Investors Alley
Biotech Gems

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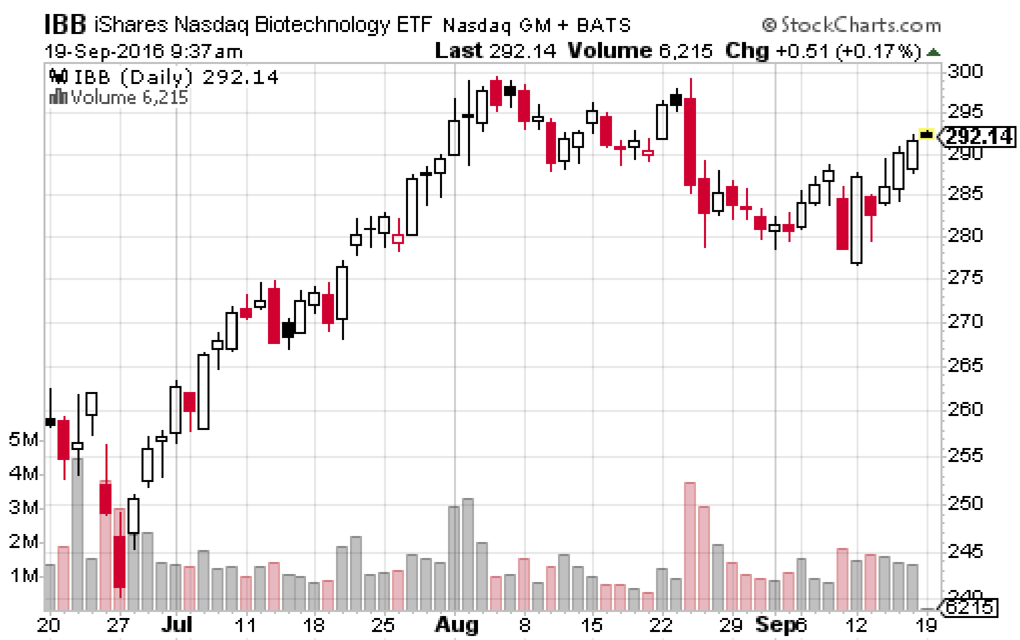
Biotech Sector Still Full of Potential

After a huge rally in July, biotech drifted down throughout August and into the early part of September. Some consolidation had to be expected after the explosive gains the sector had in July. Still, sentiment on the sector is on a much more positive stance than when the biotech indices hit their recent bear market lows in the first quarter of this year. In addition, the sector easily outperformed the S&P 500 despite the recent uptick in volatility in the market las week. Biotech is up some 20% from its bear market bottom and the sector has traded in a relatively narrow trading range since its big uptick in July.

In This Issue

Although M&A deal volume in biotech is down more than 50% from the same level a year ago, activity has picked up some as of late. Drug giant **Pfizer (NYSE: PFE)** has been particularly active since the U.S. Treasury Department derailed it's proposed merger with Irish based **Allergan (NYSE: AGN)** valued at over $150 billion. Since then, Pfizer has made several purchases worth over $20 billion culminating by outbidding French drug giant **Sanofi (NYSE: SNY)** last month for **Medivation (NASDAQ: MDVN)** for just north of $14 billion. Now that Allergan's over $40 billion sale



of its generic business to **Teva Pharmaceuticals (NASDAQ: TEVA)** has been completed, I expect it to go on the hunt for additional acquisitions. Management there has stated it is looking to do several "bolt on" purchases in four disease areas it wants to expand into which includes the gastrointestinal space. The company purchased **Vitae Pharmaceuticals (NASDAQ: VTAE)** for over a 150% premium last week to further expand into the dermatology space.

Mylan was the latest large drug giant hauled up before the Senate subcommittee around concerns around drug pricing. **Valeant Pharmaceuticals (NYSE: VRX)** has become the poster child for this political focus area before the fast approaching election. Mylan's stock price held up well and the event did not receive the media coverage I thought it might. Maybe this means we are near the end of when this will be a major overhang on the pharma and biotech sectors.

The election has noticeably tightened in recent weeks. Mrs. Clinton still holds a significant advantage in locking up the electoral college while Mr. Trump has come back recently and has even led in a couple of national polls. Key Senate Republicans in tight races are running ahead of Mr. Trump in their states. Two months is a lifetime in politics but as of now, it is hard to see the Republicans having any way of losing the House of Representatives this cycle. They also currently look like they have at least 50/50 chance to retain the Senate. The most likely outcome to the November decision looks like continued divided government. This means little likelihood that there will be any major legislative change on biotech and pharma regulation when the new government is seated in January.

