MGCD265 is in Phase I studies now, and will enter into Phase II soon. We estimate the FDA approval in 2017.

At this time, we think the risk/reward profile is balanced for MethylGene. Our target price of $0.45 per share values the Company at $225 in market cap, which we think is fair and appropriate.

PROJECTED INCOME STATEMENT

	2010A	2011A	2012A (Dec)					2013E (Dec)					2014E (Dec)	2015E (Dec)	2016E (Dec)
$ in million except per share data	FYA	FYA	Q1A	Q2A	Q3A	Q4A	FYA	Q1E	Q2E	Q3E	Q4E	FYE	FYE	FYE	FYE
R&D and Contract revenue	$1.57	$0.79	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.50	$0.50	$1.00
License and Up-front revenue	$0.82	$2.30	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$5.00	$15.00
Product Sales	$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	$0.00	$0.00
Total Revenues	**$2.39**	**$3.09**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$5.50**	**$16.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*1000.0%*	*190.9%*
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	0.00	0.00
Gross Income	**$2.39**	**$3.09**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$5.50**	**$16.00**
Gross Margin	100%	-	-	-	-	-	-	-	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
R&D	$10.87	$8.83	$2.21	$3.69	$4.23	$4.93	$15.06	$3.00	$2.00	$2.20	$2.50	$9.70	$10.00	$10.50	$12.00
% SG&A		-	-	-	-	-	-	-	-	-	-	-	-	-	
SG&A	$6.19	$4.29	$1.22	$1.09	$1.71	$1.36	$5.39	$1.20	$1.20	$1.20	$1.20	$4.80	$6.50	$7.00	$7.50
% R&D		-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	$0.02	($0.23)	$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
% Other		-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($14.69)**	**($9.8)**	**($3.4)**	**($4.8)**	**($5.9)**	**($6.3)**	**($20.4)**	**($4.2)**	**($3.2)**	**($3.4)**	**($3.7)**	**($14.5)**	**($16.0)**	**($12.0)**	**($3.5)**
Operating Margin		-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	$0.0	($0.4)	$0.1	$0.1	($0.0)	$0.1	$0.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($14.69)**	**($10.2)**	**($3.4)**	**($4.7)**	**($6.0)**	**($6.2)**	**($20.3)**	**($4.2)**	**($3.2)**	**($3.4)**	**($3.7)**	**($14.5)**	**($16.0)**	**($12.0)**	**($3.5)**
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	$0.0	$0.0
Tax Rate		*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*-0.2%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	-
Reported Net Income	**($14.69)**	**($10.2)**	**($3.4)**	**($4.7)**	**($6.0)**	**($6.3)**	**($20.3)**	**($4.2)**	**($3.2)**	**($3.4)**	**($3.7)**	**($14.5)**	**($16.0)**	**($12.0)**	**($3.5)**
YOY Growth		-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin		-	-	-	-	-	-	-	-	-	-	-	-	-	-
Deluted Shares Out	*40.4*	*247.2*	*317.9*	*317.9*	*318.1*	*398.3*	*338.0*	*497.8*	*497.8*	*497.8*	*500.0*	*498.4*	*520.0*	*550.0*	*575.0*
Reported EPS	**($0.36)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.06)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.03)**	**($0.03)**	**($0.02)**	**($0.01)**
YOY Growth		-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	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*	*0.00*	*0.00*
Non GAAP Net Income	**($14.69)**	**($10.2)**	**($3.4)**	**($4.7)**	**($6.0)**	**($6.3)**	**($20.3)**	**($4.2)**	**($3.2)**	**($3.4)**	**($3.7)**	**($14.5)**	**($16.0)**	**($12.0)**	**($3.5)**
Non GAAP EPS	**($0.36)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.06)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.03)**	**($0.03)**	**($0.02)**	**($0.01)**

