



# VOQP.OB

VioQuest Pharmaceuticals Inc.

July 29, 2008

## 510k Application Submitted for Xyfid™ and Priority Review Voucher for Lenocta™ Focuses Milestones and Share Price Appreciation

### Valuation Update

Ranking: **“BUY”**

Price at 7/28/08: **\$0.60**

52 Week Range: **\$0.20 – \$5.10**

Valuation: **\$8.55**

Market Capitalization: **\$2.94M**

Enterprise Value: **\$2.88M**

Float: **3.38M**

Shares Outstanding: **4.91M**

Fully Diluted: **18.2M**

Cash: **\$2.2M**

Fiscal Year End: **December 31**

Exchange: **NASDAQ**



**Henry McCusker**  
617.559.1080  
hwm@scimitarequity.com

**Please Read the Updated Disclosures Section At the end of this review!**

### Vouchers are awarded for drugs targeting a neglected disease

Lenocta™ (sodium stibogluconate), an inhibitor of certain protein tyrosine phosphatases, is a pentavalent antimonial drug that has been in use for over 50 years in parts of Africa and Asia for the treatment of leishmaniasis (a protozoan disease). This drug is currently being used to treat U.S. military personnel serving in parts of the world where leishmaniasis is prevalent and approval for this indication may qualify VioQuest for a Priority Review Voucher.

The Food and Drug Administration Amendments Act of 09/07 authorized the FDA to award a priority review voucher to any company that obtains approval for a treatment for a neglected tropical disease. Draft regulations were circulated for comment late last year and it is expected the program will be implemented by the FDA during Q3/08. The voucher, which is anticipated to be transferable and marketable, would entitle the bearer to a priority six-month review for another product, not necessarily a tropical disease drug. Normally, the FDA review process can take from 10 to 18 months. Economists at Duke University, who proposed the voucher concept in 2006, have calculated that reduction of the FDA approval time from 18 to 6 months could be worth more than \$300 million to a company with a top-selling drug with a net present value close to \$3 Billion. At this level, the voucher would be expected to offset the substantial investment and risk required for discovery and development of a new treatment for a neglected tropical disease.

### Xyfid™, a topical agent for the treatment of skin disorders

VioQuest announced (7/1/08) the submission of a 510(k) application to the United States Food and Drug Administration (FDA). The application seeks marketing clearance for Xyfid™ (1% uracil topical), a topical skin preparation intended to relieve and to manage the burning and itching associated with various dermatoses including hand foot syndrome, atopic dermatitis, irritant contact dermatitis, radiation dermatitis and other dry skin conditions, by maintaining a moist wound and skin environment. With this submission, VOQP.OB should be positioned to consider opportunities for partnership or collaboration to support the commercialization strategy for this novel supportive care oncology product candidate. When cleared by the FDA, Xyfid™ will be VOQP.OB's first commercial product.

### Milestone enhancements mandate a valuation increase to \$8.55

We initiated coverage on VOQP.OB) with a “BUY” ranking and a valuation model of \$3.89 on 6/16/08. VOQP.OB now has a greater investment potential with significant short term upside based on pending clinical milestones in their lead drug candidate, Xyfid™ and the newly announced Priority Review Voucher Program from the FDA that may be granted to the company as a result of its work on Lenocta™. VOQP.OB trades at a huge discount to its peers and at a venture level valuation. VOQP.OB has 3 promising drug candidates targeting unmet medical needs in oncology with mid-stage development programs advancing toward registration (2 with Orphan Drug Designation and 1 with Fast Track status) with 2 potential regulatory submissions in 2008 with a Billion dollar market opportunity. We have upgraded our 12-month valuation in this review of VioQuest Pharmaceuticals to \$8.55 per share and reiterate our ranking of “BUY”.

## Investment Thesis

**We have upgraded our 12-month valuation” for VioQuest Pharmaceuticals (VOQP.OB) to \$8.55 per share and reiterate our ranking of “BUY”.** We had initiated coverage on VioQuest Pharmaceuticals, Inc (NASDAQ: VOQP.OB) with a “BUY” ranking and a valuation model of \$3.89 on 6/16/09.

VOQP.OB's lead compound under development is Xyfid™ (1% topical uracil cream) for the treatment and prevention of Hand-Foot Syndrome (“HFS”), a common and serious side effect of chemotherapy treatments. In parallel, Xyfid™ is also being developed to treat dry skin conditions and manage the burning and itching associated with various dermatoses. VOQP.OB expects to initiate a Phase IIb program for Xyfid™ in 2008 for HFS and has filed 510(k) during Q2/08 for Xyfid™ to treat various dermatoses. The 510(k) strategy, if successful, could dramatically accelerate the speed to market and needs to be aggressively pursued if appropriate. VOQP.OB is also developing Lenocta™ (sodium stibogluconate) for certain cancer applications, which VOQP.OB previously referred to as VQD-001, a selective, small molecule inhibitor of certain protein tyrosine phosphatases (“PTPs”), such as SHP-1, SHP-2 and PTP1B, with demonstrated anti-tumor activity against a wide spectrum of cancers both alone and in combination with other approved immune activation agents, including IL-2 and interferons.

Lenocta™ is currently in a PIIa clinical trial as a potential treatment for melanoma, renal cell carcinoma and other solid tumors. In addition to its potential role as cancer therapeutic, sodium stibogluconate has been approved in most of the world for first-line treatment of leishmaniasis, an infection typically found in tropic and sub-tropic developing countries. Based on historical published data and a large observational study by the U.S. Army, data from approximately 400 patients could be utilized to support a New Drug Application (“NDA”) with the FDA in 2008. Lenocta has been granted Orphan Drug status for leishmaniasis. In that this molecule is an approved product and has been in use for 50 years, it is a generic; hence, the intellectual property that VOQP.OB is pursuing for these novel cancer applications are critical components to leverage its shareholder value. **The newly launched Priority Review Voucher Program at the FDA is an incentive for drug makers to target diseases affecting poor nations and can be a transferable currency worth millions to its recipient.**

Additionally, VOQP.OB is developing VQD-002 (tricyriline phosphate monohydrate or TCN-P), a small molecule anticancer compound that inhibits activation of protein kinase B (PKB or AKT), a key component of a signaling pathway known to promote cancer cell growth and survival as well as resistance to chemotherapy and radiotherapy. The development program necessary to demonstrate the clinical use of Tricyriline for any application requires a sophisticated series of well run PII trials that represent several partnering opportunities. To attain the initial data set that triggers this partnering, VOQP.OB will likely need one (1) successful PII clinical trial that looks and feels like it has been run by Big Pharma; that takes money, time and patience and VioQuest may be able to accomplish this as a result of how it has positioned its first two (2) products. VQD-002 is currently in Phase I/IIa clinical development for multiple tumor types and VOQP.OB expects to move the compound into a Phase II clinical trial in 2008.

