

REPOS THERAPEUTICS INC.

Form 424B4

February 07, 2011

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Registration No. 333-171196

PROSPECTUS

600,000 UNITS, CONSISTING OF 2,400,000 SHARES OF COMMON STOCK, SERIES A WARRANTS TO PURCHASE 1,800,000 SHARES OF COMMON STOCK AND SERIES B WARRANTS TO PURCHASE 1,470,000 SHARES OF COMMON STOCK

This prospectus relates to the offer and sale of 600,000 units, consisting of 2,400,000 shares of common stock, par value \$.001 per share, of Repros Therapeutics Inc. (the Company or Repros or we, us or our), Series A Warrants (Series A Warrants) to purchase 1,800,000 shares of common stock of the Company and Series B Warrants (Series B Warrants) to purchase 1,470,000 shares of common stock of the Company. Each unit will consist of four shares of common stock, Series A Warrants exercisable for three shares of our common stock at an exercise price of \$0.01 per share and Series B Warrants exercisable for 2.45 shares of our common stock at an exercise price of \$2.49 per share.

Each unit will be sold at a price of \$17.15 per unit. Units will not be issued or certificated. The shares of common stock and warrants are immediately separable and will be issued separately. Each of the Series A Warrants and Series B Warrants is exercisable immediately upon issuance and expires five years from the date of issuance. For a more detailed description of our common stock and warrants, see the section titled Description of Securities beginning on page 49 of this prospectus.

Our common stock is quoted on the Nasdaq Capital Market under the trading symbol RPRX. On January 28, 2011, the last reported sale price of our common stock on the Nasdaq Capital Market was \$2.63 per share. Upon the closing of this offering, the Series A Warrants and Series B Warrants will be listed on the Nasdaq Capital Market under the symbols RPRXW and RPRXZ, respectively. We do not intend to list the units on any securities exchange.

	Per Unit ⁽¹⁾	Total
Price to the public	\$ 17.15	\$ 10,290,000
Underwriting discounts and commissions ⁽²⁾	\$ 1.2005	\$ 720,300
Proceeds, before expenses, to Repros Therapeutics Inc.	\$ 15.9495	\$ 9,569,700

(1) The underwriter also may purchase up to an additional 90,000 units from us at the public offering price, less the underwriting discount, within 45 days after the date of this prospectus to cover over-allotments.

(2) In addition to the underwriting discount, we have agreed to pay up to \$75,000 of the fees and expenses of the underwriter in connection with this offering. See Underwriting.

INVESTING IN OUR COMMON STOCK AND WARRANTS INVOLVES SUBSTANTIAL RISKS. SEE THE SECTION TITLED RISK FACTORS BEGINNING ON PAGE 6 OF THIS PROSPECTUS TO READ

**ABOUT FACTORS YOU SHOULD CONSIDER BEFORE BUYING SHARES OF OUR COMMON STOCK
AND WARRANTS.**

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION (SEC) NOR ANY STATE SECURITIES
COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE
ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY
IS A CRIMINAL OFFENSE.**

The underwriter expects to deliver the securities to purchasers on February 8, 2011

Ladenburg Thalmann & Co. Inc.

The date of this prospectus is February 3, 2011

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You should rely only on the information contained in this prospectus or any related prospectus supplement, including the content of all documents incorporated by reference into the registration statement of which this prospectus forms a part. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in this prospectus or incorporated by reference herein is accurate only on the date of this prospectus. Our business, financial condition, results of operations and prospects may have changed since such date. Other than as required under the federal securities laws, we undertake no obligation to publicly update or revise such information, whether as a result of new information, future events or any other reason.

Until March 15, 2011, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before making an investment decision with respect to our securities. You should read this entire prospectus, including all documents incorporated by reference, carefully, especially the Risk Factors section beginning on page 6 of this prospectus and our financial statements and related notes contained in this prospectus before making an investment decision with respect to our securities. Please see the section titled, Where You Can Find More Information, beginning on page 58 of this prospectus. Unless the context indicates otherwise, references to the Company or Repros or we, us or our refers to Repros Therapeutics Inc.

About Repros Therapeutics Inc.

Repos Therapeutics Inc. (the Company or 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.

