REPROS THERAPEUTICS INC.
Form S-3
September 28, 2012

As filed with the Securities and Exchange Commission on September 28, 2012

Registration No. 333-_____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Repros Therapeutics Inc.

(Exact name of registrant as specified in its charter)

State of Delaware	76-0233274
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2408 Timberloch Place, Suite B-7
The Woodlands, Texas 77380
(281) 719-3400

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

Joseph S. Podolski,
President and Chief Executive Officer
Repros Therapeutics Inc.

2408 Timberloch Place, Suite B-7

The Woodlands, Texas 77380

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

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, check the following box: ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

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

Indicate by check mark whether the registrant is a large accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions “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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Unit(1)	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(1)
Common Stock, par value $0.001 per share	2,145,636	$ 15.13	$ 32,463,473	$ 3,720
Total				

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act and based on the average high and low prices per share of common stock on September 24, 2012, as reported on the Nasdaq Stock Market.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

Information contained herein is subject to completion or amendment. A registration statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. This prospectus shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction.

Subject to completion, dated September 28, 2012.

PROSPECTUS

2,145,636 Shares of Common Stock

We originally issued 2,145,636 shares of our common stock, par value $0.001 per share in a private placement on September 7, 2012. This prospectus relates to sales of common stock either by the purchasers in such private placement, or the transfer agent for our common stock on behalf of such purchasers. The selling stockholders may offer and sell any of the shares of common stock from time to time at fixed prices, at market prices or at negotiated prices, and may engage a broker, dealer or underwriter to sell the shares of common stock. For additional information on the possible methods of sale that may be used by the selling stockholders, read the section entitled “Plan of Distribution” beginning on page 20. We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders. We will pay all expenses incurred in effecting the registration statement of which this prospectus constitutes a part.

Our common stock is traded on The Nasdaq Stock Market, LLC under the symbol “RPRX”. On September 24, 2012, the closing price for our common stock was $14.94 per share.

Investing in our common stock involves risks. You should carefully review the information contained in this prospectus under the heading “Risk Factors” beginning on page 3.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF

THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is _____.

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About This Prospectus

You should rely only on the information contained in or incorporated by reference in this prospectus and any applicable prospectus supplement. We have not authorized anyone to provide you with different or additional information. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of securities described in this prospectus. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any prospectus supplement, as well as information we have previously filed with the Securities and Exchange Commission ("SEC") and incorporated by reference herein, is accurate as of the date on the front of those documents only. Our business, financial condition, results of operations and prospects may have changed since those dates.

Forward Looking Information

This prospectus contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"). "Forward-looking statements" are those statements that are not of historical fact, but describe management's beliefs and expectations. We have identified many of the forward-looking statements in this prospectus by using words such as "anticipate," "believe," "could," "estimate," "may," "expect," and "intend." Although we believe these beliefs and expectations are reasonable, our operations involve a number of risks and uncertainties, including those described in the "Risk Factors" section of this prospectus and other documents filed with the SEC. Therefore, our actual results could differ materially from those discussed in this prospectus and such other documents.

SUMMARY

This is only a summary and does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, including the "Risk Factors" section and the information incorporated by reference from our other filings with the SEC.

General

Repros Therapeutics Inc. (the "Company," "Repros," or "we," "us" or "our") was organized on August 20, 1987. We are a development stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. Both of our product candidates have exhibited strong efficacy results in every study completed to date, and we believe the studies presently underway or scheduled to start in 2012 will place both programs on a clear late stage clinical development path.

We are developing Androxal®, an oral therapy that normalizes testicular function, for the treatment of low testosterone due to secondary hypogonadism. Secondary hypogonadism is associated with obesity and we believe it is among the most common causes of low testosterone in men. It is estimated that 13 million men in the U.S. experience low levels of testosterone, and the condition is becoming recognized with more frequency. As of 2010, sales of preparations for the treatment of low testosterone have exceeded $1 billion in the U.S. and first tier pharmaceutical companies have entered the low testosterone marketplace.

We believe Androxal® is highly differentiated from currently marketed testosterone treatments or those treatments in late stage development because it is an oral therapy and it treats the cause of secondary hypogonadism, which is inadequate pituitary hormones. We believe that by treating the cause of secondary hypogonadism, Androxal® also has the potential to maintain reproductive status and potentially improve overall metabolic profiles.

In December 2011, we completed a Phase 2B study of Androxal® in men with secondary hypogonadism, but naïve to testosterone treatment, at the Food and Drug Administration's (the "FDA") recommendation. Top line results of this study demonstrated that Androxal® was generally well tolerated compared to placebo and that there were no drug related serious adverse events that led to discontinuation. We met with the FDA in May 2012 to discuss the design of pivotal Phase 3 efficacy studies for Androxal® as well as the components of the overall drug development program required for a New Drug Application ("NDA") submission. During this meeting, we agreed upon registration requirements for Androxal® oral therapy for the treatment of secondary hypogonadism. On July 9, 2012, we announced that we reached an agreement with the FDA for the design of the pivotal efficacy studies for Androxal®

for the treatment of secondary hypogonadism. The two identical Phase 3 pivotal studies are being conducted under a Special Protocol Assessment ("SPA") and enrollment is currently underway for the first Phase 3 study with enrollment for the second Phase 3 study to begin upon full enrollment of the first study. The FDA has agreed that we may conduct both Phase 3 pivotal studies at the same clinical sites as long as the two studies have a distinct principal investigator. Additionally, we began enrolling men into a 500 subject open label safety study in June 2012 and, as of mid-September 2012, have 158 men enrolled in this study. The Company has also begun enrolling men into a one year dual-energy X ray absorptiometry ("DEXA") study in the third quarter of 2012. Depending on study enrollment and the completion of other studies, we believe we may be able to submit an NDA in the first half of 2014.

We are also developing Proellex®, an orally administered selective blocker of the progesterone receptor in women, for the treatment of uterine fibroids and endometriosis. Uterine fibroids and endometriosis affect millions of women of reproductive age. Proellex® has shown statistically significant results in previous Phase 2 studies for endometriosis and uterine fibroids. We completed a low dose escalating study as permitted by the FDA in late 2011, to determine both signals of efficacy and safety for low oral doses of the drug. There was no evidence of elevations of liver enzymes over baseline, suggesting these lower doses avoid the type of adverse events seen at much higher doses in earlier studies. The FDA has agreed to update the full clinical hold to a partial clinical hold once an agreement is reached on the design of a Phase 2 study protocol. On July 16, 2012, we announced that we held a teleconference with the FDA to discuss the development of oral Proellex® as a treatment for endometriosis, with another meeting scheduled for the last week of August 2012, as per our July 30, 2012 announcement, to discuss the design of a Phase 2 endometriosis protocol for low dose oral Proellex®. On August 27, 2012, we announced that we had received guidance on the Phase 2 study of low dose oral Proellex® from the FDA on the trial patient population and several endpoints, including reduction in narcotic usage to control endometriosis related pelvic pain and reduction in individual elements of endometriosis related pain and overall analgesic usage. We intend to commence a Phase 2 low dose oral administration study for endometriosis in the fourth quarter of 2012, if the protocol is acceptable to the FDA.

The FDA has accepted an Investigational New Drug Application ("IND") for vaginally delivered Proellex® and, as a result, we commenced a Phase 2 vaginal administration study for uterine fibroids in the first quarter of 2012. At the end of July 2012, we satisfied our enrollment requirement of subjects for the Phase 2 study and intend to report the results around the end of 2012. We will then request an end of Phase 2 meeting with the FDA, so that we can commence a Phase 3 vaginal administration study for uterine fibroids in the first quarter of 2013. Additionally, we have begun enrolling subjects who completed the Phase 2 study into a one year open label safety trial in order to begin collecting long term safety data which we expect the FDA to require in connection with the submission of an NDA.

As of June 30, 2012, we had accumulated losses of $197.3 million, approximately $9.9 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $1.4 million.

Our offices are located at 2408 Timberloch Place, Suite B-7 The Woodlands, Texas 77380. Our phone number is (281) 719-3400 and our website is located at www.reprosrx.com. Information contained on our website is not part of this prospectus.

Recent Developments

On September 7, 2012, we completed a private placement of 2,145,636 shares of our common stock. Net proceeds to us, after deducting offering expenses, were $23.1 million. We anticipate that our current liquidity will be sufficient through the middle of 2014 for completing the necessary clinical studies required for the submission of an NDA for Androxal ®, move Proellex® into Phase 3 and general corporate purposes. We continue to explore potential additional financing alternatives (including corporate partnering opportunities); however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all.

RISK FACTORS

An investment in the securities offered by this prospectus involves a high degree of risk. You should consider carefully the following risk factors in addition to the other information contained in this prospectus before making a decision to invest in our common stock.

Risks Relating to Our Business

Our ability to continue our development efforts as planned require that we raise additional funds no later than the middle of 2014, without which we may need to cease our business operations and begin liquidation proceedings.

