

## Aegerion Pharmaceuticals

AEGR : NASDAQ : US\$18.94

BUY

Target: US\$24.00

Ritu Baral

1.212.849.3917

rbaral@canaccordgenuity.com

## COMPANY STATISTICS:

Market Cap (M): US\$334.12  
 52-week Range: US\$9.00 - 25.92

## EARNINGS SUMMARY:

FYE Dec	2010A	2011E	2012E
Revenue:	0.0	0.0	195.1
EPS:	(5.07)	(1.89)	6.94
Revenue:	Q1	0.0A	-
	Q2	0.0	-
	Q3	0.0	-
	Q4	0.0	-
Total	0.0	0.0	195.1
EPS:	Q1	(0.39)A	-
	Q2	(2.77)	(0.45)
	Q3	(3.61)	(0.59)
	Q4	(0.92)	(0.45)
Total	(5.07)	(1.89)	6.94

## SHARE PRICE PERFORMANCE:



## COMPANY DESCRIPTION:

Aegerion Pharmaceuticals is an emerging biopharmaceutical company focused on novel therapeutics to treat severe but rare genetic lipid disorders. The company's lead drug, lomitapide, is currently in pivotal development for homozygous familial hypercholesterolemia, characterized by very high LDL levels that do not respond well to statin therapy.

All amounts in US\$ unless otherwise noted.

## Life Sciences -- Biotechnology

## FULL LOMITAPIDE PHASE 3 DATA SUPPORTS BEST-IN-CLASS STATUS

## Investment recommendation

**Reiterate BUY, \$24 target on lomitapide's potential as best-in class HoFH drug.** Lomitapide is AEGR's Phase 3 MTP-1 inhibitor for homozygous familial hypercholesterolemia (HoFH), a rare genetic disease causing very high LDLs. We think lomitapide may become the best-in-class HoFH drug vs. ISIS/SNY's Phase 3 mipomersen and AEGR will submit the lomitapide NDA and MAA in Q4/11. Our \$24 target is based on a pNPV analysis.

## Investment highlights

- 56-week data closely resembles positive interim 26-week data released last fall.** LDL lowering efficacy was maintained at 44% at week 56 vs. 50% at week 26. Mipomersen's placebo-controlled Phase 3 trial showed 25% wk 26 LDL reduction.
- Incrementally positive safety: less liver fat from 26 weeks, tolerability maintained.** Hepatic fat, lomitapide's main safety concern, was 7.3% at 56 weeks vs. 9.0% at 26 weeks. There were no new instances of abnormal liver enzyme elevations. No patients have discontinued treatment due to liver toxicity.
- Data supports our belief lomitapide will be best in class for HoFH.** We think lomitapide will be approved for HoFH in the US and Europe in H2/12. We think lomitapide's sole HoFH competitor, ISIS/SNY's Phase 3 mipomersen, has inferior tolerability and LDL lowering than lomitapide.

Canaccord Genuity is the global capital markets group of Canaccord Financial Inc. (CF : TSX | CF. : AIM)

The recommendations and opinions expressed in this Investment Research accurately reflect the Investment Analyst's personal, independent and objective views about any and all the Designated Investments and Relevant Issuers discussed herein. For important information, please see the Important Disclosures section in the appendix of this document or visit Canaccord Genuity's [Online Disclosure Database](#).

## 56-WEEK LOMITAPIDE DATA SHOW MAINTAINED EFFICACY, TOLERABILITY

**56-week safety data show maintained strong LDL lowering, likely superior to mipomersen.** Phase 3 lomitapide data showed 50% and 44% reduction in LDL-C at week 26 and 56, respectively. Efficacy data from mipomersen's Phase 3 trial in HoFH showed 25% reduction at week 26 (Figure 1). We note the slight difference in ITT week 26 LDL reduction (40.1%) from previously reported levels (45%) was due to quality control adjustments. The former reduction was based off of last treatment measure carried forward, while the current measure is based on the more widely accepted last observation carried forward. Aegerion noted the time difference between last observation and last treatment went up to six weeks in some patients. We do not see the small drop in efficacy as meaningful. Lipid experts with lomitapide treatment experience noted to us they think this fall-off is likely due to patient dietary non-compliance rather than any resistance patients are developing to the drug.

