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Biotechnology

Top 3 Biotech Picks For 2010

- **Biotech in 2010.** In this report we highlight our top 3 biotech picks for 2010. Additionally, we present empirical data suggesting that the best time to buy share of biotech stocks in advance of important binary events is 3 to 4 months prior to a critical binary (clinical or regulatory) event.
- **Top 3 picks for 2010.** In our opinion, the following 3 stocks are set to meaningfully outperform the rest of the biotech space in 2010:

1) **Medivation (MDVN)**: Medivation is expected to release Phase 3 data for its clinical study of Dimebon (to treat mild to moderate Alzheimer's disease), likely in early Q2. While Alzheimer's studies are difficult to predict, we believe that odds of success of this study are ~65%. This is a controversial name, with a tremendous degree of short interest (25% of float) in this stock. If results of the Phase 3 Dimebon study are positive, the high short interest in MDVN shares will likely trigger a major short squeeze, further boosting share price.
2) **Clinical Data Inc. (CLDA)**: CLDA reported positive data for Vilazodone, to treat depression. The company expects to file an NDA in Q1 of 2010. Based on data from 2 Phase 3 studies, we believe that Vilazodone will be approved by the FDA. Our take is that CLDA will partner Vilazodone in 2010, leading to price appreciation of the shares.
3) **PROLOR BIOTECH (PBTH)**: PROLOR is expected to have Phase 1 data from its clinical study of MODG-4023 (a long-acting human growth hormone), likely in Q1 of 2010. Based on mode of action, and previous Phase 3 data released by Schering-Plough, we expect that these data will be positive. We note that PROLOR is a tremendously "under the radar" femto-cap stock. Regardless, we believe that its approach to long-acting protein therapeutics is more elegant than existing approaches (which we consider to be "hammer and tongs" approaches, by comparison), and that positive clinical data will bring more attention to this stock, leading to price appreciation.

- **Details in body of report.** We present specific reasons why we believe that the stocks mentioned will increase in value in 2010. Also, we present empirical data showing that profits can be made simply by purchasing shares of biotech companies in advance of know clinical/regulatory events, and selling prior to the event.

Reason for Report:

Roth Covered Companies Mentioned in this Report:

MDVN	$37.65	Buy
CLDA	$18.37	Buy
PBTH	$1.62	Buy
BMRN	$18.98	Hold
SVNT	$13.89	Buy
NGSX	$7.40	Buy
CHTP	$2.36	Buy
DEPO	$3.23	Buy

Stock prices are as of previous day's close, if not otherwise specified

Top picks for 2010

After a challenging year in Biotech (in which there were some standouts) we present our top 3 picks form our Biotech coverage universe. Of our 3 picks, 2 of them (MDVN and CLDA) are likely to be subject to significant binary events in 2010. This increases returns if played correctly but, also, increases risk. Our 3rd pick (PBTH) is an illiquid "femto-cap" stock that we believe is promising based on clever science: PBTH will also have a significant even in 2010 (data from its first Phase 1 clinical study, likely in Q1), but we do not believe that this will have the same stark binary character of events for MDVN and CLDA. Our picks are driven by potential for success based on scientific underpinnings of the respective drugs, together with market potential.

In addition to our top picks, we present empirical data suggesting that good excess returns can be obtaining by buying shares of biotech companies in advance of known clinical and/or regulatory events, and selling the shares immediately prior to the event. Specific details are presented below.

When to Buy?

To get a handle on the optimum time to purchase biotech stocks in advance of a major event, we looked at how biotech stocks have performed prior to such events in the past 2 years: we found 18 such examples (summarized in Table 1 and Figure 3). Of particular note in Figure 3 is that, empirically, the best time to buy shares of a biotech company in advance of a known major event is 3-4 months.