Based upon the successful completion of our recent financing and our current expense and revenue assumptions, we anticipate that we will need to obtain additional financing no later than the middle of 2014. If our expenses are greater than expected or our clinical trials take longer than expected, we may be required to raise additional funds prior to that time. We will continue to explore various financing alternatives to address our liquidity needs. No assurance can be given that we will be successful in obtaining additional financing on acceptable terms or at all. We anticipate that if we are able to secure additional financing, that such financing will result in significant dilution of the ownership interests of our stockholders and may provide certain rights to the new investors senior to the rights of our current stockholders, including but not limited to, voting rights and rights to proceeds in the event of a sale or liquidation of the Company. We expect to continue to incur significant losses for the foreseeable future, and we may never achieve or sustain profitability. In the event that we are unable to obtain adequate financing to conduct operations, we may need to cease our business operations and begin liquidation proceedings. If we need to liquidate our assets, we would likely realize significantly less from them than the values at which they are carried on our financial statements. The funds resulting from the liquidation of our assets would be used first to pay off the debt owed to any secured and unsecured creditors before any funds would be available to pay our stockholders, and any shortfall in the proceeds would directly reduce the amounts available for distribution, if any, to our creditors and to our stockholders. In the event we were required to liquidate, it is highly unlikely that stockholders would receive any value for their shares.

If we fail to obtain the capital necessary to fund our operations, we may have to delay, reduce or eliminate our research and development programs or commercialization efforts, dispose of assets or liquidate.

We expect to make additional capital outlays and to increase operating expenditures over the next several years to support our preclinical development and clinical trial activities, particularly with respect to clinical trials for Androxal® and Proellex®. Based on our current and planned clinical programs, we expect to need to raise additional capital no later than the middle of 2014 or earlier if our expenses are greater than anticipated. We will continue to seek additional funding through public or private financings, including equity or debt financings, and/or through other

means, including collaborations and license agreements. We do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on terms favorable to our stockholders or us. In recent years, the general economic and capital market conditions in the United States have deteriorated significantly and have increased the cost of capital, and there is no certainty that a recovery in the capital and credit markets, enabling us to raise capital in an amount to sufficiently fund our long-term plans, will occur in 2012 or beyond. If these economic conditions continue or become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. If we cannot raise adequate funds, we may be required to:

- delay, reduce the scope of or eliminate one or more of our development programs;
- relinquish, license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves at an earlier stage or on terms that are less favorable than might otherwise be available; or
- liquidate and dissolve our company.

Our future capital requirements will depend upon a number of factors, including:

- the size, complexity, results and timing of our clinical programs;
- the cost to obtain sufficient supply of the compounds necessary for our product candidates at a reasonable cost;
- the time and cost involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- competing technological and market developments.

These factors could result in variations from our currently projected operating and liquidity requirements.

Because the data from our preclinical studies and early clinical trials for our product candidates are not necessarily predictive of future results, we can provide no assurances that any of them will have favorable results in clinical trials or receive regulatory approval.

Before we can obtain regulatory approval for the commercial sale of any product candidate that we develop, we are required to complete preclinical development and extensive clinical trials in humans to demonstrate its safety and efficacy. To date, long-term safety and efficacy have not been demonstrated in clinical trials for any of our product candidates and, in fact, our product candidate Proellex® is currently on partial clinical hold with the FDA due to safety issues experienced in our earlier Phase 2 and Phase 3 clinical trials for endometriosis and uterine fibroids, respectively.

In addition, previous clinical trials for Androxal® have been conducted only in limited numbers of patients that may not fully represent the diversity present in larger populations. In addition, these studies have not been subjected to the exacting design requirements typically required by FDA for pivotal trials. Thus the limited data we have obtained may not predict results from studies in larger numbers of patients drawn from more diverse populations, and may not predict the ability of Androxal® to treat testosterone deficiency. We will be required to demonstrate through larger-scale clinical trials that these product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale.

Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials analyzed with more rigorous statistical methods, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays,

modifications or abandonment of ongoing or future clinical trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data; such data may be subject to change following a more comprehensive review of the data related to the applicable clinical trial. If Androxal®, Proellex®, or any other potential future product candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, we would experience potentially significant delays in, or be required to abandon, development of that product candidate. If we delay or abandon our development efforts related to Androxal® or Proellex®, we may not be able to generate sufficient revenues or raise the additional capital necessary to continue operations or become profitable.

We have a history of operating losses, and we expect to incur increasing net losses and may not achieve or maintain profitability for some time or at all.

We have experienced significant operating losses in each fiscal year since our inception. As of June 30, 2012, we had accumulated losses of $197.3 million, approximately $9.9 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $1.4 million. On September 7, 2012, we completed a private placement of 2,145,636 shares of our common stock, which resulted in net proceeds to us, after deducting offering expenses, of $23.1 million. As a result we believe we have sufficient cash to continue our clinical trials through the middle of 2014.

We expect to continue incurring net losses and we may not achieve or maintain profitability for some time if at all. As we increase expenditures for the clinical development of our products, we expect our total operating losses to increase for at least the next few years. Our ability to achieve profitability will depend on, among other things, successfully completing the development of our products, obtaining regulatory approvals, establishing marketing, sales and manufacturing capabilities or collaborative arrangements with others that possess such capabilities, and raising sufficient funds to finance our activities. There can be no assurance that we will be able to achieve profitability or that profitability, if achieved, can be sustained.

Raising additional funds by issuing securities or through collaboration and licensing arrangements may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.

We may raise additional funds through public or private equity offerings, debt financings or potential corporate collaborations and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities, our stockholders' ownership will be diluted. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. In addition, if we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. For example, we might be forced to relinquish all or a portion of our sales and marketing rights with respect to Androxal®, Proellex®, or other potential products or license intellectual property that enables licensees to develop competing products.

Our stock price could decline significantly based on the results and timing of clinical trials of, and decisions affecting, our product candidates.

Results of clinical trials and preclinical studies of our current and potential product candidates may not be viewed favorably by us or third parties, including the FDA or other regulatory authorities, investors, analysts and potential collaborators. The same may be true of how we design the clinical trials of our product candidates and regulatory decisions affecting those clinical trials. Biopharmaceutical company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when a product candidate did not otherwise meet expectations. The final results from our clinical development programs may be negative, may not meet expectations or may be perceived negatively. The designs of our clinical trials (which may change significantly and be more expensive than currently anticipated depending on our clinical results and regulatory decisions) may also be viewed negatively by third parties. We may not be successful in completing these clinical trials on our projected timetable, if at all.

Failure to initiate additional clinical trials or delays in existing clinical trials of Androxal® and Proellex®, and failure of the FDA to lift the partial clinical hold on Proellex®, or unfavorable results or decisions or negative perceptions regarding any of such clinical trials, could cause our stock price to decline significantly.

We are thinly staffed and highly dependent on a limited number of management persons and key personnel, and if we lose these members of our team or are unable to attract and retain additional qualified personnel, our future growth and ability to compete would suffer.

The competition for qualified personnel in the biopharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. We had only 18 full-time employees at June 30, 2012, including our President and Chief Executive Officer, Joseph S. Podolski. We are highly dependent on Mr. Podolski and our professional staff for the management of our company and the development of our technologies. Mr. Podolski has an employment agreement with us. There can be no assurance that any of these employees will remain with us through development of our current product candidates. The loss of the services of any of our employees could delay or curtail our research and product development efforts.

Our plan to use collaborations to leverage our capabilities may not be successful.

As part of our business strategy, we may enter into collaboration arrangements with strategic partners to develop and commercialize our product candidates. For our collaboration efforts to be successful, we must identify partners whose competencies complement ours. We must also successfully enter into collaboration agreements with them on terms attractive to us and integrate and coordinate their resources and capabilities with our own. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements. In addition, we may face a disadvantage in seeking to enter into or negotiating collaborations with potential partners because other potential collaborators may have greater management and financial resources than we do. Also, we may be unsuccessful in integrating the resources or capabilities of these collaborators. In addition, our collaborators may prove difficult to work with or less skilled than we originally expected. If we are unsuccessful in our collaborative efforts, our ability to develop and market product candidates could be severely limited.

Risks Relating to Our Product Development Efforts

Changes in existing regulations and the adoption of new regulations may increase our costs and otherwise adversely affect our business, results of operations and financial condition.

Our research and development activities, preclinical studies and clinical trials, and the manufacturing, marketing and labeling of any products we may develop, are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates or materially increase our costs. Delays in obtaining or rejections of regulatory approvals would adversely affect our ability to commercialize any product candidate we develop and our ability to receive product revenues or to receive milestone payments or royalties from any product rights we might license to others. If regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed or may be conditioned on the conduct of post-marketing surveillance studies.

Delays in the commencement of preclinical studies and clinical trials testing of our current and potential product candidates could result in increased costs to us and delay our ability to generate revenues.

