

Digesting the Market's Yearend Gains

After the significant post-election gains, the major market indices have continued to grind up in the first few weeks of December. Investors are still cheering on the idea of a new political landscape.

Lockheed Martin (NYSE: LMT) and other defense contractor stocks fell as Mr. Trump tweeted about cost overruns on the F-35 fighter program. Less than a week later, many of these same defense contractors got a boost after Trump expressed his desire to increase the amount of ships in the Navy by 30% to 40% over the next decade.

It is going to be a few months before the market settles down on exactly what the primary priorities are for the new administration. Until then, investors should avoid knee-jerk reactions and just plan to take things slow while 2017 unfolds. As far as the lay of the land for the healthcare sector, here is my take so far about the new political dynamic.

The Affordable Care Act looks sure to be repealed in some form. The questions are what provisions are likely to be kept, what will replace the program, and when this will occur. Until these details get sorted out, health insurance and hospital stocks could be more volatile.

My outlook after the election for the biotech and pharma sectors is neutral. I don't expect major legislation that will be helpful or harmful to these industries. However, there certainly could have been much worse election scenarios for these areas of the economy. There will be some volatility in these spaces for a bit as Mr. Trump says he wants to "do something" about drug prices while nominating one of the most pro-business/free market cabinets in memory.

I think the biotech sector is starting to take this in stride and I think this area of the market could trade in a relatively narrow trading range until fourth quarter earnings reports start in late January and early February. The sector could also be bolstered if we see increased M&A activity to begin the New Year. Mr. Trump's stated desires to reform the tax code and make it easier to repatriate money from overseas operations could be the most helpful policy for providing additional funds for increased acquisitions.

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Until then, I think we are just in “wait and see” mode as we look to close out 2016.

Happy Hunting



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P.S. Join me for The MoneyShow Orlando, February 8-11, at the Omni Orlando Resort at ChampionsGate. Over four days you’ll meet me and other experts in a wide variety of investment specialties who will share market outlooks, time-tested strategies, and favorite stock, bond, fund and ETF ideas.

I am giving a presentation on **“Building an Optimized Biotech Portfolio for Outsized Returns with Reduced Risk”** on Friday February 10th and would love to see my subscribers there.

[Click here to register.](#)

Recro Pharma

This month we are replacing **Ardelyx (NASDAQ: ARDX)** in the portfolio. This small cap has produced a huge return while in the portfolio. However, the stock is getting close to analyst price targets. In addition, the stock has formed a triple top over the past month at just under \$16.00 a share and price action looks tired here. It is better to book a nice gain and move on to another holding that has a better risk to reward profile.

Company Overview:

Recro Pharma (NASDAQ: REPH) is a small Pennsylvania based biopharma company focusing on developing non-opioid products for the treatment of acute pain, a very popular space these days. Given the size of the pain management market, this is understandable. Recro is trying to carve out a niche in the post-op pain market, as a movement to non-opioid products in this field is underway.

Post Op Pain Market Underserved

- \$5.9 billion market⁽¹⁾
- Predominantly opioid use
- Significant side effects / issues associated with opioids
- Dearth of non-opioid drugs in development

Inpatient procedures	
Total procedures (2009)	47.9M
Addressable	>25M

Ambulatory procedures	
Total procedures (2006)	53.3M
Addressable	>25M

Note: Addressable includes procedures expected to utilize pain medication.

Source: National Center for Health Statistics and management estimates.

(1) GBI Research, 2010 sales.

The shares came public in early 2014, and after a big spike in 2015, it is trading pretty close to its IPO debut at just under \$7 a share. The stock's 52-week high is \$12.50 and it currently sports a market capitalization of approximately \$80 million.

Pipeline:

The company has three primary drug candidates in development, the most important is an IV version of Meloxicam which is in late stage testing for acute post-operative pain.

Meloxicam

This compound has been around since the nineties. This drug is a long-acting NSAID with preferential COX-2 inhibition that possesses anti-inflammatory, analgesic, and antipyretic activities. Unfortunately, in its oral form, it takes 5-6 hours to take full effect. Recro has developed a proprietary injectable form of the drug which is in late stage testing for an IV version and earlier stage testing for an intramuscular delivery version.

The benefit of Recro's version of Meloxicam is that it is much faster acting than the oral version. This should find a ready market if approved, which seems likely given trial results to this point. The company is targeting mid-summer of 2017 for filing a NDA for its IV version of Meloxicam.

Dexmedetomidine

The company is using the same approach to develop an IV version of Dexmedetomidine, which is another pain management compound that has been around since the nineties. It is marketed under the brand name Precedex® which had approximately \$275 million in gross sales in 2015.

