Zacks Small-Cap Research

August 6, 2012
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MethylGene Inc.

(MYG-TO, MYLGF-OTC)

MYLGF: Clinical programs are on track to progress, and balance sheet continues to be strong--Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	05/22/2012
Current Price (06/03/2012)	$0.32
Twelve- Month Target Price	**$0.75**

OUTLOOK

MethylGene is a mid-stage development biotech company. The Company's two lead drug candidates MGCD290 and MGCD265 are differentiated agents targeting the fungal and cancer market respectively. MGCD290 is in Phase II, and MGCD265 is in Phase I/II clinical trials; and approval could happen in 2015 and 2017 respectively.

In addition to the two lead candidates, MethylGene also has established an impressive pipeline with diversified candidates, with some under development by its collaborators.

MethylGene is well capitalized with a strong balance sheet. We rate the Company shares Outperform.

SUMMARY DATA

52-Week High	**$0.50**
52-Week Low	**$0.19**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**8,860**
Shares Outstanding (mil)	**318**
Market Capitalization ($mil)	**$83**
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 E	0.00 E	0.00 E	0.00 E
2013					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 E	-$0.01 E	-$0.01 E	-$0.04 E
2013					-$0.04 E
2014					-$0.04 E

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

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WHAT'S NEW

Balance Sheet Continues to be Strong

On August 2, MethylGene reported its financial results for the second quarter ended June 30, 2012.

There was no revenue in the second quarter of 2012 compared to $1.3 million for the second quarter of 2011. The decline in revenue was due to the completion of the research component of the agreement with Otsuka Pharmaceutical Co. Ltd. in June of 2011.

Research and development expenditures for the second quarter of 2012 were $3.7 million versus $1.8 million in the second quarter of 2011. This increase was primarily due to increased clinical development activity for both the MGCD290 and MGCD265 programs.

General and administrative expenses in the second quarter of 2012 were $1.1 million, no change versus the second quarter of 2011.

Net loss for the second quarter of 2012 was $4.7 million, or $0.01 per share, compared to a net of $1.5 million, or $0.005 per share, for the same period last year.

We are very pleased to see the Company's balance sheet continued to be strong at the end of second quarter of 2012. Cash, cash equivalents, marketable securities and restricted cash totaled $22.2 million as at June 30, 2012. According to our model, the cash balance can last into the fourth quarter of 2013.

Clinical Programs are on Track to Advance

In addition to the financial results, MethylGene also provided an update on its clinical programs.

MGCD290 Program

In October 2011, MethylGene initiated a **Phase II (Study 290-005)** clinical study evaluating MGCD290 in combination with fluconazole vs. fluconazole alone in patients with **moderate to severe** acute vulvovaginal candidiasis **(AVVC).**

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. The primary endpoint for this trial is the Therapeutic Cure at day 28, which is a composite endpoint of Clinical Cure (resolution of signs and symptoms of the infection) and Mycological Cure (an absence of yeast in culture).

Recruitment is ongoing at sites in the US and Canada with moderate to severe AVVC. The Company expects to enroll approximately 180 patients to get 150 evaluable patients for the primary endpoint. Nineteen sites in the United States are now open for enrolment, and as of August 1, 2012, 74 patients have been enrolled in the trial. Based on the current rate of enrollment, management expects to report top line data from this trial around the end of 2012.

As recurrent VVC patients are now eligible for enrollment in the VVC trial following a protocol amendment, the Company has decided not to proceed with a separate recurrent VVC trial at this time.

MethylGene is preparing for another Phase II trial with MGCD290.

MGCD265 Program

MGCD265 is a rationally designed, orally available Met/VEGF receptor kinase inhibitor in development for oncology indications. At the ASCO Annual Meeting in June, 2012, MethylGene presented data using plasma samples from trial patients demonstrating a dose-response relationship between increased plasma concentration of MGCD265 and inhibition of Met phosphorylation in a novel ex vivo assay system. MGCD265 continues to be well tolerated in both monotherapy and in combination trials.

In the ongoing **Phase I** monotherapy trials (265-101), grade 3-4 treatment-related adverse events have been infrequent and long-term stable disease has been observed in sarcomatoid bladder, papillary renal, neuroendocrine, thymic and colon cancer.

In the **docetaxel arm** of the **Phase I** combination trial, objective responses have been observed in non-small cell lung cancer (NSCLC), prostate cancer and endometrial cancer. Of ten evaluable NSCLC patients in this trial, two achieved partial remission and all ten patients achieved disease control (partial remission or stable disease) at the first tumor assessment. These data compare favorably in the context of historical data (docetaxel monotherapy).

In the **erlotinib arm** of the **Phase I** combination trial, prolonged stable disease has been observed in gastric, esophageal, NSCLC and chordoma. MGCD265 has been well tolerated in combination with either full dose docetaxel or erlotinib.

Enrollment of patients continues in the MGCD265 monotherapy and combination trials. The development plan for MGCD265 includes expansion cohorts in select tumor types once the recommended Phase II dose is defined and data from the expansion cohorts will be used to guide randomized Phase II trials.

The Company plans to continue enrolling patients in 265-101 monotherapy and 265-103 combination trials with docetaxel or erlotinib until a maximum tolerated dose (MTD) is reached. Upon reaching the MTD, the Company intends to initiate a series of open label expansion cohorts to better characterize the effects seen in early trials and support the plans for future randomized Phase II trials.

KEY POINTS

- We maintain our Outperform rating on MethylGene (MYLGF) and reiterate our 12-month price target of $0.75 per share.

- MethylGene is a mid-stage development biotech company focused on development and commercialization for the treatment of fungal infections and cancers. The Company has two differentiated lead candidates MGCD290 and MGCD265 for fungal infections and cancers respectively.

- **MGCD290** in combination with fluconazole has entered into Phase II clinical trial targeting vulvovaginal candidiasis, both acute and recurring. MGCD290 is a first-in-class selective, oral, small molecule inhibitor of the fungal Hos2 enzyme; works in synergy with azole antifungal agents; has broad spectrum antifungal activity; can reduce drug resistance.

- We expect MGCD290 will enter into pivotal Phase III trial in 2013. We model the FDA approval of MGCD290 in 2015. Due to the advantages of MGCD290 in combination of fluconazole, the combination will command a significant market share from currently used antifungals. Also, fluconazole is the most widely used antifungal, which will drive the usage of MGCD290;

- **MGCD265** is a multi-targeted kinase inhibitor in multiple Phase I and Phase I/II clinical trials. This agent is well tolerated and has a favorable safety profile. Early signs of significant clinical activity have been observed in gastric cancer and NSCLC patients when combined with docetaxel or

erlotinib. We estimate MGCD265 could enter into Phase III study in 2014 and the FDA approval could happen in 2017.

- In addition to MGCD290 and MGCD265, MethylGene has also diversified programs under development with some of them developed by its partners. These programs provide a long term growth potential for the Company.

- MethylGene has a strong balance sheet. We forecast that the current cash can last through the 4Q2013. No debt is sitting on its balance sheet as of June 30, 2012. Current valuation is attractive.

OVERVIEW

MethylGene (MYG) is a Canada-based biopharmaceutical company focused on development and commercialization of novel therapeutics for **cancer and infectious disease**. MYG's core programs include MGCD290 for fungal disease and MGCD265 for cancer.

MGCD290 is the Company's most advanced compound, which is an oral small molecule inhibitor of the fungal enzyme Hos2. MGCD290 is initially being developed in combination with fluconazole, a drug from the azole class of antifungal drugs. MGCD290 recently entered into a **Phase II** trial in acute vulvovaginal candidiasis (AVVC), and has completed multiple Phase I studies in healthy adult volunteers.

