BioRunUp
Analyst Report

BIOD - Biodel

FDA Catalyst
Catalyst Date: 10/30/10
Drug: Linjeta
Run-Up Potential: Strong

Run-Up Valuation Report

The following Report contains detailed research and information on Biodel and its drug Linjeta (formally known as VIAject)

From $18 to $4, reasons why:
< http://www.tapebeat.com/201005037400/Companies-Profiles/biodels-viaject-may-push-mannkinds-afrezza-aside-biod-mnkd.html >
"Beyond the low risk, high reward offered to Biodel investors, BIOD is an incredible value right now. There is a back story to the VIAject clinical trials that has driven BIOD stock to the current extremely undervalued levels: Biodel went public 3 years ago and its shares traded at around $18. But in late 2008 the stock took a nose dive into a $4 range, when the company announced the preliminary efficacy results from its Phase III clinical trial of VIAject in India. The Indian trial results did not compare to the previously released trial results from patients in the United States and Germany. While non-inferiority of VIAject was achieved without the data from India, it was not achieved when the data from India was included. **The analyses by independent clinical and regulatory experts at the FDA suggested there were specific factors that explain the results in India, specifically heat. Among the causes noted in the Pre-NDA briefing package, an identifiable subset of blood samples from patients in India were found to be compromised due to excessive heat exposure in transit to a central laboratory. These anomalous results from India killed the company's stock price and it has never since recovered.**
However, when the compromised samples are accounted for in the efficacy analysis, non-inferiority in both the Type 1 and Type 2 trials is achieved. Upon recommendation by FDA advisors, the company filed the NDA, accounting for the data from heat damaged samples. On March 1st 2010, Biodel announced that the FDA accepted for review the VIAject NDA. The FDA expects the Prescription Drug User Fee Act (PDUFA) action date for this NDA to be October 30, 2010. Now one can only believe that FDA's nod in accepting the NDA for review as a big value driver (though yet to reflect in the share price), and a positive sign for the FDA's belief in the Phase III trail results showing non-inferiority (given the blood samples from patients in India were found to be compromised). Given the breadth of data with VIAject showing equivalancy (even accounting for the anomalous Indian data), its components being GRAS, and its 505(b)(2) route, I anticipate approval on the first try."
< http://www.thestreet.com/story/10719163/14/14-biotech-stocks-facing-fda-approval.html >
"VIAject is designed to be absorbed into the blood more rapidly than currently marketed insulins, according to Biodel. The two studies aimed to show that VIAject was as effective as Humulin at controlling blood sugar levels in people with diabetes. In a study of people with Type 1 diabetes in 60 centers in the United States, Germany and India, the findings were based on 131 volunteers on VIAject and 140 on Humulin. The decrease in levels of HbA1c -- a standard measure of glucose control -- was comparable among the two groups with an adjusted difference between them of 0.1 percent, Biodel said.**But due to unexplained anomalies, it said it excluded the Indian results in its initial analysis. If the company had included them, it said the trial would have failed.**"
FDA Accepts VIAject NDA for Review
< http://www.drugs.com/nda/viaject_100301.html >
-India support-
India is selected as a place to trial upcoming/possible medications because it's cost efficient and their ethics are very weak which implies attractiion to bio-companies. However, many companies are not satisfied with their end clinical trialled results taken place in India. Byetta had its India debacle, oral-Lyn had its India debacle,and BIOD has had its India debacle.The transcript (it's a bit long) below describes the problems that occur when reporting medical trials

