

Medical Technology Stock Letter



This Issue: ***Review: ASH & SABC***

Issue No. 670

December 17, 2009



Pulse of the Market by Jim McCamant

***Three-week break ahead!
Next issue will be published
January 7, 2010.***

BTK: 894.24, NBI: 806.25

Over the last two weeks, the broad market has continued its high level consolidation. This type of extended side-ways move usually results in a significant move once the market finally breaks out. We are confident that this consolidation will be resolved by a further move up in the stock market. During the current consolidation period, the economic news has improved, and more importantly, estimates for corporate earnings in 2010 have continued to improve. We have anticipated this as we are more optimistic about the strength of the recovery than the consensus. Adding to our optimism is that some of the stimulus will finally begin to kick in during the first quarter.

Understanding the market is made more complicated by the typical year end cross currents which can be frustrating, but can also provide opportunities. Some of the biotech stocks are clearly being pressured by tax-loss selling, which will end as soon as we get into January. In many years, we have seen some very nice bounces in biotech stocks as we move from the year-end pressure caused by tax-related selling into January. Many investors are willing to take on more risk in the new year as they focus on how to make money again rather than preserving profits, which can lead to stocks appreciating in January. As tax loss selling is usually finished before Christmas, now is the time to be more aggressive and take advantage of any dips in individual stocks.

Biotech Sector Analysis

The BTK and NBI are both down for the two weeks as they broke through support with the biotechs selling off post-ASH and SABC. With the year end cross currents, it felt like the traders dictated the action in many biotech names over the last two weeks. IMGN was particularly frustrating as the data was very good, yet the stock ends up flat for the two weeks.

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As we discussed above in the Pulse, instead of being frustrated, the seemingly irrational pull backs can be viewed as opportunities. We will be taking a look back at 2009 in the next Issue. We want to thank all of our subscribers for continuing to follow us through what has been a very tricky year for investors. And most importantly, we wish all our subscribers a happy holiday season.



Company Updates

FOCUS : ALTH, AMLN, BIIB, CELG, IMGN, INCY, MDCO, SGM0, ONXX.

Allos Allos' stock came out of ASH bruised and beaten as first *The New York Times* slammed them for high pricing and then CELG bought their potential competitor, Gloucester. The Times touched on the 30K monthly price tag for Folutyn despite the fact that it will mostly be used at most for two months leading to an annual price of 60K, certainly within the bounds of recently approved cancer drugs. Then some analysts concluded that CELG bought Gloucester because it has a better drug than ALTH which added to the pressure on the stock price.

Additional analyses from the PROPEL trial, as well as, new data evaluating Folutyn in cancers other than PTCL were presented at American Society of Hematology's 51st Annual Meeting over the weekend. This was complimented by launching a global COMPLETE registry trial at 75 sites and announcing a named patient program in Europe that will make PDX available to patients outside the U.S. beginning in January 2010. Overall, the data were incrementally positive with the most important data being new analyses in patient with highly refractory disease while emphasizing the protocol-specified dose modification to minimize side-effects such as mucositis. More important, is that the venue allowed Allos to build awareness for Folutyn prior to the full launch in late January 2010.

We are certainly disappointed in the stock's price action as we expected ASH to be a positive event for the company. We believe that the current valuation does not reflect the commercial potential of Folutyn or any of its potential in other cancers. The recent weakness also increases the odds that a premium takeover will occur. **ALTH is a buy under \$8.**

Amylin and their partners (Lilly & ALKS) announced positive results from a head-to-head study (DURATION 5) that

compared exenatide once weekly (LAR), to Byetta in patients with type 2 diabetes. After 24 weeks of treatment, patients taking LAR experienced a statistically superior reduction in A1C, a measure of average blood sugar over three months, of 1.6 percentage points from baseline, compared to a reduction of 0.9 percentage points for Byetta. LAR achieved a mean A1C of 7.1 percent compared with a mean A1C of 7.7 percent in those treated with Byetta. Both treatment groups achieved statistically significant weight loss by the end of the study, with an average loss of 5.1 pounds for patients taking LAR and 3.0 pounds for patients taking Byetta. This is very good data and is better than previous LAR data from DURATION 1. Most importantly, this data is better than their main competitor, Novo's Liraglutide. Also important is the fact that they used drug from their new commercial plant which should help make the FDA a little more comfortable with approving LAR. We believe this data cements the filing package for both the FDA and filing in Europe. Others obviously agree with us as Jeffries upgraded the stock after the news with a target price of \$22. **AMLN is a buy under \$12.**

