ADVENTRX PHARMACEUTICALS INC
Form 10KSB/A
August 11, 2005

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-KSB/A
AMENDMENT NO. 1

(Mark one)

þ **Annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the Fiscal Year December 31, 2004, or

o **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
Commission file number: 001-32157

ADVENTRX PHARMACEUTICALS, INC.
(Name of Small Business Issuer in its charter)

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

6725 Mesa Ridge Road, Suite 100, San Diego, California 92121
(Address of principal executive offices)
(858) 552-0866
(Issuer s telephone number, including area code)
Securities registered under Section 12(b) of the Exchange Act: **None**
Securities registered under Section 12(g) of the Exchange Act:
Common Stock, par value $0.001 per share

Indicate by check mark whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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 þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-B is not contained herein, and will not be contained, to the best of issuer 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. o

State issuer s revenues for its most recent fiscal year: $103,042

The aggregate market value of the Common Stock held by non-affiliates of the issuer, as of March 28, 2004 was approximately $53,056,708 based upon the closing price of the issuer s Common Stock reported for such date on the American Stock Exchange. For purposes of this disclosure, shares of Common Stock held by persons who the issuer believes beneficially own more than 5% of the outstanding shares of Common Stock and shares held by officers and directors of the issuer have been excluded because such persons may be deemed to be affiliates of the issuer. This determination is not necessarily conclusive.

As of March 28, 2004, 53,811,072 shares of the issuer s Common Stock were outstanding.

Portions of the definitive Proxy Statement to be delivered to stockholders in connection with the 2005 Annual Meeting of Stockholders to be held May 24, 2005 are incorporated by reference into Part III.

Certain exhibits filed with the registrant s prior forms 10-K and forms 10-Q are incorporated herein by reference into Part IV of this Report.

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Explanatory Note

This Amendment is being filed to amend Part II Sections 6 and 13 of this report in response to staff comments.

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Part II

Item 6. Plan of Operations.

This Plan of Operations should be read in conjunction with the accompanying consolidated financial statements and notes included in this report.

General

As a development-stage biomedical research company, we have not yet generated any operating revenues from the sale of our products or otherwise. We have had no operating earnings since inception, and have an accumulated deficit of $(35,182,194) as of December 31, 2004. Our expenses have related mainly to costs incurred in research activities for the development of our drug candidates and from administrative expenses required to support these efforts. We expect losses to continue for the near future, and such losses will likely increase as human clinical trials are undertaken in the U.S. and Europe for our cancer drugs. Future profitability will be dependent upon our ability to complete the development of our pharmaceutical products, obtain necessary regulatory approvals and effectively market such products. Also, future profitability will require that we establish agreements with other parties for the clinical testing, manufacturing, commercialization and sale of our products.

Since inception, we have generally funded our operations through short-term loans and the sale of equity securities. We will need to obtain additional financing in order to sustain our efforts, as discussed below under Liquidity and Capital Resources.

Plan of Operations

We have used the proceeds from recent private placements of our capital stock primarily to expand our preclinical and clinical efforts for CoFactor, as well as for general working capital. At this time we are committing significantly fewer resources to the development of our other programs.

We began a trial for metastatic colorectal cancer patients with 5-FU in a combination therapy with our drug CoFactor in QI 2004, based upon an IND application filed in the U.S. to treat metastatic colorectal cancer patients. In Q1 2005 we filed for clearance with the FDA to launch a Phase III randomized controlled trial in metastatic colorectal cancer. Additionally, we filed Clinical Trial Applications in the European Union (EU), including the United Kingdom and Germany, and in countries outside the EU for clearance to evaluate CoFactor in a Phase IIb, international, multi-center, randomized, controlled trial for metastatic colorectal cancer. In Q1 2005 we received of a final advice letter from the European Medicines Agency (EMEA) for our proposed CoFactor trial protocol in pancreatic cancer. Based on this information, the Company currently plans to file a Clinical Trial Application for a pivotal Phase III multinational study in patients with advanced pancreatic cancer in the second quarter of 2005 and will initiate the trial following regulatory clearance.

