

ACURA PHARMACEUTICALS, INC
Form S-3/A
November 14, 2007

As filed with the Securities and Exchange Commission on November 14, 2007

Registration No. 333-146416

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

Acura Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

| | | |
|---|---|--|
| New York | 2834 | 11-0853640 |
| <i>(State or other jurisdiction of incorporation or organization)</i> | <i>(Primary Standard Industrial Classification Code Number)</i> | <i>(I.R.S. Employer Identification Number)</i> |

Andrew D. Reddick
President and Chief Executive Officer
616 N. North Court, Suite 120
Palatine, Illinois 60067
(847) 705-7709

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

New York Secretary of State
Department of State
41 State Street
Albany, New York 12207

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

Copies to:

John P. Reilly
Seiden Wayne LLC
Two Penn Plaza East
Newark, New Jersey 07105
(973) 491-3354

Approximate date of commencement of proposed sale to the public:
From time to time after the effective date of this registration statement,

as determined by market conditions and other factors.

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 this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. "

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. "

CALCULATION OF REGISTRATION FEE

| Title of Each Class of Securities to Be Registered | Amount to Be Registered(1) | Proposed Maximum Offering Price Per Security(4) | Proposed Maximum Aggregate Offering Price | Am Registra |
|--|----------------------------|---|---|----------------|
| Common Stock, \$0.01 par value. | 321,917,117 | (2) \$1.50 | \$482,875,676 | |
| Common Stock, \$0.01 par value, | 20,515,617 | (3) \$1.50 | \$30,773,426 | |
| Total | 342,432,734 | \$1.50 | \$513,649,101 | |

(1) In accordance with Rule 416(a), the Registrant is also registering hereunder an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.

(2) Represents shares of the Registrant's common stock being registered for resale that have been issued to the selling stockholders named in this registration statement.

(3) Represents shares of the Registrant's common stock issuable upon exercise of warrants being registered for resale that have been issued to the selling stockholders named in this Registration Statement.

(4) Estimated pursuant to Rule 457 under the Securities Act of 1933, solely for the purposes of calculating the registration fee, upon the basis of the average bid and asked prices of our common stock as reported on the Over-the-Counter Bulletin Board on September 24, 2007, a date which is within five business days prior to the filing of this Registration Statement.

(5) 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 Commission, acting pursuant to said Section 8(a), may determine.

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. THESE SECURITIES MAY NOT 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.

PROSPECTUS

Subject to Completion, dated November 14, 2007

342,432,734 shares

Acura Pharmaceuticals, Inc.

Common Stock

This prospectus relates to the offer and sale of 342,432,734 shares of our common stock which may be disposed of from time to time by the selling stockholders named in the "Selling Stockholders" section of this prospectus, or their transferees, pledgees, donees or successors-in-interest. Of the shares offered by this prospectus, such shares include 20,515,617 shares of common stock issuable upon exercise of warrants. The shares were initially sold, and the warrants were initially issued, in private placement transactions.

The prices at which the selling stockholders may sell the shares will be determined by the selling stockholders or their transferees. While we will receive cash if and when the warrants are exercised for cash (but not in a cashless exercise), we will not receive any proceeds from the disposition of the shares of common stock covered hereby.

We will pay the expenses related to the registration of the shares covered by this prospectus. The selling stockholders will pay commissions and selling expenses, if any, incurred by them.

Our common stock is traded on the Over-the-Counter Bulletin Board under the symbol "ACUR.OB." On November 12, 2007, the last reported sale price of our common stock on the Over-the-Counter Bulletin Board was \$1.12 per share.

Our principal executive offices are located at 616 N. North Court, Palatine, Illinois 60067, and our telephone number is (847) 705-7709.

Investing in our securities involves risks. See "Risk Factors" beginning on page 3 of this prospectus.

**NEITHER THE SECURITIES AND EXCHANGE
COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED</f
ont> OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE.
ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

The date of this prospectus is _____, 2007.

TABLE OF CONTENTS

| | Page |
|---|-------------|
| Information Contained in This Prospectus | 2 |
| Special Note Regarding Forward Looking Statements | 2 |
| Risk Factors | 3 |
| About Acura Pharmaceuticals, Inc. | 12 |
| Use of Proceeds | 15 |
| Selling Stockholders | 15 |
| Plan of Distribution | 19 |
| Legal Matters | 20 |
| Experts | 20 |
| Incorporation Of Certain Information By Reference | 21 |
| Where You Can Find More Information | 22 |

INFORMATION CONTAINED IN THIS PROSPECTUS

You should rely only on the information provided or incorporated by reference in this prospectus or any prospectus supplement. Neither we nor the selling stockholders have authorized anyone to provide you with additional or different information. The selling stockholders are not making an offer of these securities in any jurisdiction where the offer is not permitted. You should assume that the information in this prospectus and any prospectus supplement is accurate only as of the date on the front of the document and that information incorporated by reference in this prospectus or any prospectus supplement is accurate only as of the date of the document incorporated by reference. In this prospectus and any prospectus supplement, unless otherwise indicated, “Acura,” “we,” “us” and “our” refer to Acura Pharmaceuticals, Inc. and its subsidiary, and do not refer to the selling stockholders. When we refer to “you” or “yours,” we mean the persons to whom offers are made hereunder. Aversion® and Acura® Pharmaceuticals are registered trademarks in the United States.

We refer to the U.S. Food and Drug Administration as the FDA.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We have made forward-looking statements in this prospectus and in documents that we incorporate by reference into this prospectus. These forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements, to be materially different from any future results, performance, or achievements expressed or implied by those forward-looking statements. The most significant of such factors include, but are not limited to, our ability to successfully close and fulfill our obligations under the Agreement with King Pharmaceuticals Research and Development, Inc. (as described below under the caption “About Acura Pharmaceuticals, Inc. - Recent Developments - King Agreement”), and our ability to fulfill the FDA’s requirements for approving our product candidates for commercial distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date and the results of other laboratory and clinical studies, to support FDA approval of our product candidates, the adequacy of the development program for our product candidates, changes in regulatory requirements, adverse safety findings relating to our product candidates, the risk that the FDA may not agree with our analysis of our clinical studies and may evaluate the results of these studies by different methods or conclude that the results of the studies are not statistically significant, clinically meaningful or that there were human errors in the conduct or otherwise of the studies, the risk that further studies of our product candidates do not support FDA approval or commercially viable product labeling, and the uncertainties inherent in

scientific research, drug development, clinical trials and the regulatory approval process. Other important factors that may also affect future results include, but are not limited to: our ability to attract and retain highly skilled personnel; our ability to secure and protect our patents, trademarks and proprietary rights; our ability to avoid infringement of patents, trademarks and other proprietary rights or trade secrets of third parties; litigation or regulatory action that could require us to pay significant damages or change the way we conduct our business; our ability to compete successfully against current and future competitors; our dependence on third-party suppliers of raw materials; our ability to secure U.S. Drug Enforcement Administration quotas and source controlled substances that constitute the active ingredients in our product candidates in development; difficulties or delays in clinical trials for our product candidates or in the manufacture of our product candidates; and other risks and uncertainties detailed in this prospectus. We are at a development stage and may not ever have any products or technologies that generate revenue. When used in this prospectus, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions are intended to identify forward-looking statements.

RISK FACTORS

An investment in our common stock involves a high degree of risk. In addition to the other information contained in this prospectus and in documents that we incorporate by reference into this prospectus, you should carefully consider the following risks before purchasing our common stock. If any of these risks occurs, our business, financial condition and operating results could be materially adversely affected. In that case, the trading price of our common stock could decline and you could lose all or part of your investment. See also "Special Note Regarding Forward-Looking Statements."

We Received a "Going Concern" Opinion from Our Registered Independent Public Accounting Firm, Have a History of Operating Losses and May Not Achieve Profitability Sufficient to Generate a Positive Return on Shareholders' Investment

We incurred net losses of \$13.8 million for the nine months ended September 30, 2007 and net losses of \$6.0 million, \$12.1 million and \$70.0 million for calendar years 2006, 2005 and 2004, respectively. As of September 30, 2007, our accumulated deficit was approximately \$331.4 million. Our consolidated financial statements for the calendar years 2006, 2005 and 2004 were prepared on a "going concern" basis. In its report dated March 13, 2007 regarding those financial statements, our registered independent public accounting firm expressed substantial doubt about our ability to continue as a going concern as a result of recurring losses, net capital deficiency and negative cash flows. Our future profitability will depend on several factors, including: (i) the Company's ability to successfully close and fulfill its obligations under the Agreement with King Pharmaceuticals Research and Development, Inc. ("King") as more fully described below under the caption "About Acura Pharmaceuticals, Inc. - Recent Developments - King Agreement", and (ii) the successful commercialization by King and other future licensees (if any) of products incorporating our Aversion® Technology without infringing the patents and other intellectual property rights of third parties. We cannot assure you that we will ever have a product approved for commercialization by the FDA or that we or our licensees will bring any product to market.

We Require Additional Funding

As of November 1, 2007, we had cash and cash equivalents of approximately \$11.3 million, which included the proceeds from an additional Bridge Loan funded in July 2007 and the net proceeds from our private unit offering. We estimate that such cash reserves will fund operations through September 2008. To fund further operations and product development activities beyond September 2008, we must raise additional financing, or must successfully close the Agreement with King described below under the caption "About Acura Pharmaceuticals, Inc. - Recent Developments - King Agreement" and receive the \$30 million up-front non-refundable cash payment anticipated to be received upon the closing of such Agreement. No assurance can be given that the conditions to the closing of the Agreement will be satisfied, that we will receive the milestone and royalty payments provided for in the Agreement, or that we will be successful in entering into similar agreements with other pharmaceutical partners to develop and commercialize products incorporating the Aversion® Technology. In the absence of our receipt of the upfront milestone payment provided for in the Agreement, the receipt of payments under similar license agreements anticipated to be negotiated and executed with other pharmaceutical company partners, or the receipt of financing from other sources, we may be required to scale back or terminate operations and possibly seek protection under applicable bankruptcy laws.