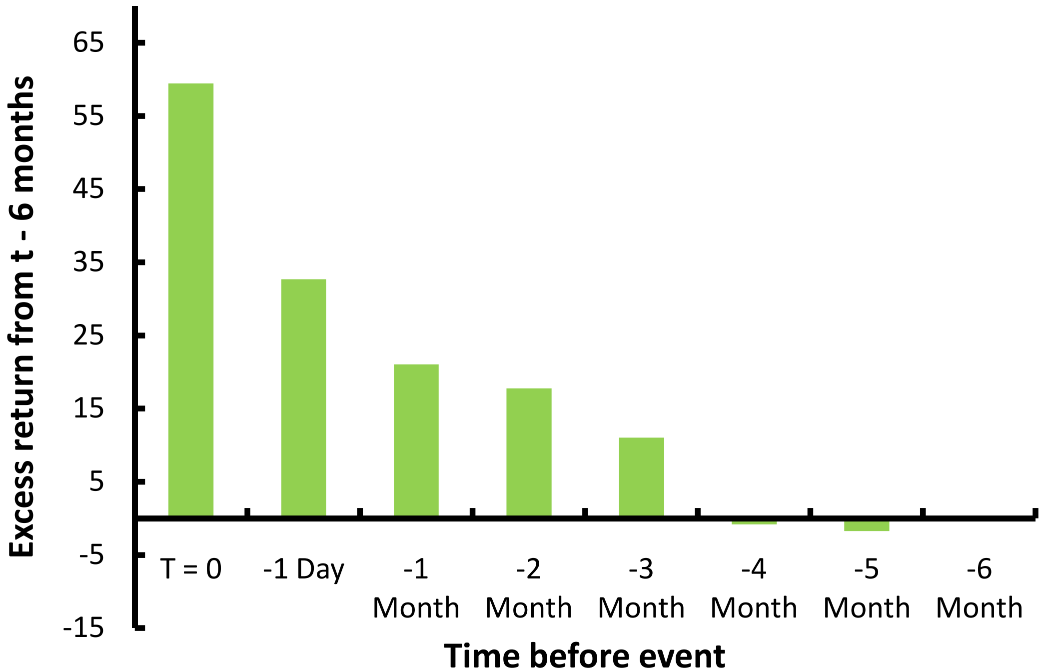
Table 1: Performance of biotech stocks in advance of major, known, events over past 2 years. Note, changes in move of NASDAQ has been subtracted for each time period.

				% Excess return from t - 6 months					
		T = 0	-1 Day	-1 Month	-2 Month	-3 Month	-4 Month	-5 Month	-6 Month
BMRN	Kuvan approval (Dec. 13, 2007), +	53.1	58.8	59.7	44.0	29.5	16.6	5.6	0.0
SVNT	Krstexxa data (Dec. 13, 2007), +	27.9	6.5	-8.1	7.5	-1.8	-4.2	-8.6	0.0
RIGL	R788 P3 (Dec. 13, 2007), +	172.5	-18.8	-7.9	0.5	-0.2	-5.9	-12.3	0.0
CADX	Acetavance P3 (Jan. 11, 2008), -	-53.9	6.3	-5.1	0.0	-5.9	0.2	7.3	0.0
NGSX	Qutenza P3 (Feb. 28, 2008), -	-30.1	-4.3	-7.5	-16.6	-1.4	1.7	22.8	0.0
OPTR	OPT-80 P3 (Nov. 10, 2008), +	27.2	-42.6	-48.0	-22.3	-25.6	-34.8	-61.2	0.0
CYPB	Savella NDA (Jan. 14,2009), +	51.7	22.7	3.5	-3.9	4.9	-20.0	22.6	0.0
OREX	Contrave P3 (July 20, 2009), +	35.8	35.5	35.9	19.4	8.0	-12.0	3.7	0.0
UTHR	Tyvaso NDA (July 30, 2009), +	41.3	7.2	-24.0	-45.5	-54.2	-32.1	19.0	0.0
ACAD	Primaserin P3 (Sept 1, 2009), -	6.3	-7.4	0.5	-4.4	-24.1	-4.4	4.9	0.0
VVUS	Qnexa P3 (Sept. 9, 2009), +	248.7	80.1	89.9	58.0	44.9	17.9	6.0	0.0
CHTP	Droxidopa P3 (Sept 24, 2009), -	25.5	282.3	195.9	186.7	154.7	60.1	-17.8	0.0
ALTH	Folotyn NDA (Sept. 25, 2009), +	-17.2	-13.3	-11.6	-7.2	-3.6	-3.5	-23.6	0.0
DEPO	Serada P3 (Oct. 5, 2009), +	92.1	46.1	3.8	26.3	15.1	-8.1	-24.9	0.0
GTXI	Toremifene NDA (Nov. 2, 2009), -	-73.4	-27.6	2.4	-17.0	-11.6	-17.0	-15.8	0.0
PARD	Picoplatin P3 (Nov. 16, 2009), -	-77.3	92.6	72.5	98.5	106.7	94.8	37.0	0.0
HGSI	Benlysta (Jul 29, 2009), +	480.7	31.8	6.0	-21.9	-47.9	-62.9	5.8	0.0
VNDA	Fanapt (May 7, 2009), +	797.0	17.3	9.8	13.4	-8.1	-9.7	-28.4	0.0
	Average*	59.5	32.7	21.1	17.8	11.0	-0.8	-1.7	0.0
	Std Dev*	136.3	74.3	57.2	55.5	51.9	35.7	23.2	0.0