Christopher P. Schnittker, CPA, joined (7/21/08) VioQuest as VP and CFO. Prior to joining VioQuest Pharmaceuticals, Mr. Schnittker served as CFO at Micromet, Inc; following being a CFO at Cytogen Corporation and Genaera Corporation. Mr. Schnittker has also held management positions in accounting and finance at GSI Commerce, Rhône-Poulenc Rorer, and Price Waterhouse LLP.

VOQP.OB develops drug therapies for cancer and the side-effects of its treatment. We believe VOQP.OB has a solid investment potential with significant short term upside based on pending clinical milestones in their lead drug candidate, Xyfid™ and the newly announced Priority Review Voucher Program from the FDA that may be granted to the company as a result of its work on Lenocta™. **Reiterating, VOQP.OB trades at a huge discount to its peers and at a venture level valuation. VOQP.OB has 3 promising drug candidates targeting unmet medical needs in oncology with mid-stage development programs advancing toward registration (2 with Orphan Drug Designation and 1 with Fast Track status) and one (1) potential regulatory submission made in 2008 with a Billion dollar market opportunity in 2008. VOQP.OB continues to complete current on-going Phase 1 and Phase 2 studies for VQD-002 and Lenocta™.**

## Valuation Analysis

We have derived a 12-month valuation for VioQuest Pharmaceuticals (VOQP.OB) of \$8.55 per share (post the reverse split) and reiterate our ranking of "BUY".

We achieve our current valuation of \$8.55 by applying a "Sum-of-the-Parts" and a "Comparable Company Analysis and combine the analysis into an Average Blended Valuation Table.

Blended Price Target/Valuation Table	
Sum-of-The-Parts	\$12.21
Comparable Company Analysis (Market Cap)	\$4.88
<b>Avg. Blended Fair Value</b>	<b>\$8.55</b>

\* (Uses Fully Diluted Share Count of 18.2M)

### Sum-of-The-Parts scenario:

- Given the recent announcement that the company has successfully filed a 510(k) Application to the FDA for Xyfid (1% topical uracil cream) on June 30<sup>th</sup>, 2008 for various skin disorders including hand-foot syndrome (HFS) associated with 5-FU based chemotherapies, and potential commercial clearance from the FDA around September 30, 2008 (90-day review period), we have added sales projections from our new revenue model for Xyfid (see end of Valuation Section).
- We use a risk adjusted NPV (rNPV) of the company's drug pipeline, which currently has several products in clinical development. We assess the company's pipeline to be worth a total of approximately \$70M; \$4M for the Sodium Stibogluconate (SSG)/Lenocta product and \$66M for the Triciribine (TCN) product.
- We also include the company's current cash reserve, and the current number of fully diluted shares outstanding post financing (see Sum-of-The-Parts figure below). **This derives a 12-month price target of \$12.21 per share.**

### VQPH.OB:

#### Sum of the Parts Analysis:

Part (in 000's)	Value
<b>2014E revenues</b>	<b>\$67,305</b>
Price/sales multiple	10x
Discount rate	35.0%
Periods	5.00
<b>Value of revenue (000's)</b>	<b>\$150,099</b>
<b>Cash (000's)</b>	<b>\$2,200</b>
<b>rNPV of Pipeline (Lenocta &amp; Triciribine)</b>	<b>\$70,000</b>
Total (in 000's)	222,299
Diluted Shares outstanding	18,200
<b>Implied fair value per share</b>	<b>\$12.21</b>

#### Breakdown Per share:

Revenues	\$	8.25
Cash	\$	0.12
rNPV of Pipeline	\$	3.85
<b>Total</b>	<b>\$</b>	<b>12.21</b>

Source: Scimitar Equity, LLC Estimates

**Valuation Analysis (continued)**

**Company Comparable Analysis:**

We support our Sum-of-The-Parts analysis above by also conducting a Company Comparable Analysis. We compare VQPH with similar companies that are also mostly in Phase 1/2 stage of development to determine a fair value for the company.

- We note that the average Market Cap for the comparable group is **~\$88.88 m** versus only **~\$2.94 m** for VQPH (see comparable table below). Therefore, the comparable group has a Market Capitalization that is approximately **30.2x** that of VOQP.OB. After our study of VOQP.OB and its peer group we believe the company should be trading in-line with its peers. Therefore, by applying a **30.2x** multiple to the market cap of VOQP.OB we derive a fair value of **\$4.77** per share using the fully diluted share count of **18.2M**.
- We use the fully diluted share count of **18.2M** rather than the basic share count of **5.46M** in order to be conservative. We feel that until the company generates enough cash flow to pay down convertible preferred stock then such dilution is inevitable over the next couple years. However, if given a successful launch of Xyfid (1% uracil topical cream) the company can pay off its convertible debt before any dilution we are happy to revisit our valuation analysis using a lower share count.

**Small-Mid Cap Company Comparables**

Company	Ticker	Price 7/24/08	Market Cap (\$mm)	Enterprise Value (EV) \$mm
Adherex Technologies	ADH	\$0.18	\$23.07	\$9.78
Ariad	ARIA	\$3.07	\$213.20	\$134.46
ArQule	ARQL	\$3.80	\$166.56	\$107.41
BioCryst	BCRX	\$3.15	\$119.96	\$55.75
Cyclacel Pharmaceuticals	CYCC	\$1.72	\$35.14	(\$12.40)
CYTORI	CYTX	\$7.02	\$183.24	\$182.03
EntreMed	ENMD	\$0.46	\$39.46	\$19.80
Hana Biosciences	HNAB	\$0.59	\$18.99	\$7.69
SUNESIS	SNSS	\$1.59	\$54.95	\$18.84
ZIOPHARM Oncology	ZIOP	\$1.60	\$34.24	\$11.89
<b>Average of Comparables</b>		<b>\$2.32</b>	<b>\$88.88</b>	<b>\$55</b>
<b>VIOQUEST</b>	<b>VOQP</b>	<b>\$0.60</b>	<b>\$2.94</b>	<b>\$3</b>
<b>Implied Multiples</b>			<b>30.2x</b>	<b>19.0x</b>
<b>Implied fair value per fully diluted share</b>			<b>\$4.77</b>	<b>\$3.00</b>
<i>Source: CapitalIQ; Standard &amp; Poor's</i>				

Source: Scimitar Equity, LLC Compilation

## Valuation Analysis (continued)

## Xyfid™ (1% uracil topical): Revenue Model

Assumptions:

- Assume about 100K Xeloda users currently worldwide and increasing to about 115K by 2014.
- About 60K cases of HFS (60%) with Xeloda in 2008 and increasing annually with increase use of Xeloda and other 5-FU therapies. It will be used as a preventative with Xeloda and other 5-FU.
- Xyfid will be priced at \$250-\$300 per one (1) week supply of single use tubes (need several weeks supply per cycle) and be given with each cycle of chemo therefore \$1200 - \$2000 per patient cycle times 6 cycles is \$7.2K to \$12K per patient/per year.
- Add 30% for other 5-FU therapies, and assume 60% penetration of market in peak year, with developing therapies such as COX-2 inhibitors and Pyridoxine capturing remaining market.

