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ViroPharma Incorporated ⁽¹⁾

July FDA Advisory Meeting Should Shed Light into Possibility of Generic Vancocin

MARKET OUTPERFORM

VPHM \$10.99

Price	\$10.99	FY: Dec		2007A	2008E	2009E
Target Price	\$12.00	Revenue (M)	1Q	\$49.0	\$50.9A	--
52-Wk Range	\$7.27 - \$14.88		2Q	\$56.1	\$59.0	--
Shares Out. (M)	69.7		3Q	\$50.9	\$53.5	--
Market Cap. (M)	\$766.0		4Q	\$47.7	\$52.6	--
Average Daily Vol. (000)	1,515		FY	\$203.7	\$215.8	\$177.0
Float (M)	69.3			2007A	2008E	2009E
Secular Growth Rate	31%	EPS	1Q	\$0.31	\$0.22A	--
ROA	19.60%		2Q	\$0.39	\$0.26	--
			3Q	\$0.26	\$0.20	--
LT Debt (M)	\$250.0		4Q	\$0.25	\$0.17	--
LT Debt/Total Cap.	22.5%		FY	\$1.21	\$0.85	\$0.43
Cash (M)	\$584.3		P/E	9.1x	12.9x	25.6x
Cash/Share	\$8.36		Previous FY	--	NC	NC
			CY	\$1.21	\$0.85	\$0.43
			P/E	9.1x	12.9x	25.6x

NC indicates no change to previous estimate. NE indicates no previous estimate.

Source: Company reports and JMP Securities

INVESTMENT HIGHLIGHTS

- FDA advisory meeting in July likely to discuss Vancocin; reiterate Market Outperform rating on ViroPharma.** On July 23, 2008, the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology office within the FDA will hold an advisory committee meeting to “receive and discuss presentations from the Office of Generic Drugs (OGD) on the bioequivalence methods for locally acting drugs that treat gastrointestinal (GI) conditions”. We believe this meeting may be a response to ViroPharma’s citizens’ petition and the January 7th meeting in which the company argued against the use of the dissolution assay to prove bioequivalence. In our view, this action demonstrates that the FDA does have some concerns regarding the establishment of bioequivalency for locally acting GI drugs that it would like to publically vet with experts. We are pleased that we now have a timeline for insights regarding the regulatory path for generic Vancocin. Our \$12 price target is derived using an EPS valuation methodology and comps analysis.
- What is the deal with the dissolution tests?** Because it is a locally acting drug, to obtain approval for generic oral vancomycin in the United States, traditional guidelines required that the formulation demonstrate bioequivalence in clinical trials. Due to the expense required to perform these studies relative to the market potential, this policy has allowed ViroPharma to maintain its market exclusivity for vancocin pulvules branded as Vancocin. In March 2006, the OGD revised its guidelines allowing a prospective manufacturer to file based on *in vitro* dissolution testing equivalence rather than clinical trials, making the development of a generic Vancocin cheaper and easier. In 2007, ViroPharma filed a citizens’ petition protesting the OGD’s new guidelines, arguing that the *in vivo* environment of the CDI colon is more complex than the *in vitro* test guidelines and therefore does not accurately gauge where in the GI tract the generic version is released compared to Vancocin. As CDI is a localized infection within the colon, this could have important ramifications for efficacy.
- Dissolution has never been used as the sole basis for establishing bioequivalency.** We have found only one example where dissolution testing has been used to establish bioequivalency and it was used as one of two assays. We cite the approval of generic basalazine on this basis, which took 2 years and 3 months from the time of submission to approval, requiring a second, pharmacokinetic test to establish bioequivalency.

