ZONAGEN INC
Form 10-Q
May 10, 2005

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2005

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-15281

ZONAGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

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

2408 Timberloch Place, Suite B-1
The Woodlands, Texas 77380
(Address of principal executive offices and zip code)

(281) 719-3400
(Registrant s telephone number, including area code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes o No þ

As of April 29, 2005, there were outstanding 10,079,601 shares of Common Stock, par value $.001 per share, of the Registrant.

ZONAGEN, INC.
(A development stage company)

For the Quarter Ended March 31, 2005

INDEX

Table of Contents

FACTORS AFFECTING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words may, anticipate, believe, expect, estimate, project, suggest, intend and similar expressions are intended forward-looking statements. Such statements are subject to certain risks, uncertainties and assumptions. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, expected, estimated, projected, suggested or intended. These risks and uncertainties include risks associated with the early stage of development of Progenta and Androxal , approval of the Company s products by the Food and Drug Administration (FDA) and regulatory bodies in other jurisdictions, the Company s ability to raise additional capital on acceptable terms or at all, manufacturing uncertainties related to Progenta , the Company s ability to obtain value from its other technologies, uncertainty relating to the Company s patent portfolio, and other risks and uncertainties described in the Company s filings with the Securities and Exchange Commission. For additional discussion of such risks, uncertainties and assumptions, see Item 1. Description of Business Business Risks included in the Company s annual report on Form 10-K for the year ended December 31, 2004 and Part I. Financial Information Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources included elsewhere in this quarterly report on Form 10-Q.

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

The following unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all necessary adjustments (which include only normal recurring adjustments) considered necessary for a fair statement of the interim periods presented have been included. The year-end balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America. Operating results for the three-month period ended March 31, 2005 are not necessarily indicative of the results that may be expected for the year ended December 31, 2005. For further information, refer to the financial statements and footnotes thereto included in the Company s annual report on Form 10-K for the year ended December 31, 2004.

Table of Contents

ZONAGEN, INC. AND SUBSIDIARY
(A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited and in thousands except share amounts)

	March 31, 2005	December 31, 2004
ASSETS		
Current Assets		
Cash and cash equivalents	$ 1,620	$ 736
Marketable securities	21,541	4,800
Prepaid expenses and other current assets	238	34
Total current assets	23,399	5,570
Fixed Assets, net	20	18
Other assets	438	1,018
Total assets	$ 23,857	$ 6,606
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities		
Accounts payable	$ 939	$ 144
Accrued expenses	213	470
Total current liabilities	1,152	614
Commitments & Contingencies		
Stockholders Equity		
Undesignated Preferred Stock, $.001 par value, 5,000,000 shares authorized, none issued and outstanding		
Common Stock, $.001 par value, 20,000,000 shares authorized, 12,016,636 and 11,989,936 shares issued, respectively, 10,079,601 and 4,992,901 shares outstanding, respectively	12	12
Additional paid-in capital	117,158	114,455
Deferred compensation	(208)	(234)
Cost of treasury stock, 1,937,035 and 6,997,035 shares, respectively	(5,948)	(21,487)
Deficit accumulated during the development stage	(88,309)	(86,754)
Total stockholders equity	22,705	5,992
Total liabilities and stockholders equity	$ 23,857	$ 6,606

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

ZONAGEN, INC. AND SUBSIDIARY
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited and in thousands except per share amounts)

	Three Months Ended March 31,		From Inception (August 20, 1987) through March 31,
	2005	**2004**	**2005**
Revenues and other income			
Licensing fees	$	$	$ 28,755
Product royalties			627
Research and development grants	4	64	1,219
Interest income	108	26	13,234
Gain on disposal of fixed assets			102
Other Income		35	35
Total revenues and other income	112	125	43,972
Expenses			
Research and development	1,236	477	95,496
General and administrative	431	434	27,054
Interest expense and amortization of intangibles			388
Total expenses	1,667	911	122,938
Loss from continuing operations	(1,555)	(786)	(78,966)
Loss from discontinued operations			(1,828)
Gain on disposal			939
Net loss before cumulative effect of change in accounting principle	(1,555)	(786)	(79,855)
Cumulative effect of change in accounting principle			(8,454)
Net loss	$ (1,555)	$ (786)	$ (88,309)
Loss per share basic and diluted	$ (0.19)	$ (0.14)	