We are developing Androxal®, an oral therapy that normalizes testicular function, for the treatment of low testosterone due to secondary hypogonadism. Secondary hypogonadism is the leading cause of low testosterone in men and is commonly associated with aging. 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. In 2009, for the first time, sales of testosterone preparations for the treatment of low testosterone exceeded \$1 billion worldwide and first tier pharmaceutical companies entered the low testosterone marketplace as evidenced by the acquisition of Solvay Pharmaceuticals and the subsequent active marketing of its AndroGel® product by Abbott Laboratories. Eli Lilly and Company also recently entered into a licensing agreement with a third party for a late stage topical testosterone treatment.

We believe Androxal® is highly differentiated from currently marketed testosterone treatments or those treatments in late stage development because it treats the cause of low testosterone in men with secondary hypogonadism, which is inadequate pituitary hormones. Androxal® is an oral therapy and also has the potential to maintain fertility and potentially improve overall metabolic profiles, which we believe may improve the condition of men suffering from type 2 diabetes, a condition present in about 20% of men with secondary hypogonadism. Retrospective analysis of completed Androxal® studies showed that Androxal® improved fasting plasma glucose levels in hypogonadal men with Type 2 diabetes, an improvement not seen in similar subjects using a topical testosterone or placebo. The Company is currently conducting a Phase 2 study under an Investigational New Drug Application (IND) filed with the Division of Metabolic and Endocrine Products at the Food and Drug Administration (FDA) for the use of Androxal® in the treatment of Type 2 diabetes in hypogonadal men.

The Company held a Type B meeting with the FDA on November 8, 2010 to discuss protocols for Phase 3 studies for Androxal® in the treatment of secondary hypogonadal men wishing to preserve their testicular function (reproductive status). Though the FDA noted that the Company may proceed to Phase 3 in the meeting, the FDA recommended that a Phase 2B study in men with secondary hypogonadism, but naïve to testosterone treatment, be conducted if the Company desired the FDA to review the Phase 3 protocols under a Special Protocol Assessment. On January 3, 2011, we announced that we have received Institutional Review Board (IRB) approval to commence the Phase 2B study of Androxal® in men with secondary hypogonadism, and we have begun enrolling patients. Depending on the rate of subject enrollment, we hope to have the study completed before the end of 2011.

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. We believe an effective treatment for these underserved conditions could result in sales of a safe and effective drug easily exceeding \$1 billion in sales in the U.S. Proellex® had shown significant success in Phase 2 studies for both endometriosis and uterine fibroids. The Company has commenced a Phase 2B study with doses from 1 to 12 mg under a partial clinical hold by the FDA, which is intended to determine both signals of efficacy and safety for low oral doses of the drug. A full clinical hold was previously imposed as a result of certain serious adverse events relating to liver toxicity observed in patients receiving the 50 mg dose of Proellex® in our prior studies in uterine fibroids; however, the FDA has

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reduced such hold to a partial clinical hold to allow us to proceed with the current low dose Phase 2B study. In addition to the low dose study, the Company has commenced two related preclinical programs: vaginal delivery of Proellex® to avoid first pass liver effects and second generation molecules that do not possess the structures Repros believes resulted in the liver toxicity observed.

Both of our product candidates have exhibited strong efficacy results in every study completed to date, and Repros believes the studies presently underway or scheduled to start shortly will place both programs on a clear late stage clinical development path and a solid position for licensing.

As of September 30, 2010, we had accumulated losses of \$178.1 million, approximately \$4.2 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately \$1.4 million. The amount of cash on hand is not sufficient to fund each of the current clinical trials for our two drug candidates, Proellex® and Androxal®. Assuming successful completion of this offering, we will have sufficient funding to complete all of the Phase 2 and 2B clinical trials currently planned or underway; however, significant additional capital will be required for us to complete 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 and other matters raise substantial doubt about our ability to continue as a going concern.

Our Research and Development Program

Our product development pipeline is summarized in the table below:

Product Candidate (Indication)	Status	Next Expected Milestone(s)
Androxal®		Commence Phase 2B study (Q1 2011)
Secondary Hypogonadism	Phase 2B	Report top line Phase 2B results (Q1 2012) (pending enrollment timing)
Type 2 diabetes	Phase 2	Report interim results (Q2 2011) (pending enrollment timing)
Proellex®		
Uterine Fibroids/Endometriosis	Phase 2	Complete low dose study (late 2011) Commence Phase 3 studies (2012) Open new IND (mid 2011) (pending
Vaginal Administration	Preclinical	outcome of animal studies) Commence Phase 3 studies (late 2012)
Second Generation Compounds	Preclinical	Complete preclinical screen (Q3 2011)

