

MidnightTrader Event Window: FDA Announcements

Historical Event Reaction Summary

| Event Date | Time | Price | Price Change | Percent Change |
|------------------------------|---------|-------|--------------|----------------|
| Aug 22, 2007 | 6:24 PM | 11.63 | -1.65 | -12.42 |
| Aug 22, 2007 | 9:00 AM | | | |
| Aug 22, 2007 | 8:17 AM | 38.55 | +0.20 | +0.5 |
| Aug 22, 2007 | 7:07 AM | 1.36 | 0 | 0 |
| Aug 21, 2007 | 5:34 PM | 10.34 | +0.47 | +4.8 |
| Aug 21, 2007 | 4:39 PM | 52.01 | -0.85 | -1.61 |
| Aug 21, 2007 | 9:06 AM | 29.80 | 0 | 0 |
| Aug 21, 2007 | 7:58 AM | 47.42 | 0 | 0 |
| Aug 20, 2007 | 9:03 AM | 52.07 | -0.59 | -1.1 |
| Aug 20, 2007 | 8:49 AM | 6.91 | 0 | 0 |
| Aug 20, 2007 | 8:05 AM | 73.41 | 0 | 0 |
| Aug 17, 2007 | 9:02 AM | | | |
| Aug 17, 2007 | 8:03 AM | 6.45 | -0.30 | -4.4 |
| Aug 17, 2007 | 6:36 AM | 5.19 | 0 | 0 |
| Aug 16, 2007 | 6:24 PM | 30.73 | -0.11 | -0.36 |
| Aug 16, 2007 | 9:08 AM | | | |
| Aug 16, 2007 | 8:19 AM | 2.50 | +0.25 | +11.11 |
| Aug 16, 2007 | 7:09 AM | 0.39 | 0 | 0 |
| Aug 15, 2007 | 7:15 AM | 74.03 | 0 | 0 |
| Aug 14, 2007 | 5:19 PM | 50.57 | +0.01 | +0.02 |
| Aug 14, 2007 | 7:33 AM | 5.58 | 0 | 0 |
| Aug 10, 2007 | 8:59 AM | | | |
| Aug 10, 2007 | 8:37 AM | 47.70 | -1.88 | -3.79 |
| Aug 10, 2007 | 8:09 AM | 24.16 | 0 | 0 |
| Aug 10, 2007 | 7:40 AM | 14.00 | 0 | 0 |
| Aug 10, 2007 | 6:46 AM | 54.91 | 0 | 0 |
| Aug 9, 2007 | 6:50 AM | 4 | 0 | 0 |
| Aug 8, 2007 | 9:30 AM | 2.91 | -0.05 | -1.69 |
| Aug 8, 2007 | 7:37 AM | 18.63 | 0 | 0 |

Extended-Hours:ZymoGenetics Slides, FDA rThrombin Review Completion Delayed 3 Months Until Jan. 17

6:24 PM, Aug 22, 2007

ZymoGenetics (ZGEN) says in a SEC filing the FDA considers the submission of additional manufacturing related information as a major amendment to the rThrombin Biologics License Application. Accordingly, the goal date for completion of FDA review under the Prescription Drug User Fee Act has been extended by three months, from October 18 to January 17, 2008.

Additionally, ZGEN says a \$40 million milestone payment due from Bayer Healthcare upon approval of rThrombin by the FDA is now expected to be received in Q108. The delay will reduce the amount of revenue recorded under the Bayer Healthcare license agreement in 2007 from \$5 - 8 million, as previously guided, to approximately \$3 million. It also says there will be no revenues from sale of rThrombin until 2008 now and approximately \$8 million of costs related to rThrombin commercial drug supply, previously assumed to be recorded as inventory, are now expected to be expensed to research and development in Q407.

Company: ZymoGenetics

Price: 11.63 Price Change: -1.65 Percent Change: -12.42

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Regular-Session:Stocks Seen Buoyed at Open by M&A Activity

9:00 AM, Aug 22, 2007

U.S. PRE-MARKET INDICATORS

-Dow Industrial futures Up 78 points at 13,195

-S&P 500 futures Up 10.7 points at 1461

-Nasdaq futures Up 10.75 points at 1930.50.

-Nasdaq-100 Pre-Market Indicator Up 11.34 at 1922.33

GLOBAL SENTIMENT

Hang Seng up 2.84%

Nikkei flat

FTSE Up 1.3%

PRE-MARKET SECTOR WATCH

(+) Large cap tech stocks: up

(+) Chip stocks: flat to higher

(+) Software stocks: flat to higher

(-,+) Small cap stocks: mixed

(+) Drug stocks: flat to higher

(+) Internet stocks: higher

UPSIDE MOVERS

(+)ETFC and AMTD each gain on a report the companies are discussing a merger.