< http://www.abc.net.au/rn/healthreport/stories/2010/2811059.htm >
What BIOD has to offer
< http://files.shareholder.com/downloads/BIOD/904042272x0x367278/9BCF1C14-AAF8-4A72-BAC9-0B628E00FAF0/Biodel_at_JPM-14Jan_10.pdf >
VIAject's Clinical trial layout
< http://www.clinicaltrials.gov/ct2/show/NCT00875108?spons=biodel&spons_ex=Y&rank=1 >
*Bonus after FDA, pipeline (I will refer more to this after my DD analysis):
< http://www.biodel.com/content/pipeline/overview.htm >
Viatab developments could be a great reason as to why investors may hold even AFTER the PDUFA date.
< http://online.wsj.com/article/PR-CO-20100712-906550.html?mod=wsjcrmain >
Progress with BIOD620 (aka "BIOD-Smart Basal, Injectable smart basal insulin 505(b)(1) NCE, Finished Pre-clinical)
Viaject update:
(In Detail)
< http://www.genengnews.com/industry-updates/final-results-of-phase-3-study-of-viaject-vs-regular-human-insulin-in-patients-with-type-2-dia/87161777/ >
(Summary)
< http://www.biosciencetechnology.com/News/FeedsAP/2010/06/biodel-reports-encouraging-viaject-study-results/ >
(Note: Imho, Scientific sessions/events such as the "American Diabetes Association 70th Scientific Sessions, June 25-29th." are usually shorted by hedge funds, one of the reasons why i didn't hold through late July/early August)
-MKTDrug-
Type 1:
< http://www.prlog.org/10776988-analysis-and-market-forecasts-for-type-1-diabetes-to-2017.html >
Type 2:
< http://www.prlog.org/10500908-the-type2-diabetes-market-is-forecast-to-grow-at-healthy-rate-between-2009-and-2016.html >
Biodel has submitted a New Drug Application to the FDA for approval ***to market VIAject® as a treatment for Type 1 and Type 2 diabetes****, based upon results from pharmacokinetic, pharmacodynamic and standardized meal studies, two pivotal 6-month Phase 3 clinical trials of VIAject® in patients with Type 1 and Type 2 diabetes, as well as interim results from the long-term, 18-month safety extension trials for patients who completed the pivotal Phase 3 clinical trials.*
< http://www.biodel.com/content/pipeline/viaject.htm >
Insulin Pump Market
< http://www.prlog.org/10809952-insulin-pumps-global-pipeline-analysis-opportunity-assessment-and-market-forecasts-to-2016.html >
Insulin Delivery Systems Market
Value
< http://www.newsguide.us/health-medical/medical-products/Global-Insulin-Delivery-Systems-Market-Syringes-and-External-Pumps-to-Exceed-5-5-Billion-by-2015-According-to-New-Report-by-Global-Industry-Analysts-I/ >
CAGR
< http://www.reportlinker.com/p0138274/Insulin-Delivery-Systems-Market-Analysis.html >

We'll discount to find out the MKTDrug for the IDSM.
Main Market Competition (Afrezza (MNKD))
< http://seekingalpha.com/article/202524-why-biodel-is-breathing-easy-part-1 >
< http://seekingalpha.com/article/202571-why-biodel-is-breathing-easy-part-2 >
Top Money Manager Holdings (Yale endowment's second largest holding):
< http://blogs.forbes.com/investor/2010/06/18/top-money-managers-embracing-etfs/ >
(Note: Yale is a University in the U.S.A. that is reknowned for its smart money management and asset allocation)

-Institutional Holdings-

Institution
The 10 Largest Institutional Investors Share Holdings Change in Share Holdings* Date Reported
Moab Capital Partners, LLC 2,386,869 549,553 12/31/09
Fidelity Management & Research 1,271,617 -1,311,300 6/30/10
Great Point Partners, LLC 1,009,187 -152,455 3/31/10
BlackRock Institutional Trust Company 931,850 161,985 3/31/10
Vivo Ventures Investments, LLC 926,352 -759,281 12/31/08
Yale University 903,400 903,400 12/31/09
Dimensional Fund Advisors, LP 443,037 -9,494 3/31/10
Wall Street Associates, LLC 386,600 -1,000 3/31/10
JP Morgan Asset Management 285,153 131,397 3/31/10
T. Rowe Price Associates, Inc. 280,300 -4,500 3/31/10
Mutual Funds
The 10 Mutual Funds with the largest holdings Share Holdings Change in Share Holdings* Date Reported
Fidelity Select Biotechnology Portfolio 1,557,448 -409,900 5/31/10
Fidelity Small Cap Growth Fund 520,000 95,000 4/30/10
iShares Russell 2000 Index Fund 211,394 12,597 5/31/10
T. Rowe Price Health Sciences Fund 200,000 0 6/30/10
iShares NASDAQ Biotechnology Index Fund 185,132 -24,710 5/31/10
Franklin Biotechnology Discovery Fund 175,900 0 4/30/10
DFA U.S. Micro Cap Series 157,030 0 4/30/10
DFA U.S. Micro Cap Portfolio 157,030 0 5/31/10
JP Morgan Small Cap Core Fund 144,400 4,900 5/31/10
Vanguard Total Stock Market Index Fund 125,832 0 3/31/10
< http://www.wsj.com >