Another key development compound is oncology product candidate **MGCD265**, which is an orally administered kinase inhibitor designed to target Met, VEGFR, RON and Tie-2 receptor tyrosine kinases (RTKs). Three **Phase I/II** studies have commenced using the agent as a monotherapy and in combination with select anti-cancer agents. One study has been completed and the other two are ongoing. Expansion cohorts to define plans for randomized, controlled Phase II studies will begin enrolment in these studies as soon as the Maximum Tolerated Dose (MTD) is defined.

Other proprietary pipeline also includes: **MG91516**, a multi-targeted kinase inhibitor for cancer; and **MG96077**, a beta-lactamase inhibitor designed to overcome antibiotic resistance.

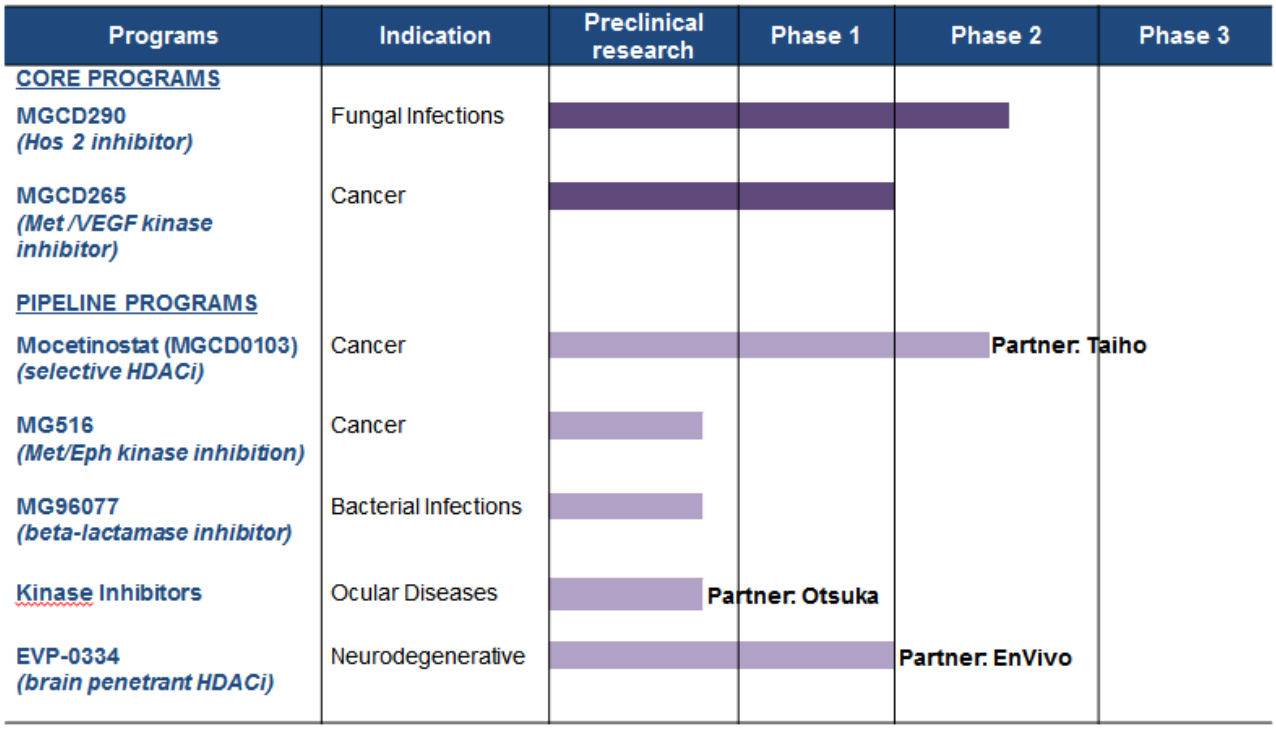
MethylGene also has multiple partnered programs. The Company has a partnership with Taiho for mocetinostat (**MGCD0103**), an orally available, isoform selective histone deacetylase (HDAC) inhibitor that has been in multiple clinical trials for the treatment of hematological malignancies. Partner **EnVivo** is developing **EVP-0334**, a central nervous system-penetrant HDAC inhibitor that is being pursued in neurodegenerative diseases. This agent was discovered using MethylGene's HDAC platform and has completed a Phase I clinical trial sponsored by EnVivo Pharmaceuticals Inc. MethylGene has also partnered with **Otsuka** to develop kinase inhibitors for ocular disease.

The Company's principal strategy is to develop its proprietary portfolio of compounds for oncology and infectious diseases through to commercial approval, either in collaboration with other parties or using its own capital and personnel. Current focus is on the development of two lead compounds, MGCD290 and MGCD265.

MethylGene's impressive pipeline of molecules is based on its strong expertise in molecular biology and chemistry. One specific area is to target the active sites of enzymes. Enzymes are responsible for many biochemical activities in the human body and many diseases are linked to abnormal enzyme function. Abnormalities in enzyme function may be caused by defects in the enzyme due to genetic mutation, over or under-expression of the enzyme or aberrant control of the enzyme.

MethylGene is headquartered in Montreal, Canada. In December, 2011, MethylGene incorporated a wholly-owned subsidiary, MethylGene US Inc., a Delaware company. MethylGene US Inc. is located in Princeton, New Jersey.

MethylGene's common shares have been listed on the Toronto Stock Exchange since June 29, 2004 under the ticker symbol "**MYG**". Its shares are also listed on Over the Count (OTC) in the US (**MYLGF-PK)**.



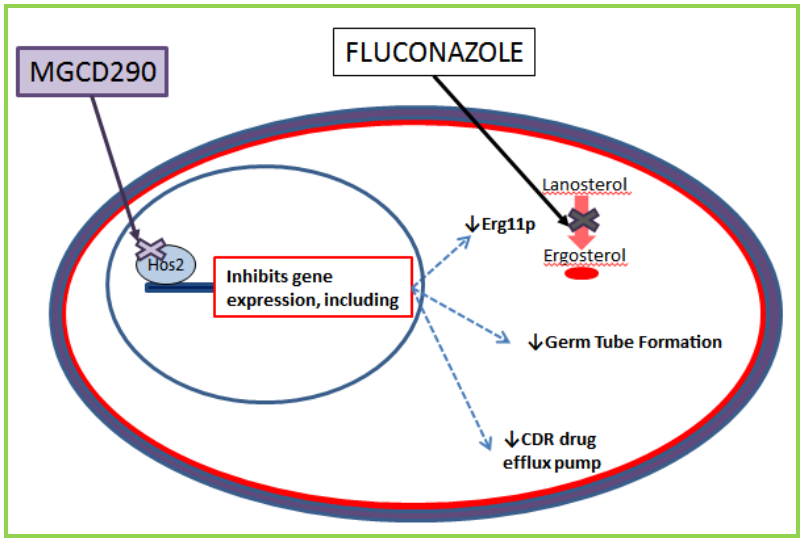
Source: Company presentation

INVESTMENT THESIS

MGCD290, a First In Class Molecule Targeting Fungal Enzyme Hos2

One of MethylGene's two lead programs is MGCD290. MGCD290 is an oral small molecule inhibitor of the fungal enzyme **Hos2**, and is designed to be used **in combination with azoles** for the treatment of fungal infections. Currently, azoles are the leading therapy for the treatment of a variety of fungal infections. However, azoles are not effective against many clinically relevant pathogens, and the treatment of fungal infections with azoles can result in the emergence of azole-resistant fungal strains, rendering azole treatment ineffective over time. There are also many toxicities, such as diarrhea, heartburn, headache, vomiting, etc., which are associated with current antifungal therapies.