We Have No Near Term Sources of Revenue and Must Rely on Current Cash Reserves, Technology Licensing Fees and Third Party Financing to Fund Operations

Pending the closing and effectiveness of the King Agreement or similar license agreements anticipated to be

negotiated and executed with other pharmaceutical company partners, of which no assurance can be given, we must rely on our current cash reserves and third-party financing to fund operations and product development activities. No assurance can be given that current cash reserves will be sufficient to fund the continued operations and development of our product candidates until such time as we generate revenue from collaborative or licensing agreements. Moreover, no assurance can be given that we will be successful in raising additional financing or, if funding is obtained, that such funding will be sufficient to fund operations until product candidates incorporating our Aversion® Technology may be commercialized.

We Are Subject to Restrictions on the Incurrence of Additional Indebtedness, Which May Adversely Impact the Company's Ability to Fund Operations and Clinical Trials

Pursuant to the terms of our outstanding secured term loan agreement we are limited as to the type and amount of future indebtedness we may incur. This restriction may adversely impact our ability to fund the development of our product candidates.

Our Product Candidates Are Based on Technology That Could Ultimately Prove Ineffective

We are committing substantially all of our resources and available capital to the development of Acurox™ (oxycodone HCl and niacin) Tablets. Additional clinical and non-clinical testing will be required to continue development of Acurox™ Tablets and for the development, preparation and submission of a 505(b)(2) New Drug Application (“NDA”) with the FDA. There can be no assurance that Acurox™ Tablets or any other product candidate developed using Aversion® (abuse deterrent) Technology will achieve the primary end points in the required clinical studies or perform as intended in other pre-clinical and clinical studies leading to commercially viable product candidates, product labeling, or leading to a NDA submission. If a NDA is submitted to the FDA for Acurox™ Tablets or any other product candidates, there can be no assurances that the FDA will accept such submission for filing and subsequently approve such NDA with commercially viable product labeling or to ultimately approve such product candidates for commercial distribution. Our failure to successfully develop and achieve final FDA approval of a product candidate utilizing Aversion® Technology will have a material adverse effect on our operations and financial condition.

If Pre-Clinical or Clinical Testing For Our Product Candidates Are Unsuccessful or Delayed, We Will Be Unable to Meet Our Anticipated Development and Commercialization Timelines

To obtain FDA approval to commercially market any of our product candidates, we must submit to the FDA a NDA demonstrating, among other things, that the product candidate is safe and effective for its intended use. This demonstration requires significant pre-clinical and clinical testing. As we do not possess the resources or employ all the personnel necessary to conduct such testing, we rely on contract research organizations ("CROs") for the majority of this testing with our product candidates. As a result, we have less control over our development program than if we performed the testing entirely on our own. Third parties may not perform their responsibilities on our anticipated schedule. Delays in our development programs could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to a delay in the development program, may also ultimately lead to denial of regulatory approval of a product candidate.

The commencement of clinical trials with our product candidates may be delayed for several reasons, including but not limited to delays in demonstrating sufficient pre-clinical safety required to obtain regulatory approval to commence a clinical trial, reaching agreements on acceptable terms with prospective licensees, manufacturing and quality assurance release of a sufficient supply of a product candidate for use in our clinical trials and/or obtaining institutional review board approval to conduct a clinical trial at a prospective clinical site. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or regulatory authorities due to several factors, including ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials, failure to conduct clinical trials in accordance with regulatory requirements, lower than anticipated recruitment or retention rate of patients in clinical trials, inspection of the clinical trial operations or trial sites by regulatory authorities, the imposition of a clinical hold by FDA, lack of adequate funding to continue clinical trials, and/or negative or unanticipated results of clinical trials.

Clinical trials required by the FDA for commercial approval, may not demonstrate safety or efficacy of our product candidates. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing.

Even if the results of our pivotal phase III clinical trials are positive, we and our licensees may have to commit substantial time and additional resources to conduct further pre-clinical and clinical studies before we or our licensees can submit NDAs or obtain regulatory approval for our product candidates.

Clinical trials may be expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Further, if participating subjects or patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we, our licensees, if any, or the FDA believes that participating patients are being exposed to unacceptable health risks, we or our licensees, if any, may suspend the clinical trials. Failure can occur at any stage of the trials, and our licensees, if any, could encounter problems causing the abandonment of clinical trials or the need to conduct additional clinical studies, relating to a product candidate.

Even if our clinical trials are completed as planned, their results may not support commercially viable product label claims. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their intended use. Such failure would cause us or our licensees, if any, to abandon a product candidate and may delay the development of other product candidates.

We Or Our Licensees May Not Obtain Required FDA Approval; the FDA Approval Process Is Time-Consuming and Expensive

The development, testing, manufacturing, marketing and sale of pharmaceutical products are subject to extensive federal, state and local regulation in the United States and other countries. Satisfaction of all regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product candidate, and requires the expenditure of substantial resources for research, development and testing. Substantially all of our operations are subject to compliance with FDA regulations. Failure to adhere to applicable FDA regulations by us or our licensees would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive.

We or our licensees may encounter delays or rejections during any stage of the regulatory approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of the product candidates to meet, the FDA's requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of an NDA, or a 505(b)(2) NDA the FDA may refuse to file the application, deny approval of the application, require additional testing or data and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. The FDA commonly takes one to two years to grant final approval for a NDA, or 505(b)(2) NDA. Further, the terms of approval of any NDA including the product labeling may be more restrictive than we or our licensees desire and could affect the marketability of products incorporating our Aversion® Technology.

Even if we comply with all FDA regulatory requirements we or our licensees may never obtain regulatory approval for any of our product candidates. If we or our licensees fail to obtain regulatory approval for any of our product candidates, we will have fewer saleable products and correspondingly lower revenues. Even if regulatory approval of our products is received, such approval may involve limitations on the indicated uses or promotional claims we or our licensees may make for our products.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the drug-approval process, to request recalls of allegedly violative products, to seize allegedly violative products, to obtain injunctions to close manufacturing plants allegedly not operating in conformity with current Good Manufacturing Practices (cGMP) and to stop shipments of allegedly violative products. As any future source of our revenue will be derived from the sale of FDA approved products, the taking of any such action by the FDA would have a material adverse effect on our operations and financial condition.

We Must Maintain FDA Approval to Manufacture Clinical Supplies of Our Product Candidates at Our Facility; Failure to Maintain Compliance with FDA Requirements May Prevent or Delay the Manufacture of Our Product Candidates and Costs of Manufacture May Be Higher Than Expected

We have constructed and installed the equipment necessary to manufacture clinical trial supplies of our Aversion® (abuse deterrent) Technology product candidates in tablet formulations at our Culver, Indiana facility. To be used in clinical trials, all of our product candidates must be manufactured in conformity with current Good Manufacturing Practice (cGMP) regulations as interpreted and enforced by the FDA. All such product candidates must be manufactured, packaged, and labeled and stored in accordance with cGMPs. Modifications, enhancements or changes in manufacturing sites of marketed products are, in many circumstances, subject to FDA approval, which may be subject to a lengthy application process or which we may be unable to obtain. Our Culver, Indiana facility, as well as those of any third-party manufacturers that we may use, are periodically subject to inspection by the FDA and other governmental agencies, and operations at these facilities could be interrupted or halted if such inspections are unsatisfactory. Failure to comply with FDA or other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production or distribution, suspension of FDA review of our product candidates, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution. We do not have the facilities, equipment or personnel to manufacture commercial quantities of our product candidates and therefore must rely on our licensees or other qualified companies with appropriate facilities and equipment to contract manufacture commercial quantities of products utilizing our Aversion Technology.

If Our Partners Do Not Satisfy Their Obligations, We Will Be Unable to Develop Our Partnered Product Candidates

On October 30, 2007, we entered into our Agreement with King Pharmaceuticals Research and Development Inc. ("King") (as more fully described under the caption "About Acura Pharmaceuticals"). The closing of the transaction contemplated by the Agreement is subject to receipt of approval under the Hart-Scott-Rodino Antitrust Improvements Act. The Company's future revenue, if any, will be derived from milestone and royalty payments relating to the Agreement and other milestone and royalty payments, if any, derived from agreements anticipated to be potentially negotiated and executed with other pharmaceutical company partners. No assurance can be given that the conditions to the closing of the Agreement with King will be satisfied, that we will receive the milestone and royalty payments provided for in such Agreement, or that we will be successful in entering into similar agreements with other pharmaceutical partners to develop and commercialize products incorporating the Aversion® Technology.

As part of such collaborative agreements, we will not have day-to-day control over the activities of our licensees with respect to any product candidate. If a collaborative partner fails to fulfill its obligations under an agreement with us, we may be unable to assume the development of the product covered by that agreement or to enter into alternative arrangements with another third-party. In addition, we may encounter delays in the commercialization of the product candidate that is the subject of a collaboration agreement. Accordingly, our ability to receive any revenue from the product candidates covered by collaboration agreements will be dependent on the efforts of our collaborative partner. We could be involved in disputes with a collaborative partner, which could lead to delays in or termination of, our development and commercialization programs and result in time consuming and expensive litigation or arbitration. In addition, any such dispute could diminish our collaborative partners' commitment to us and reduce the resources they devote to developing and commercializing our products. If any collaborative partner terminates or breaches its agreement, or otherwise fails to complete its obligations in a timely manner, our chances of successfully developing or commercializing our product candidates would be materially adversely effected. Additionally, due to the nature of the market for our product candidates, it may be necessary for us to license all or a significant portion of our product candidates to a single company thereby eliminating our opportunity to commercialize other product candidates with other collaborative partners.

The Market May Not Be Receptive to Products Incorporating Our Aversion® Technology

The commercial success of products incorporating our Aversion® Technology approved for marketing by the FDA and other regulatory authorities will depend on acceptance by health care providers and others that such products are clinically useful, cost-effective and safe. There can be no assurance given, even if we or our licensees succeed in the development of products incorporating our Aversion® Technology and receive FDA approval for such products, that products incorporating the Aversion® Technology would be accepted by health care providers and others. Factors that may materially affect market acceptance of products incorporating our Aversion® Technology include but are not limited to: (i) the relative advantages and disadvantages of our Aversion® Technology compared to competitive products; (ii) the relative timing to commercial launch of products utilizing our Aversion® Technology compared to competitive products; (iii) the relative safety and efficacy of products incorporating our Aversion® Technology compared to competitive products; and (iv) the willingness of third party payors to reimburse for or otherwise pay for products incorporating our Aversion® Technology.