Our product candidates will require continued preclinical studies and extensive clinical trials prior to the submission of a regulatory application for commercial sales. Because of the nature of clinical trials and our lack of sufficient capital, we do not know whether future planned clinical trials will begin on time, if at all. Delays in the commencement of preclinical studies and clinical trials could significantly increase our product development costs and delay any product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the

commencement of clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

The commencement of clinical trials can be delayed for a variety of reasons, including delays or failures in:

- demonstrating sufficient safety and efficacy in past clinical trials to obtain regulatory approval to commence a further clinical trial;
- convincing the FDA that we have selected valid endpoints for use in proposed clinical trials;
- reaching agreements on acceptable terms with prospective contract manufacturers for manufacturing sufficient quantities of a product candidate; and
- obtaining institutional review board approval to conduct a clinical trial at a prospective site.

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In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial.

Delays in the completion of, or the termination of, clinical testing of our current and potential product candidates could result in increased costs to us, and could delay or prevent us from generating revenues.

Once a clinical trial has begun, it may be delayed, suspended or terminated by us or the FDA or other regulatory authorities due to a number of factors, including:

- lack of adequate funding to continue clinical trials;
- lack of effectiveness of any product candidate during clinical trials;
- side effects experienced by trial participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a trial, or “clinical holds” or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, after a trial is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;

- unfavorable results from on-going clinical trials and preclinical studies;

- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise fail to perform their services in a timely or acceptable manner;

- scheduling conflicts with participating clinicians and clinical institutions;

- failure to construct appropriate clinical trial protocols;

- insufficient data to support regulatory approval;

- inability or unwillingness of medical investigators to follow our clinical protocols;

- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data;

- the timing of discussions and meetings with the FDA or other regulatory authorities regarding the scope or design of our clinical trials; and

- acceptability to the FDA of data obtained from clinical studies conducted in Europe or other non-United States jurisdictions.

Many of these factors that may lead to a delay, suspension or termination of clinical testing of a current or potential product candidate may also ultimately lead to denial of regulatory approval of a current or potential product candidate. In fact, the FDA placed Proellex® on clinical hold in summer 2009 due to liver toxicity data resulting from our clinical trials. Though the full clinical hold has been upgraded to a partial clinical hold, there can be no assurance that the partial hold will be lifted at any time.

If we experience delays in the completion of, or termination of, clinical testing of any product candidates in the future, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed.

Even if we successfully complete clinical trials for Androxal® and Proellex®, there are no assurances that we will be able to submit, or obtain FDA approval of, a new drug application.

There can be no assurance that, if our clinical trials for Androxal® and Proellex® are successfully completed, we will be able to submit an NDA to the FDA or that any NDA we submit will be approved by the FDA in a timely manner, if at all. After completing clinical trials for a product candidate in humans, a drug dossier is prepared and submitted to the FDA as an NDA, and includes all preclinical studies and clinical trial data relevant to the safety and effectiveness of the product at the suggested dose and duration of use for the proposed indication, in order to allow the FDA to review such drug dossier and to consider a product candidate for approval for commercialization in the United States. If we are unable to submit an NDA with respect to Androxal® or Proellex®, or if any NDA we submit is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject NDAs and requires additional clinical trials, even when drug candidates achieve favorable results in large-scale Phase 3 clinical trials. If we fail to commercialize Androxal® or Proellex®, we may be unable to generate sufficient revenues to continue operations or attain profitability and our reputation in the industry and in the investment community would likely be damaged.

We rely on third parties to conduct clinical trials for our product candidates, and their failure to timely and properly perform their obligations may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing our product candidates.

We rely on independent contractors, including researchers at clinical research organizations (“CROs”), and universities, in certain areas that are particularly relevant to our research and product development plans, such as for data management for the conduct of clinical trials. The competition for these relationships is intense, and we may not be able to maintain our relationships with them on acceptable terms. Independent contractors generally may terminate their engagements at any time, subject to notice. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time conducting research on and trials of our product candidates and assisting in developing them. If they do not successfully carry out their duties under their agreements with us, fail to inform us if these trials fail to comply with clinical trial protocols, or fail to meet expected deadlines, our clinical trials may need to be extended, delayed or terminated. We may not be able to enter into replacement arrangements without undue delays or excessive expenditures. If there are delays in testing or regulatory approvals as a result of the failure to perform by our independent contractors or other outside parties, our drug development costs will increase and we may not be able to attain regulatory approval for or successfully commercialize our product candidates.

In addition, we have no control over the financial health of our independent contractors. Several of our independent contractors are in possession of valuable and sensitive information relating to the safety and efficacy of our product candidates, and several others provide services to a significant percentage of the patients enrolled in the respective clinical trials in which such independent contractors participate. Should one or more of these independent contractors become insolvent, or otherwise are not able to continue to provide services to us, as a result of the current economic downturn or otherwise, the clinical trial in which such contractor participates could become significantly delayed and we may be adversely affected as a result of the delays and additional expenses associated with such event.

The risk of accidental contamination or injury resulting from our handling and disposing of hazardous materials and chemicals may expose us to litigation.

Our research and development involves the controlled use of hazardous materials and chemicals. Although we believe that our procedures for handling and disposing of those materials comply with state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If such an accident occurs, we could be held liable for resulting damages, which could have a material adverse effect on us.

Risks Relating to Manufacturing Our Products

We currently rely on third-party manufacturers and other third parties for production of our product candidates, and our dependence on these manufacturers may impair the development of our product candidates.

Currently, we do not have the ability internally to manufacture the product candidates that we need to conduct our clinical trials. We terminated our supply agreement with Gedeon Richter for the manufacturing of Proellex® due to the clinical hold imposed by the FDA in August 2009; however, we have a large supply of Proellex® currently available for our current and planned clinical trial efforts. In the event we require an additional supply of Proellex®, we believe that we have maintained a good relationship with Gedeon Richter and that an agreement could be reached with Gedeon Richter to provide such supply when and if needed, but we cannot assure you this will be the case.

We have a supply agreement with Diagnostic Chemical Limited, doing business as BioVectra, for the supply of the bulk active pharmaceutical ingredient used in Androxal®. This agreement runs through July of 2013, subject to automatic one year renewals and the ability of either party to terminate upon 12 months prior notice. We have obtained all of our supply of Androxal® to date from BioVectra. We have not faced any material problems with BioVectra in supplying us with our necessary quantities of Androxal® for our clinical trials and anticipate utilizing them for commercial production if Androxal® is approved. The Company believes that should an issue with BioVectra arise an alternative supplier could be identified, but we cannot assure you this will be the case.

For the foreseeable future, we expect to continue to rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of Androxal®, Proellex®, and any future product candidates for use in our clinical trials. These product candidates are complicated and expensive to manufacture. If our third-party manufacturers fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for these product candidates, this process would likely cause a delay in the availability of our product candidates and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which our product candidates can be produced, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates.

Identification of previously unknown problems with respect to a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility.

The FDA stringently applies regulatory standards for the manufacturing of our products. Identification of previously unknown problems with respect to a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including warning letters, suspensions of regulatory approvals, operating restrictions, delays in obtaining new product approvals, withdrawal of the product from the market, product recalls, fines, injunctions and criminal prosecution. Any of the foregoing could have a material adverse effect on us.

Our product candidates have only been manufactured in small quantities to date, and we may face delays or complications in manufacturing quantities of our product candidates in sufficient quantities to meet the demands of late stage clinical trials and marketing.

We cannot assure that we will be able to successfully increase the manufacturing capacity or scale-up manufacturing volume per batch, whether on our own or in reliance on third-party manufacturers, for any of our product candidates in a timely or economical manner, or at all. To date our product candidates have been manufactured exclusively by third parties in small quantities for preclinical studies and clinical trials. Future clinical trials of our product candidates, if any, will require increased quantities for future commercial sales in the event that such product candidates are approved by the FDA or foreign regulatory bodies. Significant scale-up of manufacturing requires certain additional developmental work, which the FDA must review and approve to assure product comparability. If we or our third-party manufacturers are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply of that product candidate.

Our product candidates require precise, high-quality manufacturing which may not be available at acceptable costs.

Androxal® and Proellex® are novel compounds that have never been produced in large scale. As in the development of any new compound, there are underlying risks associated with their manufacture. These risks include, but are not limited to, cost, process scale-up, process reproducibility, construction of a suitable process plant, timely availability of raw materials, as well as regulatory issues associated with the manufacture of an active pharmaceutical agent. Any of these risks may prevent us from successfully developing Androxal® or Proellex®. Our failure, or the failure of our third-party manufacturers to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors and reliable product packaging for diverse environmental conditions, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.

We may experience delays in the development of our product candidates if the third-party manufacturers of our product candidates cannot meet FDA requirements relating to Good Manufacturing Practices.

Our third-party manufacturers are required to produce our product candidates under FDA current Good Manufacturing Practices in order to meet acceptable standards for our clinical trials. If such standards change, the ability of third-party manufacturers to produce our product candidates on the schedule we require for our clinical trials may be affected. In addition, third-party manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to gain approval for or commercialize our product candidates. Any difficulties or delays in the manufacturing and supply of our product candidates could increase our costs or cause us to lose revenue or postpone or cancel clinical trials.