MGCD290 is a first in class molecule targeting Hos2, an epigenetic target that modulates fungal gene expression. Hos2 is one of six fungal HDAC enzymes, which regulate the expression of key fungal genes involved in cell wall biosynthesis and other important fungal parameters such as fungal virulence. Inhibition of Hos2 blocks the transcription of the gene Erg 11p, the target of the azole antifungals, resulting in a two pronged attack on this important pathway using combination therapy. The illustration below depicts the synergy of MGCD290 in combination with azoles on the ergosterol synthesis pathway.



In preclinical studies, MGCD290 has demonstrated significant antifungal effects across a wide spectrum of fungal parameters. In vitro, MGCD290 shows high levels of synergy in minimum inhibitory concentration (MIC) checkerboard testing in combination with azoles against a wide variety of clinical isolates including yeasts, molds, zygomycetes, and dermatophytes. MGCD290 is able to lower the MICs of the azoles, resulting in the crossing of interpretive breakpoints (from resistant to sensitive). MGCD290 moves fluconazole towards cidality by prolonging its post-antifungal effect, inhibiting trailing growth, and decreasing the virulence of fungi. MGCD290 is active against dermatophyte clinical isolates resistant to terbinafine. MGCD290 shows dose-dependent antifungal activity in systemic models of Candida infection, and is able to protect 100% of mice in lethal challenge study using azole cross-resistant clinical isolates (when dosed with fluconazole). MGCD290 in combination with azoles has also shown efficacy in animal Candida infection models in single-dose and prophylaxis models.

MGCD290 is synergistic with multiple azoles across fungal species

Group	Species	Synergy with MGCD290 # clinical isolates/total (%)		
		Fluconazole	Voriconazole	Posaconazole
Yeasts	*Candida spp*	60/75 (80%)	51/75 (68%)	18/30 (60%)
	Rhototorula	3/8 (38%)	4/8 (50%)	2/8 (25%)
	Cryptococcus	5/10 (50%)	4/10 (40%)	3/10 (30%)
	Trichosporon	2/5 (40%)	1/5 (20%)	1/5 (20%)
Molds	*Aspergillus spp*	6/10 (60%)	16/26 (62%)	4/10 (40%)
	Scedosporium	3/5 (60%)	3/5 (60%)	2/5 (40%)
	Fusarium	4/8 (50%)	6/8 (75%)	2/8 (25%)
Zygomycetes	*Mucor spp*	1/5 (20%)	2/5 (40%)	5/5 (100%)
	Rhizopus spp	5/10 (50%)	9/10 (90%)	9/10 (90%)
Overall		65%	63%	51%

Synergy defined by Fractional Inhibitory Concentration (FIC). Rate of Additivity significantly higher.
Table represents data from 2 studies conducted by MA Pfaller at the University of Iowa.

These preclinical studies has demonstrated that MGCD290 made fungi ultrasensitive to azole antifungals, restored azole efficacy in resistant fungi, decreased fungal virulence and extended the spectrum of activity for azoles against key fungal pathogens such as *Candida* and *Aspergillus* species.

MGCD290 addresses azole resistance

	Voriconazole				Fluconazole		
C. glabrata Clinical Isolate No.	VORI MIC (Sens)	MGCD290 CONC (µg/mL)	VORI MIC with MGCD290 (Sens)		FLU MIC (Sens)	MGCD290 CONC (µg/mL)	FLU MIC with MGCD290 (Sens)
6	8.0 (R)	1	1 (~S)		>128 (R)	0.25	NA [0.5]
7	4.0 (R)	1	0.5 (S)		>128 (R)	0.5	32 (S-DD)
8	8.0 (R)	1	0.5 (S)		>128 (R)	1	0.12 (S)
9	4.0 (R)	1	0.5 (S)		128 (R)	0.5	16 (S-DD)
10	4.0 (R)	1	0.007 (S)		>128 (R)	0.5	32 (S-DD)
11	4.0 (R)	1	0.007 (S)		>128 (R)	1	16 (S-DD)
12	2.0 (R)	0.5	0.25 (S)		128 (R)	0.5	8 (S)
13	2.0 (R)	1	0.03 (S)		64.0 (R)	0.5	2 (S)
14	8.0 (R)	1	0.5 (S)		>128 (R)	0.5	16 (S-DD)

MGCD290 converts voriconazole and fluconazole – resistant clinical isolates from resistant (R) to sensitive (S) or sensitive□dose dependent (S□DD).

The Company is developing MGCD290 initially as an adjunct or combination product to **fluconazole**, the most widely used triazole antifungal with the best safety and pharmacokinetic profile. Fluconazole is also an attractive companion agent for MGCD290 as it is available in both oral and IV formulations. Fluconazole has been generic since 2003. Pfizer's branded Diflucan (fluconazole) booked sales of $1.1 billion in 2002.

MGCD290 Has Entered Into Proof Of Concept Phase II Clinical Trials

MethylGene has completed **five Phase I** studies, including single-ascending dose studies (SAD) and multiple ascending dose studies (MAD), in healthy adult volunteers. In the SAD studies, MGCD290 was administered once orally either as a single agent (Study 290-001) or in combination with fluconazole (Study 290-002). In the MAD studies, volunteers received MGCD290 orally either as a single agent (Study 290-003) or in combination with fluconazole (Study 290-004) daily for 14 days. In addition, MGCD290 was administered once orally as a single agent (Study 290-007) in healthy female volunteers to assess the bioavailability and tissue distribution under fed versus fasting conditions.

Phase I	Monotherapy/ Combination	SAD/MAD	Patients enrolled	Cohorts/ Patient #	Dose range (mg)
Study 001	Monotherapy	SAD	56	7/8	100/200/300/450/600/810/1000
Study 002	Combination	SAD	16	2/8	300/450+400mg Fluconazole
Study 003	Monotherapy	MAD	32	4/8	100/180/360/540
Study 004	Combination	MAD	16	2/8	270/540+400mg Fluconazole
Study 007	Monotherapy	single dose		1	540

Source: Zacks Investment Research

MGCD290 has been well tolerated at all doses and schedules tested to date, both alone and in combination with fluconazole. Data also suggest that food increased exposure by approximately three-fold, and MGCD290 was detected in vaginal secretions and in patients' toenails. Based on our analysis of the Phase I and preclinical data, we are comfortable with the safety and tolerability of MGCD290 dosed both alone and in combination with fluconazole.

Based on preclinical and Phase I results, in October 2011, MethylGene initiated a **Phase II (Study 290-005)** clinical study evaluating MGCD290 in combination with fluconazole vs. fluconazole alone in patients with **moderate to severe** acute vulvovaginal candidiasis **(AVVC).**

This study is a multicenter, randomized, double-blinded, placebo-controlled trial and is currently enrolling subjects at sites in the US and Canada with moderate to severe AVVC. 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;

Dr. Jack Sobel, Chief of Infectious Diseases, Distinguished Professor of Medicine, Department of Internal Medicine, Wayne State University School of Medicine is the lead investigator for this study. The Company expects to report topline data from this trial **around year end 2012**.

While 90% cure rate is observed in the mild patients group for fluconazole, we are expecting the control group in this moderate to severe patient subset to have a 30-50% cure rate and the trail is powered to show (roughly, without going into the stats) a 20% absolute improvement i.e. improvement from 40% control to 60% treatment.

Other indications for MGCD290, such as **onychomycosis** (fungal infection of the toenail) and invasive fungal infections (such as **candidemia**), are under consideration. In its clinical trials different formulations of MGCD290 were tested, including capsules, unmicronized tablets and micronized tablets, in order to improve drug manufacturability and exposure.

