

ADVENTRX PHARMACEUTICALS INC

Form S-3/A

September 15, 2004

As filed with the Securities and Exchange Commission on September 15, 2004

Registration Statement No. 333-117022

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

AMENDMENT NO. 1
TO
FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ADVENTRX Pharmaceuticals, Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

84-1318182
(I.R.S. Employer
Identification No.)

6725 Mesa Ridge Road, Suite 100
San Diego, California 92121
(858) 552-0866
Fax : (858) 552-0876

(Address, including zip code, and telephone number, including area code,
of Registrant's principal executive offices)

Steven M. Plumb, CPA
Chief Financial Officer
ADVENTRX Pharmaceuticals, Inc.
6725 Mesa Ridge Road, Suite 100
San Diego, California 92121
(858) 552-0866
Fax : (858) 552-0876

(Name, address, including zip code, and telephone number,
including area code, of agent for service)

Copies of all communications to:

**Henry D. Evans, Esq.
Francis W. Sarena, Esq.
Bingham McCutchen LLP
Three Embarcadero Center
San Francisco, California 94111
(415) 393-2503
Fax: (415) 393-2286**

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

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. []

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, other than securities offered only in connection with dividend or interest reinvestment plans, 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, please 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: []

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box: []

CALCULATION OF REGISTRATION FEE

| Title of each class of securities to be registered (1) | Amount to be registered | Proposed maximum offering price per share (2) | Proposed maximum aggregate offering price (2) | Amount of registration fee |
|--|-------------------------|---|---|----------------------------|
| common stock, par value \$0.001 per share | 20,179,697 shares | \$1.45 | \$29,260,560.65 | \$3,707.31(3) |

(1) In addition to the common stock set forth in the table, the amount to be registered includes an indeterminate number of shares issuable pursuant to stock splits and stock dividends in accordance with Rule 416(b) under the Securities Act of 1933.

(2) Estimated solely for purposes of calculating the amount of the registration fee. The estimate is made pursuant to Rule 457(a) of the Securities Act of 1933, as amended.

(3) Previously paid.

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 THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.

The information in this prospectus is not complete and may be changed. No securities may be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION,

Dated: September 15, 2004

PROSPECTUS

20,179,697 Shares

Common Stock

**ADVENTRX Pharmaceuticals, Inc.
6725 Mesa Ridge Road, Suite 100
San Diego, California 92121
(858) 552-0866
Fax : (858) 552-0876**

The security holders of ADVENTRX Pharmaceuticals, Inc. (the Company) listed in this prospectus are offering an aggregate of 20,179,697 shares of common stock, including shares issuable upon exercise of outstanding warrants.

The shares and warrants were sold to the selling security holders in transactions exempt from registration under the Securities Act of 1933, as amended (the Securities Act). We will not receive any of the proceeds from the sale of the shares of common stock offered hereby although we will receive the proceeds of sales of shares of common stock to the selling security holders upon exercise of their warrants (except to the extent warrants are exercised on a net exercise basis).

Each of the selling security holders may sell the shares covered by this prospectus from time to time in transactions on the American Stock Exchange LLC, in the over-the-counter market or in negotiated transactions. Each of the selling security holders directly, or through agents or dealers designated from time to time, may sell the shares of common stock offered by them at fixed prices, at prevailing market prices at the time of sale, at varying prices determined at the time of sale or at negotiated prices.

Our common stock is listed on the American Stock Exchange LLC under the symbol ANX . On September 13, 2004, the last reported sale price of our common stock on the American Stock Exchange LLC was \$1.46 per share.

**INVESTING IN THE COMMON STOCK INVOLVES RISKS.
SEE RISK FACTORS BEGINNING ON PAGE 4.**

Neither the Securities and Exchange Commission nor any state securities regulator has approved or disapproved the shares of common stock covered by this prospectus, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is ____ __, 2004

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In this prospectus, ADVENTRX, the company, we, us, and our refer to ADVENTRX Pharmaceuticals, Inc.

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. This prospectus is offering to sell, and is seeking offers to buy, shares of common stock only in jurisdictions where such offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus.

Special Note Regarding Forward-Looking Statements

Some of the statements under Our Company, Risk Factors and elsewhere in this prospectus constitute forward-looking statements. These statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. These factors include, among others, those listed under Risk Factors and elsewhere in this

prospectus.

In some cases, you can identify forward-looking statements by terms such as may, will, should, expects, anticipate, believes, estimates, predicts, potential, or continue or similar terms.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements.

Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of these statements. We undertake no obligation to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this prospectus may not occur.

Where You Can Find More Information About Us

We file annual, quarterly and special reports and other information with the Securities and Exchange Commission (the Commission). You may read and copy any document we file with the Commission at the Public Reference Room at the Commission, at Room 1024, Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549. Please call 1-800-SEC-0330 for further information concerning the Public Reference Room. The Commission also makes these documents and other information available on its website at <http://www.sec.gov>. We also maintain a website at <http://www.adventrx.com>. The material on our website is not a part of this prospectus

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We have filed with the Commission a registration statement on Form S-3 under the Securities Act relating to the common stock offered by this prospectus. This prospectus constitutes a part of the registration statement but does not contain all of the information set forth in the registration statement and its exhibits. For further information, we refer you to the registration statement and its exhibits.

The Commission allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to another document we have filed with the Commission. The information incorporated by reference is an important part of this prospectus and information that we file later with the Commission will automatically update and supersede this information. We incorporate by reference the following:

- the description of our common stock contained in the Registration Statement on Form 8-A filed with the Commission on April 27, 2004;
- our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 filed with the Commission on March 26, 2004;
- our Quarterly Report on Form 10-QSB for the quarter ended March 31, 2004 filed with the Commission on May 12, 2004;
- our Current Report on Form 8-K filed with the Commission on April 5, 2004, as amended on April 13, 2004;
- our Quarterly Report on Form 10-QSB for the quarter ended June 30, 2004 filed with the Commission on August 10, 2004;
- our Current Report on Form 8-K filed with the Commission on September 8, 2004; and

- any future filings we make with the Commission under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), until the selling security holders sell all of the common stock offered by them pursuant to this prospectus.

We will provide exhibits to these filings at no cost only if they are specifically incorporated into those filings.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address or telephone number:

Steven M. Plumb, CPA
Chief Financial Officer
ADVENTRX Pharmaceuticals, Inc.
6725 Mesa Ridge Road, Suite 100
San Diego , California 92121
(858) 552-0866

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Our Company

We were initially organized as a corporation under the Delaware General Corporation Law in December 1995. In October 2000, we closed the merger of our wholly-owned subsidiary, Biokeys Acquisition Corp., with and into Biokeys, Inc. In consideration of the merger, we issued an aggregate of 6,999,990 shares of common stock to the holders of capital stock of Biokeys, Inc.

On May 30, 2003 , our then wholly-owned subsidiary, Biokeys, Inc., merged into us and we changed our name from Biokeys Pharmaceuticals, Inc. to ADVENTRX Pharmaceuticals, Inc. The merger had no effect on our financial statements.

We are a biomedical research and development business focused on treatments for viral infections and cancer. Our business is in the development stage; we have not generated any significant revenues or any operating revenues and we have not yet commercialized or marketed any products. Pursuant to license agreements with the University of Texas M.D. Anderson Cancer Center, the National Institutes of Health and the University of Southern California , we have been granted development, commercialization, manufacturing and marketing rights to a number of drug candidates in the fields of antiviral and anticancer therapy, which are in varying stages of development. Our goal is to become a leading developer of drug therapies for the treatment of the Human Immunodeficiency Virus, Acquired Immune Deficiency Syndrome and cancer.

Risk Factors

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment.

We have a substantial accumulated deficit and limited working capital.