## Xyfid™ (1% topical uracil): Revenue Model

Worldwide	2008E	2009E	2010E	2011E	2012E	2013E	2014E
<b>Annual Number Patients on Xeloda®</b>	100,000	102,000	104,040	106,121	108,243	110,408	112,616
% Xeloda pts. afflicted by Hand-Foot Syndrome (HFS)	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%
<b># Treatable Patients (HFS) on Xeloda</b>	60,000	61,200	62,424	63,672	64,946	66,245	67,570
% pts. Eligible or who have access to Xyfid treatment	90%	90%	90%	90%	90%	90%	90%
<b># treatment cycles per patient on Xeloda per year</b>	6	6	6	6	6	6	6
Maximum # treatable Xeloda cycles	324,000	330,480	337,090	343,831	350,708	357,722	364,877
% Penetration Rate		10%	20%	40%	60%	60%	60%
<b>Cost per cycle Xyfid treatment Hand-Foot Syndrome</b>	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200
<b>Revenue from Xeloda Patients</b>	\$0	\$39,657,600	\$80,901,504	\$165,039,068	\$252,509,774	\$257,559,970	\$262,711,169
Additional Revenue for other 5-FU therapies (add 30%)	30%	30%	30%	30%	30%	30%	30%
<b>Total Revenue from Xeloda &amp; other 5-FU patients</b>	\$0	\$51,554,880	\$105,171,955	\$214,550,789	\$328,262,707	\$334,827,961	\$341,524,520
~\$30M Payment to original inventor (amortized)		\$5,000,000	\$5,000,000	\$5,000,000	\$5,000,000	\$5,000,000	\$5,000,000
<b>Post Inventor Total Revenue</b>		\$46,554,880	\$100,171,955	\$209,550,789	\$323,262,707	\$329,827,961	\$336,524,520
<b>Estimated Royalty Rate from Partner</b>		17%	18%	20%	20%	20%	20%
<b>Total Royalty Revenue to VioQuest</b>	\$0	\$7,914,330	\$18,030,952	\$41,910,158	\$64,652,541	\$65,965,592	\$67,304,904

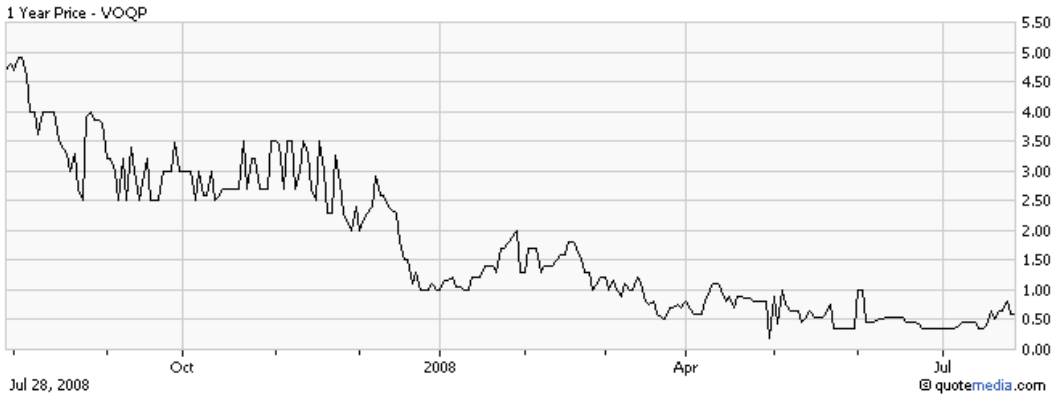
Source: Scimitar Equity, LLC Estimates

Capitalization

Financial Instruments	# of Shares
Common Shares Outstanding ***	5,462,429
Convertible Preferred A (\$0.06)	5,774,167
B (\$0.38)	896,096
Options***	1,087,106
Warrants***	5,394,472
Fully Diluted ****	18,164,269

Charts

Chart for VOQP.OB:



Comparables Chart for VOQP.OB:



- VioQuest (VOQP.OB) - Black
- Ariad (ARIA) - Green
- ArQule (ARQL) - Orange
- BioCryst (BCRX) - Purple
- CYTORI (CYTX) - Brown
- EntreMed (ENMD) - Gray
- SUNESIS (SNSS) - Light Blue
- Ziopharma (ZIOP) - Dark Green
- Cyclacel (CYCC) - Dark Blue
- Adherex (ADH) - Dark Gray

## Company Description

VioQuest Pharmaceuticals is a New Jersey-based biotechnology company developing novel drug therapies targeting both the molecular basis of cancer and side effects of treatment. VOQP.OB's oncology portfolio includes: Xyfid™ (1% uracil topical), for the treatment and prevention of Hand-Foot Syndrome, a common side effect from certain chemotherapy treatments, and to treat dry skin conditions and manage the burning and itching associated with various dermatoses; VQD-002 (tricitiribine phosphate monohydrate), a targeted inhibitor of Akt activation; and Lenocta™ (sodium stibogluconate), an inhibitor of certain protein tyrosine phosphatases such as SHP-1, SHP-2, and PTP1B. **VioQuest's lead compound under development is Xyfid (1% topical uracil) for the treatment and prevention of Hand-Foot Syndrome ("HFS"), a common and serious side effect of chemotherapy treatments. In parallel, Xyfid is also being developed to treat dry skin conditions and manage the burning and itching associated with various diseases of the skin, or dermatoses. VOQP.OB expects to initiate a Phase IIb program for Xyfid in 2008 for HFS, and has filed a 510(k) Premarket Notification submission during Q2/08 for Xyfid to treat various dermatoses.** Additionally, VOQP.OB is developing VQD-002 (tricitiribine phosphate monohydrate or TCN-P), a small molecule anticancer compound that inhibits activation of protein kinase B (PKB or AKT), a key component of a signaling pathway known to promote cancer cell growth and survival as well as resistance to chemotherapy and radiotherapy. **VQD-002 is currently in Phase I clinical development for multiple tumor types and VOQP.OB expects to advance VQD-002 into Phase II clinical development during 2008.** VOQP.OB is also developing Lenocta (sodium stibogluconate), which it previously referred to as VQD-001, a selective, small molecule inhibitor of certain protein tyrosine phosphatases ("PTPs"), such as SHP-1, SHP-2 and PTP1B, with demonstrated anti-tumor activity against a wide spectrum of cancers both alone and in combination with other approved immune activation agents, including IL-2 and interferons. Lenocta is currently in a Phase IIa clinical trial as a potential treatment for melanoma, renal cell carcinoma, and other solid tumors. In addition to its potential role as a cancer therapeutic, sodium stibogluconate has been approved in most of the world for first-line treatment of leishmaniasis, an infection typically found in tropic and sub-tropic developing countries. **This drug is currently being used to treat U.S. military personnel serving in parts of the world where leishmaniasis is prevalent and may qualify VioQuest for a Priority Review Voucher.** Based on historical published data and a large observational study by the U.S. Army, data from approximately 400 patients could be utilized to support a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") in 2008. **Lenocta has been granted Orphan Drug status for leishmaniasis.**