Recent Developments

On October 14, 2010, the Company effected a 1-for-4 reverse split of its common stock. The split-adjusted shares of the Company's common stock began trading on the Nasdaq Capital Market on October 15, 2010. The 1-for-4 reverse stock split converted all shares of the Company's common stock issued and outstanding, plus all outstanding stock options and the number of shares of common stock available for issuance under the Company's approved stock plans. The number of authorized shares of common stock was not affected by the reverse split. The reverse split enabled the Company to meet the continued listing rules of the Nasdaq Capital Market. All share and per share amounts described

in this prospectus are presented on a post-reverse stock split basis, except with respect to materials incorporated by reference herein which were filed by us prior to the effective date of the reverse stock split.

Corporate Information

We were organized as a Delaware corporation in August 1987. Our principal executive offices are located at 2408 Timberloch Place, Suite B-7, The Woodlands, Texas 77380, and our telephone number is (281) 719-3400. We maintain an Internet website at *www.reprosrx.com*. The information on our website or any other website is not incorporated by reference into this prospectus and does not constitute a part of this prospectus.

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The Offering

Securities offered by the Company

Up to 600,000 units. Each unit will consist of four shares of common stock, three Series A Warrants and 2.45 Series B Warrants. The common stock and warrants comprising the units will be issued separately.

Offering price

\$17.15 per unit.

Description of Series A Warrants

Each Series A Warrant will be exercisable for one share of our common stock at an exercise price of \$0.01 per share. The Series A Warrants are exercisable immediately upon issuance and expire five years from the date of issuance. The number of shares of common stock issuable to a holder upon any exercise of Series A Warrants shall be 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 does not exceed 9.999% of the total number of outstanding shares our common stock. This restriction may be waived by such holder upon not less than 61 days prior notice to us, except to the extent such waiver would cause such holder to beneficially own 20% or more of our common stock.

Description of Series B Warrants

Each Series B Warrant will be 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 are exercisable immediately upon issuance and expire five years from the date of issuance.

The number of shares of common stock issuable to a holder upon any exercise of Series B Warrants shall be 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 does not exceed 9.999% of the total number of outstanding shares our common stock. This restriction may be waived by such holder upon not less than 61 days prior notice to us. In no event, however, may a holder exercise warrants if, following such exercise, such holder would beneficially own 20% or more of our outstanding common stock.

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, subject to certain limitations. See the section titled Description of Securities beginning on page 49 of this prospectus.

Common stock outstanding prior to this offering

8,930,022 shares.

Common stock to be outstanding after this offering

11,330,022 shares.

Over-allotment option

Up to an additional 90,000 units.

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Use of proceeds

We intend to use the net proceeds from this offering for general corporate purposes, including continuing our clinical trials for Androxal® and Proellex®. See Use of Proceeds for additional information.

Nasdaq Capital Market symbols:

Common Stock

RPRX

Series A Warrants

RPRXW

Series B Warrants

RPRXZ

The number of shares of common stock outstanding immediately prior to and to be outstanding immediately after this offering is based on the number of shares outstanding as of September 30, 2010, and does not include:

538,582 shares of common stock issuable upon the exercise of outstanding options at a weighted average exercise price of \$14.10 per share;

288,421 shares of common stock available for future issuance under our stock option plans;

3,270,000 shares of common stock issuable upon exercise of warrants included in the units in this offering;

shares of common stock and warrants issuable upon exercise of the underwriter's over-allotment option; and

286,187 shares of common stock sold by us since September 30, 2010.

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The following tables summarize our financial data for the periods presented. The summary statements of operations data for the years ended December 31, 2009, 2008 and 2007, and the balance sheet data as of December 31, 2009 and 2008, have been derived from our audited financial statements, which are incorporated by reference into this prospectus. The summary statements of operations data for the years ended December 31, 2006 and 2005, and the balance sheet data as of December 31, 2007, 2006 and 2005, have been derived from our audited financial statements, which are not incorporated by reference into this prospectus. The summary statements of operations data for the nine months ended September 30, 2010 and 2009, and the balance sheet data as of September 30, 2010, have been derived from our unaudited financial statements, which are included elsewhere in this prospectus. The historical results are not necessarily indicative of the results to be expected for any future periods. You should read this data together with the financial statements and related notes incorporated by reference into this prospectus or included elsewhere in this prospectus, as well as Management's Discussion and Analysis of Financial Condition and Results of Operations and the other financial information incorporated by reference into this prospectus.