**Figure 1: Lomitapide vs. mipomersen (ISIS) Phase 3 LDL-C reduction in HoFH**

	n	LDL-C (mean % change from baseline)
Lomitapide ITT @ week 26	29	-40.1%
Lomitapide Completer Analysis @ week 26	23	-50.2%
Lomitapide @ week 56	23	-44.0%
Mipomersen ITT @ week 26	34	-24.7%

Source: Company reports

**56-week lomitapide safety data show excellent tolerability, we think better than mipomersen.** Mild-to-moderate GI adverse events have been the most commonly reported adverse events in the lomitapide Phase 3 trial (Figure 2). Aegerion has indicated most incidences of problematic GI distress occur in the titration phase of treatment. As a result, we do not think a meaningful number (if any) of serious GI adverse events occurred during the second half of the trial. Lipid experts we have spoken with indicate GI side effects become less of an issue over time with lomitapide treatment as patients learn what foods to avoid. For mipomersen, which is delivered via subcutaneous injection, injection site reactions have been the most commonly reported adverse event, with rates of 70+% in some trials. While these injection site reactions are not life threatening, lipid experts with mipomersen experience say they are severe enough to cause patients to discontinue treatment (Figure 3). Investigators we have spoken to with experience with both drugs unanimously indicate their belief lomitapide-associated diarrhea has been easier to tolerate than mipomersen-associated injection site reactions.

**Hepatic fat declined slightly with increased lomitapide treatment duration.** Liver fat did not get worse and slightly improved from 9.0% at week 26 to 7.3% at week 56. Lipid experts we have spoken to believe this is a result of physiological accommodation of MTP-1 inhibition in the liver. The exact mechanism of this accommodation is not well understood, though experts suggest it may be related to differential expression of the MTP-1 transporter due to feedback upregulation. We do not have liver fat data from mipomersen's Phase 3 in HoFH.

**We view the final liver fat levels as very encouraging and clinically benign.** HoFH experts have indicated they would consider liver fat levels of ~15% as the threshold they would regard as potentially problematic. Even the most conservative experts acknowledge hepatic fat levels in the single digits would be largely benign if seen in the absence of liver enzyme changes. As mentioned earlier, no patients in the lomitapide Phase 3 study have discontinued due to changes in liver enzyme levels.

**Figure 2: Lomitapide Phase 3 in HoFH, adverse events and liver fat.**

	Number	Percentage
Enrolled	29	100%
Completers	23	79%
Discontinued due to GI adverse events	3	10%
Withdrawn consent	3	10%
Discontinued due to liver function test elevations	0	0%
With ALT elevations > 5x ULN	4	14%

Hepatic Fat (mean %)	Week 26	Week 56
n	22	21
Baseline	1.0%	1.2%
End of measurement period	9.0%	7.3%

Source: Company reports

**Figure 3: Mipomersen (ISIS) Phase 3 in HoFH, adverse events (liver fat not reported).**

	Mipomersen		Placebo	
	Number	%	Number	%
Enrolled	34	100%	17	100%
Completers	28	82%	17	100%
Injection site reaction	26	76%	4	24%
Discontinued due to elevations in liver transaminases	1	3%	0	0%
With ALT elevations > 3x ULN	4	12%	0	0%

Source: Company reports

31 May 2011

**Figure 4: AEGR expected upcoming catalysts**

Expected date	Drug/Program	Item	Impact
Q3/11	Lomitapide in HoFH	78-week safety data	+
Q4/11	Lomitapide in HoFH	NDA filing	+
H1/12	Lomitapide in HoFH	Advisory committee meeting	++