## Investment Risks

VOQP.OB's stock may face liquidity risk because of its low stock price, cash position and volatile movement on little volume. VOQP.OB most likely will need to rely heavily on equity financing to fund its on-going operations. VOQP.OB's auditors issued a "going concern" warning in VOQP.OB's latest 10-K filing. VOQP.OB's common stock is considered to be a "penny stock." VOQP.OB is an early stage development stage company with a history of losses and can provide no assurance as to future operating results. As a result of losses which will continue throughout VOQP.OB's development stage, they may exhaust their financial resources and be unable to complete the development of their production. VOQP.OB is subject to numerous risks inherent in conducting clinical trials. Successful development of biopharmaceuticals is highly uncertain and is dependent on numerous factors, many of which are beyond VOQP.OB's control. Products that appear promising in the early phases of development may fail to reach the market for several reasons. VOQP.OB can provide no assurance that these products will obtain regulatory approval or that the results of clinical studies will be favorable. **Investors should always read the risk factors in VOQP.OB's latest 10-K and 10-Q SEC filings before making any investment decisions**

## Patents, Rights and Licenses

Through the acquisition of Greenwich Therapeutics, Inc. in 10/05, VOQP.OB obtained the rights to develop and commercialize 2 oncology drug candidates - Lenocta and VQD-002. VioQuest holds rights to Lenocta and VQD-002, pursuant to license agreements with The Cleveland Clinic Foundation and the University of South Florida Research Foundation. In 3/07, VOQP.OB acquired license rights to develop and commercialize Xyfid and rights to Xyfid are governed by a license agreement with Asymmetric Therapeutics, LLC and Onc Res, Inc., as assigned by Fiordland Pharmaceuticals, Inc. These licenses give VioQuest the right to develop, manufacture, use, commercialize, lease, sell and/or sublicense Lenocta, VQD-002 and Xyfid.

## Catalysts and Milestones

<b>Xyfid™ Milestones</b>		
<b>DATE</b>	<b>EVENTS</b>	<b>STATUS</b>
Q1/08	Manufacture GMP clinical trial supplies	Completed
Q3/08	510(k) regulatory submission to FDA	Completed
Q3/08	510(k) response due from FDA for potential commercial clearance	
Q4/08	Initiate Phase II study for prevention of Hand-Foot Syndrome	

<b>Triciribine Milestones</b>		
<b>DATE</b>	<b>EVENTS</b>	<b>STATUS</b>
Q4/07	Present preliminary Phase I solid tumor data at EORTC-NCI-AACR annual meeting	Completed
Q4/07	Present preliminary Phase I leukemia data at ASH annual meeting	Completed
Q4/07	Publication of preclinical data demonstrating ability to overcome Herceptin® resistance in breast cancer	Completed
Q1/08	Publication of preclinical data demonstrating ability to overcome cisplatin resistance in ovarian cancer	Completed
Q1/08	Obtain Orphan Drug status for treatment of multiple myeloma	Completed
Q1/08	Enter into Clinical Trial Agreement (CTA) with NCI	Completed
Q2/08	Present preclinical data at AACR annual meeting	Completed
1 <sup>st</sup> Half 08	Complete Phase I dose escalation studies in solid tumors and leukemia	
FY 2008	NCI to initiate Phase I/II study in non-small cell lung cancer (NSCLC) with erlotinib under CTA 2008	
Q4/08	Submit final Phase I leukemia data for ASH 2008	

<b>Lenocta™ Milestones</b>		
<b>DATE</b>	<b>EVENTS</b>	<b>STATUS</b>
Q4/07	Present preliminary Phase I solid tumor study results at EORTC-NCI-AACR annual meeting Q4 2007	Completed
Q4/07	Initiate Phase IIa study in solid tumors Q4 2007	Completed
Q2/08	Present Phase I solid tumor results at ASCO 2008	Completed
Q4/08	Complete enrollment in ongoing Phase IIa solid tumor study (combo w/ interferon) Q4 2008	
FY 2008	Convene advisory board for leishmaniasis, discuss findings with FDA, possible NDA	
1 <sup>st</sup> Half 09	Submit Phase IIa solid tumor data for ASCO 2009	

## Technology

### Xyfid™ (1% uracil topical cream)

Xyfid™ (1% uracil topical): VioQuest has been developing Xyfid for the treatment and prevention of palmar-plantar erythrodysesthesia (PPE), also known as hand-foot syndrome (HFS), a relatively common dose-limiting side effect of cytotoxic chemotherapy - most frequently fluoropyrimidines, such as continuous infusion 5-fluorouracil (5-FU), and the oral 5-FU prodrug capecitabine (Xeloda® by Roche).

**Annually, more than 100,000 patients worldwide take Xeloda® with approximately six treatment cycles per year.**

Therefore the market for Xyfid™ is approximately 600,000 treatment cycles per year for Xeloda® alone. Treatment of HFS priced at ~\$1,200 per cycle would be competitive with other supportive care products addressing dose limiting toxicities, such as blood growth factors. Accordingly, the potential market opportunity for treating HFS is nearly \$1 Billion.

Fluoropyrimidines are among the most commonly used cancer chemotherapeutics nearly 50 years after their introduction. Fluoropyrimidines, alone or in combination therapy, are commonly given for cancers of the head and neck, breast, cervix, and gastrointestinal tract. **There are currently no treatments or preventative agents for HFS, which is characterized by the progressive redness and cracking of the hands and feet. The severity of HFS is typically defined by three grade levels: Grade 1: numbness, tingling, painless swelling; Grade 2: painful discomfort, swelling; Grade 3: ulceration, blistering, severe pain and discomfort, unable to work or perform activities of daily living. Up to 60% of all capecitabine patients experience HFS and up to 20% experience severe HFS (Grade 3).** According to the prescribing information for capecitabine, if grade 2 or 3 HFS occurs, administration of capecitabine should be interrupted until the event resolves or decreases in intensity to grade 1. Following grade 3 HFS, subsequent doses of capecitabine should be decreased. Uracil, the active ingredient in Xyfid, is a naturally occurring substrate for enzymes, such as thymidine phosphorylase (TP) and dihydropyrimidine dehydrogenase (DPD), that metabolize fluoropyrimidines into toxic metabolites.