Source: Company filing and Zacks Investment Research

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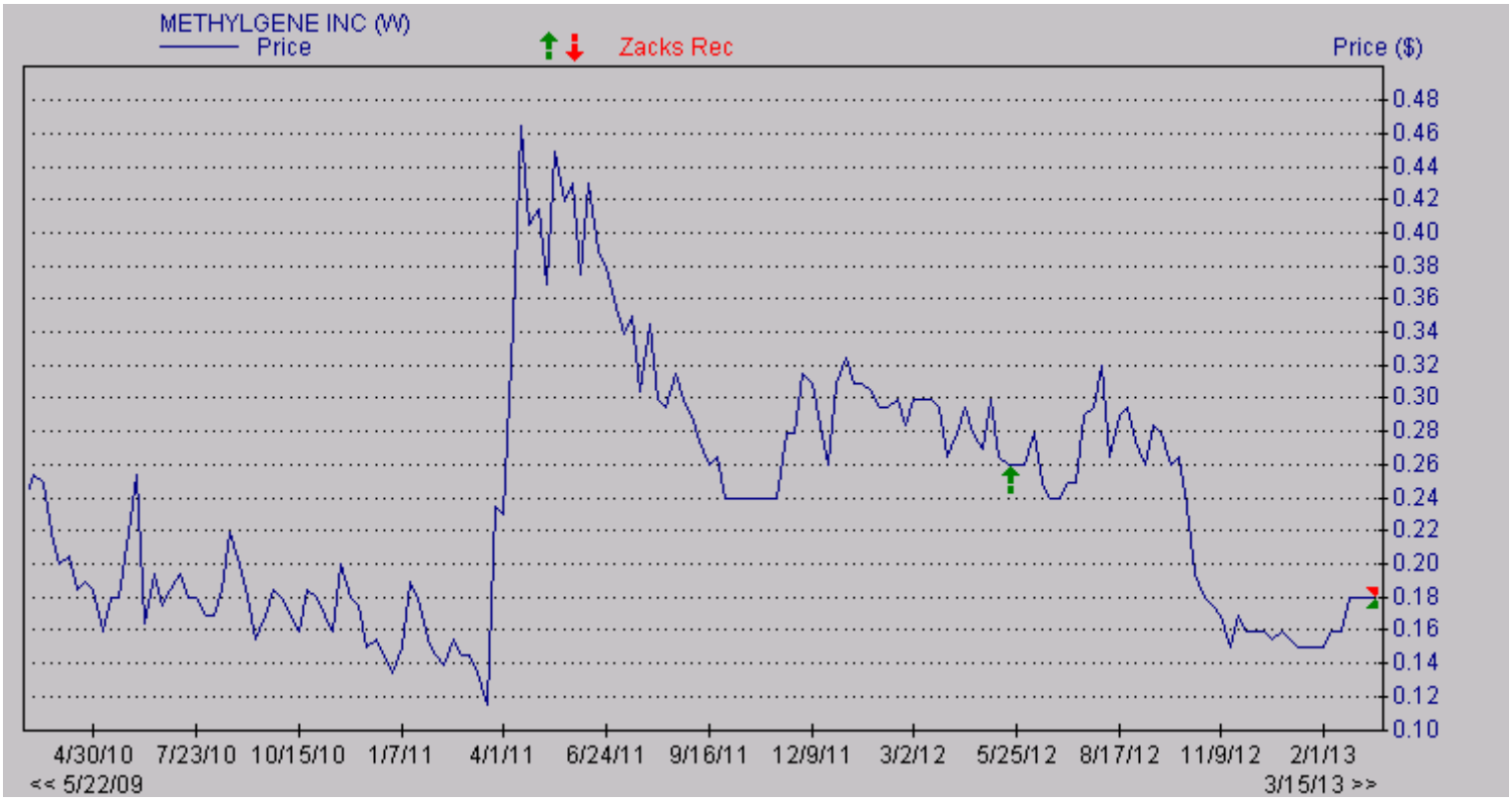
HISTORICAL ZACKS RECOMMENDATIONS



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