VioQuest Pharmaceuticals Form 10KSB March 31, 2005

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### FORM 10-KSB

x Annual Report pursuant to Section	13 or 15(d) of the Securities	Exchange Act of 1934 for th	e fiscal year ended
December 31, 2004			

oTransition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from \_\_\_to\_\_\_

#### Commission File Number 0-16686

#### VIOQUEST PHARMACEUTICALS, INC.

(Exact name of issuer as specified in its charter)

<u>Minnesota</u> <u>58-1486040</u>

(State or other jurisdiction of incorporation or organization)

(IRS Employer Identification No.)

7 Deer Park Drive, Suite E, Monmouth

Junction, NJ

08852 (Zip Code)

(Address of Principal Executive Offices)

(732) 274-0399

(Issuer's telephone number)

Securities registered pursuant to Section 12(b) of the Exchange Act:

None

## Securities registered pursuant to Section 12(g) of the Exchange Act:

Common Stock, \$.01 par value

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the issuer was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Check if there is no disclosure of delinquent filers pursuant to Item 405 of Regulation S-B is not contained herein, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

The issuer's revenues for the fiscal year ended December 31, 2004 were\$1,485,148.

The aggregate market value of the voting common stock of the issuer held by non-affiliates of the issuer on March 14, 2005 based on the \$.90 closing price of the common stock as quoted by the NASD Over-the-Counter Bulletin Board on such date was \$10,220,443.

As of March 14, 2005 there were 17,827,924 outstanding shares of common stock, par value \$.01 per share.

Transitional Small Business Disclosure Format: Yes o No x

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References to the "Company," the "Registrant," "we," "us," "our" or in this Annual Report on Form 10-KSB refer to VioQuest Pharmaceuticals, Inc., formerly Chiral Quest, Inc., a Minnesota corporation, and our consolidated subsidiaries, together taken as a whole, unless the context indicates otherwise.

## **Forward-Looking Statements**

This Annual Report on Form 10-KSB contains statements that are not historical but are forward-looking in nature, including statements regarding our current expectations, beliefs, intentions or strategies regarding the future. In particular, the "Risk Factors" section following Item 1 and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section in Item 6 of this annual report include forward-looking statements that reflect our current views with respect to future events and financial performance. We use words such as we "expect," "anticipate," "believe," and "intend" and similar expressions to identify forward-looking statements. Investors should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties inherent in future events, particularly those risks identified in the subsection entitled "Risk Factors" following Item 1 in this Annual Report, and should not unduly rely on these forward looking statements.

#### **PART I**

#### ITEM 1. DESCRIPTION OF BUSINESS

#### Overview

VioQuest Pharmaceuticals, Inc. has two subsidiaries - VioQuest Drug Development, Inc., which was created for the purpose of acquiring, developing and eventually commercializing human therapeutics in the areas of oncology, metabolic and inflammatory diseases and disorders that are current unmet medical needs, and Chiral Quest, Inc., which continues our historical business of providing chiral products, technology and services to pharmaceutical and fine chemical companies in all stages of the product lifecycles with innovative chiral products and services. Chiral Quest has two main lines of products and services - proprietary chiral catalysts and chiral building blocks or client-defined molecules. We have the rights to certain chemical compounds known as chiral ligands which, with the introduction of a metal, serve as catalysts in facilitating the production of chiral molecules in such a manner that there is a preferential manufacture of the desired molecule versus the unwanted mirror-image molecule. We provide pharmaceutical and fine chemical manufacturers and other prospective clients with broad access to our technologies for testing purposes at a low upfront cost, coupled with the opportunity to gain access to such technologies for specific applications for fees, royalties and certain manufacturing and development rights. Our ligands may also find use in producing fine chemicals other than pharmaceuticals - chiral molecules are used in flavors, fragrances, agrochemicals, animal health, food and feed additives (including vitamins) and nutraceuticals. In connection with our chiral technology, we provide specialized services to pharmaceutical, biotechnology and fine chemical companies relating to the development of chiral manufacturing processes for their products.