We had an accumulated deficit of \$28,481,146 as of December 31, 2003 and \$30,700,863 as of June 30, 2004. Since we presently have no source of revenues and are committed to continuing our product research and development program, significant expenditures and losses will continue until development of new products is completed and such products have been clinically tested, approved by the Food and Drug Administration and successfully marketed. In addition, we funded our operations primarily through the sale of securities, and have had limited working capital for our product development and other activities. We do not believe that debt financing from financial institutions will be available until at least the time that one of our products is approved for commercial production.

We have no current product sales revenues or profits.

We have devoted our resources to developing a new generation of therapeutic drug products, but such products cannot be marketed until clinical testing is completed and governmental approvals have been obtained. Accordingly, there is no current source of revenues, much less profits, to sustain our present activities, and no revenues will likely be available until, and unless, the new products are clinically tested, approved by the Food and Drug Administration and successfully marketed, either by us or a marketing partner, an outcome which we are not able to guarantee.

It is uncertain that we will have access to future capital or government grants.

It is not expected that we will generate positive cash flow from operations for at least the next several years. As a result, substantial additional equity or debt financing or the receipt of one or more government grants for research and development or clinical development will be required to fund our activities. We cannot be certain that we will be able to consummate any such financing on favorable terms, if at all, or receive any such government grants or that such financing or government grants will be adequate to meet our capital requirements. Any additional equity financing could result in substantial dilution to stockholders, and debt financing, if available, will most likely involve restrictive covenants which preclude us from making distributions to stockholders and taking other actions beneficial to stockholders. If adequate funds are not available, we may be required to delay or reduce the scope of our drug development program or attempt to continue development by entering into arrangements with collaborative partners or others that may require us to relinquish some or all of our rights to proprietary drugs. The inability to fund our capital requirements would have a material adverse effect on us

We are not certain that we will be successful in the development of our drug candidates.

The successful development of any new drug is highly uncertain and is subject to a number of significant risks. Our drug candidates, all of which are in a development stage, require significant, time-consuming and costly development, testing and regulatory clearance. This process typically takes several years and can require substantially more time. Risks include, among others, the possibility that a drug candidate will (i) be found to be ineffective or unacceptably toxic, (ii) have unacceptable side effects, (iii) fail to receive necessary regulatory clearances, (iv) not achieve broad market acceptance, (v) be subject to competition from third parties who may market equivalent or superior products, or (vi) be affected by third parties holding proprietary rights that will preclude us from marketing a drug product. There can be no assurance that the development of our drug candidates will demonstrate the efficacy and safety of our drug candidates as therapeutic drugs, or, even if demonstrated, that there will be sufficient advantages to their use over other drugs or treatments so as to render the drug product commercially viable. In the event that we are not successful in developing and commercializing one or more drug candidates, investors are likely to realize a loss of their entire investment.

Positive results in preclinical and early clinical trials do not ensure that future clinical trials will be successful or that drug candidates will receive any necessary regulatory approvals for the marketing, distribution or sale of such drug candidates.

Success in preclinical and early clinical trials does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict.

We will face intense competition from other companies in the pharmaceutical industry.

We are engaged in a segment of the pharmaceutical industry that is highly competitive and rapidly changing. If successfully developed and approved, any of our drug candidates will likely compete with several existing therapies. In addition, other companies are pursuing the development of pharmaceuticals that target the same diseases as are targeted by the drugs being developed by us. We anticipate that we will face intense and increasing competition in the future as new products enter the market and advanced technologies become available. We cannot assure that existing products or new products developed by competitors will not be more effective, or more effectively marketed and sold than those we may market and sell. Competitive products may render our drugs obsolete or noncompetitive prior to our recovery of development and commercialization expenses.

Many of our competitors will also have significantly greater financial, technical and human resources and will likely be better equipped to develop, manufacture and market products. In addition, many of these competitors have extensive experience in preclinical testing and clinical trials, obtaining Food and Drug Administration and other regulatory approvals and manufacturing and marketing pharmaceutical products. A number of these competitors also have products that have been approved or are in late-stage development and operate large, well-funded research and development programs. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, academic institutions, government agencies and other public and private research organizations are becoming increasingly aware of the commercial value of their inventions and are actively seeking to commercialize the technology they have developed. Accordingly, competitors may succeed in commercializing products more rapidly or effectively than us, which would have a material adverse effect us

There is no assurance that our products will have market acceptance.

Our success will depend in substantial part on the extent to which a drug product, once approved, achieves market acceptance. The degree of market acceptance will depend upon a number of factors, including (i) the receipt and scope of regulatory approvals, (ii) the establishment and demonstration in the medical community of the safety and efficacy of a drug product, (iii) the product's potential advantages over existing treatment methods and (iv) reimbursement policies of government and third party payors. We cannot predict or guarantee that physicians, patients, healthcare insurers or maintenance organizations, or the medical community in general, will accept or utilize any of our drug products.

The unavailability of health care reimbursement for any of our products will likely adversely impact our ability to effectively market such products and whether health care reimbursement will be available for any of our products is uncertain.

Our ability to commercialize our technology successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly-approved medical products. We cannot guarantee that adequate third-party insurance coverage will be available for us to establish and maintain price levels sufficient for realization of an appropriate return on its investments in developing new therapies. Government, private health insurers, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of

reimbursement for new therapeutic products approved for marketing by the Food and Drug Administration. Accordingly, even if coverage and reimbursement are provided by government, private health insurers, and third-party payors for use of our products, the market acceptance of these products would be adversely affected if the amount of reimbursement available for the use of our therapies proved to be unprofitable for health care providers

Uncertainties related to health care reform measures may affect our success.

There have been a number of federal and state proposals during the last few years to subject the pricing of health care goods and services, including prescription drugs, to government control and to make other changes to U.S. health care system. It is uncertain which legislative proposals will be adopted or what actions federal, state, or private payors for health care treatment and services may take in response to any health care reform proposals or legislation. We cannot predict the effect health care reforms may have on our business, and there is no guarantee that any such reforms will not have a material adverse effect on us.

Further testing of our drug candidates will be required and there is no assurance of Food and Drug Administration approval.

The Food and Drug Administration and comparable agencies in foreign countries impose substantial requirements upon the introduction of medical products, through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more and varies substantially based upon the type, complexity, and novelty of the product.

The effect of government regulation and the need for Food and Drug Administration approval will delay marketing of new products for a considerable period of time, impose costly procedures upon our activities, and provide an advantage to larger companies that compete with us. There can be no assurance that Food and Drug Administration or other regulatory approval for any products developed by us will be granted on a timely basis or at all. Any such delay in obtaining, or failure to obtain, such approvals would materially and adversely affect the marketing of any contemplated products and the ability to earn product revenue. Further, regulation of manufacturing facilities by state, local, and other authorities is subject to change. Any additional regulation could result in limitations or restrictions on the company's ability to utilize any of its technologies, thereby adversely affecting our operations.

Human pharmaceutical products are subject to rigorous preclinical testing and clinical trials and other approval procedures mandated by the Food and Drug Administration and foreign regulatory authorities. Various federal and foreign statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U.S. and foreign statutes and regulations are time-consuming and require the expenditure of substantial resources. In addition, these requirements and processes vary widely from country to country.

Among the uncertainties and risks of the Food and Drug Administration approval process are the following: (i) the possibility that studies and clinical trials will fail to prove the safety and efficacy of the drug, or that any demonstrated efficacy will be so limited as to significantly reduce or altogether eliminate the acceptability of the drug in the marketplace, (ii) the possibility that the costs of development, which can far exceed the best of estimates, may render commercialization of the drug marginally profitable or altogether unprofitable, and (iii) the possibility that the amount of time required for Food and Drug Administration approval of a drug may extend for years beyond that which is originally estimated. In addition, the Food and Drug Administration or similar foreign regulatory authorities may require additional clinical trials, which could result in increased costs and significant development delays. Delays or rejections may also be encountered based upon changes in Food and Drug Administration policy and the

establishment of additional regulations during the period of product development and Food and Drug Administration review. Similar delays or rejections may be encountered in other countries.