STATEMENTS OF OPERATIONS DATA:

	Year Ended December 31,					Nine Months Ended September 30,	
	2009	2008	2007	2006	2005	2010	2009
	(In thousands, except per share data)						
Revenues and Other Income							
Interest income	\$4	\$433	\$1,508	\$596	\$630	\$	\$4
Research and development grants					4		
Other income	547					138	
Total revenues	551	433	1,508	596	634	138	4
Expenses:							
Research and development	23,062	22,575	12,420	11,912	6,101	1,950	21,765
General and administrative	4,723	3,060	2,788	2,879	1,924	1,772	4,126
Total expenses	27,785	25,635	15,208	14,791	8,025	3,722	25,891
Net loss	\$(27,234)	\$(25,202)	\$(13,700)	\$(14,195)	\$(7,391)	\$(3,584)	\$(25,887)
Net loss per share - basic and diluted ⁽¹⁾⁽²⁾	\$(6.28)	\$(7.54)	\$(4.38)	\$(5.60)	\$(3.06)	\$(0.46)	\$(6.77)
Shares used in loss per share calculation ⁽²⁾	4,336	3,343	3,131	2,537	2,412	7,763	3,821

(1) See Note 2. Summary of Significant Accounting Policies of Notes to our Consolidated Financial Statements incorporated by reference into this prospectus for a description of the computation of loss per share.

(2) The basic and diluted net loss per share and shares used in loss per share calculation have been adjusted to reflect the one-for-four reverse stock split that was effected on October 14, 2010.

BALANCE SHEET DATA:

	As of December 31,					As of September 30, 2010
	2009	2008	2007	2006	2005	
Cash, cash equivalents and marketable securities	\$1,886	\$19,470	\$25,903	\$6,736	\$16,832	\$4,216
Total assets	\$2,960	\$22,603	\$27,599	\$7,849	\$17,682	\$5,567
Deficit accumulated during the development stage	\$(174,476)	\$(147,242)	\$(122,040)	\$(108,340)	\$(94,145)	\$(178,060)
Total stockholders equity	\$562	\$15,614	\$24,060	\$3,790	\$16,955	\$4,213

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RISK FACTORS

An investment in our securities involves a high degree of risk. Before you decide to invest in our securities, you should consider carefully all of the information in this prospectus, including the risks described below. Any of these risks could have a material adverse effect on our business, prospects, financial condition and results of operations. In any such case, the trading price of our common stock or warrants could decline and you could lose all or part of your investment. You should also refer to the other information contained in this prospectus, or incorporated herein by reference, including our financial statements and the notes to those statements, and the information set forth under the caption Forward Looking Statements. The risks described below and contained in our other periodic reports are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business operations.

Risks Relating to Our Business

Assuming completion of this offering, our ability to continue as a going concern may require that we raise additional funds by the end of the second quarter of 2012, without which we may need to cease our business operations and begin liquidation proceedings.

Assuming completion of this offering, our ability to continue as a going concern is dependent upon our ability to obtain additional financing by the end of the second quarter of 2012 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 after this offering 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 purchasers of securities in this offering, including but not limited to, voting rights and rights to proceeds in the event of a sale or liquidation of the Company. The current FDA partial clinical hold of our clinical trials for Proellex® will make it more difficult for us to obtain additional financing. In addition, the class action lawsuits filed against us will make our ability to raise funds even more difficult. 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.

The Company and certain of its officers and directors were named as a party in several class action lawsuits which could result in a material adverse affect on our business and financial condition.

The Company and certain of its officers were named as parties in several shareholder class action lawsuits alleging,

among other things, that the Company and such officers violated certain provisions of the Exchange Act by issuing materially false and misleading press releases regarding the results of clinical trials for its drug Proellex®. Our bylaws require us to indemnify our officers in certain proceedings, subject to certain limited exceptions. In addition, each of our directors has an indemnification agreement with the Company providing for certain additional indemnification benefits for such persons in the event of a lawsuit. As a result of the class action lawsuits, we are obligated to pay for certain costs and expenses of our officers and directors and may be liable for substantial damages, costs and expenses if such class action is successful. Such litigation could also divert the attention of our management and our resources in general from day-to-day operations. Further, it is possible that additional claims beyond those that have already been filed will be brought by the current plaintiffs or by others in an effort to seek monetary relief from us.