(+)NMX rallies on confirmation it has held merger talks but did not specify with whom. It also says it may implement a cost savings plan that would include layoffs and possibly selling its headquarters.

(+)MGM jumps on a \$5 billion investment with Dubai World.

(+)BRLC is up on a report Teco Electric & Machinery may be interested in investing in the company.

(+)SPWR is up after it says it expects to have enough silicon for solar cell production in 2008.

(+)BYI holds steep gains made late Tuesday on bullish FY07 and FY08 guidance and an analyst upgrade this morning.

(+)BCSI jumps on better-than-expected Q1 results and guidance.

(+)TECD rises on stronger-than-expected Q2 results and forecasts for Q3 sales to top estimates.

(+)HNAB soars on FDA fast track status for Marqibo for leukemia.

(+)TOL rises after beating Q3 estimates.

(+)DRYS holds gains made late Tuesday on better-than-expected Q2 results and upbeat comments.

(+)QTWW jumps on a deal with FRPT.

(+)BTJ rises on better-than-expected Q4 results.

(+)NBIX holds gains made late Tuesday when it said the FDA named December 12 as an action date for Indiplon.

(+)CTIC rises after a subsidiary, Systems Medicine, enters a cancer research pact with the NCI/NIH.

DOWNSIDE MOVERS

(-)LEND slips after it says it will restructure. The restructuring will include layoffs, closing branches and not taking loan applications.

(-)ABIX tumbles after it said late Tuesday it intends to voluntarily delist from Nasdaq and terminate SEC reporting.

(-)EFUT holds losses made late Tuesday when it reported a 1H net loss despite higher sales from a year ago.

MARKET DIRECTION

Stocks are expected to open higher, lifted by some mergers and acquisitions news. E*Trade (ETFC) and TD Ameritrade (AMTD) each gain on a report the companies are discussing a merger. Nymex (NMX) rallies on confirmation it has held merger talks but did not specify with whom. It also says it may implement a cost savings plan that would include layoffs and possibly selling its headquarters. MGM Mirage (MGM) jumps on a \$5 billion investment with Dubai World. Syntax-Brilliant (BRLC) is up on a report Teco Electric & Machinery may be interested in investing in the company.

Other gainers include SunPower (SPWR), which is up after it says it expects to have enough silicon for solar cell production in 2008. Bally Technologies (BYI) holds steep gains made late Tuesday on bullish FY07 and FY08 guidance and an analyst upgrade this morning. Blue Coat Systems (BCSI) jumps on better-than-expected Q1 results and guidance. Tech Data (TECD) rises on stronger-than-expected Q2 results and forecasts for Q3 sales to top estimates. Hana Biosciences (HNAB) soars on FDA fast track status for Marqibo for leukemia. Toll Brothers (TOL) rises after beating Q3 estimates. DryShips (DRYS) holds gains made late Tuesday on better-than-expected Q2 results and upbeat comments. Quantum Fuel Systems (QTWW) jumps on a deal with Force Protection (FRPT). Bolt Technology (BTJ) rises on better-than-expected Q4 results. Neurocrine (NBIX) holds gains made late Tuesday when it said the FDA named December 12 as an action date for Indiplon. Cell Therapeutics (CTIC) rises after a

subsidiary, Systems Medicine, enters a cancer research pact with the NCI/NIH.

Decliners include Accredited (LEND), which slides after it says it will restructure. The restructuring will include layoffs, closing branches and not taking loan applications. Abatix (ABIX) tumbles after it said late Tuesday it intends to voluntarily delist from Nasdaq and terminate SEC reporting. e-Future (EFUT) holds losses made late Tuesday when it reported a 1H net loss despite higher sales from a year ago.

Later today, investors will see weekly crude inventories data. However, with all that is going in credit markets, investors will be looking more towards any company news that might offer hints as to the health of that market, instead.

In earnings, Intuit (INTU), JDSU (JDSU), Abercrombie & Fitch (ANF), Synopsys (SNPS), Books-A-Million (BAMM), Limited (LTD), Men's Wearhouse (MW), Gymboree (GYMB), Zumiez (ZUMZ), Hot Topic (HOTT), Tandy Brands (TBAC), AFC Enterprises (AFCE), Foot Locker (FL), Phillips-Van Heusen (PVH), ValueVision (VVTV), WCI Communities (WCI), XETA Technologies (XETA), Astro-Med (ALOT) and Urologix (ULGX) are among those slated to report.