We previously reported that we intended to file an IND application in QI 2005 to initiate a clinical trial using Thiovir in HIV patients. Because of continued unexpected manufacturing delays we do not currently anticipate having the issue resolved until Q4 2005.

Additional detail regarding the human trials and INDs that we plan to file are discussed in Part I, Item 1, Description of Business, of this annual report. We currently expect to expend the estimated amounts set forth below over the next 12 months:

Expenditure	Estimated Cost
CoFactor trials	$ 5,453,000
Other research and development costs	2,875,000
Total estimated research and development	8,328,000
Estimated selling, general and administrative	3,058,000
Total estimated costs	$11,386,000

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Our current cash position of $13,032,263 is sufficient to meet our currently expected expenditures over the next 12 months as set forth above. However, we continue to evaluate our need to raise additional capital to execute our research and development plans and believe that we will need to raise additional capital prior to receiving regulatory approval to sell any of our products.

Our facility is under lease through August 2009. We do not currently believe we will need any additional space for the remainder of 2005.

In conjunction with the additional research and development activities we expect to conduct, we anticipate adding six development and administrative personnel in the next 12 months.

Liquidity and Capital Resources

We have incurred negative cash flows since inception, and have funded our activities primarily through short-term loans and sales of equity securities. As of December 31, 2004 and 2003, we had cash and cash equivalents of $13,032,263 and $4,226,397. We expect our cash flow to continue to be negative in the foreseeable future and until such time as one of our drug candidates is approved for commercial production.

We do not have any bank or any other commercial financing arrangements. Our operations over the last 12 months have been funded by the proceeds from private equity placements.

Our dependence on raising additional capital will continue at least until we are able to commercially market one or more of our products at significant sales level. Depending on profit margins and other factors, we may still need additional funding to continue research and development efforts. Our future capital requirements and the adequacy of our financing depend upon numerous factors, including: the successful commercialization of our drug candidates; progress in our product development efforts; progress with preclinical studies and clinical trials; the cost and timing of production arrangements; the development of effective sales and marketing activities; the cost of filing, prosecuting, defending and enforcing intellectual property rights; competing technological and market developments; and the development of strategic alliances for the marketing of our products.

We will be required to obtain such funding through equity or debt financing, strategic alliances with corporate partners and others, or through other sources not yet identified. 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 do not have any committed sources of additional financing, and cannot guarantee that additional funding will be available on acceptable terms, if at all. If adequate funds are not available, we will be required to delay, scale-back or eliminate certain aspects of our operations or attempt to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets.

Quantitative and Qualitative Information About Market Risk

We do not engage in trading market-risk sensitive instruments and do not purchase hedging instruments or other than trading instruments that are likely to expose us to market risk, whether interest rate, foreign currency exchange, commodity price or equity price risk. We have no outstanding debt instruments, have not entered into any forward or future contracts, and have purchased no options and entered into no swaps. We have no credit lines or other borrowing facilities, and do not view ourselves as subject to interest rate fluctuation risk at the present time.

Critical Accounting Policies

Use of Estimates

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The preparation of financial statements in conformity with accounting principles generally accepted in the U. S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management believes that the estimates utilized in preparing our financial statements are reasonable and prudent. Actual results could differ from those estimates.

The most significant accounting estimates relate to valuing equity transactions as described below. The value assigned to stock warrants granted to non-employees are accounted for in accordance with SFAS No. 123 and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, which require that such costs be measured at the end of each reporting period to account for changes in the fair value of our Common Stock until the options are vested. We value warrants using the Black-Scholes pricing model. Common Stock is valued using the market price of Common Stock on the measurement date as defined in EITF 96-18.

Accounting for Stock-Based Compensation

We apply Statement of Financial Accounting Standards No. 123 and related interpretations in accounting for employee stock-based compensation and include the required footnote disclosures thereon.