Source: Company reports, Canaccord Genuity estimates

**Figure 5: AEGR pNPV**

Drug name	Indication	Status	Launch	Success	Sales (US\$m)	Royalty	Profitability	NPV (US\$)
lomitapide	HoFH - genotype diagnosis	Phase 3	2012	70%	89.0	90%	75%	6.72
lomitapide	HoFH - phenotype diagnosis	Phase 3	2012	60%	187.3	90%	75%	12.12
lomitapide	HoFH - functional diagnosis	Phase 3	2012	33%	140.5	90%	75%	5.00
<b>Total</b>								<b>23.85</b>

Source: Canaccord Genuity estimates

31 May 2011

Figure 6: AEGR P&amp;L

	2010A	Q1/11A	Q2/11E	Q3/11E	Q4/11E	2011E	2012E	2013E
Lomitapide - US	-	-	-	-	-	-	98.5	169.7
Lomitapide - EU/SA	-	-	-	-	-	-	96.6	164.8
<b>Total product revenues</b>	-	-	-	-	-	-	<b>195.1</b>	<b>334.5</b>
Revenue from royalties and royalty rights	-	-	-	-	-	-	-	3.0
Revenues from license agreements	-	-	-	-	-	-	-	0.5
<b>Total revenues</b>	-	-	-	-	-	-	<b>195.1</b>	<b>338.0</b>
Cost of goods sold	-	-	-	-	-	-	19.5	33.4
<b>Gross Profit</b>	-	-	-	-	-	-	<b>175.6</b>	<b>304.5</b>
R&D expense	7.6	3.3	5.0	5.0	5.0	18.3	20.0	20.0
SG&A expense	5.9	3.5	3.0	3.5	4.0	14.0	20.0	20.0
Other operating expense	-	-	-	-	-	-	-	-
<b>Total operating expense</b>	<b>13.6</b>	<b>6.8</b>	<b>8.0</b>	<b>8.5</b>	<b>9.0</b>	<b>32.3</b>	<b>40.0</b>	<b>40.0</b>
<b>Operating income</b>	<b>(13.6)</b>	<b>(6.8)</b>	<b>(8.0)</b>	<b>(8.5)</b>	<b>(9.0)</b>	<b>(32.3)</b>	<b>135.6</b>	<b>264.5</b>
(interest expense)	(2.4)	(0.1)	(0.3)	(0.4)	(0.6)	(1.4)	(1.6)	(1.6)
Interest income	0.1	0.1	0.0	0.0	0.1	0.2	0.2	0.2
Change in fair value warrant liability	(0.4)	-	0.2	(1.8)	1.1	(0.6)	-	-
Other non-operating income (expense)	0.2	-	0.0	0.0	0.2	0.3	-	-
<b>Pre-tax income</b>	<b>(16.0)</b>	<b>(6.8)</b>	<b>(8.1)</b>	<b>(10.7)</b>	<b>(8.2)</b>	<b>(33.9)</b>	<b>134.2</b>	<b>263.1</b>
Income tax expense (benefit)	(1.8)	-	-	-	-	-	1.8	6.3
Accretion of Dividends	8.8	-	-	-	-	-	-	-
<b>Net income</b>	<b>(23.0)</b>	<b>(6.8)</b>	<b>(8.1)</b>	<b>(10.7)</b>	<b>(8.2)</b>	<b>(33.9)</b>	<b>132.4</b>	<b>256.8</b>
<b>Basic EPS</b>	<b>(5.07)</b>	<b>(0.39)</b>	<b>(0.45)</b>	<b>(0.59)</b>	<b>(0.45)</b>	<b>(1.89)</b>	<b>6.94</b>	<b>12.82</b>
<b>Diluted EPS</b>	<b>(5.07)</b>	<b>(0.39)</b>	<b>(0.45)</b>	<b>(0.59)</b>	<b>(0.45)</b>	<b>(1.89)</b>	<b>6.94</b>	<b>12.82</b>
Basic shares outstanding	4.5	17.6	17.8	18.0	18.2	17.9	19.1	20.0
Diluted shares outstanding	4.5	17.6	17.8	18.0	18.2	17.9	19.1	20.0