Shares used in loss per share calculation:		
Basic	8,326	5,492
Diluted	8,326	5,492

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

ZONAGEN, INC. AND SUBSIDIARY
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited and in thousands)

	Three Months Ended March 31,		From Inception (August 20, 1987) through
	2005	2004	March 31, 2005
Cash Flows from Operating Activities			
Net loss	$ (1,555)	$ (786)	$ (88,309)
Gain on disposal of discontinued operations			(939)
Gain on disposal of fixed assets			(102)
Adjustments to reconcile net loss to net cash used in operating activities:			
Noncash financing costs			316
Noncash inventory impairment			4,417
Noncash patent impairment			1,339
Noncash decrease in accounts payable			(1,308)
Depreciation and amortization	1	2	3,774
Noncash expenses related to stock-based transactions	4		2,732
Common stock issued for agreement not to compete			200
Series B Preferred Stock issued for consulting services			18
Maturities (purchases) of marketable securities	(16,740)	(4,100)	6,995
Changes in operating assets and liabilities (net effects of purchase of businesses in 1988 and 1994):			
Decrease (increase) in receivables			(199)
Decrease (increase) in inventory			(4,447)
Decrease (increase) in prepaid expenses and other current assets	(205)	(42)	60
(Decrease) increase in accounts payable and accrued expenses	538	(145)	2,347
Decrease (increase) in other assets	600	284	
Net cash used in operating activities	(17,357)	(4,787)	(73,106)
Cash Flows from Investing Activities			
Maturities (purchases) of marketable securities			(28,723)
Capital expenditures	(3)	(3)	(2,292)
Purchase of technology rights and other assets	(21)	(53)	(2,459)
Proceeds from sale of PP&E			225
Cash acquired in purchase of FTI			3

Proceeds from sale of subsidiary, less $12,345 for operating losses during 1990 phase-out period			138
Proceeds from sale of the assets of FTI			2,250
Increase in net assets held for disposal			(213)
Net cash used in investing activities	(24)	(56)	(31,071)
Cash Flows from Financing Activities			
Proceeds from issuance of common stock, net of offering costs	18,180		102,404
Exercise of stock options	85		85
Proceeds from issuance of preferred stock			23,688
Purchase of treasury stock		(13,956)	(21,487)
Proceeds from issuance of notes payable			2,839
Principal payments on notes payable			(1,732)
Net cash provided by (used in) financing activities	18,265	(13,956)	105,797
Net increase (decrease) in cash and cash equivalents	884	(18,799)	1,620
Cash and cash equivalents at beginning of period	736	20,946	
Cash and cash equivalents at end of period	$ 1,620	$ 2,147	$ 1,620

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

ZONAGEN, INC. AND SUBSIDIARY
(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2005
(Unaudited)

NOTE 1 Organization and Operations

Zonagen, Inc. (the Company , Zonagen, or we, us or our) was organized on August 28, 1987 and is a developm stage company. We are a biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. Our lead product candidate, Progenta , is an orally available small molecule compound that we are developing for the treatment of uterine fibroids and endometriosis. Our second product candidate is Androxal , an orally available small molecule compound being developed for the treatment of testosterone deficiency in men.

On February 1, 2005 the Company completed its follow-on public offering of 5,060,000 shares of its common stock at $4.00 per share (which included the underwriters exercise of its over allotment option for 660,000 shares). The shares offered by the Company were issued out of its existing treasury stock, and the offering resulted in net proceeds to the Company of approximately $18.2 million.

In January 2004, the Company accepted for purchase 6,547,635 shares (approximately 57% of its outstanding common stock, at that time) at a purchase price of $2.10 per share in accordance with the terms of its self tender offer, which included 60,888 shares issuable upon exercise of options tendered by directors, for a total aggregate cost of approximately $14.0 million, inclusive of costs associated with the offer.

The Company has experienced negative cash flows from operations since inception and has funded its activities to date primarily from equity financings and corporate collaborations. The Company will continue to require substantial funds for research and development, including preclinical studies and clinical trials of our product candidates, and to commence sales and marketing efforts if appropriate, if the FDA or other regulatory approvals are obtained. The Company believes that its existing capital resources under its current operating plan will be sufficient to fund the Company s operations through at least the first quarter of 2006. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

Zonagen s results of operations may vary significantly from year to year and quarter to quarter, and depend, among other factors, on the Company s ability to be successful in our clinical trials, the regulatory approval process in the United States and other foreign jurisdictions and the ability to complete new licenses and product development agreements. The timing of our revenues may not match the timing of our associated product development expenses. To date, research and development expenses have generally exceeded revenue in any particular period and/or fiscal year.

