PRO PHARMACEUTICALS INC
Form 10QSB
August 14, 2003
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

(Mark One)

[X] Quarterly report under Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended June 30, 2003

[ ] Transition report under Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to

Commission file number 000-32877

PRO-PHARMACEUTICALS, INC.

(Exact name of small business issuer as specified in its charter)

Nevada	04-3562325
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

189 Wells Avenue, Newton, Massachusetts 02459

(Address of principal executive offices)

(617) 559-0033

(Issuer s telephone number)

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY

PROCEEDINGS DURING THE PRECEDING FIVE YEARS

Check whether the issuer filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Exchange Act after the distribution of securities under a plan confirmed by a court. Yes [ ] No [ ]

NOT APPLICABLE

APPLICABLE ONLY TO CORPORATE ISSUERS

State the number of shares outstanding of each of the issuer s classes of common equity, as of the latest practicable date: The total number of shares of common stock, par value $0.001 per share, outstanding as of June 30, 2003 was 20,343,571.

Transitional Small Business Disclosure Format (Check one): Yes [ ] No [X]

Table of Contents

TABLE OF CONTENTS

Table of Contents

Part 1 Financial Information

Item 1. Financial Statements

PRO-PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED BALANCE SHEETS (Unaudited)

	June 30, 2003	December 31, 2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,791,058	$ 1,921,233
Prepaid expenses and other current assets	93,619	72,733
Total current assets	1,884,677	1,993,966
PROPERTY AND EQUIPMENT, Net	181,354	177,160
INTANGIBLE ASSETS	114,669	85,090
DEPOSITS AND OTHER ASSETS	26,951	26,951
Total assets	$ 2,207,651	$ 2,283,167
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 364,226	$ 302,899
Accrued expenses	36,209	174,644
Offering costs payable	17,230	174,250
Convertible notes payable		15,000
Total current liabilities	417,665	666,793
STOCKHOLDERS EQUITY:		
Common stock, $0.001 par value; 100,000,000 shares authorized, 5,000,000 undesignated shares, 20,343,571 and 19,034,647 issued and outstanding at June 30, 2003 and December 31, 2002, respectively	20,343	19,034
Additional paid-in capital	11,600,983	9,635,531
Stock subscriptions receivable		(150,000)
Deferred compensation	(78,633)	(54,959)
Deficit accumulated during the development stage	(9,752,707)	(7,833,232)

Total stockholders equity	1,789,986	1,616,374
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 2,207,651	$ 2,283,167

See notes to condensed financial statements.

Table of Contents

PRO-PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Cumulative Period From Inception (July 10, 2000) To June 30,
	2003	2002	2003	2002	2003
OPERATING EXPENSES:					
Research and development	$ 407,944	$ 451,630	$ 801,823	$ 760,712	$ 3,278,557
General and administrative (a)	573,912	389,871	1,133,100	797,957	4,292,626
Total operating expenses	(981,856)	(841,501)	(1,934,923)	(1,558,669)	(7,571,183)
INTEREST INCOME	7,713	6,287	19,303	11,957	68,739
INTEREST EXPENSE	(465)	(107,196)	(3,855)	(347,991)	(2,250,263)
Net loss	$ (974,608)	$ (942,410)	$ (1,919,475)	$ (1,894,703)	$ (9,752,707)
NET LOSS PER SHARE BASIC AND DILUTED	$ (0.05)	$ (0.06)	$ (0.10)	$ (0.12)	
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING					
Basic and diluted	20,343,571	15,665,749	20,168,378	15,595,079	
(a) The following summarizes the allocation of the stock-based compensation charge:					
General and administrative	$ 37,100	$ 24,654	$ 84,061	$ 40,726	

See notes to condensed financial statements.