Our success will depend on licenses and proprietary rights we receive from other parties, and on any patents we may obtain.

Our success will depend in large part on our ability and our licensors' ability to (i) maintain license and patent protection with respect to their drug products, (ii) defend patents and licenses once obtained, (iii) maintain trade secrets, (iv) operate without infringing upon the patents and proprietary rights of others and (v) obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, both in the U.S. and in foreign countries. We have obtained licenses to patents and other proprietary rights from M.D. Anderson, University of Southern California and the National Institutes of Health.

The patent positions of pharmaceutical companies, including those of the company, are uncertain and involve complex legal and factual questions. There is no guarantee that we or our licensors have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any of the pending applications or that claims allowed will be sufficient to protect the technology licensed to us. In addition, we cannot be certain that any patents issued to or licensed by us will not be challenged, invalidated, infringed or circumvented, or that the rights granted thereunder will provide competitive disadvantages to us.

Litigation, which could result in substantial cost, may also be necessary to enforce any patents to which we have rights, or to determine the scope, validity and unenforceability of other parties' proprietary rights, which may affect our rights. U.S. patents carry a presumption of validity and generally can be invalidated only through clear and convincing evidence. There can be no assurance that our licensed patents would be held valid by a court or administrative body or that an alleged infringer would be found to be infringing. The mere uncertainty resulting from the institution and continuation of any technology-related litigation or interference proceeding could have a material adverse effect on us pending resolution of the disputed matters.

We may also rely on unpatented trade secrets and know-how to maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants and others. There can be no assurance that these agreements will not be breached or terminated, that we will have adequate remedies for any breach, or that trade secrets will not otherwise become known or be independently discovered by competitors.

Our license agreements can be terminated in the event of a breach.

The license agreements pursuant to which we license our core technologies for our potential drug products permit the licensors, respectively M.D. Anderson, National Institutes of Health and University of Southern California, to terminate the agreements under certain circumstances, such as the failure by us to use our reasonable best efforts to commercialize the subject drug or the occurrence of any other uncured material breach by us. The license agreements also provide that the licensor is primarily responsible for obtaining patent protection for the technology licensed, and we are required to reimburse the licensor for the costs it incurs in performing these activities. The license agreements also require the payment of specified royalties. Any inability or failure to observe these terms or pay these costs or royalties could result in the termination of the applicable license agreement in certain cases. The termination of any license agreement would have a material adverse effect on us.

Protecting our proprietary rights is difficult and costly.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict the breadth of claims allowed in these

companies' patents or whether we may infringe or be infringing these claims. Patent disputes are common and could preclude the commercialization of our products. Patent litigation is costly in its own right and could subject us to significant liabilities to third parties. In addition, an adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or product in dispute.

Our success is dependent on our key personnel.

We depend on a small management group and scientific/clinical team and on independent researchers, some of whom are inventors of the patents licensed to us for core technologies and drugs developed at M.D. Anderson and University of Southern California. Scientific personnel may from time to time serve as consultants to the company and may devote a portion of their time to our business, as well as continue to devote substantial time to the furtherance of our sponsored research at M.D. Anderson, University of Southern California and other affiliated institutions as may be agreed to in the future, but such personnel are not our employees and are not bound under written employment agreements. The services of such persons are important to us, and the loss of any of these services may adversely affect us.

We may be unable to retain skilled personnel and maintain key relationships.

The success of our business depends, in large part, on our ability to attract and retain highly qualified management, scientific and other personnel, and on our ability to develop and maintain important relationships with leading research institutions and consultants and advisors. Competition for these types of personnel and relationships is intense from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on commercially acceptable terms or at all, and the failure to do so would have a material adverse effect on us.

We currently have no sales or marketing capability.

We currently do not have marketing or sales personnel. We will have to develop a sales force, or rely on marketing partners or other arrangements with third parties for the marketing, distribution and sale of any drug product which is ready for distribution. There is no guarantee that we will be able to establish marketing, distribution or sales capabilities or make arrangements with third parties to perform those activities on terms satisfactory to us, or that any internal capabilities or third party arrangements will be cost-effective.

In addition, any third parties with which we may establish marketing, distribution or sales arrangements may have significant control over important aspects of the commercialization of a drug product, including market identification, marketing methods, pricing, composition of sales force and promotional activities. There can be no assurance that we will be able to control the amount and timing of resources that any third party may devote to the products of the company or prevent any third party from pursuing alternative technologies or products that could result in the development of products that compete with, or the withdrawal of support for, our products.

We do not have manufacturing capabilities and may not be able to efficiently develop manufacturing capabilities or contract for such services from third parties on commercially acceptable terms.

We do not have any manufacturing capacity. When required, we will seek to establish relationships with third-party manufacturers for the manufacture of clinical trial material and the commercial production of drug products as we have with Merck Eprova AG, Multiple Peptide Systems, Inc., Peptisyntha, Inc., deCode genetics, Inc., and MediChem Research, Inc. There can be no assurance that we will be able to establish relationships with third-party manufacturers on commercially acceptable terms or that third-party manufacturers will be able to manufacture a drug product on a cost-effective basis in commercial quantities under good manufacturing practices mandated by the Food and Drug Administration.

The dependence upon third parties for the manufacture of products may adversely affect future costs and the ability to develop and commercialize a drug product on a timely and competitive basis. Further, there can be no assurance that manufacturing or quality control problems will not arise in connection with the manufacture of our drug products or that third party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such products. Any failure to establish relationships with third parties for our manufacturing requirements on commercially acceptable terms would have a material adverse effect on us.

We are dependent in part on third parties for drug development and research facilities.

We do not possess research and development facilities necessary to conduct all of our drug development activities. We engage consultants and independent contract research organizations to design and conduct clinical trials in connection with the development of our drugs. As a result, these important aspects of a drug's development will be outside our direct control. In addition, there can be no assurance that such third parties will perform all of their obligations under arrangements with us or will perform those obligations satisfactorily.

In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage and it is uncertain that such increased or additional insurance coverage can be obtained on commercially reasonable terms.

Our business will expose us to potential product liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. There can be no assurance that product liability claims will not be asserted against us. We intend to obtain additional limited product liability insurance for our clinical trials, directly or through our marketing development partners or CRO (contract research organization) partners, when they begin in the U.S. and to expand its insurance coverage if and when we begin marketing commercial products. However, there can be no assurance that we will be able to obtain product liability insurance on commercially acceptable terms or that we will be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect against potential losses. A successful product liability claim or series of claims brought against us could have a material adverse effect on us.

Insurance coverage is increasingly more difficult to obtain or maintain.

Obtaining insurance for our business, property and products is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to third-party claims or suffer a loss or damage in excess of our insurance coverage, we may be required to share that risk in excess of our insurance limits. Furthermore, any first- or third-party claims made on any of our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all in the future.

The market price of our shares, like that of many biotechnology companies, is highly volatile.

Market prices for our common stock and the securities of other medical and biomedical technology companies have been highly volatile and may continue to be highly volatile in the future. Factors such as announcements of technological innovations or new products by us or our competitors, government regulatory action, litigation, patent or proprietary rights developments, and market conditions for medical and high technology stocks in general can have a significant impact on any future market for our common stock.

We are not paying dividends on our common stock.

We have never paid cash dividends on our common stock, and do not intend to do so in the foreseeable future.

The issuance of shares of our preferred stock may adversely affect our common stock.