Fungal Market is Huge

Fungi are ubiquitous in the environment and unavoidable. Fungal infections are classified broadly into **four groups**:

- Invasive, life-threatening infections (e.g. aspergillosis and candidiasis);
- Mucosal infections (e.g. oral and vaginal thrush);
- Skin infections (e.g. athlete's foot, ringworm and fungal nail infections);

- And allergic infections (e.g. asthma and chronic sinusitis);

Currently, there are **4 classes** of established antifungal drugs on the market:

- polyenes (e.g. amphotericin B);
- azoles (e.g. fluconazole and itraconazole);
- allylamines (e.g. terbinafine);
- and the newly introduced echinocandins (e.g. caspofungin) by Merck;

The fungal market is a multi-billion dollar market. According to Research and Markets, in 2009, the worldwide antifungal market was valued at US $7.4 billion, and the market is expected to reach $8.4 billion in 2016. Currently, the antifungal market is dominated by the **azoles**, the most successful of which is Pfizer's Diflucan (fluconazole), which was first launched in the mid-1980s and reached sales of over $1billion before the drug went generic in 2003. Fluconazole succeeded in displacing **amphotericin** for the treatment of invasive Candida infections. The toxicity problems of amphotericin have been ameliorated to some extent by the development of liposome formulations, the most successful of which is Gilead's Ambisome.

A new class of antifungal drug, the **echinocandins,** has recently reached the market. The first representative is Merck's Candidas (caspofungin), which was launched early in 2002 for salvage therapy for invasive aspergillosis, for which it showed superiority over amphotericin. But the drug's distinguishing feature is its fungicidal activity against the more common Candida species. Sales of Candidas in 2011 were $640 million. The second echinocandin, Fujusawa's Funguard (micafungin) was launched in 2002 (Japan only) and closely resembles Merck's product.

The problem of **drug resistance** is still an issue for most antifungals although it is less serious than that seen with antibacterials. On the other hand each year new pathogenic, mainly filamentous, fungi are identified, highlighting the need for broad **spectrum coverage**.

Despite the commercial success of the azoles and the introduction of the echinocandins mortality of invasive fungal infections remains high, particularly in those caused by filamentous fungi. The high mortality associated with invasive aspergillosis is probably a consequence of the compromised immune function of most of the patients and the fact that none of the currently available drugs are sufficiently cidal.

We think over the next few years echinocandins can be expected to displace amphotericin, including the liposome formulations, in the majority of current iv indications, except for invasive aspergillosis where voriconazole will dominate. However, the competition between the azoles and the echinocandins will be mainly limited to the hospital unless an oral echinocandin is developed.

Opportunities and Advantages for MGCD290

MethylGene's current focus for MGCD290 is **vulvovaginal candidiasis (VVC)**. Vulvovaginal candidiasis is a yeast infection caused by the Candida fungal species, which affects an estimated 70-75% of healthy women at least once and nearly 50% adult women will have two or more episodes within their lifetime. Up to 5% of women are afflicted with a more complicated from of VVC called recurrent vulvovaginal candidiasis (RVVC) which is defined as four or more episodes of VVC in one year. About 13 million AVVC cases and 10 million office visits annually in the US alone. Approximately 6-8 million women have recurrent candidial infections. There is a growing number of non-C. albicans species, and more widespread antifungal resistance, which will lead to increased medical need for effective forms of treatment for RVVC.

Azoles are the most commonly used agents for AVVC. Topical azole agents can achieve cure rates in excess of 80%. The only oral azole agent approved for AVVC by the FDA is **fluconazole**, which also achieves a high rate of cure.

However, there are no approved agents for the treatment of RVVC. The optimal treatment for recurrent vulvovaginal candidiasis has not yet been defined. Current treatment for RVVC is typically off-label with the antifungal drug **fluconazole**. However, treatment is often long-term (at least six months) and upon completion of treatment there is a high relapse rate. Due to the high relapse rate of RVVC over the long term and the growing de-sensitivity of yeasts, especially non-albicans Candida, to treatment with azoles, new therapies are needed for this indication.

Therefore, if approved, MGCD290 could command a high percentage of RVVC market share due to lack of already approved agent for the RVVC.

While MGCD290 is initially focused on the treatment of vulvovaginal candidiasis, MethylGene is currently planning for expanded development in other mucosal and systemic fungal infections including onychomycosis and systemic fungal infection.

Onychomycosis is a fungal infection of the nail (fingers, toes) and nail bed. It is a very prevalent disease. In the U.S. alone up to 13% of the population are estimated to suffer from onychomycosis. While there are a number of topical treatments under development, it is difficult to get the drug into the nail bed where it can actually treat the underlying infection. The most effective marketed treatment for onychomycosis is **terbinafine** developed by Novartis**.** Terbinafine is an oral agent that had sales of $1.2 billion prior to the arrival of generic substitutes in 2007. This drug continues to be widely prescribed, despite liver safety concerns. There are currently few systemic agents in development.

Systemic fungal infections have become more common in recent years, with a nearly 500% increase in the incidence of blood-stream infection with Candida spp. since the 1980s. Most systemic fungal infections are in fact due to Candida, but Aspergillus infections are also seen. There are about 14 million patients are at risk of systemic fungal infection in major markets according to literature. This market alone is estimated at $3 billion. The mainstay of antifungal therapy for systemic fungal infection is still amphotericin B, but it's expensive and also causes severe toxicity. Fluconazole and other azoles are also used for systemic fungal infections mainly caused by C. albicans. But resistance is a problem for fluconazole. Therefore, MGCD290 in combination with fluconazole could meet these challenges for systemic fungal infections.

Even only considering the two indications of VVC and onychomycosis, the market is huge for MGCD290. Given MGCD290's strong synergy with fluconazole and favorable safety profile, we believe MGCD290 has a high success rate of development for these two indications.

***MGCD290 has the following advantages*:**

- first-in-class selective, oral, small molecule inhibitor of the fungal Hos2 enzyme;
- works in synergy with azole antifungal agents;
- has broad spectrum antifungal activity;
- can reduce drug resistance;
- fluconazole is the most widely used antifungal, which will drive the usage of MGCD290;

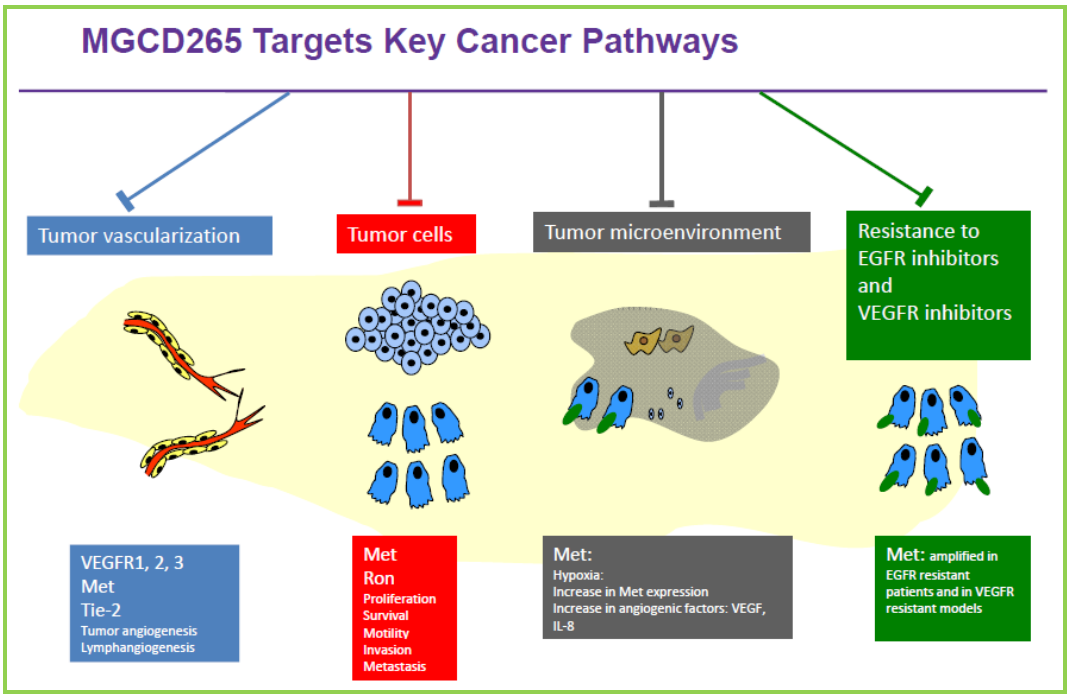
MGCD265, Multi-targeted Kinase Inhibitor for Cancer