*Excludes VNDA result

Source: First Call and Roth Capital Partners Research LLC.

Figure 1: Excess return of biotech stocks in advance of known major events.



Source: First Call and Roth Capital Partners Research LLC.

Buying in advance of outcome

The data in Figure 3 suggest that good excess returns may be obtained by purchasing shares of companies facing important events 3 to 4 months prior to the event, and selling before the event. This approach, to a degree, can shield investors from the actual outcome itself. It is important to note that these data are empirical, and from a limited number of examples.

Details on the scope and limitations of data:

- Only looked at last 2 years
- Companies with major binary events <u>that were known in advance</u> (i.e. “surprises” like SVNT’s 2008 ACR presentation are not included)
- Only considered stocks trading at >$5 either prior to or after event
- Excess return was determined by subtracting corresponding moves in NASDAQ
- 18 examples, 12+/6- were included

Specific recommendations

We present below our top three picks for 2010, and provide additional detail. We believe that MDVN will be the biotech story of 2010 and, consistent with this, focus extra space on the company.

1. **Medivation (MDVN, BUY rated, MC [Dec. 22/09]: $1.2 billion)**

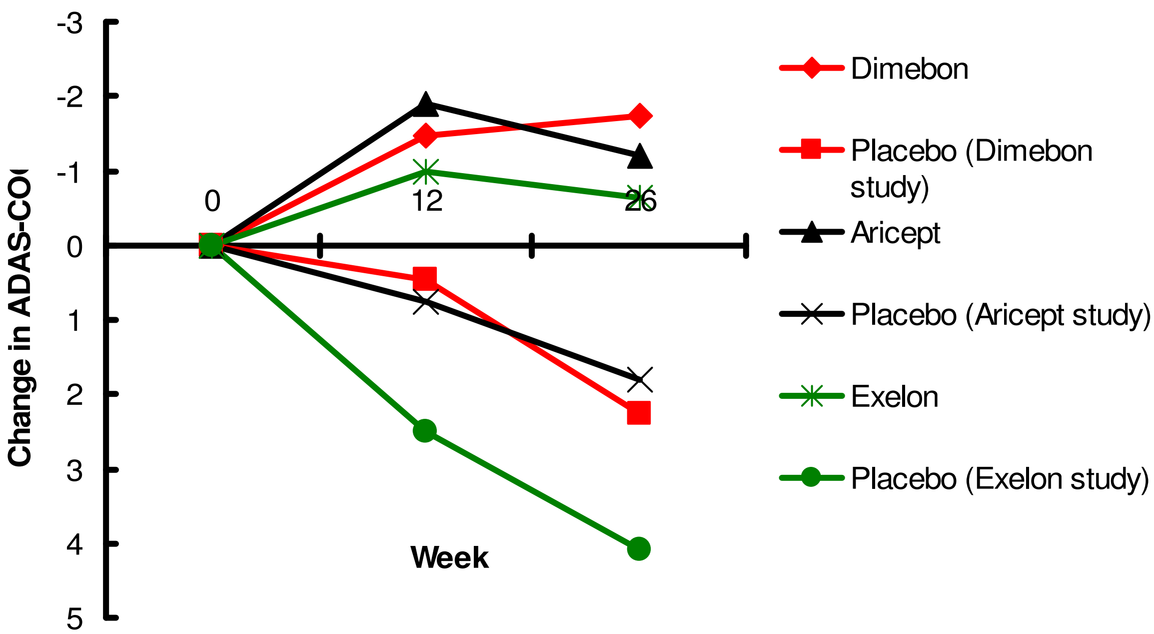
Why we like the stock: MDVN’s first Phase 3 study of Dimebon (to treat mild to moderate Alzheimer’s) is almost certain to be the big biotech story of 2010. Our take is that, despite the recent run in MDVN share price, there is still room to move up in advance of the result (expected in early Q2 2010). Our overall take, based on Phase 2 data, is that odds of success of Dimebon are 65%.