Company:

Price: Price Change: Percent Change:

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Regular-Session:--GE's Healthcare Unit Gets FDA Approval for Mobile Mammography System

8:17 AM, Aug 22, 2007

Company: General Electric

Price: 38.55 Price Change: +0.20 Percent Change: +0.5

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Regular-Session:Hana Biosciences Gets FDA Fast Track Status for Marqibo for Relapsed Acute Lymphoblastic Leukemia

7:07 AM, Aug 22, 2007

No bid/ask action yet, but issue is likely to generate some volume interest later in the pre-market.

Company: Hana Biosciences

Price: 1.36 Price Change: 0 Percent Change: 0

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Extended-Hours:Neurocrine Firm - Says FDA Sets December Action Date for Indiplon Capsules

5:34 PM, Aug 21, 2007

Neurocrine Biosciences (NBIX) has received notification today that the U.S. FDA has accepted the company's resubmission of its New Drug Application (NDA) for indiplon 5 mg and 10 mg capsules for the treatment of insomnia and has set a PDUFA action date of December 12, 2007.

Company: Neurocrine Biosciences, Inc.

Price: 10.34 Price Change: +0.47 Percent Change: +4.8

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Extended-Hours:--Medtronic Says FDA Panel to Review Endeavor Drug Eluting Stent in October

4:39 PM, Aug 21, 2007

Company: Medtronic

Price: 52.01 Price Change: -0.85 Percent Change: -1.61

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Regular-Session:--Watson Gets FDA Approval For Generic Duragesic - Bid/Ask at 28.75-33.15

9:06 AM, Aug 21, 2007

Company: Watson Pharmaceuticals

Price: 29.80 Price Change: 0 Percent Change: 0

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Regular-Session:DJO Gets FDA Market Approval - Pre-Market Bid/Ask Gap Wide

7:58 AM, Aug 21, 2007

DJO (DJO) today announced that it has received FDA approval for a supplement to the company's existing Pre-Market Approval (PMA).

The PMA supplement covers several new product features that are built into the control modules for its CombinedMagnetic Field (CMF) OL1000 and SpinaLogic bone growth stimulation product lines. The new product features enhance patients' ease of use.

Company: DJO Inc.

Price: 47.42 Price Change: 0 Percent Change: 0

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Regular-Session:Novartis' Reclast Gets FDA OK as 1st Once-Yearly Treatment for Postmenopausal Osteoporosis - NVS Slips

9:03 AM, Aug 20, 2007

Unlike oral bisphosphonate therapies that have to be taken daily, weekly or monthly, Reclast is given as a once-a-year 15-minute intravenous (IV) infusion. This means with a single treatment a patient can receive a full year's protection against the effects of osteoporosis -- a disorder that causes bones to break easily, the company says.

U.S. approval comes a few weeks after the Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending approval for the medicine in the European Union, under the brand name Aclasta. The European Commission generally follows the CHMP's recommendations and is expected to issue a final decision within three months.

Company: Novartis

Price: 52.07 Price Change: -0.59 Percent Change: -1.1

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Regular-Session:--IsoTis Gets FDA OK for Accell Family of Bone Graft, Filler Products - Bid/Ask Gap Wide

8:49 AM, Aug 20, 2007

Company: IsoTis

Price: 6.91 Price Change: 0 Percent Change: 0

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Regular-Session:Bayer, Onyx Get FDA Priority Review for Liver Cancer Drug

8:05 AM, Aug 20, 2007

Bayer HealthCare Pharmaceuticals (BAY) and Onyx Pharmaceuticals (ONXX) say the supplemental New Drug Application (sNDA) for Nexavar tablets to treat hepatocellular carcinoma, the most common form of liver cancer, has been accepted for review and granted Priority Review status by the FDA.

Company: Bayer

Price: 73.41 Price Change: 0 Percent Change: 0

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Regular-Session:Stocks Swing Higher, Eye Strong Open As Fed Steps In to Grease Financial Skids With Discount Rate Cut

9:02 AM, Aug 17, 2007

U.S. PRE-MARKET INDICATORS

- Dow Industrial futures Up 186 points
- S&P 500 futures Up 29.5 points at 1,454
- Nasdaq 100 futures Up 36 points at 1,892.
- Nasdaq-100 Pre-Market Indicator Up 42.81 at 1888.9

GLOBAL SENTIMENT

Hang Seng Down 1.4%

Nikkei Down 5.4%

FTSE Up 3.0%

PRE-MARKET SECTOR WATCH

(+) Large cap tech stocks: firmer

(+) Chip stocks: firmer

(+) Software stocks: firmer

(+) Small cap stocks: firmer

(+) Drug stocks: firmer

(+) Internet stocks: firmer

(+) Financial stocks: firmer

UPSIDE MOVERS

(+) CFC jumps on Fed move, upgrade based on credit facility tap. LEND and other mortgage firms also up sharply.