This week, Facet's shareholders rejected **Biogen Idec's** unsolicited tender offer, and BIIB subsequently terminated its tender offer. BIIB has

been very aggressive throughout this process, and we figure they were just trying to steal a company if they could get away with it. Not our favorite corporate strategy, particularly when dealing with a partner, but BIIB basically stole IDEC, so they have a track record of being a horrible partner. Back to the war room for BIIB as they figure out which company they want to alienate next. The company itself remains a takeover target, which if nothing else is ironic. **BIIB is a buy under \$55.**

Today, **Celgene** and the National Cancer Institute announced initial results from the CALGB trial of Revlimid maintenance therapy following autologous stem cell transplant (ASCT). The trial was stopped early after the second interim analysis (28% of events) found Revlimid delayed disease progression. The median time to progression (TTP) post transplant was 778 days (25.5 months) with placebo and has not been reached in Revlimid arm. These data provide increased evidence of the benefit of Revlimid as a maintenance therapy. While the recently released MM-015 trial was controversial because of worse than expected outcome in the MPR (no maintenance) arm, this trial appears much cleaner. These results bode well for another maintenance trial IFM 2005-02 which is expected to report in

1H2010. The above being said, an important question remains as to whether PFS or TTP is an approvable endpoint for the maintenance setting. This data combined with a positive IFM 2005-02 trial would lead to meaningful adoption in the maintenance setting and we are not surprised by the stock's appreciation on this news, with it up over 10% today.

CELG presented the highly anticipated Revlimid trial data from trial 015 for the treatment of multiple myeloma (MM) at ASH met some expectations. Bears are focused on the lackluster performance of Revlimid in the induction phase of treatment. We agree that 10mg of Revlimid is not the best induction, nor will it be the only option for maintenance, but the point of the study was to use low dose Revlimid to demonstrate long term sustained treatment in the maintenance setting. Towards that goal Revlimid:

- Achieved 50% reduction in the risk of disease progression for patients on maintenance dosage.
- Proved tolerable – only 15% of patients dropped off maintenance suggesting long term dosing is achievable.
- The data so far compare favorably to Velcade's VISTA trial; one year survival of 92% for Revlimid is an

improvement to the 88% one-year survival observed for Velcade.

CELG also announced the acquisition of privately-held Gloucester Pharma for up to \$640 million in cash. The key driver is Istodax (romidepsin), a histone deacetylase inhibitor (HDAC), approved in the U.S. in November 2009 for Cutaneous T-cell lymphoma (CTCL) and for which a pivotal Phase 2 trial in peripheral T-cell lymphoma (PTCL) is ongoing.

Celgene will pay \$300 million in cash upfront and expects the deal to close in January 2010. Gloucester share holders will receive \$185 million in cash upon romidepsin's U.S. approval in PTCL and \$125 million upon European approval. Globally the CTCL opportunity is 2,000-3,000 or roughly \$100-200 million. PTCL represents a \$300-400 million global opportunity with roughly 15,000+ patients. We believe this acquisition makes sense for multiple reasons. 1) Istodax is a recently approved agent which will be another product in CELG sales reps' portfolio and help leverage the salesforce. 2) The PTCL opportunity is large enough to support two marketers on a global basis. 3) European orphan drug designation will provide 10 years of exclusivity upon approval. 4) With Istodax revenues ramping up for CTCL and PTCL in 2010/2011 CELG will be better able to manage the 2011

revenue decline when Vidaza's U.S. exclusivity expires.