The result of Medivation's Phase 3 study of Dimebon to treat Alzheimer's disease (AD) is likely to be the biggest biotech story of 2010. This Phase 3 study (of 598 patients), which will seek to reproduce data observed in a Russian Phase 2 clinical study, was fully enrolled in June 2009. The observation period in this trial is 6 months. Accordingly, we expect that data will be released early in Q2 2010: based on empirical data presented above, buying shares of MDVN in advance of this result should be profitable.

Recap of Phase 2 AD data

In September 2006, Medivation released results of a 183 patient, double-blinded, placebo controlled, Phase 2 study comparing Dimebon to placebo. The study was conducted at eleven sites in Russia. Results of this study, published in *The Lancet*, were encouraging. The primary endpoint of the study was the ADAS-COG (Alzheimer Disease Assessment Scale-Cognitive), a qualitative—but widely accepted—measure of cognitive function. By this measure, patients on Dimebon experienced a 4 point improvement ($p < 0.001$), as compared to placebo, over 26 weeks. Figure 4 depicts ADAS-COG data for the Russian Phase 2 Dimebon study compared to equivalent data used in the approval of Aricept and Exelon.

Figure 2: Change in ADAS-COG from clinical studies of Aricept, Dimebon, and Exelon. Note, last data points for Aricept study are from week 24.



Source: Company reports, FDA, and Roth Capital Partners LLC Research.

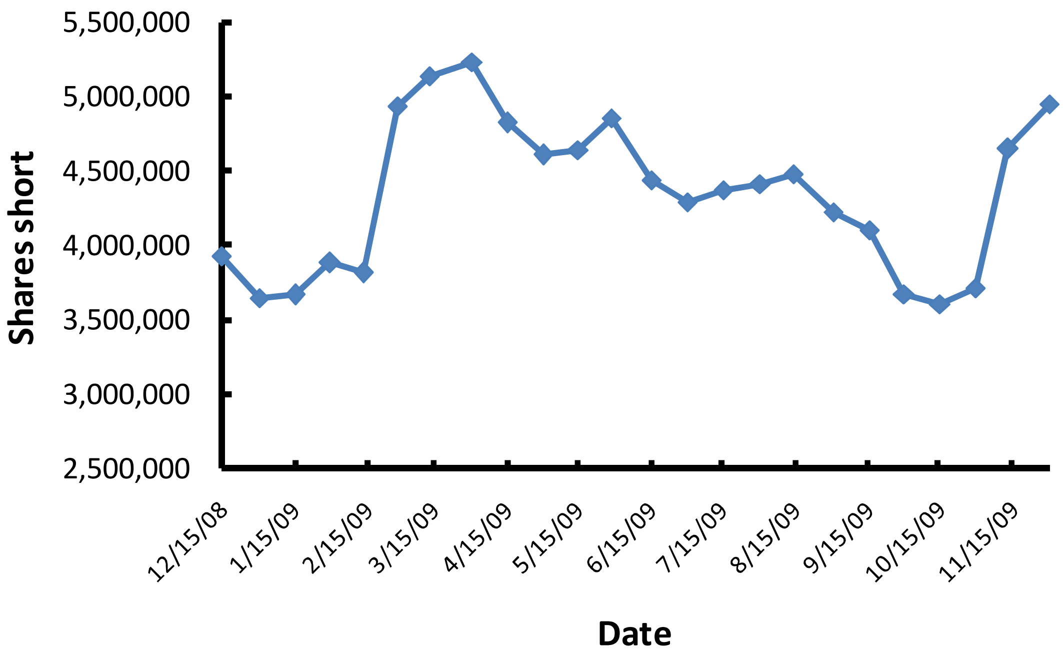
Of note in Figure 4 is the near superimposibility of the Dimebon placebo data with placebo data for Aricept. While comparing data from different clinical trials can be iffy, this seems to us an encouraging negative control. The safety profile of Dimebon was excellent, with dry mouth (18%) the most common AE.