Our product candidates, if successfully developed and commercially launched, will compete with both currently marketed and new products marketed by other companies. Health care providers may not accept or utilize any of our product candidates. Physicians and other prescribers may not be inclined to prescribe the products utilizing our Aversion® Technology unless our products bring clear and demonstrable advantages over other products currently marketed for the same indications. If our products do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

In the Event That We or Our Licensees Are Successful in Bringing Any Products to Market, Our Revenues May Be Adversely Affected If We Fail to Obtain Acceptable Prices or Adequate Reimbursement For Our Products From Third-Party Payors

The ability of our licensees to successfully commercialize our products may depend in part on the availability of reimbursement for our products from government health administration authorities, private health insurers, and other third-party payors and administrators, including Medicaid and Medicare. We cannot predict the availability of reimbursement for newly-approved products incorporating our Aversion® Technology. Third-party payors and administrators, including state Medicaid programs and Medicare, are challenging the prices charged for pharmaceutical products. Government and other third-party payors increasingly are limiting both coverage and the level of reimbursement for new drugs. Third-party insurance coverage may not be available to patients for any of our products. The continuing efforts of government and third-party payors to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payors do not provide adequate coverage and reimbursement for any product incorporating our Aversion® Technology, health care providers may not prescribe them or patients may ask their health care providers to prescribe competing products with more favorable reimbursement. In some foreign markets, pricing and profitability of pharmaceutical products are subject to government control. In the United States, we expect there will be federal and state proposals for similar controls. In addition, we expect that increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we charge for any products in the future. Further, cost control initiatives could impair our ability or the ability of our licensees to commercialize our products and our ability to earn revenues from this commercialization.

Our Success Depends on Our Ability to Protect Our Intellectual Property

Our success depends in significant part on our ability to obtain patent protection for our Aversion® Technology, in the United States and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual questions. Notwithstanding our receipt of U.S. Patent No. 7,201,920 from the USPTO relating to the Aversion® Technology, there is no assurance that any of our patent application claims in our other pending non-provisional and provisional patent applications for our Aversion® Technology will issue or if issued, that any such patent claims will be valid and enforceable against third-party infringement or that our products will not infringe any third-party patent or intellectual property. Moreover, any patent claims relating to the Aversion® Technology may not be sufficiently broad to protect the products incorporating the Aversion® Technology. In addition, issued patent claims may be challenged, invalidated or circumvented. Our patent claims may not afford us protection against competitors with similar technology or permit the commercialization of our products without infringing third-party patents or other intellectual property rights.

Our success also depends on our not infringing patents issued to competitors or others. We may become aware of patents and patent applications belonging to competitors and others that could require us to alter our technologies. Such alterations could be time consuming and costly. We may not be able to obtain a license to any technology owned by or licensed to a third party that we or our licensees require to manufacture or market one or more products incorporating our Aversion® Technology. Even if we can obtain a license, the financial and other terms may be disadvantageous.

Our success also depends on our maintaining the confidentiality of our trade secrets and know-how. We seek to protect such information by entering into confidentiality agreements with employees, potential licensees, raw material suppliers, potential investors and consultants. These agreements may be breached by such parties. We may not be able to obtain an adequate, or perhaps, any remedy to such a breach. In addition, our trade secrets may otherwise become known or be independently developed by our competitors. Our inability to protect our intellectual property or to commercialize our products without infringing third-party patents or other intellectual property rights would have a material adverse affect on our operations and financial condition.

We May Become Involved in Patent Litigation or Other Intellectual Property Proceedings Relating to Our Aversion® Technology or Product Candidates Which Could Result in Liability for Damages or Delay or Stop Our Development and Commercialization Efforts

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include: (i) litigation or other proceedings we may initiate against third parties to enforce our patent rights or other intellectual property rights; (ii) litigation or other proceedings we may initiate against third parties to seek to invalidate the patents held by such third parties or to obtain a judgment that our product candidates do not infringe such third parties' patents; (iii) if our competitors file patent applications that claim technology also claimed by us, we may participate in interference or opposition proceedings to determine the priority of invention; and (iv) if third parties initiate litigation claiming that our product candidates infringe their patent or other intellectual property rights, we will need to defend against such proceedings. Our failure to avoid infringing third-party patents and intellectual property rights in the commercialization of products utilizing the Aversion® Technology will have a material adverse affect on our operations and financial condition.

The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Most of our competitors will be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

Our Aversion® Technology may be found to infringe upon claims of patents owned by others. If we determine or if we are found to be infringing on a patent held by another, we or our licensees might have to seek a license to make, use, and sell the patented technologies. In that case, we or our licensees might not be able to obtain such license on acceptable terms, or at all. The failure to obtain a license to any technology that may be required would materially harm our business, financial condition and results of operations. If a legal action is brought against us, we could incur substantial defense costs, and any such action might not be resolved in our favor. If such a dispute is resolved against us, we may have to pay the other party large sums of money and our use of our Aversion® Technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited. Even prior to resolution of such a dispute, use of our Aversion® Technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited.

Moreover, other parties could have blocking patent rights to products made using the Aversion® Technology. We are aware of certain United States and international pending patent applications owned by third parties claiming abuse deterrent technologies, including at least one pending patent application which, if issued in its present form, may encompass our lead product candidate. If such patent applications result in issued patents, with claims encompassing our Aversion® Technology or products, we or our licensees may need to obtain a license to such patents, should one be available, or alternatively, alter the Aversion® Technology so as to avoid infringing such third-party patents. If we or our licensees are unable to obtain a license on commercially reasonable terms, we or our licensees could be restricted or prevented from commercializing products utilizing the Aversion® Technology. Additionally, any alterations to the Aversion® Technology in view of pending third-party patent applications could be time consuming and costly and may not result in technologies or products that are non-infringing or commercially viable. We cannot assure that our products and/or actions in developing products incorporating our Aversion® Technology will not infringe third-party patents.

We May Be Exposed to Product Liability Claims and May Not Be Able to Obtain Adequate Product Liability Insurance

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by patients, health care providers or pharmaceutical companies or others that sell or consume our products. These claims may be made even with respect to those products that possess regulatory approval for commercial sale.

We are currently covered by clinical trial product liability insurance on a claims-made basis. This coverage may not be adequate to cover any product liability claims. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance at a reasonable cost or in sufficient amounts to protect us against losses due to liability claims. Any claims that are not covered by product liability insurance could have a material adverse effect on our business, financial condition and results of operations.

The pharmaceutical industry is characterized by frequent litigation. Those companies with significant financial resources will be better able to bring and defend any such litigation. No assurance can be given that we would not become involved in such litigation. Such litigation may have material adverse consequences to our financial condition and results of operations.

We Face Significant Competition Which May Result in Others Developing or Commercializing Products Before or More Successfully Than We Do

The pharmaceutical industry is highly competitive and is affected by new technologies, governmental regulations, health care legislation, availability of financing, litigation and other factors. If our product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience, clinical or other benefits for a specific indication than our products, or may offer comparable performance at lower costs. If our products are unable to capture and maintain market share, we or our licensees will not achieve significant product revenues and our financial condition and results of operations will be materially adversely affected.

We will compete for market share against fully integrated pharmaceutical companies or other companies that collaborate with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have products already approved, marketed or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs, have substantially greater financial resources, experience in developing products, obtaining FDA and other regulatory approvals, formulating and manufacturing drugs, and commercializing drugs than we do.

We are concentrating substantially all of our efforts on developing product candidates incorporating our Aversion® Technology. The commercial success of products using our Aversion® Technology will depend, in large part, on the intensity of competition and the relative timing and sequence of new product approvals from other companies developing, marketing, selling and distributing products that compete with the products incorporating our Aversion® Technology. Alternative technologies and products are being developed to improve or replace the use of opioid analgesics. In the event that such alternatives to opioid analgesics are widely adopted, then the market for products incorporating our Aversion® Technology may be substantially decreased subsequently reducing our ability to generate future profits.

Key Personnel Are Critical to Our Business, and Our Success Depends on Our Ability to Retain Them

We are highly dependent on our management and scientific team, including Andrew D. Reddick, our President and Chief Executive Officer, and Ron J. Spivey, Ph.D. our Senior Vice President and Chief Scientific Officer. We may not be able to attract and retain personnel on acceptable terms given the intense competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. While we have employment agreements with certain employees, all of our employees are at-will employees who may terminate their employment at any time. We do not have key personnel insurance on any of our officers or employees. The loss of any of our key personnel, or the inability to attract and retain such personnel, may significantly delay or prevent the achievement of our product and technology development and business objectives and could materially adversely affect our business, financial condition and results of operations.

The U.S. Drug Enforcement Administration ("DEA") Limits the Availability of the Active Ingredients Used in Our Product Candidates and, as a Result, Our Quota May Not Be Sufficient to Complete Clinical Trials or May Result in Development Delays

The DEA regulates certain finished drug products and active pharmaceutical ingredients. Certain opioid active pharmaceutical ingredients in our current product candidates are classified by the DEA as Schedule II substances under the Controlled Substances Act of 1970. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of regulation. Furthermore, the amount of Schedule II substances we can obtain for our clinical trials is limited by the DEA and our quota may not be sufficient to complete clinical trials. There is a risk that DEA regulations may interfere with the supply of the products used in our clinical trials.

The Market Price of Our Common Stock May Be Volatile

The market price of our common stock, like the market price for securities of pharmaceutical, biopharmaceutical and biotechnology companies, has historically been highly volatile. The stock market from time to time experiences significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors, such as fluctuations in our operating results, future sales of our common stock, announcements of technological innovations or new therapeutic products by us or our competitors, announcements regarding collaborative agreements, laboratory or clinical trial results, government regulation, developments in patent or other proprietary rights, public concern as to the safety of drugs developed by us or others, changes in reimbursement policies, comments made by securities analysts and general market conditions may have a significant effect on the market price of our common stock. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources and result in a material adverse effect on our financial condition and results of operations.