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

Kinases are a large set of enzymes which regulate the transmission of signals in cells to control biological processes such as cell growth and differentiation. Although needed in normal cell function, RTKs may be inappropriately regulated or used in cancerous tissues. In particular, RTKs are critical in angiogenesis (a process whereby new blood vessels are formed to nourish the tumors), tumor cell metastasis, tumor development and survival. VEGFR is a validated target for oncology, with multiple products approved (Avastin from Roche, Sutent from Pfizer, Nexavar from Bayer), while Met is a potential target of high scientific interest because of its direct involvement in tumor cell survival and angiogenesis. In addition,

there is strong evidence that Met levels are associated with several major tumor types including non-small cell lung cancer (NSCLC), head and neck, gastric and prostate. Met activation may also be associated with resistance to EGFR and VEGFR inhibitors.

MGCD265 potently inhibits Met and VEGF receptors 1, 2 and 3, and also inhibits the Tie-2 and RON RTKs.



Source: Company presentation

Preclinical studies, in a variety of in vivo tumor models, have demonstrated that MGCD265 has relatively low toxicity and in many cases appears equal or more effective in vivo than some of the leading multi-targeted kinase inhibitors including Sutent®, Nexavar®, Pfizer's (Met) inhibitor Xalkori®, as well as Astra Zeneca's multi-targeted kinase inhibitor Zactima.

MGCD265 Has Shown Excellent Tolerability and Clinical Activity

MethylGene has completed a Phase I monotherapy study (**Trial 265-102**, intermittent dosing) for MGCD265. Another monotherapy Phase I study (**Trial 265-101**, continuous dosing) and a Phase I/II (**Trial 265-103** combination study with two arms: MGCD265+full dose docetaxel, or MGCD265+full dose erlotinib) are ongoing.

Phase	Study	Schedule of Administration	N	Early Signs of Clinical Activity	DLTs
I	265-101	Single-agent Continuous daily	57	Colorectal, thymic, bladder, renal, neuroendocrine	Fatigue, hypertension (n=1), lipase elevation
I	265-102 Complete	Single-agent Daily, one week on/one week off	47		Fatigue, mood change, hemoptysis (n=1)
I/II	265-103	Combination Docetaxel arm: Continuous daily	36	NSCLC, prostate, endometrial	Fatigue, diarrhea, lipase elevation
		Combination Erlotinib arm: Continuous daily	46	NSCLC, gastroesophageal	Fatigue, diarrhea, rash, rhabdomyolosis (n=1)

Source: Company presentation as of March 2012

The completed Phase I trial 265-102:

Trial 102 was a **Phase I** dose-escalation study in patients with advanced solid tumors. Oral MGCD265 was administered **intermittently** (one week on/one week off) over 28-day cycles. The primary objectives were to determine the maximum tolerated dose (MTD), dose-limiting toxicities (DLTs) and safety of MGCD265. Forty seven (47) patients with advanced solid tumors were treated. MGCD265 was administered once a day (QD) in the initial cohorts and then twice daily (BID) in the last two cohorts with increased exposure following the introduction of the BID schedule. Patients received doses up to 340 mg/m2.

MGCD265 is safe and well tolerated when using the intermittent schedule of administration. Prolonged stable disease was observed in 4 patients. The observed DLTs were grade 3 mood alteration, and grade 3 fatigue and grade 3 hemoptysis all at the dose of 170 mg/m2 BID. As MGCD265 was administered safely at doses higher than 170 mg/m2 in other studies, the intermittent schedule has been abandoned in favor of the continuous schedule for all future studies.

MethylGene also completed a **Phase I pharmacokinetics** trial 265-105 in healthy volunteers in a fed versus fasted state. This Phase I study was conducted to compare the pharmacokinetics of a single 100 mg dose of MGCD265 under fed conditions versus those after a 10-hr overnight fast. A total of 14 subjects were recruited. Preliminary data showed that the fed condition was associated with a ~3 fold increase in exposure. No serious AEs were reported. There were no clinically significant changes in vital signs, ECG or laboratory values.

The ongoing Phase I trial 265-101:

Patients with advanced malignancies are enrolling in this Phase I, open-label, dose escalating study. MGCD265 is administered orally every day over a 21-day cycle. The aim of this study is to determine the safety profile including the MTD and the DLTs of MGCD265. Two schedules of MGCD265 were tested sequentially: once (QD) and twice daily (BID), respectively with a ~ 2 fold increase in the steady state exposure after the introduction of BID dosing. Data is available for 57 patients that received MGCD265 in doses escalating from 24 mg/m2 QD to 313 mg/m2 BID.

- To date, the safety profile continues to be favorable in this ongoing Phase I program. The most common drug-related adverse events (AEs) (greater than 10%) were diarrhea (n=25, including one grade 3), anorexia and nausea (n=12), fatigue (n=11 including two grade 3), vomiting (n=9). These were mostly mild. There were no grade 4 toxicities;

- DLTs (all observed at daily doses ≥250 mg/m2) included (n=1 for each event) grade 2 hypertension (per protocol definition), grade 3 fatigue and grade 3 pituitary hemorrhage in a patient with a previously undiagnosed pituitary adenoma. Additional grade 3 drug-related AEs (n=1) were elevated lipase and elevated alkaline phosphatase. AEs do not appear to be dose-related;

- Stable disease more than 2 cycles was observed in 23 of 57 intent-to-treat (ITT) patients; of these, treatment continues in 3 patients. Seven patients achieved SD for ≥6 cycles, including up to 12 cycles in one patient; these patients had a range of tumors and no correlation was observed between tumor type and prolonged response. Dose escalation is ongoing.

The ongoing Phase I/II trial 265-103:

This dose-escalating **Phase I/II** clinical trial is evaluating MGCD265 in combination with the approved anticancer agent docetaxel (Taxotere®) and erlotinib (Tarceva®). The trial continues to enroll patients with advanced metastatic malignancies in both the MGCD265+docetaxel arm and the MGCD265 plus erolotinib arm. Key objectives for this study are to evaluate the safety of the combination treatments, to measure the pharmacodynamic and pharmacokinetic characteristics and to determine the MTD to be used in the preparation for future studies.

In the combination of **MGCD265+docetaxel**,

- MGCD265 was administered every day over a 3-week cycle and docetaxel (50 then 75 mg/m2) was given intravenously once every 3 weeks;

- Over 37 patients have been enrolled. Data is available for 36 patients. The MTD of the combination was initially defined as MGCD265 (72 mg/m2 BID)+docetaxel (75 mg/m2 q3w) based on the occurrence of DLTs in 2 patients who were treated with MGCD265 at 96 mg/m2 BID (fatigue in 1 patient and diarrhea & lipase elevation in the other patient);

- MGCD265 was found to be well tolerated in combination with full-dose docetaxel. Does has escalated to 128 mg/m2 BID, and enrollment is ongoing;

- Initial efficacy data are encouraging. Partial response and stable disease have been observed in NSCLC (2/9 objective partial responses, and 3/9 stable disease), in prostate cancer (1/3 partial response) and in endometrial cancer (1/1 partial response). Treatment-related ≥ grade 3 toxicity reported in ≥ 2 patients were neutropenia, leukopenia, diarrhea and elevated lipase.

