ACURA PHARMACEUTICALS, INC
Form S-8 POS
March 02, 2011

As filed with the Securities and Exchange Commission on March 2, 2011.

Registration No 333-151653

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

POST-EFFECTIVE AMENDMENT NO. 1 TO FORM S-8

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

ACURA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

| New York | 11-0853640 |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (IRS Employer Identification No.) |

616 N. North Court, Suite 120, Palatine, Illinois 60067
(Address of Principal Executive Offices)

Acura Pharmaceuticals, Inc. 2005 Restricted Stock Unit Award Plan
(Full Title of the Plan)

Peter A. Clemens
Senior Vice President and Chief Financial Officer
Acura Pharmaceuticals, Inc.
616 N. North Court, Suite 120, Palatine, Illinois 60067
(Name and Address Of Agent For Service of Process)

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With a Copy to:

John P. Reilly, Esq.
LeClairRyan
1037 Raymond Blvd, Newark, New Jersey 07102
(973) 491-3600

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

| Large accelerated filer ¨ | Accelerated filer ¨ |
|---|---|

Non-accelerated filer þ (Do not check if a small reporting company) Smaller reporting company ¨

EXPLANATORY STATEMENT

This Post-Effective Amendment contains a reoffer prospectus replacing in its entirety the prior reoffer prospectus in the Registration Statements, which this Post-Effective Amendment amends, to be used by certain of our executive officers and directors, identified in the reoffer prospectus and other selling stockholders to be identified with respect to the control securities acquired by them or to be acquired by them pursuant to the Registrant's employee benefit plans – namely our 1995 Stock Option and Restricted Stock Purchase Plan, our 1998 Stock Option Plan (the "1998 Stock Option Plan"), our 2008 Stock Option Plan (the "2008 Stock Option Plan") and our 2005 Restricted Stock Unit Award Plan. Pursuant to Rule 429 of the Securities Act of 1933, as amended, this Registration Statement shall act as a Post-Effective Amendment to the Registration Statements on Form S-8 identified by the following Registration Numbers: 333-151653 (pursuant to which we registered shares 500,000 shares underlying our 2005 Restricted Stock Unit Award Plan); 33-98396 (pursuant to which we registered shares underlying our 1995 Stock Option and Restricted Stock Purchase Plan); 333-63288 (pursuant to which we registered 810,000 shares underlying our 1998 Stock Option Plan); 333-123615 (pursuant to which we registered 1,190,000 shares underlying our 1998 Stock Option Plan); 333-133172 (pursuant to which we registered 3,000,000 shares under our 2005 Restricted Stock Unit Award Plan); and 333-151620 (pursuant to which we registered 6,000,000 shares underlying our 2008 Stock Option Plan). All share numbers used in this Registration Statement give effect for a 1 for 10 reverse stock split effected December 5, 2007.

PART I

Reoffer Prospectus

8,251,835 Shares

ACURA PHARMACEUTICALS, INC.

Common Stock

This reoffer prospectus relates to the offering and sale from time to time for the account of certain of our directors and executive officers identified in this reoffer prospectus and other selling stockholders to be identified (collectively, "Selling Stockholders") 8,251,835 shares of common stock, par value $.01 per share, of Acura Pharmaceuticals, Inc. The shares of common stock offered by this prospectus include the following:

- 20,000 shares previously acquired by Selling Stockholders upon exercise of options under our 1995 Stock Option and Restricted Stock Purchase Plan;
- 4,000 shares underlying options, which options were issued to Selling Stockholders pursuant to our 1995 Stock Option and Restricted Stock Purchase Plan;
- 191,247 shares previously acquired by Selling Stockholders upon exercise of options under our 1998 Stock Option Plan;
    - 678,700 shares underlying options, which options were issued pursuant to our 1998 Stock Option Plan;
- 2,195,333 shares underlying options, which options were issued to Selling Stockholders pursuant to our 2008 Stock Option Plan;
        - 3,095,334 remaining shares that may be issued under our 2008 Stock Option Plan;
- 350,596 shares issued to Selling Stockholders upon exchange of Restricted Stock Units under our 2005 Restricted Stock Unit Award Plan;
    - 1,532,625 shares underlying outstanding Restricted Stock Units held by Selling Stockholders; and
    - 184,000 remaining shares that may be issued under our 2005 Restricted Stock Unit Award Plan.

Except for the aggregate exercise price of the options exercised by the Selling Stockholders, and $0.01 per share for each Restricted Stock Unit we will not receive any of the proceeds from the sale of the common stock being offered by this reoffer prospectus. All expenses of registration incurred in connection with the offering being made by this reoffer prospectus are being borne by us, but any brokerage commissions and other expenses incurred by a Selling Stockholder will be borne by such Selling Stockholder.

The Selling Stockholders may sell all or a portion of their shares from time to time through public or private transactions, directly or through brokers or otherwise, and at market prices prevailing at the time of sale or at prices otherwise negotiated. The Selling Stockholders may sell the shares of common stock covered by this reoffer prospectus in a number of different ways and at varying prices. For additional information on the methods of sale, you should refer to the section entitled “Plan of Distribution” beginning on page 27. The inclusion of the individuals listed under the "Selling Stockholders" section of the prospectus does not constitute a commitment to sell any or all of the stated number of shares of common stock. The number of shares offered shall be determined from time to time by each Selling Stockholder at their sole discretion.

The common stock is traded in the NASDAQ Capital Market under the symbol “ACUR.” On March 1, 2011, the last sale price for the common stock as reported on the NASDAQ Capital Market was $3.21 per share.

See “Risk Factors” commencing on page 4 for certain information that should be considered by prospective investors.

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS REOFFER PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this reoffer prospectus is March 2, 2011.

EXPLANATORY NOTE

This prospectus contains the form of reoffer prospectus to be used by certain of our officers, directors and employees identified in this prospectus and other selling stockholders to be identified with respect to the control securities acquired or to be acquired by them pursuant to our employee benefit plans.

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INFORMATION CONTAINED IN THIS PROSPECTUS

You should rely only on the information provided or incorporated by reference in this reoffer 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.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this prospectus and in documents that we incorporate by reference into this reoffer prospectus constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such 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 such forward-looking statements. The most significant of such factors include, but are not limited to, our ability and the ability of King Pharmaceuticals Research and Development, Inc. (“King”), a wholly owned subsidiary of King Pharmaceuticals, Inc. (to whom we have licensed our Aversion® Technology for certain opioid analgesic products in the United States, Canada and Mexico) and the ability other pharmaceutical companies, if any, to whom we may license our Aversion® Technology or Impede™ Technology, to obtain necessary regulatory approvals and commercialize products utilizing such technologies, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability to fulfill the U.S. Food and Drug Administration’s (“FDA”) requirements for approving our product candidates for commercial manufacturing and 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 laboratory and clinical studies we may complete in the future, to support FDA approval of our product candidates, the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of 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 of the studies or the risk that further studies of our product candidates are not positive or otherwise do not support FDA approval, whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications or for abuse deterrent features, whether our product candidates will ultimately deter abuse in commercial settings, and the uncertainties inherent in scientific research, drug development, laboratory and 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 skilled personnel; our ability to secure and protect our patents, trademarks and other proprietary rights; 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 ("DEA") quotas and source the active ingredients for our products in development; difficulties or delays in conducting clinical trials for our product candidates or in the commercial manufacture and supply of our products; and other risks and uncertainties detailed in this Prospectus. When used in this reoffer prospectus, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions identify forward-looking statements.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus and in documents that we incorporate by reference into this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on such forward-looking statements.

## RISK FACTORS

Our future operating results may vary substantially from anticipated results due to a number of factors, many of which are beyond our control. The following discussion highlights some of these factors and the possible impact of these factors on future results of operations. If any of the following factors actually occur, our business, financial condition or results of operations could be materially harmed. In that case, the value of our common stock could decline substantially.