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Additionally, such class action lawsuits are covered by the Company's director and officer insurance policy. In the event there are adverse judgments against the Company in such lawsuits, the Company's insurance coverage may not be adequate to cover such judgments and the Company's cash position may not be sufficient to satisfy such judgment. Such adverse judgments could have a material and adverse affect on the Company.

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®. Assuming completion of this offering and based on our current and planned clinical programs, we expect to need to raise additional capital by the end of the second quarter of 2012 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 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

If we fail to obtain the capital necessary to fund our operations, we may have to delay, reduce or eliminate our rese

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 type 2 diabetes. Furthermore, the only data that we obtained to date relating to Androxal® is 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.

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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 September 30, 2010, we had accumulated losses of \$178.1 million, approximately \$4.2 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. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern.

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

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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 any of our other current or future product candidates, 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 have only 6 full-time employees at the present time, 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.

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.

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Risks Relating to Our Product Development Efforts

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;

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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;
ongoing discussions 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.

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 a new drug application, or 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, or CROs, and universities, in certain areas that are particularly relevant to our research and product development plans, such as 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

Even if we successfully complete clinical trials for Androxal® and Proellex®, there are no assurances that we will be

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.

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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.

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 five year 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 2012, 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.

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 sale 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

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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

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

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;

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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.

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;

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

obtain regulatory approval for products before we do; or
commit more resources than we can to developing, marketing and selling competing products.

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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®. 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.

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. In our prior filings with the SEC, we have described our request to the U.S. Patent and Trademark Office, or PTO, for re-examination of one of these patents based on prior art. The third party amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a re-examination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and we filed a second request for re-examination by the PTO in light of a number of these additional publications and other publications cited by the PTO. 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 Board) which affirmed the rejection of all of the claims. The patent holder subsequently filed a request for rehearing, which led the Board to reverse the rejections of several dependent claims in view of those publications under consideration. The patent holder has filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit contesting the rejections maintained by the Board. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated by the PTO we may be required to obtain a license from the holder of such patents in order to develop Androxal® further or attempts may be made to undertake further legal action to invalidate such patents. If such licenses were not available on acceptable terms, or at all, we may not be able to successfully commercialize or out-license Androxal®.

We licensed our rights to Proellex® from 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 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, NIH will agree to revised objectives. NIH has the ability to terminate the agreement for an uncured material breach of the agreement, if we made a false

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statement or willful omission in our license application, if we do not keep Proellex® reasonably available to the public after commercial launch, if we cannot reasonably satisfy unmet health and safety needs, or if we cannot reasonably justify a failure to comply with the domestic production requirement unless such requirement has been waived.

We cannot assure 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

We cannot assure that our manufacture, use or sale of our product candidates will not infringe on the patent rights of

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 to potential liability for damages; or consume a substantial portion of our managerial, scientific and financial resources; or be costly, regardless of the outcome.

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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 or warrants.

We face substantial 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

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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 this Offering and our Common Stock and Warrants

We will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

We will have broad discretion in the application of the net proceeds from this offering and could allocate the net proceeds in ways that do not improve our results of operations or enhance the value of our common stock or warrants. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock or warrants to decline.

Purchasers in this offering will experience immediate and substantial dilution.

As of September 30, 2010, we had a net tangible book value of \$3.1 million which yields a net tangible book value of approximately \$0.35 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. See the section titled "Dilution" on page 24 of this prospectus. The exercise of outstanding options and the warrants issued in connection with this offering 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, 2008 through January 28, 2011, the sale price of our stock price has fluctuated from a low of \$1.11 to a high of \$55.76. The market price for our common stock and warrants 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;

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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 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 and warrants;
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 or our competitors 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.

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 additional 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 and/or warrants being delisted, which could affect their 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 and/or warrants 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 and/or warrants may be recommended for delisting (subject to any appeal we would file). If our common stock or warrants were delisted, it could be more difficult to buy or sell our common stock or warrants and to obtain accurate quotations, and the price of our common stock or warrants could suffer a material decline. Delisting would also impair our ability to raise capital.

The market price of our common stock may fall below the exercise price of the warrants issued in connection with this offering.

The warrants being issued in connection with this offering will be exercisable immediately upon issuance and will expire five years from the date of issuance. The market price of our common stock may fall below the exercise price for the warrants prior to their expiration. Any warrants not exercised by their date of expiration will expire worthless and we will be under no further obligation to the holders of such warrants.