FOR DISCLOSURE AND FOOTNOTE INFORMATION, REFER TO THE JMP FACTS AND DISCLOSURES SECTION

- **Akorn's ANDA.** To date, the only company to file for approval of generic Vancocin is Akorn Therapeutics. FDA approval has not yet been granted. Our model assumes generic erosion beginning in 2009. Akorn has stated that the company will likely price generic vancomycin pulvules at about 70% of the price of the branded version, a modest discount compared to typical generic drugs. Given that treatment of CDI is a relatively low financial burden to society but it can be deadly, we do not believe price is as significant a driver for treatment decisions as in more common and chronic diseases such as arthritis or atherosclerosis. Thus, we do not believe generic erosion will be as immediate as in other indications.
- **It's a balancing act between cost and safety.** We note that the FDA as a whole has come under intense pressure to more thoroughly and conservatively assess the safety and efficacy of pharmaceutical products. At the same time, there is increasing pricing pressure on the healthcare system, and the OGD is encouraged to approve generics when possible. Our conversations with industry leaders suggest that the dissolution assay for Vancocin bioequivalence is weak at best and that ViroPharma has presented a decent case to FDA. Ultimately, the decision whether to approve generic Vancocin rests with the OGD, and we believe this meeting should give us a good indication of the Agency's position on how bioequivalence for Vancocin will be established.
- **Predictions for outcome of the meeting.** So what does this mean for Vancocin's future? While we do not yet know the specific questions the FDA will pose to the committee, outcomes of committee meetings are typically grouped into 3 buckets: disagree, agree, or further discussion needed. We believe that, depending on the precise wording of the question, two of the three outcomes would be positive for ViroPharma: agree or disagree (the wording of the question could put a nail in the coffin for Akorn's ANDA); further discussion needed would signal a delay. Briefing documents for the advisory committee containing details of the questions to be addressed at the meeting will be available on July 20. We spoke with ViroPharma management yesterday. They informed us they will begin preparing for a presentation of the company's argument against the dissolution method of establishing bioequivalence during the one hour public commentary part of the meeting. Based on our research, we believe that the likely outcome of the meeting will be a requirement for a second marker of bioequivalence, which could delay the arrival of generic Vancocin.

INVESTMENT RISKS

Clinical development risk. Drug development is a risky business. Historically, approximately one of every ten drugs that enter clinical trials makes it to the market.

Regulatory risk. ViroPharma, like all other drug development companies, is reliant on the FDA's pace for evaluating new drugs and the agency's willingness to approve new drugs.

Competitive risk. Due to the unmet need and rapid growth available in the anti-infective space, there are several companies developing products targeting similar diseases as ViroPharma. Some are presently in later stage clinical development and, if they are approved and launched, could potentially have a negative impact on sales of ViroPharma's products.

Partnership risk. ViroPharma is developing two of its products on a partnered basis. As a result, ViroPharma is reliant on the cooperation and progress of its partners to drive value from these programs.

Intellectual property risk. Like all other technology driven companies, ViroPharma's success may depend upon its ability to protect its intellectual property.

Sector risk. Valuation of biotechnology stocks is subject to both investors' assessments of the prospects of the underlying companies as well as investors' tolerance for risk and their confidence in the prospects of biotechnology stocks as a group. Therefore, ViroPharma stock may fall even while ViroPharma meets or exceeds investor expectations.

COMPANY DESCRIPTION

Exton, Pennsylvania-based ViroPharma Inc. is a commercial-stage biotechnology company with one marketed product and two product candidates in clinical development. Vancocin, its marketed product, was acquired from Eli Lilly and is used to treat *Clostridium difficile* associated diarrhea (CDAD). ViroPharma's two development candidates include Maribavir for the treatment and prevention of the cytomegalovirus (CMV) and HCV-796 targeting the Hepatitis C Virus (HCV).

JMP FACTS AND DISCLOSURES

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Publicly Traded Companies Mentioned in This Report:

ViroPharma Incorporated (1), VPHM, \$10.99, Market Outperform.

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JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	Regulatory Rating	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months	% of Co's With This Rating
Market Outperform	Buy	146	64%	Buy	146	64%	20	14%
Market Perform	Hold	74	32%	Hold	74	32%	2	3%
Market Underperform	Sell	9	4%	Sell	9	4%	0	0%
TOTAL:		229	100%		229	100%	22	10%

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. If the latest date is different than the report date, then the price is as of the previous day's close. The action reflected in this note is not annotated in the stock price chart. Source: FactSet and JMP Securities.



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