Risks Relating to Our Business and Industry

We have a history of operating losses and may not achieve profitability sufficient to generate a positive return on shareholders' investment.

We had a net loss of $12.7 million for the year ended December 31, 2010, a net loss of $15.8 million for the year ended December 31, 2009 and net income of $14.5 million for the year ended December 31, 2008. Our future profitability will depend on several factors, including:

- our receipt of milestone payments and royalties relating to products developed and commercialized under our license agreement with King (the "King Agreement"); and

- the receipt of FDA approval and the successful commercialization by King and other future licensees (if any) of products utilizing our Aversion® and Impede™ Technologies 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 recognized revenues of $3.3 and $3.8 million in the years ended December 31, 2010 and 2009, respectively, from payments received under the King Agreement. However, we have not yet generated any revenues from Aversion® Technology product sales. Even if we succeed in commercializing one or more of our Aversion® Technology product candidates, we expect to continue using cash reserves for the foreseeable future. Our expenses may increase in the foreseeable future as a result of continued research and development of additional product candidates, maintaining and expanding the scope of our intellectual property, commercializing our Impede™ PSE product, and hiring of additional research and development staff.

We will need to generate revenues from direct product sales or indirectly from royalties on sales to achieve and maintain profitability. If we cannot successfully develop, obtain regulatory approval for and commercialize our product candidates licensed to King under the King Agreement or other product candidates under similar license agreements anticipated to be negotiated and executed with other pharmaceutical companies, of which no assurance can be given, we will not be able to generate such royalty revenues or achieve future profitability. Our failure to achieve or maintain profitability would have a material adverse impact on the market price of our common stock.

We must rely on current cash reserves, technology licensing fees and third party financing to fund operations.

Pending the receipt of milestone payments and royalties, if any, under the King Agreement or under similar license agreements anticipated to be negotiated and executed with other pharmaceutical companies, of which no assurance can be given, we must rely on our current cash reserves, revenues from sales of our Impede™ PSE product, if any, and third-party financing to fund operations and product development activities. No assurance can be given that current cash reserves or revenues from Impede™ PSE product sales will be sufficient to fund the continued operations and development of our product candidates until such time as we generate additional revenue from the King Agreement or similar license agreements anticipated to be negotiated and executed with the other pharmaceutical companies. 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 utilizing our Aversion® and Impede™ Technologies may be commercialized.

Our product candidates are unproven and may not be approved by the FDA.

We are committing a majority of our resources to the development of Acurox® Tablets and other product candidates utilizing our Aversion® and Impede™ Technologies. There can be no assurance that the FDA will ultimately approve Acurox® Tablets (with or without niacin) or any other product candidate utilizing Aversion® Technology for commercial distribution. Further there can be no assurance that other product candidates developed using Aversion® Technology or Impede™ Technology will achieve the targeted end points in the required clinical studies or perform as intended in other pre-clinical and clinical studies or lead to a NDA submission or filing acceptance. 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 financial condition.

Even if the FDA Approves Acurox® Tablets for commercial distribution, if Acurox® Tablets (with or without niacin) are not approved with labeling describing its abuse deterrent features, we will be unable to refer to the abuse deterrent characteristics of Acurox® to promote the product.

Our strategy for Acurox® Tablets depends upon our ability to distinguish Acurox® Tablets from other immediate release oxycodone HCl containing products based primarily on abuse deterrent features. As with all of our product candidates utilizing Aversion® Technology, even if Acurox® Tablets are approved by the FDA, our failure to achieve approval of product labeling that sufficiently differentiates Acurox® Tablets from other immediate release oxycodone HCl containing tablets may adversely affect our business and results of operations. The FDA has publicly stated that explicit indications or claims of abuse deterrence will not be permitted unless such indications or claims are supported by double blind controlled clinical studies demonstrating an actual reduction in product abuse by patients or drug abusers. Because the cost, time and practicality of designing and implementing clinical studies adequate to support explicit claims of abuse deterrence are prohibitive, we are not pursuing and have not conducted the clinical trials necessary to include an explicit product label claim of abuse deterrence. Instead, we intend to rely on certain clinical and laboratory studies to support the inclusion of information about the abuse deterrent features of Acurox® Tablets to support promotion by our licensee(s) of the product. We intend to include in the product labels of our product candidates both a physical description of the abuse deterrent features and information from our laboratory and clinical studies designed to simulate the relative difficulty of abusing our product candidates. However, the extent to which such information will be included in the FDA approved product label will be the subject of our discussions with, and agreement by, the FDA as part of the NDA review process for each of our product candidates. The outcome of those discussions with the FDA will determine whether our licensee will be able to market our product candidates with labeling that sufficiently differentiates them from other products that have comparable therapeutic profiles. If the FDA does not approve the Acurox® Tablet labeling with such information, our licensee will not be able to promote Acurox® Tablets based on its abuse deterrent features, may not be able to differentiate Acurox® Tablets from other oxycodone HCl containing immediate release products, and may not be able to charge a premium above the price of such other products which could materially adversely affect our business and results of operations.

Because FDA closely regulates promotional materials and other promotional activities, even if FDA initially approves product labeling that includes a description of the abuse deterrent characteristics of our product, FDA may object to our or our licensee’s marketing claims and product advertising campaigns.

Relying on third party contract research organizations ("CROs") may result in delays in our pre-clinical, clinical or laboratory testing. If pre-clinical, clinical or laboratory 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 sell and distribute in the U.S. any of our prescription product candidates, we or our licensees must submit to the FDA an NDA demonstrating, among other things, that the product candidate is safe and effective for its intended use. This demonstration requires significant testing. As we do not possess the resources or employ all the personnel necessary to conduct such testing, we rely on 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.

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 assure 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 are expensive and at times 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 or the FDA believes that participating patients are being exposed to unacceptable health risks, we or our licensees may suspend the clinical trials. Failure can occur at any stage of the trials, and we or our licensees 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 and laboratory testing 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 may cause us or our licensees to abandon a product candidate and may delay the development of other product candidates.

We have no commercial manufacturing capacity and rely on third-party contract manufacturers to produce our commercial quantities.

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 third party contract manufactures with appropriate facilities and equipment to contract manufacture commercial quantities of products utilizing our Aversion® and Impede™ Technologies. These licensees and third party contract manufacturers are also subject to cGMP regulations. Any performance failure on the part of our licensees or contract manufacturers could delay commercialization of any approved products, depriving us of potential product revenue.

Our drug candidates, including our Impede™ PSE Tablets, require precise, high quality manufacturing. Failure by our contract manufacturers to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could materially adversely affect our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMP and other applicable government regulations; however, we do not have control over third-party manufacturers' compliance with these regulations and standards.

If for some reason our contract manufacturers cannot perform as agreed, we may be required to replace them. Although we believe there are a number of potential replacements, we may incur added costs and delays in identifying and qualifying any such replacements. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drug 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 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 distribution and 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 review and 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, 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 more than a year to grant final approval for an NDA. The Prescription Drug User Fee Act (“PDUFA”) sets time standards for FDA’s review of NDA’s. The FDA's timelines described in the PDUFA guidance are flexible and subject to change based on workload and other potential review issues and may delay the FDA’s review of an 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 our products.

Even if we comply with all the 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 commercialized 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, or otherwise not permit labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles but without abuse deterrent features. Such events would have a material adverse effect on our operations and financial condition. We may market certain of our products without the prior application to and approval by the FDA. The FDA may subsequently require us to withdraw such products and submit NDAs for approval prior to re-marketing.