This week, CELG announced Phase 2 data for apremilast in moderate-to-severe plaque psoriasis. The oral PDE4 inhibitor showed a 35% placebo adjusted PASI 75 score at the highest dose after 16 weeks ($p < 0.001$) with a manageable safety profile. The plaque psoriasis data in the moderate-severe population clearly demonstrate that apremilast has efficacy in this disease. While apremilast's efficacy is not as strong as the more active injectable agents, apremilast has a clear advantage in terms of its oral delivery. From a tolerability standpoint, the GI toxicity appears manageable with an increase in nausea and diarrhea but only a modest increase in discontinuations (14% vs. 6%). We believe this data might bode well for apremilast in the psoriasis market, which has been relatively hesitant to accept the biologics because of the injectable delivery and infection risk. The Phase 3 program is planning to start in 2010, which could lead to data in the 2011/2012 time frame with potential for approval in 2012/2013. While the Celgene story is still primarily based on Revlimid, this compound is getting more interesting as data accumulates demonstrating a favorable efficacy and toxicity profile in large disease areas, such as psoriasis.

CELG has had a very productive two weeks with solid data at ASH, progress with apremilast in psoriasis, and lastly, today's unexpected very good news. We hope subscribers added to or established positions in CELG while it was below the buy limit. **CELG is a buy under \$48.**

ImmunoGen bizarrely released the T-DM1 data mid-day on December 9th during market trading in an 8-K filing. Are you kidding us, this is crazy with the excuse being it was mistakenly included in the SABC book. This was too important a data event to have this kind of premature data release. Nevertheless, the stock moved over \$9 when the 8-K hit the tape and investors read the outstanding 32.7% objective response rate (ORR). Coming into ASH positive expectations were that T-DM1 would at least meet or exceed the previous trial's 25% ORR. The latest ORR was a strong 32.7% and, as importantly, the side effect profile was exceptional, with only 1 patient (1/110 or 0.9%) with pre-existing liver disease experienced a hepatic fatality. Subsequent details over the weekend suggest the true response was even stronger than the top-line ORR - the clinical benefit rate (including stable disease of at least 6 months) was 45%. Most importantly, duration of response and progression-free survival are not yet mature - meaning patients are still

living longer on T-DM1 - and was 7.3 months as of the presentation. Previous PFS in second-line therapy (e.g., Tykerb) has been reported at 6.2 months for their registration trial - suggesting a significantly larger market for T-DM1 than current forecasts. The patients in the IMGN/Roche study had progressing disease despite being treated with an average of seven different drugs (including Herceptin, Tykerb, Xeloda). On the SABC conference call it was not disclosed whether or not Roche will file early next year and this probably has contributed to the weakness in IMGN's stock price post-SABC. We think the most important development from the call was the announcement by Roche that they are starting a single agent T-DM1 trial in adjuvant mBC. We believe that Roche's ultimate goal is to gain approval of T-DM1 for all lines of HER2+ mBC, similar to Herceptin. In summary, T-DM1 is likely to be approved by the end of next year, the market appears larger than expected and represents a major transformative and de-risking event for IMGN.

ASH: IMGN released data on IMGN901 (anti-CD56/DM1) in 26 patients with relapsed/refractory MM, resulting in a 46% overall clinical benefit rate (objective response and stable disease) in a very difficult patient population. Multiple 901 studies are underway in MM (901 plus Revlimid) and CD56+ solid tumors. Ten patients remained on

901 longer than on regimens received earlier in the course of their disease, and eight of these patients were on 901 longer than on their last regimen with approved therapies. This is impressive because typically patients have their best treatment responses early in the course of their disease and respond less well to later therapies.

A Phase 1B trial SAR3419 found that 17 of 27 (63%) patients who were response-evaluable at the time of data cut-off for presentation experienced a reduction in tumor size (7% to 86% reduction). These included 7 of 14 (50%) patients who had disease that was refractory to treatment with Rituxan. SAR3419 is an investigational compound designed to target and kill cancer cells that express the protein, CD19, on their surface. The compound is in development by sanofi-aventis for the treatment of relapsed/refractory CD19-expressing non-Hodgkin's lymphoma and other B-cell malignancies.