In the combination of **MGCD265+erlotinib**,

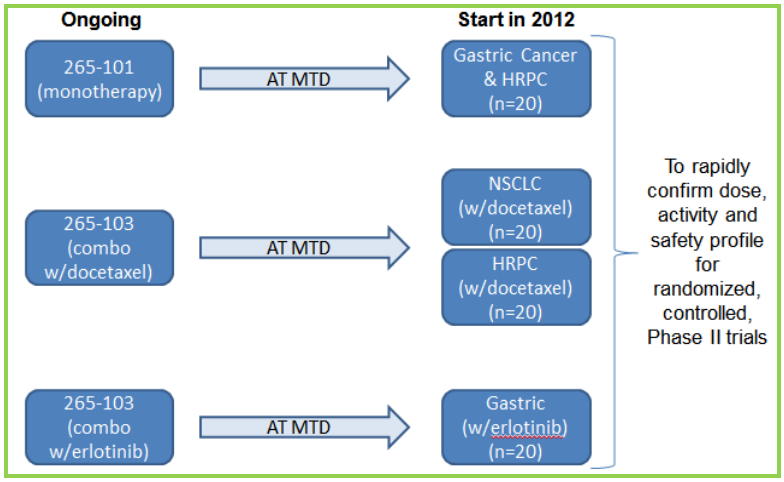
- MGCD265 and erlotinib were administered every day over a 3-week cycle; Over 49 patients have been enrolled. MGCD265 was dose escalated from 96 mg/m2 QD to 162 mg/m2 BID, in combination with erlotinib (initially at 100 mg then at 150 mg QD). Data is available for 46 patients.

- MGCD265 is well tolerated in combination with erlotinib. Diarrhea and fatigue were the only treatment-related ≥ grade 3 adverse event observed in ≥ 2 patients.

- Preliminary data from this arm are also encouraging. Of ten evaluable NSCLC patients in this trial, two achieved partial remission and all ten patients achieved disease control (partial remission or stable disease) at the first tumor assessment. These data compare favorably in the context of historical data (docetaxel monotherapy).

- Current dose of 162 mg/m2 BID is being evaluated and enrolment is ongoing;

As of April 30, 2012, over 198 patients have been treated in these trials. MethylGene plans to expand the monotherapy and combination therapy trials with selected cohorts of tumor types once the maximum tolerated dose is reached. The Company expects to report results from these studies on an ongoing basis. The data from the expansion cohorts will be used to guide randomized **phase II** studies.



Other Proprietary Pipeline Programs

In addition to the two lead proprietary programs MGCD290 and MGCD265, MethylGene also has two proprietary **preclinical** programs.

MG91516 is a rationally designed, oral, multi-targeted kinase inhibitor designed to target the Met/Eph and RET. Eph are overexpressed in several cancers including gastric, lung, breast, uterine, prostate, esophageal, ovarian, brain and skin. Eph is involved in the regulation of cell migration and contributes to the invasion properties of tumors. EphA2 is involved in resistance to HER2 inhibitors. RET (Rearranged during Transfection) is a co-receptor for the GDNF (glial cell line-derived neurotrophic factor) family of ligands and RET is expressed in cell lineages derived from the neuronal crest and tissues of the urogenital system.

MG91516 has good oral bioavailability in mice, rats and dogs, and excellent anti-tumor activities in multiple human xenograft tumor models in mice. MG91516 is in **advanced preclinical development** and ready to commence IND-enabling studies.

MG96077 is a novel, broad spectrum, non-beta-lactam beta-lactamase inhibitor designed to overcome beta-lactamase mediated antibiotic resistance. MG96077 possesses a broad-spectrum inhibitory profile for both class A and class C beta-lactamase enzymes. In addition, the compound overcomes resistance in beta-lactam-resistant organisms such as *Pseudomonas aeruginosa* and *Klebsiella pneumoniae*. MG96077 is in **advanced preclinical development** and ready to commence IND-enabling studies. MethylGene has regained the rights to its beta-lactamase inhibitor program from Merck. As the Company's focus is on its oncology programs, no significant research and development resources are being invested in the beta-lactamase program.

Although MethylGene is not actively developing MG91516 and MG96077, the Company is continuing to pursue partnering or funding opportunities for them.

Partnered Programs

Mocetinostat (MGCD0103) is an oral, isoform-selective, small molecule human **HDAC inhibitor**. HDAC (Histone deacetylases) is a family of 11 enzymes (isoforms) that appear to act as a master regulator of genes affecting many diseases, including cancer. Inhibition of HDACs may result in multiple anti-cancer effects such as the inhibition of cancer cell proliferation, the induction of apoptosis of cancer cells,

improved cell cycle regulation, and the induction of tumor suppressor genes. These multiple effects may provide an advantage for HDAC inhibitors in cancer. HDAC inhibitors that have been approved, or are currently in clinical trials, have shown activity and represent a novel class of molecular targeted anti-tumor agents.

Mocetinostat has shown clinical activity in several Phase I and **Phase II** clinical trials both as a single-agent and in combination with Vidaza® and Gemzar®.

Mocetinostat was out-licensed to Pharmion (part of **Celgene** now**)** in 2006 for the North America, Europe, the Middle East and certain other markets. In January, 2009, the agreement with Celgene terminated and MethylGene reacquired exclusive rights for mocetinostat in the territories previously licensed to Celgene. The Company does not expect to conduct any significant studies during 2012 without a NA partner.

Mocetinostat was out-licensed to **Taiho**, a leading Japanese specialty oncology company (part of Otsuka), in October 2003 for market in Japan, South Korea, Taiwan, and China. Taiho is responsible for the development and commercialization costs in its territory, and MethylGene will receive royalties, in addition to upfront and milestone payments, based on sales of HDAC oncology products in these territories.

In March, 2008, MethylGene entered into a worldwide research collaboration and license agreement with **Otsuka**, a Japanese pharmaceutical company for the development of novel, small molecule, **kinase inhibitors** for the local delivery and treatment of ocular disease, excluding cancer. Research funding from Otsuka continued until September 2009, but Otsuka extended the research term of the collaboration to the end of March 2010, resulting in additional funding to MethylGene. The research portion of the collaboration with Otsuka ended in June of 2011. However, MethylGene will receive a milestone payment from Otsuka should they move the lead ophthalmology candidate into IND-enabling toxicity studies.

HDAC Inhibitors for Neurodegenerative and Other Diseases

MethylGene has extensive knowledge and expertise in the HDACs for both cancers and other diseases. Potential non-oncology indications for HDAC inhibitors include, but are not limited to, neurodegenerative diseases (such as Alzheimer's, Parkinson's, Huntington's), CNS diseases, inflammatory diseases, metabolic disorders and fungal infections.

As part of this effort, MethylGene has granted **EnVivo** exclusive rights to its HDAC inhibitors including EVP-0334 for specific neurodegenerative diseases. EVP-0334 represents a first-in-class, CNS-penetrant HDAC inhibitor in development expressly for neurodegenerative diseases that has successfully and safely completed **Phase I** clinical trials. This compound was co-discovered under the collaboration between MethylGene and EnVivo.

MethylGene will receive royalties on net sales of any approved compound and will share in any sublicense income from future partnerships that EnVivo may enter into.

MethylGene is Well Capitalized with a Strong Balance Sheet

Not like most other small cap biotech companies, which need to raise money constantly, MethylGene is well capitalized with a strong balance sheet.

As of March 31, 2012, MethylGene has cash, cash equivalents, marketable securities and restricted cash totaling $25.1 million. Current financial resources can carry forward its current clinical development and operating plans into the fourth quarter of 2013.

MethylGene had no debt on its balance sheet as of March 31, 2012.