-MKTShare-

For the Insulin Pump market, there exists a lot of competition out there (80% right now is claimed, 58% being Medtronic). China has some major players with huge dominance over the IPM, so i'm only going to assume a 5% market Share to be safe.
For the Insulin Delivery Systems Market, BIOD is included in this mix, but again even though there is a growing demand for pens, the market share will correlate with the IPM, therefore let's also keep this at a 5% market share to be safe.
(for the record, I included the IDSM because insulin pens does count within the system:
Insulin Delivery Devices
Present Devices

-- Insulin Pens
-- Insulin Pumps
-- Insulin Syringes
-- Insulin Jet Injectors
Future Devices
-- Oral Insulin <------ VIAtab possibility (i'll explain later on in this post)
-- Insulin Patch
-- Implantable Insulin Pumps
< http://uclue.com/?xq=4038 >)
For the type 1 diabetes market, the major current usage of subcutaneous insulin pump treatments are Medtronic Paradigm, Animas, OmniPod, and ACCU-CHEK Spirit. As mentioned before, there exists 20% up for grabs. However, we must take into consideration that MNKD's Afrezza is still in the mix (and yes, Afrezza can target patients with type 1 and 2 diabetes). Therefore, let's keep this at a 10% market share to be safe.
< http://www.mannkindcorp.com/afresa-background.aspx >
For the type 2 diabetes market, the leading companies are Medtronic (Paradigm 512/712 insulin pump), Roche (Accutrend GC/GCT),and Takeda (TAK-654).
< http://www.mediligence.com/rpt/rpt-d500.htm >
There is approximately 20% left in the market share, with the potential Afrezza in the mix. BIOD compared Humalog (Insulin products from Eli Lilly), and Humulin (originally developed by Genentech, now acquired by Eli Lilly), and has demonstrated a much more efficient AUC GIR which can add to this market share, but let's keep it at 20% to be fair. Therefore since we're still including Afrezza in the mix, let's keep this at a 10% market share to be safe.
< http://www.biodel.com/images/diagrams/phase2mealstudy.gif >
< http://www.annualreports.com/HostedData/AnnualReports/PDFArchive/biod2008.pdf >
*VIAtab is a potential huge blockbuster and seeks to deliver insulin sublingually. They will likely get it to market before any competitors get any oral or digested insulin to market.
Modify:
-The injection site pain issue was resolved by rendering the ph neutral. Users in the VIAject trial arm said that the pain was less severe than those in the Humalog study. See bridge study filed with FDA.
Many big pharma's have seen their Diabetic drugs get pummeled over the last few years.
Lambert's Rezulin
Pfizer's Exubera
Glaxo's Avandia
SNY's Lantus
Speaking of Lantus we cannot diregard-
< http://www.fiercepharma.com/story/sanofis-lantus-linked-cancer-risk/2009-06-29 >
And then Biodel's recent response to Lantus-
< http://investor.biodel.com/releasedetail.cfm?ReleaseID=487208 >
-Financials-
(Note: Since i was in vacation, i will post an *Update* refering to Biodel's most recent quarter as a good comparison since we will not have to face another earnings date till after November which is irrelevant to us right now)
-Earnings:
Biodel is generating no revenue through sales of products, therefore we're dealing with a pure burn

situation. Their operation expenses has been very consistent, 3/31/10 being $10.391M and an average of $10.913M, with a standard deviation of $514,000 (aka the spread is very tight) for the past 5 qtrs. Within these operating expenses, the main driving factors are obviously research and developement costs and general and administrative costs ($7.01M and $3.38M respectively). Biodel has been handling their earnings very well showing no major earning surprises for the last 5 qtrs.

Update

Again, operating expenses was still being driven by R&D and G&A being $5.89M & $2.78M respectively. Since taxes ($36,000) barely affected their costs, this quarter has been their best quarter in terms of earnings for the past 5 quarters. EPS was -$0.36 which was $0.04 better than the average estimate and $0.01 better than the highest estimate on the streets. Overall, earnings under a burn situation was good. (Slightly off topic to us biorunneruppers, but interesting: on the wall street journal, the highest estimated EPS for the december 6th report date is $1.61)

-Cash Flow:

Their major change in cash flow came from operating activities. Within the cash flow from operating activities came the major driving force being the net income attributable to Biodel which was $21.56M, with an average of -$26.09M and a standard deviation of $10.99M (large spread). Cash flow from investing activities give or take canel out the cash flow from financing activities for the last 2 qrts (3 quarters ago, cash flow increased from investing activities due to sales of marketable securities).