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. In the event the FDA takes any such action relating to our products (if any are approved by FDA), such actions 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 installed the equipment necessary to manufacture clinical trial supplies of our Aversion® and Impede™ 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 cGMP regulations. 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, and those of any third-party manufacturers that we or our licensees 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 the FDA deems 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 develop our products, and manufacture clinical supplies, at a single location. Any disruption at this facility could adversely affect our business and results of operations.

We rely on our Culver, Indiana facility for developing our product candidates and the manufacture of clinical supplies of our product candidates. If the Culver, Indiana facility were damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to repair or replace. If our Culver facility were affected by a disaster, we would be forced to rely entirely on CROs and third party contract manufacturers while repairs were being made. Although we believe we possess adequate insurance for damage to our property and for the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. Moreover, any disruptions or delays at our Culver, Indiana facility could impair our ability to develop our product candidates utilizing the Aversion® or Impede™ Technologies, which could adversely affect our business and results of operations.

Our operations are subject to environmental, health and safety, and other laws and regulations, with which compliance is costly and which exposes us to penalties for non-compliance.

Our business, properties and product candidates are subject to federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage and disposal of hazardous substances, waste and other regulated materials. Because we own and operate real property, various environmental laws also may impose liability on us for the costs of cleaning up and responding to hazardous substances that may have been released on our property, including releases unknown to us. These environmental laws and regulations also could require us to pay for environmental remediation and response costs at third-party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or may be altered in the future, could adversely affect our financial condition and results of operations.

If our licensees do not satisfy their obligations, we will be unable to develop our licensed product candidates.

On October 30, 2007, we entered into an Agreement with King (as more fully described under the caption "About Acura Pharmaceuticals-King Agreement"). At December 31, 2010 we had received aggregate payments of $58.3 million from King, consisting of a $30.0 million non-refundable upfront cash payment, $17.3 million in reimbursed research and development expenses relating to our licensed product candidates, $6.0 million in option exercise fees relating to King's exercise of its option to license an undisclosed opioid analgesic tablet product and Vycavert® with Niacin Tablets, and a $5.0 million milestone fee relating to our successful achievement of the primary end points for our pivotal Phase III clinical study for Acurox® with Niacin Tablets. Our future revenue, if any, will be derived from milestone payments and royalties under the King Agreement and under similar license agreements anticipated to be potentially negotiated and executed with other pharmaceutical companies. No assurance can be given that we will receive the milestone and royalty payments provided for in the King Agreement, or that we will be successful in entering into similar agreements with other pharmaceutical companies to develop and commercialize products utilizing our Aversion® or Impede™ Technologies.

As part of such license agreements, we will not have day-to-day control over the activities of our licensees with respect to any product candidate. If a licensee fails to fulfill its obligations under an agreement with us, we may be unable to assume the development of the product candidate 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 license agreement. Accordingly, our ability to receive any revenue from the product candidates covered by such agreements will be dependent on the efforts of our licensee. We could be involved in disputes with a licensee, 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 licensee's commitment to us and reduce the resources they devote to developing and commercializing our products. If any licensee 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 licensees.

If we fail to maintain our license agreement with King, we may have to reduce or delay our product candidate development.

Our plan for developing, manufacturing and commercializing Acurox® Tablets and other opioid analgesic product candidates utilizing our Aversion® Technology currently requires us to successfully maintain our license agreement with King. In addition to other customary termination provisions, the King Agreement provides that King may terminate the King Agreement at any time upon written notice to us. If King elects to terminate the King Agreement, or if we are otherwise unable to maintain our existing relationship with King, we may have to limit the size or scope of, or delay or abandon the development of, Acurox® Tablets and other opioid analgesic product candidates or undertake and fund development of these product candidates ourselves. If we were required to fund development and commercialization efforts with respect to Acurox® Tablets and other opioid analgesic product candidates on our own, we may need to obtain additional financing, which may not be available on acceptable terms, or at all.

If King is not successful in commercializing Acurox® Tablets (with or without niacin) and other licensed product candidates incorporating the Aversion® Technology our revenues and our business will suffer.

Pursuant to the King Agreement, King is responsible for manufacturing, marketing, pricing, promoting, selling, and distributing certain of our product candidates in the US, Canada and Mexico. If such agreement is terminated in accordance with its terms, including due to a party's failure to perform its obligations or responsibilities under the agreement, then we would need to commercialize the products ourselves for which we currently have no infrastructure or alternatively enter into a new agreement with another pharmaceutical company, of which no assurance can be given. In this event our revenues and/or royalties for these products could be adversely impacted.

King's manufacturing facility is currently the sole commercial source of supply for Acurox® Tablets and our other product candidates licensed to King. If King's manufacturing facility fails to obtain sufficient DEA quotas for the opioid active ingredients contained in such product candidates, fails to source adequate quantities of active and inactive ingredients, fails to comply with regulatory requirements, or otherwise experiences disruptions in commercial supply of our product candidates, product revenue and our royalties could be adversely impacted.

King has a diversified product line for which Acurox® Tablets and our other product candidates licensed to King will vie for King's promotional, marketing, and selling resources. If King fails to commit sufficient promotional, marketing and selling resources to our products, product revenue and our royalties could be adversely impacted. Additionally, in view of Pfizer, Inc.'s recent acquisition of King Pharmaceuticals in February, 2011, there can be no assurance that Pfizer will commit the resources required for the successful development and commercialization of our product candidates.

The market for our opioid product candidates is highly competitive with many marketed non abuse deterrent brand and generic products and other abuse deterrent product candidates in development. If King prices our product candidates inappropriately, fails to position our products properly, targets inappropriate physician specialties, or otherwise does not provide sufficient promotional support, product revenue and our royalties could be adversely impacted.

The market may not be receptive to products incorporating our Aversion® Technology.

The commercial success of our products 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 that our products utilizing the Aversion® or Impede™ Technologies would be accepted by health care providers and others. Factors that may materially affect market acceptance of our product candidates include but are not limited to:

- the relative advantages and disadvantages of our products compared to competitive products;
- the relative timing to commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
- the product labeling approved by the FDA for our products;
- the willingness of third party payers to reimburse for our prescription products; and
- the willingness of consumers to pay for our products.

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

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If we, our licensees or others identify serious adverse events or deaths relating to any of our products once on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate revenues.

We or our licensees are required to report to relevant regulatory authorities all serious adverse events or deaths involving our product candidates or approved products. If we, our licensees, or others identify such events, regulatory authorities may withdraw their approvals of such products; we or our licensees may be required to reformulate our products; we or our licensees may have to recall the affected products from the market and may not be able to reintroduce them onto the market; our reputation in the marketplace may suffer; and we may become the target of lawsuits, including class actions suits. Any of these events could harm or prevent sales of the affected products and could materially adversely affect our business and financial condition.

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 insurance coverage or adequate reimbursement for our products from third-party payers.

The ability of our licensees to successfully commercialize our products may depend in part on the availability of reimbursement for our prescription products from government health administration authorities, private health insurers, and other third-party payers and administrators, including Medicaid and Medicare. We cannot predict the availability of reimbursement for newly-approved products utilizing our Aversion® Technology. Third-party payers and administrators, including state Medicaid programs and Medicare, are challenging the prices charged for pharmaceutical products. Government and other third-party payers 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 candidates. The continuing efforts of government and third-party payers to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payers do not provide adequate coverage and reimbursement for any product utilizing 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 may 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 or our licensees charge for any of our 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 commercialization.

Consolidation in the healthcare industry could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or results of operations.

Because healthcare costs have risen significantly, numerous initiatives and reforms by legislatures, regulators and third-party payers to curb these cost increases have resulted in a trend in the healthcare industry to consolidate product suppliers and purchasers. As the healthcare industry consolidates, competition among suppliers to provide products to purchasers has become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, and large single accounts continue to use their market power to influence product pricing and purchasing decisions. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to influence the worldwide healthcare industry, resulting in further business consolidations, which may exert further downward pressure on the prices of our anticipated products. This downward pricing pressure may adversely impact our business, financial condition or results of operations.

