Epizyme (NASDAQ:EPZM)

May 8, 2020

CATALYST SUMMARY

Companies developing cancer drugs frequently follow a tried-and-true strategy: Win approval in a small cancer indication, then leverage the first approval to move the drug into a bigger market. Epizyme followed this strategy to the letter with its drug Tazverik (tazemetostat).

The FDA approved Tazverik in January 2020 to treat epithelioid sarcoma (ES), which may afflict 800 patients in the US. Concurrent with its ES application, Epizyme advanced Tazverik to treat follicular lymphoma (FL). *SanaCurrents* **assigns a pivotal sentiment** the FDA will approve Tazverik in FL prior to the June 18, 2020 PDUFA date.

FL comprises about 14,000 of the 75,000 annual non-Hodgkin lymphoma (NHL) cases diagnosed in the US annually. FL, a slow-growing or indolent cancer, arises from aberrant B-lymphocytes. The disease is treated with different drug regimens at discrete stages of progression.

Epizyme is positioning Tazverik to be used initially in a third-line treatment, in patients who have failed two prior regimens. The June PDUFA will address an indication as a third-line treatment, but Epizyme has its sights set on potentially gaining approval for the orally administered drug in second and first line treatment.

Tazverik encountered safety concerns when it was under review for ES. In a single arm, 62-patient study, 37% of the patients taking 800 mg of Tazverik twice a day experienced a serious adverse event, while 34% had to adjust dosing because of toxicity. Still, the **FDA approved the drug based on a 15% overall response rate** in the trial. Because ES is a notorious, hard-to-treat cancer with surgery as the primary alternative, the FDA likely overlooked Tazverik's safety issues.

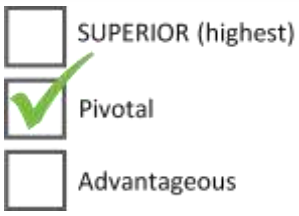
Epizyme claims Tazverik had a better safety profile in FL. Again, the company successfully negotiated with the FDA to gain a PDUFA date in FL based on a single-arm, phase II trial. In the 99-patient trial, only 8% of patients discontinued treatment due to side effects, and just 9% required adjustments to their dosing.

The trial tested Tazverik in two segments of FL patients – those with an EZH2 gene mutation and those without. Of the patients with an EZH2 gene mutation, 69% responded to therapy while 35% of the non-EZH2 mutation, also known as wild type, also responded. EZH2-mutated patients had a median duration of response lasting 11 months, compared with 13 months for those with wild-type EZH2. Patients in the FL trial experienced severe or worse side effects, which included lower blood counts, anemia, weakness and fatigue.

THE EDGE

As noted above, the safety profile of Tazverik is not stellar. The FDA staff expressed the same concerns in Epizyme's ES application. However, the concerns largely were regarded as not important after a unanimous advisory committee vote to approve the ES indication. The FDA noted at the time 50%

PROBABILITY SENTIMENT



Key Catalyst(s)

- PDUFA decision on Tazverik in Follicular Lymphoma (FL)

Key Catalyst Date(s)

- June 18, 2020

Insider & Institutional Holdings

4.04% % of Shares Held by All Insider

100.97% % of Shares Held by Institutions

105.22% % of Float Held by Institutions

199 # of Inst Holding Shares

Key Executives

Mr. Robert B. Bazemore Jr., Pres, CEO, Sec. & Director

Mr. Paolo Tombesi, Chief Financial Officer

Mr. Matthew E. Ros, Chief Strategy & Bus. Officer

Dr. Shefali Agarwal M.D., MPH, Chief Medical Officer

Dr. H. Robert Horvitz, Co-Founder & Chairman of the Scientific Advisory Board

Location

400 Technology Square
4th Floor
Cambridge, MA 02139
United States
617-229-5872
http://www.epizyme.com

General Guidelines for Probability Sentiments

Based on SanaCurrents' analytical model, Superior and Pivotal sentiments reflect a probability score of at least 60% that the company will announce a positive result to the specified catalyst. In our experience, a positive result typically increases the company's share price. An Advantageous sentiment reflects a score of less than 60%.