(+) RAI gets Jim Cramer plug as dividend play in volatile markets.

(+) WFC gets Cramer plug as likely to increase mortgage market share.

(+) DELL carries over positive trading from Thursday night, seen after co. announces accounting review concludes.

(+) ADSK bounces on pre-market upgrade.

(+) CROX gets bullish nod from Cramer.

(+) SAP gets upgrade.

DOWNSIDE MOVERS

(-) HSOA at 52-week low, Street.com's Cramer says shares still overvalued.

(-) IDEV gets FDA approvable letter.

(-) VMW is giving back part of huge run-up on IPO.

MARKET DIRECTION

Stock futures and other market indicators turned higher on a dime about half way through the pre-market session, and several financial issues were also in the green, energized by the Federal Reserve's dramatic action to boost credit market liquidity. The Fed says its move comes as downside risks to the economy as a result of credit market concerns have increased. Traders stress that volatility could persist as it has all week. The dollar and oil both moved higher.

Stocks were sharply lower ahead of the Fed's action, taking cues from Asian trading. Japan's benchmark Nikkei 225 suffered its worst single day point decline in some seven years; the weekly loss is the deepest in 10 years. Stocks had rebounded late Thursday

and spent the after-hours higher thanks to mostly positive earnings results.

The Fed cut, by a half percentage point, borrowing terms at its "discount window" used by banks and financial institutions that need short-term liquidity in exchange for selling the Fed securities. The Fed, along with other central banks, had been injecting liquidity with daily short-term transactions but felt compelled to take this more serious action to get those funds spread more readily to other financial markets, including mortgages.

Stock market analysts were generally calling the move a positive way to oil the gears of the financial system without signaling too much worry on the part of the central bank. A more desperate move would be a cut to the bank's benchmark fed funds rate. The Fed next meets in September to take up that rate, although can act on it between meetings if it chooses. The discount rate is a more precise tool at the Fed's disposal vs its fed funds rate, according to most analysis.

The Federal Reserve issued this statement: "To promote the restoration of orderly conditions in financial markets, the Federal Reserve Board approved temporary changes to its primary credit discount window facility. The Board approved a 50 basis point reduction in the primary credit rate to 5-3/4 percent, to narrow the spread between the primary credit rate and the Federal Open Market Committee's target federal funds rate to 50 basis points."

"The Board is also announcing a change to the Reserve Banks' usual practices to allow the provision of term financing for as long as 30 days, renewable by the borrower. These changes will remain in place until the Federal Reserve determines that market liquidity has improved materially. These changes are designed to provide depositories with greater assurance about the cost and availability of funding. The Federal Reserve will continue to accept a broad range of collateral for discount window loans, including home mortgages and related assets."

Countrywide (CFC) is among the financial stocks getting a jolt this morning. It was already trending up following an upgrade to Neutral at BofA. The move follows the lender's announcement Thursday it will tap its \$11.5 billion credit facility, which Banc of America Securities analysts say should provide Countrywide (CFC) with time to address liquidity and capital concerns. BofA did cut its price target to \$21 from \$31.

Several retailers will be issuing earnings on Monday and Tuesday of next week, among other companies that are due to report. On the docket: LOW, AEO, BJ, BJ, DKS, TGT, SKS and SPLS.

Company:

Price: Price Change: Percent Change:

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Regular-Session:Indevus Down 4.5% in Pre-Market - Gets FDA Approvable Letter but Still Added Data Sought by Agency

8:03 AM, Aug 17, 2007

Indevus Pharmaceuticals (IDEV) today announced that it has received an approvable letter from the FDA for VALSTAR. VALSTAR, a sterile solution of valrubicin for intravesical instillation, is the only product approved by the FDA for therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma in situ (CIS) of the urinary bladder.

VALSTAR was removed from the market in 2002 due to impurities in the original formulation and was placed on the FDA Drug Shortages List. Indevus solved the impurity issue and submitted a chemistry, manufacturing and controls (CMC) NDA supplement to the FDA in May 2007. The FDA approvable letter was in response to this chemistry supplement.

In the approvable letter, the FDA asked for clarification regarding manufacturing validation protocols and for additional data on the manufacturing process.

Company: Indevus Pharmaceuticals, Inc.