Table of Contents

As of March 31, 2005, the Company had an accumulated deficit of $88.3 million. Losses have resulted principally from costs incurred in conducting clinical trials for VASOMAX® and the related female sexual dysfunction product, in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. Due to various tax regulations, including change in control provisions in the tax code, the value of this tax asset to the Company can be substantially diminished.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Recent Accounting Pronouncement

In December 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment. SFAS No. 123(R) will require that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. SFAS No. 123(R) covers a wide range of share-based compensation arrangements including share options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. SFAS No. 123(R) replaces FASB Statement No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS No. 123, as originally issued in 1995, established as preferable a fair value-based method of accounting for share-based payment transactions with employees. However, that Statement permitted entities the option of continuing to apply the guidance in APB Opinion No. 25, as long as the footnotes to financial statements disclosed what net income would have been had the preferable fair value-based method been used. Public entities will be required to apply SFAS No. 123(R) as of the first annual reporting period that begins after June 15, 2005. We are in the process of evaluating the impact the adoption of SFAS No. 123(R) will have on our consolidated financial position, results of operations and cash flows.

NOTE 2 Stock-based Compensation

The Company accounts for its stock option plans under APB No. 25 Accounting for Stock Issued to Employees. Accordingly, deferred compensation is recorded for stock options based on the excess of the market value of the common stock on the measurement date over the exercise price of the options. This deferred compensation is amortized over the vesting period of each option.

The Company has adopted the disclosure requirements of SFAS No. 123, Accounting for Stock-Based Compensation as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure (SFAS 123/148) and has elected not to record related compensation expense in accordance with this statement. Had compensation expense for its stock option plans been determined consistent with SFAS No. 123/148, the Company s net loss and loss per share would have been increased to the following pro forma amounts (in thousands,

Table of Contents

except for per share amounts):

	Three Months Ended March 31,	
	2005	2004
Net loss, as reported	$ (1,555)	$ (786)
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	4	
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(275)	(20)
Pro forma net loss	$ (1,826)	$ (806)
Loss per share -		
Basic as reported	$ (0.19)	$ (0.14)
Basic pro forma	(0.22)	(0.15)
Diluted as reported	(0.19)	(0.14)
Diluted pro forma	(0.22)	(0.15)

Under SFAS No. 123/148, the fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model. There were no options granted in the three-month period ended March 31, 2005. The following weighted average assumptions were used for grants in the three-month period ended March 31, 2004: risk-free interest rate of 3.9%; no expected dividends; expected lives of 5.7 years and expected volatility of 87%. The weighted fair value of options granted for the three-month period ended March 31, 2004 was $1.89.

The Black-Scholes option valuation model and other existing models were developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of and are highly sensitive to subjective assumptions including the expected stock price volatility. The Company s employee stock options have characteristics significantly different from those of traded options and changes in the subjective input assumptions can materially affect the fair value estimate.

NOTE 3 Marketable Securities

Management determines the appropriate classification of investments in debt and equity securities at the time of purchase and re-evaluates such designation as of each subsequent balance sheet date. Securities which the Company has the ability and intent to hold to maturity are classified as held to maturity . Securities classified as trading securities are recorded at fair value. Gains and losses on trading securities, realized and unrealized, are included in earnings and are calculated using the specific identification method. Any other securities are classified as available for sale. At March 31, 2005, all securities were classified as trading securities. The cost basis including purchased premium, which approximates fair value, for these securities was $21.5 million and $4.8 million at March 31, 2005 and December 31, 2004, respectively.

Short-term marketable securities have a remaining maturity of less than twelve months and long-term marketable securities have a remaining maturity of greater than twelve months.

Table of Contents

Marketable securities as of March 31, 2005 consist of only short-term investments totaling $21.5 million. The Company s investments typically include corporate bonds and notes, Euro-dollar bonds, taxable auction securities and asset-backed securities. The Company s policy is to require minimum credit ratings of A2/A and A1/P1 with maturities of up to three years. The average life of the investment portfolio may not exceed 24 months.