The FDA also requires that we demonstrate structural and functional comparability between the same drug product produced by different third-party manufacturers. Because we may use multiple sources to manufacture Androxal® and Proellex®, we may need to conduct comparability studies to assess whether manufacturing changes have affected the product safety, identity, purity or potency of any commercial product candidate compared to the product candidate used in clinical trials. If we are unable to demonstrate comparability, the FDA could require us to conduct additional clinical trials, which would be expensive and significantly delay commercialization of our product candidates.

Risks Relating to Product Commercialization

If commercialized, our product candidates may not be approved for sufficient governmental or third-party reimbursements, which would adversely affect our ability to market our product candidates.

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicaid, Medicare and private payers for Proellex® and Androxal®. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes requirements for the distribution and pricing of prescription drugs, which may negatively affect the marketing of our potential products.

If we successfully develop products but those products do not achieve and maintain market acceptance, our business will not be profitable.

Even if our product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payers and our profitability and growth will depend on a number of factors, including:

- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability, effectiveness and cost of alternative treatments;
- pricing and cost effectiveness of our drugs;
- effectiveness of our or collaborators' sales and marketing strategies; and
- our ability to obtain sufficient third-party insurance coverage or reimbursement.

If Androxal® does not provide a treatment regime that is more beneficial than AndroGel®, the current standard of care for the treatment of testosterone deficiency, or otherwise provide patient benefit, it likely will not be accepted favorably by the market. If any products we may develop do not achieve market acceptance, then we will not generate sufficient revenue to achieve or maintain profitability.

In addition, even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if:

- new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete;
- unforeseen complications arise with respect to use of our products; or

- sufficient third-party insurance coverage or reimbursement does not remain available.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our profitability.

Our liability insurance may neither provide adequate coverage nor may it always be available on favorable terms or at all.

Neither Androxal® nor Proellex® has been approved for commercial sale. However, the current and future use of our product candidates by us and potential corporate collaborators in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made directly by consumers or healthcare providers or indirectly by pharmaceutical companies, potential corporate collaborators or others selling such products. We may experience financial losses in the future due to product liability claims. We have obtained limited general commercial liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or for liabilities in excess of our insurance limits, our assets may not be sufficient to cover such claims and our business operations could be impaired.

We face significant competition from many companies with substantially greater resources than we have and other possible advantages.

We are engaged in biopharmaceutical product development, an industry that is characterized by extensive research efforts and rapid technological progress. The biopharmaceutical industry is also highly competitive. Our success will depend on our ability to acquire, develop and commercialize products and our ability to establish and maintain markets for any products for which we receive marketing approval. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies. Many of our competitors have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we do. Accordingly, our competitors may:

- develop or license products or other novel technologies that are more effective, safer or less costly than the product candidates that we are developing;
- obtain regulatory approval for products before we do; or
- commit more resources than we can to developing, marketing and selling competing products.

Our main competitors for the treatment of testosterone deficiency are the testosterone replacement therapies currently being marketed. The current standard of care is AndroGel®, a topical gel for the replacement of testosterone developed by Solvay Pharmaceuticals (which was acquired by Abbott Laboratories). Abbott is a much larger company than we are, with greater resources and marketing ability. Androxal® would also compete with other forms of testosterone replacement therapies such as oral treatments, patches, injectables and a tablet applied to the upper gum. There is another topical gel currently marketed by Auxilium Pharmaceuticals called Testim®, and a transdermal patch marketed by Watson Pharmaceuticals called AndroDerm®. Eli Lilly and Company also entered into a licensing agreement with a third party for a late stage topical testosterone treatment called Axiron®, which has recently become available in pharmacies. There can be no assurance that our product candidates will be more successful than competitive products. In addition, other potential competitors may be developing testosterone therapies similar to ours.

The main therapeutic products competitive with Proellex® for the treatment of uterine fibroids and endometriosis are GnRH agonists, including Lupron® and the use of approved progestin-based contraceptives for the treatment of endometriosis. In addition, surgical treatment of both uterine fibroids and endometriosis would compete with Proellex®, if approved, by removing uterine fibroids and by removing misplaced tissue in women with endometriosis. Furthermore, Abbott has recently licensed a Phase 3–ready molecule from Neurocrine Biosciences Inc. for the treatment of endometriosis. Gedeon Richter and Watson Pharmaceuticals have also entered into an exclusive license agreement to develop and market Esmya™ (an orally selective progesterone receptor modulator) in the U.S. and Canada.

Risks Relating to Our Intellectual Property

There is a third party individual patent holder that claims priority over our patent application for Androxal®.

A third party individual holds two issued patents related to the use of an anti-estrogen such as clomiphene citrate and others for use in the treatment of androgen deficiency and disorders related thereto. We requested re-examination of one of these patents by the U.S. Patent and Trademark Office ("PTO") based on prior art. The patent holder amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims were patentable in view of those publications under consideration and a re-examination certificate was issued. We subsequently filed a second request for re-examination by the PTO in light of a number of additional publications. The request was granted and all of the claims were finally rejected by the PTO in the re-examination. The patent holder appealed the rejections to the PTO Board of Patent Appeals and Interferences (the "PTO Board") which ultimately reversed the rejections of several dependent claims in view of those publications under consideration. The patent holder filed a Notice of Appeal to the Federal Circuit on September 28, 2010 contesting the rejections maintained by the PTO Board. A decision was rendered by the Federal Circuit on December 12, 2011, affirming the rejection of the appealed claims. We expect that a re-examination certificate will be issued confirming the patentability of the remaining claims; however, if such a re-examination certificate were to issue, we believe that our development of Androxal® would not infringe any of the remaining claims and that all of the remaining claims are invalid on various grounds including additional prior art publications. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. If necessary, we intend to vigorously defend any and all claims, against the holder of such patents in a court of competent jurisdiction in order to develop Androxal® further. Adverse determinations in litigation proceedings could require us to seek licenses which may not be available on commercially reasonable terms, or at all, or subject us to significant liabilities, in which case we may not be able to successfully commercialize or out-license Androxal® until such patents expire or are otherwise no longer in force.

We licensed our rights to Proellex® from the NIH and our inability to fulfill our commitments and obligations under such license may result in forfeiture of our rights.

Our rights to Proellex® are licensed exclusively to us from the NIH under a license agreement. This license agreement contains numerous detailed performance obligations, with time sensitive dates for compliance, relating to clinical development and commercialization activities required by us or our designated third-party providers, as well as additional financial milestones and royalties. Failure to achieve the benchmarks specified in the commercial development plan attached to the license agreement or meet payment obligations could result in termination of the license agreement and the loss of our rights to develop and commercialize Proellex®. We periodically update the commercial development plan as such plans evolve. There can be no assurance that we will be able to meet any or all of the performance objectives in the future on a timely basis or at all, or that, if we fail to meet any of such objectives, the NIH will agree to revised objectives. The NIH also has the ability to terminate the agreement for an uncured material breach of the agreement, if we do not keep Proellex® reasonably available to the public after commercial launch or if we cannot reasonably satisfy unmet health and safety needs, among other reasons.

There can be no assurance that our manufacture, use or sale of our product candidates will not infringe on the patent rights of others.

There can be no assurance that the manufacture, use or sale of any of our product candidates will not infringe the patent rights of others. We may be unable to avoid infringement of the patent rights of others and may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. There can be no assurance that a license to the allegedly infringed patents will be available to us on terms and conditions acceptable to us, if at all, or that we will prevail in any patent litigation. Patent litigation is extremely costly and time-consuming, and there can be no assurance that we will have sufficient resources to defend any possible litigation related to such infringement. If we do not obtain a license on acceptable terms under such patents, or are found liable for infringement, or are not able to have such patents declared invalid, we may be liable for significant money damages, may encounter significant delays in bringing our product candidates to market, or may be precluded from participating in the manufacture, use or sale of any such product candidates, any of which would materially and adversely affect our business.

A dispute regarding the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be costly and result in delays in our research and development activities.

Our commercial success depends upon our ability to develop and manufacture our product candidates and market and sell drugs, if any, and conduct our research and development activities without infringing or misappropriating the proprietary rights of others. We may be exposed to future litigation by others based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. Numerous United States and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for

the therapeutic targets for, which we are developing drugs. These could materially affect our ability to develop our product candidates or sell drugs, and our activities, or those of our licensor or future collaborators, could be determined to infringe these patents. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our product candidates or technologies may infringe. Further, there may be issued patents and pending patent applications in fields relevant to our business, of which we are or may become aware, that we believe we do not infringe or that we believe are invalid or relate to immaterial portions of our overall drug discovery and development efforts. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seeking to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

In addition, others may infringe or misappropriate our proprietary rights, and we may have to institute costly legal action to protect our intellectual property rights. We may not be able to afford the costs of enforcing or defending our intellectual property rights against others. There could also be significant litigation and other administrative proceedings in our industry that affect us regarding patent and other intellectual property rights. Any legal action or administrative action against us, or our collaborators, claiming damages or seeking to enjoin commercial activities relating to our drug discovery and development programs could:

- require us, or potential collaborators, to obtain a license to continue to use, manufacture or market the affected drugs, methods or processes, which may not be available on commercially reasonable terms, if at all;

- prevent us from importing, making, using, selling or offering to sell the subject matter claimed in patents held by others and subject us to potential liability for damages; or

- consume a substantial portion of our managerial, scientific and financial resources; or be costly, regardless of the outcome.