Despite a very good two weeks of good to outstanding data, IMGN's stock price remains where we were before the good news. While disappointing short-term, significant progress has been made at IMGN and the value they have created will eventually be reflected in the stock price. The twisted release of the T-DM1 data, a large number of traders in the stock, and finally a weak

market all combined to make for a disappointing week for long-term shareholders of IMGN. That being said, the odds of a premium buy-out have increased given the stock's low price and the company's proprietary antibody platform. **IMGN is a buy under \$8.**

InCyte presented strong data for 424 at ASH and the stock price was basically flat as the Novartis deal made the data presentation less important for investors. In essence, the Novartis deal provided huge validation for the data before it was even presented. The following quote sums up their progress. Srdan Verstovsek, M.D., Ph.D., Associate Professor, Leukemia Department, Myeloproliferative Disorders Program Leader, University of Texas M.D. Anderson Cancer Center, and the principal investigator for the INCB18424 myeloproliferative neoplasms clinical programs, stated, "INCB18424 continues to provide durable and previously unachievable clinical benefits in patients with myelofibrosis with or without JAK2 activating mutations. It is equally gratifying to see significant clinical benefits in patients with advanced polycythemia vera and essential thrombocythemia including normalization of blood counts, normalization of hematocrit without the need for phlebotomy, rapid and durable

reductions in enlarged spleens as well as rapid and durable reductions in symptoms, particularly pruritus."

At SABC, INCY announced positive results from an ongoing Phase 1/2 clinical trial for its selective oral sheddase inhibitor, INCB7839, involving 46 patients with HER2 positive metastatic breast cancer (mBC). The results suggest that, when compared to a historical control study of trastuzumab as monotherapy, INCB7839 in combination with Herceptin provided improvements in time to progression and response rate in patients with HER2 positive mBC. The improved response rate observed in this study are thought to result from an increased response in the p95HER2 positive subpopulation (n=15).

The presence of p95HER2 have been associated with more aggressive disease and poor clinical responses to Herceptin based regimens. These results provide optimism that 7839 in combination with Herceptin will be able to treat the 25-30% of mBC patients of HER2 over-expressing that also expresses p95HER2. By focusing on this specific patient subpopulation, there should be a relatively clean path to potential FDA approval. The company believes that modestly sized trials will be all that is needed to show a clinical benefit. 7839 has been mostly forgotten by INCY investors as it has

been awhile since we had a data update. It looks like 7839 will be a very nice niche drug that may be able to get at 25-30% of the \$4 billion Herceptin market, not too shabby.

We continue to be very impressed with INCY and their execution. The company has really delivered on all fronts during the second half of this year. The stock has held below our buy limit of \$8 for the most part despite the outstanding Novartis deal. This week, the stock finally broke above \$8 when it was upgraded by BofA/Merrill. INCY has numerous catalysts next year, in addition to more partnership announcements. We believe that the company is poised to move higher and are raising our buy limit to \$10. **INCY is now a buy under \$10.**

The Medicines Company announced this week that it is voluntarily recalling eleven lots of Cleviprex injectable emulsion due to the potential presence of visible particulate matter which has been observed in some vials during a routine annual inspection. When present in low numbers as observed, particles of this size are not known to constitute a health hazard. Experimental animal and human data indicate that they are scavenged by macrophages (white blood cells) without adverse effects. That being said, this is not good news, though the

stock price has only sold off a bit. To date, there have been no reports of adverse events and the company is cooperating closely with the FDA.

MDCO is a hold.

Sangamo presented preliminary data from their Phase 2 clinical trial of its ZFP Therapeutic(TM) program to develop SB-509 as a treatment for amyotrophic lateral sclerosis (ALS) at the 20th International Symposium on ALS/MND held in Berlin. The preliminary data were from the first subjects enrolled in the company's Phase 2 clinical trial, SB-509-801, and demonstrate an approximate doubling of frequency of improved muscle function in subjects with ALS who received two treatments of SB-509 (32%) compared to matched historic controls (17%). In early stage ALS clinical trials, an historic control is frequently used rather than a placebo to maximize the number of subjects receiving the drug. While this early data, we are impressed in the improvement which we believe shows that 509 has the potential to re-grow nerves. This is dramatically different from all other previous approaches to treat ALS which at best have been able to slow rate of ALS. We look forward to seeing the final data from this trial next year. 509 has now shown proof of concept in two diseases, diabetic neuropathy and ALS, yet we have a

stock price that has been in decline since hitting \$8 two months ago when they signed the expanded deal with Sigma Aldrich. The stock is very attractive at current levels as SGMO has made substantial progress on all fronts this year. **SGMO is a buy under \$8.**

Onyx Oynx has had a busy two weeks with important data presentations at both ASH and SABC. Carfilzomib data presentations at ASH were strong and support ONXX' decision to buy Proteolix.