Update

Once again, cash from operating activities was the major factor given that the net income attributable to Biodel was $30.186M. Add an adjustment of $6M plus a purchase of marketable sales of $6.01M gives us a net change of cash of $42.79M. This was the highest burn for the last 4 quarters. Overall, this quarterly cash flow statement could have been better.

-Balance Sheet:

Their balance sheet has been their best statement for the past 5 quarters. Cash has been >91.6% of the total current assets, with the last quarter being $32.72M. Their total current liabilities has always been low and very manageable, with last quarter being $7.27M which implies a great quick ratio. There has been no long term debt, but total equity has been decreasing which isn't a surprise under a burn situation.

Update

Cash has been burnt down to $17.85M, yet the marketable securities and other receivables make up for the new total current assets of $26.76M (cash is now 66.7% of their total current assets. Total assets add up to $29.95M given that the net property and equipment is valued at $3.14M. Good thing is that current liabilities went down to $5.11M, and still no long term debt. 103,000 shares were added which shows that there hasn't been any major dilution at all within this time frame (and going back 5 quarters ago, dilution is only at <1%. Balance sheet remains to be the best aspect of this quarterly statement.

< http://www.wsj.com >

-Technicals-

Gross margins will be estimated since BIOD hasn't generated any revenue.

Held by Insiders = 34.87%

Held by Institutions = 38.10%

Even though there has been roughly a 2% drop in holdings from insiders and institutions, the actual percentage being hold is relatively high.

Technicals from the time that i took my vacation until now has improved (target, support, resistance, pivot price, MA(5,20,200), %K(14,3) & %D(3), and RSI(14)) for the most part. The price has been clos-

ing avoce it's short term moving average for a small while implying bullish movement in the short-term and neutral/bearish (bearish if you take parameters MA(200,250) into consideration) in the long term. MACD is on a good note implying a good chance for a bullish crossover next week. As for the bollinger bands, they don't provide a clear suggestion as to where the future direction of prices for BIOD will be at since it has been very random this month. The EMA(20) has been following the 1st support level for the past month. CCI(20) is at -73.95, and at my last post when i said it was getting high, because of that positive EPS it has reached up to 280.40: the highest point since April 12th. The slow stochastics are positioned at %K(14) = 14.62 & %D(3) = 18.33, higher than when i last checked a month ago which was 9.73 and 9.33 respectively. I have support positioned awkardley at $3.89 and resistance at $5.16, with a Float of 18.86M shares (78.95% of total shares out).

< http://stockcharts.com/c-sc/sc?s=BIOD&p=D&b=5&g=0&i=0&r=8518 >

-Updates in-between my DD from before my vacation- :

1) Item 8.01. Other Events on Form 8-K

(http://www.biorunup.com/forum/potential-manufacturing-issues-t244.html)

It's a warning from the FDA (what's new , cause we all know how risk averse they are) to AMRI, not BIOD. BIOD is connected with AMRI because "Hyaluron is **one of the two contract manufacturers** that produced vials of the finished product included in Biodel's new drug application (the "NDA") for VIAject". Also to note, "AMRI informed Biodel that the FDA inspection that resulted in the warning letter was unrelated to the review of Biodel's NDA for VIAject, **but rather was related to the review of another sponsor's product candidate.**" Regardless, "Biodel has previously disclosed that it does not intend to commercially launch VIAject until a disposable pen version of the product is approved and that it intends to submit this pen to the FDA for review in early 2011", which means this gives BIOD a lot of time to perhaps talk to Wockhardt Ltd., the second contract manufacturer producing finished VIAject product. This warning does not affect AMRI's production at any way, and apparently AMRI was well aware in March about the FDA inspection and subsequent violations (there was a contamination issue going on and the FDA wants to figure out the main cause of it).

IF anything, VIAject would not be delayed, but i bet production would be slower than expected to about 50% (not sure how much share of production AMRI or Wockhardt will have) in the extreme short term, therefore i'm reducing my gross margin from 40% to 20% JUST to take this aspect into consideration.