Dexmedetomidine has an extensive history of intravenous use in acute and surgical settings, utilizing its sedative properties. Recro formulated their version of Dexmedetomidine at an eighth or a tenth of the dose in the currently recommended IV dosage levels. Based upon the lower dose, the company has seen very little sedation, to date, in their clinical trials while still

Clinical Stage Pipeline

Product	PC	I	II	III	Rights
Meloxicam					WW
IV formulation					
Acute post operative pain					Phase III
IM formulation					
Acute pain					
Dexmedetomidine ("Dex")					WW, exc. Europe, Turkey, CIS
Dex-IN (intranasal)					
Peri-procedural pain					Phase II
Cancer breakthrough pain					
Dex-SL (sublingual)					
Fadolmidine ("Fado")					WW, exc. Europe, Turkey, CIS
Intrathecal					
Topical					



demonstrating an analgesic effect. The compound is in early and mid-stage testing for several pain indications such as Peri-procedural pain.

Fadolmidine

This is a similar compound to Dexmedetomidine, but it does not cross the blood/brain barrier. This allows for the use of Fadolmidine for intrathecal (injection into the spine) administration for pain or anesthesia. It can also be used for topical treatment of regional nerve pain from underlying nerve damage, also called "neuropathies".

A Phase II clinical trial successfully demonstrated that intrathecal Fadolmidine, in combination with bupivacaine, produced analgesic effects compared to bupivacaine alone in bunionectomy patients. The intrathecal version of Fadolmidine is in mid-stage testing while the topical version is in early clinical testing.

Recro Pharma also has a manufacturing business which it purchased in 2015. It produced some \$52 million in revenues through the first three quarters of 2016. This business consists of a 97,000-square foot, DEA-licensed

facility that manufactures five commercial products. The business receives manufacturing revenues and royalties associated with the sale of these products. Revenues are only growing slightly for this side of the business (up 2.5% year over year). Also, the company posted a loss of \$5.4 million in the third quarter due to the costs of trial development and interest costs (\$1.5 million a quarter) associated with the debt taken on for the facility.

Analyst Commentary and Balance Sheet:

The company just raised some \$40 million through a secondary offering that will go to cover its costs. These costs include those for its NDA, preparations for commercial activities for IV meloxicam and the Phase 3b program, as well as general corporate purposes. Combined with the cash on hand at the end of the third quarter, the company has over \$60 million of cash on the books and currently has solid financial flexibility. If IV meloxicam is approved as expected, the company will owe **Alkermes (ALKS)** a tidy milestone payment in connection with its purchase of the rights to IV meloxicam and the company's manufacturing facility in March of 2015.

Analyst support is strong, but must be tempered somewhat given the company just raised capital via the secondary markets. The median analyst price target on Recro is just north of \$22 a share. At the end of November, Aegis Capital, H.C. Wainwright and Roth Capital all reiterated the shares as a Buy on the same day. Price targets proffered ranged from \$19 at Wainwright to \$25 at Aegis.

Roth's analyst, in reissuing his Buy rating and \$24 price target, stated the following on Recro Pharma and its prospects, "We reiterate our Buy rating as we believe that IV meloxicam is approvable and could represent an alternative to opioid pain medications." REPH reports second positive efficacy trial for IV meloxicam. Recro Pharma announced positive results from its second phase 3 clinical trial evaluating intravenous (IV) meloxicam for the treatment of acute post-operative pain following abdominoplasty surgery.

IV meloxicam achieved its primary endpoint of a statistically significant difference in Summed Pain Intensity Difference (SPID) over the first 24 hours. The study also achieved statistical significance for 10 of the 19 secondary endpoints with pain relief as early as SPID12 (SPID6 did work in the first trial, SPID48 achieved significance in both trials). Even the missed secondary endpoints appeared to trend in the right direction.

Takeaway #1 – Road to market is becoming clear. This was the second pivotal efficacy trial and the last remaining high risk event for investors, in our opinion. The gating factor to filing a New Drug Application (NDA), however, remains the long-term safety study (which should complete enrollment in late first quarter 2017/early second quarter 2017). We do not expect surprises in the long-term safety study given that the adverse event profile appears safe in the efficacy trials.

Takeaway #2 – Filing target remains "summer 2017".

Outlook:

It should be noted there was some small stock purchases by several officers in the company this May. In addition, a beneficial owner increased his stake in Recro by some 15% in August, almost \$3 million in new shares. This is an impressive vote of confidence. IV Meloxicam seems on its way to approval and commercialization. This should represent an important new revenue stream for the company. Recro Pharma has the "shots on goals" that I like to see before taking a stake in a promising developmental concern. It also has a manufacturing facility already in place, which is a rarity in this space.