Price: 6.45 Price Change: -0.30 Percent Change: -4.4

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Regular-Session:--Anesiva Gets FDA OK for Zingo to Cut Pain From Needle Insertion Procedures in Children

6:36 AM, Aug 17, 2007

Company: Anesiva

Price: 5.19 Price Change: 0 Percent Change: 0

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Extended-Hours:Endo Pharmaceuticals, Vernalis Say FDA Ask for Extension to Review Frova Supplemental NDA

6:24 PM, Aug 16, 2007

Endo Pharmaceuticals, a unit of Endo Pharmaceuticals Holdings (ENDP), and Vernalis pls said the FDA has requested an extension of the August 19 review date to have more time to review the supplemental New Drug Application for FROVA 2.5 mg tablets for the additional indication as short-term (six days) prevention of menstrual migraine.

Company: Endo Pharmaceuticals

Price: 30.73 Price Change: -0.11 Percent Change: -0.36

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Regular-Session: Stocks Still Expected Lower, Though Pre-Market Crumble Has Been Halved

9:08 AM, Aug 16, 2007

U.S. PRE-MARKET INDICATORS

-S&P 500 futures Down 16.4 points at 1,397.90

-Nasdaq 100 futures Down 17.75 points at 1,860.75.

-Dow Industrial futures Down 121 points.

Nasdaq-100 Pre-Market Indicator Down 14.7 at 1850.22

GLOBAL SENTIMENT

Hang Seng Down 3.3%

Nikkei Down 2%

FTSE Down 3.1%

PRE-MARKET SECTOR WATCH

(-) Large cap tech stocks: flat to down

(-,+) Chip stocks: mixed

(-) Software stocks: flat to lower

(-,+) Small cap stocks: mixed

(-,+) Drug stocks: mixed

(-,+) Internet stocks: mixed

DOWNSIDE MOVERS

- (-) CFC is drawing on credit facility.
- (-) ANX says cancer injection gets fast-track status at FDA.
- (-) KFT is reportedly in early stages to sell Post cereal brand, WSJ reports.
- (-) EL offers mixed guidance.

UPSIDE MOVERS

- (+) INTC is just firm after upgraded to Outperform at Credit Suisse; stock spent part of pre-bell session in the red.
- (+) NTAP gains after evening earnings beat, buyback announced Thurs. evening.
- (+) KFN rebounds from recent slide after saying it has ample liquidity.
- (+) FCTR bid gaps higher, being bought by Fifth Third (FITB) for \$31 per share.
- (+) JCP says Q2 EPS just top as sales guidance mixed.
- (+) CPHD gets 5-year deal with Northrup Grumman.
- (+) LMS is being bought for \$27 per share.
- (+) GGBM gets order.

MARKET DIRECTION

Stock futures remain sharply lower, although are off their worst levels of the pre-market session. Still, a broadly lower open is expected at the bell as Wall Street continues to assess compromised credit conditions and whether or not the Federal Reserve will respond by lowering interest rates. The Fed meets in both September and October and again in December. St. Louis Fed President William Poole told Bloomberg News in an interview that only a calamity would justify an interest-rate cut. The central bank and its overseas counterparts have been injecting liquidity into short-term borrowing markets in recent days. The Fed stepped into the repo market again today.

Jitters and uncertainty persist in the financial markets. Oil futures dropped \$1.60 to \$71.61 a barrel. The dollar hit a 13-month low against the Japanese yen and Treasury yields fell to 4.667%, meaning their price was driven up, both indications of growing risk aversion. Value stock-pickers maintain that the recent decline signals nothing but buying opportunities.

On the economic front, housing data wasn't helping the mood on the Street. Housing starts fell 6.1% in July to an annual rate of 1.381 million, the lowest since January 1997

and lower than what most economists looked for. Authorized building permits dropped 2.8% in July to a seasonally adjusted annual rate of 1.373 million, the lowest since October 1996.

Also out this morning, jobless benefits claims for the week ending Aug. 11 rose by 6,000 to 322,000, the highest level since June 16, government data showed. The four-week average of new claims also rose, climbing by 4,750 to 312,500.

The post-bell earnings docket includes: KSS, JWN, RRGB, HPQ, ADSK, BEAS, among others.

Credit conditions continue to be the main focus of the Street.

Mortgage giant Countrywide (CFC) plunged but then clawed up from its worst pre-market levels after saying this morning it has supplemented its funding liquidity position by drawing on an \$11.5 billion credit facility. In addition, it says it has accelerated its plans to migrate its mortgage production operations into Countrywide Bank, FSB. Over 70% of the credit facility has an existing term greater than four years and the remainder has a term of at least 364 days, it says.

KKR Financial (KFN), an affiliate of leveraged buyout firm Kohlberg Kravis Roberts & Co, says it has \$452 million in liquidity to meet "any and all" investment opportunities or business contingencies, such as margin calls, that may arise, according to Reuters. Shares plunged on Wednesday on credit worries.