Our Common Stock is Currently Traded on the Over-the-Counter Bulletin Board, and the Liquidity of our Stock may be Seriously Limited

Our common stock is currently traded on the Over-the-Counter Bulletin Board. Trading on the Over-the Counter Bulletin Board may adversely impact our stock price and liquidity, and the ability of our stockholders to purchase and sell our shares in an orderly manner. As our common stock is not quoted on a stock exchange and is not qualified for inclusion on the NASDAQ Capital Market or AMEX market, our common stock could be subject to a rule of the Securities and Exchange Commission that imposes additional sales practice requirements on broker-dealers who sell such securities to persons other than established customers and accredited investors. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent for a transaction prior to sale. Consequently, the rule may affect the ability of broker-dealers to sell our common stock. There is no guarantee that an active trading market for our common stock will be maintained on the Over-the-Counter Bulletin Board.

Our Quarterly Results of Operations Will Fluctuate, and These Fluctuations Could Cause Our Stock Price to Decline

Our quarterly operating results are likely to fluctuate in the future. These fluctuations could cause our stock price to decline. The nature of our business involves variable factors, such as the timing of the research, development and regulatory submissions of our product candidates that could cause our operating results to fluctuate.

We Do Not Anticipate Paying Dividends on Our Common Stock in the Foreseeable Future

We have not declared and paid cash dividends on our common stock in the past, and we do not anticipate paying any cash dividends in the foreseeable future. Our senior term loan indebtedness prohibits the payment of cash dividends.

GCE Holdings LLC Can Control All Matters Requiring Approval By Shareholders

GCE Holdings LLC beneficially owns approximately 78% of the Company's outstanding common stock as of November 1, 2007 (calculated in accordance with Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended). In addition, pursuant to the terms of the Amended and Restated Voting Agreement dated February 6, 2004, as amended, between us and the former holders of our previously outstanding convertible preferred stock, all such shareholders have agreed that our Board of Directors shall be comprised of not more than seven members, four of whom shall be the designees of GCE Holdings LLC. As a result, GCE Holdings LLC, in view of its ownership percentage of our common stock and by virtue of its controlling position on our Board of Directors, will be able to control all matters requiring approval by our shareholders, including the approval or rejection of mergers, sales or licenses of all or substantially all of our assets, or other business combination transactions. The interests of GCE Holdings LLC may not always coincide with the interests of our other shareholders and such entity may we take action in advance of its interests to the detriment of our other shareholders. Accordingly, you may not be able to influence any action we take or consider taking, even if it requires a shareholder holder vote.

Any Future Sale of a Substantial Number of Shares Eligible for Resale Could Depress the Trading Price of our Stock, Lower our Value and Make It More Difficult for us to Raise Capital

342,432,734 shares (representing approximately 66.5% of our shares outstanding on a fully-diluted basis - including all derivative securities, whether or not currently exercisable) are being offered for sale by selling stockholders hereby, including 313,497,569 shares held by affiliates. An additional 81 million shares of our common stock and common stock underlying stock options, restricted stock units and warrants, not being offered hereby are held by affiliates. If some or all shares offered hereby are sold by affiliates and others or if affiliates sell other shares, it will likely have the effect of depressing the trading price of our common stock. In addition, such sales could lower our value and make it more difficult for us to raise capital.

There Can Be No Assurance That The Total Market Capitalization Of Our Common Stock (The Aggregate Value Of Our Common Stock At The Then Market Price) After Our Reverse Stock Split Will Be Equal To Or Greater Than The Total Market Capitalization Before Our Reverse Stock Split Or That The Per Share Market Price Of Our Common Stock Following Our Reverse Stock Split Will Equal Or Exceed The Current Per Share Market Price

On December 14, 2006, our shareholders authorized our Board of Directors, in its discretion, to effect a reverse stock split of our common stock at one of six ratios on or prior to December 14, 2007. On October 30, 2007, our Board of Directors approved an amendment to our Restated Certificate of Incorporation to take effect on or about December 5, 2007, subject to compliance with OTC Bulletin Board requirements, to effect a one for ten reverse stock split of our common stock. There can be no assurance that the market price per new share of our common stock after the reverse stock split will increase in proportion to the reduction in the number of old shares of our common stock outstanding before the reverse stock split. For example, if the market price of our common stock on the OTC Bulletin Board before the effective date of our reverse split was \$1.00 per share, and after giving effect to the one for ten reverse split ratio adopted by our Board, there can be no assurance that the post-split market price of our common stock would be \$10.00 per share or greater. By decreasing the number of outstanding shares of common stock without altering the aggregate economic interest represented by the shares, we believe the market price will be proportionally increased. The higher the market price of our common stock rises above the two dollar minimum bid price requirement for obtaining a listing on the American Stock Exchange, if we elect to apply for listing there, or the four dollar minimum bid price requirement for obtaining a listing on the Nasdaq Capital Market, if we elect to apply for listing there, the less risk there will be that we will fail to meet the relevant minimum bid price requirement. However, there can be no assurance that the market price of our common stock will rise to or maintain any particular level or that we will at any time or at all times be able to meet the minimum-bid-price and other requirements for obtaining a listing of our common stock on the American Stock Exchange or the Nasdaq Capital Market and for maintaining such a listing.

Following The Effective Date of Our Reverse Stock Split, The Resulting Per-Share Stock Price May Not Attract Institutional Investors Or Investment Funds And May Not Satisfy The Investing Guidelines Of Such Investors

There can be no assurance that our one for ten reverse split to be effective on or about December 5, 2007 will result in a per-share price that will attract institutional investors or investment funds or that such share price will satisfy the investing guidelines of institutional investors or investment funds.

ABOUT ACURA PHARMACEUTICALS, INC.

General

We are a specialty pharmaceutical company engaged in research, development and manufacture of our innovative Aversion® Technology and related product candidates. Product candidates developed with Aversion® Technology and containing opioid analgesic active ingredients are intended to effectively treat pain and also discourage the three most common methods of pharmaceutical product misuse and abuse including: (i) intravenous injection of dissolved tablets or capsules, (ii) nasal snorting of crushed tablets or capsules and (iii) intentional swallowing of excessive numbers of tablets or capsules. Acurox™ (oxycodone HCl and niacin) Tablets (formerly known as OxyADF), our lead product candidate utilizing Aversion® Technology, is being developed pursuant to an active investigational new drug application (“IND”) on file with the U.S. Food and Drug Administration (“FDA”). We conduct internal research, development, laboratory, manufacturing and warehousing activities for Aversion® Technology at our Culver, Indiana facility. The 28,000 square foot facility is registered by the U.S. Drug Enforcement Administration (“DEA”) to perform research, development and manufacture of certain Schedule II - V finished dosage form products. In addition to internal capabilities and activities, we engage numerous contract research organizations (“CROs”) with expertise in regulatory affairs, clinical trial design and monitoring, clinical data management, biostatistics, medical writing, laboratory testing and related services. Such CROs perform development services for Acurox™ Tablets and other product candidates under our direction.

Aversion® Technology is applicable to orally administered tablets and capsules. Aversion® Technology can be formulated into orally administered tablets containing commonly utilized opioid active pharmaceutical ingredients (such as oxycodone, hydrocodone, hydromorphone, oxymorphone, morphine, codeine, tramadol, propoxyphene, etc.), or other potentially abuseable drugs. In addition to the opioid active ingredient, Aversion® Technology utilizes certain combinations of pharmaceutical product inactive excipients and active ingredients intended to discourage or deter pharmaceutical product abuse. Aversion® Technology does not utilize opioid antagonists such as naltrexone and naloxone.

Acurox™ (oxycodone HCl and niacin) Tablets, our lead product candidate with Aversion® Technology, is an orally administered immediate release tablet containing oxycodone HCl as its sole active analgesic ingredient and a sub therapeutic amount of niacin. We intend to file a 505(b)(2) NDA for OxyADF Tablets with an anticipated indication for treating moderate to moderately severe pain. Acurox™ Tablets are intended to effectively treat moderate to moderately severe pain while also discouraging the three most common methods of misuse and abuse. OxyADF Tablets are being developed pursuant to an active IND on file with the FDA. The FDA has provided written guidance to us stating that Acurox™ Tablets are an appropriate product candidate for submission as a 505(b)(2) NDA.

Acurox™ Tablets are currently the subject of a clinical study (referred to by us as Study AP-ADF-105) titled “A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter, Repeat-dose Study of the Safety and Efficacy of Acurox™ (oxycodone HCl and niacin) Tablets versus Placebo for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Patients.” This short term phase III study is planned to enroll approximately 400 patients with moderate to severe pain following bunionectomy surgery. We submitted the study protocol to the FDA and requested a Special Protocol Assessment (SPA). Clinical protocols for Phase III trials whose data will form the primary basis for an efficacy claim are eligible for a SPA. A SPA from the FDA is an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses plan are acceptable to support regulatory approval. A SPA is binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after the testing is begun. On June 19, 2007, we announced that we had reached agreement with the FDA on the SPA for Study AP-ADF-105. We believe the completion of Study AP-ADF-105 is the critical time and events path to a 505(b)(2) NDA submission for Acurox™ Tablets.

In April 2007, the United States Patent and Trademark Office (the “USPTO”) granted us a U.S. Patent No. 7,201,920 titled “Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms”. The allowed patent claims encompass pharmaceutical compositions intended to reduce or discourage the three most common methods of prescription opioid analgesic product misuse and abuse including; (i) intravenous injection of dissolved tablets or capsules; (ii) snorting of crushed tablets or capsules; and (iii) intentionally swallowing excess quantities of tablets or capsules. The opioid analgesics in the allowed patent claims include oxycodone, hydrocodone, hydromorphone, morphine, codeine, tramadol, propoxyphene and many others. In addition to issued U.S. Patent No. 7,201,920, we currently have pending five U.S. non-provisional patent applications, three WO/PCT patent applications and multiple additional U.S. provisional and international patent filings relating to compositions containing opioid analgesics and other abuseable drugs.

