VioQuest Pharmaceuticals, Inc. Form S-1/A July 22, 2008

#### As filed with the Securities and Exchange Commission on July 21, 2008

Registration No. 333-151115

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

PRE-EFFECTIVE AMENDMENT NO. 1
TO
FORM S-1
REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

#### VioQuest Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

**Delaware** 

(State or jurisdiction of incorporation or organization) 2834

(Primary Standard Industrial Classification Code Number)

58-1486040

(I.R.S. Employer Identification No.)

# 180 Mount Airy Road, Suite 102 Basking Ridge, NJ 07920

(Address and telephone number of principal executive offices and principal place of business)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filed, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filed," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer o Smaller reporting company x

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.

A registration statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. This prospectus shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Subject to completion, dated July 21, 2008

#### **OFFERING PROSPECTUS**

VioQuest Pharmaceuticals, Inc.

10,413,409 Shares

**Common Stock** 

The selling stockholders identified on pages 19-21 of this prospectus are offering on a resale basis a total of 10,413,409 shares of our common stock, including 3,743,146 shares issuable upon the exercise of outstanding warrants. We will not receive any proceeds from the sale of these shares by the selling stockholders.

Our common stock is quoted on the OTC Bulletin Board under the symbol "VOQP." On July 18, 2008, the last sale price for our common stock as reported on the OTC Bulletin Board was \$ 0.64.

The securities offered by this prospectus involve a high degree of risk. See "Risk Factors" beginning on page 12.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined that this prospectus is truthful or complete. A representation to the contrary is a criminal offense.

The date of this Prospectus is , 2008.

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#### PROSPECTUS SUMMARY

This summary provides a brief overview of the key aspects of this offering. Because it is only a summary, it does not contain all of the detailed information contained elsewhere in this prospectus or in the documents included as exhibits to the registration statement that contains this prospectus. Accordingly, you are urged to carefully review this prospectus in its entirety.

#### **Our Company**

## **Product Pipeline**

VioQuest Pharmaceuticals, Inc. is a biopharmaceutical company focused on the acquisition, development and commercialization of clinical stage drug therapies targeting both the molecular basis of cancer and side effects of cancer treatment. Our lead compound under development is Xyfid<sup>TM</sup> (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. We expect to initiate a Phase IIb program for Xyfid in 2008 for HFS and we filed our 510(k) Premarket Notification application with the U.S. Food and Drug Administration ("FDA") on June 30, 2008, seeking marketing clearance for Xyfid to treat various dermatoses. Additionally, we are developing VOD-002 (triciribine 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 we expect to advance VQD-002 into Phase II clinical development during 2008. We are also developing Lenocta<sup>TM</sup> (sodium stibogluconate), which we 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. 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. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates.

### Xyfid<sup>TM</sup> (1% Topical Uracil)

A pilot clinical study of seven patients has shown topical application of Xyfid to patients' hands and feet to be effective in preventing the recurrence of HFS, the dose limiting effect from the use of Xeloda<sup>TM</sup> (capecitabine or 5-FU). The FDA has granted Xyfid fast track designation for the prevention of HFS in patients receiving capecitabine for the treatment of advanced metastatic breast cancer. There are no existing treatments or preventions for HFS. The only way to reduce HFS in patients who receive capecitabine or 5-FU is to lower the dosing levels, or completely stop the use, of capecitabine; however, capecitabine dose reductions may diminish chemotherapeutic efficacy in the treatment of life-threatening cancer. We expect to initiate a Phase IIb program for Xyfid<sup>TM</sup> in the first half of 2008.

We are pursuing FDA approval of Xyfid as a medical device pursuant to Section 510(k) of the Food Drug and Cosmetic Act, or FDCA, and have submitted our 510(k) application on June 30, 2008. This process is generally known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring pre-market approval,

or PMA approval. When a 510(k) clearance is required, the device sponsor must submit a premarket notification demonstrating that its proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution. The evidence required to prove substantial equivalence varies with the risk posed by the device and its complexity. After a device receives 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, will require a new 510(k) clearance or could require a PMA approval application.