NOTE 4 Patents

As of March 31, 2005, the Company had approximately $438,000 in internal capitalized patent costs reflected on its balance sheet. Of this amount, $292,000 relates to patents for Progenta, which is being developed as an oral treatment for uterine fibroids and endometriosis, and $146,000 relates to Androxal, which is being developed as an oral treatment for testosterone deficiency. The Company is no longer maintaining its patent portfolio for its vaccine adjuvants, prostate cancer vaccines, hCG and zona pellucida immuno-contraceptive vaccines.

NOTE 5 Loss Per Share

Basic loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the year. Diluted loss per share is computed in the same manner as basic loss per share, except that, among other changes, the average share price for the period is used in all cases when applying the treasury stock method of potentially dilutive outstanding options.

The following table presents information necessary to calculate earnings per share for the three-month periods ended March 31, 2005 and 2004 (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2005	**2004**
Net loss	$ (1,555)	$ (786)
Weighted average common shares outstanding	8,326	5,492
Basic loss per share	$ (0.19)	$ (0.14)
Weighted average common and dilutive potential common shares outstanding:		
Weighted average common shares outstanding	8,326	5,492
Diluted loss per share	$ (0.19)	$ (0.14)

Common stock equivalents of 1,685,397 and 1,316,582 for the periods ended March 31, 2005 and 2004, respectively, were excluded from the above calculation of diluted loss per share since they were antidilutive.

NOTE 6 Stockholders Equity

Table of Contents

As of March 31, 2005, the Company had 10,079,601 shares outstanding and 1,937,035 shares of treasury stock. On February 1, 2005, the Company completed its follow-on public offering of 5,060,000 shares of its common stock at $4.00 per share (which included the underwriters exercise of its over allotment option for 660,000 shares). The shares offered by the Company were issued out of its existing treasury stock, and the offering resulted in net proceeds to the Company of approximately $18.2 million.

The Company received $85,000 for the exercise of 26,700 stock options for the three-month period ended March 31, 2005.

In January 2004, Zonagen purchased 6,547,635 shares of its common stock (approximately 57% of its outstanding common stock) at a purchase price of $2.10 per share in accordance with the terms of its self tender offer, which expired on January 7, 2004 at a total aggregate cost of approximately $14.0 million, inclusive of costs associated with the offer.

On March 29, 2004, the Compensation Committee approved grants to the Company s executive officers of incentive options to purchase 79,486 shares of its common stock that were to vest in the event certain milestones were attained. The options were granted at an exercise price of $2.72, the fair market value of the Company s common stock on the date of grant. Additionally, the Compensation Committee approved grants to the Company s non-executive employees of incentive options to purchase 17,504 shares of its common stock that were to vest in the event certain milestones were attained. These options were granted at an exercise price of $2.72, the fair market value of the Company s common stock on the date of grant. The Company records compensation expense under variable plan accounting for these incentive options, however no compensation expense was recorded for the quarters ended March 31, 2005 or 2004 as no milestones were achieved in these quarters.

As of March 31, 2005 a total of 39,743 executive officer and 8,752 non-executive employee incentive options had been earned due to achievement of milestones under these grants. No options were earned as of March 31, 2004 under these grants. On April 21, 2005 the Compensation Committee modified the original grant terms to allow for additional vesting of 23,845 executive officer and 5,251 non-executive employee incentive options. All remaining options under these grants were terminated.

NOTE 7 Commitments and Contingencies

As of March 31, 2005, in addition to general operating obligations, the Company also had purchase orders primarily relating to the clinical development of both Progenta and Androxal in the amounts of $837,800 and $624,000, respectively.

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements reflect the Company s current views with respect to future events and financial performance and are subject to certain risks, uncertainties and assumptions. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated in such forward-looking statements. See Factors Affecting Forward-Looking Statements included elsewhere in this quarterly report on Form 10-Q. The following discussion of financial condition should be read in conjuction with the accompanying consolidated financial statements and related notes.

Overview

Zonagen, Inc. (the Company, Zonagen, or we, us or our) was organized on August 28, 1987 and is a developr stage company. We are a clinical stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders.