**Addition of uracil to systemic fluoropyrimidine treatment regimens, such as tegafur-uracil, or UFT, is well-established to significantly diminish the incidence of HFS.** Whereas such combination products have been licensed in Japan and much of Europe, they have not been approved for use in the United States due, in part, to FDA questions regarding the demonstrable non-inferiority of the combination drug compared with fluoropyrimidines alone. In contrast to systemic exposure, topical application of uracil would potentially allow for the treatment and prevention of HFS without compromising the efficacy of systemic fluoropyrimidine therapy. **In a small pilot study, Xyfid has been effective at preventing the both the incidence and recurrence of dose limiting HFS when applied topically.**

VOQP.OB believes that Xyfid may be substantially equivalent to several predicate devices designed to improve dry skin conditions and to relieve and to manage the burning and itching associated with various dermatoses including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and other dry skin conditions, by maintaining a moist wound and skin environment. A pilot clinical study in patients has demonstrated that topical application of Xyfid to the hands and feet may be effective in preventing the recurrence of dose limiting HFS. On this basis, an investigational new drug application (IND) was submitted and accepted by the FDA. Subsequently, Xyfid was granted fast track designation for the prevention of HFS in patients receiving capecitabine for the treatment of advanced metastatic breast cancer. Pursuant to this IND, we expect to evaluate the safety, tolerability and activity of Xyfid and its ability to reduce the incidence of HFS. VioQuest is considering a 60-patient Phase IIb study in breast cancer patients receiving capecitabine that could begin during 2008. The outcome of the Phase IIb study could support plans for registration of Xyfid under the NDA process. **Xyfid has been awarded fast-track status by the FDA in this setting.**

Combination products using systemic uracil have been licensed in Japan and much of Europe, they have not been approved for use in the United States due, in part, to FDA questions regarding (“does DPD inhibition negatively effect therapeutic outcome”) the demonstrable noninferiority of the combination drug compared with 5-FU alone.

Technology (continued)

Examples of Grade 3 Hand-Foot Syndrome (HFS)



## Technology (continued)

### Clinical Effects of Hand-Foot Syndrome (HFS)

"If grade 2 or 3 hand-and-foot syndrome occurs, administration of XELODA should be interrupted until the event resolves or decreases in intensity to grade 1. Following grade 3 hand-and-foot syndrome, subsequent doses of XELODA should be decreased."

(Source: Roche - XELODA prescribing information)

Grading Hand-Foot Syndrome			
Grade	NCI Definition	Clinical Trial Definition	
		Clinical	Functional
1	Minimal skin changes or dermatitis (e.g., erythema, peeling) with altered sensations (e.g., numbness, tingling, burning) but do not interfere with activities of daily living	Numbness, dysesthesia/paraesthesia, tingling, painless swelling or erythema	Discomfort that does not disrupt normal activities
2	Skin changes present with accompanying pain interfering little with activities of daily living; skin surface remains intact	Painful erythema with swelling	Discomfort that affects activities of daily living
3	Ulcerative dermatitis or skin changes with severe pain interfering with activities of daily living; tissue breakdown is evident (e.g., peeling, blisters, bleeding, edema)	Moist desquamation, ulceration, blistering, severe pain	Severe discomfort, unable to work or perform activities of daily living

Source: SM Gressett, et al. *J Oncol Pharm Pract.* 2006 Sep; 12(3):131-41. Review.

### Xyfid™: Treatment for Hand-Foot Syndrome (HFS)

- **Uracil, the active ingredient in Xyfid™, is a naturally occurring substrate that directly competes with 5-FU for the enzymes that metabolize 5-FU to its toxic metabolites**
- **When applied topically, the concentration of uracil in the skin greatly exceeds the concentrations of 5-FU, thus blocking the formation of 5-FU's toxic metabolites**
- **In a pilot study, Xyfid™ applied topically twice daily to the palms of the hands and soles of the feet was effective at preventing HFS**
  - Xyfid™ mechanism of action also supported through systemic uracil (e.g., UFT)
  - Safety also supported through systemic absorption studies of topically applied fluorouracil (Efudex®) performed on patients with actinic keratoses using tracer amounts of radio labeled fluorouracil added to a 5% preparation
    - Negligible amounts of labeled material were found in plasma, urine
- **Issued patents covering method/formulation as well as combination kit incorporating 5-FU and Xyfid™**
  - **Xeloda patent expiry around 2013**
  - **Combination kit example: Ribavirin with Intron-A for Hepatitis C**

---

## Technology (continued)

### Xyfid™: Parallel Regulatory Paths for Different Indications

#### NDA route

Xyfid™ for prevention of Hand-Foot Syndrome

- Pilot study completed
  - Demonstrated reversal of HFS and re-escalation of the dose of Xeloda
    - IND submitted and accepted
    - Fast track designation
    - Phase IIb study expected to begin mid-2008

#### 510(k) route

Xyfid™ to treat dry skin conditions and to relieve and manage the burning, itching associated with various dermatoses

- 510(k) submission made June 30, 2008
- Standard 90-day review
- Potential commercial clearance approximately Q3/08 –Q4/08

### Xyfid™: Market Opportunity

- **600,000 cycles of Xeloda therapy appropriate for prophylactic treatment**
  - **100,000 patients treated with Xeloda annually**
  - **Average six cycles of Xeloda per year**
- **Treatment of HFS priced at ~\$1,200 per cycle would be competitive with other supportive care products addressing dose limiting toxicities**
  - **For example, blood growth factors**
- **Potential peak market opportunity is nearly \$1 billion**
  - **Not including combination kit opportunity w/ 5FU after 2013**
- **Partnership discussions ongoing**

## Technology (continued)

### Lenocta™ (sodium stibogluconate)

Lenocta™ is a selective, small molecule inhibitor of certain protein tyrosine phosphatases (PTPs), such as SHP-1, SHP-2 and PTP1B, with demonstrated anti-tumor activity against a wide spectrum of cancers both alone and in combination with other approved immune activation agents, including IL-2 and interferons. **PTPs are a family of proteins that regulate signal transduction pathways in cells and have been implicated in a number of diseases including cancer, diabetes, and neurodegeneration.**