Furthermore, because of the substantial amount of pre-trial documents and witness discovery required in connection with intellectual property litigation, there is risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

We face substa*n*tial uncertainty in our ability to protect our patents and proprietary technology.

Our ability to commercialize our products will depend, in part, on our or our licensor’s ability to obtain patents, to enforce those patents and preserve trade secrets, and to operate without infringing on the proprietary rights of others. The patent positions of biopharmaceutical companies are highly uncertain and involve complex legal and factual questions. There can be no assurance that:

- patent applications for and relating to our products candidates, Androxal® and Proellex®, will result in issued patents;

- patent protection will be secured for any particular technology;

- any patents that have been or may be issued to us, such as our issued patents and/or pending patent applications relating to Proellex® or Androxal®, or any patents that have been or may be issued to our licensor, such as the patent(s) and application(s) underlying our Proellex® compound, when issued, will be valid and enforceable;

- any patents will provide meaningful protection to us;

- others will not be able to design around the patents; or

- our patents will provide a competitive advantage or have commercial application.

The failure to obtain and maintain adequate patent protection would have a material adverse effect on us and may adversely affect our ability to enter into, or affect the terms of, any arrangement for the marketing of any product.

We cannot assure that our patents will not be challenged by others.

There can be no assurance that patents owned by or licensed to us will not be challenged by others. We could incur substantial costs in proceedings, including interference proceedings before the PTO and comparable proceedings before similar agencies in other countries in connection with any claims that may arise in the future. These proceedings could result in adverse decisions about the patentability of our or our licensor's inventions and products, as well as about the enforceability, validity or scope of protection afforded by the patents. Any adverse decisions about the patentability of our product candidates could cause us to either lose rights to develop and commercialize our product candidates or to license such rights at substantial cost to us. In addition, even if we were successful in such proceedings, the cost and delay of such proceedings would most likely have a material adverse effect on our business.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information, may not adequately protect our intellectual property, and will not prevent third parties from independently discovering technology similar to or in competition with our intellectual property.

We rely on trade secrets and other unpatented proprietary information in our product development activities. To the extent we rely on trade secrets and unpatented know-how to maintain our competitive technological position, there can be no assurance that others may not independently develop the same or similar technologies. We seek to protect trade secrets and proprietary knowledge, in part, through confidentiality agreements with our employees, consultants, advisors, collaborators and contractors. Nevertheless, these agreements may not effectively prevent disclosure of our confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure of such information. If our employees, scientific consultants, advisors, collaborators or contractors develop inventions or processes independently that may be applicable to our technologies, product candidates or products, disputes may arise about ownership of proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may remain the property of those persons or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights. If we fail to obtain or maintain trade secret protection for any reason, the competition we face could increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

We cannot protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on all of our drug discovery technologies and all of our potential drug candidates throughout the world would be prohibitively expensive. Competitors may use our technologies to develop their own drugs in jurisdictions where we have not obtained patent protection. These drugs may compete with our drugs, if any, and may not be covered by any of our patent claims or other intellectual property rights. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a

patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to "work" the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our drug candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which makes it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Risks Related to our Common Stock

Purchasers in this offering will experience immediate and substantial dilution.

As of June 30, 2012, we had a net tangible book value of $8.8 million which yields a net tangible book value of approximately $0.59 per share of common stock, assuming no exercise of any warrants or options. The net tangible book value per share is less than the current market price per share. If you pay more than the net tangible book value per share for common stock in this offering, you will experience immediate dilution. The exercise of outstanding options and the warrants will result in further dilution in your investment. In addition, if we issue additional equity securities in the future, the newly issued securities may further dilute your ownership interest.

The trading price of our common stock has been volatile and is likely to be volatile in the future.

The trading price of our common stock has been highly volatile. Since January 1, 2011 through September 24, 2012, the sale price of our stock price has fluctuated from a low of $2.37 to a high of $16.37. The market price for our common stock will be affected by a number of factors, including:

- the denial or delay of regulatory clearances or approvals of our drug candidates or receipt of regulatory approval of competing products;
- our ability to accomplish clinical, regulatory and other product development milestones;
- the ability of our product candidates, if they receive regulatory approval, to achieve market success;
- the performance of third-party manufacturers and suppliers;
- actual or anticipated variations in our results of operations or those of our competitors;
- developments with respect to our patents and other intellectual property rights;
- sales of common stock or other securities by us or our stockholders in the future;

- additions or departures of key scientific or management personnel;

- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;

- trading volume of our common stock;

- investor perceptions about us and our industry;

- public reaction to our press releases, other public announcements and SEC and other filings;

- the failure of analysts to cover our common stock, or changes in analysts' estimates or recommendations;

- the failure by us to meet analysts' projections or guidance;

- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors; and

- the other factors described elsewhere in these "Risk Factors" or the section titled "Risk Factors" contained in our other public filings.

The stock prices of many companies in the biotechnology industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Following periods of volatility in the market price of a company's securities, securities class action litigation often has been initiated against a company. If any class action litigation is initiated against us, we may incur substantial costs and our management's attention may be diverted from our operations, which could significantly harm our business.

Our inability to comply with the listing requirements of the Nasdaq Capital Market could result in our common stock being delisted, which could affect its market price and liquidity and reduce our ability to raise capital.

We are required to meet certain qualitative and financial tests (including a minimum closing bid price of $1.00 per share for our common stock) to maintain the listing of our common stock on the Nasdaq Capital Market. If we do not maintain compliance with the continued listing requirements for the Nasdaq Capital Market within specified periods and subject to permitted extensions, our common stock may be recommended for delisting (subject to any appeal we would file). If our common stock is delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our common stock could suffer a material decline. Delisting would also impair our ability to raise capital.

Our rights agreement and certain provisions in our charter documents and Delaware law could delay or prevent a change in management or a takeover attempt that you may consider to be in your best interest.

We have adopted certain anti-takeover provisions, including a rights agreement. The rights agreement will cause substantial dilution to any person who attempts to acquire us in a manner or on terms not approved by our board of directors.

The rights agreement and certain provisions in our certificate of incorporation and bylaws and under Delaware law could delay or prevent the removal of directors and other management and could make more difficult a merger, tender offer or proxy contest involving us that you may consider to be in your best interest. For example, these provisions:

- allow our board of directors to issue preferred stock without stockholder approval;
- limit who can call a special meeting of stockholders; and
- establish advance notice requirements for nomination for election to the board of directors or for proposing matters to be acted upon at stockholder meetings.

Use Of Proceeds

The selling stockholders will receive all of the proceeds from the sale of the shares of our common stock covered hereby, or interests therein. We will not receive any proceeds from any such sale made by the selling stockholders or by the transfer agent for the common stock, on behalf of the selling stockholders.

SELLING STOCKHOLDERS

On September 7, 2012, we completed a private placement of an aggregate of 2,145,636 shares of common stock (the "subject shares"), pursuant to a Securities Purchase Agreement dated as of August 31, 2012 (the "Purchase Agreement"), between us and the purchasers identified therein. In connection with the Purchase Agreement, we entered into a Registration Rights Agreement with such purchasers dated as of August 31, 2012, the (the "Registration Rights Agreement"), pursuant to which we agreed to prepare and file a registration statement to register the sale of the subject shares within sixty (60) days following the date of the Registration Rights Agreement, to use our commercially reasonable efforts to have such registration statement declared effective as promptly as reasonably practicable and to maintain such registration statement until the earlier of: (i) the date on which all of the subject shares registered thereunder have been sold, or (ii) the date on which all of the subject shares may be sold pursuant to Rule 144 of the Securities Act, without regard to any volume limitation requirements under Rule 144 of the Securities Act.

Pursuant to the terms of the Registration Rights Agreement, we filed a registration statement on Form S-3, of which this prospectus constitutes a part, in order to permit the selling stockholders to resell to the public any or all of the shares of our common stock issued in connection therewith. When we refer to the "selling stockholders" in this prospectus, we mean the entities listed in the table below, as well as their transferees, pledgees or donees or its respective successors.