Upcoming catalysts in 2017 could boost sentiment on the stock, and increasingly positive commentary on the concern from analysts could trigger this as well.

Recommendation: Buy REPH up to \$8.00 a share

Position: Long REPH

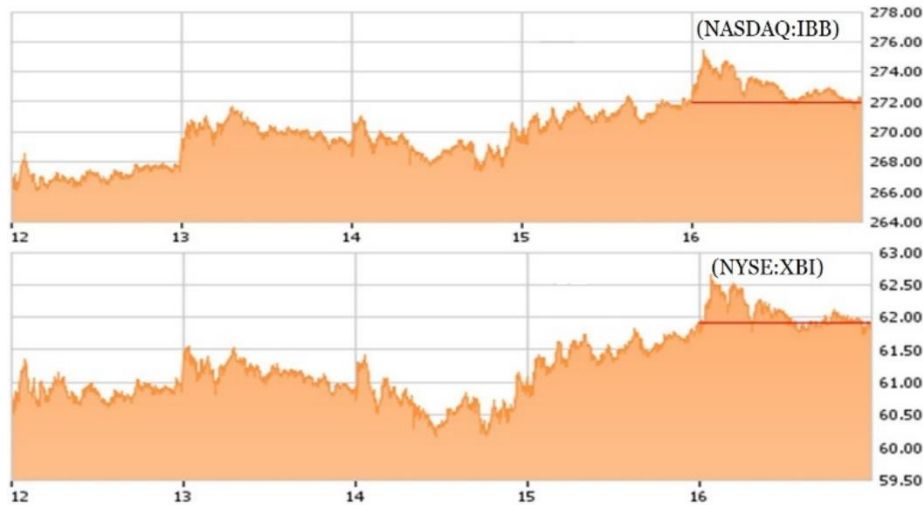
Portfolio News

"There can be no failure to a man who has not lost his courage, his character, his self-respect, or his self-confidence. He is still a King." *Orison Swett Marden*

Biotech slowly drifted up last week with large caps performing better than the small caps. With a huge surge after the election, followed by profit taking throughout the back half of November, the sector ended largely where it started.

It is quite possible we get some sort of Santa Claus rally in this area of the market over the next week. I also expect some of the most beaten-down names in the sector to continue to perform better as the brunt of tax-loss selling is coming to an end.

However, I think it is unlikely to see any major movements through year end, either up or down.



Fourth quarter earnings season for the industry does not begin until late January and trading is likely to be very light in the upcoming week thanks to the holidays. Which way we start out 2017 will largely depend on whether we see an immediate pick up in M&A activity or not.

Performance Update:

The **iShares Nasdaq Biotechnology ETF (NASDAQ:IBB)**, the largest ETF focused on the biotech sector, is now down 20.68% since we launched the Biotech Gems service at the start of May of 2015.

Our large cap core positions are down 6.29% on average while our small cap portion of our portfolio is now down 6.96% on average, both not including dividends. Using the minimum 50% allocation recommended to our core positions, this gives us a blended loss of 6.63%, 1,405 basis points above our benchmark. The most conservative allocation of 75% dedicated to the large cap core positions results in a loss of 6.46%, 1,422 basis points above the benchmark.

Portfolio News:

As stated above, large caps improved more than small caps this week. This is not surprising as tax loss selling ebbs. This is also due to the dearth of M&A activity over the holidays, which is a main trigger for the small and mid-cap names in the portfolio. **Celgene (NASDAQ: CELG)** was strong this week as Jefferies became the

latest analyst firm to chime in with a Buy rating last week. **Amgen (NASDAQ: AMGN)** also had a nice rise this week. **Gilead Sciences (NASDAQ: GILD)** posted an up week as well despite a litigation setback in its long running battle with **Merck (NYSE: MRK)**.

Among our small caps, **Amicus Therapeutics (NASDAQ: FOLD)**, continued its recent decline after announcing it was raising some \$225 million in convertible debt. Earlier this month, the FDA decided not to provide accelerated approval for galafold, even as the drug was approved in Europe for the second quarter, pushing the shares further into decline for the week.

However, one can make the case that the company is undervalued just for galafold's long-term sales potential in Europe. In addition, two other compounds are in late-stage development, and we will get a key trial readout on one of those in the next few weeks. Because of this, we are holding on to our shares.

Lexicon Pharmaceuticals (NASDAQ: LXRX) rose some 10% on the week. The shares have been buoyed by a couple of Buy ratings in December.