If this continues to be the case, I would not be surprised if these sectors behave positively into nationwide voting. Large biotech concerns are one of the few areas of the market that are seeing solid earnings and revenue growth right now despite the challenging global environment. Collectively, they are selling at some of their lowest valuations in many years. I would not be surprised if these names are strong performers in 2017 compared to the overall market. Something definitely worth looking for to in the coming months.

Happy Hunting,

Bret Jensen
Editor
Biotech Gems

Egalet: Developing a Safer Painkiller

In this month's edition of Biotech Gems we are replacing **Novavax (NASDAQ: NVAX)** in the portfolio for obvious reasons**.** With the stock trading near the cash on the balance sheet and a couple of other early and mid-stage vaccines in its pipeline, I am going to hold my shares for now. The company is meeting with analysts and shareholders on October 11th. I am hoping once they have had a few weeks to digest this unexpected news, they can lay out a credible way forward and the stock might get a bit of bounce if they do. However, a more promising opportunity with much shorter-term catalysts and a better risk/reward profile is now available and will be taking Novavax's place in our model 20 stock portfolio.

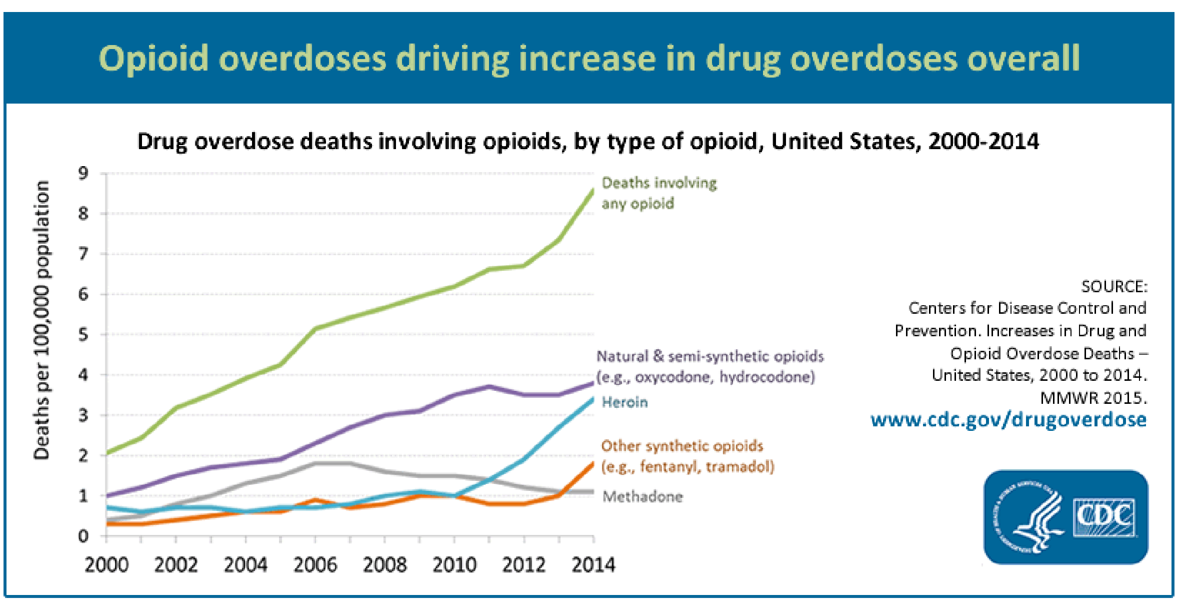
Company Overview:

Egalet Corporation (NASDAQ: EGLT) is a pharmaceutical company specializing in pain treatments that deter physical abuse and chemical manipulation. The company was founded in 2010 and came public early in 2014. The stock currently has a market capitalization of approximately $175 million and is currently selling at just over $7 a share currently.

Egalet is taking advantage of an intriguing opportunity to enter existing markets by providing abuse-deterrent formulations of a couple of the most effective pain relief medications on the market today (MS Contin and IR Morphine). By addressing a 2011 call to action from the FDA, the company is also tapping into a significant need for treatment options that help deter potential abuse, while also satisfying existing market demands for effective pain relievers. Opioid addiction and deaths from overdoses have exploded in recent years and have even become a campaign issue in many states.