We filed our 510(k) submission based upon our belief that both Epiceram® and Xclair® provide substantial predicate device equivalence in order for the FDA to grant 510(k) clearance for Xyfid. Our strategy with Xyfid is based upon the same skin irritant indication as Epiceram®, where we can use our uracilbased product to treat the initial symptoms of HFS, to act as a barrier or protectant to the skin's environment, which is well documented to include erythema and may progress to burning pain with dryness, cracking, desquamation, ulceration and oedema. By regulation, the FDA is required to complete its review of a 510(k) within 90 days of submission of the application. As a practical matter, however, clearance often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. If we are not successful in obtaining 510(k) clearance for Xyfid, our regulatory strategy for Xyfid would be the more conventional pathway for pharmaceutical products under the FDCA.

## *VQD-002* (tricirbine phosphate monohydrate)

We are currently evaluating VQD-002 in patients with hyper-activated, phosphorylated AKT in two Phase I/IIa studies, with up to 42 patients at the Moffitt Cancer Center in solid tumors and at the M.D. Anderson Cancer Center in hematological tumors, with particular attention in leukemias. We expect to complete our Phase I/IIa solid and hematologic tumor studies in 2008. We expect to initiate Phase II studies in 2008. VQD-002 is a nucleoside analog that was previously advanced into clinical trials by the National Cancer Institute in the 1980s and early 1990s, and showed compelling anti-cancer activities. In the first quarter of 2008, VQD-002 received orphan drug designation by the FDA for the treatment of multiple myeloma. We filed with the FDA an IND relating to VQD-002, which was accepted in April 2006. Pursuant to this IND, we are currently evaluating the safety, tolerability and activity of VQD-002 and its ability to reduce AKT phosphorylation in our two Phase I/IIa clinical trials.

# Lenocta<sup>TM</sup> (sodium stibogluconate)

We are currently evaluating Lenocta in combination with alpha interferon ("IFN a-2b") in a Phase IIa study, with up to 54-patients at the M.D. Anderson Cancer Center and the University of New Mexico, with advanced malignancies and solid tumors that have been non-responsive in previous cytokine therapy. We expect to complete enrollment in our Phase IIa solid tumor trial in 2008. Lenocta has shown to be an inhibitor of multiple protein tyrosine phosphatases (PTPases), specifically the SRC homology PTPases such as SHP-1, SHP-2 and PTP1B. We filed with the FDA an IND for Lenocta, which the FDA accepted in August 2006, allowing us to commence clinical trials of Lenocta. Potential advantages of Lenocta over existing therapies include Lenocta's long history of use, acceptable toxicity, known safety profiles, and efficacy in preclinical cancer models.

Lenocta 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). According to the World Health Organization, leishmaniasis currently threatens 350 million men, women, and children in 88 countries around the world. This drug is currently being used to treat military personnel serving in parts of the world where leishmaniasis is prevalent, and we are currently in collaboration with the U.S. Army under an executed Cooperative Research and Development Agreement. In the second half of 2006, Lenocta received orphan drug designation by the FDA for the treatment of leishmaniasis.

## **Overview of Drug Development Status**

To date, we have not received approval for the sale of any drug candidates in any market and, therefore, have not generated any revenues from our drug candidates. The successful development of our product candidates is highly uncertain. Product development costs and timelines can vary significantly for each product candidate and are difficult to accurately predict. Various laws and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of each product. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect our business.

Assuming we do not encounter any unforeseen safety issues or other during the course of developing our product candidates, we do not expect to complete the development of: Xyfid until approximately 2008 through a 510(k) submission, 2010 for Xyfid through an NDA submission, and 2013 for oncology indications of VQD-002 and Lenocta, if ever. In addition, as we continue the development of our product candidates, our research and development expenses will significantly increase. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of these product candidates. Our major sources of working capital have been proceeds from various private financings, primarily private sales of our common stock and other equity securities.