The following table, to our knowledge, sets forth information regarding the beneficial ownership of our common stock by the selling stockholders as of September 7, 2012 and the number of shares being offered hereby by the selling stockholders. The information is based in part on information provided by or on behalf of the selling stockholders. Beneficial ownership is determined in accordance with Rule 13d-3 promulgated by the SEC under the Exchange Act, and includes voting or investment power with respect to shares, as well as any shares as to which the selling stockholders have the right to acquire beneficial ownership within sixty (60) days after September 7, 2012, through the exercise or conversion of any stock options, warrants, convertible debt or otherwise. Unless otherwise indicated below, the selling stockholders have sole voting and investment power with respect to their shares of common stock. The inclusion of any shares in this table does not constitute an admission of beneficial ownership by the selling stockholders.

The actual number of shares of common stock that may be sold by the selling stockholders will be determined by the selling stockholders. Because the selling stockholders may sell all, some or none of the shares of common stock which they hold, no estimate can be given as to the number of shares of common stock that will be held by the selling stockholders after completion of the sales. The information set forth in the following table regarding the beneficial ownership after resale of shares is based on the assumption that the selling stockholders will sell all of their shares of common stock covered by this prospectus.

	Shares Beneficially Owned Before Offering(1)		Shares Offered Hereby(2)	**Shares Beneficially Owned After Offering(1)**	
Name of Selling Stockholder	Number	Percent	Number	Number	Percent
Alta Partners VIII, L.P. (3)	546,661	3.22	113,636	433,025	2.55
Baker Bros. Advisors, LLC and its affiliates (4)	1,162,936	6.85	591,000	571,936	3.37
Caduceus Capital Master Fund Limited (5)	229,000	1.35	229,000	0	*
Caduceus Capital II, L.P. (5)	207,000	1.22	207,000	0	*
UBS Eucalyptus Fund, L.L.C. (5)	83,000	*	83,000	0	*
Summer Street Life Sciences Hedge Fund Investors, LLC (5)	72,000	*	72,000	0	*
Quogue Capital LLC (6)	1,685,271	9.93	209,091	1,476,180	8.69
QVT Fund V LP (7)	1,258,922	7.41	159,367	1,099,555	6.48
QVT Fund IV LP (8)	214,596	1.26	27,121	187,475	1.10
Quintessence Fund LP (9)	211,753	1.25	22,603	189,150	1.11
VenBio Select Fund LLC	98,182	*	68,182	30,000	*
VHCP Co-Investment Holdings, LLC (10)	56,232	*	56,232	0	*
Venrock Healthcare Capital Partners, L.P.(10)	307,404	1.81	307,404	0	*
Total			2,145,636		

* Does not exceed 1%.

(1) The percentage of shares beneficially owned is based on 16,979,625 shares of our common stock issued and outstanding as of September 7, 2012, excluding common stock issuable upon the exercise of outstanding options and warrants.

(2) We do not know when or in what amounts a selling stockholder may offer for sale shares of common stock covered by this prospectus. The selling stockholders may not sell any or all of such shares offered by this prospectus. Because the selling stockholders may offer all or some of the shares of common stock covered by this prospectus pursuant to this offering, we cannot estimate the number of shares that will be held by the selling stockholders after completion of this offering. However, for purposes of this table, we have assumed that, after completion of this offering, none of the shares of common stock covered by this prospectus will be held by the selling stockholders.

(3) Alta Partners Management VIII, LLC is the general partner of Alta Partners VIII, L.P. and may be deemed to share the right to direct the voting and dispositive control over the shares held by such fund. Alta Partners Management VIII, LLC disclaims beneficial ownership of all such shares, except to the extent of its pecuniary interest therein. Mr. Daniel Janney is a managing director of Alta Partners Management VIII, LLC and may be deemed to share the right to direct voting and dispositive control over the shares held by such fund. Mr. Janney disclaims beneficial ownership of all such shares, except to the extent of his pecuniary interest therein. Mr. Guy Nohra is a managing director of Alta Partners Management VIII, LLC and may be deemed to share the right to direct the voting and dispositive control over the shares held by such fund. Mr. Nohra disclaims beneficial ownership of such shares,

except to the extent of his pecuniary interest therein. Ms. Farah Champsi is a managing director of Alta Partners Management VIII, LLC and may be deemed to share the right to direct the voting and dispositive control over the shares held by such fund. Ms. Champsi disclaims beneficial ownership of all such shares, except to the extent of her pecuniary interest therein.

(4) The number of shares beneficially owned before the offering includes 1,096,969 shares of Common Stock directly owned by Baker Brothers Life Sciences, L.P. ("Life Sciences"), a limited partnership the sole general partner of which is Baker Brothers Life Sciences Capital, L.P., a limited partnership the sole general partner of which is Baker Brothers Life Sciences Capital (GP), LLC, 39,817 shares of Common Stock directly owned by 667, L.P. ("667"), a limited partnership the sole general partner of which is Baker Biotech Capital, L.P., a limited partnership the sole general partner of which is Baker Biotech Capital (GP), LLC, and 26,150 shares of Common Stock directly owned by 14159, L.P. ("14159", and together with Life Sciences and 667, the "Baker Entities"), a limited partnership the sole general partner of which is 14159 Capital, L.P., a limited partnership the sole general partner of which is 14159 Capital (GP), LLC. Of the 591,000 shares of Common Stock covered by this prospectus, 538,178 shares were directly owned before the offering by Life Sciences, 39,817 shares were directly owned before the offering by 667 and 13,005 shares were directly owned before the offering by 14159. Julian C. Baker and Felix J. Baker are the controlling members of the general partners of the general partners of the Baker Entities. Baker Bros. Advisors, LLC (the "Adviser") serves as the Investment Adviser to each of the Baker Entities. Pursuant to amended and restated management agreements between the Adviser, each of the Baker Entities and the general partners of the Baker Entities, the Adviser has complete and unlimited discretion and authority with respect to the Baker Entities investments and voting power over investments. Julian C. Baker and Felix J. Baker are the principals of the Adviser and each may be deemed to control the Adviser and to indirectly beneficially own the shares beneficially owned by it. Julian C. Baker and Felix J. Baker disclaim beneficial ownership of the securities directly owned by the Baker Entities, and this disclosure shall not be deemed to be an admission that Julian C. Baker and/or Felix J. Baker are the beneficial owners of such securities for purposes of Section 13(d) or any other purpose. The address for Baker Bros. Advisors, LLC and its affiliates is 667 Madison Avenue, 21st Floor, New York, NY 10065.

(5) Represents 229,000 shares of common stock held by Caduceus Capital Master Fund Limited, 207,000 shares of common stock held by Caduceus Capital II, L.P., 83,000 shares of common stock held by UBS Eucalyptus Fund, L.L.C., and 72,000 shares of common stock held by Summer Street Life Sciences Hedge Fund Investors, LLC. OrbiMed Capital LLC is the investment adviser or investment manager of Caduceus Capital Master Fund Limited and Summer Street Life Sciences Hedge Fund Investors, LLC. OrbiMed Advisors LLC is the general partner of Caduceus Capital II, L.P. and manages the portfolio of UBS Eucalyptus Fund, L.L.C. Samuel D. Isaly is the managing member of and owner of a controlling interest in each of OrbiMed Capital LLC and OrbiMed Advisors LLC and accordingly may be deemed to have voting and investment control over the shares of common stock held by Caduceus Capital Master Fund Limited, Caduceus Capital II, L.P., UBS Eucalyptus Fund, L.L.C. and Summer Street Life Sciences Hedge Fund Investor, LLC. Each of OrbiMed Capital LLC, OrbiMed Advisors LLC and Mr. Isaly disclaims beneficial ownership of such shares, except to the extent of its or his pecuniary interest therein, if any.

(6) Represents 1,685,271 shares of common stock held by Quogue Capital LLC but excluding 874,635 Series A Warrants and 714,286 Series B Warrants held by Quogue Capital LLC. Pursuant to the provisions of Section 6(e) of the Warrant Agreement for each of the Series A Warrants and Series B Warrants, the number of shares of common stock that may be acquired by the registered holder upon any exercise of Series A Warrants and Series B Warrants is limited to the extent necessary to ensure that, following such exercise, the total number of shares of common stock then beneficially owned by such holder and any other persons whose beneficial ownership of common stock would be

aggregated with the holder's for purposes of Section 13(d) of the Exchange Act does not exceed 9.999% of the total number of issued and outstanding shares of our common stock (including for such purpose the shares of common stock issuable upon such exercise). Mr. Wayne Rothbaum is a managing member of Quogue Capital LLC and may be deemed to beneficially own the shares held by such fund. Mr. Rothbaum disclaims beneficial ownership of all such shares, except to the extent of his pecuniary interest therein.