- An 18% Overall response rate in patients failing Velcade treatment suggests the drug adds significant benefit to this late stage patient population
- The increase in response rate from 46% to 53% in general late stage multiple myeloma (MM) population when the carfilzomib dose was increased from 20mg to 27mg gives us confidence that the carfilzomib dose can be increased without significant toxicity to achieve optimal response; again the goal is to maintain longer treatment durations at all stages of MM disease.
- Increasing odds of approval as the FDA is more willing to approve access to treatments that demonstrate good tolerability.

• We expect that more tolerable treatments will eventually displace the more toxic agents currently used in the front-line and maintenance settings for MM where drug toxicity could otherwise take away from the response to treatment.

Following up a strong ASH, ONXX presented promising details on two Phase 2 trials testing Nexavar in combination with chemo. The first of these studies evaluated Nexavar in combination with capecitabine and the second study evaluated Nexavar in combination with paclitaxel. Patients receiving capecitabine plus Nexavar had a 74% improvement in progression-free survival (the primary endpoint) as compared to those who received chemotherapy alone. The increase in median PFS of capecitabine plus Nexavar versus capecitabine plus placebo was statistically significant

(median 6.4 months vs. 4.1 months, HR=.576, p=0.0006). In a post-hoc, subgroup analysis of first-line patients, the combination of capecitabine plus Nexavar significantly extended progression-free survival to 7.6 months compared to 4.1 months (HR= 0.498, p=0.0022). In a second post-hoc subgroup analysis of second-line patients, the combination of Nexavar and capecitabine significantly extended progression-free survival 5.7 months compared to 4.1 months (HR=0.652, p=0.0339). ONXX will use this combined data to guide their Phase 3 development program which they expect to start next year, most likely in combination with capecitabine which was the stronger data set.

The company also presented some earlier data testing Nexavar that helped re-sensitize breast cancer to treatment with aromatase inhibitors, drugs given

to post-menopausal women with hormone-sensitive breast cancers. In a trial of 35 post-menopausal women with advanced breast cancer resistant to treatment with aromatase inhibitors 23% of the women in the study had a clinical benefit. It appears that Nexavar somehow circumvents the mechanism used by the cancer to resist the effects of aromatase inhibitors. We are intrigued by the potential for Nexavar to help this patient population. In sum, we are pleased with the data presented by ONXX at both ASH and SABC. For whatever reason, most of Wall Street remains negative on ONXX. We certainly believe in ONXX and Nexavar, and are also impressed with their new pipeline. We continue to believe that patience is required and eventually there will be a large reward for ONXX shareholders. **ONXX is a buy under \$35.**

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"THE BACK PAGE"		PRICE					# of	Mkt.	
Symbol	Company	Orig. Rec.	Lo (52-Week)	Hi	Current	Target	shrs. (m)	Value (\$ mil.)	Recommendation
ALKS	Alkermes	10.13	7.14	13.16	8.83	30	95.0	838.9	BUY under \$6
ALTH	Allos	3.43	5.22	9.30	5.88	15	80.8	475.1	BUY under \$8
AMLN	Amylin	7.88	7.89	15.69	14.70	25	137.3	2,018.3	BUY under \$12
ARQL	Arqule	7.99	2.62	6.38	3.58	12	43.9	157.2	BUY under \$6
BIIB	Biogen Idec	36.04	41.75	55.34	49.45	75	293.9	14,533.4	BUY under \$55
BMRN	BioMarin	12.68	9.93	21.23	17.98	24	99.9	1,796.2	BUY under \$14
CELG	Celgene	49.93	36.90	58.31	50.62	100	468.9	23,735.7	BUY under \$48
ELN	Elan Corp.	20.05	4.61	9.13	6.52	25	474.6	3,094.4	BUY under \$10
GNVC	GenVec	3.93	0.33	1.18	0.92	10	88.4	81.0	BUY under \$1
IMGN	ImmunoGen	4.86	3.82	10.13	7.99	17	50.8	405.9	BUY under \$8
INCY *	Incyte	5.88	1.96	8.64	8.10	20	92.4	748.4	BUY under \$10 *
ISIS	Isis	7.63	9.77	18.81	9.95	30	100.2	997.0	BUY under \$15
MDCO	Medicines Co.	10.50	6.15	16.77	7.84	14	51.9	406.9	HOLD
OGXI	OncoGenex	36.82	2.87	42.99	29.76	75	6.0	179.5	BUY under \$45
ONXX	Onyx	5.97	21.85	37.02	28.37	70	57.2	1,622.8	BUY under \$35
PGNX	Progenix	9.95	3.53	10.81	4.11	20	30.0	123.3	BUY under \$13
SGMO	Sangamo	4.77	2.68	9.39	5.09	20	41.1	209.0	BUY under \$8