THE EDGE cont'd

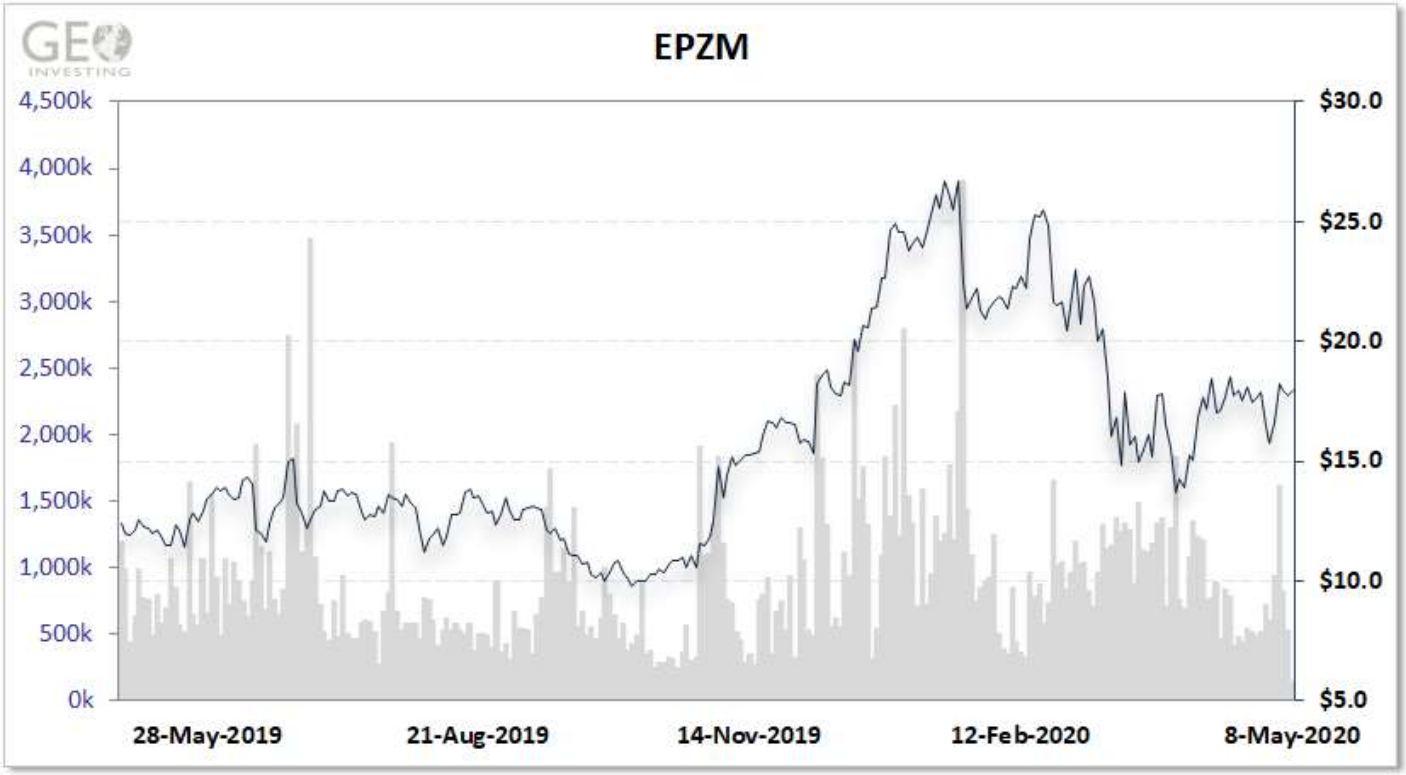
of ES patients would have had metastatic disease at the time of diagnosis, perhaps justifying a risky treatment to provide some potential benefit to very sick patients.