We account for nonemployee stock-based compensation in accordance with Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Amounts are based on the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

The value assigned to stock warrants granted to non-employees are accounted for in accordance with SFAS No. 123 and EITF 96-18, which require that such costs be measured at the end of each reporting period to account for changes in the fair value of our Common Stock until the options are vested. We value warrants using the Black-Scholes pricing model. Common Stock is valued using the market price of Common Stock on the measurement date as defined in EITF 96-18.

Revenue Recognition

We recognize revenue at the time service is performed on commercial contracts and when ability to collect is assured. Revenue from government grants is a reimbursement for expenditures associated with the research. We submit bills to the grant agency and revenue is recognized at the time the reimbursement request is submitted.

New Accounting Pronouncements

In December 2004, the FASB issued Statement of Financial Accounting standards No. 123 (revised 2004), Share-Based Payment (SFAS 123R). We currently recognize our option grants and associated expenses in accordance with SFAS 123R guidance, and therefore SFAS 123R is not expected to have a material effect on our consolidated financial position or results of operations.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29. The guidance in APB Opinion No 29, Accounting for Nonmonetary Transactions, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of assets exchanged. The guidance in that Opinion, however, included certain exceptions to that principle. This Statement amends Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for nonmonetary exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS No. 153 is not expected to have a material impact on our financial position and results of operations.

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In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. This statement amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts idle facility expense, freight, handling costs, and wasted material (spoilage). We currently have no inventory, sales or cost of goods, and therefore it is not expected to have a material impact on our financial position and results of operations.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS No. 150 changes the accounting for certain financial instruments with characteristics of both liabilities and equity that, under previous pronouncements, issuers could account for as equity. The new accounting guidance contained in SFAS No. 150 requires that those instruments be classified as liabilities in the balance sheet. The adoption of this new accounting pronouncement is not expected to have a material impact on the Company s financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities* (FIN 46R) which addressed consolidation by business enterprises of variable interest entities that meet certain criteria. FIN 46R was effective upon issuance, but did not have an impact on the Company s financial position or results of operations.

Risk Factors

If any of the following risks actually occur, our business, results of operations and financial condition could suffer significantly.

We have a substantial accumulated deficit and limited working capital.

We had an accumulated deficit of $35,182,194 as of December 31, 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 FDA or other regulatory agencies and successfully marketed. In addition, we fund 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 FDA or other regulatory agencies 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.

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 for research and development or clinical development will be required to fund our activities. Although we have raised such equity financing in April 2004, we cannot be certain that we will be able to continue to obtain such financing on favorable or satisfactory terms, if at all, or that it will be sufficient to meet our cash requirements. Any additional equity financing could result in substantial dilution to stockholders, and debt financing, if available, will most likely involve restrictive covenants that 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

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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, (vi) be affected by third parties holding proprietary rights that will preclude us from marketing a drug product, or (vii) not be able to be manufactured by manufacturers in a timely manner in accordance with required standards of quality. 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.

We have been delayed at certain times in the past in the development of our drug products by limited funding. In addition, if certain of our scientific and technical personnel resigned at or about the same time, the development of our drug products would probably be delayed until new personnel were hired and became familiar with the development programs.

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. There is a significant risk that any of our drug candidates could fail to show satisfactory results in continued trials, and would not justify further development.

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. CoFactor, our leading drug candidate, would likely compete against a well-established product, leucovorin. In addition, there are numerous companies with a focus in oncology and/or anti-viral therapeutics that are pursuing the development of new 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 such as Merck and Pfizer 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 FDA 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

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becoming increasingly aware of the commercial value of their inventions and are actively seeking to commercialize the technology they have developed. Companies such as Gilead, Roche and GlaxoSmithKline all have drugs in various stages of development that could become competitors. Accordingly, competitors may succeed in commercializing products more rapidly or effectively than us, which would have a material adverse effect on 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 our investments in developing new therapies. If we are successful in getting FDA approval for CoFactor, we will be competing against a generic drug, leucovorin, which has a lower cost and a long, established history of reimbursement. Receiving sufficient reimbursement for purchase costs of CoFactor will be necessary to make it cost effective and competitive versus the established drug, leucovorin. 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 FDA. 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 some federal and state proposals in the past 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. None of the proposals seems to have affected any of the drugs in our programs. However, it is uncertain if future legislative proposals would be adopted that might affect the drugs in our programs or what actions federal, state, or private payors for health care treatment and services may take in response to any such health care reform proposals or legislation. Any such health care reforms could have a material adverse effect on the marketability of any drugs for which we ultimately require FDA approval.