#### **Corporate Information**

We were originally formed in October 2000, as a Pennsylvania limited liability company under the name Chiral Quest, LLC. In February 2003, we completed a reverse acquisition of Surg II, Inc., a publicly-held Minnesota shell corporation and were renamed to Chiral Quest, Inc. In August 2004, we then changed our name to VioQuest Pharmaceuticals, Inc. and formed Chiral Quest, Inc. as our wholly-owned subsidiary. In October 2005, we reincorporated under Delaware law by merging into a wholly-owned subsidiary VioQuest Delaware, Inc., incorporated under Delaware law as the surviving corporation and our wholly-owned subsidiary. Immediately following the reincorporation, we acquired Greenwich Therapeutics, Inc., a privately-held, New York City based drug development company, in a merger transaction in which we merged our wholly-owned subsidiary VioQuest Delaware, Inc. with and into Greenwich Therapeutics, with Greenwich Therapeutics remaining as the surviving corporation and our wholly-owned subsidiary. As a result of the acquisition of Greenwich Therapeutics, we acquired the rights to develop and commercialize two oncology drug candidates – Lenocta, and VQD-002.

In July 2007, we sold all of our shares of capital stock of our Chiral Quest subsidiary. Chiral Quest provided innovative chiral products, technology and custom synthesis services to pharmaceutical and final chemical companies in all stages of a products' life cycle.

Lenocta<sup>TM</sup> is our trademark for our sodium stibogluconate product candidate. Xyfid<sup>TM</sup> is the trademark for our topical uracil product candidate. All other trademarks and tradenames mentioned in this prospectus are the property of their respective owners. We have applied for rights to the Lenocta and Xyfid trademarks from the U.S. Patent and Trademark Office.

Our executive offices are located at 180 Mount Airy Road, Suite 102, Basking Ridge, New Jersey 07920 and our telephone number is (908) 766-4400. Our Internet site is <a href="https://www.vioquestpharm.com">www.vioquestpharm.com</a>.

#### **Risk Factors**

For a discussion of some of the risks you should consider before purchasing shares of our common stock, you are urged to carefully review and consider the section entitled "Risk Factors" beginning on page 12 of this prospectus.

## The Offering

This prospectus covers the resale of 10,413,409 shares of our common stock. We determined the number of shares covered by this prospectus by assuming the conversion of all of our issued and outstanding Series A Convertible Preferred Stock and Series B Convertible Preferred Stock and assuming the exercise of all of the warrants issued to the selling shareholders and the placement agents in both the 2007 private placement of our convertible promissory notes and the 2008 private placement of the Series A Convertible Preferred Stock.

The total dollar value of the common stock being registered for resale pursuant to this prospectus is \$10,413,409, as determined by the market price of our common stock on April 9, 2008. The total dollar value of the shares of common stock underlying the Series A Convertible Preferred Stock was \$5,774,167, and the total dollar value of the shares of common stock underlying the Series B Convertible Preferred Stock was \$896,096. Additionally, the aggregate dollar value of the shares of common stock underlying the investor warrants and placement agent warrants was \$3,743,146.

The selling stockholders identified on pages 19-21 of this prospectus are offering on a resale basis a total of 10,413,409 shares of our common stock, as follows:

- 243,397 shares of our common stock issuable at a price of \$4.00 per share upon exercise of warrants issued to the investors in our 2007 private placement of our convertible promissory notes;
- 5,774,167 shares of our common stock underlying 3,464.5 shares of our Series A
  Convertible Preferred Stock convertible at a price of \$0.60 per share issued to the
  investors in our private placement of Series A Convertible Preferred stock;
- 2,887,083 shares of our common stock issuable at a price of \$1.00 per share upon the exercise of warrants issued to the investors in our private placement of Series A Convertible Preferred stock;
- 896,096 shares of our common stock underlying 3,405.165 shares of our Series B
   Convertible Preferred Stock convertible at a price of \$3.80 per share as issued to
   our former note holders upon the conversion of the note's principal and accrued
   interest into shares of our Series B Convertible Preferred Stock;
- 492,416 shares of our common stock issuable at a price of \$0.80 per share upon the exercise of warrants issued to the placement agents in connection with our private placement of Series A Preferred Stock.
- 120,250 shares of our common stock issuable at a price of \$4.20 per share upon the exercise of warrants issued to the placement agents in connection with our private placement of our convertible promissory notes.