Lenocta™ (sodium stibogluconate). Lenocta is a selective, small molecule inhibitor of certain protein tyrosine phosphatases (PTPs), such as SHP-1, SHP-2 and PTP1B, with demonstrated anti-tumor activity against a wide spectrum of cancers both alone and in combination with other approved immune activation agents, including IL-2 and interferons. PTPs are a family of proteins that regulate signal transduction pathways in cells and have been implicated in a number of diseases including cancer, diabetes, and neurodegeneration. Lenocta has been shown to have anti-proliferative activity against a broad number of tumor cell lines, including melanoma and renal cell lines. Pre-clinical work in nude mice with cancer xenografts has shown that Lenocta can control malignancies in vivo as well. These effects were seen whether used as part of a combination therapy with existing treatments, including interferon and interleukin-2, or alone. **In addition, preclinical data also suggests that monotherapy with Lenocta may be useful to treat certain other tumor types, including prostate cancer.**

The preclinical data suggests that Lenocta utilizes multiple modes of action, including having a direct effect on cancer cells, as well as generally enhancing the body's immune system. **These multiple modes of action, along with Lenocta's known historical toxicity profile, demonstrate that Lenocta is a potentially attractive drug candidate to evaluate as an anti-cancer agent.** Phase I data from our combination trial of Lenocta and alpha interferon ("IFN a-2b") demonstrated pharmacodynamic activity in some solid tumors as demonstrated by increases in the activities of natural killer cells, CD8 and type II dendritic cells, and two patients with ocular melanoma (1) and adenocystic carcinoma (1) have remained stable by Response Evaluation Criteria in Solid Tumors, or RECIST, on first assessment. There have been 17 subjects evaluable for response.

A complete treatment cycle is for six weeks, with week 1 the patient is intravenously dosed with Lenocta for five days as a monotherapy, week 2 the patient is dosed with Lenocta and IFN a-2b, week 3 is a rest period, weeks 4 and 5 the patient is dosed with Lenocta and IFN a-2b, and then there is a week rest before a subsequent cycle is initiated. Patients have been given five different dose cohorts: 400 mg/m<sup>2</sup>, 600 mg/m<sup>2</sup>, 900 mg/m<sup>2</sup>, 1350 mg/m<sup>2</sup> and a dose reduced cohort of 1125 mg/m<sup>2</sup>. Lenocta with IFN a-2b has been well tolerated at doses up to 900 mg/m<sup>2</sup>. **VOQP.OB plans to initiate an expansion phase for 20 patients to have twelve subjects evaluable for response at a dose of 900 mg/m<sup>2</sup>.**

**VOQP.OB has filed with the FDA an IND for Lenocta, which the FDA accepted in 8/06, allowing commencement of clinical trials of Lenocta. Lenocta is currently being studied at the M.D. Anderson Cancer Center and the University of New Mexico in a Phase IIa corporate-sponsored clinical trial in combination with IFN a-2b in up to 54-patients with melanoma, renal cell carcinoma, and other solid tumors that have been non-responsive in previous cytokine therapy.** In November 2007, we dosed our first patient in our Phase IIa solid tumor study. VOQP.OB expects to complete enrollment in the Phase IIa solid tumor study in 2008. The Phase IIa trial has been designed to evaluate the clinical efficacy and biological effectiveness of Lenocta at the highest tolerable does in combination with IFN a-2b in patients with advanced-stage solid tumors.

**Additional Potential Indication of Lenocta:** VOQP.OB continues to develop Lenocta for indications primarily used for an oncology drug candidate; VioQuest is also in the process of evaluating its potential development as a treatment for leishmaniasis. According to the WHO, leishmaniasis currently threatens 350 m men, women and children in 88 countries around the world. The leishmaniasis are parasitic diseases with a wide range of clinical symptoms, including skin ulcers, partial or total destruction of the mucus membrane and irregular bouts of fever, substantial weight loss, swelling of the spleen and liver, and anemia (occasionally serious). In collaboration with the U.S. Army, through an executed Cooperative Research and Development Agreement; VioQuest is evaluating the potential development of Lenocta in the treatment of leishmaniasis. Lenocta was granted orphan drug designation by the FDA in the second half of 2006 for the treatment of leishmaniasis. VioQuest has also convened an advisory board to evaluate the potential submission of an NDA to the FDA for Lenocta for the treatment of leishmaniasis in 2008.

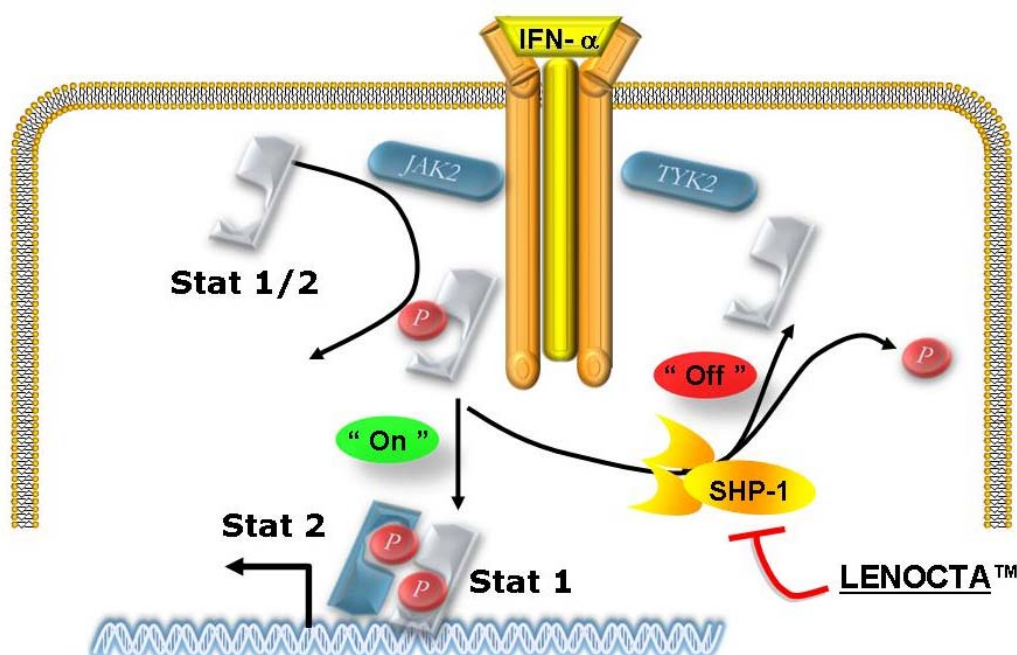
## Technology (continued)

### Lenocta™: Novel Inhibitor of PTP Signaling

- Lenocta (sodium stibogluconate or SSG), a pentavalent antimonial, has been used to treat human leishmaniasis for the past 60 years
- In 2001, Lenocta first identified as a potent inhibitor of specific protein tyrosine phosphatases (PTPs)
  - SHP-1, SHP-2, and PTP1B
    - SHP-1 is a negative regulator in the Janus kinase (Jak)/Stat pathway that mediates the signaling of cytokines
- Demonstrated preclinical anticancer activity with several approved cytokine therapies (interferon alpha, IL-2, etc.)
  - Enhances the antiproliferative effects of cytokine therapy

Source: MK Pathak, et al. *J Immunol.* 2001 Sep 15;167(6):3391-7.