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Our success depends on our ability to protect our intellectual property.

Our success depends on our ability to obtain and maintain patent protection for products developed utilizing our technologies, 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, U.S. Patent No. 7,476,402 and U.S. Patent No. 7,510,726 from the United States Patent and Trademark Office ("USPTO") encompassing our opioid product candidates utilizing our Aversion® Technology, there is no assurance that any of our patent claims in our other pending non-provisional and provisional patent applications relating to our technologies 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 our technologies may not be sufficiently broad to protect our products. In addition, issued patent claims may be challenged, potentially invalidated or potentially 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 others. We may become aware of patents belonging to competitors and others that could require us to obtain licenses to such patents or alter our technologies. Obtaining such licenses or altering our technology 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 of our products. Even if we can obtain a license, the financial and other terms may be disadvantageous.

Our success also depends on 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, contract research organizations, contract manufacturers, potential investors, consultants and other parties. 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® or Impede™ Technologies 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:

- litigation or other proceedings we may initiate against third parties to enforce our patent rights or other intellectual property rights;
- litigation or other proceedings we may initiate against third parties seeking to invalidate the patents held by such third parties or to obtain a judgment that our products do not infringe such third parties' patents;
- litigation or other proceedings third parties may initiate against us to seek to invalidate our patents or to obtain a judgment that third party products do not infringe our patents;

- if our competitors file patent applications that claim technology also claimed by us, we may be forced to participate in interference or opposition proceedings to determine the priority of invention and whether we are entitled to patent rights on such invention; and
- if third parties initiate litigation claiming that our products infringe their patent or other intellectual property rights, we will need to defend against such proceedings.

The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Many of our potential 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 technologies or products may be found to infringe claims of patents owned by others. If we determine or if we are found to be infringing a patent held by another party, we, our suppliers or our licensees might have to seek a license to make, use, and sell the patented technologies and products. In that case, we, our suppliers 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 third party 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 use of our 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 technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited.

We are aware of certain United States and international pending patent applications owned by third parties with claims potentially encompassing our product candidates. While we do not expect the claims contained in such pending patent applications will issue in their present form, there can be no assurance that such patent applications will not issue as patents with claims encompassing one or more of our product candidates. If such patent applications result in valid and enforceable issued patents, containing claims in their current form or otherwise encompassing our products we or our licensees may be required to obtain a license to such patents, should one be available, or alternatively, alter our products so as to avoid infringing such third-party patents. If we or our licensees are unable to obtain a license on commercially reasonable terms, or at all, we or our licensees could be restricted or prevented from commercializing our products. Additionally, any alterations to our products or our technologies could be time consuming and costly and may not result in technologies or products that are non-infringing or commercially viable.

We cannot assure you that our technologies, products and/or actions in developing our products will not infringe third-party patents. Our failure to avoid infringing third-party patents and intellectual property rights in the development and commercialization of our products would have a material adverse affect on our operations and financial condition.

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, or health care providers 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 product 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 drug products 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 may not achieve significant product revenues and our financial condition and results of operations will be materially adversely affected.

We or our licensees 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 products than we do.

We are concentrating a substantial majority of our efforts and resources on developing product candidates utilizing our Aversion® and Impede™ Technologies. The commercial success of products utilizing such technologies will depend, in large part, on the intensity of competition, FDA approved product labeling for our products compared to competitive products, and the relative timing and sequence for commercial launch of new products by other companies developing, marketing, selling and distributing products that compete with the products utilizing our Aversion® and Impede™ Technologies. Alternative technologies and non-opioid 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 utilizing our Aversion® and Impede™ Technologies may be substantially decreased thus 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 dependent on our management and scientific team, including Andrew D. Reddick, our President and Chief Executive Officer, Robert Jones, our Senior Vice President and Chief Operating Officer, and Albert W. Brzeczko, Ph.D., our Vice President of Technical Affairs. We may not be able to attract and retain personnel on acceptable terms given the 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, including certain opioid active pharmaceutical ingredients and pseudoephedrine HCl in our current product candidates. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of regulation. Furthermore, the amount of active ingredients 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.

Prior ownership changes limit our ability to use our tax net operating loss carryforwards.

Significant equity restructuring often results in an Internal Revenue Section 382 ownership change that limits the future use of Net Operating Loss ("NOL") carryforwards and other tax attributes. We have determined that an ownership change (as defined by Section 382 of the Internal Revenue Code) did occur as a result of restructuring that occurred in 2004. Neither the amount of our NOL carryforwards nor the amount of limitation of such carryforwards claimed by us have been audited or otherwise validated by the Internal Revenue Service, which could challenge the amount we have calculated. The recognition and measurement of our tax benefit includes estimates and judgment by our management, which includes subjectivity. Changes in estimates may create volatility in our tax rate in future periods based on new information about particular tax positions that may cause management to change its estimates.

Risks Relating to Our Common Stock

Our quarterly results of operations will fluctuate, and these fluctuations could cause our stock price to decline.
Our quarterly and annual 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. The forecasting of the timing of sales of our product candidates is difficult due to the uncertainty inherent in seeking FDA and other necessary approvals for our product candidates. As a result, in some future quarters or years our clinical, financial or operating results may not meet the expectations of securities analysts and investors which could result in a decline in the price of our stock.

Volatility in stock prices of other companies may contribute to volatility in our stock price.

The market price of our common stock, like the market price for securities of pharmaceutical and biotechnology companies, has historically been highly volatile. The stock market from time to time experiences significant price and volume fluctuations 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, FDA determinations on the approval of a product candidate NDA submission, 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 substantial 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 and shareholder derivative litigation has often been instituted. A securities class action suit or shareholder derivative 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 affect on our financial condition and results of operations. A pending securities class action litigation has been filed against us in the United States District Court for the Northern District of Illinois, Eastern Division, and three shareholder derivative suits have been filed in the Circuit Court of Cook County, Illinois, Chancery Division. These complaints generally allege that certain of our officers made false or misleading statements, or failed to disclose material facts in order to make statements not misleading, relating to our Acurox® Tablets (with niacin) product candidate, resulting in violations of Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), Rule 10b-5 under the Exchange Act and Section 20(a) of the Exchange Act.

Our stock price has been volatile and there may not be an active, liquid trading market for our common stock.

Our stock price has experienced significant price and volume fluctuations and may continue to experience volatility in the future. Factors that have a material impact on the price of our common stock, in addition to the other issues described herein, include results of or delays in our pre-clinical and clinical studies, any delays in, or failure to receive FDA approval of our product candidates, the success of our license agreement with King, announcements of technological innovations or new commercial products by us or others, developments in patents and other proprietary rights by us or others, future sales of our common stock by existing stockholders, regulatory developments or changes in regulatory guidance, the departure of our officers, directors or key employees, and period-to-period fluctuations in our financial results. Also, you may not be able to sell your shares at the best market price if trading in our stock is not active or if the volume is low. There is no assurance that an active trading market for our common stock will be maintained on the NASDAQ Capital Market.

The National Association of Securities Dealers, Inc., or NASD, and the Securities and Exchange Commission, or SEC, have adopted rules relating to the listing of publicly traded stock. If we were unable to continue to comply with such rules, we could be delisted from trading on the NASDAQ Capital Market and thereafter trading in our common stock, if any, would be conducted through the Over-the-Counter Bulletin Board of the NASD. As a consequence of such delisting, an investor would likely find it more difficult to dispose of, or to obtain quotations as to the price of, our common stock. Delisting of our common stock from the NASDAQ Capital Market could also result in lower prices per share of our common stock than would otherwise prevail.

We do not have a history of paying dividends on our common stock.