Our Board of Directors is authorized to designate one or more series of preferred stock and to fix the rights, preferences, privileges and restrictions thereof, without any action by the stockholders. The designation and issuance of such shares of our preferred stock may adversely affect the common stock, if the rights, preferences and privileges of such preferred stock (i) restrict the declaration or payment of dividends on common stock, (ii) dilute the voting power of common stock, (iii) impair the liquidation rights of the common stock or (iv) delay or prevent a change in control of the company from occurring, among other possibilities.

Under provisions of our certificate of incorporation, bylaws and Delaware law, our management may be able to block or impede a change in control.

The issuance of preferred stock may make it more difficult for a third party to acquire, or may discourage a third party from acquiring, a majority of the voting stock. These and other provisions of our certificate of incorporation and our by-laws, as well as certain provisions of Delaware law, could delay or impede the removal of incumbent directors and could make more difficult a merger, tender offer or proxy contest involving a change of control of the company, even if such events could be beneficial to the interest of the stockholders as a whole. Such provisions could limit the price that certain investors might be willing to pay in the future for our common stock.

Officers and directors liabilities are limited under Delaware law.

Pursuant to our certificate of incorporation and by-laws, as authorized under applicable Delaware law, directors are not liable for monetary damages for breach of fiduciary duty, except in connection with a breach of the duty of loyalty, for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, for dividend payments or stock repurchases illegal under Delaware law or for any transaction in which a director has derived an improper personal benefit. Our certificate of incorporation and by-laws provide that we must indemnify our officers and directors to the fullest extent permitted by Delaware law for all expenses incurred in the settlement of any actions against such persons in connection with their having served as officers or directors.

Use Of Proceeds

All of the shares of common stock offered pursuant to this prospectus are being offered by the selling security holders listed under Selling Security Holders. We will not receive any proceeds from sales of shares of common stock by the selling security holders. The shares offered hereby include an aggregate of 7,162,894 shares issuable upon exercise of outstanding warrants held by security holders named in this prospectus. We will receive proceeds from any exercise of these warrants (except to the extent warrants are exercised on a net exercise basis). The proceeds, if any, will be added to our working capital and be available for general corporate purposes.

Selling Security Holders

All of the shares of our common stock and shares of our common stock issuable upon exercise of warrants registered for sale under this prospectus (the Registered Shares) are owned, as of the date of this prospectus, by the selling security holders listed in the table below. We issued the Registered Shares (or the warrants exercisable for Registered Shares, as the case may be) in the ordinary course of business in separate private placements or in consideration of services rendered to us. We are registering the Registered Shares for the selling security holders. At the time of the issuance of the Registered Shares (or the warrants exercisable for Registered Shares, as the case may be) we had no agreement or understanding with any selling security holder to distribute any of our securities.

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The following table sets forth information as of August 31, 2004 with respect to the selling security holders and the respective number of shares of common stock beneficially owned by each selling security holder. For purposes of computing the number and percentage of shares beneficially owned by a selling security holder on August 31, 2004, any shares which such person has the right to acquire within 60 days after such date are deemed to be outstanding, but those shares are not deemed to be outstanding for the purpose of computing the percentage ownership of any other selling security holder:

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| Name | Shares Owned Before Offering | Percent Owned Before Offering (1) | Shares Being Offered(2) | Shares Owned Upon Completion Of Offering | Percent Owned After Offering(1) |
|--|------------------------------|-----------------------------------|-------------------------|--|---------------------------------|
| Alan Sheinwald | 19,500 (3) | * | 19,500 | 0 | 0 |
| Anasazi Partners II LLC | 130,000 (4) | * | 130,000 | 0 | 0 |
| Anasazi Partners III LLC | 337,498 (5) | * | 337,498 | 0 | 0 |
| Anasazi Partners III Offshore Ltd | 337,498 (6) | * | 337,498 | 0 | 0 |
| Balkrishna E. Shagrithaya | 162,500 (7) | * | 37,500 | 125,000 | * |
| Ball Family Trust (Edward D. Ball and Susan E. Ball, Trustees) | 630,000 (8) | 1.2 | 130,000 | 500,000 | * |
| Benjamin Partners Savings Plan FBO Jeffrey Benison | 65,000 (9) | * | 65,000 | 0 | 0 |
| Bristol Investment Fund, Ltd | 399,998 (10) | * | 399,998 | 0 | 0 |
| BSI New BioMedical Frontier (SICAV) | 1,134,500 (11) | 2.1 | 800,000 | 334,500 | * |
| BSI SA | 149,250 (12) | * | 149,250 | 0 | 0 |
| Capital Ventures International | 999,998 (13) | 1.8 | 999,998 | 0 | 0 |
| Castle Creek Healthcare Partners LLC | 500,000 (14) | * | 500,000 | 0 | 0 |
| CD Investment Partners, Ltd. | 375,000 (15) | * | 375,000 | 0 | 0 |

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| Name | Shares Owned Before Offering | Percent Owned Before Offering (1) | Shares Being Offered (2) | Shares Owned Upon Completion Of Offering | Percent Owned After Offering (1) |
|---------------------------------------|------------------------------|-----------------------------------|--------------------------|--|----------------------------------|
| Chicago Private Investments | 65,000 (16) | * | 65,000 | 0 | 0 |
| Christopher Baker | 546,000 (17) | 1.0 | 475,000 | 71,000 | * |
| Crescent International Ltd | 270,000 (18) | * | 270,000 | 0 | 0 |
| Dannie King | 32,500 (19) | * | 32,500 | 0 | 0 |
| David and Jennifer Brown | 650 (20) | * | 650 | 0 | 0 |
| David W. Penney & Sarah B. McAllister | 20,000 (21) | * | 13,000 | 7,000 | * |
| David Wiener Revocable Trust 96 | 1,195,000 (22) | 2.2 | 145,000 | 1,050,000 | 2.0 |
| Deborah Melnick | 13,000 (23) | * | 13,000 | 0 | 0 |

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| | | | | | |
|---|--------------|---|---------|--------|---|
| Deborah Young, M.D. APC Employees Retirement Trust Y/A DTD 4/2/91 | 45,500 (24) | * | 20,500 | 25,000 | * |
| E. Todd Tracy | 150,000 (25) | * | 150,000 | 0 | 0 |
| Enable Growth Partners | 300,000 (26) | * | 300,000 | 0 | 0 |
| Gamma Opportunity Capital Partners, LP | 399,998 (28) | * | 399,998 | 0 | 0 |

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| Name | Shares Owned Before Offering | Percent Owned Before Offering (1) | Shares Being Offered (2) | Shares Owned Upon Completion Of Offering | Percent Owned After Offering (1) |
|--|---------------------------------|---|-----------------------------|---|--|
| Gene Salkind, M.D. | 155,000 (29) | * | 155,000 | 0 | 0 |
| Gilad Ottensoser | 7,000 (30) | * | 7,000 | 0 | 0 |
| Hans Gaverstrom | 44,708 (31) | * | 24,708 | 20,000 | * |
| Haywood Securities Inc in Trust for Bridge Finance Ltd. | 65,000 (32) | * | 65,000 | 0 | 0 |
| HSB Capital | 32,500 (33) | * | 32,500 | 0 | 0 |
| James Ladner | 75,452 (34) | * | 50,485 | 24,967 | * |
| Jay S. and Gabrielle Kunin | 19,500 (35) | * | 19,500 | 0 | 0 |
| Jeff Hermanson | 95,000 (36) | * | 32,500 | 62,500 | * |
| JIBS Equities | 199,998 (37) | * | 199,998 | 0 | 0 |
| Jillian E. and Robert J. Boldway | 20,750 (38) | * | 7,500 | 13,250 | * |
| John R. and Marjorie B. Brown | 2,600 (39) | * | 2,600 | 0 | 0 |
| Jonathan Balk | 173,750 (40) | * | 32,250 | 141,500 | * |
| Joseph Reynolds | 65,000 (41) | * | 65,000 | 0 | 0 |
| Julie A. Gegner | 3,250 (42) | * | 750 | 2,500 | * |
| Kanter Family Foundation | 65,000 (43) | * | 65,000 | 0 | 0 |