### Lenocta™ Potentiates IFN- $\alpha$ Signaling by Inhibiting SHP-1



Adapted From Platanias. *Nature Reviews Immunology* 5, 375-386 (May 2005)

Technology (continued)

Lenocta™ Phase I Study Design

- Twenty-one patients with advanced solid tumors were enrolled at M.D. Anderson and University of New Mexico
  - Including 5 with melanoma, 4 with pancreatic cancer, and 3 with colorectal cancer
- Treatment cycle was six weeks in duration and used escalating doses of Lenocta administered daily (30-minute infusion) on weeks one, two, four and five and a fixed dose of IFN alpha-2b (3 million units subcutaneously) administered on three days during weeks two, four and five
  - Lenocta doses: 400 mg/m2, 600 mg/m2, 900 mg/m2, 1125 mg/m2, and 1350 mg/m2
- Primary objective of the Phase 1 dose escalation study was to determine the safety and tolerability of the combination regimen for patients with advanced solid tumors
  - Secondary objective was to assess immunologic efficacy

Lenocta™ Preliminary Efficacy Demonstrated in Phase I Study

- Lenocta in combination with IFN α-2b as studied in this regimen was well tolerated for doses up to 900 mg/m2
  - Anemia, thrombocytopenia, and Hypokalemia were dose limiting toxicities above 900 mg/m2
- Results demonstrate increased adaptive and innate immune responses following therapy with Lenocta in combination with IFN α-2b
  - Increased IFN-α production by toll-like receptor (TLR) 7 and 8 activated plasmacytoid dendritic cells
  - Increased perforin production by NKT and CD8+ T-cells
  - Increased IL-2 production by CD4+ T-cells
  - Decreased T-regulatory cells (Treg)
- Objective of Phase 2a expansion to demonstrate clinical anti-cancer activity (PFS)

Lenocta™ Phase IIa Solid Tumor Study Launched November 2007

- Opened enrollment in Q4 2007
  - MD Anderson and University of New Mexico
- Study design
  - Open label
  - Solid tumors
- Primary endpoint is progression free survival

Potential Lenocta™ Registration Strategy

- CRADA with U.S. Army supports development of Lenocta to treat cutaneous leishmaniasis
- Data from ~400 patients being evaluated to support possible NDA in 2008
  - Army received Orphan Drug Status for use in treating cutaneous leishmaniasis
  - Clinical data from Army



## Please Read these Important Disclosures!

### Reg. AC, Analyst Certification

I, Henry W. McCusker, hereby certify that all the views expressed in this review, accurately reflect my personal views about the subject Company or companies and its or their securities. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views contained in this review.

<http://www.scimitarequity.com/disclosure/index.jsp>

### Compensation for Products and Services

Scimitar makes publicly available an excel format statement of yearly payments by covered companies.

[http://www.scimitarequity.com/disclosure/company\\_specific\\_disclosure.jsp](http://www.scimitarequity.com/disclosure/company_specific_disclosure.jsp)

### Regulatory Disclosure

Scimitar Equity Research, Inc. (Scimitar) "clearly and prominently" articulates a statement of financial sponsorship and has a compensation arrangement for this valuation update (\$8,500) research review. Scimitar is an independent equity research firm providing unbiased and insightful analysis for emerging healthcare companies and publishes research utilizing the "sponsored" or "paid-for" compensation model to increase visibility and access to the investing communities. Scimitar provides a comprehensive qualitative narrative and quantitative financial analyses to identify those companies demonstrating real progress towards their vision while meeting quarterly expectations Scimitar delivers this research via the world-wide web and our proprietary database to the institutional, advisory and retail investment communities. To maximize transparency in analyst certification, we are required to disclose any potential conflicts of interest thus insuring independence. We do not accept payment of any fees in company stock or any form of security.

[http://www.scimitarequity.com/disclosure/regulatory\\_disclosure.jsp](http://www.scimitarequity.com/disclosure/regulatory_disclosure.jsp)

### Company Specific Risk Disclosure

The specific risks for those companies covered by Scimitar Equity Research, Inc. (Scimitar) may be greater than the general risks involved with common stock. The majority of the companies covered by Scimitar are development stage companies that are not profitable, and may not be profitable in the foreseeable future. The majority of the companies we cover rely heavily on equity financing to fund their continuing operation. If one or more of these companies is/are unable to sell equity to fund its operations, then that/those particular company/ies may become insolvent. The futures of these companies are reliant on approval of their drugs/diagnostics by the FDA. Also, if clinical and regulatory approvals are granted for one of the company's products, then that does not necessarily guarantee revenue. The companies are subject to manufacturing and regulatory risks as well. These risks could adversely affect future earnings of each company. The shareholders of each company are reliant on the board of directors and management to objectively manage the company in a manner that maximizes shareholder value. The board of directors and management of a particular company may have different objectives or lack competency to reach the shareholders' goals. A misalignment of corporate governance would put that particular company at financial risk. These companies are dependent on key employees and are reliant on current management to run each company. If there is a sudden change of management for any number of reasons, it could affect the future performance of the company. The ability to hire skilled workers and retain them is necessary for each company's success. There is no guarantee that certain patents and trademarks that a particular company claims to will be upheld in the United States or abroad. These intellectual properties, patents and trademarks may be infringed by other companies without financial recourse to a particular company. The company/ies may also be sued by other companies or individuals for patent/trademark infringement, clinical/manufacturing faults, or for any number of legal/contractual reasons. Development stage companies face several competitors in the biotechnology/diagnostics/devices field that may have greater access to capital, clinical expertise, and marketing expertise. Their competitors may have better products, manufacturing capabilities and reach FDA approval with a similar product before these companies. Increased competition in these fields may adversely affect a particular company's stock price. Many companies covered by Scimitar are classified as "penny stocks" and the price of these companies' stocks may move substantially on little volume are subject to increased market price volatility, risk and have an increased degree of volatility relative to the overall market. Risk-averse investors, and all other investors, should be aware of the risks associated with these companies and read all 10-K's and 10-Q's before considering any investment. Investors are expected to be knowledgeable and competent of these risks themselves, or otherwise, speak to their investment advisors before purchasing any securities in the market. Scimitar does not accept any liability for whatever actions an investor takes on their own, or with the advice of their investment advisor after reading Scimitar's research reviews.