< http://biz.yahoo.com/e/100824/biod8-k.html >

< http://www.marketwatch.com/story/biodel-stem-cell-biotechs-lead-drug-stock-south-2010-08-24 >

2) Dilution

Tuesday's closing price/excercised warrants & shares times the number of shares currently out there equals it's market capital at that time divided from the amount of cash raised at that time reflects the dilution rate. So:

($3.93)(23.99M) = 94.28M

$9.4M/94.28M = 9.97% dilution rate

(Further proof just in case dilution seems confusing, take that dilution rate (9.97%), and multiply that by the old number of shares to get the number of shares to be sold)

(9.97%)(23.99M) = 2.391M shares

(This will be added to the sum of shares on my evaluation to take this event into consideration)

"Biodel Inc. (BIOD) said it has agreed to sell 2.4 million shares and an equal number of warrants to two institutional investors to raise about $9.4 million"

< http://online.wsj.com/article/BT-CO-20100825-708881.html?mod=wsjcrmain >

This makes sense. Their cash levels first of all hasn't been this low since September 30th, 2005 (when

they had 2 drugs in phase I) so raising some cash before judgement day seems appropriate for the institutes, this amount raised is for the production of VIAject solely, and they're most likely establishing confidence to large holders since the actual amount being raised is quite small implying a positive cash flow soon (and hence the positive EPS figures from wall street analysts).

-EVALUATION-

(1) Drug Market = weighted average{MKTDrug, MKTShare}
DM = ([$2.7B x 1.061] x 10%) + ([$21.9B x 1.112] x 10%) + ([$586.4M x 1.09] x 5%) + ($2.44B x 5%)
DM = $286.47M + $2435.28M + $31.96M + $122M
DM = $2.875B
(2) Sum of Shares = (No. of shares + extra shares sold to public)(standard 25% rate of dilution)
Q = (23.99M + 2.391M)(1.25)
Q = 32.98M
(3) Gross Margin will be fixed at 20% instead of the standard 40% as stated above on my post to take the AMRI situation into consideration for a stricter price prediction.
(4) Gross Revenue Margin = (Gross Margin)(Drug Market)
GRM = (20%)($2.875B)
GRM = $575M
(5) Here comes the challenging part: figuring out the costs. [i]Since this projection is based on 1 year[/i], I'm going to make the projected operating expenses equal to the highest operating expense in 5 years plus 4 times (4 other drugs in development) the highest research and development cost in 5 years plus the highest general and administrative cost in 5 years.
OExp = max{oexp} + 4(max{R&D}) + max{G&A}
OExp = $47.35M + 4($32.55M) + $14.8M
OExp = $192.35M
The costs from financing activities tend to cancel out with the costs from investing activities, so for the total costs i will include the costs of goods sold plus an extra cost which would include costs such as payroll, income taxes payable, compensation/bonuses, clinical trial expenses, and construction costs. I figure that these costs all combined will lead to approximately 40% of all total costs.
Total Costs = Operating expenses + COGS + Extra Costs
TC = $192.35M + (20% x $575M) + (40% x $575M)
TC = $192.35M + $115M + $230M
TC = $537.35M
(6) Profit = Gross Revenue Margin - Total Costs
TT = $575M - $537.35M
TT = $37.65M ---> 6.5% profit margin
(7) Let's assume a price/earnings ratio of 20 to be fair. Then,
Value = Market Capital = (Price/Earnings)(Profit)
V = (20)($37.65M)
V = $753M
(8) Price Per Share = Value / Sum of Shares
PPS = $753M / 32.98M
PPS = $22.83
(9) Probability of Approval/Aftermath = Standard rate +/- extra factors
P(A) = 50%
- 10%("Burn" situation: if FDA rejects, BIOD will have burnt alot of cash & will struggle in the near future)

- 10%("Same Sample Failure" Situation: Some investors, regardless that the india contamination wasn't BIOD's fault, will still remember their history and set their potential down until FDA approves).

P(A) = 30%

(10) Target Price = (P(A))(PPS)

P* = (30%)($22.83)

P* = $6.85

-BioRunUp has a target of $7.50 (prior to dilution)- EDIT added by BioRunUp

-Wall Street Journal has a mean of $14.75, median of $14.50, high of $17.00 and a low of $13.00

Extras that others asked for

- I have a Book Value of $1.04 (which by the way implies a lot of potential for BIOD, and this implies that the P/E ratio should be much higher than 20 but i kept it at 20 to get a strict price target.)
- I have a 95% Confidence Interval that the price target before the PDUFA will be between $5.26 & $8.44 (Monte Carlo Simulation)
- Cash per share is literally $0.99 which implies that book value per share is aggressively close to equalling its cash value per share

That's my run up price target in my opinion. I wanted to set a much more aggressive price target this time so that this way if the price does go higher than my target then at least nothing is lost to us runneruppers! I will be buying my position tomorrow near closing to avoid the 10% reduction (so prices should be around $3.60 (was at $4 on the dot at the announcement of the ~10% dilution).