Historically we have not declared and paid any cash dividends on our common stock. We intend to retain all of our earnings for the foreseeable future to finance the operation and expansion of our business. As a result, you may only receive a return on your investment in our common stock if the market price of our common stock increases.

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GCE Holdings LLC can control all matters requiring approval by shareholders.

GCE Holdings LLC beneficially owns approximately 74.7% of our outstanding common stock as of December 31, 2010 (calculated in accordance with Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended). As a result, GCE Holdings LLC, in view of its ownership percentage of our common stock, 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 as such we may 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 vote.

We are currently a "Controlled Company" within the meaning of the NASDAQ Capital Market Listing Requirements and, as a result, are exempt from certain corporate governance requirements.

Because GCE Holdings LLC controls more than 50% of the voting power of our common stock, we are currently considered to be a "controlled company" for purposes of a NASDAQ Capital Market listing requirements. As such, we are permitted, and have elected, to opt out of the NASDAQ Capital Market listing requirements that would otherwise require our board of directors to have a majority of independent directors, our board nominations to be selected, or recommended for the board's selection either by a nominating committee comprised entirely of independent directors or by a majority of independent directors, and our compensation committee to be comprised entirely of independent directors. Accordingly, you may not have the same protections afforded to stockholders of companies that are subject to all of the NASDAQ Capital Market corporate governance requirements.

Any future sale of a substantial number of shares included in our current registration statement could depress the trading price of our stock, lower our value and make it more difficult for us to raise capital.

In accordance with the terms of the Securities Purchase Agreement dated August 20, 2007 between us and the investors named therein, we filed a registration statement with the SEC to register the shares included in our Units issued pursuant to the Securities Purchase Agreement, including shares underlying warrants included in the Units. In addition, pursuant to the exercise of previously granted piggyback registration rights, each of GCE Holdings, LLC, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP and Essex Woodlands Health Ventures V, L.P. have exercised their piggyback registration rights to include an aggregate of 26,584,016 shares in such registration statement. As a result, 34,243,273 shares (representing approximately 74.7% of our shares outstanding on a fully-diluted basis – including all derivative securities, whether or not currently exercisable) are included in the registration statement for resale by selling stockholders. Such registration statement was declared effective by the SEC on November 20, 2007. If some or all of such shares included in such registration statement are sold by our affiliates and others it may 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 if needed in the future.

ABOUT ACURA PHARMACEUTICALS, INC.

General

We are a specialty pharmaceutical company engaged in research, development and manufacture of product candidates intended to provide abuse deterrent features and benefits utilizing our proprietary Aversion® and Impede™ Technologies. Our Aversion® Technology opioid analgesic product candidates are intended to effectively relieve pain while simultaneously discouraging common methods of opioid product misuse and abuse, including the:

- intravenous injection of dissolved tablets or capsules;
- nasal snorting of crushed tablets or capsules; and
- intentional swallowing of excess quantities of tablets or capsules (when product candidates are formulated with niacin).

We and our licensee, King are jointly developing opioid analgesic product candidates both with and without niacin utilizing our patented Aversion® Technology. In addition to Acurox® (oxycodone HCl) Tablets, we and King are developing Vycavert® (hydrocodone bitartrate/acetaminophen) Tablets, Acuracet® (oxycodone HCl/ acetaminophen) Tablets, Acurox® with Niacin (oxycodone HCl/niacin) Tablets and additional undisclosed opioid product candidates utilizing our Aversion® Technology. We and King have submitted a New Drug Application (NDA) for Acurox® with Niacin Tablets. Four opioid product candidates (both with and without niacin) are licensed to King under our License, Development and Commercialization Agreement dated October 30, 2007. We are also developing an undisclosed benzodiazepine tablet product candidate utilizing Aversion® Technology intended for the treatment of anxiety disorders, and a pseudoephedrine HCl tablet product utilizing Impede™ Technology intended for treatment of nasal congestion.

All of our opioid product candidates utilize Aversion® Technology (both with and without niacin) and are covered by issued U.S. patents, which in combination with our anticipated product labeling and drug product listing strategies are anticipated to provide our opioid products with barriers to market entry for generic competition through the expiration of our patents in 2025.

In addition to our Aversion® Technology, as part of our continuing research efforts we are investigating and developing novel mechanisms to incorporate abuse deterrent features into abused and misused pharmaceutical products. In this regard we have developed Impede™ PSE, a pseudoephedrine hydrochloride ("PSE") tablet product candidate utilizing our Impede™ Technology. Impede™ Technology utilizes a proprietary mixture of functional inactive ingredients intended to limit or impede extraction of PSE from tablets for use as a starting material in producing the illicit drug methamphetamine. An 18 subject clinical study demonstrated our Impede™ PSE Tablets are bioequivalent to Sudafed® brand PSE tablets and a leading generic PSE store brand tablet. We are currently negotiating with a contract manufacturer for the scale up and commercial manufacture of our Impede™ PSE Tablets. It is our current expectation to market our Impede™ PSE Tablets directly to national and regional drug store chains.

Acurox® Tablets is an orally administered immediate release tablet containing oxycodone hydrochloride (HCl) as its sole active analgesic ingredient and is intended for the relief of moderate to severe pain. On December 17, 2010, King submitted a New Drug Application ("NDA") for Acurox® Tablets to the FDA, including a request for priority review classification. On February 10, 2011 the FDA notified King of the FDA's acceptance for filing of the Acurox® Tablets NDA and the grant of a priority review classification. The priority review classification establishes a non-binding date of June 17, 2011 for the FDA to complete its review of the Acurox® Tablets NDA under the Prescription Drug User Fee Act (PDUFA). In addition to filing acceptance and assignment of a Priority review classification, the FDA's filing communication letter to King also includes preliminary comments about potential review issues relating to an intranasal abuse liability study included in the NDA and requests additional information relating to this study and other issues. The preliminary notice of potential review issues is not indicative of deficiencies that may be identified during the FDA's review of the NDA. No assurance can be given that any issues raised as part of the FDA's review of the Acurox® NDA (including the potential review issues in the FDA's filing communication letter) will be addressed to the FDA's satisfaction or that the Acurox® NDA will be approved by the FDA. Acurox® Tablets utilizes our patented Aversion® Technology which is designed to limit or impede abuse by intravenous injection of dissolved tablets and nasal snorting of crushed tablets. A separate NDA for Acurox® with Niacin (oxycodone HCl/niacin) Tablets, which is designed to deter intravenous, nasal, and abuse by excess oral consumption, is subject to an FDA Complete Response Letter.

We conduct research, development, laboratory, manufacturing, and warehousing activities at our operations facility in Culver, Indiana and lease an administrative office in Palatine, Illinois. In addition to internal capabilities and activities, we engage numerous clinical 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, under our direction, development and regulatory services relating to our technologies and product candidates. We also intend to contract with a third-party pharmaceutical product manufacturer and packager to supply commercial requirements for our Impede™ PSE Tablets.

Our goal is to become a leading specialty pharmaceutical company focused on addressing the growing societal problem of pharmaceutical drug abuse by developing a broad portfolio of products with abuse deterrent features and benefits. Specifically, we intend to:

- Capitalize on our Experience and Expertise in the Research and Development of Pharmaceutical Products with Abuse Deterrent Features and Benefits. Our strategy is to facilitate rapid product development and minimize risk by utilizing active pharmaceutical ingredients with proven safety and efficacy profiles with known potential for abuse, and develop new products utilizing our proprietary technologies using the FDA's 505(b)(2) NDA and other regulatory pathways and processes.