Common stock offered 10,413,409 shares
Common stock outstanding before the offering<sup>(1)</sup> 5,461,644 shares
Common stock outstanding after the offering<sup>(2)</sup> 15,875,053 shares
Common Stock OTC Bulletin Board symbol VOQP.OB

<sup>(1)</sup> Based on the number of shares outstanding as of May 19, 2008, not including 2,738,382 shares issuable upon exercise of various warrants and options to purchase common stock.

(2) Assumes the issuance of all shares offered hereby that are issuable upon exercise of warrants.

As of the date of this prospectus, none of the shares of common stock underlying our Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, investor warrants, or placement agent warrants have been issued or are outstanding.

#### **Recent Developments**

#### **Appointment of Chief Financial Officer**

On July 21, 2008, we hired Christopher P. Schnittker as our Chief Financial Officer and Vice President. Mr. Schnittker replaced Brian Lenz who resigned his office as Chief Financial Officer on July 21, 2008. Mr. Schnittker previously served as Senior Vice President and Chief Financial Officer of Micromet, Inc. We entered into an employment agreement with Mr. Schnittker with a two-year term and a base salary of \$185,000. We granted Mr. Schnittker stock options and he is eligible to receive bonuses as described below in "Executive Compensation – Employment Agreements with Named Executives – Christoper Schnittker."

#### **Amendment of Escrow Agreement**

On July 8, 2008, we amended our escrow agreement with J. Jay Lobell, as stockholders' representative, U.S. Bank National Association, as the escrow agent, and Greenwich Therapeutics, Inc., to extend the termination date for the escrow agreement until June 30, 2009. The amendment was made effective as of June 30, 2008, and replaced the original escrow termination Date of the same date. All other obligations set forth in the original escrow agreement remain in full force and effect. We previously filed a current report on Form 8-K on July 10, 2008 disclosing the amendment of the escrow agreement.

#### **Reverse Stock Split**

On April 25, 2008, we effected a 1-for-10 reverse stock split of our common stock. Upon the effective time of the split, each shareholder owning 10 shares of pre-split common stock received 1 share of post-split common stock. In lieu of fractional shares, each record holder of securities at the effective time, who would otherwise have been entitled to receive a fractional security is entitled to, upon surrender of such holder's certificates representing pre-split securities, a cash payment (without interest). Pursuant to the reverse stock split, all of our warrants, options, and conversion ratios were adjusted accordingly. Unless otherwise noted in this prospectus, all of the figures for the number of outstanding shares of common stock and shares of common stock underlying preferred stock, warrants, and options contained herein have been adjusted to reflect the 1-for-10 reverse split.

### **Note Offering**

On June 29, 2007 and July 3, 2007, we issued a series of convertible promissory notes resulting in aggregate gross proceeds of \$3.7 million. As a condition to the initial closing of the private placement of our Series A Convertible Preferred Stock, a majority of the principal amount outstanding under these notes agreed to convert all principal, together with accrued interest, into approximately 3,405 shares of our newly-designated Series B Convertible Preferred Stock. Each share of Series B Convertible Preferred Stock is convertible into shares of our common stock at \$4.00 per share, or approximately 896,096 shares of common stock in the aggregate.

#### Placement Agent Commission and Fees

In connection with our offering of our convertible promissory notes, we paid an aggregate of approximately \$256,000 in placement agent commissions to all of the placement agents, including \$119,700 to Paramount BioCapital, Inc. We also paid the placement agents approximately \$24,000 as non-accountable expense allowance and we issued the placement agent's five-year warrants to purchase as adjusted for the 1-for-10 reverse stock, an aggregate of approximately 120,000 shares of common stock exercisable at a price of \$4.20 per share.

## Officer and Director Participation

Brian Lenz, our former Chief Financial Officer, and Michael Weiser, one of our directors, both invested in our offering of senior convertible promissory notes in June and July 2007. Mr. Lenz was issued a senior convertible promissory note in the amount of \$5,000. Mr. Weiser was issued a senior convertible promissory note in the amount of \$10,000. Please refer to "Description of Private Placement of Preferred Stock - Conversion of Notes Held by Officers and Directors" for more information.