The bar for FL is not as low but Epizyme is seeking approval for in third-line treatment, where patients already have progressed through two drug regimens. Moreover, Epizyme successfully cross-referenced the FL application with the first ES application. With the approval of Tazverik in ES, components such as preclinical, CMC and clinical pharmacology already have been established as acceptable by the FDA. And in some respects, so has the safety.

Approval of Tazverik in FS will rest largely on the efficacy interpretation of the single-arm trial. While the efficacy results are not exceptional, they are stronger than in ES.

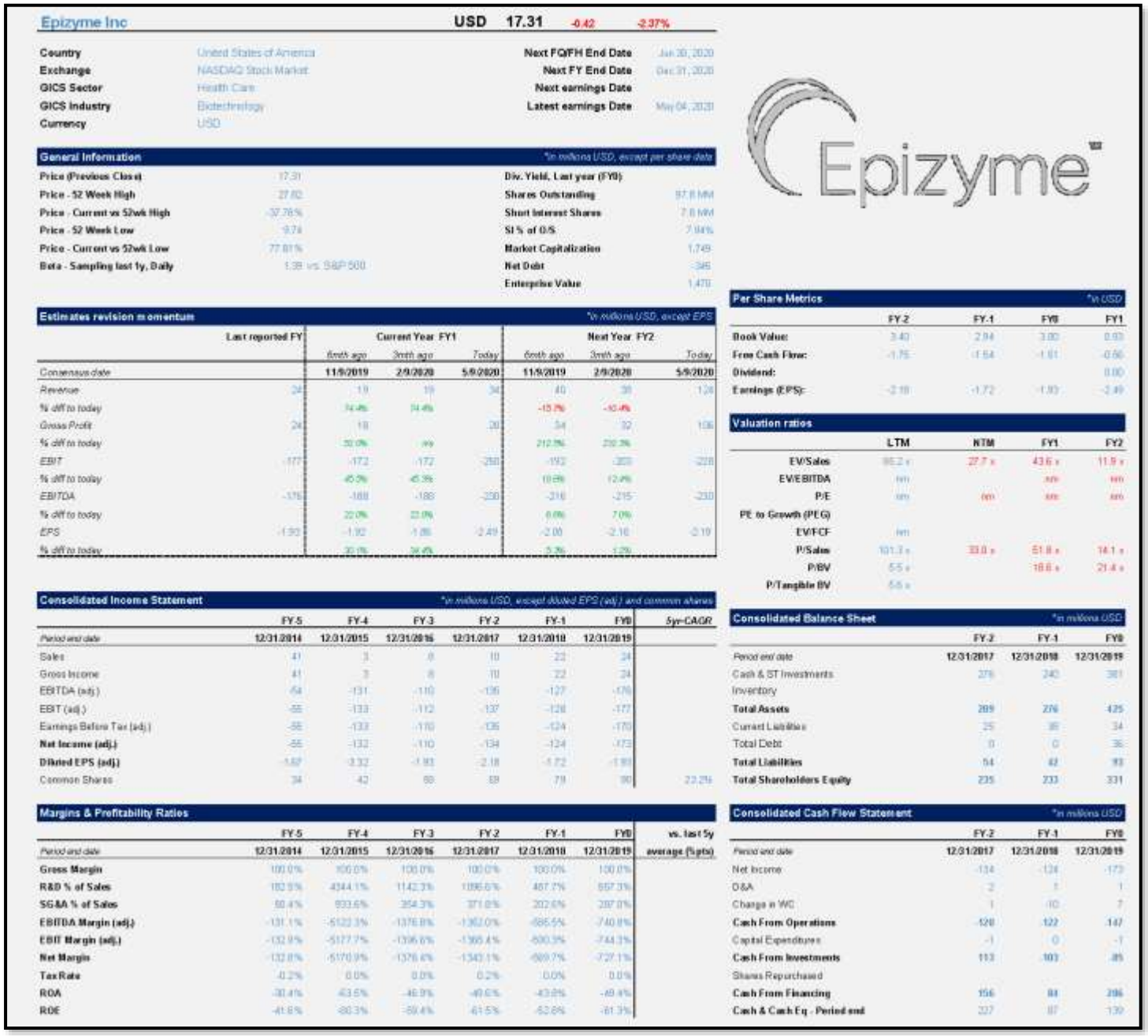
In addition, Epizyme is conducting a phase Ib/III randomized trial testing Tazverik with Rituxan and Bristol-Myers Squibb's (NYSE:BMS) Revlimid (lenalidomide), a combination known as R2, in patients with second-line FL. Epizyme has started the phase Ib portion to establish the safety of the combination treatment and plans to start the phase III efficacy segment later this year.