Our lead product candidate is Progenta, an orally available small molecule compound being developed for the treatment of uterine fibroids and endometriosis. We are developing Progenta under an exclusive, worldwide license from the National Institutes of Health, or NIH. Progenta is being developed to alleviate adverse symptoms associated with both uterine fibroids and endometriosis by selectively blocking the progesterone receptor in women. We believe it may be superior to the current standards of care for uterine fibroids and endometriosis, which include surgery and treatment with gonadotropin releasing hormone agonists, or GnRH agonists, such as Lupron®. Unlike Progenta, GnRH agonists induce a low estrogen, menopausal-like state in women, and estrogen is necessary for the maintenance of bone mineral density. Therefore, GnRH agonists tend to promote bone loss and cannot be used for more than six months at a time. When women cease treatment with GnRH agonists, the fibroids rapidly regenerate and symptoms associated with endometriosis quickly reappear. We believe Progenta may provide an attractive alternative to surgery because of its potential to treat these conditions in a long-term, or chronic, fashion, resolving the symptoms that most commonly lead to invasive therapies. We believe Progenta may also be effective as a pre-surgical treatment for uterine fibroids.

We recently completed a European Phase Ib clinical study of Progenta, which studied the drug s safety and efficacy when administered for three months to women diagnosed with uterine fibroids, indicated that Progenta may be safe and have the potential to significantly reduce fibroid size. The Company believes it has sufficient data from this trial to adequately select dose for an advanced Phase II U.S. trial. Zonagen has scheduled a pre-IND meeting with the FDA for May 20, 2005 and pending those discussions, the Company s goal is to commence this Phase II trial by year end 2005. The Company hopes that this Phase II trial may be the first pivotal trial of two required pivotal trials. This trial is subject the FDA s review of our European Phase 1b data and clinical trial protocol and completion of additional preclinical animal safety studies . We anticipate initial study data by the end of the first half of 2006 and anticipate filing a New Drug Application, or NDA for Progenta, for the treatment of uterine fibroids in the year 2008. We also plan to begin a Phase II clinical trial in Poland for Progenta for the treatment of endometriosis by

Table of Contents

year end 2005. The FDA has deemed Progenta to be a new chemical entity.

Our second product candidate is Androxal, an orally available small molecule compound being developed for the treatment of testosterone deficiency in men. Androxal, our proprietary compound, is designed to restore normal testosterone production in males with functional testes and diminished pituitary function, a condition commonly referred to as andropause. Both of these conditions have been associated with prostate disease and abnormally high peaks of testosterone levels have also been associated with excitation, aggressive behavior, sleeplessness, anxiety, depression and headaches.

We have completed a Phase I/II clinical trial in the United States for Androxal for the treatment of men with testosterone deficiency and have submitted a full study report to the FDA. We met with FDA staff members on November 10, 2004 to review our clinical plan for the approval of Androxal. The FDA agreed to review our protocols for our trials in a timely fashion under a special protocol assessment, or SPA. We intend to begin a Phase III clinical trial for Androxal in the United States for the treatment of testosterone deficiency by year end 2005, subject to review of our clinical trial protocol by the FDA and completion of additional preclinical animal safety studies. We believe that initial study data will be available at the end of the first half of 2006. We anticipate filing a NDA for Androxal for the treatment of testosterone deficiency in the year 2008. The FDA has deemed Androxal to be a new chemical entity.

Before we can conduct a Phase II study with Progenta or a Phase III study with Androxal in the United States, we must first provide the FDA with three months of animal safety data that the FDA deems acceptable for each respective product. We are currently conducting these animal safety studies as a means of beginning these human clinical studies in the United States by year end 2005. In addition, as a result of both Progenta and Androxal being deemed new chemical entities, we must provide the FDA with additional data from lengthy animal studies before long term human studies may be initiated in the United States and a NDA may be submitted. The Company s current ongoing animal safety studies are expected to provide both safety data to support the initiation of the Company s Phase II study with Progenta and Phase III study with Androxal for initiation by year end 2005 as well as provide some long term safety data that will be used toward the support of future long term human studies.

For a detailed discussion regarding the development, scientific rationale and risks involving both Progenta and Androxal as well as a discussion of our prior product candidates, see Part I. Item 1. Business included in the Company s annual report on Form 10-K for the year ended December 31, 2004.

We have five full-time employees who utilize the services of contract research organizations, contract manufacturers and various consultants to assist us in performing regulatory services for the clinical development of our products. We are highly dependent on our various contract groups to adequately perform the activities required to obtain regulatory approval of our products.

On February 1, 2005, we completed our follow-on public offering of 5,060,000 shares of our common stock at $4.00 per share (which included the underwriters exercise of its over allotment option for 660,000 shares). The shares offered by us were issued out of our existing treasury stock,

Table of Contents

and the offering resulted in net proceeds to us of approximately $18.2 million.