Source: Company reports and Canaccord Genuity estimates

**Investment risks**

Development risk -- Previous clinical trials have shown problematic safety/tolerability

Previous higher dose non-titration lomitapide trials have shown rates of liver fat and liver enzyme elevations that were deemed unacceptable by clinicians for treatment of a broad patient population with moderately elevated LDL levels. Additionally, GI tolerability in these trials was very poor. Although safety and tolerability data to date is significantly better due to lower dose and titration, some patients still experience side effects that could reach problematic levels, albeit we think the data thus far suggests the drug, at its current dose and treatment schedule, will be a safe and relatively well-tolerated therapy.

Regulatory risk -- Despite unmet need, a single, open-label, uncontrolled Phase 3 trial may not be sufficient to secure FDA or European approval

The FDA normally requires two randomized placebo-controlled pivotal trials for drug approval. Aegerion plans to submit the lomitapide NDA with data from a single uncontrolled open-label Phase 3 trial with a small number of patients. Also, the company does not have a Special Protocol Assessment (SPA) from the FDA, although it has had extensive discussions with the agency as part of the SPA process.

Commercial risk -- Lomitapide may not have as large a market as estimated, since current market assumptions are relatively new and as yet unproven

While there is little dispute on the number of HoFH patients with definitive genotypic diagnosis (600-1,000 patients worldwide), there is controversy over the additional number of HoFH patients whose exact genetic mutations have not yet been identified. Lomitapide may not be approved or reimbursed for patients with LDL levels characteristic of HoFH but without genotypic, cell culture or familial history diagnosis. Furthermore, Aegerion may face pricing pressure on lomitapide's orphan pricing. As such, the exact potential patient population and market size for lomitapide is uncertain.

Competitive risk -- Lomitapide may compete with Isis' mipomersen, which is partnered with Genzyme, a large-cap biotechnology with an established orphan business unit.

We believe that lomitapide may be approved for HoFH around the same time as Isis Pharmaceuticals' mipomersen, partnered with Genzyme. We note that Genzyme has pioneered the orphan disease business model and has considerable experience at launching and commercializing orphan drugs. However, we think that lomitapide still has a very good chance at becoming the gold standard HoFH treatment based on its superior efficacy, safety and ease of use, as well as its (at worst) comparable tolerability.