In addition to broader use of Tazverik, the goal of the phase Ib/III trial is to bring about improved treatment in FL. There is no cure for FL, only different stages of treatment in a chronic disease. Tazverik offers the potential to improve FL treatment. In recent months, as evidenced in ES, the FDA appears to be more obliging to approve drugs that potentially can improve treatment and bring down long-term costs. Epizyme and Tazverik likely will benefit from the trend.



Epizyme (NASDAQ:EPZM)

Tear Sheet



Epizyme Inc — USD 17.31 -0.42 -2.37%

Country	United States of America	Next FQ/FH End Date	Jun 30, 2020
Exchange	NASDAQ Stock Market	Next FY End Date	Dec 31, 2020
GICS Sector	Health Care	Next earnings Date	
GICS Industry	Biotechnology	Latest earnings Date	May 04, 2020
Currency	USD		

General Information *in millions USD, except per share data

Price (Previous Close)	17.31	Div. Yield, Last year (FY0)	
Price - 52 Week High	27.82	Shares Outstanding	97.8 MM
Price - Current vs 52wk High	-37.78%	Short Interest Shares	7.8 MM
Price - 52 Week Low	9.74	SI % of O/S	7.94%
Price - Current vs 52wk Low	77.81%	Market Capitalization	1,749
Beta - Sampling last 1y, Daily	1.39 vs. S&P 500	Net Debt	-345
		Enterprise Value	1,470

Estimates revision momentum *in millions USD, except EPS

	Last reported FY	Current Year FY1			Next Year FY2		
		6mth ago	3mth ago	Today	6mth ago	3mth ago	Today
Consensus date		11/5/2019	2/5/2020	5/5/2020	11/5/2019	2/5/2020	5/5/2020
Revenue	24	19	19	34	40	39	124
% diff to today		74.4%	74.4%		-15.7%	-10.4%	
Gross Profit	24	19		20	34	32	106
% diff to today		20.0%	n/a		212.5%	230.3%	
EBIT	-177	-172	-172	-250	-193	-203	-228
% diff to today		-45.3%	-45.3%		-10.6%	-12.4%	
EBITDA	-176	-168	-168	-230	-216	-215	-230
% diff to today		22.0%	22.0%		6.6%	7.0%	
EPS	-1.93	-1.92	-1.86	-2.49	-2.06	-2.16	-2.19
% diff to today		29.1%	34.4%		-5.3%	-1.2%	

Per Share Metrics *in USD

	FY-2	FY-1	FY0	FY1
Book Value:	3.40	2.94	3.00	0.93
Free Cash Flow:	-1.75	-1.54	-1.61	-0.66
Dividend:				0.00
Earnings (EPS):	-2.19	-1.72	-1.93	-2.49

Valuation ratios

	LTM	NTM	FY1	FY2
EV/Sales	86.2 x	27.7 x	43.6 x	11.9 x
EV/EBITDA	nm		nm	nm
P/E	nm	nm	nm	nm
PE to Growth (PEG)				
EV/FCF	nm			
P/Sales	101.3 x	33.0 x	51.8 x	14.1 x
P/BV	5.5 x		18.6 x	21.4 x
P/Tangible BV	5.6 x			

