

REPROS THERAPEUTICS INC.
Form POS AM
August 14, 2012

As filed with the Securities and Exchange Commission on August 14, 2012
Registration No. 333-171196

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Post-Effective Amendment No. 1 to

**FORM S-1
ON
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	2836	76-0233274
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(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:

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

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

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

If this Form is a post-effective amendment to a registration statement filed pursuant to 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 Smaller reporting company
(Do not check if a smaller reporting company)

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration

statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

Explanatory Note

On December 15, 2010, Repros Therapeutics Inc. (the "Company") filed with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-1 (File No. 333-171196), which was amended by a pre-effective amendment filed February 3, 2011, (the "Registration Statement" or the "Form S-1"), to register the offer and sale of 690,000 Units with each Unit consisting of four shares of common stock, par value \$.001 per share ("Common Stock"), three Series A Warrants ("Series A Warrants") to purchase shares of Common Stock and 2.45 Series B Warrants ("Series B Warrants" and, together with Series A Warrants, the "Warrants") to purchase shares of Common Stock. The Registration Statement was declared effective by the SEC on February 3, 2011. The Company sold an aggregate of 690,000 Units pursuant to the Registration Statement.

This Post-Effective Amendment No. 1 to Form S-1 on Form S-3 is being filed to (1) convert the Registration Statement into a registration statement on Form S-3 and (2) register only the shares of Common Stock to be issued upon exercise of the Warrants already issued, consisting of 3,436,095 shares of Common Stock issuable upon exercise of the Warrants. The Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3. No further offering will be made pursuant to this Post-Effective Amendment. All filing fees payable in connection with the registration of the sale of these securities were previously paid in connection with the filing of the Registration Statement.

This Post-Effective Amendment also contains an updated prospectus relating to an aggregate of 3,436,095 shares of Common Stock issuable upon the exercise of the Warrants previously issued to investors in connection with the offering of the Units. This Post-Effective Amendment is being filed in compliance with Section 10(a)(3) of the Securities Act of 1933, as amended.

PROSPECTUS

Repros Therapeutics Inc.

Up to 3,436,095 Shares of Common Stock Issuable Upon Exercise of Warrants

We previously sold 690,000 Units with each Unit consisting of four shares of our common stock, par value \$.001 per share ("Common Stock"), three Series A Warrants to purchase shares of Common Stock and 2.45 Series B Warrants to purchase shares of Common Stock. All of the warrants are currently exercisable and expire on February 8, 2016. This prospectus relates to the issuance of up to 3,436,095 shares of our Common Stock upon the exercise of all of the outstanding warrants. There are a total of 1,749,270 Series A Warrants to purchase 1,749,270 shares of Common Stock at an exercise price of \$0.01 per share and a total of 1,686,825 Series B Warrants to purchase 1,686,825 shares of Common Stock at an exercise price of \$2.49 per share outstanding. For a more detailed description of our Common Stock and warrants, see "Description of Capital Stock" beginning on page 22 of this prospectus.

Our Common Stock, the Series A Warrants and the Series B Warrants are traded on The Nasdaq Stock Market, LLC under the symbols "RPRX", "RPRXW" and "RPRXZ", respectively. On August 8, 2012, the closing price for our Common Stock was \$9.32 per share. There is not an active trading market for the warrants.

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 4.

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 _____, 2012.

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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 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, and Section 21E of the Securities and Exchange Act of 1934, as amended. “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 Securities and Exchange Commission. 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 was 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 pivotal studies are being conducted under a Special Protocol Assessment (“SPA”) and are expected to be initiated in the third quarter of 2012. Additionally, we began enrolling men

into a 500 subject open label safety study in June 2012 and will begin 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 quarter 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. 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. 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. We intend to commence a Phase 2 low dose oral administration study for endometriosis in the third quarter of 2012.

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. On February 1, 2012, we completed a registered direct offering to certain institutional investors, including certain existing shareholders, of 2,463,537 shares of our common stock at a price per share of \$4.50. Net proceeds to us, after deducting placement agent's fees and offering expenses, were approximately \$10.3 million. We anticipate that our current liquidity will be sufficient to continue these planned studies into the second quarter of 2013; however, significant additional capital will be required for us to complete the studies and development of either of our product candidates. We continue to explore potential additional financing alternatives (including corporate partnering opportunities) that would provide sufficient funds to enable us to continue to develop our two product candidates through completion of the outlined clinical trials; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all. The foregoing matters raise substantial doubt about our ability to continue as a going concern.

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.reprosr.com. Information contained on our website is not part of this prospectus.

Recent Developments

Under the terms of the Series B Warrants issued in our February 8, 2011 public offering, we may require the exercise of all of the Series B Warrants if our common stock trades at or above \$8.00 per share for a period of at least 20 trading days of 30 consecutive trading days, on sixty days notice. In the event that a Holder of Series B Warrants is restricted from exercising the Warrants pursuant to the terms of Section 6(e) of the Warrant Agreement (which provides for certain beneficial ownership limitations), the Holder is required to use commercially reasonable efforts to sell shares of Common Stock of the Company held by such Holder to the extent necessary to allow such Holder to exercise the Series B Warrants without the restrictions of such Section 6(e). On July 3, 2012, our common stock reached this price threshold. Currently, there are 1,686,825 Series B Warrants outstanding with an exercise price of \$2.49 per share. See “Description of Capital Stock” commencing on page 22 of this prospectus.

The Offering

Securities offered	Up to 3,436,095 shares of common stock issuable upon exercise of the warrants
Description of Series A Warrants	<p>Each Series A Warrant is exercisable for one share of our common stock at an exercise price of \$0.01 per share. The Series A Warrants expire February 8, 2016.</p> <p>Each Series B Warrant is exercisable for one share of our common stock at an exercise price of \$2.49 per share; however, issuances resulting in fractional warrants will be rounded down. The Series B Warrants expire February 8, 2016.</p>
Description of Series B Warrants	We may require the exercise of all of the Series B Warrants if our common stock trades at or above \$8.00 per share for a period of at least 20 trading days of 30 consecutive trading days. See the section titled “Description of Capital Stock” beginning on page 22 of this prospectus.
Common stock outstanding as of June 30, 2012	14,833,989 shares
Common stock to be outstanding after the exercise of all warrants for the shares covered by this prospectus	18,270,084 shares
Use of proceeds	We may receive up to a total of approximately \$4.2 million in net proceeds. However, as we are unable to predict the timing or amount of potential warrant exercises, we have not allocated any proceeds of such exercises to any particular purpose. Accordingly, all such proceeds are allocated to working capital. It is possible that the warrants may expire and may never be exercised.
Risk factors	The shares of common stock offered hereby involve a high degree of risk. See the section below entitled, “Risk Factors.”
Dividend policy	We intend to retain any future earnings to fund the development and growth of our business. As a result, we do not anticipate paying cash dividends on our common stock.
NASDAQ Symbol	<p>“RPRX” Common Stock</p> <p>“RPRXW” Series A Warrants</p>

“RPRXZ” Series B Warrants

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 as a going concern may require that we raise additional funds no later than the second quarter of 2013, without which we may need to cease our business operations and begin liquidation proceedings.

Our ability to continue as a going concern is dependent upon our ability to obtain additional financing no later than the second quarter of 2013 based upon our current expense and revenue assumptions. If our expenses are greater than expected or our revenues are less 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 second quarter of 2013 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. If adequate funds are not available to us, 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 candidate 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 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. 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 Joseph S. Podolski. We are highly dependent on 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 intend to 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 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.

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.