Our proprietary chiral technology was developed by Dr. Xumu Zhang, a professor at Pennsylvania State University ("Penn State") and is owned by the Penn State Research Foundation ("PSRF"), the technology development arm of Penn State. In November 2000, we obtained from the PSRF an exclusive, worldwide license to certain patents based on Dr. Zhang's research relating to asymmetrical catalysis. This license gives us the right to, among other things, sub-license technology rights on a non-exclusive basis to clients, or sell molecule groups, known as ligands, to pharmaceutical and fine chemical company clients for both research and commercial applications.

Through Chiral Quest, we are also engaged in developing and making client-defined building blocks and drug candidate fragments, mainly in the chiral area. With this process chemistry offering to life sciences companies, we develop new synthetic routes or optimize existing ones and produce certain quantities of material for further processing at the clients' needs either for further elaboration, clinical trials or beyond.

We are a Minnesota corporation that resulted from the reverse merger of Chiral Quest, LLC, a Pennsylvania limited liability company that commenced operations in October 2000, and Surg II, Inc., a Minnesota corporation, on February 18, 2003.

## **Chiral Business**

Over 50 percent of the 500 top-selling pharmaceutical drugs on the market are comprised of chiral molecules, including drugs used to treat anxiety, depression, indigestion, heartburn, cancer, arthritis, AIDS and allergies. In 2004, chiral drug sales were over \$175 billion, based on a report in *SRI Consulting*, which represents over one third of the complete drug market of over \$470 billion. The majority of new drug candidates under development by pharmaceutical companies consist of chiral chemicals.

A molecule is considered "chiral" because it exists in two "enantiomers," or non-superimposable mirror-like images analogous to one's left and right hands. Most drugs interact with biological targets in a specific manner, requiring the drug to be of a specific shape and orientation. Contaminating "wrong-handed" enantiomers of the active drug molecule will probably not interact with the biological drug target, or worse, interact with a different biological molecule in an unintended and often toxic manner. Thalidomide, the morning sickness drug used by pregnant women in the 1960's, is a notorious example of an impure chiral drug. One enantiomer of the drug's chiral molecules treated morning sickness, while its undesired enantiomer impurity caused birth defects. Pharmaceutical companies are typically required, at great expense, to purify the active mirror-image form of the drug molecule away from its contaminating or inactive counterpart.

#### **Products and Services**

We offer two business lines, one in products and one in services in order to provide clients with critical solutions for the efficient manufacturing of chiral products or therapeutic drugs. Its products include bulk chiral catalysts, proprietary building blocks / client-defined targets and a proprietary "Chiral ToolKit", comprised of a diverse set of chiral ligands that are combined with transition metals to catalyze reactions leading to chiral molecules. Chiral Quest also offers a variety of services covering specialized chiral transformation screening, chiral synthetic or process support and manufacturing solutions to be delivered on a partnership/contract basis with client firms. Chiral Quest products and services are applicable throughout the full life cycle of a chiral drug, from early lead discovery, through development and in commercialization.

The Chiral Quest "CQ" Chiral Library depicted below identifies the current commercial portfolio of proprietary ligands from which clients order both the Chiral ToolKit selection sets for Research and Development testing as well as bulk quantities for larger scale uses and commercialization.

Chiral ToolKit. We currently sell products which represent several of the proprietary families of our chiral ligands to which the Company has exclusive rights. These ligands are sold in research quantities packaged in convenient Chiral ToolKit sets for exclusive use in research applications by client companies. These innovative, patent protected ligands are screened by clients for applications in the manufacture of their chiral molecules. Clients use this screening process to determine which ligands may prove optimal for their chiral manufacturing needs. The sale of research quantities of ligands allows clients to gain initial access to our technology and to independently validate the advantages provided by that technology.

Bulk Ligands. We also sell larger quantities of proprietary chiral ligands to which we have exclusive rights, including some that are not included in our Chiral ToolKit. These ligands are sold individually to clients in amounts specified by the client according to its research, development or semi-commercial needs. One of our objectives is to provide clients with their required ligands and catalysts, either from our own laboratories or through third parties, for research, clinical and commercial purposes. The use of CQ bulk ligands in commercial drug applications will generally require license fees and/or other related payments to us, subject to negotiation.