Table of Contents

PRO-PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	Six Months Ended June 30,		Cumulative Period From Inception (July 10, 2000) To June 30,
	2003	2002	2003
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (1,919,475)	$ (1,894,703)	$ (9,752,707)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	36,908	16,215	92,747
Amortization of debt discount on convertible notes			1,258,012
Amortization of deferred extension costs through interest expense		100,625	167,497
Expense related to issuance of warrants to purchase common stock		235,987	235,987
Writeoff of intangible assets			107,000
Debt conversion expense			503,019
Settlement of accrued interest through issuance of common stock		8,179	10,274
Stock based compensation expense	84,061	40,726	336,707
Changes in current assets and liabilities:			
Prepaid and other expenses	(20,886)	(7,752)	(90,491)
Deposits and other assets			(26,951)
Accounts payable	61,327	318,255	355,198
Accrued expenses	(25,179)	(70,566)	149,465
Net cash used in operating activities	(1,783,244)	(1,253,034)	(6,654,243)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(39,360)	(80,695)	(272,359)
Increase in patents costs and other assets	(31,321)	(19,433)	(116,411)
Net cash used in investing activities	(70,681)	(100,128)	(388,770)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net proceeds from issuance of common stock and warrants			2,229,750
Net proceeds from issuance of common stock	1,723,750	650,998	5,360,691
Net proceeds from issuance of convertible notes payable			1,320,602
Repayment of convertible notes payable			(86,000)
Proceeds from shareholder advances			9,028
Net cash provided by financing activities	1,723,750	650,998	8,834,071

NET INCREASE IN CASH AND CASH EQUIVALENTS	(130,175)	(702,164)	1,791,058
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	1,921,233	1,491,172	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 1,791,058	$ 789,008	$ 1,791,058

See notes to condensed financial statements.

Table of Contents

PRO-PHARMACEUTICALS, INC.

(A Development Stage Company)

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

June 30, 2003

1. NATURE OF OPERATIONS, BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

NATURE OF OPERATIONS

Pro-Pharmaceuticals, Inc. (the Company) was established in July 2000. The Company is in the development stage and is in the process of developing technology that is intended to reduce the toxicity and improve the efficacy of currently existing chemotherapy drugs by combining the drugs with its proprietary carbohydrate compounds.

The Company is devoting substantially all of its efforts toward product research and development, and raising capital.

One of its product candidates began Phase I clinical trials in February 2003.

During the quarter ended June 30, 2003, the Company raised net proceeds of approximately $473,770 in capital through a private placement of securities which began in May 2003, as discussed in Note 3. Subsequent to the end of the quarter, the Company raised additional net proceeds of approximately $4.22 million in connection with this private placement.

BASIS OF PRESENTATION

The Company is subject to a number of risks similar to those of other development stage companies, including dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with clinical trials of products, dependence on third-party collaborators for research operations, need for regulatory approval of products, risks associated with protection of intellectual property, and competition with larger, better-capitalized companies.

The Company plans to raise additional capital through private placements or public offerings of equity securities in order to cover future budgets. Given the Company s recent attempts to raise additional capital and its available cash and cash equivalents as of June 30, 2003, the Company believes that it will be able to proceed with its current plan of operations and meet its obligations for all of 2003 and through at least the third quarter of 2004. If actual expenses exceed the budget, however, the Company will need to raise additional capital sooner in order to meet its cash needs. If the Company cannot raise the additional funds when needed, the Company would slow or halt its research and development expenditures until adequate funding became available. The Company s business structure is somewhat flexible because the

Company outsources most of its research and development.

Pursuant to the rules and regulations of the Securities and Exchange Commission, the Company has prepared the condensed financial statements included herein. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted

Table of Contents

accounting principles have been condensed or omitted pursuant to such rules and regulations. The Company believes, however, that the disclosures are adequate to make the information presented not misleading. It is suggested that these condensed financial statements be read in conjunction with the financial statements and the notes thereto included in the Company s latest annual report on Form 10-KSB.

The condensed financial statements, in the opinion of management, include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the Company s financial position and the results of operations. These results are not necessarily indicative of the results to be expected for the entire year.

SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies followed by the Company in preparing its financial statements are set forth in Note 2 to the financial statements included in its report on Form 10-KSB for the year ended December 31, 2002. The Company has made no changes to these policies during this quarter.

Reclassifications: Certain prior period amounts have been reclassified to conform to the current period presentation.

Stock-Based Compensation: As allowed by Statement of Financial Accounting Standard (SFAS) No. 123, Accounting for Stock-Based Compensation, the Company has elected to account for stock-based compensation at intrinsic value with disclosure of the effects of fair value accounting on net loss and net loss per share on a pro forma basis. The Company accounts for awards issued to employees under the plan using the recognition and measurement principles of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. No compensation expense has been recognized in connection with its stock option plans, as all options granted under the plan had an exercise price equal to or greater than the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net loss and net loss per share had the Company adopted the fair value recognition provisions of SFAS No. 123:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
Net loss, as reported	$ (974,608)	$ (942,410)	$ (1,919,475)	$ (1,894,703)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(84,663)	(9,883)	(124,760)	(9,883)
Pro forma net loss	$ (1,059,271)	$ (952,293)	(2,044,235)	(1,904,586)
Net loss per share:				
Basic and diluted as reported	(0.05)	(0.05)	(0.10)	(0.12)
Basic and diluted pro forma	(0.05)	(0.05)	(0.10)	(0.12)