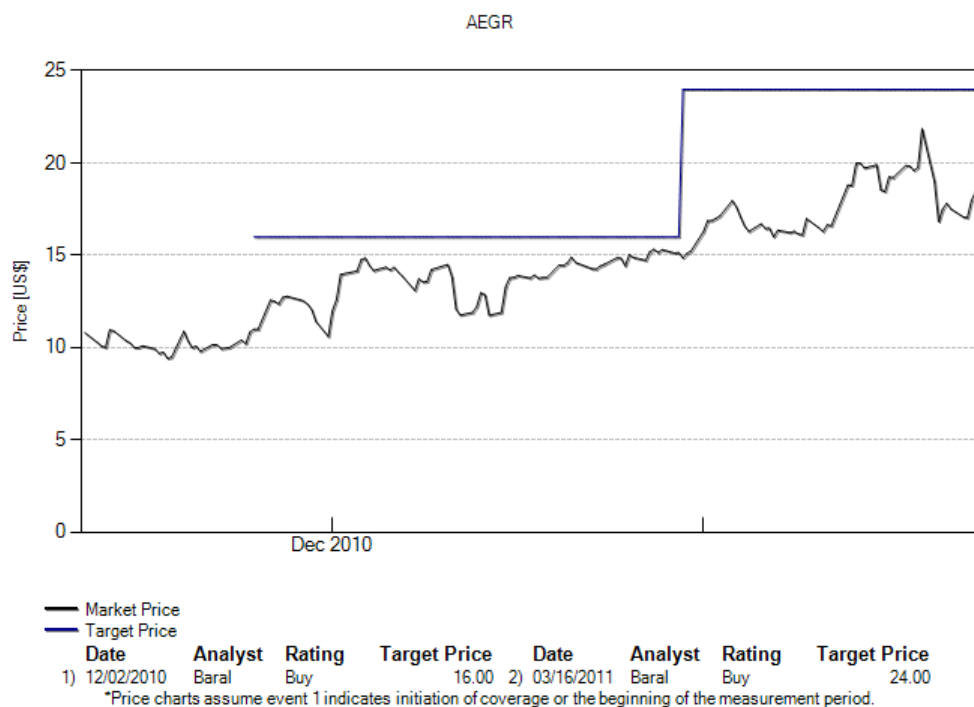
---

**APPENDIX: IMPORTANT DISCLOSURES****Analyst Certification:**

Each authoring analyst of Canaccord Genuity whose name appears on the front page of this investment research hereby certifies that (i) the recommendations and opinions expressed in this investment research accurately reflect the authoring analyst's personal, independent and objective views about any and all of the designated investments or relevant issuers discussed herein that are within such authoring analyst's coverage universe and (ii) no part of the authoring analyst's compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed by the authoring analyst in the investment research.

**Site Visit:**

An analyst has not visited the issuer's material operations.

**Price Chart:\*****Distribution of Ratings:**

Global Stock Ratings  
(as of 3 May 2011)

Rating	Coverage Universe		IB Clients	
	#	%	#	%
Buy	466	59.4%	36	36.7%
Speculative Buy	67	8.5%	50	62.7%
Hold	234	29.8%	17	17.5%
Sell	18	2.3%	12	11.1%
	785	100.0%		

**Canaccord Ratings System:**

**BUY:** The stock is expected to generate risk-adjusted returns of over 10% during the next 12 months.

**HOLD:** The stock is expected to generate risk-adjusted returns of 0-10% during the next 12 months.

**SELL:** The stock is expected to generate negative risk-adjusted returns during the next 12 months.

**NOT RATED:** Canaccord Genuity does not provide research coverage of the relevant issuer.

"Risk-adjusted return" refers to the expected return in relation to the amount of risk associated with the designated investment or the relevant issuer.

**Risk Qualifier:**

**SPECULATIVE:** Stocks bear significantly higher risk that typically cannot be valued by normal fundamental criteria. Investments in the stock may result in material loss.

**Canaccord Research Disclosures as of 31 May 2011**

Company	Disclosure
---------	------------

Aegerion Pharmaceuticals		1A, 2, 3, 5, 7
1	The relevant issuer currently is, or in the past 12 months was, a client of Canaccord Genuity or its affiliated companies. During this period, Canaccord Genuity or its affiliated companies provided the following services to the relevant issuer: A. investment banking services. B. non-investment banking securities-related services. C. non-securities related services.	
2	In the past 12 months, Canaccord Genuity or its affiliated companies have received compensation for Corporate Finance/Investment Banking services from the relevant issuer.	
3	In the past 12 months, Canaccord Genuity or any of its affiliated companies have been lead manager, co-lead manager or co-manager of a public offering of securities of the relevant issuer or any publicly disclosed offer of securities of the relevant issuer or in any related derivatives.	
4	Canaccord Genuity acts as corporate broker for the relevant issuer and/or Canaccord Genuity or any of its affiliated companies may have an agreement with the relevant issuer relating to the provision of Corporate Finance/Investment Banking services.	
5	Canaccord Genuity or any of its affiliated companies is a market maker or liquidity provider in the securities of the relevant issuer or in any related derivatives.	
6	In the past 12 months, Canaccord Genuity, its partners, affiliated companies, officers or directors, or any authoring analyst involved in the preparation of this investment research has provided services to the relevant issuer for remuneration, other than normal course investment advisory or trade execution services.	
7	Canaccord Genuity intends to seek or expects to receive compensation for Corporate Finance/Investment Banking services from the relevant issuer in the next six months.	
8	The authoring analyst, a member of the authoring analyst's household, or any individual directly involved in the preparation of this investment research, has a long position in the shares or derivatives, or has any other financial interest in the relevant issuer, the value of which increases as the value of the underlying equity increases.	
9	The authoring analyst, a member of the authoring analyst's household, or any individual directly involved in the preparation of this investment research, has a short position in the shares or derivatives, or has any other financial interest in the relevant issuer, the value of which increases as the value of the underlying equity decreases.	
10	Those persons identified as the author(s) of this investment research, or any individual involved in the preparation of this investment research, have purchased/received shares in the relevant issuer prior to a public offering of those shares, and such person's name and details are disclosed above.	
11	A partner, director, officer, employee or agent of Canaccord Genuity and its affiliated companies, or a member of his/her household, is an officer, or director, or serves as an advisor or board member of the relevant issuer and/or one of its subsidiaries, and such person's name is disclosed above.	
12	As of the month end immediately preceding the date of publication of this investment research, or the prior month end if publication is within 10 days following a month end, Canaccord Genuity or its affiliate companies, in the aggregate, beneficially owned 1% or more of any class of the total issued share capital or other common equity securities of the relevant issuer or held any other financial interests in the relevant issuer which are significant in relation to the investment research (as disclosed above).	
13	As of the month end immediately preceding the date of publication of this investment research, or the prior month end if publication is within 10 days following a month end, the relevant issuer owned 1% or more of any class of the total issued share capital in Canaccord Genuity or any of its affiliated companies.	
14	Other specific disclosures as described above.	