*Screening Services*. We also provide focused screening of client supplied target compounds using our proprietary ligands. In addition to the select ligands included in the Chiral ToolKit, we have several families of chiral ligands that are used to screen target compounds. We identify and prepare individual ligands optimized for particular client needs.

Proprietary Building Blocks / Client-Defined Targets. We work with our clients to help optimize the conditions under which our ligands are used and also produce certain molecules of customer interest. This may involve the development of novel manufacturing processes, for which we will derive additional compensation. We may also structure our client agreements to assure the use of our ligands within the manufacturing process, thereby requiring our customers to buy the ligands from us in commercial quantities in order for the client to successfully manufacture its compound. We may also produce and sell certain selected chiral products defined by our clients such as chiral building blocks or intermediates.

## Strategy

Our business strategy is focused on exploiting our asymmetric catalysis technology by:

- Focusing our research group on designing and discovering additional commercially useful ligands and manufacturing processes;
- Providing screening services necessary to test the selectivity and activity of a broad portfolio of proprietary technologies for client substrates;
- Granting access to a selection of our ligands through non-exclusive licenses for research and development purposes;
- Granting compound-specific exclusive rights to clients whose businesses require commercial use of one or more of our ligands;
- Developing proprietary process methods for producing chirally pure pharmaceutical ingredients, intermediates and building blocks in exchange for fees, milestone payments and royalties; and
- Assisting clients in the development of chiral drugs, the development of which has been slowed or halted due to manufacturing inefficiencies, which are amenable to improvements through our technology.

#### Sales and Marketing

We sell our products and services directly to clients both in the pharmaceutical and fine chemical areas. In October 2003, and January 2005, we hired a senior executive and Vice President of Business Development respectively who are focused on sales and marketing activities. We intend to hire additional marketing personnel in the near future.

#### Dependence on Certain Customers

In fiscal 2004, we had two customers that accounted for approximately 34 percent and 26 percent of our revenue, a major pharmaceutical company and biotech company respectively. The loss of these accounts would have a material adverse effect on our business; however, we believe our relationships with these customers are strong.

#### Competition

Competition in the traditional area of separation manufacture of chiral molecules comes from a few distinct sources, including Chiral Technologies Inc., ChromTech Ltd., NovaSep, Inc. and Advance Separation Technologies Inc. Traditional methods of manufacturing chiral molecules involve the production of a mixture of both chiral forms of

molecules of interest, followed by a process which separates the desired enantiomer from the undesired enantiomer. This methodology, though still commonly used, is extremely cost-ineffective, as it results in the loss of greater than 50 percent of the intermediate product at each chiral purification step. We believe we have a competitive advantage over companies using traditional methods of separation because our technology drives the preferential manufacture of chiral enantiomers of interest, which can result in 95 to 99 percent yields. This can result in significant cost savings in the manufacturing process, particularly for chiral molecules that may require several chiral separation steps by traditional methods.

In the area of chemical catalysts for chiral drug manufacture, we compete with pharmaceutical and fine chemical companies, including our current and potential clients and collaborators, academic and research institutions. Some of these companies include the Dow Chemical Company, Degussa AG, Rhodia ChiRex Inc. and Solvias AG. Many of these companies are developing or marketing technologies and services similar to the ones developed or offered by us. We anticipate continued competition from other manufacturers of chiral catalysts in the future.

Some of our competitors, such as Codexis, a wholly owned subsidiary of Maxygen, or Diversa Corporation, attempt to genetically modify biological enzymes for the purpose of serving as biological catalysts for asymmetric chiral manufacturing. While this approach works in certain circumstances, it is extremely time-consuming to develop for each individual manufacturing process. We believe our technology has the competitive advantage of being more broadly applicable to a number of common asymmetric transformations.