On August 4, 2016, an FDA advisory panel gave ARYMO ER impressive support to be labeled as an abuse-deterrent product. ARYMO ER was developed using Egalet's proprietary Guardian™ Technology for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate

To be more specific the Ad Comm panel recommended ARYMO ER for approval by an 18 to 1 vote. The panel also voted that the drug be recommended with the important "abuse-deterrent" in a 16 to 3 vote for oral ingestion. The panel did same for the nasal & IV paths



by an 18 to 1 vote. With this positive sign still fresh in the rear view mirror and with a PDUFA date for ARYMO ER coming up on October 14, 2016, Egalet is ripe for a closer look.

Pipeline:

Egalet has two pain products on the market today which are bringing in increasing amounts of revenue. SPRIX Nasal Spray is a non-steroidal anti-inflammatory drug for adults with short-term pain. OXAYDO (launched in September 2015) is an immediate-release oxycodone product designed to discourage abuse via snorting for patients that require daily or extended use for chronic-moderate to chronic severe pain.

Additionally, Egalet has two late stage candidates that leverage a proprietary technology, Guardian™, to prevent abuse of its products. Abusers swallow, snort, smoke, or dissolve medications in liquid in order to inject it for a more immediate effect. Tablets produced using Egalet's Guardian Technology have physical and chemical properties that are intended to minimize the potential for these forms of abuse. ARYMO ER is an abuse-deterrent formulation of morphine, and Egalet-002, which is currently in Phase III trials, is an abuse-deterrent formulation of oxycodone.

__Late Stage Therapies__

ARYMO ER

What it Does: ARYMO ER is an abuse-deterrent morphine sulfate compound for the management of pain severe enough to require daily long-term treatment.

Key Differentiator(s):

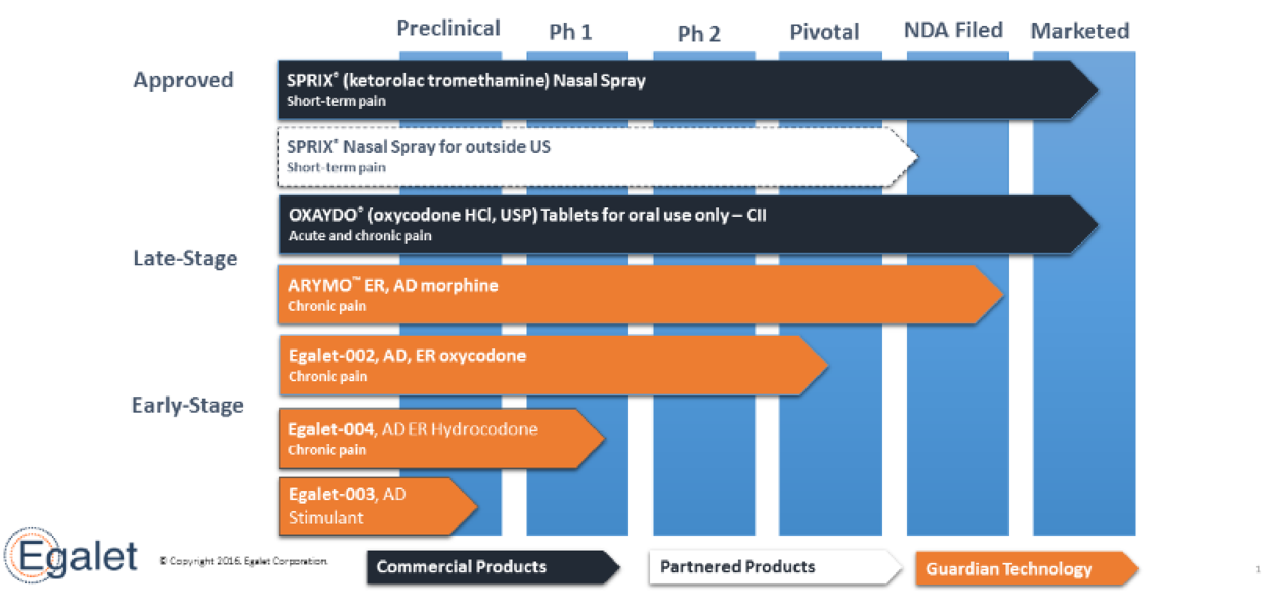
A convenient extended-release oral formulation

A safer, abuse-resistant improvement over existing products

Able to reuse existing sales force which is already actively promoting other current products to 11,500 physicians

Phase / Status / Expected Launch: PDUFA date is October 14, 2016, if approved, the company plans to begin actively promoting ARYMO in early Q1 of next year.