Canaccord Genuity is the business name used by certain subsidiaries of Canaccord Financial Inc., including Canaccord Genuity Inc., Canaccord Genuity Limited, and Canaccord Genuity Corp.

The authoring analysts who are responsible for the preparation of this investment research are employed by Canaccord Genuity Corp. a Canadian broker-dealer with principal offices located in Vancouver, Calgary, Toronto, Montreal, or Canaccord Genuity Inc., a US broker-dealer with principal offices located in Boston, New York, San Francisco and Houston or Canaccord Genuity Limited., a UK broker-dealer with principal offices located in London and Edinburgh (UK).

In the event that this is compendium investment research (covering six or more relevant issuers), Canaccord Genuity and its affiliated companies may choose to provide specific disclosures of the subject companies by reference, as well as its policies and procedures regarding the dissemination of investment research. To access this material or for more information, please send a request to Canaccord Genuity Research, Attn: Disclosures, P.O. Box 10337 Pacific Centre, 2200-609 Granville Street, Vancouver, BC, Canada V7Y 1H2 or [disclosures@canaccordgenuity.com](mailto:disclosures@canaccordgenuity.com).



The authoring analysts who are responsible for the preparation of this investment research have received (or will receive) compensation based upon (among other factors) the Corporate Finance/Investment Banking revenues and general profits of Canaccord Genuity. However, such authoring analysts have not received, and will not receive, compensation that is directly based upon or linked to one or more specific Corporate Finance/Investment Banking activities, or to recommendations contained in the investment research.

Canaccord Genuity and its affiliated companies may have a Corporate Finance/Investment Banking or other relationship with the company that is the subject of this investment research and may trade in any of the designated investments mentioned herein either for their own account or the accounts of their customers, in good faith or in the normal course of market making. Accordingly, Canaccord Genuity or their affiliated companies, principals or employees (other than the authoring analyst(s) who prepared this investment research) may at any time have a long or short position in any such designated investments, related designated investments or in options, futures or other derivative instruments based thereon.

Some regulators require that a firm must establish, implement and make available a policy for managing conflicts of interest arising as a result of publication or distribution of investment research. This investment research has been prepared in accordance with Canaccord Genuity's policy on managing conflicts of interest, and information barriers or firewalls have been used where appropriate. Canaccord Genuity's policy is available upon request.

The information contained in this investment research has been compiled by Canaccord Genuity from sources believed to be reliable, but (with the exception of the information about Canaccord Genuity) no representation or warranty, express or implied, is made by Canaccord Genuity, its affiliated companies or any other person as to its fairness, accuracy, completeness or correctness. Canaccord Genuity has not independently verified the facts, assumptions, and estimates contained herein. All estimates, opinions and other information contained in this investment research constitute Canaccord Genuity's judgement as of the date of this investment research, are subject to change without notice and are provided in good faith but without legal responsibility or liability.