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| Name | Shares Owned Before Offering | Percent Owned Before Offering (1) | Shares Being Offered (2) | Shares Owned Upon Completion Of Offering | Percent Owned After Offering (1) |
|--|---------------------------------|---|-----------------------------|---|--|
| Kenneth Cerruto | 15,000 (44) | * | 15,000 | 0 | 0 |
| Kenneth Greif | 499,998 (45) | * | 499,998 | 0 | 0 |
| Laddcap Value Partners LP | 150,000 (46) | * | 150,000 | 0 | 0 |
| Larry Rice | 65,000 (47) | * | 65,000 | 0 | 0 |
| Lilienthal Investment Foundation | 51,000 (49) | * | 51,000 | 0 | 0 |
| Lisa Rachlin | 650 (50) | * | 650 | 0 | 0 |
| Longview Fund, LP | 249,998 (51) | * | 249,998 | 0 | 0 |
| Marital Trust GST Subject U/T/W of Leopold Salkind DTD 10/29/02 , Marilyn Salkind, Gene Salkind, Trustees | 32,500 (52) | * | 32,500 | 0 | 0 |
| Mark Collins | 47,750 (53) | * | 18,750 | 29,000 | * |

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| | | | | | |
|---------------------|--------------|---|--------|---------|---|
| Mark A. Ford | 13,000 (54) | * | 13,000 | 0 | 0 |
| Mark Eugene Reaman | 32,500 (55) | * | 32,500 | 0 | 0 |
| Michael Elconin | 13,000 (56) | * | 13,000 | 0 | 0 |
| Michael M. Goldberg | 451,000 (57) | * | 26,000 | 425,000 | * |
| Michael Loew | 212,498 (59) | * | 87,498 | 125,000 | * |

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| Name | Shares Owned Before Offering | Percent Owned Before Offering (1) | Shares Being Offered (2) | Shares Owned Upon Completion Of Offering | Percent Owned After Offering (1) |
|---|------------------------------|-----------------------------------|--------------------------|--|----------------------------------|
| OTAPE Investments LLC | 99,998 (60) | * | 99,998 | 0 | 0 |
| Paul H. Robbins | 162,500 (61) | * | 37,500 | 125,000 | * |
| Paul Scharfer | 202,500 (62) | * | 202,500 | 0 | 0 |
| Peter Levitch | 187,000 (63) | * | 140,000 | 47,000 | * |
| ProMed Offshore Fund, Ltd. | 109,500 (64) | * | 109,500 | 0 | 0 |
| ProMed Partners II, L.P. | 167,500 (65) | * | 146,700 | 20,800 | 0 |
| ProMed Partners, L.P. | 676,500 (66) | 1.3 | 676,500 | 0 | 0 |
| RHP Master Fund, Ltd. | 300,000 (67) | * | 300,000 | 0 | 0 |
| Richard & Carolyn Burgoon | 6,500 (68) | * | 1,500 | 5,000 | * |
| Richard L. Hoffman and Ricki Hoffman | 65,000 (69) | * | 15,000 | 50,000 | * |
| Richard Reiss | 62,500 (71) | * | 37,500 | 25,000 | * |
| Ritchie Long/Short Trading Ltd. | 750,000 (72) | 1.4 | 750,000 | 0 | 0 |
| Robert J. and Sandra S. Neborsky JTWROS | 80,254 (73) | * | 80,254 | 0 | 0 |

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| Name | Shares Owned Before Offering | Percent Owned Before Offering (1) | Shares Being Offered (2) | Shares Owned Upon Completion Of Offering | Percent Owned After Offering (1) |
|--|------------------------------|-----------------------------------|--------------------------|--|----------------------------------|
| Robert J. Neborsky, MD, Inc. Combination Retirement Trust U/T/A 11/30/82 | 1,295,283 (74) | 2.7 | 672,500 | 622,783 | 1.2 |
| Robert Melnick | 168,900 (75) | * | 168,900 | 0 | 0 |
| Robert Nathan | 61,499 (76) | * | 42,829 | 18,670 | * |
| Sabbatical Ventures, LLC | 30,000 (77) | * | 30,000 | 0 | 0 |
| Sandi Yurichuk | 32,500 (78) | * | 32,500 | 0 | 0 |
| SF Capital Partners Ltd. | 750,000 (80) | 1.4 | 750,000 | 0 | 0 |
| Sunrise Overseas, Ltd. | 249,000 (81) | * | 249,000 | 0 | 0 |
| TCMP3 Partners | 150,000 (82) | * | 150,000 | 0 | 0 |
| TEK Investments Inc. | 1,375,000 (83) | 2.5 | 375,000 | 1,000,000 | 1.9 |
| Wayne Saker | 60,000 (84) | * | 60,000 | 0 | 0 |
| Whalehaven Fund Limited | 124,998 (85) | * | 124,998 | 0 | 0 |
| William Newman | 116,000 (86) | * | 116,000 | 0 | 0 |

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| | | | | | |
|------------------|--------------|-----|---------|---------|---|
| Xmark Fund, L.P. | 572,500 (87) | 1.1 | 322,500 | 250,000 | * |
| Xmark Fund, LTD | 897,500 (88) | 1.7 | 397,500 | 500,000 | * |

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| Name | Shares Owned Before Offering | Percent Owned Before Offering(1) | Shares Being Offered(2) | Shares Owned Upon Completion Of Offering | Percent Owned After Offering(1) |
|--|------------------------------|----------------------------------|-------------------------|--|---------------------------------|
| Stonestreet LP | 349,998(89) | * | 349,998 | 0 | 0 |
| Sean Quinn | 105,000(90) | * | 105,000 | 0 | 0 |
| Brian M. Herman | 32,500(91) | * | 32,500 | 0 | 0 |
| Alpha Capital AG | 499,998(92) | * | 499,998 | 0 | 0 |
| Katherine A. Wiener | 65,000(93) | * | 15,000 | 50,000 | * |
| Sean M. Callahan | 19,500(94) | * | 19,500 | 0 | 0 |
| Roland Hartmann | 63,500(96) | * | 63,500 | 0 | 0 |
| Clariden Investments Ltd. | 148,000(97) | * | 148,000 | 0 | 0 |
| SDS Merchant Fund, LP | 1,137,500(98) | 2.1 | 512,500 | 625,000 | 1.2 |
| SDS Capital Group SPC, Ltd. | 999,998(99) | 1.8 | 999,998 | 0 | 0 |
| BayStar Capital II, L.P. | 300,000(100) | * | 300,000 | 0 | 0 |
| North Sound Legacy International Ltd. | 384,000(101) | * | 384,000 | 0 | 0 |
| North Sound Legacy Institutional Fund LLC | 198,000(102) | * | 198,000 | 0 | 0 |
| North Sound Legacy Fund LLC | 18,000(103) | * | 18,000 | 0 | 0 |
| Bullbear Capital Partners, LLC | 544,000(104) | * | 544,000 | 0 | 0 |
| Robert Wexler | 47,500(107) | * | 22,500 | 25,000 | * |
| Crestview Capital Master, L.L.C. | 999,998(108) | 1.8 | 999,998 | 0 | 0 |
| Jurg Fluck | 11,700(109) | * | 9,000 | 2,700 | * |
| Greenwich Growth Fund Limited | 99,998(110) | * | 99,998 | 0 | 0 |
| Bank Sal. Oppenheim jr. & Cie (Switzerland) AG | 27,500(111) | * | 7,500 | 20,000 | * |
| Peter J. and Elaine Chortek Family Trust, dated January 24, 1994 as amended and restated | 65,000(112) | * | 65,000 | 0 | 0 |
| Botka-Liu Family Revocable Trust, dated 8/10/2000 | 26,000(113) | * | 26,000 | 0 | 0 |
| Franklin M. Berger | 254,998(114) | * | 249,998 | 5,000 | * |
| Scott Weisman | 25,911(115) | * | 15,455 | 10,456 | * |
| Saad Investments Company Limited | 225,000(116) | * | 225,000 | 0 | 0 |

* Less than 1.0%.