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FORWARD-LOOKING STATEMENTS

Some of the statements contained (i) in this prospectus and any accompanying prospectus supplement or (ii) incorporated by reference into this prospectus are 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 Exchange Act of 1934, as amended (the Exchange Act), and are subject to the safe harbor created by the Securities Litigation Reform Act of 1995. Examples of these forward-looking statements include, but are not limited to:

our ability to continue as a going concern and to raise additional capital, as necessary, on acceptable terms or at all;
having available funding for the continued development of Proellex® and Androxal®;
our ability to successfully defend the class action lawsuits;
the removal of the current partial clinical hold on further clinical trials for Proellex® by the FDA and the reestablishment of safe dosing in clinical trials for Proellex®;
uncertainty related to our ability to obtain approval of our products by the FDA and regulatory bodies in other jurisdictions;
uncertainty relating to our patent portfolio;
market acceptance of our products and the estimated potential size of these markets;
dependence on third parties for clinical development and manufacturing;
dependence on a limited number of key employees;
competition and risk of competitive new products;
volatility in the value of our common stock;
volatility in the financial markets generally; and
any other risks and uncertainties described under Risk Factors or elsewhere in this prospectus.

While these forward-looking statements made by us are based on our current intent, beliefs and judgments, they are subject to risks and uncertainties that could cause actual results to vary from the projections in the forward-looking statements. You should consider the risks above carefully in addition to other information contained in this prospectus before engaging in any transaction involving our securities. If any of these risks occur, they could seriously harm our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment.

In addition, in this prospectus, any prospectus supplement and the documents incorporated by reference into this prospectus, the words believe, should, predict, future, may, will, estimate, continue, anticipate, in potential, continue, or opportunity, or other words and terms of similar meaning, as they relate to us, our business, future financial or operating performance or our management, are intended to identify forward-looking statements. Any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update or revise any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Past financial or operating performance is not necessarily a reliable indicator of future performance and you should not use our historical performance to anticipate results or future period trends.

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USE OF PROCEEDS

We expect to receive approximately \$9.3 million in net proceeds from the sale of the 600,000 units offered by us in this offering based on the offering price of \$17.15 per unit, or approximately \$10.7 million if the underwriter exercises its over-allotment in full based on the offering price of \$17.15 per unit. Net proceeds is what we expect to receive after paying the expenses of this offering, including the underwriting discounts and commissions as described in Underwriting and other estimated offering expenses payable by us, which include legal, accounting and printing fees; however, it does not include proceeds that we may receive upon exercise of warrants.

We intend to use the net proceeds from this offering for general corporate purposes, including continuing our clinical trials for Androxal® and Proellex®. We have not yet determined with certainty the manner in which we will allocate the net proceeds; however, we currently anticipate using:

approximately \$1.6 million to conduct our Phase 2B secondary hypogonadism trial for Androxal®;
approximately \$1.6 million to complete our current Phase 2 type 2 diabetes trial for Androxal®; and
approximately \$1.0 million to complete our current escalating low dose study for Proellex®.

The amounts described above are only an estimate of the expenses we currently anticipate will be necessary to complete each trial. Our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

Until we use the net proceeds of this offering, we intend to invest the funds in short-term, investment grade, interest-bearing securities.

TABLE OF CONTENTS**CAPITALIZATION**

The following table presents a summary of our cash and cash equivalents and capitalization as of September 30, 2010:

on an actual basis; and

on an as adjusted basis, giving effect to the sale of 600,000 units to be sold in this offering at a public offering price of \$17.15 per unit, after deducting estimated underwriting discounts and commissions and offering expenses, and the application of the net proceeds of this offering as described in Use of Proceeds.

You should read the following table in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operation and the historical consolidated financial statements and the related notes thereto incorporated by reference into this prospectus.