## **Drug Development**

Through our VioQuest Drug Development subsidiary, we plan to acquire, develop and bring to market therapies for oncology, metabolic and inflammatory diseases and disorders that are current unmet medical needs. We do not currently own the rights to develop or commercialize any drug candidate, but are actively seeking to acquire the rights to develop and commercialize novel therapeutic drug candidates. Because pharmaceutical products are often in development for several years before final approval from the FDA is obtained, if ever, we do not expect that VioQuest Drug Development will generate any revenues from operations for a number of years after we acquire a drug candidate. Additionally, because drug development requires large investments of time, effort and money, we will need significant additional financing in order to complete the development of any drug candidate.

#### **Intellectual Property**

License with the Penn State Research Foundation. We have an exclusive, worldwide license from the PSRF to certain chiral technologies developed by Dr. Zhang. The license agreement has been amended on five occasions, four of which provide us with additional rights, including the rights to new patent applications. The PSRF license agreement grants us rights to any conversions, re-issues, extensions, divisional applications, continuations, continuations in part, and any patents issuing thereon, and any improvements to the licensed patents. Under the license agreement, the PSRF received an equity stake in our Company as partial consideration for the license. The license agreement also obligates us to reimburse the PSRF for its patent expenses relating to the licensed technology.

The PSRF license agreement requires us to use our reasonable best efforts to achieve annual gross revenue of \$250,000 in calendar year 2004, which we achieved, and at least \$350,000 in calendar year 2005, and at least \$500,000 in calendar year 2006. Should we fail to obtain these milestones, the PSRF has the right, but not the obligation, to terminate the license agreement on the grounds that we failed to use our best efforts to achieve those milestones.

Additionally, in accordance with the license agreement, the PSRF'S obligation to license to us, at no additional cost, any new technology subsequently discovered by Dr. Zhang and the other researchers at Penn State expired on November 8, 2002. Accordingly, if Dr. Zhang develops a new invention that does not constitute an "improvement" on the existing patent rights, then we will have to license the right to such invention from the PSRF.

**Patents.** Chiral Quest has an exclusive license to 13 United States patent applications filed by the Penn State Research Foundation covering many classes of ligands. The U.S. Patent and Trademark Office ("PTO") has issued seven (7) letters of patents in connection with these applications (i.e., U.S. Pat. Nos. 6,380,392, 6,525,210, 6,521,769, 6,337,406, 6,576,772, 6,534,657 and 6,653,485). In addition, the PTO has issued notices of allowance on one (1) other application for which we anticipate a patent being issued in 2004. The remaining five (5) patent applications are still pending. Chiral Quest also has rights to international patent applications based on many of the US application filings. National Phase Applications have been filed for six (6) international applications (PCT) corresponding to the originally filed U.S. applications.

#### **Employees and Consultants**

We currently employ 27 people: Daniel Greenleaf, our President, and Chief Executive Officer, Brian Lenz our Chief Financial Officer and Corporate Secretary, Ronald Brandt our Business Unit Head of Chiral Quest, Yaping Hong our Vice President of Research and Development, Michael Cannarsa our Vice President of Business Development, Bing Yu, our Director of Global Operations, and 20 full time chemists. We also engage Dr. Xumu Zhang, who serves as our Chief Technology Officer, on a consultancy basis. Additionally, we fund four post-doctoral fellows, under the supervision of Dr. Zhang, pursuant to an agreement with Penn State. Of the 32 persons providing services to our Company, either as employees or consultants, 16 hold Ph.D. degrees. As we develop our technology and business, we anticipate the need to hire additional employees, especially employees with expertise in the areas of chemistry, sales and marketing.

#### **RISK FACTORS**

#### **Risks Related to Our Securities**

Trading of our common stock is limited, which may make it difficult for you to sell your shares at times and prices that you feel are appropriate.

Trading of our common stock, which is conducted on the Over-the-Counter Bulletin Board (or "OTC Bulletin Board"), has been limited. This adversely effects the liquidity of our common stock, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of us. This may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked prices for our common stock.