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

The FDA 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 FDA 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 the FDA or other regulatory approval for any

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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 our ability to utilize any of our 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 FDA 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 FDA 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 FDA approval of a drug may extend for years beyond that which is originally estimated. In addition, the FDA 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 FDA policy and the establishment of additional regulations during the period of product development and FDA 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 (iv) 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 ours, 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.

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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 agreement 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. Although we have not been notified of any patent infringement, nor notified others of patent infringement, such 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.

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. We are currently dependent upon our scientific staff, which has a deep background in our drug candidates and the ongoing preclinical and clinical trials. Recruiting and retaining senior employees with relevant drug development experience in oncology and anti-viral therapeutics is costly and time-consuming. There can be no assurance that we will be able to attract and retain such individuals on an uninterrupted basis and on commercially acceptable terms, and the failure to do so could have a material adverse effect on us by significantly delaying one or more of our drug development programs. These individuals are employed under offer letters, rather than employment agreements.

We currently have no sales capability, and limited marketing capability.

We currently do not have sales personnel. We have limited marketing and business development 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 our products 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 our current manufacturing partners. 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

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manufacturers will be able to manufacture a drug product on a cost-effective basis in commercial quantities under good manufacturing practices mandated by the FDA.

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 contract research organization (CRO) partners, when they begin in the U.S. and to expand our 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.

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

Market prices for the 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 the Common Stock.

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Item 13. Exhibits.

Exhibits.

The exhibit list called for by this item is incorporated by reference to the Exhibit Index filed with this amended report.

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SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this amendment to report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 11th day of August 2005.

ADVENTRX PHARMACEUTICALS, INC

By: /s/ CARRIE CARLANDER

Carrie Carlander
Chief Financial Officer
(currently, principal financial officer of the Registrant; was serving as principal financial and accounting officer of the Registrant on the date of filing of the 10-KSB which this filing amends)

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Exhibit	Description
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3.2[1]	Certificate of Amendment of Certificate of Incorporation of Victoria Enterprises, Inc.
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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.
3.8[3]	Certificate of Designation of BioQuest, Inc.
3.9[4]	Certificate of Designation of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock of Biokeys Pharmaceuticals, Inc.
4.1[5]	Common Stock and Warrant Purchase Agreement, dated as of April 5, 2004, among the Company and the Investors named therein
4.2[5]	A-1 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement with the Investors
4.3[5]	A-2 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement with the Investors
4.4[6]	Common Stock and Warrant Purchase Agreement, dated April 8, 2004, between the Company and CD Investment Partners, Ltd.
4.5[6]	A-1 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
4.6[6]	A-2 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
4.7[6]	Warrant to Purchase Common Stock issued on April 8, 2004 to Burnham Hill Partners
4.8[6]	Warrant to Purchase Common Stock issued on April 8, 2004 to Ernest Pernet
4.9[6]	Warrant to Purchase Common Stock issued on April 8, 2004 to W.R. Hambrecht + Co., LLC
4.10[5]	Registration Rights Agreement, dated as of April 5, 2004, among the Company and the Investors named therein
4.11[6]	

Registration Rights Agreement, dated as of April 8, 2004, between the Company and CD Investment Partners, Ltd.