On October 30, 2007, we entered into an Agreement with King Pharmaceuticals Research and Development Inc., ("King") as more fully described below under the caption "King Agreement" (the "Agreement"). Pursuant to the Agreement, we and King will develop and commercialize certain opioid analgesic products utilizing our Aversion® (abuse deterrent) Technology including Acurox™ Tablets. The closing of the transaction contemplated by the Agreement is subject to receipt of approval under the Hart-Scott-Rodino Antitrust Improvements Act. Our future revenue, if any, will be derived from milestone and royalty payments relating to the Agreement and other milestone and royalty payments, if any, derived from agreements anticipated to be potentially negotiated and executed with other pharmaceutical company partners.

Our consolidated financial statements for each of the last four years in the period ended December 31, 2006 were prepared on a going-concern basis, expressing substantial doubt about our ability to continue as a going-concern as a result of recurring losses and negative cash flows. Our future profitability will depend on several factors, including (i) our ability to successfully close and fulfill our obligations pursuant to the Agreement with King, and (ii) the successful commercialization by King and other future potential licensees (if any) of products incorporating our Aversion® Technology.

Pending the closing and effectiveness of the Agreement with King or similar license agreements anticipated to be negotiated and executed with other pharmaceuticals company partners, or other sources of funding, of which no assurance can be given, we must rely on our current cash reserves to fund operations and product development activities. No assurance can be given that the condition to the closing of the Agreement will be satisfied, that we will receive the milestone and royalty payments provided for in the Agreement, or that we will be successful in entering into similar agreements with other pharmaceuticals partners to develop and commercialize products incorporating the Aversion® Technology. In the absence of our receipt of the upfront, milestone payment provided for in the Agreement, the receipt of payments under similar license agreements anticipated to be negotiated and executed with other pharmaceutical company partners, or the receipt of financing from other sources, we may be required to scale back or terminate operations and possibly seek protection under applicable bankruptcy laws. Our failure to successfully develop the Aversion® Technology in a timely manner, and to avoid infringing patents and other intellectual property rights of third parties will have a material adverse impact on our financial condition and results of operations.

We are a publicly traded New York corporation. Our shares of common stock are traded on the Over-the-Counter Bulletin Board under the symbol "acur.ob".

Recent Developments

King Agreement

On October 30, 2007, we and King Pharmaceuticals Research and Development, Inc. ("King"), a wholly-owned subsidiary of King Pharmaceuticals, Inc., entered into a License, Development and Commercialization Agreement (the "Agreement") to develop and commercialize in the United States, Canada and Mexico (the "Territory") certain opioid analgesic products utilizing our proprietary Aversion® (abuse deterrent) Technology including Acurox™ Tablets (formerly known as OxyADF). The Agreement provides King with an exclusive license in the Territory for Acurox™ Tablets and another undisclosed opioid product utilizing Acura's Aversion® Technology. In addition, the Agreement provides King with an option to license in the Territory all future opioid analgesic products developed utilizing Acura's Aversion® Technology. The Agreement closing is subject to antitrust review under the Hart-Scott-Rodino Antitrust Improvements Act.

Under the terms of the Agreement, King will make an upfront cash payment to us of \$30 million. Depending on the achievement of certain development and regulatory milestones, King could also make additional cash payments to us

of up to \$28 million relating to Acurox™ Tablets and similar amounts with respect to each subsequent Aversion® Technology product developed under the Agreement. King will reimburse us for all research and development expenses incurred beginning from September 19, 2007 for Acurox™ Tablets and all research and development expenses related to future products after King's exercise of its option to an exclusive license for each future product. King will record net sales of all products and pay us a royalty ranging from 5% to 25% based on the level of combined annual net sales for all products subject to the Agreement. King will also make a one-time cash payment to us of \$50 million in the first year in which the combined annual net sales of all products exceed \$750 million.

We and King will form a joint steering committee to coordinate development and commercialization strategies. With King's oversight, we will conduct all Acurox™ Tablet development activities through approval of a New Drug Application ("NDA") and thereafter King will commercialize Acurox™ in the U.S. With respect to all other products subject to the Agreement, King will be responsible for development and regulatory activities following either acceptance of an Investigational New Drug Application by the U.S. Food and Drug Administration ("FDA") or our demonstration of certain stability and pharmacokinetic characteristics for each future product. All products developed pursuant to the Agreement will be manufactured by King or a third party contract manufacturer under the direction of King. Subject to the Agreement, King will have final decision making authority with respect to all development and commercialization activities for all products licensed.

The foregoing description of the Agreement contains forward-looking statements about the revenue generating potential of Acurox™ Tablets and other opioid analgesic products developed pursuant to the Agreement. As with any pharmaceutical products under development or proposed to be developed, substantial risks and uncertainties exist in development, regulatory review and commercialization process. There can be no assurance that any product developed, in whole or in part, pursuant to the Agreement will receive regulatory approval or prove to be commercially successful. Accordingly, investors should recognize that there is no assurance that we will receive the milestone payments or royalty revenues described in the Agreement or even if such milestones are achieved that the related products will be successfully commercialized and that any royalty revenues payable to us by King will materialize.

Reverse Stock Split

On October 30, 2007, our Board of Directors approved an Amendment to our Restated Certificate of Incorporation to effect a 1 for 10 reverse stock split. The reverse stock split will take effect on or about December 5, 2007, subject to compliance with OTC Bulletin Board requirements.

Unit Offering

In August 2007, we completed a private offering of 23,651,847 units, at a price of \$1.08 per unit, with each unit consisting of four shares of common stock and a seven-year warrant to purchase one share of common stock exercisable at a price of \$0.34 per share. 13,888,886 of the units were issued for cash with the balance of 9,762,961 units issued in consideration of the conversion to units of an aggregate of \$10.544 million in principal amount of outstanding bridge loan indebtedness. Estimated net cash proceeds from the private offering of units, after related expenses, were approximately \$14.2 million. We will utilize the net proceeds from the private offering for general working capital and to fund our Pivotal Phase III Clinical Trial for OxyADF Tablets, our lead product candidate utilizing our Aversion® Technology.

After giving effect to the issuance of the units, as of September 25, 2007, we had 426,756,493 shares issued and outstanding, 39,715,662 shares underlying outstanding warrants, 18,994,995 shares underlying outstanding stock options and 29,500,000 shares underlying outstanding restricted stock units.

Also on August 20, 2007, we amended our Loan Agreement dated as of March 29, 2000 and related \$5,000,000 note (the "Note") held by certain lenders, to (i) extend the maturity of the Note to December 31, 2008 from September 30, 2007, (ii) reduce the interest rate to the fixed rate of 10% per annum from the prime rate plus four and one-half percent, and (iii) have interest paid quarterly in cash, instead of stock. In addition, the Note is subject to mandatory prepayment in whole or in part, with all proceeds in excess of \$5 million that we might receive from a third party pharmaceutical company or companies pursuant to a licensing agreement (a "Prepayment Event"). We expect to repay in full the principal and accrued interest under the Note simultaneous with the closing of our Agreement with King. The Loan Agreement and Note were further amended effective September 24, 2007 to defer the payment of cash interest until the earlier to occur of (i) the December 31, 2008 maturity date and (ii) the occurrence of a Prepayment

Event.

As a result of the above transaction, our outstanding debt balance as of August 20, 2007 of \$15,544,000 was reduced to \$5,000,000 and our stockholders' equity balance increased by approximately \$24,690,000.

14

USE OF PROCEEDS

All proceeds from the sale of the shares of common stock will be for the account of the selling stockholders. We will not receive any of the proceeds from the sale of the shares of common stock sold under this prospectus. If all of the warrants are exercised for cash (rather than on a cashless basis), we will, however, receive up to approximately \$9.98 million. We will use these proceeds, if any, for working capital purposes and for such other uses as our Board deems advisable at the time of exercise. We will not receive any proceeds from the exercise of warrants in a cashless exercise. See “Selling Stockholders” and “Plan of Distribution.”

SELLING STOCKHOLDERS

Of the 342,432,734 shares covered by this prospectus, 76,592,570 of such shares (including shares underlying warrants) were acquired in a private placement pursuant to a securities purchase agreement dated as of August 20, 2007 (the “PIPE Transaction”). In the PIPE Transaction, we issued 23,651,847 units at a price of \$1.08 per unit, with each unit consisting of four shares of common stock and a warrant exercisable for seven years to purchase an additional share of common stock with an exercise price of \$0.34 per share. We agreed to file a registration statement with the SEC covering the resale of the shares issued in the foregoing transactions, including the shares issuable upon exercise of the warrants. GCE Holdings LLC, an investor in the PIPE Transaction, has elected to exclude from this prospectus, 41,666,665 shares of common stock (including shares underlying warrants) acquired by GCE Holdings LLC in the PIPE Transaction.

The remaining 265,840,164 shares of common stock (including shares underlying warrants) covered by this prospectus were acquired by the selling stockholders from us in previous private placement transactions - the overwhelming majority of such shares being attributable to private placements occurring in 1998 and 2004 - and are included herein because selling stockholders elected to exercise piggyback registration rights with respect to such shares.

Ian Meierdierks and Blair Johnson, two of the selling stockholders listed below, are associated persons of broker dealers. Each of such selling stockholders represented to us at the time of his investment in the PIPE Transaction that he acquired the units in the PIPE Transaction for his own account as principal and had no arrangement to effect a distribution of the units or the underlying shares or warrants.

We prepared the following table based on the information supplied to us by the selling stockholders named in the table. The selling stockholders may, however, have sold, transferred or otherwise disposed of all or a portion of their shares of common stock since the date on which they provided such information. Except as provided in the table below, none of the selling stockholders has held any position or office with, or has otherwise had a material relationship with, us or any of our subsidiaries within the past three years.