THE MODEL PORTFOLIO

Company	Shares Owned	Total Cost	Today's Value
Alkermes	770	8,401	6,799
Allos	835	3,189	4,910
Amylin	510	1,595	7,497
Biogen Idec	500	18,044	24,725
BioMarin	2,000	24,540	35,960
Celgene	750	37,822	37,965
Elan	3,000	60,752	19,560
GenVec	4,010	7,533	3,674
ImmunoGen	7,000	34,784	55,930
Incyte	4,125	27,590	33,413
Isis	5,000	45,151	49,750
Medicines Co.	700	13,922	5,488
OncoGenex	1,000	37,188	29,760
Onyx	1,500	42,999	42,555
Sangamo	5,000	23,250	25,450

17-Dec-09	Equities	\$383,435
	Cash	\$1,102
	Portfolio Value	\$384,537

THE TRADER'S PORTFOLIO

Company	Shares Owned	Total Cost	Today's Value
<i>LONG positions</i>			
Allos	758	4,859	4,454
Amylin	938	28,179	13,781
ArQule	563	4,540	2,014
Biogen Idec	188	7,067	9,272
BioMarin	2,000	24,540	35,960
Celgene	563	28,367	28,474
Elan	1,500	30,376	9,780
GenVec	2,923	5,132	2,678
ImmunoGen	1,875	9,318	14,981
Incyte	2,278	13,955	18,448
Isis	2,625	32,443	26,119
Medicines Co.	758	17,062	5,939
OncoGenex	1,500	55,819	44,640
Onyx	750	19,741	21,278
Sangamo	5,000	23,250	25,450

Position total	\$263,266
Margin	-\$133,174
Portfolio Value	\$130,092

BENCHMARKS

	NASDAQ	S&P500	Model	Trader's
Last 2 weeks	0.3%	-0.3%	-3.9%	-9.0%
2009 year to date	38.2%	21.3%	5.3%	-20.2%
Calendar Year 2008	-40.5%	-38.5%	-36.4%	-63.9%
Calendar Year 2007	9.8%	3.5%	-14.9%	-27.6%
Calendar Year 2006	9.5%	13.6%	0.4%	-0.7%

THE MEDICAL TECHNOLOGY STOCK LETTER

John McCamant, Editor
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MODEL PORTFOLIO: The Model Portfolio is designed to reflect specific recommendations. We began the Model Portfolio on 12/23/83 with \$100,000. On 4/13/84, we became fully invested. All profits are reinvested. Stocks recommended since then may be equally attractive, but may not be in the Model Portfolio. Transactions and positions are valued at closing prices. No dividends are created, and a 1% commission is charged. We don't use margin. Interest income is credited only on large cash balances.

TRADER'S PORTFOLIO: The Trader's Portfolio joined the Model Portfolio on 1/6/05 with \$500,000 and is designed to take advantage of short-term opportunities throughout the biotech sector. The Trader's Portfolio will hold both long and short positions in stocks, trade in options, and use margin. These strategies increase risk. Although there is no limit on the time any purchase can be held, the timeframe for most investments will be weeks to months.

NEW MONEY BUYS (when under our buy limit)

1st tier: AMLN, BIIB, BMRN, CELG, ELN, ONXX
 2nd tier: ALTH, INCY, ISIS
 3rd tier: IMGN, OGXI, SGMO

* Changed recommendation