	As of September 30, 2010 (in thousands except share and per share amounts)	
	Actual	As Adjusted
Cash and cash equivalents	\$4,216	\$13,516
Stockholders' equity		
Undesignated preferred stock, \$.001 par value: 5,000,000 shares authorized; none issued and outstanding		
Common stock ((i) Actual: 75,000,000 shares authorized, par value \$0.001; 9,042,407 shares issued and 8,930,057 shares outstanding and (ii) As Adjusted: 75,000,000 shares authorized, par value \$0.001; 11,442,407 shares issued and 11,330,057 shares outstanding)	\$9	\$11
Additional paid-in capital/warrants	183,644	192,942
Cost of treasury stock, 112,350 shares	(1,380)	(1,380)
Deficit accumulated during the development stage	(178,060)	(178,060)
Total stockholders' equity	\$4,213	\$13,513
Total capitalization	\$4,213	\$13,513

The number of shares in the table above excludes as of September 30, 2010:

538,582 shares of common stock issuable upon the exercise of outstanding options at a weighted average exercise price of \$14.10 per share;

288,421 shares of common stock available for future issuance under our stock option plans;

3,270,000 shares of common stock issuable upon exercise of warrants included in the units in this offering;

shares of common stock and warrants issuable upon exercise of the underwriter's over-allotment option; and

286,187 shares of common stock sold by us since September 30, 2010.

TABLE OF CONTENTS**MARKET PRICE AND DIVIDEND INFORMATION**

Our common stock is quoted on the Nasdaq Capital Market under the symbol **RPRX**. The following table shows the high and low sale prices per share of our common stock as reported by the Nasdaq Stock Market during the periods presented. Prices per share of our common stock have been adjusted to reflect the 1-for-4 reverse split of our common stock that was effected on October 14, 2010.

	Price Range	
	High	Low
2008		
First Quarter	\$ 40.80	\$ 32.44
Second Quarter	44.36	32.84
Third Quarter	40.00	21.24
Fourth Quarter	45.00	22.72
2009		
First Quarter	\$ 55.76	\$ 23.36
Second Quarter	33.20	22.80
Third Quarter	24.04	2.60
Fourth Quarter	9.92	2.56
2010		
First Quarter	\$ 4.88	\$ 2.52
Second Quarter	4.52	1.44
Third Quarter	2.68	1.12
Fourth Quarter	4.56	1.11
2011		
First Quarter (January 1 st through January 28 th)	\$ 3.36	\$ 2.61

All of the foregoing prices reflect interdealer quotations, without retail mark-up, markdowns or commissions and may not necessarily represent actual transactions in the common stock.

On January 28, 2011, the last sale price of our common stock, as reported by the Nasdaq Capital Market, was \$2.63 per share. On December 31, 2010, there were approximately 170 holders of record and approximately 3,525 beneficial holders of our common stock.

Dividend Policy**General**

We have never declared or paid cash dividends on our capital stock. We currently intend to retain our future earnings, if any, for use in our business and therefore do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs.

Rights Plan

We are party to a rights agreement, as amended, pursuant to which a dividend consisting of one preferred stock purchase right was distributed for each share of our common stock held as of the close of business on September 13, 1999, and to each share of common stock issued thereafter until the earlier of (i) the distribution date which is defined in the rights plan, (ii) the redemption date which is defined in the rights plan or (iii) September 13, 2015. The rights plan is designed to deter coercive takeover tactics and to prevent an acquirer from gaining control of us without offering fair value to our stockholders. The rights will expire on September 13, 2015, subject to earlier redemption or exchange as provided in the rights plan. Each right entitles its holder to purchase from us one one-hundredth of a share of a new series of Series One Junior Participating Preferred Stock at a price of \$20.00 per one one-hundredth of a share, subject to adjustment. The rights are generally exercisable only if a person acquires beneficial ownership of 20% or more of our outstanding common stock.

A complete description of the rights, the rights plan with Computershare Trust Company, N.A., as rights agent, and the Series One Junior Participating Preferred Stock is hereby incorporated by reference from the information appearing under the caption "Item 1. Description of the Registrant's Securities to be Registered" contained in the Registration Statement on Form 8-A filed on September 3, 1999, and 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.

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DILUTION

Our unaudited net tangible book value as of September 30, 2010 was approximately \$3.1 million, or approximately \$0.35 per share of common stock. Net tangible book value per share represents total assets minus capitalized patent costs and total liabilities, divided by the number of shares of common stock outstanding. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of units in this offering (assuming exercise of the Series A Warrants) and the net tangible book value per share of our common stock immediately after the offering (assuming exercise of the Series A Warrants).

After giving effect to the sale of 600,000 units to be sold in this offering at the offering price of \$17.15 per unit, and after deduction of estimated underwriting discounts and commissions and offering expenses payable by us, our pro forma net tangible book value as of September 30, 2010 would have been approximately \$12.4 million, or \$0.94 per share (assuming exercise of the Series A Warrants). The adjustments made to determine pro forma net tangible book value per share are the following:

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