(1) The percentage of ownership of common stock is based on 53,811,072 shares of common stock outstanding as of August 31, 2004 and excludes all shares of common stock issuable upon the exercise of outstanding options or

warrants to purchase common stock or conversion of any of our outstanding preferred stock, other than the shares of common stock issuable upon the exercise of options or warrants to purchase common stock held by the named person to the extent such options or warrants are exercisable within 60 days of August 31, 2004.

(2) Options and warrants to purchase our common stock that are presently exercisable or exercisable within 60 days of August 31, 2004 are included in the total number of shares beneficially owned for the person holding those options or warrants and are considered outstanding for the purpose of calculating percentage ownership of the particular holder.

(3) Includes a warrant to purchase 4,500 shares of our common stock, all of which will be offered.

(4) Includes a warrant to purchase 30,000 shares of our common stock, all of which will be offered.

(5) Includes warrants to purchase 95,832 shares of our common stock, all of which will be offered.

(6) Includes warrants to purchase 95,832 shares of our common stock., all of which will be offered.

(7) Includes a warrant to purchase 37,500 shares of our common stock, all of which will be offered.

(8) Includes a warrant to purchase 30,000 shares of our common stock, all of which will be offered. Since February 2004, Edward D. Ball has been a member of our Scientific Advisory Board.

(9) Includes a warrant to purchase 15,000 shares of our common stock, all of which will be offered.

(10) Includes warrants to purchase 133,332 shares of our common stock, all of which will be offered.

(11) Includes warrants to purchase 200,000 shares of our common stock, all of which will be offered.

(12) Includes warrants to purchase 49,750 shares of our common stock, all of which will be offered.

(13) Includes warrants to purchase 333,332 shares of our common stock, all of which will be offered.

(14) Includes warrants to purchase 166,666 shares of our common stock, all of which will be offered.

(15) Includes warrants to purchase 125,000 shares of our common stock, all of which will be offered.

(16) Includes a warrant to purchase 15,000 shares of our common stock, all of which will be offered.

(17) Includes warrants to purchase 125,000 shares of our common stock, all of which will be offered.

(18) Includes warrants to purchase 90,000 shares of our common stock, all of which will be offered.

(19) Includes a warrant to purchase 7,500 shares of our common stock, all of which will be offered.

(20) Includes a warrant to purchase 150 shares of our common stock, all of which will be offered.

(21) Includes warrants to purchase 10,000 shares of our common stock, 3,000 of which will be offered.

(22) Includes warrants to purchase 45,000 shares of our common stock, all of which will be offered.

(23) Includes a warrant to purchase 3,000 shares of our common stock, all of which will be offered.

- (24) Includes warrants to purchase 10,500 shares of our common stock, all of which will be offered.
- (25) Includes warrants to purchase 50,000 shares of our common stock, all of which will be offered.
- (26) Includes warrants to purchase 100,000 shares of our common stock, all of which will be offered.

- (27) Not used.
- (28) Includes warrants to purchase 133,332 shares of our common stock, all of which will be offered.
- (29) Includes warrants to purchase 45,000 shares of our common stock, all of which will be offered.
- (30) Includes a warrant to purchase 7,000 shares of our common stock, all of which will be offered.
- (31) Includes warrants to purchase 24,708 shares of our common stock, all of which will be offered.
- (32) Includes a warrant to purchase 15,000 shares of our common stock, all of which will be offered.
- (33) Includes a warrant to purchase 7,500 shares of our common stock, all of which will be offered.
- (34) Includes warrants to purchase 20,495 shares of our common stock, all of which will be offered.
- (35) Includes a warrant to purchase 4,500 shares of our common stock, all of which will be offered.
- (36) Includes a warrant to purchase 7,500 shares of our common stock, all of which will be offered.
- (37) Includes warrants to purchase 66,665 shares of our common stock, all of which will be offered.
- (38) Includes a warrant to purchase 7,500 shares of our common stock, all of which will be offered.
- (39) Includes a warrant to purchase 600 shares of our common stock, all of which will be offered.
- (40) Includes warrants to purchase 32,250 shares of our common stock, all of which will be offered.
- (41) Includes a warrant to purchase 15,000 shares of our common stock, all of which will be offered.
- (42) Includes a warrant to purchase 750 shares of our common stock, all of which will be offered.
- (43) Includes a warrant to purchase 15,000 shares of our common stock, all of which will be offered.
- (44) Includes a warrant to purchase 15,000 shares of our common stock, all of which will be offered.
- (45) Includes warrants to purchase 166,665 shares of our common stock, all of which will be offered.
- (46) Includes warrants to purchase 50,000 shares of our common stock, all of which will be offered.
- (47) Includes a warrant to purchase 15,000 shares of our common stock, all of which will be offered.
- (48) Not used.

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- (49) Includes warrants to purchase 17,000 shares of our common stock, all of which will be offered.
- (50) Includes a warrant to purchase 150 shares of our common stock, all of which will be offered.
- (51) Includes a warrant to purchase 83,332 shares of our common stock, all of which will be offered.
- (52) Includes a warrant to purchase 7,500 shares of our common stock, all of which will be offered.
- (53) Includes a warrant to purchase 18,750 shares of our common stock, all of which will be offered.
- (54) Includes a warrant to purchase 3,000 shares of our common stock, all of which will be offered.
- (55) Includes a warrant to purchase 7,500 shares of our common stock, all of which will be offered.
- (56) Includes a warrant to purchase 3,000 shares of our common stock, all of which will be offered.
- (57) Includes a warrant to purchase 6,000 shares of our common stock, all of which will be offered, and 400,000 shares of common stock held by Emisphere Technologies, Inc., of which Mr. Goldberg is the Chief Executive Officer. Mr. Goldberg disclaims beneficial ownership of all shares of common stock held by Emisphere Technologies, Inc. Since January 2004, Mr. Goldberg has been a member of our Board of Directors.
- (58) Not used.
- (59) Includes warrants to purchase 54,165 shares of our common stock, all of which will be offered.
- (60) Includes warrants to purchase 33,332 shares of our common stock, all of which will be offered.
- (61) Includes a warrant to purchase 37,500 shares of our common stock, all of which will be offered.
- (62) Includes warrants to purchase 67,500 shares of our common stock, all of which will be offered.
- (63) Includes warrants to purchase 49,000 shares of our common stock, 40,000 of which will be offered.
- (64) Includes warrants to purchase 36,500 shares of our common stock, all of which will be offered.
- (65) Includes warrants to purchase 48,900 shares of our common stock, all of which will be offered.
- (66) Includes warrants to purchase 225,500 shares of our common stock, all of which will be offered.
- (67) Includes warrants to purchase 100,000 shares of our common stock, all of which will be offered. RHP Master Fund, Ltd. is a party to an investment management agreement with Rock Hill Investment Management, L.P., a limited partnership of which the general partner is RHP General Partner, LLC. Pursuant to such agreement, Rock Hill Investment Management directs the voting and disposition of shares owned by RHP Master Fund, Ltd. Messrs. Wayne Bloch, Gary Kaminsky and Peter Lockhart own all of the interests in RHP General Partner, LLC. The aforementioned entities and individuals disclaim beneficial ownership of shares of our common stock owned by RHP Master Fund, Ltd.
- (68) Includes a warrant to purchase 1,500 shares of our common stock, all of which will be offered.
- (69) Includes a warrant to purchase 15,000 shares of our common stock, all of which will be offered.