4.12 Not used

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Exhibit	Description
4.13	Not used
4.14[7]	Common Stock and Warrant Purchase Agreement, dated April 19, 2004, between the Company and Franklin Berger
4.15[7]	A-1 Warrant to Purchase Common Stock issued to Franklin Berger
4.16[7]	A-2 Warrant to Purchase Common Stock issued to Franklin Berger
4.17[7]	Registration Rights Agreement, dated as of April 19, 2004, between the Company and Franklin Berger
4.18[5]	Registration Rights Agreement, dated ___, 2001, between the Company and certain stockholders
4.19[5]	Warrant to Purchase Common Stock issued by the Company
4.20[5]	Stock Subscription Agreement
4.21[5]	Warrant to Purchase Common Stock issued by the Company
4.22[5]	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
10.1[8]	Patent and Technology License Agreement, dated June 14, 1996, among the Company, the Board of Regents of the University of Texas System and the University of Texas M. D. Anderson Cancer Center (Request for confidential treatment of certain data)
10.2[8]	Amendment No. 1 to Patent and Technology License Agreement, dated June 15, 2000, between the Company and the University of Texas M. D. Anderson Cancer Center(Request for confidential treatment of certain data)
10.3[8]	Option and License Agreement, dated January 23, 1998, between the Company and the University of Southern California (Request for confidential treatment of certain data)
10.4[2]	First Amendment to License Agreement, dated August 16, 2000, between the Company and the University of Southern California (Request for confidential treatment of certain data)
10.5[8]	Option and License Agreement, dated August 17, 2000, between the Company and the University of Southern California (Request for confidential treatment of certain data)
10.6[9]	Standard Multi-Tenant Office Lease Gross, dated June 3, 2004, between the Company and George V. Casey & Ellen M. Casey, Trustees of the Casey Family Trust dated June 22, 1998
10.7[10]	Patent License Agreement, effective August 1, 2002, between the Company and the National Institutes of Health
10.9[11]	Offer Letter, dated March 5, 2003, from the Company to Joan M. Robbins, Ph.D.

10.10[(12)]	Amendment to Option and License Agreement, dated April 21, 2003, the Company and the University of Southern California
10.11	Offer Letter, dated March 1, 2004, from the Company to Cellia Habita, Ph.D.
10.12	Offer Letter, dated November 15, 2004, from the Company to Brian Culley

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Exhibit	Description
10.13	Offer Letter, dated November 17, 2004, from the Company to Carrie Carlander[13]
10.14(13)	Burnham Hill Partners Agreement
21.1	Subsidiaries of ADVENTRX Pharmaceuticals, Inc.
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Powers of Attorney (included on signature page)
31.1(13)	Rule 13a-14(a)/15d-14(a) Certification
31.2(13)	Rule 13a-14(a)/15d-14(a) Certification
32.1	Section 1350 Certifications
32.2	Section 1350 Certifications

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

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

(3) Incorporated by reference to Exhibit 4.1 to the Company s Registration Statement on Form 10-SB, filed October 2, 2001.

(4) Incorporated by reference to Exhibit 4.2 to the Company s Quarterly Report on Form 10-QSB, filed November 26, 2002 (exhibit included in the body of the Form 10-QSB and not filed as a separate exhibit file).

(5) Incorporated by reference to the same-numbered exhibit to the Company s Registration Statement on Form S-3, filed June 30, 2004.

(6) Incorporated by reference to the same-numbered exhibit to the Company s Current Report on Form 8-K, filed April 13, 2004.

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

(8) Incorporated by reference to the same-numbered exhibit to the

Company s Registration Statement on Form 10-SB/A, filed January 14, 2002.

(9) Incorporated by reference to the same-numbered exhibit to the Company s Quarterly Report on Form 10-QSB, filed August 10, 2004.

(10) Incorporated by reference to the same-numbered exhibit to the Company s Quarterly Report on Form 10-QSB, filed November 26, 2002.

(11) Incorporated by reference to the same-numbered exhibit to the Company s Annual Report on Form 10-KSB, filed April 16, 2003.

(12) Incorporated by reference to Exhibit 10.6 to the Company s Quarterly Report on Form 10-QSB, filed August 14, 2003.

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(13) Filed with this Amendment No. 1 to Form 10-KSB for the year ended December 31, 2004. Unless otherwise indicated, all other exhibits were filed with the original filing of the Form 10-KSB or are incorporated by reference into the original report.