## Because it is a "penny stock," it will be more difficult for you to sell shares of our common stock.

In addition, our common stock is considered a "penny stock" under SEC rules because it has been trading on the OTC Bulletin Board at a price lower than \$5.00. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. This document provides information about penny stocks and the nature and level of risks involved in investing in the penny-stock market. A broker must also give a purchaser, orally or in writing, bid and offer quotations and information regarding broker and salesperson compensation, make a written determination that the penny stock is a suitable investment for the purchaser, and obtain the purchaser's written agreement to the purchase. Broker-dealers also must provide customers that hold penny stocks in their accounts with such broker-dealer a monthly statement containing price and market information relating to the penny stock. If a penny stock is sold to you in violation of the penny stock rules, you may be able to cancel your purchase and get your money back. The penny stock rules may make it difficult for you to sell your shares of our stock, however, and because of the rules, there is less trading in penny stocks. Also, many brokers simply choose not to participate in penny-stock transactions. Accordingly, you may not always be able to resell shares of our common stock publicly at times and prices that you feel are appropriate.

## Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit.

The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

- · announcements of technological innovations or new commercial products by our competitors or us;
  - · developments concerning proprietary rights, including patents;
  - · regulatory developments in the United States and foreign countries;
    - · economic or other crises and other external factors:
  - · period-to-period fluctuations in our revenues and other results of operations;
    - · changes in financial estimates by securities analysts; and
      - · sales of our common stock.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

Because we do not expect to pay dividends, you will not realize any income from an investment in our common stock unless and until you sell your shares at profit.

We have never paid dividends on our common stock and do not anticipate paying any dividends for the foreseeable future. You should not rely on an investment in our stock if you require dividend income. Further, you will only realize income on an investment in our shares in the event you sell or otherwise dispose of your shares at a price higher than the price you paid for your shares. Such a gain would result only from an increase in the market price of our common stock, which is uncertain and unpredictable.

#### **Risks Related to Our Company**

Our future success is highly dependent on the continued availability of Dr. Xumu Zhang and other key employees and consultants.

In connection with the continued development of our products and services, we are substantially dependent upon on the continued service of our existing research personnel, including in particular, Xumu Zhang, Ph.D. Dr. Zhang, a professor at Penn State, who serves as our Chief Technology Officer and provides essential services to us pursuant to a consulting agreement. Although we maintain a \$5 million key-man insurance policy with respect to Dr. Zhang and he has entered into a non-compete agreement with us, the loss of his services would have a material adverse effect on our business. In addition to Dr. Zhang, we employ other research scientists who are also critical to our success. Although these research scientists have entered into confidentiality agreements, most have not entered into noncompete agreements with us. The loss of one or more of our research personnel could prevent or delay the ongoing

development of our products and services, which would materially and adversely affect our business.

#### We have no meaningful operating history on which to evaluate our business or prospects.

We commenced operations in October 2000 and, therefore, have only a limited operating history on which you can base an evaluation of our business and prospects. Accordingly, our business prospects must be considered in light of the risks, uncertainties, expenses and difficulties frequently encountered by companies in their early stages of development, particularly companies in new and rapidly evolving markets, such as the fine chemical, pharmaceutical and biotechnology markets.

#### Our management anticipates incurring losses for the foreseeable future.

For the year ended December 31, 2004, we had a net loss of \$4,023,558 and since our inception in October 2000 through December 31, 2004; we have incurred an aggregate net loss of \$7,434,763. As of December 31, 2004, we had total assets of \$4,876,741, of which \$3,065,547 was cash or cash equivalents. We expect operating losses to continue for the foreseeable future and there can be no assurance that we will ever be able to operate profitably.

# We will require additional financing in order to complete the development of our products and services and otherwise develop our business operations. Such financing may not be available on acceptable terms, if at all.

Following the completion of our February 2004 private placement, we anticipate that our current capital will be adequate to fund our operations through at least July 31, 2005. However, changes may occur that would consume available capital resources before that time. Our combined capital requirements will depend on numerous factors, including: competing technological and market developments, changes in our existing collaborative relationships, the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights and the outcome of any potentially related litigation or other dispute, the purchase of additional capital equipment, acquisition of technologies, and the development and regulatory approval progress of our customers' product candidates into which our technology will be incorporated. Additionally, working capital will be impacted by the costs associated with the drug development process related to acquiring a drug candidate. Unless we are able to significantly increase our revenues, we will most likely require additional financing by the end of the second quarter of 2005 in order to continue operations. The most likely source of such financing includes private placements of our equity or debt securities or bridge loans to us from third party lenders. These factors raise substantial doubt about our ability to continue as a going concern.