We do not know when or in what amounts a selling stockholder may offer shares of common stock for sale. For purposes of the columns entitled “**Number of shares beneficially owned after the Offering**” and “**Percentage Ownership After Offering**” we assumed that all shares included in the column labeled “**Number of Shares being offered**” will be sold. The selling stockholders may choose not to sell any of the shares offered by this prospectus. Except as otherwise set forth below, each selling stockholder has sole voting control over the shares shown as beneficially owned.

| Name of Selling Stockholder | Number of shares beneficially owned prior to the | Number of shares being offered | Number of shares beneficially | Percentage Ownership After |
|------------------------------------|---|---------------------------------------|--------------------------------------|-----------------------------------|
|------------------------------------|---|---------------------------------------|--------------------------------------|-----------------------------------|

| | | offering (1) | | owned after the Offering | Offering |
|--|------|-------------------------------|-----------------------------|--------------------------------|----------|
| GCE Holdings LLC | (2) | 345,649,572 ⁽¹²⁾ | 303,982,907 ⁽¹²⁾ | 41,666,665 ⁽³⁴⁾ | 9.6% |
| Galen Partners III, L.P. | (3) | 6,156,335 ⁽¹³⁾⁽¹⁴⁾ | 6,006,335 ⁽¹³⁾ | 150,000 | * |
| Galen Partners International, III, L.P. | (3) | 508,597 ⁽¹⁵⁾ | 508,597 ⁽¹⁵⁾ | 0 | * |
| Galen Employee Fund III, L.P. | (3) | 26,047 ⁽¹⁶⁾ | 26,047 ⁽¹⁶⁾ | 0 | * |
| Essex Woodlands Health Ventures Fund V, L.P. | (4) | 1,806,781 ⁽¹⁷⁾⁽¹⁸⁾ | 1,706,781 ⁽¹⁷⁾ | 100,000 | * |
| Care Capital Investments II, LP | (5) | 1,279,147 ⁽¹⁹⁾⁽²⁰⁾ | 1,185,567 ⁽¹⁹⁾ | 93,580 | * |
| Care Capital Offshore Investments II, LP | (5) | 87,755 ⁽²¹⁾⁽²²⁾ | 81,335 ⁽²²⁾ | 6,420 | * |
| Vivo Ventures Fund VI, L.P. | (6) | 24,818,180 ⁽²³⁾ | 24,818,180 ⁽²³⁾ | 0 | * |
| Vivo Ventures VI Affiliates Fund, L.P. | (6) | 181,820 ⁽²⁴⁾ | 181,820 ⁽²⁴⁾ | 0 | * |
| CGM IRACustodian f/b/o Michael M. Weisbrot | (7) | 1,114,925 ⁽²⁵⁾ | 925,925 ⁽²⁵⁾ | 189,000 | * |
| Michael Weisbrot and Susan Weisbrot JT | (8) | 5,392,649 ⁽²⁶⁾ | 694,440 ⁽²⁷⁾ | 4,698,209 | 1.1% |
| Dennis Adams | (9) | 5,349,641 ⁽²⁸⁾ | 694,440 ⁽²⁸⁾ | 4,700,201 | 1.1% |
| George Boudreau | (10) | 910,211 ⁽²⁹⁾ | 694,440 ⁽²⁹⁾ | 215,771 | * |
| Greg Wood | | 894,639 ⁽³⁰⁾ | 231,480 ⁽³⁰⁾ | 663,159 | * |
| Peter Stieglitz | (11) | 265,565 ⁽³¹⁾ | 231,480 ⁽³¹⁾ | 34,085 | * |
| Ian Meierdiercks | | 231,480 ⁽³²⁾ | 231,480 ⁽³²⁾ | 0 | * |
| Blair Johnson | | 231,480 ⁽³³⁾ | 231,480 ⁽³³⁾ | 0 | * |

* Less than One Percent

- (1) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. Amounts in this column assume full exercise by the respective selling stockholders of all warrants whose underlying shares are covered by this Prospectus.
- (2) GCE Holdings LLC, a Delaware limited liability company, was the assignee of all of our preferred stock (prior to its conversion into common stock) and bridge loans entered into in 2005, 2006 and 2007 (prior to their conversion into common stock and warrants) formerly held by each of Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. (collectively, "Galen"), Care Capital Investments II, LP, Care Capital Offshore Investments II, LP (collectively, "Care Capital") and Essex Woodlands Health Ventures Fund V, L.P. ("Essex"). Galen, Care Capital and Essex own approximately 39.8%, 30.6% and 29.6%, respectively, of the membership interests in GCE Holdings LLC. The following natural persons exercise voting, investment and dispositive rights over our securities held of record by GCE Holdings LLC: (i) Galen Partners III, L.P., Galen Partners International III, L.P. and Galen Employee Fund III, L.P.: Bruce F. Wesson, L. John Wilkenson, David W. Jahns, and Zubeen Shroff; (ii) Care Capital Investments II, LP and Care Capital Offshore Investments II, LP: Jan Leschly, Richard Markham, Argeris Karabelas and David Ramsay; and (iii) Essex Woodlands Health Ventures Fund V, L.P.: Immanuel Thangaraj, James L. Currie and Martin P. Sutter. Pursuant to a voting agreement, GCE Holdings LLC has the right to designate four members to our Board of Directors. It has currently exercised such right with respect to three directors: Immanuel Tharangaj, Richard Markham and Bruce Wesson. Amounts listed for GCE Holdings LLC exclude amounts held by Galen, Care Capital or Essex. GCE Holdings LLC acquired units in the PIPE Transaction for \$9 million in cash and conversion of \$10.294 million in bridge loans acquired from Galen, Care Capital and Essex. The shares and shares underlying the units acquired by GCE Holdings LLC in the PIPE Transaction for cash are not being offered hereby.
- (3) Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. (collectively, "Galen") collectively own approximately 39.8% of GCE Holdings LLC. Prior to November 2005, Galen had the right to designate one member to our Board of Directors. Galen had been one of our bridge lenders in the past three years and also holds a 35.1% interest in a secured \$5 million note issued by us, which must be repaid upon the closing of the King Agreement. Galen assigned to GCE Holdings LLC its interest in \$3,431,333 in principal of our bridge loans prior to the closing of the PIPE Transaction and GCE Holdings LLC converted such bridge loans into units in the PIPE Transaction. The following natural persons exercise voting, investment and dispositive rights over our securities held by Galen: (i) Bruce F. Wesson, L. John Wilkenson, David W. Jahns, and Zubeen Shroff. Bruce Wesson has been one of our directors since March 1998, including as designee of Galen and currently as designee of GCE Holdings LLC. The amounts listed for each Galen entity exclude amounts held by any other Galen entity or GCE Holdings LLC.
- (4) Essex Woodlands Health Ventures Fund V, L.P. ("Essex") owns approximately 29.6% of GCE Holdings LLC. Prior to November 2005, Essex had the right to designate one member to our Board of Directors. Essex had been one of our bridge lenders in the past three years and also holds a 35.1% an interest in a secured \$5 million note issued by us, which must be repaid upon the closing of the King Agreement. Essex assigned to GCE

Holdings LLC its interest in \$3,431,333 in principal of our bridge loans prior to the closing of the PIPE Transaction and GCE Holdings LLC converted those bridge loans into units in the PIPE Transaction. The following natural persons exercise voting, investment and dispositive rights over our securities held by Essex: Immanuel Thangaraj, James L. Currie and Martin P. Sutter. Mr. Tharangaj has been one of our directors since December 2002, as designee of Essex and now as designee of GCE Holdings LLC. The amounts listed for Essex exclude amounts held by GCE Holdings LLC.

- (5) Care Capital Investments II, LP and Care Capital Offshore Investments II, LP (collectively, "Care Capital") collectively own approximately 30.6% of GCE Holdings LLC. Prior to November 2005, Care Capital had the right to designate one member to our Board of Directors. Care Capital had been one of our bridge lenders in the past three years and also holds a 27.0% interest in a \$5 Million note issued by us, which must be repaid upon the closing of the King Agreement. Care Capital assigned to GCE Holdings LLC its interest in \$3,431,333 of our bridge loans prior to the closing of the PIPE Transaction and GCE Holdings LLC converted those loans into units in the PIPE Transaction. The following natural persons exercise voting, investment and dispositive rights over our securities held by Care Capital: Jan Leschly, Richard Markham, Argeris Karabelas and David Ramsay. Argeris Karabelas was one of our directors from December 2002 to May 2006, as designee of Care Capital and Richard Markham has been a director since May 2006, as designee of Care Capital and now as designee of GCE Holdings LLC. The amounts listed for each Care Capital entity exclude amounts held by any other Care Capital entity or GCE Holdings LLC.

- (6) Vivo Ventures Fund VI, L.P. and Vivo Ventures VI Affiliates Fund, L.P. are affiliated entities (the “Vivo Entities”). Vivo Ventures Fund VI, L.P. has the right to designate an observer to attend meetings of our Board of Directors, until such time as it disposes of 50% of the securities it acquired in the PIPE Transaction and Vivo Ventures Fund VI, L.P. has designated Albert Cha as such observer. The amounts listed for each of the Vivo Entities excludes the amounts held by any other Vivo Entity. All shares held by each Vivo Entity were acquired in the PIPE Transaction. Vivo Ventures Fund VI, L.P. invested \$5 million and Vivo Ventures VI Affiliates Fund, L.P. invested \$0.4 million in the PIPE Transaction.
- (7) CGM IRA Custodian f/b/o Michael M. Weisbrot invested \$200,000 in cash in the PIPE Transaction. Amounts exclude shares and shares underlying warrants held by Michael and Susan Weisbrot.
- (8) Michael and Susan Weisbrot own a 1.2% interest in a secured \$5 million note issued by us, which must be repaid upon the closing of the King Agreement.
- (9) Amounts include shares and shares underlying warrants acquired by Mr. Adams for \$100,000 in cash and upon conversion of \$50,000 in bridge loans extended in November 2005 into units in the PIPE Transaction. Mr. Adams owns a 0.9% interest in a secured \$5 million note issued by us, which must be repaid upon the closing of the King Agreement.
- (10) Amounts include shares and shares underlying warrants acquired by Mr. Boudreau for \$100,000 in cash and upon conversion of \$50,000 in bridge loans extended in November 2005 into units in the PIPE Transaction. Mr. Boudreau owns a 0.4% interest in a secured \$5 million note issued by us, which must be repaid upon the closing of the King Agreement.
- (11) Amounts include shares and shares underlying warrants acquired by Mr. Stieglitz for \$50,000 in cash in the PIPE Transaction. Mr. Stieglitz owns a 0.15% interest in a secured \$5 million note issued by us, which must be repaid upon the closing of the King Agreement.
- (12) Includes 9,531,481 shares underlying warrants acquired in the PIPE Transaction, exercisable at \$0.34 per share.
- (13) Includes 424,663, 137,030 and 3,732,365 shares underlying warrants exercisable at \$0.99, \$0.1285, and \$0.34, respectively.
- (14) Includes 100,000 shares underlying options exercisable at \$0.36 per share and 50,000 shares underlying options with exercise prices ranging from \$1.14 to \$2.375 per share.
- (15) Includes 37,284, 12,409 and 337,797 shares underlying warrants exercisable at \$0.99, \$0.1285 and \$0.34, respectively.
- (16) Includes 4,716, 561 and 15,279 shares underlying warrants exercisable at \$0.99, \$0.1285 and \$0.34, respectively.
- (17) Includes 345,000 shares underlying warrants exercisable at \$0.1285 per share.