(7) Represents 1,258,922 shares of common stock held by of QVT Fund V LP but excluding 649,881 Series A Warrants and 530,587 Series B Warrants held by QVT Fund V LP. (See footnote (6) above for further information relating to the Series A Warrants and Series B Warrants). Management of QVT Fund V LP is vested in its general partner, QVT Associates GP LLC, which may be deemed to beneficially own the securities held by QVT Fund V LP. QVT Financial LP is the investment manager of QVT Fund V LP and has the power to direct the vote and disposition of the securities held by QVT Fund V LP. QVT Financial GP LLC is the general partner of QVT Financial LP and as such has complete discretion in the management and control of the business affairs of QVT Financial LP. The managing members of each of QVT Financial GP LLC and QVT Associates GP LLC are Daniel Gold, Nicholas Brumm, Arthur Chu and Tracy Fu. Each of Daniel Gold, Nicholas Brumm, Arthur Chu and Tracy Fu disclaims beneficial ownership of the securities held by QVT Fund V LP.

(8) Represents 214,596 shares of common stock held by of QVT Fund IV LP but excluding 110,798 Series A Warrants and 90,516 Series B Warrants held by QVT Fund IV LP. (See footnote (6) above for further information relating to the Series A Warrants and Series B Warrants). Management of QVT Fund IV LP is vested in its general partner, QVT Associates GP LLC, which may be deemed to beneficially own the securities held by QVT Fund IV LP. QVT Financial LP is the investment manager of QVT Fund IV LP and has the power to direct the vote and disposition of the securities held by QVT Fund IV LP. QVT Financial GP LLC is the general partner of QVT Financial LP and as such has complete discretion in the management and control of the business affairs of QVT Financial LP. The managing members of each of QVT Financial GP LLC and QVT Associates GP LLC are Daniel Gold, Nicholas Brumm, Arthur Chu and Tracy Fu. Each of Daniel Gold, Nicholas Brumm, Arthur Chu and Tracy Fu disclaims beneficial ownership of the securities held by QVT Fund IV LP.

(9) Represents 211,753 shares of common stock held by of Quintessence Fund L.P. but excluding 113,956 Series A Warrants and 93,183 Series B Warrants held by Quintessence Fund L.P. (See footnote (6) above for further information relating to the Series A Warrants and Series B Warrants). Management of Quintessence Fund L.P. is vested in its general partner, QVT Associates GP LLC, which may be deemed to beneficially own the securities held by Quintessence Fund L.P. QVT Financial LP is the investment manager of Quintessence Fund L.P. and has the power to direct the vote and disposition of the securities held by Quintessence Fund L.P. QVT Financial GP LLC is the general partner of QVT Financial LP and as such has complete discretion in the management and control of the business affairs of QVT Financial LP. The managing members of each of QVT Financial GP LLC and QVT Associates GP LLC are Daniel Gold, Nicholas Brumm, Arthur Chu and Tracy Fu. Each of Daniel Gold, Nicholas Brumm, Arthur Chu and Tracy Fu disclaims beneficial ownership of the securities held by Quintessence Fund L.P.

(10) Represents 307,404 shares of Common Stock held by Venrock Healthcare Capital Partners, L.P. (“VHCP”) and 56,232 shares of Common Stock held by VHCP Co-Investment Holdings, LLC (“VHCP Co-Invest”) (collectively, the “Venrock Funds”). VHCP Management, LLC (“VHCP Management”) is the general partner of VHCP and the manager of VHCP Co-Invest and may be deemed to beneficially own these shares. VHCP Management expressely disclaims beneficial ownership over all shares held by VHCP and VHCP Co-Invest except to the extent of its indirect pecuniary interest therein. Anders Hove and Bryan Roberts are the managing members of VHCP Management. Drs Hove and Roberts expressly disclaim beneficial ownership over all shares held by VHCP, VHCP Co-Invest, and VHCP Management except to the extent of their indirect pecuniary interest therein.

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Plan of Distribution

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer so solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales effected after the date the registration statement of which this prospectus is a part is declared effective by the SEC;
- 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 by law.

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, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act 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.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be "underwriters" within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders will be subject to the prospectus delivery requirements of the Securities Act, unless an exemption therefrom is available.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

There can be no assurance that any selling shareholder will sell any or all of the shares of common stock registered pursuant to the shelf registration statement. of which this prospectus forms a part.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, to the extent applicable we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, estimated to be $77,220 in total, including, without limitation, SEC filing fees and expenses of compliance

with state securities or “blue sky” laws and the selling stockholders’ expenses; provided, however, that a selling shareholder will pay all underwriting discounts and selling commissions, if any.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or (2) the date on which the shares may be sold pursuant to Rule 144 of the Securities Act without regard to any volume limitation requirements under Rule 144 of the Securities Act.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Jackson Walker L.L.P., Houston, Texas.

EXPERTS

The consolidated financial statements incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2011 have been so incorporated in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The consolidated statements of stockholders' equity for each of the eight years in the period ended December 31, 2001 were audited by Arthur Andersen LLP. Arthur Andersen LLP has not consented to the incorporation of their reports on the consolidated statements of stockholders' equity for each of the eight years in the period ended December 31, 2001 incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2011, and we have dispensed with the requirement to file their consent in reliance upon Rule 437a of the Securities Act of 1933. Because Arthur Andersen LLP has not consented to the incorporation of their reports in this prospectus, you will not be able to recover against Arthur Andersen LLP under Section 11 of the Securities Act of 1933 for any untrue statements of a material fact contained in the financial statements audited by Arthur Andersen LLP or any omissions to state a material fact required to be stated therein.

WHERE YOU CAN FIND MORE INFORMATION

We are required to file annual, quarterly and current reports, and other information with the SEC. You may read and copy any document which we have filed at the SEC's public reference room at:

Securities and Exchange Commission
100 F. Street, N.E.
Washington, D.C. 20549

Please call the SEC at 1-800-SEC-0330 for more information on the operation of the public reference room. Copies of our SEC filings are also available to the public from the SEC's web site at http://www.sec.gov.

Documents filed by us pursuant to the Securities Exchange Act may be reviewed and/or obtained through the SEC's Electronic Data Gathering Analysis and Retrieval System, which is publicly available through the SEC's web site (http://www.sec.gov).

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the reports or documents that have been incorporated by reference in the prospectus contained in the registration statement of which this prospectus is a part but not delivered with this prospectus. We will provide those reports and documents upon written or oral request and at no cost to the requester. Requests for reports or documents should be submitted to the company at the following address or telephone number:

Repros Therapeutics Inc

2408 Timberloch Place, Suite B-7

The Woodlands, Texas 77380

(281) 719-3400

Each of the reports and documents may also be accessed through our website which is located at www.reprosrx.com.

This prospectus is part of a registration statement that we have filed with the SEC relating to the securities offered hereby. As permitted by SEC rules, this prospectus does not contain all of the information we have included in the registration statement and the accompanying exhibits and schedules we file with the SEC. You may refer to the registration statement, exhibits and schedules for more information about us and such securities. The registration statement, exhibits and schedules are available at the SEC's public reference room or through its Internet website.

The SEC allows us to "incorporate by reference" information into this Prospectus, which means that we can disclose important information to you by referring you to another document or report filed separately with the SEC. The information incorporated by reference is deemed to be a part of this prospectus, except to the extent any information is superseded by this prospectus. The following documents which have been filed by us with the SEC and contain important information about us are incorporated into this prospectus:

- Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC on March 27, 2012;

- Quarterly Reports on Form 10-Q for the quarters ended March 31, 2012 and June 30, 2012 filed with the SEC on May 15, 2012 and August 13, 2012, respectively;

- Current Reports on Form 8-K filed with the SEC on January 3, 2012, January 4, 2012, January 5, 2012, January 13, 2012, January 27, 2012, February 27, 2012, April 30, 2012, May 9, 2012, May 16, 2012, May 22, 2012, May 29, 2012, June 4, 2012, June 14, 2012, June 18, 2012, July 9, 2012, July 16, 2012, July 23, 2012, August 27, 2012, September 5, 2012 and September 12, 2012; and

- The description of Repros' common stock contained in Repros' Registration Statement on Form 8-A filed on September 3, 1999, as amended by amendments to such registration statement on Form 8-A/A filed on September 11, 2002, October 31, 2002, June 30, 2005, January 10, 2008, October 10, 2008 and September 9, 2010.

Notwithstanding the foregoing, information that we elect to furnish, but not file, or have furnished, but not filed, with the SEC in accordance with SEC rules and regulations is not incorporated into the registration statement or this prospectus and does not constitute a part hereof.

All documents filed by Repros pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (excluding any information furnished to the SEC) subsequent to the date of this filing and prior to the termination of this offering shall be deemed to be incorporated in this Prospectus and to be a part hereof from the date of the filing of such document. Any statement contained in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

2,145,636 Shares

Common Stock

PROSPECTUS

The date of this prospectus is _____

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PART II
INFORMATION NOT REQUIRED IN THE PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The following table sets forth the fees and expenses, other than discounts, commissions and concessions payable to broker-dealers and agents, in connection with the offering and distribution of the securities being offered hereunder. All amounts other than the filing fee for the registration statement are estimates. All of these fees and expenses will be borne by the registrant.