Consolidated Income Statement *in millions USD, except diluted EPS (adj.) and common shares

	FY-5	FY-4	FY-3	FY-2	FY-1	FY0	5yr-CAGR
Period end date	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019	
Sales	41	3	0	10	22	24	
Gross Income	41	3	0	10	22	24	
EBITDA (adj.)	-54	-131	-110	-135	-127	-176	
EBIT (adj.)	-55	-133	-112	-137	-128	-177	
Earnings Before Tax (adj.)	-55	-133	-110	-135	-124	-170	
Net Income (adj.)	-55	-132	-110	-134	-124	-173	
Diluted EPS (adj.)	-1.67	-3.32	-1.93	-2.18	-1.72	-1.93	
Common Shares	34	42	59	59	73	90	23.2%

Consolidated Balance Sheet *in millions USD

	FY-2	FY-1	FY0
Period end date	12/31/2017	12/31/2018	12/31/2019
Cash & ST Investments	276	240	381
Inventory			
Total Assets	289	276	425
Current Liabilities	25	35	34
Total Debt	0	0	36
Total Liabilities	54	42	93
Total Shareholders Equity	235	233	331

Margins & Profitability Ratios

	FY-5	FY-4	FY-3	FY-2	FY-1	FY0	vs. last 5y average (%pts)
Period end date	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019	
Gross Margin	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	
R&D % of Sales	182.5%	4344.1%	11422.3%	1086.6%	467.7%	557.3%	
SG&A % of Sales	59.4%	933.6%	3543.3%	371.6%	202.6%	297.0%	
EBITDA Margin (adj.)	-131.1%	-5122.3%	-13776.8%	-1362.0%	-586.5%	-740.8%	
EBIT Margin (adj.)	-132.9%	-5177.7%	-13966.6%	-1365.4%	-600.3%	-744.3%	
Net Margin	-132.8%	-5170.9%	-13764.6%	-1343.1%	-569.7%	-727.1%	
Tax Rate	-0.2%	0.0%	0.0%	0.2%	0.0%	0.0%	
ROA	-30.4%	-43.5%	-46.9%	-49.6%	-43.8%	-49.4%	
ROE	-41.8%	-80.3%	-59.4%	-61.5%	-52.6%	-61.3%	

Consolidated Cash Flow Statement *in millions USD

	FY-2	FY-1	FY0
Period end date	12/31/2017	12/31/2018	12/31/2019
Net Income	-134	-124	-173
D&A	2	1	1
Change in WC	1	-10	7
Cash From Operations	-128	-122	-147
Capital Expenditures	-1	0	-1
Cash From Investments	113	-103	-85
Shares Repurchased			
Cash From Financing	156	84	286
Cash & Cash Eq. - Period end	227	87	130

Disclosure of General Guidelines for SanaCurrents Strategy

In most situations, SanaCurrents partners take a position in a stock (or buy shares) shortly after a report on a catalyst is published. This is particularly true if the catalyst is within 90 days of the published report. For catalysts with horizons of 6-9 months, or longer, SanaCurrents anticipates the biopharma and device stocks from which it selects catalysts can rise or fall 20-30% in the months following the date of the published report. While buying at a dip, naturally, is preferred, SanaCurrents does not forecast or model in swings in share price prior to the catalyst. SanaCurrents' analytics score models the probability a compelling catalyst will be positive. SanaCurrents expects a positive announcement regarding a catalyst will drive a company's stock to higher level than the price on the date of the report, based on the company's value and capital structure when the report was published. That said, subscribers should exercise their preferred, individual discipline when timing trades, buy or sell, regarding the catalyst forecast.

Disclaimer

Please be advised that GeoInvesting™ is strictly a research and publishing firm, of general and regular circulation, which falls within the publisher's exemption to the definition of an "investment advisor" under Section 202(a)(11)(A) – (E) of the Securities Act (15 U.S.C. 77d(a)(6) (the "Securities Act"). GeoInvesting™ is not registered as an investment advisor under the Securities Act or under any state laws. None of our trading or investing information, including the Content, GeoInvesting™ Email, Executive Casts and/or content or communication (collectively, "Information") provides individualized trading or investment advice and should not be construed as such.