This is unusual. For most small cap biotech companies, liquidity is usually an important factor to weigh on their share prices. These small cap biotech companies need to issue new shares or convertible notes on a regular basis to raise funds, which dilute existing shareholder base. We do not see a need for the Company to raise fund and dilute the current shareholder base until the third quarter of 2013.

Experienced Management Team

Charles Grubsztajn, MBA, BCL,
President and CEO
Mr. Grubsztajn was appointed President and CEO of MethylGene in September 2010. Prior to this, he led MethylGene's business development activities since 2005 with responsibilities that included executing licensing opportunities, corporate partnerships, strategic alliances and research collaborations. Mr. Grubsztajn played a lead role in out-licensing deals that together have generated more than US$100 million in cash for the Company. He led MethylGene's 2006 US$272M cancer co-development and profit-share deal with Pharmion Corporation (now Celgene Corporation) and a second research collaboration with Pharmion worth up to $100M for the development of inhibitors targeting sirtuins for cancer. In addition, he secured a $55M research partnership with Otsuka Pharmaceuticals for ocular diseases. Prior to joining MethylGene, Mr. Grubsztajn was employed at Caprion Pharmaceuticals (now Caprion Proteomics) where he was involved in numerous technology out-licensing and in-licensing deals with pharmaceutical and biotechnology companies, as well as academia and governments. Mr Grubsztajn is a member of the Licensing Executives Society and has presented at several workshops. He has been a board or committee member of the Maimonides Geriatric Centre Foundation since 2001. In 2008, Mr. Grubsztajn was granted the Certified Licensing Professional designation from the Licensing Executives Society. He received his MBA and Law degrees from McGill University.

Jeffrey M. Besterman, PhD
EVP, R&D and Chief Scientific Officer
Dr. Besterman joined MethylGene in January 1997 and headed the Company's research and development programs. He has over 25 years of drug discovery research and development experience in the pharmaceutical and biotechnology industries. Dr. Besterman previously served as Head, Oncology Research Section and later as Head, Department of Cell Biology and Member, Research Executive Committee at Glaxo Research Institute in Research Triangle Park, North Carolina. Dr. Besterman led a multi-disciplinary team of over 30 scientists and clinicians in the exploration, identification and early clinical development of Glaxo's first anti-cancer compound, Lurtotecan. At MethylGene, Dr. Besterman has led the discovery, preclinical and clinical development of three anticancer compounds and one antifungal compound. Dr. Besterman has been a member of the National Cancer Institute's Special Review Committee for Natural Product Drug Discovery and an external reviewer for the National Science Foundation. He is also on the external review board of the Biotechnology Research Institute of the National Research Council of Canada. He is a co-inventor of 25 United States patents and patent applications and 90 peer reviewed scientific publications. Dr. Besterman received a B.Sc. in Biology from the State University of New York, a Ph.D. in Physiology and Biophysics from the University of Vermont's School of Medicine and completed his post-doctoral research at Pennsylvania State University's Medical Center. Dr. Besterman currently lectures in the graduate biotechnology program at McGill University.

Rachel Humphrey, MD
EVP and Chief Medical Officer
Dr. Humphrey joined MethylGene in 2012 and leads the development of the Company's clinical programs. Previously she was Vice President, Global Development Lead, Immuno-Oncology at Bristol-Myers Squibb. During her eight-year tenure at Bristol-Myers Squibb, Dr. Humphrey supervised a number of in-licensed and internal development programs including the Phase II – IV development of ipilimumab (YERVOY®), which achieved global approval for the treatment of metastatic melanoma in 2011. From 1997 until 2003 Dr. Humphrey held increasingly senior clinical development positions at Bayer, leading the IND filing and the development of the multiple kinase inhibitor sorafenib (Nexavar®), which subsequently achieved global approval for advanced renal cell carcinoma and hepatocellular carcinoma. Dr. Humphrey received her B.A. degree in biochemistry from Harvard University, her M.D. degree from

Case Western Reserve University, and completed her Medical Residency at the Johns Hopkins Hospital. From 1992 until 1997 Dr. Humphrey worked at the U.S. National Cancer Institute (NCI), first as a Clinical Oncology Fellow and later as a Staff Physician/Scientist in the NCI's HIV and AIDS Malignancy Branch.

Klaus B. Kepper, MBA, CMA
VP Finance & Chief Financial Officer
Mr. Kepper joined MethylGene in October 2000 as Chief Financial Officer. He has over 25 years of financial, operational and accounting experience. He previously served 15 years at Smith & Nephew, most recently as Vice President, Finance of their German operations, which include Germany, Austria, Switzerland and Eastern Europe. Mr. Kepper has been Vice President, Finance and Chief Financial Officer as well as Treasurer and Secretary and member of the Board of Directors of Smith & Nephew Canada from 1989 to 1995 having been promoted from Controller. Mr. Kepper held other financial, accounting and controllership positions with Mallinkrodt Canada Inc. and Sommerville Belkin Industries Inc. Mr. Kepper holds B. Comm. and MBA degrees from Concordia University and is a Certified Management Accountant.

Joseph Walewicz, MBA, CFA
Vice President, Business & Corporate Development
Mr. Walewicz joined MethylGene in 2011 as Vice President, Business and Corporate Development. He has over 17 years of finance, business development and marketing experience in the biopharma industry. Prior to joining MethylGene Mr. Walewicz was the Vice President, Special Projects at Paladin Labs Inc., a specialty pharmaceutical company, and Chief Operating Officer of its Paladin Biosciences division. Previously Mr. Walewicz was a senior healthcare equity research analyst for several prominent North American healthcare investment banks, most recently as Executive Director, Institutional Equity Research at CIBC World Markets. Mr. Walewicz holds a B.A. in Economics and a B.Sc. in Biochemistry from Queen's University, an M.B.A. from McGill University, and is a CFA Charter holder.

VALUATION AND RECOMMENDATION

We maintain our Outperform rating on MethylGene (MYLGF) and reiterate our 12-month price target of $0.75 per share.

MethylGene is a middle 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.

We think MethylGene's two lead candidates MGCD290 and MGCD265 are both highly promising and differentiated drug candidates. MGCD290 is a first in class anti-fungal agent, which has high synergy with marketed azole anti-fungal agents. MGCD290 also reduce drug resistance related to azole agents. Considering fluconazole is the most commonly used antifungal, the combination of MGCD290 with fluconazole will capture a significant market share of current anti-fungal market. MGCD290 is in Phase II clinical studies and we expect MGCD290 will enter into pivotal Phase III in 2013. Approval could happen in early 2015.

The Company's kinase inhibitor MGCD265 is also 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/II studies now. We estimate the FDA approval in 2017.

In addition to the above two lead candidates, MethylGene has additional products in its pipeline which also have the potential to address current medical needs.

In terms of valuation, we think MethylGene shares are undervalued. Currently, the shares are trading at $0.26 per share, which values the Company at $83 million in market cap based on 318 million shares outstanding. This is certainly a deep discount. As we discussed about, the Company's two lead drug candidates MGCD290 and MGCD265 have already entered into Phase II clinical studies and may be on the market in 2015 and 2017 respectively. According to our model, MethylGene will be close to breakeven in 2015, and turn profitable in 2016 with an EPS of $0.06 on total revenue of $46 million. We think MethylGene should be trading at 25x to 30x P/E multiples. Discount rate should be at 25% to 30%. Based on this, we think the Company should be valued at $0.50 to $0.75 per share, which values the Company at $160 to 240 million in market cap. Our $0.75 price target is based on our estimated EPS of $0.06 in 2016, multiplied by 30 x P/E ratio, discounted at 25% for 4 years.

Our valuation does not consider the value of the Company's preclinical and partnered programs. Any progress in these programs could be a bonus for the Company and drive share price higher.

