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ViroPharma Incorporated

VPHM \$10.34 OPEN
Rating Neutral
Price Target N/A

52-Week Range \$7.11 - \$15.00
Mkt Cap \$* \$723.8
Enterprise Value \$* \$381
Shares Outstanding* 70
Avg Daily Vol* 793
Net Cash/share 4.99
* \$ mln

FY Ends: Dec		GAAP - Fully			
Diluted					
EPS (\$)	2007A	2008E	Prior	2009E	Prior
1Q	\$0.31	0.22		0.08	
2Q	\$0.39	0.29		(0.10)	
3Q	\$0.26	0.24		(0.18)	
4Q	\$0.25	0.20		(0.24)	
FY	\$1.20	0.95		(0.44)	
FY Rev*	203.77	216.15		75.20	
* \$ mln					

VPHM Share Price (LTM)



Source: SFG Research and company reports

ViroPharma Incorporated

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FDA Announces Advisory Committee Meeting to Discuss Bioequivalence Methods for Locally Acting Drugs to Treat GI Conditions

ViroPharma's ongoing efforts to retain the monopoly on oral vancomycin have so far prevented the approval of an Abbreviated New Drug Application (ANDA) by the FDA's Office of Generic Drugs (OGD). After more than two years of silence from the FDA, ViroPharma's request for an open, public forum discussion of bioequivalence standards will be realized on July 23, 2008. This will be the first opportunity to hear from the FDA since March 2007 when the OGD issued new guidance requesting evidence demonstrating rapid *in vitro* dissolution for a waiver of *in vivo* bioavailability and bioequivalence studies. What resulted from this change in guidance was an immediate erosion in ViroPharma's valuation followed by a petition for a stay of action by ViroPharma and eventually an ANDA filing by Akorn for a generic version of Vancocin. We are hopeful that this committee meeting will lead to a resolution; however, we believe it is unlikely that Akorn's ANDA will ultimately be rejected, and we believe the current stock valuation favors generic entry this year or early 2009.

HIGHLIGHTS

- FDA Advisory committee to discuss bioequivalence of locally acting GI drug.** While not explicit in the announcement, we believe that this discussion will center around the Office of Generic Drugs' standards for demonstrating bioequivalence to ViroPharma's Vancocin (oral vancomycin). This will be the first opportunity to hear from the FDA since March 2007 when the OGD requested evidence demonstrating rapid *in vitro* dissolution for a waiver of guidance in *in vivo* bioavailability and bioequivalence studies. We believe this meeting will be a major catalyst for ViroPharma by giving investors insight into the probability of Akorn's ANDA approval. **Neutral Factor**
- Probability of success of VPHM's Citizen's Petition is very small.** Given a historical failure rate of approximately 90%, Citizen's Petitions do not usually provide more than a delay for the filer. However, it appears that ViroPharma's has had some level of success in that an ANDA has not yet been approved, and it now seems that the FDA will be taking the issue to a public forum. We still believe that, ultimately, Akorn's ANDA will be approved and ViroPharma's high margins on Vancocin will quickly disappear, but the tone of the committee meeting may change our perceptions. **Positive Factor**
- Generic manufacturer modeling 2008 oral vancomycin sales.** Last year, Akorn Pharmaceuticals guided for a late 2007 ANDA approval for oral vancomycin. When this failed to materialize, the CEO recognized on the FY07 earnings call that the delay was likely due to ViroPharma's Citizen's Petition. However his tone on the 1Q08 earnings call became slightly more bullish and, while not providing an estimate for an approval date, did include vancomycin in 2008 revenue numbers. **Negative Factor**
- Camvia begins transition to center stage.** For the last five years, ViroPharma has been a Vancocin story. As the reality of generic competition comes closer, the upside on the stock is becoming dependent on Camvia (maribavir) to prevent CMV disease in transplant patients. We note that the stock has run up recently following a 2008 low of \$8.21 in mid-March following news of the completion of enrollment in one of the two Phase III trials and the publication of the positive Phase II results in the reputable scientific journal *Blood*. We have high expectations for Camvia and believe that as we roll into the fall, the focus of the investor community will be on Camvia. **Positive Factor**

VALUATION

In our sum-of-the-parts analysis, we estimate sustainable/terminal sales of ~\$30 mln for Vancocin (adjusting for generic erosion) and \$500 mln peak sales for maribavir (very generous). We had previously removed HCV-796 projections from our models. With a small addition of non-toxic C. diff. and the potential royalties for pleconoril and net cash of \$4.99, we see a valuation of approximately \$11 per share. With no significant data from the Camvia trials for over a year, we see the stock trading at current levels. We believe these valuation exercises are helpful as a guideline, but given the uncertainty that remains on timing of generic Vancocin, it is difficult to say how much of that expectation is now in

the stock; i.e., the reality of generic Vancocin (which we expect in early 2009) is likely to keep valuations in check before the VPHM story fully transitions to a Camvia driven valuation thesis.