- (70) Not used.
- (71) Includes warrants to purchase 12,500 shares of our common stock, all of which will be offered.
- (72) Includes warrants to purchase 250,000 shares of our common stock, all of which will be offered.
- (73) Includes warrants to purchase 60,254 shares of our common stock, all of which will be offered.
- (74) Includes warrants to purchase 287,500 shares of our common stock, all of which will be offered.
- (75) Includes warrants to purchase 52,500 shares of our common stock, all of which will be offered.

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- (76) Includes a warrant to purchase 42,829 shares of our common stock, all of which will be offered.
- (77) Includes a warrant to purchase 30,000 shares of our common stock, all of which will be offered.
- (78) Includes a warrant to purchase 7,500 shares of our common stock, all of which will be offered.
- (79) Not used.
- (80) Includes warrants to purchase 250,000 shares of our common stock, all of which will be offered.
- (81) Includes warrants to purchase 83,000 shares of our common stock, all of which will be offered.
- (82) Includes warrants to purchase 50,000 shares of our common stock, all of which will be offered.
- (83) Includes a warrant to purchase 375,000 shares of our common stock, all of which will be offered.
- (84) Includes warrants to purchase 20,000 shares of our common stock, all of which will be offered.
- (85) Includes warrants to purchase 41,665 shares of our common stock, all of which will be offered.
- (86) Includes warrants to purchase 32,000 shares of our common stock, all of which will be offered.
- (87) Includes warrants to purchase 157,500 shares of our common stock, all of which will be offered.
- (88) Includes warrants to purchase 232,500 shares of our common stock, all of which will be offered.
- (89) Includes warrants to purchase 116,665 shares of our common stock, all of which will be offered.
- (90) Includes warrants to purchase 35,000 shares of our common stock, all of which will be offered.
- (91) Includes a warrant to purchase 7,500 shares of our common stock, all of which will be offered.
- (92) Includes warrants to purchase 166,665 shares of our common stock, all of which will be offered.
- (93) Includes warrants to purchase 15,000 shares of our common stock, all of which will be offered.
- (94) Includes warrants to purchase 4,500 shares of our common stock, all of which will be offered.

- (95) Not used.
- (96) Includes warrants to purchase 18,500 shares of our common stock, all of which will be offered.
- (97) Includes warrants to purchase 51,000 shares of our common stock, all of which will be offered.
- (98) Includes warrants to purchase 262,500 shares of our common stock, all of which will be offered.
- (99) Includes warrants to purchase 333,332 shares of our common stock, all of which will be offered. We have been advised by SDS Capital Group SPC, Ltd. that it is also the beneficial owner of the 1,137,500 shares of our common stock beneficially owned by SDS Merchant Fund, LP.
- (100) Includes warrants to purchase 100,000 shares of our common stock, all of which will be offered.
- (101) Includes warrants to purchase 128,000 shares of our common stock, all of which will be offered.
- (102) Includes warrants to purchase 66,000 shares of our common stock, all of which will be offered.
- (103) Includes warrants to purchase 6,000 shares of our common stock, all of which will be offered.
- (104) Includes a warrant to purchase 75,000 shares of our common stock, all of which will be offered.
- (105) Not used.
- (106) Not used.
- (107) Includes warrants to purchase 12,500 shares of our common stock, all of which will be offered.
- (108) Includes warrants to purchase 333,332 shares of our common stock, all of which will be offered.
- (109) Includes a warrant to purchase 2,700 shares of our common stock, none of which will be offered.
- (110) Includes warrants to purchase 33,332 shares of our common stock, all of which will be offered.
- (111) Includes warrants to purchase 2,500 shares of our common stock, all of which will be offered.
- (112) Includes warrants to purchase 15,000 shares of our common stock, all of which will be offered.
- (113) Includes a warrant to purchase 6,000 shares of our common stock, all of which will be offered.
- (114) Includes warrants to purchase 83,332 shares of our common stock, all of which will be offered.
- (115) Includes warrants to purchase 10,000 shares of our common stock, all of which will be offered.
- (116) Includes warrants to purchase 75,000 shares of our common stock, all of which will be offered.

Within the past three years, other than as noted in footnotes 8 and 57, none of the selling security holders had any position, office or other material relationship with us or any of our predecessors or affiliates.

PLAN OF DISTRIBUTION

We are registering the shares of common stock on behalf of the selling security holders. Sales of shares may be made by selling security holders, including their respective donees, transferees, pledgees or other successors-in-interest directly to purchasers or to or through underwriters, broker-dealers or through agents. Sales may be made from time to time on the American Stock Exchange, any other exchange or market upon which our shares may trade in the future, in the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to market prices, or at negotiated or fixed prices. The shares may be sold by one or more of, or a combination of, the following:

a block trade in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction (including crosses in which the same broker acts as agent for both sides of the transaction);

purchases by a broker-dealer as principal and resale by such broker-dealer, including resales for its account, pursuant to this prospectus;

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchases;

through options, swaps or derivatives;

in privately negotiated transactions;

in making short sales or in transactions to cover short sales entered into after the date of this prospectus;

put or call option transactions relating to the shares; or

any other method permitted by applicable law.

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The selling security holders may effect these transactions by selling shares directly to purchasers or to or through broker-dealers, which may act as agents or principals. These broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling security holders and/or the purchasers of shares for whom such broker-dealers may act as agents or to whom they sell as principals, or both (which compensation as to a particular broker-dealer might be in excess of customary commissions). Each of the selling security holders has advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities.

Each selling security holder will act independently of us in making decisions regarding the timing, manner and size of each sale of shares of common stock covered by this registration statement.

Each of the selling security holders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with those transactions, the broker-dealers or other financial institutions may engage in short sales of the shares or of securities convertible into or exchangeable for the shares in the course of hedging positions they assume with the selling security holders. Each of the selling security holders may also enter into options or other transactions with broker-dealers or other financial institutions which require the delivery of shares offered by this prospectus to those broker-dealers or other financial institutions. The broker-dealer or other financial institution may then resell the shares pursuant to this prospectus (as amended or supplemented, if required by applicable law, to reflect those transactions).

Each of the selling security holders and any broker-dealers that act in connection with the sale of shares may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act, and any commissions received by broker-dealers or any profit on the resale of the shares sold by them while acting as principals may be deemed to be underwriting discounts or commissions under the Securities Act. Each of the selling security holders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares against liabilities, including liabilities arising under the Securities Act. We have agreed to indemnify each of the selling security holders and each selling security holder has agreed, severally and not jointly, to indemnify us against some liabilities in connection with the offering of the shares, including liabilities arising under the Securities Act.

Each selling security holder and any other persons participating in a distribution of the securities covered by this registration statement will be subject to the prospectus delivery requirements of the Securities Act and will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M, which may restrict certain activities of, and limit the timing of purchases and sales of securities by, selling security holders and other persons participating in a distribution of securities. Furthermore, under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to such securities for a specified period of time prior to the commencement of such distribution, subject to specified exceptions or exemptions. All of the foregoing may affect the marketability of the securities offered hereby.

Each of the selling security holders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act rather than under this prospectus, provided they meet the criteria and conform to the requirements of Rule 144.

Upon being notified by a selling security holder that a material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required pursuant to Rule 424(b) under the Securities Act, disclosing:

the name of each such selling security holder and of the participating broker-dealer(s);

the number of shares involved;

the initial price at which the shares were sold;

the commissions paid or discounts or concessions allowed to the broker-dealer(s), where applicable;

that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and

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other facts material to the transactions.

In addition, if required under applicable law or the rules or regulations of the Commission, we will file a supplement to this prospectus when a selling security holder notifies us that a donee or pledgee intends to sell more than 500 shares of common stock.