Short interest could play a role

While the Russian Phase 2 data were positive, there are skeptics. To be fair, the average age in the Russian Phase 2 study (68) is younger than the average age (74) in other Alzheimer's studies. Age plays a critical role in occurrence of AD, and this may be an issue. It is worth noting that the cognitive function of the patients in this study, as measured by the mini mental state exam (MMSE) was 10 to 24, consistent with previous AD studies.

The number of shares of MDVN held short has increased to nearly 5 million (Figure 5), or 27% of float. A positive result in the AD study is likely to trigger a substantial short squeeze, that could amplify price movement on a positive result.

Figure 3: Shares of MDVN held short.



Source: NASDAQ.com and Roth Capital Partners LLC Research

Overall take

We believe that at current trading, risk/reward for MDVN shares favors reward. With the paucity of current treatments for AD, a positive result for Medivation's first Dimebon Phase 3 study is likely to move the stock up substantially. Our take is that odds of success of Dimebon are 65%.

2. **Clinical Data Inc. (CLDA, BUY rated, MC [Dec. 22/09]: $500 million)**

Why we like the stock: CLDA is expected to file an NDA for its drug Vilazodone, to treat depression, in Q1 2010. Based on Phase 3 clinical data, we believe that odds of approval are 75%, and that CLDA will enter into a partnership to market Vilzaodone after the NDA is filed.

CLDA is expected to file an NDA for Vilazodone, to treat depression, in Q1 2010. We believe that the drug is likely to be approved by the end of 2010 (or in January 2011, at worst). The market for anti-depressants is robust, with over 130 million prescriptions filled per year. Up to 45% of patients do not respond to the first or second anti-depressant tried: we believe that, based on Vilazodone's dual mode of action and differentiated safety profile, sales of the drug could exceed $1 billion/year 5 years post-launch.

CLDA announced in June results of a second Phase 3 clinical study of Vilazodone, a dual-action 5-HT reuptake inhibitor/5-HT_{1a} agonist, to treat depression. The drug was effective, affording a statistically significant 2.5 point improvement in MADRS (a measure of depression and the primary endpoint of the study) compared to placebo. Also, the drug was safe and well tolerated, though there was a high incidence of diarrhea (>25%). It should be noted that the diarrhea was mild to moderate, and tended to occur only in the first few days of treatment. Further, of 445 patients treated with Vilazodone, only 4 discontinued due to diarrhea. Unlike many anti-depressants, there were no reported sexual side effects associated with Vilazodone, providing a differentiated adverse event profile.

In addition to Vilazodone, CLDA is engaged in a Phase 3 clinical study of Stedivaze as a cardiac perfusion agent. While we believe that this drug may add value to CLDA, for 2010, the story will be all about Vilazodone.

Overall take

We believe that odds of approval of Vilazodone by the end of 2010 are 75%, and that the drug will be able to generate sales in excess of $1 billion annually. We expect that CLDA will enter into a partnership for Vilazodone in 2010, likely after the NDA is filed.

3. **PROLOR (PBTH, BUY rated, MC [Dec. 22/09]: $35 million)**

Why we like the stock: PBTH is an under-the-radar femto-cap stock that is pursuing, what we believe to be, a clever approach to extending the half-life of protein therapeutics. The company has *de facto* Phase 3 proof of concept that its technology works, and is expected to present Phase 1 clinical data on its first drug (long acting human growth hormone) likely in February. Our take is that as the company moves further into clinical development its profile will increase.

PROLOR is developing so-called carboxy terminated peptides (CTP) to increase the half-life of protein therapeutics in the body. CTP is a 28 amino acid segment that has been demonstrated to retard degradation of proteins. Most technologies to extend the half life of proteins (for example, adding polymers like PEGs, antibodies, or albumin) are, in our opinion, of the 'hammer and tongs' variety. PBTH's approach, of simply adding 28 amino acid segments, seems to use more elegant. A particular advantage of the CTP approach is that the overall effect on protein conformation is lessened, which should serve to maintain the fidelity of the protein's reactivity.