- Emerge as a Leader in Developing and Commercializing Products with Abuse Deterrent Features and Benefits Able to Uniquely Address the Growing Problem of Abuse of Prescription Drugs. We believe that Acurox® Tablets and our other opioid product candidates in development have demonstrated that Aversion® Technology allows products to provide the analgesic benefit they were intended to deliver, while simultaneously having features that are intended to deter misuse and abuse. We believe these benefits will be attractive to physicians, third party payers, and public advocacy groups sensitive to the problem of prescription drug abuse.

- Optimize Shareholder Value and Temper Risk by Licensing our Product Candidates to Strategically Focused Pharmaceutical Companies in the U.S. and Other Geographic Territories. On October 30, 2007, we and King entered into the King Agreement to develop and commercialize in the United States, Canada and Mexico (the "King Territory") opioid analgesic products utilizing Aversion® Technology. We believe opportunities exist to enter into similar agreements with other partners for these same opioid products outside the King Territory, and in the United States and worldwide for developing additional Aversion® Technology and Impede™ Technology product candidates

for other abusable drugs such as tranquilizers, stimulants, sedatives and decongestants. By licensing our product candidates to strategically focused companies with expertise and infrastructure in commercialization of pharmaceuticals, we are able to leverage our expertise, intellectual property rights and Aversion® and Impede™ Technologies without the need to invest in and build costly sales and manufacturing infrastructure. We anticipate that our future revenue, if any, will be derived from milestone and royalty payments related to the commercialization of products utilizing our Aversion® and Impede™ Technologies and from our commercialization of our Impede™ PSE Tablets.

- In-license or Acquire Alternative Technologies and Product Candidates to Expand our Portfolio of Abuse Deterrent Technologies and Products. We intend to pursue the in-license or acquisition of product candidates and technologies that will allow us to expand our portfolio of products with abuse deterrent features and benefits. Such in-licensing or acquisition transactions, if successfully completed, of which no assurance can be given, may include product candidates or technologies for pain relief, and other drugs susceptible to misuse and abuse.

- Apply our Aversion® and Impede™ Technologies to Non-Opioid Drugs Susceptible to Abuse. We intend to first develop a portfolio of opioid analgesic products, and thereafter we intend to expand to other pharmaceutical product categories containing potentially abusable active ingredients such as tranquillizers (brand products such as Valium®, Xanax®, Klonopin® and Ativan®), stimulants (brand products such as Dexedrine®, Adderall®, Ritalin® and Concerta®), sedatives (brand products such as Nembutal®, Butisol®, and Seconal®) and decongestants (brand products such as Sudafed®, Zyrtec-D®, Allegra-D®, and Claritin-D®). These products, like opioid analgesics, may also be prone to misuse and abuse.

- Maintain our Efficient Internal Cost Structure. We maintain a streamlined and highly efficient cost structure focused on: (i) selection, formulation development, laboratory evaluation, manufacture, quality assurance, and stability testing of certain finished dosage form product candidates; (ii) development and prosecution of our patent applications; (iii) negotiation and execution of license and development agreements with strategically focused pharmaceutical companies, and (iv) utilizing third-party contract manufacturers/packagers to supply our commercial requirements for our Impede™ PSE Tablet product. By outsourcing the high cost elements of our product development and commercialization process, we believe that we substantially minimize required fixed overhead and capital investment and thereby reduce our business risk. We currently do not intend to use a physician focused sales force to commercialize products on our own.

King Agreement

On October 30, 2007, we and King entered into the King Agreement to develop and commercialize in the King Territory certain opioid analgesic products utilizing our proprietary Aversion® Technology. In addition, the King Agreement provides King with an option to license in the King Territory certain future opioid analgesic products developed utilizing Aversion® Technology. At December 31, 2010, King had exercised its option to license two additional product candidates including an undisclosed opioid analgesic tablet product and Vycavert® (hydrocodone bitartrate/niacin/acetominophan) Tablets, each of which utilize our Aversion® Technology. We are responsible for using commercially reasonable efforts to develop Acurox® with Niacin Tablets through regulatory approval by the FDA. The King Agreement provides that we or King may develop additional opioid analgesic product candidates utilizing our Aversion® Technology and, if King exercises its option to license such additional product candidates, they will be subject to the milestone and royalty payments and other terms of the King Agreement.

At December 31, 2010, we had received aggregate payments of $58.3 million from King, consisting of a $30.0 million non-refundable upfront cash payment, $17.3 million in reimbursed research and development expenses relating to Acurox® with Niacin Tablets and Acurox® Tablets, $6.0 million in fees relating to King's exercise of its option to license an undisclosed opioid analgesic tablet product and Vycavert® with Niacin Tablets, and a $5.0 million milestone fee relating to our successful achievement of the primary endpoints for our pivotal Phase III clinical study for Acurox® with Niacin Tablets. The King Agreement also provides for King's payment to us of a $3.0 million fee upon King's exercise of its option for each future opioid analgesic utilizing Aversion® Technology ("Future Product"). In the event that King does not exercise its option for a Future Product, King may be required to reimburse us for certain of our expenses relating to such Future Product. Further, we may receive up to $23 million in additional non-refundable milestone payments for each active opioid analgesic ingredient licensed to King which achieves certain regulatory milestones in specific countries in the King Territory. An opioid analgesic product formulated with and without niacin is considered a single product candidate for purposes of the option fees and milestone payments payable under the King Agreement. We can also receive a one-time $50 million sales milestone payment upon the first attainment of $750 million in net sales of all of our licensed products across all King Territories. In addition, for sales occurring following the one year anniversary of the first commercial sale of the first licensed product sold, King will pay us a royalty at one of 6 rates ranging from 5% to 25% based on the level of combined annual net sales for all products licensed by us to King across all King Territories, with the highest applicable royalty rate applied to such combined annual sales. King's royalty payment obligations expire on a product by product and country-by-country basis upon the later of (i) the expiration of the last valid patent claim covering such product in such country, or (ii) fifteen (15) years from the first commercial sale of such product in such country. No minimum annual fees are payable by either party under the King Agreement.

The King Agreement expires upon the expiration of King's royalty payment and other payment obligations under the King Agreement. King may terminate the King Agreement (i) in its entirety at any time by written notice to us, and (ii) with respect to any product at any time upon the provision of not less than 12 months' prior written notice. We may terminate the King Agreement with respect to a product in the United States in the event such product is not commercially launched by King within 120 days after receipt of regulatory approval of such product or in its entirety if King commences any interference or opposition proceeding challenging the validity or enforceability any of our patent rights licensed to King under the King Agreement. Either party has the right to terminate the King Agreement on a product by product and country-by-country basis if the other party is in material breach of its obligations under the King Agreement relating to such product and such country, and to terminate the Agreement in its entirety in the event the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy or otherwise seeks relief under applicable bankruptcy laws, in each case subject to applicable cure periods.

In the event of termination, no payments are due except those royalties and milestones that have accrued prior to termination under the King Agreement and all licenses under the King Agreement are terminated. For all Acura terminations and termination by King where we are not in breach, the King Agreement provides for the transition of development and marketing of the licensed products from King to us, including the conveyance by King to us of the trademarks and all regulatory filings and approvals solely used in connection with the commercialization of such licensed products and, in certain cases, for King's supply of such licensed products for a transitional period at King's cost plus a mark-up.

The foregoing description of the King Agreement contains forward-looking statements about Acurox® Tablets and other product candidates being developed pursuant to the King 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 the King Agreement will not be terminated by its terms prior to receipt of regulatory approval for any product developed pursuant to the King Agreement. Further, there can be no assurance that any product developed, in whole or in part, pursuant to the King Agreement will receive regulatory approval or prove to be commercially successful. Accordingly, investors in the Company should recognize

that there is no assurance that the Company will receive the milestone payments or royalty revenues described in the King 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. For further discussion of other risks and uncertainties associated with the Company, see “Risk Factors”, above.