We are paying all expenses and fees customarily paid by the issuer in connection with the registration of the shares. Each of the selling security holders will bear all brokerage or underwriting discounts or commissions paid to broker-dealers in connection with the sale of the shares.

Legal Matters

The validity of the issuance of shares of common stock offered hereby will be passed upon for us by Bingham McCutchen LLP, San Francisco, California. To our knowledge, no attorney at Bingham McCutchen LLP who has worked on substantive matters for us owns any of our securities.

Experts

Our consolidated balance sheets as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for the years then ended and for the period from June 12, 1996 (date of inception) through December 31, 2003, have been incorporated by reference in this prospectus and in the registration statement in reliance on the report of J.H. Cohn LLP, independent registered public accounting firm, given upon the authority of said firm as experts in accounting and auditing. The report of J.H. Cohn LLP indicated that the consolidated financial statements for the period from June 12, 1996 (date of inception) through December 31, 2001, were audited by other auditors. J.H. Cohn LLP's opinion insofar as it relates to the period from June 12, 1996 to December 31, 2001, is based solely on the report of the other auditors.

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20,179,697 SHARES

ADVENTRX PHARMACEUTICALS, INC.

COMMON STOCK

PROSPECTUS

_____, 2004

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PART II

Information Not Required In Prospectus

Item 14. Other Expenses Of Issuance And Distribution

The estimated expenses in connection with the distribution of the securities being registered, all of which are to be paid by us, are as follows:

| | |
|---|-------------|
| Securities and Exchange Commission Registration Fee | \$3,707.31 |
| Legal Fees and Expenses | \$70,000.00 |

| | |
|---------------------------------|--------------------|
| Accounting Fees and Expenses | \$25,000.00 |
| Miscellaneous Fees and Expenses | \$500.00 |
| Total | \$99,207.31 |

Item 15. Indemnification Of Directors And Officers

Section 145 of the Delaware General Corporation Law grants corporations the power to indemnify their directors, officers, employees and agents in accordance with the provisions thereof. Article VI of our by-laws provide for indemnification of our directors, officers, agents and employees to the full extent permissible under Section 145 of the Delaware General Corporation Law. Section 102(b)(7) of the Delaware General Corporation Law authorizes a corporation to eliminate the liability of directors for breach of fiduciary duty in certain cases. Article VI of our certificate of incorporation eliminates such liability to the full extent permitted by Section 145.

Pursuant to warrants issued by us and registration rights agreements entered into between us and certain selling security holders, we are obligated to indemnify certain of the selling security holders with respect to various matters.

We maintain directors and officers liability insurance coverage protecting our officers and directors against certain liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

Item 16. Exhibits And Financial Statement Schedules

(a) Exhibits

An Exhibit Index has been attached as part of this Registration Statement and is incorporated herein by reference.

(b) Financial Statement Schedules

Schedules are omitted because they are either not required, are not applicable or because equivalent information has been included in the financial statements, the notes thereto or elsewhere herein.

Item 17. Undertakings

a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(a) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(b) To reflect in this prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement;

(c) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (1)(a) and (1)(b) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions described under Item 15, Indemnification of Directors and Officers above, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment to the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

c) The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on a Form S-3 and has duly caused this Amendment No. 1 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California, on September 15, 2004.

ADVENTRX Pharmaceuticals, Inc.

By: /s/ Steven M. Plumb

Name: Steven M. Plumb, CPA

Title: Chief Financial Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 1 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|--------------------------------------|--|---------------|
| <u>/s/ M. Ross Johnson*</u> | Director, Chairman of the Board | September 15, |
| M. Ross Johnson, Ph.D | | |
| <u>/s/ Evan M. Levine</u> | Chief Executive Officer and President (Principal Executive Officer), Vice-Chairman of the Board and Secretary | September 15, |
| Evan M. Levine | | |
| <u>/s/ Steven M. Plumb</u> | Chief Financial Officer (Principal Financial and Accounting Officer) | September 15, |
| Steven M. Plumb, CPA | | |
| <u>/s/ Michael M. Goldberg*</u> | Director | September 15, |
| Michael M. Goldberg, M.D. | | |
| <u>/s/ Mark J. Pykett*</u> | Director | September 15, |
| Mark J. Pykett, V.M.D., Ph.D. | | |
| <u>/s/ Mark Bagnall*</u> | Director | September 15, |
| Mark Bagnall | | |
| <u>*By: /s/ Steven M. Plumb</u> | | September 15, |
| Steven M. Plumb, Attorney-in-fact | | |

Exhibit Index

| Exhibit Number | Description |
|-------------------|---|
| 3.1 (1) | Certificate of Incorporation of Victoria Enterprises, Inc. |
| 3.2 (1) | Certificate of Amendment of Certificate of Incorporation of Victoria Enterprises, Inc. |
| 3.3 (1) | Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc. |
| 3.4 (1) | Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc. |
| 3.5 (1) | Certificate of Ownership and Merger Merging Biokeys, Inc. with and into Biokeys Pharmaceuticals, Inc. |
| 3.6 (2) | Amended and Restated Bylaws of Biokeys Pharmaceuticals, Inc. |
| 3.7 (1) | Certificate of Amendment to the Certificate of Incorporation of ADVENTRX Pharmaceuticals, Inc. |
| 4.1* | Common Stock and Warrant Purchase Agreement, dated as of April 5, 2004 , among the Registrant and the Investors named therein |
| 4.2* | A-1 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement with the Investors |

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- 4.3* A-2 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement with the Investors
- 4.4 (3) Common Stock and Warrant Purchase Agreement, dated April 8, 2004 , between the Registrant and CD Investment Partners, Ltd.
- 4.5 (3) A-1 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
- 4.6 (3) A-2 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
- 4.7 (3) Warrant to Purchase Common Stock issued on April 8, 2004 to Burnham Hill Partners
- 4.8 (3) Warrant to Purchase Common Stock issued on April 8, 2004 to Ernest Pernet
- 4.9 (3) Warrant to Purchase Common Stock issued on April 8, 2004 to W.R. Hambrecht + Co. , LLC
- 4.10* Registration Rights Agreement, dated as of April 5, 2004 , among the Registrant and the Investors named therein
- 4.11 (3) Registration Rights Agreement, dated as of April 8, 2004 , between the Registrant and CD Investment Partners, Ltd.
- 4.12 Not used
- 4.13 Not used
- 4.14 (4) Common Stock and Warrant Purchase Agreement, dated April 19, 2004 , between the Registrant and Franklin Berger
- 4.15 (4) A-1 Warrant to Purchase Common Stock issued to Franklin Berger
- 4.16 (4) A-2 Warrant to Purchase Common Stock issued to Franklin Berger
- 4.17 (4) Registration Rights Agreement, dated as of April 8, 2004 , between the Registrant and Franklin Berger
- 4.18 Registration Rights Agreement, dated _____, 2001, between the Registrant and certain stockholders
- 4.19* Warrant to Purchase Common Stock issued by the Registrant
- 4.20* Stock Subscription Agreement
- 4.21* Warrant to Purchase Common Stock issued by the Registrant
- 4.22* Warrant for the Purchase of Shares of Common Stock No. WA-2A issued June 14, 2001 to Robert J. Neborsky and Sandra S. Neborsky, JTWROS
- 5.1 Opinion of Bingham McCutchen LLP
- 23.1 Consent of J. H. Cohn LLP
- 23.2 Consent of Bingham McCutchen LLP (included in Exhibit 5.1)
- 24* Power of Attorney (filed as part of signature page to Registration Statement)

* Previously filed.

(1) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 8-A filed April 27, 2004.

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(2) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 10-SB, filed October 2, 2001, as amended.

(3) Incorporated by reference to the same-numbered exhibit to the Company's Current Report on Form 8-K, as amended, dated April 5, 2004.

(4) Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB filed May 12, 2004.

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