## Offering of Preferred Stock

On March 14, and April 9, 2008 we closed on our private placement of our Series A Convertible Preferred Stock. We issued an aggregate of 3,464.5 shares of our Series A Convertible Preferred Stock to our investors, along with five year warrants to purchase an aggregate of 2.88 million shares of our common stock at a price of \$1.00 per share. We engaged Paramount BioCapital, Inc., as our placement agent and paid Paramount a commission of \$54,000 and a reimbursement for fees. Please refer to "Description of Private Placement of Preferred Stock" below for more information about the offering.

A description of the rights of the Series A Convertible Preferred Stock and the Series B Convertible Preferred Stock may be found below under "Description of Capital Stock."

#### DESCRIPTION OF PRIVATE PLACEMENT OF PREFERRED STOCK

On March 14, 2008, we issued 765 shares of Series A Convertible Preferred Stock at a price of \$1,000 per share resulting in aggregate gross proceeds of \$765,000. On April 9, 2008, we issued 2,194.5 shares of Series A Convertible Preferred Stock at a price of \$1,000 per share resulting in aggregate gross proceeds of \$2,194,500, and reissued the shares originally issued on March 14, 2008, for total gross proceeds of \$2,959,500. Each share of Series A Convertible Preferred Stock sold is convertible into shares of our common stock at \$0.60 per share, or approximately 4.93 million shares of common stock in the aggregate. In addition, two investors elected to convert a portion of the principal and unpaid but accrued interest of their note into 505 shares of Series A Convertible Preferred Stock on the same terms as their purchase of Series A Convertible Preferred Stock. We also issued to investors five-year warrants to purchase an aggregate of approximately 2.88 million shares of our common stock at an exercise price of \$1.00 per share. The Series A Preferred Stock was sold to 35 investors, each of which we reasonably believed was an "accredited investor," as defined under Rule 501(a) of the Securities Act of 1933, and no means of general solicitation or advertising was used in connection with the offering. Accordingly, we relied on the exemptions from the registration requirements of the Securities Act provided by Section 4(2) and Rule 506.

#### **Placement Agent Commission and Fees**

In connection with the offering, we engaged Paramount as our placement agent. Dr. Lindsay A. Rosenwald is the Chairman, CEO and sole stockholder of Paramount and a substantial holder of our stock. In consideration for the placement agent's services, we paid an aggregate of approximately \$54,000 in commissions to Paramount in connection with the offering. We also paid to Paramount \$35,000 as a non-accountable expense allowance. In addition, we issued to Paramount five-year warrants to purchase an aggregate of approximately 492,416 shares of common stock, which are exercisable at a price of \$0.80 per share. Dr. Rosenwald participated in this financing, through a family investment partnership, of which he is the managing member.

## **Total Potential Investor Profit From Preferred Stock**

The table below sets forth the total possible investor profit arising from the private placement of our Series A Convertible Preferred Stock on April 9, 2008. As stated in the table, the investors purchasing our Series A Convertible Preferred Stock received an aggregate discount of \$1,154,833.40 from the market price of our common stock on April 8, 2008.

#### Series A Convertible Preferred Stock

Ma	rket Price of	Fixed	Total Number of		Aggregate	
Coı	mmon Stock	Conversion	n Shares of Common	Total Market Price of	<b>Conversion Price</b>	Total Discount
C	n April 8,	Price of Seri	es Stock Underlying	Shares Underlying	of Shares at Fixed	for Series A
	2008*	A Stock	Series A Stock	Series A Stock	Conversion Price	Purchasers
\$	0.80	\$ 0	.60 5,774,167	\$ 4,619,333.60	\$ 3,464,500.20	\$ 1,154,833.40

<sup>\*</sup> The final closing of the Series A Convertible Preferred Stock private placement occurred on April 9, 2008.

The table below sets froth the total possible investor profit arising from the conversion of our senior convertible promissory notes into shares our Series B Convertible Preferred Stock on March 14, 2008.

#### Series B Convertible Preferred Stock

Market Price o	f	Fixed	Total Number of		Aggregate	
Common Stock		Conversion	Shares of Common	Total Market Price of	<b>Conversion Price</b>	Total Premium
on March 13,		Price of Series	Stock Underlying	Shares Underlying	of Shares at Fixed	for Series B
2008*		B Stock	Series B Stock	Series B Stock	Conversion Price	Purchasers
\$ 0.8	80	\$ 3.80	896,096	\$		