The clinical development of pharmaceutical products is a complex undertaking, and many products that begin the clinical development process do not obtain regulatory approval. The costs associated with our clinical trials may be impacted by a number of internal and external factors, including the number and complexity of clinical trials necessary to obtain regulatory approval, the number of eligible patients necessary to complete our clinical trials and any difficulty in enrolling these patients, and the length of time to complete our clinical trials. Given the uncertainty of these potential costs, we are unable to estimate the total costs we will incur for the clinical development of our product candidates over those costs currently projected. We do, however, expect these costs to increase substantially in future periods as we continue later-stage clinical trials, initiate new clinical trials for additional indications and seek to obtain regulatory approvals. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations.

Out-Licensing

The Company has limited financial resources and personnel and anticipates that it will need to raise additional capital and hire a significant number of employees in order to be able to successfully develop each of its current product candidates through the clinical trials and to be able to market them, should regulatory approval be obtained, on a worldwide basis. Alternatively, the Company may elect to partner with a larger and more experienced pharmaceutical company with better resources for one or more of its product candidates and/or target indications. As a result, the Company believes that an out-license of one or more of its product candidates could occur at some point in the future, and discussions are held from time to time with potential partners to explore possible arrangements. No such agreement is in process or anticipated in the near future, although there can be no assurance that such an agreement will not be entered into by us.

The Company is continuing its out-licensing efforts relating to its phentolamine-based product candidates, including VASOMAX®, which had previously been approved for marketing in several countries in Latin America for the treatment of male erectile dysfunction, or MED. VASOMAX is currently on partial clinical hold in the United States but is not on clinical hold in Europe. There can be no assurance that the Company will be able to create any value from out-licensing activities of its phentolamine-based product candidates.

Results of Operations

Three Month Periods Ended March 31, 2005 and 2004

Our results of operations may vary significantly from quarter to quarter and year to year, and depend, among other factors, on our ability to be successful in our clinical trials, the regulatory approval process in the United States and other foreign jurisdictions and the ability to complete new licenses and product development agreements. The timing of our revenues may not match the timing of our associated product development expenses. To date, research and development expenses have generally exceeded revenue in any particular period and/or fiscal

Table of Contents

year.

Revenues and other income. Total revenues and other income for the three-month period ended March 31, 2005 decreased to $112,000 as compared with $125,000 for the same period in the prior year.

Research and development grant revenues for the three-month period ended March 31, 2005 were $4,000 as compared to $64,000 for the same period in the prior year. Grant revenue relates to a $836,441 Phase II Small Business Innovative Research grant that was awarded to the Company in 2002 for the development of Progenta as an oral treatment for endometriosis. This SBIR grant has come to its anticipated conclusion and is essentially depleted.

Interest income increased 315% to $108,000 for the three-month period ended March 31, 2005, as compared to $26,000 for the same period in the prior year. This increase is primarily due to the increase in marketable securities as a result of the Company completing its follow-on public offering on February 1, 2005 in which it received approximately $18.2 million in net proceeds.

Other revenue included in the three-month period ended March 31, 2004 of $35,000 was from the sale of some of the Company s preclinical phentolamine data that is to be used for a purpose that does not compete with the Company s sexual dysfunction technologies.

Research and Development Expenses. Research and development (R&D) expenses include contracted research, regulatory affairs activities and general research and development expenses. R&D expenses increased 159% to $1.2 million for the three-month period ended March 31, 2005 as compared to $477,000 for the same period in the prior year. The increase in R&D expenses for the three-month period ended March 31, 2005 as compared to the same period in the prior year is primarily due to an increase of $499,000 and $292,000 related to the Company s clinical development programs for Progenta and Androxal, respectively, partially offset by a decrease of $60,000 in costs associated with the Company s SBIR grant funded R&D.

General and Administrative Expenses. General and administrative expenses remained relatively constant at $431,000 for the three-month period ended March 31, 2005, as compared to $434,000 for the same period in the prior year. The slight decrease in expenses for the three-month period ended March 31, 2005 is primarily due to a decrease in directors and officers insurance expense and professional services, partially offset by an increase in directors expense.