- (18) Includes 100,000 shares underlying options exercisable at \$0.36 per share.
- (19) Includes 140,370 shares underlying warrants exercisable at \$0.1285 per share.
- (20) Includes 93,580 shares underlying options exercisable at \$0.36 per share.
- (21) Includes 9,630 shares underlying warrants exercisable at \$0.1285 per share.
- (22) Includes 6,420 shares underlying options exercisable at \$0.36 per share.
- (23) Includes 4,963,636 shares underlying warrants acquired in the PIPE Transaction, exercisable at \$0.34 per share.
- (24) Includes 36,364 shares underlying warrants acquired in the PIPE Transaction, exercisable at \$0.34 per share.
- (25) Includes 185,185 shares underlying warrants acquired in the PIPE Transaction, exercisable at \$0.34 per share.

- (26) Amounts include shares and shares underlying warrants acquired by Susan and Michael Weisbrot upon conversion of \$150,000 in bridge loans extended in November 2005 into units in the PIPE Transaction. Amounts include shares and shares underlying warrants of CGM IRA Custodian f/b/o Michael M. Weisbrot, over which Michael Weisbrot has voting and investment control. Included in the foregoing are 324,073 shares underlying warrants acquired in the PIPE Transaction by Susan and Michael Weisbrot and by CGM IRA Custodian f/b/o Michael M. Weisbrot, exercisable at \$0.34 per share. Also includes the following over which Michael Weisbrot has or shares voting and investment control: 6,438 shares in another retirement account owned by Michael Weisbrot and 10,000 shares held by Michael Weisbrot as custodian for the son of Michael and Susan Weisbrot. Also includes the following over which Susan Weisbrot has or shares voting and investment control: 6,323 shares in a retirement account owned by Susan Weisbrot, and 12,000 shares held jointly by Susan Weisbrot and the daughter of Michael and Susan Weisbrot. Michael and Susan Weisbrot each share voting and investment control over the remaining shares.
- (27) Includes 138,888 shares underlying warrants acquired in the PIPE Transaction by Susan and Michael Weisbrot exercisable at \$0.34 per share. Excludes shares and shares underlying warrants being offered by CGM IRA Custodian f/b/o Michael M. Weisbrot.
- (28) Includes 138,888 shares underlying warrants acquired in the PIPE Transaction, exercisable at \$0.34 per share.
- (29) Includes 138,888 shares underlying warrants acquired in the PIPE Transaction, exercisable at \$0.34 per share.
- (30) Includes 46,296 shares underlying warrants acquired in the PIPE Transaction, exercisable at \$0.34 per share. Mr. Wood invested \$50,000 in cash in the PIPE Transaction.
- (31) Includes 46,296 shares underlying warrants acquired in the PIPE Transaction, exercisable at \$0.34 per share.
- (32) Includes 46,296 shares underlying warrants acquired in the PIPE Transaction, exercisable at \$0.34 per share. Mr. Meierdiercks invested \$50,000 in cash in the PIPE Transaction.
- (33) Includes 46,296 shares underlying warrants acquired in the PIPE Transaction, exercisable at \$0.34 per share. Mr. Johnson invested \$50,000 in cash in the PIPE Transaction.
- (34) Includes 8,333,333 shares underlying warrants acquired in the PIPE Transaction, exercisable at \$0.34 per share.

PLAN OF DISTRIBUTION

The selling stockholders may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by a selling stockholder. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 supplementing or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 supplementing or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We are required to pay all fees and expenses incident to the registration of the shares of common stock. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by any selling stockholder. If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus. If the selling stockholders use this prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of our common stock and activities of the selling stockholders.

LEGAL MATTERS

The validity of the common stock offered hereby has been passed upon by Seiden Wayne LLC. Seiden Wayne LLC holds 24,530 shares of our common stock.

EXPERTS

The consolidated financial statements incorporated by reference in this Prospectus and in the Registration Statement have been audited by BDO Seidman, LLP, an independent registered public accounting firm, to the extent and for the periods set forth in their report incorporated herein and are included herein in reliance upon such report, given upon authority of said firm as experts in auditing and accounting. This report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The Securities and Exchange Commission, or SEC, allows us to “incorporate by reference” in this prospectus the information that we file with them. This means that we can disclose important information to you in this document by referring you to other filings we have made with the SEC. The information incorporated by reference is considered to be part of this prospectus, and later information we file with the SEC will update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Section 13(a), 13(c), 14, or 15(d) of the Exchange Act prior to the completion of the offering covered by this prospectus: In addition, all filings filed by us pursuant to the Exchange Act after the date of the initial registration statement and prior to the effectiveness of the registration statement shall be deemed to be incorporated by reference into this prospectus.

- our Annual Report on Form 10-K for our fiscal year ended December 31, 2006;
- our Current Report on Form 8-K filed with the SEC on February 20, 2007;
- our Current Reports on Form 8-K each filed with the SEC on March 15, 2007;
- our Current Report on Form 8-K filed with the SEC on April 2, 2007;
- our Amendment to Current Report on Form 8-K/A filed with the SEC on April 3, 2007, amending our Current Report on Form 8-K filed on April 2, 2007
- our Current Report on Form 8-K filed with the SEC on May 4, 2007;
- our Quarterly Report on Form 10-Q for our fiscal quarter ended March 31, 2007 filed with the SEC on May 4, 2007;
- our Current Report on Form 8-K filed with the SEC on May 18, 2007;
- our Current Report on Form 8-K filed with the SEC on June 19, 2007;
- our Current Report on Form 8-K filed with the SEC on July 5, 2007;
- our Current Report on Form 8-K filed with the SEC on July 10, 2007;
- our Current Report on Form 8-K filed with the SEC on August 9, 2007;
- our Quarterly Report on Form 10-Q for our fiscal quarter ended June 30, 2007 filed with the SEC on August 9, 2007;
- our Current Report on Form 8-K filed with the SEC on August 21, 2007;
- our Current Report on Form 8-K filed with the SEC on September 24, 2007;
- our Quarterly Report on Form 10-Q for our fiscal quarter ended September 30, 2007 filed with the SEC on November 2, 2007;
- our Current Reports (two) on Form 8-K filed with the SEC on November 2, 2007; and

- the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on November 14, 1988.

Documents incorporated by reference in this prospectus, filed after the date of any other document incorporated by reference may contain information that updates, modifies or is contrary to information in such earlier document. This prospectus may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus. Reports we file with the SEC after the date of this prospectus may also contain information that updates, modifies or is contrary to information in this prospectus or in documents incorporated by reference in this prospectus. Investors should review these reports as they may disclose a change in our business, prospects, financial condition or other affairs after the date of this prospectus.

Upon your written or oral request, we will provide at no cost to you a copy of any and all of the information that is incorporated by reference in this prospectus.

Requests for such documents should be directed to:

Acura Pharmaceuticals, Inc.
Attn: Investor Relations
616 N. North Court, Suite 120
Palatine, Illinois 60067
(847) 705-7709

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-3, of which this prospectus is a part, under the Securities Act with respect to the shares of common stock offered hereby. This prospectus does not contain all of the information included in the registration statement. Statements in this prospectus concerning the provisions of any document are not necessarily complete. You should refer to the copies of these documents filed as exhibits to the registration statement or otherwise filed by us with the SEC for a more complete understanding of the matter involved. Each statement concerning these documents is qualified in its entirety by such reference.

We are subject to the informational requirements of the Securities and Exchange Act of 1934, as amended, and, accordingly, file reports, proxy statements and other information with the SEC. The SEC maintains a web site at <http://www.sec.gov> that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. Copies of our reports, proxy statements and other information also may be inspected and copied at the SEC's Public Reference Room located at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

342,432,734 Shares

ACURA PHARMACEUTICALS, INC.

Common Stock

PROSPECTUS

, 2007

PART II**INFORMATION NOT REQUIRED IN THE PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth the costs and expenses payable by us in connection with the sale of common stock being registered. All amounts are estimates except the Securities and Exchange Commission registration fee.

| | |
|---|------------|
| Securities and Exchange Commission registration fee | \$ 17,688 |
| Legal fees and expenses | \$ 60,000 |
| Accounting fees and expenses | \$ 20,000 |
| Transfer Agent and Registrar fees | \$ 2,000 |
| Miscellaneous expenses | \$ 15,000 |
| Total | \$ 114,688 |

Item 15. Indemnification of Directors and Officers.

Section 722 of the New York Business Corporation Law (the "BCL") provides that a corporation may indemnify directors and officers as well as other employees and individuals against judgments, fines, amounts paid in settlement and reasonable expenses, including attorney's fees, in connection with actions or proceedings, whether civil or criminal (other than an action by or in the right of the corporation, referred to as a "derivative action"), if they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe their conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification only extends to amounts paid in settlement and reasonable expenses (including attorney's fees) incurred in connection with the defense or settlement of such actions, and the statute does not apply in respect of a threatened action, or a pending action that is settled or otherwise disposed of, and requires court approval before there can be any indemnification where the person seeking indemnification has been found liable to the corporation. Section 721 of the BCL provides that Article 7 of the BCL is not exclusive of other indemnification that may be granted by a corporation's certificate of incorporation or by-laws. Article Ninth of our Restated Certificate of Incorporation and Article IV, Section 6 of our Restated By-Laws require us to indemnify its officers and directors to the fullest extent permitted under the BCL.