Additional capital that may be needed by us in the future may not be available on reasonable terms, or at all. If adequate financing is not available, we may be required to terminate or significantly curtail our operations, or enter into arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, or potential markets that we would not otherwise relinquish.

## Our operating results will fluctuate, making it difficult to predict our results of operations in any future period.

As we develop our business, we expect our revenues and operating results to vary significantly from quarter-to-quarter. As a result, quarter-to-quarter comparisons of our revenues and operating results may not be meaningful. In addition, due to the fact that we have little or no significant operating history with our new technology, we cannot predict our future revenues or results of operations accurately. Our current and future expense levels are based largely on our planned expenditures and estimates of future revenues. Accordingly, we may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall, and any significant shortfall in revenues relative to our planned expenditures could have an immediate adverse effect on our business and results of operations.

## We may be unable to develop successful customer relationships.

We intend to establish relationships with various types of customers and partners, such as pharmaceutical and fine chemical manufacturers. Each of these relationships will involve negotiation of terms and fees. We cannot be certain that we will be able to negotiate profitable relationships or that we can successfully fulfill our obligations under development agreements that will allow us to continue these relationships.

# Our license agreement with Penn State Research Foundation may be terminated if we do not achieve certain milestones.

Our business is based on technically complex products and services. We do not directly own our proprietary technology, but rather we have the exclusive, worldwide right to use it pursuant to a license agreement with the Penn State Research Foundation. Currently, our commercial success depends entirely on this licensed technology. Pursuant to the license agreement, we are required to use our best efforts to achieve "gross revenue" (as defined in the license agreement) of at least \$250,000 in 2004 which we achieved, and at least \$350,000 in 2005 and at least \$500,000 in 2006. In the event we fail to achieve these milestones in 2005 or 2006, or otherwise materially breach the license agreement, the Penn State Research Foundation may have the right, but not the obligation, to terminate the license. Unless we subsequently develop our own technology independent of the Penn State Research Foundation, termination of this license would preclude us from implementing our business plan.

#### We will need to create and grow our scientific, sales and support operations.

We will need to create and substantially grow our direct and indirect sales operations, both domestically and internationally, in order to create and increase market awareness and sales of our products and services. The sale of our products and services will require the engagement of sophisticated and highly knowledgeable sales personnel. Similarly, the anticipated complexity of our products and services and the difficulty of customizing them will require us to hire research and development personnel and customer service and support personnel, highly trained in chiral chemistry and chemical engineering. Competition among our company and others to retain qualified sales personnel, chemists and chemical engineers is intense due to the limited number of available qualified candidates for such positions. Many of our competitors are in a financial position to offer potential employees greater compensation and benefits than those which may be offered by us. Failure to recruit and retain such persons will have a material adverse effect on our business operations.

#### We are dependent on a few customers.

We are currently dependent on two customers who accounted for 34 percent and 26 percent, a major pharmaceutical company and a biotech company respectively, of our fiscal 2004 revenue. The loss of either customer would have a material adverse effect on our business.

#### Our future success is dependent on the management of our potential growth.

Our future success depends upon our ability to grow our business. Such growth, if it occurs, will require us to establish management and operating systems, hire additional technical support and sales personnel, and establish and maintain our own independent office, research and production facilities. Failure to manage that growth efficiently could have a material adverse affect on our business.