On October 12, 2010, Pfizer, Inc. announced a tender offer to acquire all of the outstanding shares of King Pharmaceuticals, Inc. Pfizer's tender offer acquisition of King Pharmaceuticals was completed on January 31, 2011, resulting in King becoming a majority-owned subsidiary of Pfizer. Pfizer has advised that it intends to complete a short-form merger with King on or about February 28, 2011, pursuant to which King will become a wholly-owned subsidiary of Pfizer. King will remain the responsible party under the King Agreement following such merger transaction.

We are a publicly traded New York corporation. Our shares are traded on the Nasdaq Capital Market under the symbol "ACUR".

## USE OF PROCEEDS

Except for the aggregate exercise price of the options exercised by the Selling Stockholders in connection with the sale of the shares offered by this reoffer prospectus and the payment of $0.01 par value per share of common stock upon the distribution of shares in exchange for restricted stock units, we will not receive any of the proceeds from such sales of common stock. All such proceeds will be received by the Selling Stockholders. See "Selling Stockholders."

## SELLING STOCKHOLDERS

We will issue any unissued shares of the common stock being offered by this reoffer prospectus upon the (i) exercise of options to purchase common stock issued to the Selling Stockholders pursuant to our 1995 Stock Option and Restricted Stock Purchase Plan, our 1998 Stock Option Plan; (ii) exercise of options to purchase common stock issued or to be issued to the Selling Stockholders pursuant to our 2008 Stock Option Plan, and (iii) distribution of shares of common stock in satisfaction of Restricted Stock Units issued or to be issued to the Selling Stockholders pursuant to our 2005 Restricted Stock Unit Award Plan.

The following table sets forth certain information regarding the ownership of our common stock by the Selling Stockholders as of the date of this reoffer prospectus, and the number of shares of our common stock being currently being offered by each Selling Stockholder pursuant to this reoffer prospectus. As of February 28, 2011 we had 44,640,268 shares of common stock outstanding.

The inclusion in the table of the individuals named therein shall not be deemed to be an admission that any such individuals are "affiliates". The address of each Selling Stockholder is c/o Acura Pharmaceuticals, Inc., 616 N. North Court, Suite 120 Palatine, Illinois 60067.

| Name of Selling Stockholder | Position in our Company | Number of shares beneficially owned prior to the offering (1) | Number of shares being offered | Number of shares beneficially owned after the Offering | Percentage Ownership After Offering |
|---|---|---|---|---|---|
| Andrew D. Reddick | President and Chief Executive Officer | 2,025,942 (2) | 2,025,942 (2) | -0- | 0 % |
| Robert B. Jones | Senior Vice President and Chief Operating Officer | 695,000 (3) | 695,000 (3) | 0 | 0 % |
| Peter A. Clemens | Senior Vice President and Chief Financial Officer | 725,659 (4) | 720,232 (4) | 5,427 | <1% |
| Albert Brzeczko | Vice President, Technical Affairs of Acura Pharmaceutical Technologies Inc. | 152,000 (5) | 152,000 (5) | | |
| Robert A. Seiser | Vice President, Corporate Controller and Treasurer | 404,503 (6) | 404,503 (6) | 0 | 0 % |
| James F. Emigh | Vice President of Marketing and Administration | 363,400 (7) | 358,900 (7) | 4,500 | <1% |
| Bruce F. Wesson | Director | 72,000 (8) (9) | 72,000 (8)(9) | 0 | 0 % |
| Richard J. Markham | Director | 60,000 (8) (10) | 60,000 (8) 10) | 0 | 0 % |
| Immanuel Thangaraj | Director | 70,000 (8) (11) | 70,000 (8)(11) | 0 | 0 % |
| George K. Ross | Director | 60,000 (12) | 60,000 (12) | 0 | 0 % |
| William G. Skelly | Director | 172,000 (9)(13) | 172,000 (9)(13) | 0 | 0 % |
| William A. Sumner | Director | 181,924 (14) | 181,924 (14) | 0 | 0 % |

(1) Includes Restricted Stock Units (”RSUs”) even though holders of such units have no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying the RSUs until the shares are issued by us

pursuant to the terms of our 2005 Restricted Stock Unit Award Plan (the "RSU Plan"). The amounts for each selling stockholder assume full vesting and exercise of all outstanding options to purchase common stock held by that Selling Stockholder.

(2) Includes (i) 450,000 shares of common stock issuable upon the exercise of options granted under the 1998 Stock Option Plan, which are exercisable in four equal annual installments commencing January 1, 2011 and (ii) 583,333 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 503,472 are exercisable within 60 days of February 1, 2011. Includes 682,500 restricted stock unit awards ("RSUs") granted to Mr. Reddick.

(3) Includes (i) 30,000 shares of common stock issuable upon the exercise of options granted under the 1998 Stock Option Plan of which 30,000 are exercisable within 60 days of February 1, 2011 and (ii) 570,000 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 355,000 are exercisable within 60 days of February 1, 2011. Includes 71,250 RSUs granted to Mr. Jones.

(4) Includes (i) 28,125 shares of common stock issuable upon the exercise of options granted under the 1998 Stock Option Plan, which are exercisable in three equal annual installments commencing January 1, 2012 and (ii) 260,000 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 221,667 are exercisable within 60 days of February 1, 2011. Includes 352,500 RSUs granted to Mr. Clemens. Shares beneficially owned before offering include 5127 shares held by minor children, but shares being sold in offering do not include such number.

(5) Includes (i) 128,000 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 101,333 are exercisable within 60 days of February 1, 2011. Includes 18,000 RSUs granted to Dr. Brzeczko.

(6) Includes (i) 27,400 shares of common stock issuable upon the exercise of options granted under the 1998 Stock Option Plan, which are exercisable in four equal annual installments commencing January 1, 2011 and (ii) 208,000 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 177,333 are exercisable within 60 days of February 1, 2011. Includes 141,750 RSUs granted to Mr. Seiser.

(7) Includes (i) 21,175 shares of common stock issuable upon the exercise of options granted under the 1998 Stock Option Plan, which are exercisable in three equal annual installments commencing January 1, 2012 and (ii) 176,000 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 153,000 are exercisable within 60 days of February 1, 2011. Includes 116,625 RSUs granted to Mr. Emigh.

(8) GCE Holdings LLC, a Delaware limited liability company, was the assignee of all of the 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 among us, GCE Holdings LLC and certain other shareholders, GCE Holdings LLC has the right to designate three of the seven members of the Company's Board of Directors. The Board designees of GCE Holdings LLC are Immanuel Thangaraj, Richard Markham and Bruce Wesson. GCE Holdings beneficially owns 34,564,956 shares including 1,786,481 shares underlying warrants, exercisable at $3.40 per share.

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(9) Includes (i) 2,000 shares of common stock issuable upon the exercise of options granted under the 1995 Stock Option Plan of which 2,000 are exercisable within 60 days of February 1, 2011, (ii) 25,000 shares of common stock issuable upon the exercise of options granted under the 1998 Stock Option Plan of which 25,000 are exercisable within 60 days of February 1, 2011 and (iii) 45,000 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 33,750 are exercisable within 60 days of February 1, 2011. Mr. Wesson's holdings do not include securities held by GCE or by Galen.

(10) Includes (i) 15,000 shares of common stock issuable upon the exercise of options granted under the 1998 Stock Option Plan of which 15,000 are exercisable within 60 days of February 1, 2011 and (ii) 45,000 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 33,750 are exercisable within 60 days of February 1, 2011. Mr. Markham's holdings do not include amounts held by GCE or Care Capital of which Mr. Markham disclaims beneficial ownership.

(11) Includes (i) 25,000 shares of common stock issuable upon the exercise of options granted under the 1998 Stock Option Plan of which 25,000 are exercisable within 60 days of February 1, 2011 and (ii) 45,000 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 33,750 are exercisable within 60 days of February 1, 2011. Mr. Thangaraj's holdings do not include securities held by GCE or by Essex. Mr. Thangaraj disclaims beneficial ownership in securities held by GCE and Essex except to the extent of his pecuniary interest therein.