Eaton Vance (EV) is lower after Merrill Lynch cut its rating on the stock to Sell. Merrill expects net flows to Eaton Vance (EV) to slow due to bank loan outflows and closed-end fund sales, which the analyst thinks could pressure the company's premium. Merrill is positive on the company's management and most products but says its products are weighted towards bank loans, closed-end funds, high yield and large-cap value, all areas it would expect to under perform in the current credit environment.

In earnings, Estee Lauder (EL) is lower after it reports Q4 sales of \$1.76 billion, a 10% increase from \$1.60 billion a year earlier. EPS were \$0.45 compared with \$0.23, including charges, in the same prior-year period. The Thomson FC mean was for \$0.50 on \$1.72 billion in sales. For Q1, net sales are expected to grow between 5% and 7%. EPS from continuing ops are put at between \$0.05 and \$0.11. The Street is at \$0.33, but may not be directly comparable. For FY, net sales are forecasted to grow between 7% and 9%. EPS from continuing ops are put at \$2.28 and \$2.40. The Street is at \$2.21.

On the upside, FTD (FTD) shoots higher after it says Q4 sales were \$169.8 million, below the FC mean for \$173 million. Net income was \$0.36 per share, above the FC mean for \$0.28. FY08 sales are seen about \$645 million, below the FC mean for \$654 million. EPS are seen at \$1.18, above the FC mean for \$1.04.

J.C. Penney (JCP) reports Q2 EPS from continuing of \$0.78 vs \$0.75 a year earlier. Last

year's results included \$0.11 per share in one-time federal and state income tax credits. Sales were \$4.39 billion in the period. The FC mean was for \$0.77 per share on \$4.42 billion in sales.

For Q3, JCP guides for total department store sales to increase by low- to mid- single digits. Comparable department store sales are expected to increase low-single digits. Q3 EPS are put at \$1.28 vs the FC mean for \$1.43. Q4 EPS are put at \$2.41 vs the FC mean for \$2.25. For FY, management is increasing guidance for earnings from continuing operations to \$5.50 per share compared to previous guidance of \$5.49 per share. The Street is at \$5.48.

Company:

Price: Price Change: Percent Change:

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Regular-Session:--Adventrx Jumps, CoFactor Cancer Injection Gets FDA Fast Track Status

8:19 AM, Aug 16, 2007

Company: Adventrx Pharmaceuticals

Price: 2.50 Price Change: +0.25 Percent Change: +11.11

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Regular-Session:Pro-Pharmaceuticals Says FDA Grants "Compassionate Use" IND for DAVANAT

7:09 AM, Aug 16, 2007

Early pre-bell volume interest light.

Company: Pro-Pharmaceuticals

Price: 0.39 Price Change: 0 Percent Change: 0

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Regular-Session:Shire Reports Expiry of Waiting Period for JUVISTA License, to Pay Upon FDA Approval - Ask Lower in Thin Volume

7:15 AM, Aug 15, 2007

The license agreement, giving Shire exclusive rights, became effective on August 15,

2007. JUVISTA is a biopharmaceutical investigational drug and when injected at the time of surgery has been shown in clinical trials to markedly improve subsequent scar appearance in the skin.

On the FDA's acceptance of filing of JUVISTA's biologics license application, Shire will pay US\$25 million and on FDA approval, between US\$50 and US\$150 million depending on the characteristics of the approved product labelling. Shire will also pay Renovo royalties on sales of JUVISTA and milestone payments of up to US\$525 million on the achievement of very significant sales targets.

Company: Shire

Price: 74.03 Price Change: 0 Percent Change: 0

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Extended-Hours:Glaxo Just Positive - FDA Allows Updates for Avandia Prescribing Information

5:19 PM, Aug 14, 2007

GlaxoSmithKline (GSK) says the FDA has approved updated US prescribing information for the thiazolidinediones (TZD) class of medicines used in the treatment of Type 2 diabetes. This approval allows GSK to implement changes in the label for Avandia(rosiglitazone maleate) as previously committed.

The label will contain a boxed warning, which increases the prominence of an already existing warning for all medicines in the TZD class on the risk of congestive heart failure (CHF), a well known and well characterized risk in this class of medicine. The boxed warning also will note that TZDs are not recommended in patients with symptomatic heart failure, and that initiation of TZDs in patients with established NYHA Class III or IV heart failure is contraindicated. The Contraindications have also been updated regarding initiation of Avandia in patients with NYHA Class III or IV heart failure.