Set forth below is Article Ninth of Acura Pharmaceuticals, Inc. Restated Certificate of Incorporation:

NINTH: The Corporation shall, to the fullest extent possible permitted by Sections 721 through 726 of the Business Corporation Law of New York, indemnify any and all directors and officers whom it shall have the power to indemnify under said sections from and against any and all of the expenses, liabilities or other matters referred to in or covered by such sections of the Business Corporation Law, and the indemnification provided for herein shall not be deemed exclusive of any other rights to which the person so indemnified may be entitled under any By-Law, agreement, vote of shareholders or disinterested directors or otherwise, both as to action in his/her official capacity and as to action in another capacity by holding such office, and shall continue as to a person who has ceased to be a director or officer and shall inure to the benefit of the heirs, executors and administrators of such person.

Set forth below is Article IV, Section 6 of Acura Pharmaceuticals' Inc.'s Restated By-Laws:

SECTION 6. Indemnification. It is expressly provided that any and every person made a party to any action, suit, or proceeding by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he, his testator or intestate, is or was a director or officer of this corporation or of any corporation which he served as such at the request of this corporation, may be indemnified by the corporation to the full extent permitted by law, against any and all reasonable expenses, including attorneys' fees, actually and necessarily incurred by him in connection with the defense of such action or in connection with any appeal therein, except in relation to matters as to which it shall be adjudged in such action, suit or proceeding that such officer or director has breached his duty to the corporation.

It is further expressly provided that any and every person made a party to any action, suit, or proceeding other than one by or in the right of the corporation to procure a judgment in its favor, whether civil or criminal, including an action by or in the right of any other corporation of any type or kind, domestic or foreign, which any director or officer of the corporation served in any capacity at the request of the corporation, by reason of the fact that he, his testator or intestate, was a director or officer of the corporation, or served such other corporation in any capacity, may be indemnified by the corporation, to the full extent permitted by law, against judgments, fines, amounts paid in settlement, and reasonable expenses, including attorneys' fees, actually and necessarily incurred as a result of such action, suit or proceeding, or any appeal therein, if such person acted in good faith for a purpose which he reasonably believed to be in the best interests of the corporation and, in criminal actions or proceedings, in addition, had no reasonable cause to believe that his conduct was unlawful.

We maintain a director and officer liability insurance policy that, subject to the terms, conditions and limits of the policy, provides coverage for wrongful acts (as defined by the policy) committed by a director or officer in his or her capacity as a director or officer of the Registrant. The policy reimburses us for amounts spent in lawful indemnification of a director or officer or amounts provided by us to indemnify its directors and officers as required or permitted by law.

Agreements between the registrant and the selling stockholders provides for cross-indemnification in connection with registration of the registrant's common stock on behalf of such investors.

Item 16. Exhibits.

- 3.1 Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K filed on February 10, 2004).
- 3.2 Restated By-Laws (incorporated by reference to Exhibit 3.3 to our Annual Report on Form 10-K for the year ended December 31, 1998).
- *5.1 Legal Opinion of Seiden Wayne LLC regarding the legality of the securities being registered
- 10.1 Form of Securities Purchase Agreement among the Company and certain investors in connection with the PIPE Transaction completed on August 20, 2007 (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on August 21, 2007).
- 10.2 Form of Warrant issued to investors in the PIPE Transaction on August 20, 2007 (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on August 21, 2007).
- *10.3 Form of Warrants dated August 15, 2001 issued to Galen Partners III, L.P., Galen Partners International, III, L.P. and Galen Employee Fund III, L.P. (currently exercisable for an aggregate of 466,663 shares at an exercise price of \$0.99 per share).
- *10.4 Form of Warrants dated January 9, 2002, February 1, 2002, March 1, 2002, and April 5, 2002 issued to Galen Partners III, L.P., Galen Partners International, III, L.P. and Galen Employee Fund III, L.P. (currently exercisable for an aggregate of 433,126 shares at an exercise price of \$0.34 per share).
- *10.5 Form of Warrants dated May 8, 2002, June 3, 2002, July 1, 2002, July 23, 2002, August 5, 2002, September 3, 2002, October 1, 2002, November 4, 2002, November 12, 2002, November 21, 2002 and December 5, 2002 issued to Galen Partners III, L.P., Galen Partners International, III, L.P. and Galen Employee Fund III, L.P. (current exercisable for an aggregate of 3,652,315 shares at an exercise price of \$0.34 per share).
- *10.6 Form of Warrant dated May 5, 2003 issued to Galen Partners III, L.P., Galen Partners International, III, L.P., Galen Employee Fund III, L.P., Essex Woodlands Health Ventures Fund V, L.P. and Care Capital Investments II, LP (currently exercisable for an aggregate of 645,000 shares at an exercise price of \$0.1285 per share).
- 10.7 Amended and Restated Voting Agreement dated as of February 6, 2004 by and among the Registrant, Galen Partners III, LP and the other signatories thereto (incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K filed on February 10, 2004).
- 10.8 Joinder and Amendment to Amended and Restated Voting Agreement dated November 9, 2005 between the Registrant, Galen Partners III, LP, GCE Holdings LLC and the other signatories thereto (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on

November 10, 2006).

10.9 Amended and Restated Registration Rights Agreement dated as of February 6, 2004 by and among the Registrant, Watson Pharmaceuticals, Galen Partners III, L.P. and the other signatories thereto (incorporated by reference to Exhibit 10.6 to our Current Report on Form 8- filed on February 10, 2004).

23.1 Consent of BDO Seidman, LLP, independent registered public accounting firm.

*23.2 Consent of Seiden Wayne LLC (included with opinion filed as Exhibit 5.1).

*24 Power of Attorney (included on signature page of this registration statement).

* Previously Filed

II-3

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:

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

(ii) To reflect in the 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. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) 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 the undertakings set forth in clauses (i) and (ii) above shall not apply if the information required to be included in a post-effective amendment by these clauses is contained in periodic reports filed by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in this 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) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement 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.

- (c) 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 foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC 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 by 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 by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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 Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Exton, State of Pennsylvania, on the 13th day of November, 2007.

ACURA
PHARMACEUTICALS,
INC.

By: /s/Andrew
 D.
 Reddick
Andrew D.
Reddick
President
and Chief
Executive
Officer

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|----------------------|
| <u>/S/ Andrew D. Reddick</u> <u>Andrew D. Reddick</u> | President and Chief Executive Officer, Director (Principal Executive Officer) | November 13, 2007 |
| <u>/S/ Peter A. Clemens</u> <u>Peter A. Clemens</u> | Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) | November 13, 2007 |
| <u>/S/ *</u> <u>Bruce F. Wesson*</u> | Director | November 13, 2007 |
| <u>/S/ *</u> <u>William Skelly*</u> | Director | November 13, 2007 |
| <u>/S/ *</u> <u>William Sumner*</u> | Director | November 13, 2007 |
| <u>/S/ *</u> <u>Richard J. Markham*</u> | Director | November 13, 2007 |

/s/ *
Immanuel
Thangaraj*

Director

November 13,
2007

* By /s/ Peter A. Clemens
Peter A. Clemens, Attorney in Fact

Index to Exhibits

- 3.1 Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K filed on February 10, 2004).
- 3.2 Restated By-Laws (incorporated by reference to Exhibit 3.3 to our Annual Report on Form 10-K for the year ended December 31, 1998).
- *5.1 Legal Opinion of Seiden Wayne LLC regarding the legality of the securities being registered
- 10.1 Form of Securities Purchase Agreement among the Company and certain investors in connection with the PIPE Transaction completed on August 20, 2007 (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on August 21, 2007).
- 10.2 Form of Warrant issued to investors in the PIPE Transaction on August 20, 2007 (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on August 21, 2007).
- *10.3 Form of Warrants dated August 15, 2001 issued to Galen Partners III, L.P., Galen Partners International, III, L.P. and Galen Employee Fund III, L.P. (currently exercisable for an aggregate of 466,663 shares at an exercise price of \$0.99 per share).
- *10.4 Form of Warrants dated January 9, 2002, February 1, 2002, March 1, 2002, and April 5, 2002 issued to Galen Partners III, L.P., Galen Partners International, III, L.P. and Galen Employee Fund III, L.P. (currently exercisable for an aggregate of 433,126 shares at an exercise price of \$0.34 per share).
- *10.5 Form of Warrants dated May 8, 2002, June 3, 2002, July 1, 2002, July 23, 2002, August 5, 2002, September 3, 2002, October 1, 2002, November 4, 2002, November 12, 2002, November 21, 2002 and December 5, 2002 issued to Galen Partners III, L.P., Galen Partners International, III, L.P. and Galen Employee Fund III, L.P. (current exercisable for an aggregate of 3,652,315 shares at an exercise price of \$0.34 per share).
- *10.6 Form of Warrants dated May 5, 2003 issued to Galen Partners III, L.P., Galen Partners International, III, L.P., Galen Employee Fund III, L.P., Essex Woodlands Health Ventures Fund V, L.P. and Care Capital Investments II, LP (currently exercisable for an aggregate of 645,000 shares at an exercise price of \$0.1285 per share).
- 10.7 Amended and Restated Voting Agreement dated as of February 6, 2004 by and among the Registrant, Galen Partners III, LP and the other signatories thereto (incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K filed on February 10, 2004).
- 10.8 Joinder and Amendment to Amended and Restated Voting Agreement dated November 9, 2005 between the Registrant, Galen Partners III, LP, GCE Holdings LLC and the other signatories thereto (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on November 10, 2006).
- 10.9 Amended and Restated Registration Rights Agreement dated as of February 6, 2004 by and among the Registrant, Watson Pharmaceuticals, Galen Partners III, L.P. and the other signatories thereto (incorporated by

reference to Exhibit 10.6 to our Current Report on Form 8-K filed on February 10, 2004).

23.1 Consent of BDO Seidman, LLP, independent registered public accounting firm.

*23.2 Consent of Seiden Wayne LLC (included with opinion filed as Exhibit 5.1).

*24 Power of Attorney (included on signature page of this registration statement).

* Previously Filed