(12) Includes (i) 15,000 shares of common stock issuable upon the exercise of options granted under the 1998 Stock Option Plan of which 15,000 are exercisable within 60 days of February 1, 2011 and (ii) 45,000 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 33,750 are exercisable within 60 days of February 1, 2011.

(13) Includes (i) 1,000 shares of common stock issuable upon the exercise of options granted under the 1995 Stock Option Plan, all of which are exercisable within 60 days of February 1, 2011, (ii) 26,000 shares of common stock issuable upon the exercise of options granted under the 1998 Stock Option Plan of which 26,000 are exercisable within 60 days of February 1, 2011 and (iii) 45,000 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 33,750 are exercisable within 60 days of February 1, 2011. Includes 75,000 RSUs granted to Mr. Skelly.

(14) Includes (i) 1,000 shares of common stock issuable upon the exercise of options granted under the 1995 Stock Option Plan, all of which are exercisable within 60 days of February 1, 2011, (ii) 16,000 shares of common stock issuable upon the exercise of options granted under the 1998 Stock Option Plan of which 16,000 are exercisable within 60 days of February 1, 2011 and (iii) 45,000 shares of common stock issuable upon the exercise of options granted under the 2008 Stock Option Plan of which 33,750 are exercisable within 60 days of February 1, 2011. Includes 75,000 RSUs granted to Mr. Sumner.

The Company will supplement this prospectus from time to time as required by the rules of the Commission to include certain information concerning the security ownership of the Selling Stockholders or any new Selling Stockholders, the number of shares offered for resale and the position, office or other material relationship which a Selling Stockholder has had within the past three years with the Company or any of its predecessors or affiliates.

## 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;
- 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 will pay all fees and expenses incident to the registration of the shares of common stock. We may 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 legality of the common stock to be offered hereby has been passed upon for us by LeClairRyan, a Virginia professional corporation.

## EXPERTS

The financial statements as of December 31, 2010 and 2009 and for each of the three years in the period ended December 31, 2010 incorporated by reference in this Prospectus have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this reoffer prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and, until the termination of this offering, any future filings we will make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934:

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- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed with the Commission on March 1, 2011.

- Our Current Reports on Form 8-K filed with the Commission on February 14, 2011 and March 1, 2011.

- The description of our common stock contained in Form 8-A filed with the Commission on January 31, 2008 under the Securities Exchange Act of 1934, as amended.

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-8, 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.

8,251,835 SHARES OF COMMON STOCK
ACURA PHARMACEUTICALS, INC.

Common Stock

PROSPECTUS

March 2 , 2011

PART II

INFORMATION REQUIRED IN THE REGISTRATION STATEMENT

ITEM 1. PLAN INFORMATION

Not required to be filed with this Registration Statement.

ITEM 2. REGISTRANT INFORMATION AND EMPLOYEE PLAN ANNUAL INFORMATION

Not required to be filed with this Registration Statement.

ITEM 3. DOCUMENTS INCORPORATED BY REFERENCE

We hereby incorporate by reference into this Registration Statement the following documents filed with the Securities and Exchange Commission (the "Commission"):

1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed with the Commission on March 1, 2011.

2. Our Current Reports on Form 8-K filed with the Commission on February 14, 2011 and March 1, 2011.

3. The description of our common stock contained in Form 8-A filed with the Commission on January 31, 2008 under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

In addition, all documents and reports subsequently filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act after the date hereof and prior to the filing of a Post-Effective Amendment which indicates that all securities offered have been sold or which deregisters all securities then remaining unsold, shall be deemed to be incorporated by reference and to be a part hereof from the date of filing of such documents. Any statement contained in a document incorporated or deemed to be incorporated herein by reference shall be deemed to be modified or superceded for purposes of this Registration Statement to the extent that a statement contained herein or in any subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supercedes that statement. Any such statement so modified or superceded shall not constitute a part of this Registration Statement, except as so modified or superseded.

ITEM 4. DESCRIPTION OF SECURITIES

Not applicable.

ITEM 5. INTERESTS OF NAMED EXPERTS AND COUNSEL

Not Applicable.

ITEM 6. 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 our officers and directors to the fullest extent permitted under the BCL.

Set forth below is Article Ninth of Acura Pharmaceuticals, Inc.’s 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 be 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 interstate, 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.

Section 402(b) of the BCL provides that a corporation may include a provision in its certificate of incorporation limiting the liability of its directors to the corporation or its shareholders for damages for the breach of any duty, except for a breach involving intentional misconduct, bad faith, a knowing violation of law or receipt of an improper personal benefit or for certain illegal dividends, loans or stock repurchases. Article Tenth of our Restated Certificate of Incorporation contains such a provision, applicable to acts or omissions after its effectiveness.

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 acting in his or her capacity as our director or officer. 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 7. EXEMPTION FROM REGISTRATION CLAIMED

Not applicable.

ITEM 8. EXHIBITS

See Index of Exhibits on Page II-7.

ITEM 9. 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 this 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 Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(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 paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the Registration Statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective amendment by these paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in 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 that 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 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.

(h) 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 Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment 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, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 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 March 1, 2011.

ACURA PHARMACEUTICALS, INC.

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

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Andrew Reddick and Peter A. Clemens, or either of them, his true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments (including post-effective amendments) to this Registration Statement, and to file the same, with all Exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission granting unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and deed requisite and necessary to be done in connection with the above premises, and fully for all intents and purposes as he might or could do in person, hereby ratifying and conforming all that said attorney-in-fact and agents, each acting alone, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| Signatures | Title | Date |
|---|---|---|
| /s/ Andrew D. Reddick<br>Andrew D. Reddick | President, Chief Executive Officer<br>and Director | March 1, 2011 |
| /s/ Richard Markham<br>Richard Markham | Director | March 1, 2011 |
| /s/ William G. Skelly<br>William G. Skelly | Director | March 1, 2011 |
| /s/ Bruce F. Wesson<br>Bruce F. Wesson | Director | March 1, 2011 |
| /s/ William Sumner<br>William Sumner | Director | March 1, 2011 |
| /s/ Immanuel Thangaraj<br>Immanuel Thangaraj | Director | March 1, 2011 |
| /s/ George Ross<br>George Ross | Director | March 1, 2011 |
| /s/ Peter A. Clemens<br>Peter A. Clemens | Senior Vice President and<br>Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 1, 2011 |

INDEX OF EXHIBITS

| Number | Description |
|---|---|
| 3.1 | Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on June 25, 2009). |
| 3.2 | Certificate of Amendment Reverse Splitting Common Stock and restating but not changing text of part of Article III of Restated Certificate of Incorporation (incorporated by Reference to Exhibit 3.1 to the Form 8-K filed December 4, 2007) |
| 3.3 | Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on October 12, 2007) |
| 10.1 | Registrant's 1995 Stock Option and Restricted Stock Purchase Plan (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8, File No. 33-98396). |
| 10.2 | Registrant's 1998 Stock Option Plan, as amended (incorporated by reference to Appendix C to the Registrant's Proxy Statement filed on May 12, 2009). |
| 10.3 | Registrant's 2005 Restricted Stock Unit Award Plan, as amended (incorporated by reference to Appendix B to the Registrant's Proxy Statement filed on April 2, 2008). |
| 10.4 | Registrant's 2008 Stock Option Plan, as amended on June 25, 2009 (incorporated by reference to Appendix B to our Proxy Statement filed on May 12, 2009) |
| 23.1 | Consent of BDO USA, LLP |
| 24.1 | Power of Attorney (included on the signature page hereto) |