<http://www.scimitarequity.com/content/disclosure/company-specific-disclosure.jsp>

### Legal Disclaimer

The information, opinions, scientific data, quantitative and qualitative statements contained in these reviews have been obtained from research, trade and statistical services as well as other sources believed to be reliable. The information, opinions, or recommendations contained in these reviews are submitted solely for advisory and informational purposes. The opinions expressed are our current opinions as of the date appearing on the review only. Our analysis is subject to possible change without notice. This research contains forward looking statements, which involve risk and uncertainty. The reviews are not a complete analysis of every material fact regarding this company, industry, or security. The information in these reviews are not intended to be used as the primary basis of investment decisions, and because of individual or investment objectives it should not be construed as advice designated to meet the particular investment needs of any investor. Investors are expected to take full responsibility for any and all of their investment decisions. Investors must make investment decisions based on their evaluation of their own investment goals, risk tolerance, and financial condition. Scimitar Equity Research, Inc., our officers, our advisors, and our partners accept no liability whatsoever for any direct or consequential losses arising from any use of the information obtained on or through our web site. The information in these company reviews is not a representation or warranty and is not a solicitation of any offer to buy or sell this security.

[http://www.scimitarequity.com/disclosure/legal\\_disclaimer.jsp](http://www.scimitarequity.com/disclosure/legal_disclaimer.jsp)

## Please Read these Important Disclosures! (Continued)

### Estimates, Models and Valuation Methodology

Scimitar prudently performs analysis and creates quantitative models and estimates derived from our own research and due diligence without any assistance from the/any represented company. Scimitar's estimates and models reflect "our" current judgment only; they are neither all-inclusive nor can they be guaranteed. "Our" analysis and models are subject to change based on share pricing, share/capitalization increases or decreases, regulatory status and certainly market conditions. Projecting the valuation of emerging healthcare companies can be truly "inexact". In these current volatile market times; Scimitar has stepped back from making specific price targets. Valuation should be understood in terms of an objective quantitative model and a comprehensive qualitative explanation that enlightens investors to expectation and potential. Reiterating, "NO" part of our compensation is related to the specific valuation recommendations or views contained in this review.

<http://www.scimitarequity.com/content/disclosure/valuation-methodology.jsp>

### Research Dissemination

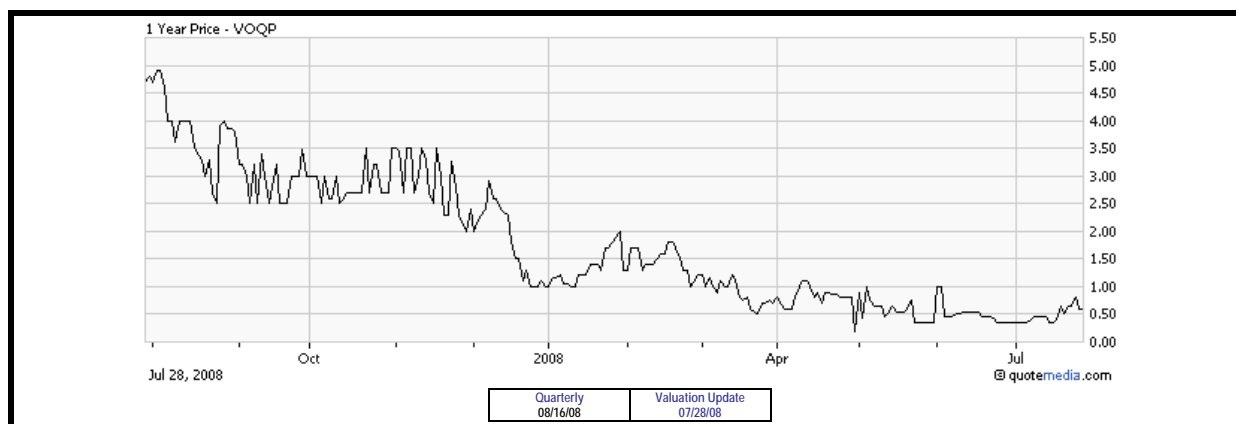
The information presented on our web site is provided only as an aid for informing those who make their own investment decisions and are not to be used or considered as an offer to sell or solicitation of an offer to buy any financial products. Clients may also receive our research via Thomson Financial: FirstCall- Investext. Security laws of these resident countries vary significantly. This site is intended to be accessed by residents of the United States and by residents of other jurisdictions only where permitted by law.

<http://www.scimitarequity.com/content/disclosure/research-dissemination.jsp>

### Rating Definitions

Informational: It has been our practice to generate an informational company review when we initiate coverage. A "Buy" ranking could accompany a price target but these company reviews generally entail that additional information is needed to determine or clarify the companies approach to the growth opportunity. Stocks ranked "Buy" are those stocks Scimitar recommend actively buying. These are stocks that are demonstrating their vision while meeting expectation and should appreciate at least 10% over the next 6 months. Stocks ranked "Hold" are those stocks Scimitar would continue to hold in a portfolio. These are stocks that are making progress strategically and operationally but are not expected to demonstrate significant appreciation in the next 6 months. Stocks ranked "Sell" are those Scimitar would sell; these are stocks that appear not to be able to fulfill or deliver on their disclosed milestones and are expected to depreciate at least 10% over the next 6 months. Termination (of coverage): In the event an analyst's coverage is terminated, there is a requirement that firms notify investors when coverage is dropped. This notice must include a final ranking or recommendation. The rule specifically calls for notice to be made in the same manner as in research coverage was first initiated.

<http://www.scimitarequity.com/content/disclosure/distribution-rankings.jsp>



### Privacy Policy

Scimitar is committed to respecting the rights of those individuals viewing or utilizing this website, and the protection of any information that might be collected or that which you as a subscriber may choose to share.

<http://www.scimitarequity.com/disclosure/privacy.jsp>

### Obtaining Current Disclosures

[http://www.scimitarequity.com/disclosure/disclosures\\_supporting\\_reporting.jsp](http://www.scimitarequity.com/disclosure/disclosures_supporting_reporting.jsp)

Applicable current disclosures can be downloaded from our website, by calling the telephone number listed below, or by writing to the address listed below:

Scimitar Equity, LLC.

6 Barley Lane

Wayland, MA 01778

Tel: 617.559.1080

[info@scimitarequity.com](mailto:info@scimitarequity.com)

[www.scimitarequity.com](http://www.scimitarequity.com)