Company: GlaxoSmithKline

Price: 50.57 Price Change: +0.01 Percent Change: +0.02

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Regular-Session:Chelsea Therapeutics Gets Two Orphan Medicinal Product Designations - Pre-Market Volume Interest Light

7:33 AM, Aug 14, 2007

Chelsea Therapeutics (CHTP) announced today that Droxidopa was granted two orphan medicinal product designations by the European Commission for the treatment of orthostatic hypotension in patients with Pure Autonomic Failure (PAF) and patients with Multiple Systems Atrophy (MSA). The designations are based on a recommendation from the Committee for Orphan Medicinal Products of the European Medicines Agency (EMA) and follow the previously announced Orphan Drug designation granted by the U.S. FDA in January 2007.

Company: Chelsea Therapeutics

Price: 5.58 Price Change: 0 Percent Change: 0

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Regular-Session: Bruised Stocks Set For More Pain Though Fed Action Helps - Financials Leading Pre-Bell Decliners

8:59 AM, Aug 10, 2007

PRE-MARKET SECTOR WATCH

- (-) Large cap tech stocks: lower
- (-) Small cap stocks: mostly lower
- (-) Software stocks: lower
- (-) Chip stocks: lower
- (-,+) Drug stocks: mixed
- (-) Internet stocks: lower
- (-) Financials: lower

DOWNSIDE MOVERS

- (-) CFC is tumbling by double digits after a slide overnight on more cautious comments due to the subprime mortgage meltdown.
- (-) WM is also warning of mortgage impact in an SEC filing.
- (-) MER, GS, C, MS, BSC, JPM, HBC, UBS are trading lower; some banks reportedly subjects of informal SEC review of subprime mortgage exposure and reporting.

- (-) ABN is lower amid concerns for financing its buyout.
- (-) MRO, VLO are lower despite energy sector upgrades at Citi.
- (-) FSLR prices shares.
- (-) RZ reports Q2 volume below year ago.
- (-) HWAY gets analyst downgrade.
- (-) CPKI continues evening decline seen on weaker 2H warning.
- (-) NTRI says CFO resigns to pursue other interests.
- (-) RMBS delays filing.
- (-) LLNW hits 52-week low on downgrade.
- (-) NVDA is finding new extended hours lows this morning, co. gained initially on results Thurs. evening but turned lower in second half after conference call failed to inspire confidence in coming quarters.
- (-) WYE gets FDA notice that Schizophrenia drug not approvable now.

UPSIDE MOVERS

- (+) MYL gets FDA OK for Verapamil Hydrochloride extended-release capsules.
- (+) LEND jumping, continues extended hours action of late after getting regulatory OK for Lone Star acquisition.

MARKET DIRECTION

Wall Street is bracing for another wild ride Friday. Stock futures contracts and the Nasdaq 100 Pre-Market Indicator are both sharply lower as the opening bell nears. Credit market concerns continue amid earnings warnings from some banks, an informal SEC review of how Wall Street is pricing its exposure, and concern some deals won't get done in this climate. Several central banks also continue to add liquidity in short-term money markets. In fact, the futures markets clawed off their pre-market lows amid reports the Fed had injected more funds into the financial system.

Still, talk of an emergency Fed interest rate cut has picked up steam, even as some observers argue a cut won't solve a near-term liquidity shortage in global money markets. Futures markets that track the fed funds rate have fully priced in a cut next month and see a more than 30% chance the Fed reduces its benchmark rate yet this

month, before its next official meeting.

On the economic front, prices of goods imported into the U.S. climbed a sharper-than-expected 1.5% in July, a sixth straight increase and one led by a big rise for the price of petroleum. The gain was the largest increase since March and suggests some inflationary pressure from abroad, a challenge for a Fed weighing credit concerns against ongoing inflation vigilance. Petroleum prices rose 7.0% in July, following a 4.4% gain in June. This is the biggest increase since March.

The biggest individual movers this morning tended to be those issues with links to credit market worries.

Countrywide Financial (CFC) issued some cautious commentary late Thursday night in an SEC filing. CFC cited unprecedented poor conditions in the secondary-mortgage market for forcing it to retain more loans until investor demand improves. If such conditions continue then the company suggested it could have a negative hit on its future financial results.

Washington Mutual (WM) is lower this morning. It too said late Thursday in a SEC filing that difficult mortgage conditions are likely to hurt its operations. The co. says liquidity in the market for less-than-prime home loans and securities backed by the loans has "diminished significantly." It said that while this persists, its ability to raise liquidity by selling home loans will be "adversely affected."