In preclinical studies, PBTH demonstrated that a single injection of hGH-CTP afforded the same weight gain in rats as 11 daily injection of normal hGH. More importantly, Schering-Plough (now Merck) announced in 2008 that, in a Phase 3 clinical study of 1,500 women, a single dose of follicle stimulating hormone (FSH) conjugated to the CTP was equivalent to 7 daily doses of FSH in promoting pregnancy. Our take is <u>that this provides clinical proof of concept for PBTH's technology.</u> PROLOR is currently engaged in a Phase 1 clinical study of human growth hormone (hGH) conjugated to CTP, with an additional Phase 1 study of use of CTP to extend the half-life of interferon β_{1a} to follow.

Overall take

We believe that PBTH's approach to drug delivery is clever and promising. PBTH's share price has been, in our opinion, suppressed by the lack of any clinical data. We believe that once the company begins to disclose actual clinical information it will move from under the radar, with a concomitant increase in price as investors learn more about the story.

Valuation and Risks

Medivation Inc. (MDVN), BUY rated

We rate MDVN shares a BUY with a $34 price target. Our price target reflects a 25X multiple of our estimated fully diluted FY13 EPS of $2.52 discounted back to late 2010 by 25% annually. Factors that could impede the stock from reaching our target price include negative results in ongoing and upcoming clinical trials, delays in submitting NDA's to the FDA, failure to receive approvals from the FDA, increased competition, and lessened confidence in the company's pipeline, financing risk and an adverse change in general market conditions.

Clinical Data Inc. (CLDA), BUY rated

We rate shares of CLDA a BUY, with a 12-month target price of $24/share. Our price target reflects a 20X multiple of our risk-adjusted estimated FY14 EPS of $2.45 (fully diluted) discounted at 20% annually. Factors that could impede the stock from reaching our target price include negative results in upcoming clinical trials, delays in submissions to the FDA, failure to receive approvals from the FDA, increased competition, lessened confidence in the company's pipeline, financing risk, changes in government regulation, and an adverse change in general market conditions.

PROLOR (PBTH), BUY rated

We rate shares of PROLOR a Buy, with a 12-month target price of $4. Our price target reflects a 25X multiple of our risk-adjusted estimated FY14 EPS of $0.82 (fully diluted) discounted by 35% annually. Factors that could impede the stock from reaching our target price include negative results in upcoming clinical trials, delays in submissions to the FDA, failure to receive approvals from the FDA, increased competition, lessened confidence in the company's pipeline, financing risk, changes in government regulation, and an adverse change in general market conditions. PROLOR carries out some of its operations in Israel, adding geopolitical risk as well as risks associated with currency fluctuations.

Disclosures:

ROTH makes a market in shares of Medivation, Inc. and as such, buys and sells from customers on a principal basis.

Within the last twelve months, ROTH has received compensation for investment banking services from Clinical Data, Inc.

ROTH makes a market in shares of Clinical Data, Inc. and as such, buys and sells from customers on a principal basis.

Within the last twelve months, ROTH has managed or co-managed a public offering for Clinical Data, Inc.

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A Research Analyst and/or a member of the Analyst's household own(s) shares of PROLOR stock.

Shares of PROLOR may not be eligible for sale in one or more states.

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Distribution of IB Services Firmwide

			IB Serv./Past 12 Mos. as of 12/23/09	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY [B]	**153**	**71.8**	**21**	**13.7**
HOLD [H]	**55**	**25.8**	**0**	**0**
SELL [S]	**5**	**2.3**	**0**	**0**
NOT RATED [NR]	**0**	**0.0**	**0**	**0**

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

Ratings System Definitions - ROTH employs a rating system based on the following:

Buy: A security, which at the time the rating is instituted and or reiterated, indicates an expectation of a total return of at least 10% over the next 12 months.

Hold: A security, which at the time the rating is instituted and or reiterated, indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A security, which at the time the rating is instituted and or reiterated, indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Not Rated: A security which at the time the rating is instituted and or reiterated, indicates that we have no opinion or expectations as to the price of the security over the next 12 months.

Not Covered (NC): ROTH does not publish research or have an opinion about this security.

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