Expected Market: In 2013, 259 million Opioid analgesics prescriptions were written and more specifically, in 2015, 6.4 million extended-release morphine prescriptions were written.



AD = abuse-deterrent; ER = extended release.

*Management of pain severe enough to require around-the-clock opioid treatment and for which alternative treatments are inadequate.

Other Considerations:

The August 4 FDA advisory panel approval to label ARYMO ER as an abuse-deterrent product is based on trial results where Egalet compared ARYMO ER with market leaders MS Contin and IR Morphine and showed that in comparison, ARYMO ER was more tamper proof, had lower likeability (a key indicator of the potential for abuse), and had lower pharmacokinetic evaluation scores (longer lasting drug effects with lower potential for abuse).

Approval increases the likelihood of the potential for a possible buyout, specifically by the existing drug companies that would be threatened by this new product.

A competitor REMOXY is seeking approval on September 25th, but flaws in the design of this candidate's trial has been mentioned in recent coverage.

EGALET 002

What it Does: Like ARYMO, it is an abuse-deterrent, extended-release, oral formulation of an existing pain therapy (oxycodone).

Key Differentiator(s): It is a safer, abuse resistant improvement over existing products.

Phase / Status / Expected Launch: In Phase III trials, with the potential to file an NDA late in 2016 or early 2017.

Expected Market: Since its introduction in 1996, Purdue has earned more than $31 billion from OxyContin (its version of Oxycodone)

Early Stage Therapies

Egalet's future growth plans are focused on developing different classes of pharmaceutical products on the Guardian™ Technology abuse-deterrent platform. These include Egalet-004, an abuse-deterrent version of hydrocodone, and Egalet-003, an abuse-deterrent stimulant.

Balance Sheet:

As of June 30, 2016 the company had cash and marketable securities totaling $103.7 million. The company also reported strong improvement in product sales, increasing revenue to $3.5 million for the quarter ended June 30, 2016 compared to $959,000 for the same period in the prior year.

Egalet burned through some $24 million in the quarter as it ramped up its sales force and R&D expenses rose to support two late stage drug candidates. The company has enough cash on hand to continue to fund its pipeline into the commercialization stage of ARYMO ER next month. It also has a loan agreement/facility with Hercules in place.

Outlook:

One investment analyst recently expressed support for the stock indicating, "Now that we know ARYMO ER is almost assuredly going to be approved by the FDA, I believe Egalet Corporation's current market valuation of $200 million is very undervalued."

Cantor Fitzgerald analyst reiterated a Buy rating on Egalet on August 4th with a price target of $21. "We believe that Arymo is a superior product to Pfizer's Embeda, which does some 9,000 scripts per month."

Beyond its existing product sales and collaboration/expansion plans with Acura Pharmaceuticals, Inc. to commercialize OXAYDO tablets internationally, Egalet's future is focused on desired products in already strong markets. All the signs are so far positive that their upcoming PDUFA date will result in approval. Should the product be approved, the company may be well positioned to sell Doctors (through existing relationships) on the merits of prescribing the abuse-deterrent version of Morphine. FDA approval of this product should therefore either result in significant sales revenue or a possible takeover by existing product owners who will see these developments as a threat, and either way it is likely going to be good for investors in Egalet.

Before the bear market hit the biotech and biopharma sectors last summer, the shares of Egalet sold for north of $15.00 a share. If sentiment continues to improve on the sector, ARYMO ER is approved by the FDA as expected, and commercialization efforts go smoothly I believe the stock can claw its way back up to those levels over the next 12-24 months, a more than solid return scenario.

Recommendation: Buy EGLT up to $8.50 a share.

Position: Long EGLT

Portfolio News

"Show me someone who has done something worthwhile, and I'll show you someone who has overcome adversity." – Lou Holtz

After drifting down for the month of August and digesting its huge gains in July, biotech has perked up a bit here in September. The sector easily outperformed the S&P 500 last week and is back to trading near the top of a range it has been in over the past two months or so. M&A activity seems to be picking up especially in the small cap part of the sector with **Allergan (NYSE: AGN)** making a small purchase with a huge premium to expand its offerings in dermatology.