#### A small group of persons is able to exert significant control over us.

Our current officers and directors beneficially own or control approximately 22% of our common stock. Individually and in the aggregate, these persons will have significant influence over the management of our business, the election

of directors and all matters requiring shareholder approval. In particular, this concentration of ownership may have the effect of facilitating, delaying, deferring or preventing a potential acquisition of our company and may adversely affect the market price of our common stock. Additionally, two members of our Board of Directors are employees of Paramount BioCapital, Inc., or one of its affiliates. Dr. Lindsay A. Rosenwald is the chairman and sole owner of Paramount BioCapital, Inc. and such affiliates. Dr. Rosenwald beneficially owns 5.5% of our outstanding common stock, and several trusts for the benefit of Dr. Rosenwald and his family beneficially own 10.7% of our outstanding common stock. Although Dr. Rosenwald does not have the legal authority to exercise voting power or investment discretion over the shares held by those trusts, he nevertheless may have the ability to exert significant influence over the Company.

## **Risks Relating to Our Industry**

#### We face intense competition.

We compete directly with the in-house research departments of fine chemical, pharmaceutical and biotechnology companies, as well as contract research companies, and research and academic institutions. Many of our competitors have greater financial and other resources than us. As new companies enter the market and as more advanced technologies become available, we expect to face increased competition. In the future, any one of our competitors may develop technological advances that render obsolete the products or services that we provide or may provide in the future. While we plan to develop new and better technologies, which will give us competitive advantages, our competitors plan to do the same. We may not be able to develop the technologies we need to successfully compete in the future, and our competitors may be able to develop such technologies before we do. Consequently, we may not be able to successfully compete in the future.

#### The fine chemical, pharmaceutical and biotechnology industries involve rapidly changing technologies.

Rapid technological change and uncertainty due to new and emerging technologies characterize the drug and fine chemical development industries. We may not be able to develop, integrate and market, on a timely basis, the new and enhanced products and services necessary to keep pace with competitors. Failure to anticipate or to respond to changing technologies, or significant delays in product development or introduction, could cause our customers to delay or decide against purchases of our products or services.

Since many of or customers and potential customers are pharmaceutical and biotechnology companies, we are and will be subject to risks, uncertainties and trends that affect companies in these industries.

For the foreseeable future, we will derive a substantial portion of our revenue from pharmaceutical and biotechnology companies. As a result, we will be subject to risks and uncertainties that affect the pharmaceutical and biotechnology industries and possible reduction and delays in research and development expenditures by companies in these industries. Our future revenues may also be adversely affected by mergers and consolidation in the pharmaceutical and biotechnology industries, which will reduce the number of potential customers.

In particular, pharmaceutical and biotechnology companies face significant regulation by governmental entities in the United States and other countries. The nature and the extent to which such regulation may apply to our customers will vary depending on the nature of any such customers' products. Most of the pharmaceutical products developed by our customers will require regulatory approval by governmental agencies prior to commercialization. In particular, human pharmaceutical therapeutic products are subject to rigorous preclinical and clinical testing and other approval procedures by the FDA and by foreign regulatory authorities. Various federal and, in some cases, state laws also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of such pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate federal and foreign statutes and regulations are time consuming, can cause significant delays in the commercialization of a drug, and often require the expenditure of substantial resources. To the extent our customers experience significant delays in obtaining the necessary regulatory approvals to market their pharmaceutical products, or are unable to obtain such approvals at all, these customers will not purchase our proprietary ligands and other services used in the manufacture of the ultimate pharmaceutical product.

## We may be held liable for harm caused by drugs that our customers develop and test.

Often times, our ligands will be used by our customers to produce drugs for human use. If any of the drugs cause injuries or illness to people, we may be required to incur substantial costs in defending against claims and may be required to pay damages arising therefrom. Although we have liability insurance and will use commercially reasonable efforts to obtain indemnification covenants from our customers for their use of our products, such protections may not be sufficient to protect us from the cost of such claims. Damages awarded in a product liability action could be substantial and could have a material adverse effect on our financial condition.

#### We may be held liable for contamination or other harm caused by hazardous materials that we use.

Some of our research and development processes involve the use of hazardous materials and, therefore, we are subject to federal, state and local regulation governing the use, manufacture, handling, storage and disposal of hazardous materials. We cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any contamination or injury. We may also incur expenses relating to compliance with environmental laws. Such expenses or liability may have a material adverse effect on our financial condition.

## **Risks Relating to Our Chiral Technology**