ABN Amro (ABN) declined in European trading and is taking a hit in the pre-market as financing for one of its buyout offers is in question amid credit turmoil. A Reuters story, citing analysts, says worries have emerged that Fortis may find it difficult to finance its part of the offer to buy ABN with Royal Bank of Scotland and Santander. The trio has made a mostly-cash 71 billion euro (\$97.83 billion) bid for ABN, the Netherlands' biggest bank, while U.K.'s Barclays is offering about 65 billion euros.

Merrill Lynch (MER) and Goldman Sachs (GS), among others in the sector, are in the red during today's pre-market. The SEC is combing the books at top Wall Street brokerage firms and banks to make sure they aren't hiding subprime mortgage losses, the Wall Street Journal reports Friday, citing people familiar with the informal probe. The SEC is assessing whether Wall Street brokers are using consistent methods to calculate the value of subprime mortgage assets in their own inventory as well as assets held for customers such as hedge funds, the article says. The checks are expected to include the top five Wall Street banks.

Company:

Price: Price Change: Percent Change:

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Regular-Session:Wyeth Down Nearly 4%, FDA Says Schizophrenia Treatment Not Approvable Now

8:37 AM, Aug 10, 2007

Wyeth (WYE) and Solvay Pharmaceuticals say they have received an FDA action letter for Bifeprunox, an investigational treatment for schizophrenia. The letter said the drug is not approvable at this time.

The FDA wanted more information and indicated a second positive maintenance study could be sufficient to support a maintenance claim for bifeprunox.

Company: Wyeth

Price: 47.70 Price Change: -1.88 Percent Change: -3.79

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Regular-Session:Abraxis Pharmaceutical Gets FDA OK for Cefotetan Disodium for Injection

8:09 AM, Aug 10, 2007

Abraxis Pharmaceutical, part of Abraxis BioScience (ABBI), says it received FDA approval to market Cefotetan Disodium for Injection, the generic equivalent of AstraZeneca's Cefotan.

Company: Abraxis BioScience

Price: 24.16 Price Change: 0 Percent Change: 0

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Regular-Session:--Mylan Gets Final FDA OK for Verapamil Hydrochloride Extended-Release Capsules

7:40 AM, Aug 10, 2007

Company: Mylan

Price: 14.00 Price Change: 0 Percent Change: 0

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Regular-Session:Novartis Gets Extended Marketing Exclusivity for Diovan

6:46 AM, Aug 10, 2007

Novartis (NVS) says the FDA has granted its Diovan high blood pressure medicine pediatric exclusivity, with the patent extended by six months to September 2012. An FDA decision on a possible indication to treat children and adolescents with high blood pressure is anticipated by the end of 2007, the company says.

Company: Novartis

Price: 54.91 Price Change: 0 Percent Change: 0

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Regular-Session:Spectrum Pharma Gets FDA OK for INDA for Compound Treating Recurrent or Progressive Carcinoma

6:50 AM, Aug 9, 2007

SPI-1620 is a highly selective endothelin-B agonist that has demonstrated in experimental animal models a transient and selective increase in blood flow to tumors by over 300% and an increased delivery of anticancer drugs to the tumor while essentially sparing normal tissues and organs, thereby increasing the efficacy and the therapeutic index of these drugs, the company says.

Company: Spectrum Pharmaceuticals

Price: 4 Price Change: 0 Percent Change: 0

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Regular-Session:Santarus Hits New 52-Wk Low, Gets Notice From Par of Filing for Competing Drug

9:30 AM, Aug 8, 2007

Santarus (SNTS) said late Tuesday it received a Paragraph IV Certification Notice from Par Pharmaceutical advising of the submission of an Abbreviated New Drug Application for omeprazole and sodium bicarbonate capsules, 20 mg/1100 mg and 40 mg/1100 mg.

SNTS says it has 45 days to commence a patent infringement lawsuit against Par that would automatically stay, or bar, the FDA from approving Par's ANDA for 30 months or until a district court decision that is adverse to SNTS, whichever may occur earlier.

Company: Santarus

Price: 2.91 Price Change: -0.05 Percent Change: -1.69

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Regular-Session:Biovail Q2 Results Below Year Ago - Wide Bid/Ask Gap

7:37 AM, Aug 8, 2007

Biovail (BVF) reports Q2 revenue at \$203.0 million compared with \$255.1 million for the second quarter of 2006. GAAP EPS are \$0.42 vs \$0.53 in the same quarter a year ago. The Thomson FC mean, which may not be directly comparable, was for \$0.37 per share on \$199 million in revs.

Company says it has an Aug. 14 meeting scheduled with FDA over approvable letter for its candidate of a formulation of bupropion.

Company: Biovail Corporation

Price: 18.63 Price Change: 0 Percent Change: 0

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