The Company estimated the fair value on the date of grant using the Black-Scholes option pricing model. Key assumption used to apply this pricing model were a deemed fair market values of the Company s common stock ranging from $2.89 to $3.50 per share on the grant date, risk free interest rates ranging from 2.06% to 2.32%, a weighted average expected life of three years, and a dividend rate of 0.0%.

7

Table of Contents

2. NET LOSS PER SHARE

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, Earnings per Share, for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period, less shares subject to repurchase. Diluted weighted-average shares are the same as basic weighted-average shares since the inclusion of 1,900,501 and 1,852,423 shares at June 30, 2003 and December 31, 2002, respectively, issuable pursuant to the exercise of stock options and warrants and conversion of convertible debt would have been antidilutive.

3. STOCKHOLDERS EQUITY

May 2003 Private Placement In May 2003, the Company began a private placement of securities at $2.00 per share of up to 2,500,000 shares of common stock, exempt from registration pursuant to Rule 506 of Regulation D under the Securities Act of 1933 in order to raise up to $5,000,000 to cover its expenditures. Such shares, insofar as they are restricted securities , were sold at a price approximately 25 percent below the market price of the shares of the Company s common stock that were trading at the time the private placement began. During the quarter ended June 30, 2003, the Company sold approximately 245,500 shares under this offering for gross proceeds of approximately $491,000. As of June 30, 2003, the Company had not yet issued shares of common stock in connection with proceeds received and has accordingly classified the proceeds as additional paid-in capital. The Company continued to offer securities under this private placement through July 15, 2003 and received approximately $4.3 million in incremental gross proceeds.

In consideration for services performed as part of the private placement, the Company has agreed to compensate a registered investment advisor, a finder registered under applicable law, and such finder s agents, for identifying qualified investors; and two registered broker dealers (collectively, the Placement Group). As of June 30, 2003, the Placement Group was entitled to receive $17,230 in cash and 14,213 warrants to purchase common stock at $5.40 per share, expiring on July 15, 2006. Subsequent to the end of the quarter, the Placement Group was entitled to receive approximately $115,240 in cash and 95,400 warrants to purchase common stock at $5.40 per share expiring on July 15, 2006.

4. STOCK OPTION PLANS

In March 2003, the Company entered into a contract with a board member and shareholder of the Company, pursuant to which such director would provide consulting services in connection with its business development and related financial services. The Company agreed to compensate the shareholder by granting options to purchase 24,000 shares of Common Stock, at an exercise price of $3.50 per share, which vest at a rate of 2,000 shares of Common Stock per month through March 1, 2004. The options expire 10 years from the grant date. The options were initially valued at $33,403, using the Black-Scholes option pricing model, based on a deemed fair value of the Company s common stock of $2.59 per share, an assumed volatility of 95%, a risk-free interest rate of 1.75%, a weighed average expected life of three years, and a dividend rate of 0.0%.

Table of Contents

During 2002, a board member and stockholder of the Company provided consulting services to the Company. In April 2003, such individual agreed to receive compensation for such services in the form of 25,324 shares of common stock and 25,324 options at an exercise price of $2.96 to purchase common stock of the Company. As of December 31, 2002, the Company recorded the deemed fair value of such compensation of approximately $121,956 as an accrued liability. The common stock has been valued at $75,972, based on the closing price of the publicly traded shares of common stock on the date of grant. The options were valued at $45,984, using the Black-Scholes option pricing model, based on a deemed fair value of the Company s common stock of $3.00 per share, an assumed volatility of 95%, a risk-free interest rate of 2.91%, a weighed average expected life of three years, and a dividend rate of 0.0%.

In May 2003, the Company granted a member of its Scientific Advisory Board non-qualified stock options to purchase 10,000 shares of Common Stock exercisable for five years at $3.50 per share, the exercise rights to which vest with respect to 5,000 options as of May 8, 2003, and 5,000 options as of May 8, 2005. The options were valued at $15,507, using the Black-Scholes option pricing model, based on a deemed fair value of the Company s common stock of $2.80 per share, an assumed volatility of 95%, a risk-free interest rate of 1.75%, a weighed average expected life of three years, and a dividend rate of 0.0%.