*As mentioned in the earlier section, we will be closing out position in **Ardelyx (NASDAQ:ARDX)**. Effective after this issue, Ardelyx will now be found in the 'Closed Positions' section and will no longer be covered in any updates.*

Current Portfolio

Company	Entry Date	Entry Price	Recent Price	Buy Up To	Returns
Recro Pharmaceuticals (REPH)	12/16/16	\$7.15	\$7.15	\$8.00	N/A
Trevana Inc. (TRVN)	11/21/16	\$6.48	\$5.90	\$7.25	-9.0%
Vascular Biogenics (VBLT)	10/17/16	\$4.95	\$4.65	\$6.00	-6.1%
Egalet Corporation (EGLT)	09/16/16	\$7.13	\$8.30	\$8.50	16.4%
Amicus Therapeutics (FOLD)	08/15/16	\$7.15	\$4.90	\$8.00	-31.5%
Progenics Pharmaceuticals (PGNX)	07/07/16	\$5.44	\$8.94	\$6.25	64.3%
Supernus (SUPN)	06/13/16	\$18.70	\$25.65	\$21.50	37.2%
Artana Therapeutics (PETX)	05/12/16	\$5.49	\$7.64	\$12.00	39.2%
Celgene (CELG) - Core	03/31/16	\$100.09	\$115.73	\$110.00	15.6%
Merrimack Pharmaceuticals (MACK)	03/07/16	\$7.49	\$5.35	\$8.00	-28.6%
Eagle Pharmaceuticals (EGRX)	02/16/16	\$56.54	\$75.46	\$65.00	33.5%
TG Therapeutics (TGTX)	01/13/16	\$8.47	\$4.75	\$11.00	-43.9%
Xencor Inc. (XNCR)	10/07/15	\$12.49	\$26.76	\$15.00	114.3%
AbbVie (ABBV) - Core	09/28/15	\$52.50	\$62.22	\$62.50	18.5%
Lexicon Pharmaceuticals (LXRX)	08/24/15	\$11.33	\$16.37	\$12.50	44.5%
Mylan (MYL) - Core	08/10/15	\$57.52	\$37.49	\$60.00	-34.8%
TRACON Pharmaceuticals (TCON)	08/10/15	\$11.40	\$5.00	\$13.00	-56.1%
Amgen (AMGN) - Core	07/07/15	\$155.39	\$147.74	\$160.00	-4.9%
Synergy Pharmaceuticals (SGYP)	06/05/15	\$4.90	\$5.20	\$5.50	6.1%
Gilead Sciences (GILD) - Core	05/08/15	\$103.85	\$74.40	\$115.00	-28.4%

**Recent price is determined by the last "Close" price at the closing of the market on the day before publication; most recent update: 12/19/16.

Closed Positions

Company	Entry Date	Entry Price	Close Price	Returns	Close Date
Ardelyx (ARDX)	04/20/16	\$8.05	\$14.30	77.6%	12/16/16
Synthetic Biologics (SYN)	09/10/15	\$2.44	\$0.88	-63.9%	11/21/16
pSivida Corporation (PSDV)	06/22/15	\$4.03	\$2.28	-43.4%	10/17/16
Novavax (NVAX)	07/22/16	\$7.35	\$1.29	-82.4%	09/16/16
Inovio Pharmaceuticals (INO)	05/08/15	\$8.01	\$20.60	10.9%	08/15/16
Relypsa (RLYP)	11/13/15	\$18.96	\$32.07	69.1%	07/22/16
Celsion Corporation (CLSN)	07/21/15	\$2.45	\$1.30	-46.9%	07/07/16
XOMA Corporation	06/22/15	\$4.28	\$0.63	-85.3%	06/13/16
Pernix Therapeutics Holdings (PTX)	07/07/15	\$5.63	\$0.53	-90.6%	05/05/16
Pacific Biosciences of Calif. (PACB)	05/08/15	\$6.09	\$9.07	48.9%	04/20/16
Biogen Idec (BIIB)	10/23/15	\$276.99	\$260.32	-6.0%	03/31/16
Horizon Pharma (HZNP)	09/10/15	\$28.58	\$17.33	-39.4%	03/07/16
Heat Biologics (HTBX)	06/05/15	\$6.51	\$0.94	-85.6%	03/07/16
Protalix BioTherapeutics (PLX)	05/08/15	\$2.17	\$0.86	-60.4%	02/16/16

Notes:

Positions designated as “Core” represent the large-cap stocks in the portfolio that should make up 50% to 75% of an investors biotech portfolio depending on each subscriber's individual risk profile.

Entry price is determined by the last "Close" price at the closing of the market on the day before publication, which also serves as the Entry Date. Buy Up To is the upper share price limited recommended for buying new shares. Returns data is share price appreciation or depreciation between entry price and recent price.

This is not real-time data and should not be interpreted as such. All data is subject to change without notice.

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