Accordingly, please do not attempt to contact GeoInvesting™, or SanaCurrents™, its members, partners, affiliates, employees, consultants and/or hedge funds managed by partners of GeoInvesting™ (collectively, the "GeoInvesting™ Parties") to request personalized investment advice, which they cannot provide. The Information does not reflect the views or opinions of any other publication or newsletter.

We publish Information regarding certain stocks, options, futures, bonds, derivatives, commodities, currencies and/or other securities (collectively, "Securities") that we believe may interest our Users. The Information is provided for information purposes only, and GeoInvesting™ is not engaged in rendering investment advice or providing investment-related recommendations, nor does GeoInvesting™ solicit the purchase of or sale of, or offer any, Securities featured by and/or through the GeoInvesting™ Offerings and nothing we do and no element of the GeoInvesting™ Offerings should be construed as such. Without limiting the foregoing, the Information is not intended to be construed as a recommendation to buy, hold or sell any specific Securities, or otherwise invest in any specific Securities. Trading in Securities involves risk and volatility. Past results are not necessarily indicative of future performance.

The Information represents an expression of our opinions, which we have based upon generally available information, field research, inferences and deductions through our due diligence and analytical processes. Due to the fact that opinions and market conditions change over time, opinions made available by and through the GeoInvesting™ Offerings may differ from time-to-time, and varying opinions may also be included in the GeoInvesting™ Offerings simultaneously. To the best of our ability and belief, all Information is accurate and reliable, and has been obtained from public sources that we believe to be accurate and reliable, and who are not insiders or connected persons of the applicable Securities covered or who may otherwise owe any fiduciary duty or duty of confidentiality to the issuer. However, such Information is presented on an "as is," "as available" basis, without warranty of any kind, whether express or implied. GeoInvesting™ makes no representation, express or implied, as to the accuracy, timeliness or completeness of any such Information or with regard to the results to be obtained from its use. All expressions of opinion are subject to change without notice, and GeoInvesting™ does not undertake to update or supplement any of the Information.

The Information may include, or may be based upon, "Forward-Looking" statements as defined in the Securities Litigation Reform Act of 1995. Forward-Looking statements may convey our expectations or forecasts of future events, and you can identify such statements: (a) because they do not strictly relate to historical or current facts; (b) because they use such words such as "anticipate," "estimate," "expect(s)," "project," "intend," "plan," "believe," "may," "will," "should," "anticipates" or the negative thereof or other similar terms; or (c) because of language used in discussions, broadcasts or trade ideas that involve risks and uncertainties, in connection with a description of potential earnings or financial performance. There exists a variety of risks/uncertainties that may cause actual results to differ from the Forward-Looking statements. We do not assume any obligation to update any Forward-Looking statements whether as a result of new information, future events or otherwise, and such statements are current only as of the date they are made.

You acknowledge and agree that use of GeoInvesting's™ Information is at your own risk. In no event will GeoInvesting™ or any affiliated party be liable for any direct or indirect trading losses caused by any Information featured by and through the GeoInvesting™ Offerings. You agree to do your own research and due diligence before making any investment decision with respect to Securities featured by and through the GeoInvesting™ Offerings. You represent to GeoInvesting™ that you have sufficient investment sophistication to critically assess the Information. If you choose to engage in trading or investing that you do not fully understand, we may not advise you regarding the applicable trade or investment. We also may not directly discuss personal trading or investing ideas with you. The Information made available by and through the GeoInvesting™ Offerings is not a substitute for professional financial advice. You should always check with your professional financial, legal and tax advisors to be sure that any Securities, investments, advice, products and/or services featured by and through the GeoInvesting™ Offerings, as well as any associated risks, are appropriate for you.