Figure 1. VPHM SOP Model

	LT Gr	Disct Rt	Yrs. to Mkt	% Success	Peak Sales Mln's	Term Val
Vancocin	0%	15%	0	100.0%	\$30.00	\$200
NPV						\$0.82
Maribavir	3%	20%	2	50.0%	\$500.00	\$2,941
NPV						\$4.19
NTX	3%	50%	7	10.0%	\$100.00	\$213
NPV						\$0.01
Royalty-Pleconoril	3%	15%	4	20.0%	\$30.00	\$250
NPV						\$0.12
Net Margin						32%
MM Shrs OS						78.0
Total						\$5.13
Net Cash/Shr						\$4.99
Grand Total						\$10.12

Source: SFG estimates

RISKS

ViroPharma's petition for a stay of action prevents generic Vancocin entry. Slower progression of clinical development or failure for Camvia program.

DISCUSSION

In vitro or *in vivo* testing?

Based on our discussions with the attorneys, we have a greater appreciation that the OGD may favor testing in a beaker to bioequivalence testing in man, as the OGD's primary concern is whether the generic formulation released the active pharmaceutical ingredient in the same way as the innovator drug. In fact, the OGD's view is that bioequivalence testing in man may be less precise and less reliable than a test conducted in a dish, especially for locally acting drugs. In fact, the OGD views comparative clinical trials that are used as a substitute for bioequivalence studies, such as those proposed by VPHM (not to be confused with clinical trials designed to show efficacy and safety leading to a drug's approval), as burdensome, insensitive, unreliable, and a barrier to entry for generic drugs. We review the OGD's stance in the discussion below.

Bioequivalence (as defined in 21 CFR § 320.1): *absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.*

For drugs whose site of action is the GI tract, determination of bioequivalence is more complicated because local drug concentrations cannot be measured directly.

Figure 2a. Plasma Drug Levels Connected to Product Effectiveness for Systemic Acting Drugs

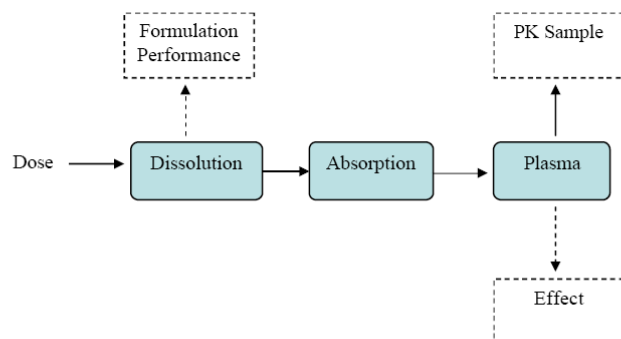


Figure 1: Systemic acting drugs

Source: http://www.fda.gov/ohrms/dockets/ac/04/briefing/2004-4078B1_07_Bioequivalence-Testing.pdf

Figure 2b. Plasma Drug Levels Not Connected to Product Effectiveness for Locally Acting Drugs

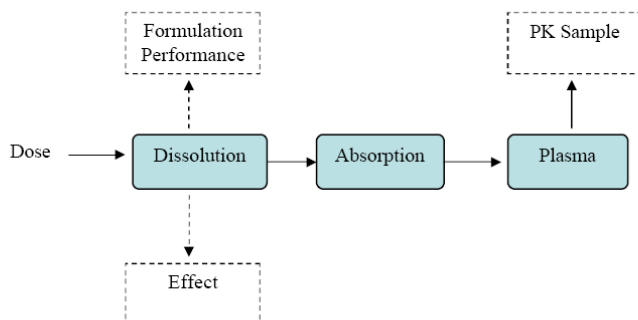


Figure 2: Locally acting GI drugs

Source: http://www.fda.gov/ohrms/dockets/ac/04/briefing/2004-4078B1_07_Bioequivalence-Testing.pdf

The Advisory Committee for Pharmaceutical Science (ACPS; now known as the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology) met on October 19-20, 2004. One session focused on bioequivalence testing for locally acting gastrointestinal drugs (<http://www.fda.gov/ohrms/dockets/ac/cder04.html#PharmScience>).