In addition, the upcoming election should result in some clarity as well as a continued divided government in the most likely scenario. Most of the rhetoric around drug price "gouging" should go away as the parties shift away from political sound bites and work on areas where they might get something done like an infrastructure bill to repair roads and bridges. Both developments should be good for the biotech and pharma sectors.

Performance Update:

Our benchmark the **iShares Nasdaq Biotechnology ETF (NASDAQ:IBB)**, the largest ETF focused on the biotech sector with almost $9 billion in assets, is now down 15.22% since we launched the Biotech Gems service in May 2015.

Our large cap core positions are down 2.87% on average while our small cap portion of our portfolio has shown marked improvement and is now down 6.60% on average, both not including dividends. Using the minimum 50% allocation recommended to our core positions gives us a blended loss of 4.74%, 1,048 basis points above our benchmark. The most conservative allocation of 75% dedicated to the large cap core positions results in a loss of 3.80%, 1,142 basis points above the benchmark.

Portfolio News:

Novavax (NASDAQ: NVAX) put a real damper on the week. As we put out in a special bulletin late in the week, the stock plunged on very disappointing Phase III trial results from its key RSV vaccine. This caught not only investors by surprise but also analysts who held the company in nearly universal esteem prior to the news. It also seemed to catch management completely by surprise as they were already starting to ramp up hiring and other activities in anticipation of good results, eventual approval and commercialization of this much needed biologic.

The news from Novavax overshadowed what was a very good week for the majority of the small cap holdings within the Biotech Gems portfolio. **Synergy Pharmaceuticals (NASDAQ: SGYP)** had a nice run up last week as Citigroup speculated the name could make a logical buyout target for Takeda Pharmaceuticals. Also up between 10% and 20% on the week were **Ardelyx (NASDAQ: ARDX), Amicus Therapeutics (NASDAQ: FOLD), Supernus Pharmaceuticals (NASDAQ: SUPN), TG Therapeutics (NASDAQ: TGTX)** and **Xencor (NASDAQ: XNCR). Mylan (NYSE: MYL)** also performed much better last week after appearing before the Senate subcommittee the week before around pricing on its EpiPen product.

Current Portfolio

Company	Entry Date	Entry Price	Recent Price	Buy Up To	Returns
Egalet Corportation (EGLT)	09/16/16	$7.13	$7.13	$8.50	N/A
Amicus Therapeutics (FOLD)	08/15/16	$7.15	$7.28	$8.00	1.8%
Progenics Pharmaceuticals (PGNX)	07/07/16	$5.44	$6.10	$6.25	12.1%
Supernus (SUPN)	06/13/16	$18.70	$25.09	$21.50	34.2%
Artana Therapeutics (PETX)	05/12/16	$5.49	$9.19	$12.00	67.4%
Ardelyx (ARDX)	04/20/16	$8.05	$11.20	$9.50	39.1%
Celgene (CELG) - Core	03/31/16	$100.09	$108.54	$110.00	8.4%
Merrimack Pharmaceuticals (MACK)	03/07/16	$7.49	$4.69	$8.00	-37.4%
Eagle Pharmaceuticals (EGRX)	02/16/16	$56.54	$60.95	$65.00	7.8%
TG Therapeutics (TGTX)	01/13/16	$8.47	$7.29	$11.00	-13.9%
Xencor Inc. (XNCR)	10/07/15	$12.49	$24.63	$15.00	97.2%
AbbVie (ABBV) - Core	09/28/15	$52.50	$63.27	$62.50	20.5%
Synthetic Biologics (SYN)	09/10/15	$2.44	$1.75	$2.75	-28.3%
Lexicon Pharmaceuticals (LXRX)	08/24/15	$11.33	$18.90	$12.50	66.8%
Mylan (MYL) - Core	08/10/15	$57.52	$41.79	$60.00	-27.3%
TRACON Pharmaceuticals (TCON)	08/10/15	$11.40	$5.65	$13.00	-50.4%
Amgen (AMGN) - Core	07/07/15	$155.39	$172.96	$160.00	11.3%
pSivida Corporation (PSDV)	06/22/15	$4.03	$3.55	$4.50	-11.9%
Synergy Pharmaceuticals (SGYP)	06/05/15	$4.90	$5.56	$5.50	13.5%
Gilead Sciences (GILD) - Core	05/08/15	$103.85	$78.80	$115.00	-24.1%

**Recent price is determined by the last "Close" price at the closing of the market on the day before publication; most recent update: 09/16/16.

Closed Positions

Company	Entry Date	Entry Price	Close Price	Returns	Close Date
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.