Upcoming catalysts:

- MGCD290: AVVC study report results, 4Q12;
- MGCD290: Start of pivotal studies, 4Q12 or 1Q13;
- MGCD265: start of Phase I expansion cohorts
- MGCD265: start of randomized, controlled, Phase II studies

Risks related to our price target include:

- Regulatory risk: Our valuation of MethylGene is based on the assumption that the Company's two lead drug candidates will be approved by the FDA in 2015 and 2016 respectively. Any clinical failure could deny or delay the approval, and share price will suffer.

- Trading risk: MethylGene is a Canadian company, which is traded in OTC market in the US. Trading on OTC market usually is more sporadic, liquidity may be an issue.

PROJECTED INCOME STATEMENT

	2011A (Dec)					2012E (Dec)					2013E (Dec)	2014E (Dec)	2015E (Dec)	2016E (Dec)
$ in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1A	Q2A	Q3E	Q4E	FYE	FYE	FYE	FYE	FYE
R&D and Contract revenue	$0.40	$0.39	$0.00	$0.00	$0.79	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.50	$0.50	$1.00
License and Up-front revenue	$0.88	$0.88	$0.07	$0.47	$2.30	$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	$10.00	$30.00
Total Revenues	**$1.28**	**$1.27**	**$0.07**	**$0.47**	**$3.09**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$15.50**	**$46.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*3000.0%*	*196.8%*
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
Gross Income	**$1.28**	**$1.27**	**$0.07**	**$0.47**	**$3.09**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$15.50**	**$46.00**
Gross Margin	-	*100.0%*	-	-	-	-	-	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
R&D	$1.83	$1.79	$2.09	$3.13	$8.83	$2.21	$3.69	$2.27	$2.30	$10.47	$9.50	$10.00	$10.50	$12.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	
SG&A	$1.03	$1.06	$1.18	$1.02	$4.29	$1.22	$1.09	$1.24	$1.25	$4.81	$5.00	$6.50	$7.00	$7.50
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	$0.00	($0.11)	($0.12)	$0.00	($0.23)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($1.6)**	**($1.5)**	**($3.1)**	**($3.7)**	**($9.8)**	**($3.4)**	**($4.8)**	**($3.5)**	**($3.6)**	**($15.3)**	**($14.5)**	**($16.0)**	**($2.0)**	**$26.5**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	$0.0	($0.3)	$0.0	$0.6	($0.4)	$0.1	$0.1	$0.1	$0.1	$0.3	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($1.6)**	**($1.8)**	**($3.1)**	**($3.0)**	**($10.2)**	**($3.4)**	**($4.7)**	**($3.5)**	**($3.5)**	**($15.0)**	**($14.5)**	**($16.0)**	**($2.0)**	**$26.5**
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
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*-0.1%*	*0.0%*	*0.0%*	*0.0%*	-
Reported Net Income	**($1.6)**	**($1.8)**	**($3.1)**	**($3.0)**	**($10.2)**	**($3.4)**	**($4.7)**	**($3.5)**	**($3.5)**	**($15.0)**	**($14.5)**	**($16.0)**	**($2.0)**	**$26.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Deluted Shares Out	*40.4*	*308.8*	*317.9*	*321.7*	*247.2*	*317.9*	*317.9*	*317.9*	*317.9*	*317.9*	*345.0*	*365.0*	*400.0*	*450.0*
Reported EPS	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.01)**	**$0.06**
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*
Non GAAP Net Income	**($1.6)**	**($1.8)**	**($3.1)**	**($3.0)**	**($10.2)**	**($3.4)**	**($4.7)**	**($3.5)**	**($3.5)**	**($15.0)**	**($14.5)**	**($16.0)**	**($2.0)**	**$26.5**
Non GAAP EPS	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.01)**	**$0.06**

Source: Company filing and Zacks Investment Research

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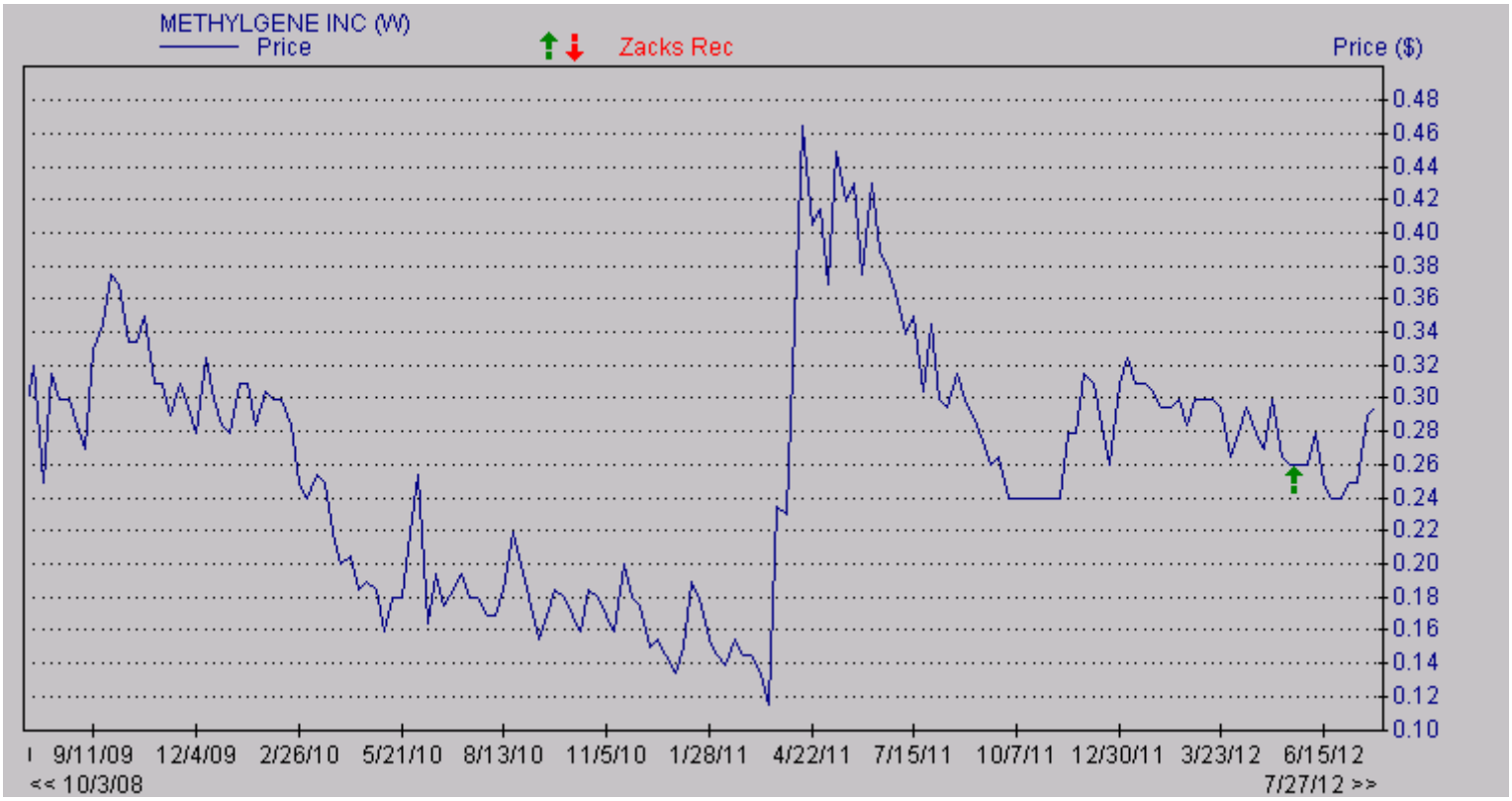
HISTORICAL ZACKS RECOMMENDATIONS



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