We summarize the key points from the discussion and the committee's conclusion:

On the use of dissolution testing to establish bioequivalence for drugs that act in the GI tract:

- “In general, for locally acting GI drugs, dissolution directly determines the rate and extent of delivery to the site of action (bioequivalence) . . . Thus, GI acting drugs should focus more attention on dissolution testing for demonstrating bioequivalence. The main concern is, of course, how well *in vitro* dissolution reflects *in vivo* dissolution.” (quotes from meeting transcripts: <http://www.fda.gov/ohrms/dockets/ac/04/transcripts/2004-4078T2.htm>)
- *In vitro* testing is good if there is control over the test. The members emphasized that dissolution tests are needed early on in the process, in order to narrow down the variables. Further, pharmacokinetics studies are useful to assure safety of the test product.
- Dissolution tests are formulation tests, and can be a surrogate for clinical tests.
- Dissolution tests can be very discriminating if the studies are designed well; however, dissolution test procedures can be simple for some drugs, but complicated for others. The Committee argued that when a lot of background information is available, the dissolution test could be used. The members added, however, that when doing dissolution testing, careful attention needs to be paid to the calibrator.
- The committee members emphasized that as local acting products, such as GI, nasal, or topical, are part of the Critical Path Initiative, they could contribute to the timely approval of generic drugs.

In conclusion, the Committee agreed it was difficult to reach a consensus, but that in order to prove bioequivalence, *in vitro* dissolution along with pharmacokinetics should be acceptable.

COMPANY DESCRIPTION

ViroPharma Incorporated (VPHM) is an early stage biotechnology company focused in the infectious disease area. The company is developing a non-nucleoside polymerase inhibitor for HCV, a novel drug Maribavir to treat CMV (cytomegalovirus), and currently has an annual run rate north of \$200 mln driven from Vancocin. Generic threats exist for Vancocin and are likely to dramatically erode Vancocin sales. The company has a strong balance sheet with approximately \$460 mln cash (3/2007) and \$250 mln in convertible debt (due in 2017 and convertible at ~\$19/share).

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Suspended: The previously published rating and/or estimates are currently suspended and under review.

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Net Positive which carried the same definition as Positive above

Net Neutral which carried the same definition as Neutral above

Net Negative which carried the same definition as Negative above

SFG Fundamental Research: 211 companies under coverage (as of 3-31-2008)

Covered companies in each rating category

Positive (Buy): 60% (127 securities)

Neutral (Hold): 37% (78 securities)

Negative (Sell): 2% (5 securities)

Investment banking clients in each rating category

Positive (Buy): 9% (11 securities)

Neutral (Hold): 0% (0 securities)

Negative (Sell): 0% (0 securities)

From January, 2006 to June, 2006 SFG used the following ranking system in addition to the above.

SIG Q SCORE™ is a hybrid quantitative modeling tool designed to cover a broad universe of stocks. It compares multi-factor analysis of historical, company reported financials and other quantitative trading and performance data to derive a ranking designed to provide a relative performance tool. The end result is a composite rank from 1 to 5 with 5 indicating the highest predicted return. The ranking is meant to be regarded as an indicator of relative performance. Based on these rankings, we would expect stocks ranked 5 to outperform those ranked 4 or lower over the next 12 months, those ranked 4 to outperform those ranked 3 or lower, and so on. The entire universe of analyzed stocks (of which SFG Small-Cap coverage is a subset) is divided into fifths, such that the percentage of stocks in each category will remain largely consistent over time. Changes in quantitative and other factors that occur after the ranking are not reflected until the model is run again next quarter.

Beginning July, 2006 SFG changed the ranking system to include only three SIG Q SCORE rankings from 1 to 3, with a SIG Q SCORE of 1 representing the highest ranking. The methodology of computing the rankings remains as above; however, the result is now divided into thirds rather than fifths and the order inverts with 1 now being the highest ranking.

SFG Small-Cap Research: 0 companies under coverage (as of 03-31-2008)

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Price/Rating Chart Legend for all charts below

Net Neut	Net Neutral	Cov Disc	Coverage Discontinued
Net Pos	Net Positive	Cov Res	Coverage Resumed
Net Neg	Net Negative	◆	Indicates SIG Q SCORE system change, 07-01-2006
▲	Indicates Split	*	Indicates previous SIG Q SCORE system ranking

All dates are in mm-dd-yyyy format.

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