Securities and Exchange Commission Filing Fee	$3,720
Legal Fees and Expenses	$50,000
Accounting and Auditor Fees	$20,000
Printing and Miscellaneous Fees	$3,500
Total	$77,220

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Section 145 of the Delaware General Corporation Law and the Company's Restated Bylaws provide the Company with broad powers and authority to indemnify its directors and officers and to purchase and maintain insurance for such purposes.

Additionally, the Company's Restated Certificate of Incorporation (as amended, the "Restated Certificate of Incorporation"), provides that a director of the Company shall not be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Company or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law, as the same may be amended, or (iv) for any transaction from which the director derived an improper personal benefit. If the Delaware General Corporation Law is amended to authorize the further elimination or limitation on personal liability of directors, then the liability of a director of the Company, in addition to the limitation on personal liability provided herein, shall be limited to the fullest extent permitted by the amended

Delaware General Corporation Law.

The Company's Restated Certificate of Incorporation further provides that each person who was or is made a party or is threatened to be made a party to or is involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "proceeding"), by reason of the fact that he or she, or a person of whom he or she is the legal representative, is or was a director or officer, of the Company or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, whether the basis of such proceeding is alleged action in an official capacity as a director, officer, employee or agent or in any other capacity while serving as a director, officer, employee or agent shall be indemnified and held harmless by the Company to the fullest extent authorized by the Delaware General Corporation Law, as amended (but, in the case of any such amendment, only to the extent that such amendment permits the Company to provide broader indemnification rights than said law permitted the Company to provide prior to such amendment), against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes or penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such person in connection therewith and such indemnification shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of his or her heirs, executors and administrators; provided, however, that except for certain exceptions set forth in the Restated Certificate of Incorporation, the Company shall indemnify any such person seeking indemnification in connection with a proceeding (or part thereof) initiated by such person only if such proceeding (or part thereof) was authorized by the Board of Directors of the Company. The right to indemnification set forth in the Restated Certificate of Incorporation is a contract right and includes the right to be paid by the Company the expenses incurred in defending any such proceeding in advance of its final disposition; provided, however, that, if the Delaware General Corporation Law requires the payment of such expenses incurred by a director or officer in his or her capacity as a director or officer (and not in any other capacity in which service was or is rendered by such person while a director or officer, including, without limitation, service to an employee benefit plan) in advance of the final disposition of a proceeding, payment shall be made only upon delivery to the Company of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified under the Restated Certificate of Incorporation. The Company may, by action of its Board of Directors, provide indemnification to employees and agents of the Company with the same scope and effect as the foregoing indemnification of directors or officers.

The Company’s Restated Certificate of Incorporation and Bylaws also provide that the Company may maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Company or another corporation, partnership, joint venture, trust or other enterprise against any such expense, liability or loss, whether or not the Company would have the power to indemnify such person against such expense, liability or loss under the Delaware General Corporation Law.

ITEM 16. EXHIBITS.

Exhibit Number	Identification Of Exhibit
3.1(a)	Restated Certificate of Incorporation. Exhibit 3.3 to the Company's Registration Statement on Form SB-2 (No. 33-57728-FW), as amended ("Registration Statement"), is incorporated herein by reference.
3.1(b)	Certificate of Amendment to the Company's Restated Certificate of Incorporation, dated as of May 2, 2006. Exhibit 3.1 to the Company's Current Report on Form 8-K as filed with the SEC on May 2, 2006 is incorporated herein by reference.
3.1(c)	Certificate of Designation of Series One Junior Participating Preferred Stock dated September 2, 1999. Exhibit A to Exhibit 4.1 to the Company's Registration Statement on Form 8-A as filed with the SEC on September 3, 1999 (the "Rights Plan Registration Statement"), is incorporated herein by reference.
3.1(d)	Certificate of Amendment to Restated Certificate of Incorporation, dated as of December 16, 2008. Exhibit 3.1(d) to the Company’s Current Report on Form 8-K as filed with the SEC on December 23, 2008 is incorporated herein by reference.
3.1(e)	Certificate of Amendment to Restated Certificate of Incorporation, dated as of November 18, 2009. Exhibit 3.1(e) to the Company’s Current Report on Form 8-K dated November 19, 2009 is incorporated herein by reference.
3.1(f)	Certificate of Amendment to Restated Certificate of Incorporation, dated October 14, 2010. Exhibit 3.1(f) to the Company’s Current Report on Form 8-K dated October 14, 2010 is incorporated herein by reference.
3.2	Restated Bylaws of the Company. Exhibit 3.4 to the Registration Statement is incorporated herein by reference.
4.1	Specimen Certificate of Common Stock, $.001 par value, of the Company. Exhibit 4.1 to the Registration Statement is incorporated herein by reference.
4.2	Rights Agreement dated September 1, 1999 between the Company and Computershare Investor Services LLC (as successor in interest to Harris Trust & Savings Bank), as Rights Agent. Exhibit 4.1 to the Rights Plan Registration Statement is incorporated herein by reference.

Exhibit Number	Identification Of Exhibit
4.3	First Amendment to Rights Agreement, dated as of September 6, 2002, between the Company, Harris Trust & Savings Bank and Computershare Investor Services LLC. Exhibit 4.3 to Amendment No. 1 to the Rights Plan Registration Statement on Form 8-A/A as filed with the SEC on September 11, 2002 is incorporated herein by reference.
4.4	Second Amendment to Rights Agreement, dated as of October 30, 2002, between the Company and Computershare Investor Services LLC. Exhibit 4.4 to Amendment No. 2 to the Rights Plan Registration Statement on Form 8-A/A as filed with the SEC on October 31, 2002 is incorporated herein by reference.
4.5	Third Amendment to Rights Agreement, dated as of June 30, 2005, between the Company and Computershare Trust Company, Inc. (as successor in interest to Computershare Investor Services, LLC). Exhibit 4.4 to the Company's Current Report on Form 8-K as filed with the SEC on June 30, 2005 is incorporated herein by reference.
4.6	Fourth Amendment to Rights Agreement, dated as of January 9, 2008, between the Company and Computershare Trust Company, Inc. (as successor in interest to Computershare Investor Services, LLC). Exhibit 4.5 to the Company's Current Report on Form 8-K as filed with the SEC on January 10, 2008 is incorporated herein by reference.
4.7	Fifth Amendment to Rights Agreement, dated as of October 10, 2008, between the Company and Computershare Trust Company, Inc. (as successor in interest to Computershare Investor Services, LLC). Exhibit 4.6 to the Company’s Current Report on Form 8-K as filed with the SEC on January 10, 2008 is incorporated herein by reference.
4.8	Sixth Amendment to Rights Agreement, dated as of September 9, 2010, between the Company and Computershare Trust Company, Inc. (as successor in interest to Computershare Investor Services, LLC). Exhibit 4.7 to the Company’s Current Report on Form 8-K as filed with the SEC on September 10, 2010 is incorporated herein by reference.
4.9	Form of Rights Certificate. Exhibit B to Exhibit 4.1 to the Rights Plan Registration Statement is incorporated herein by reference.
5.1*	Opinion of Jackson Walker L.L.P.
23.1*	Consent of PricewaterhouseCoopers LLP
23.2*	Consent of Jackson Walker L.L.P. (included in Exhibit 5.1)
21.1	Power of Attorney (see the signature page to this registration statement)

* Filed herewith.

ITEM 17. UNDERTAKINGS.

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 of 1933;

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

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

Provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the registration statement is on Form S-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of this registration statement as of the date the filed prospectus was deemed part of and included in this registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in this registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of this registration statement or made in a document incorporated or deemed incorporated by reference into this registration statement or prospectus that is part of this registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in this registration statement or prospectus that was part of this registration statement or made in any such document immediately prior to such effective date.

(5) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) 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.

(6) To deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 and Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

(7) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act of 1933 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 of whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, Repros Therapeutics Inc. has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in The Woodlands, State of Texas, on September 28, 2012.

REPROS THERAPEUTICS INC.

By: /s/ Joseph S. Podolski
Joseph S. Podolski
President and Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Katherine A. Anderson, his or her true and lawful attorney-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any related registration statement filed pursuant to Rule 462(b) under the Security Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granted unto said attorney-in-fact and agents, full power and authority to do and to perform each and every act and thing required and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agents, or any of them or their substitutes or substitutes, could 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 by the following persons in the capacities indicated.

/s/ Joseph S. Podolski Joseph S. Podolski	President, Chief Executive Officer (Principal Executive Officer) and Director	September 28, 2012
/s/ Katherine A. Anderson Katherine A. Anderson	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) and Secretary	September 28, 2012
/s/ Nola Masterson Nola Masterson	Chair of the Board and Director	September 28, 2012
/s/ Daniel F. Cain	Director	

Daniel F. Cain		September 28, 2012
/s/ Jean L. Fourcroy Jean L. Fourcroy, M.D., Ph.D., M.P.H.	Director	September 28, 2012
/s/ Jaye Thompson Jaye Thompson	Director	September 28, 2012
/s/ Michael Wyllie Michael Wyllie, Ph.D.	Director	September 28, 2012