Liquidity and Capital Resources

The Company had cash, cash equivalents and marketable securities of approximately $23.2 million at March 31, 2005 as compared to $5.5 million at December 31, 2004. This increase in cash is due to the February 1, 2005 completion of our public offering of 5,060,000 shares of common stock in which we received net proceeds of approximately $18.2 million. We believe that our existing capital resources under our current operating plan will be sufficient to fund our operations through the first quarter of 2006. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

Excluding purchases of marketable investment securities of $16.7 million, we used

Table of Contents

$617,000 during the three-month period ended March 31, 2005 for operating activities. The major uses of cash for operating activities during the three-month period ended March 31, 2005 was to fund the Company s clinical development programs and administrative costs of approximately $1.6 million and to prepay the majority of the Company s annual insurance policies. Cash used in investing activities was $24,000 in the three-month period ended March 31, 2005, primarily for investments in technology rights related to our Progenta and Androxal patent portfolios. Cash provided by financing activities was approximately $18.3 million in the three-month period ended March 31, 2005, relating to the follow-on public offering which was completed in February 2005 and the exercise of 26,700 stock options in the three-month period ended March 31, 2005. As of March 31, 2005, in addition to general operating obligations, the Company also had non-cancelable purchase orders primarily relating to the clinical development of both Progenta and Androxal in the amounts of $837,800 and $624,000, respectively.

As of March 31, 2005, we had an accumulated deficit of $88.3 million. The Company has incurred losses since its inception and expects to continue to incur losses for the foreseeable future. Inception to date losses have resulted principally from costs incurred in conducting clinical trials for VASOMAX, our previous lead product candidate for the oral treatment of male erectile dysfunction, in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. We do not intend to commit any additional resources toward the development of VASOMAX. We have financed our operations primarily with proceeds from public offerings and private placements of equity securities, funds received under collaborative agreements and SBIR grants. We will require substantial additional capital to further develop Progenta as our oral treatment for uterine fibroids and endometriosis and Androxal for the oral treatment of testosterone deficiency.

Our capital requirements will depend on many factors, including the costs and timing of seeking regulatory approvals of the Company s products; the problems, delays, expenses and complications frequently encountered by development stage companies; the progress of the Company s preclinical and clinical activities; the costs associated with any future collaborative research, manufacturing, marketing or other funding arrangements; the Company s ability to obtain regulatory approvals; the success of the Company s potential future sales and marketing programs; the cost of filing, prosecuting and defending and enforcing any patent claims and other intellectual property rights; changes in economic, regulatory or competitive conditions of the Company s planned business; and additional costs associated with being a publicly-traded company. Estimates about the adequacy of funding for the Company s activities are based on certain assumptions, including the assumption that the development and regulatory approval of the Company s products can be completed at projected costs and that product approvals and introductions will be timely and successful. There can be no assurance that changes in the Company s research and development plans, acquisitions or other events will not result in accelerated or unexpected expenditures. To satisfy its capital requirements, the Company may seek to raise additional funds in the public or private capital markets. The Company may seek additional funding through corporate collaborations and other financing vehicles. There can be no assurance that any such funding will be available to the Company on favorable terms or at all. If the Company is successful in obtaining additional financing, the terms of such financing may have the effect of diluting or adversely affecting the holdings or the rights of the holders of the

Table of Contents

Company s common stock.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. Cash, cash equivalents and investments were approximately $23.2 million at March 31, 2005. These assets were primarily invested in investment grade corporate bonds and commercial paper with maturities of less than 18 months, which are classified as Trading Securities. We do not invest in derivative securities. Although our portfolio is subject to fluctuations in interest rates and market conditions, no significant gain or loss on any security is expected to be recognized in earnings due to the expected short holding period.

Item 4. Controls and Procedures

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, the Company s Chief Executive Officer and Chief Financial Officer have concluded that the Company s disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) are effective in insuring that the information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the required time periods.

In connection with the evaluation described above, the Company identified no change in internal control over financial reporting that occurred during the fiscal quarter ended March 31, 2005 that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

Table of Contents

PART II OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings.

Item 5. Other Information

None

Item 6. Exhibits

31.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).

31.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).

32.1 Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).

32.2 Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).

Table of Contents

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ZONAGEN, INC.

Date: May 9, 2005

By: /s/ Joseph S. Podolski

Joseph S. Podolski
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 9, 2005

By: /s/ Louis Ploth, Jr.

Louis Ploth, Jr.
Vice President Business Development, Chief Financial Officer, Director and Secretary
(Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

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