Canaccord Genuity's salespeople, traders, and other professionals may provide oral or written market commentary or trading strategies to our clients and our proprietary trading desk that reflect opinions that are contrary to the opinions expressed in this investment research. Canaccord Genuity's affiliates, principal trading desk, and investing businesses may make investment decisions that are inconsistent with the recommendations or views expressed in this investment research.

This investment research is provided for information purposes only and does not constitute an offer or solicitation to buy or sell any designated investments discussed herein in any jurisdiction where such offer or solicitation would be prohibited. As a result, the designated investments discussed in this investment research may not be eligible for sale in some jurisdictions. This investment research is not, and under no circumstances should be construed as, a solicitation to act as a securities broker or dealer in any jurisdiction by any person or company that is not legally permitted to carry on the business of a securities broker or dealer in that jurisdiction. This material is prepared for general circulation to clients and does not have regard to the investment objectives, financial situation or particular needs of any particular person. Investors should obtain advice based on their own individual circumstances before making an investment decision. To the fullest extent permitted by law, none of Canaccord Genuity, its affiliated companies or any other person accepts any liability whatsoever for any direct or consequential loss arising from or relating to any use of the information contained in this investment research.

**For Canadian Residents:** This Investment Research has been approved by Canaccord Genuity Corp., which accepts sole responsibility for this Investment Research and its dissemination in Canada. Canadian clients wishing to effect transactions in any Designated Investment discussed should do so through a qualified salesperson of Canaccord Genuity Corp. in their particular jurisdiction.

**For United Kingdom Residents:** This investment research is distributed in the United Kingdom, as third party research by Canaccord Genuity Limited, which is authorized and regulated by the Financial Services Authority. This research is for distribution only to persons who are Eligible Counterparties or Professional Clients only and is exempt from the general restrictions in section 21 of the Financial Services and Markets Act 2000 on the communication of invitations or inducements to engage in investment activity on the grounds that it is being distributed in the United Kingdom only to persons of a kind described in Article 19(5) (Investment Professionals) and 49(2) (High Net Worth companies, unincorporated associations etc) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended). It is not intended to be distributed or passed on, directly or indirectly, to any other class of persons. This material is not for distribution in the United Kingdom to retail clients, as defined under the rules of the Financial Services Authority.

**For United States Residents:** Canaccord Genuity Inc., a US registered broker-dealer, accepts responsibility for this Investment Research and its dissemination in the United States. This Investment Research is intended for distribution in the United States only to certain US institutional investors. US clients wishing to effect transactions in any Designated Investment discussed should do so through a qualified salesperson of Canaccord Genuity Inc. Analyst(s) preparing this report that are not employed by Canaccord Genuity Inc are resident outside the United States

and are not associated persons or employees of any US regulated broker-dealer. Such analyst(s) may not be subject to Rule 2711 restrictions on communications with a subject company, public appearances and trading securities held by a research analyst account.

**For European Residents:** If this Investment Research is intended for disclosure in any jurisdiction other than the United Kingdom, the US or Canada, then the relevant rules and regulatory requirements of that jurisdiction will apply.

**Additional information is available on request.**

Copyright © Canaccord Genuity Corp. 2011. – Member IIROC/Canadian Investor Protection Fund

Copyright © Canaccord Genuity Limited 2011. – Member LSE, authorized and regulated by the Financial Services Authority.

Copyright © Canaccord Genuity Inc. 2011. – Member FINRA/SIPC

All rights reserved. All material presented in this document, unless specifically indicated otherwise, is under copyright to Canaccord Genuity Corp., Canaccord Genuity Limited, and Canaccord Genuity Inc. None of the material, nor its content, nor any copy of it, may be altered in any way, or transmitted to or distributed to any other party, without the prior express written permission of the entities listed above.