Stock options granted to non-employees are accounted for in accordance with SFAS No. 123 and the Emerging Issues Task Force (EITF) Abstract No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, and the related interpretations, which generally requires the value of options to be periodically remeasured and charged to expense as they are earned over the performance period. The fair value of the options is determined using the Black-Scholes option pricing model. Compensation expense for non-employee options recorded in the accompanying financial statements was $84,061 and $40,726 for the six months ended June 30, 2003 and 2002, respectively, and $37,100 and $24,654 for the three months ended June 30, 2003 and 2002 respectively.

5. COMMITMENTS AND CONTINGENCIES

On May 14, 2003 an action titled Sheila Jayaraj v. Pro-Pharmaceuticals, Inc. and David Platt (Commonwealth of Massachusetts, Middlesex Superior Court, Case No. 03-2102) was instituted against the Company. A related complainant letter dated May 14, 2003 was filed with the Occupational Safety and Health Administration of the U.S. Department of Labor. The plaintiff, who was Vice President of Investor Relations and Corporate Strategy for approximately five months, asserts against the Company claims for wrongful discharge in violation of public policy and of employee protection provided for under the Sarbanes-Oxley Act of 2002. The plaintiff seeks monetary damages and full reinstatement of her position at Pro-Pharmaceuticals, Inc. Based on a preliminary investigation, the Company believes the claims are without merit, and accordingly intends to defend the allegations vigorously.

Table of Contents

Item 2. Plan of Operation

This quarterly report on Form 10-QSB contains, in addition to historical information, forward-looking statements. These statements can be identified by the use of forward-looking terminology such as may, will, could, expect, anticipate, estimate, continue or other similar w These forward-looking statements are based on management s current expectations and are subject to a number of factors and uncertainties, which could cause actual results to differ materially from those described in such statements. We caution investors that actual results or business conditions may differ materially from those projected or suggested in forward-looking statements as a result of various factors including, but not limited to, those described in the Risk Factors section in our Annual Report on Form 10-KSB for the year ended December 31, 2002 and our Registration Statement filed on Form SB-2 with the Securities and Exchange Commission on July 17, 2003, as amended on July 30, 2003. We cannot assure you that we have identified all the factors that create uncertainties. Readers should not place undue reliance on forward-looking statements. We undertake no obligation to publicly release the result of any revision of these forward-looking statements to reflect events or circumstances after the date they are made or to reflect the occurrence of unanticipated events.

Overview

We are engaged in research and development of drug technologies to enable targeted delivery of chemotherapy drugs. We intend initially to combine our proprietary carbohydrate compounds with existing widely-used chemotherapies. We believe our technology will increase the body s tolerance to these toxic drugs by targeting the delivery directly to cancerous cells. We also believe our approach of improving existing chemotherapy drugs by adding a targeting mechanism should also increase the efficacy of these drugs thereby, together with toxicity reduction, creating a preferable treatment to existing first line oncology regimens. Additionally, we believe that this drug development strategy will enable our company to gain patent protection on drugs we reformulate with our carbohydrate compounds.

The U.S. Food and Drug Administration (the FDA) has approved our first Investigational New Drug Application (IND) for Phase I human clinical trials relating to colorectal cancer. Additionally, the FDA also approved our amendment to broaden the scope of our IND to include all solid tumors. In February, 2003, we began clinical trials of our drug and are in the process of collecting results. Also, we are currently conducting pre-clinical animal experiments with additional IND candidates. We have not yet generated any operating revenues.

We were incorporated under Nevada law in January 2001. Shares of our common stock currently are quoted on the OTC Bulletin Board under the symbol PROH .

Research and Development

Our drug development program is focused on novel drug delivery platforms to upgrade the efficacy and reduce the toxicity of some of the proven, commonly used anti-cancer drugs. We believe we can enhance the delivery of the chemotherapeutic drugs by exploiting liquid recognition of sugar-specific receptors found on cancer cells. Our studies indicate that a polysaccharide with a suitable chemical structure and charge in combination with a chemotherapy drug, will increase cellular membrane fluidity and permeability, thereby facilitating delivery to the affected cell.

Table of Contents

The first group of drugs selected to go through our upgrade programs are 5-Fluorouracil, Adriamycin®, Taxol®, Cytoxan® and Cisplatin®. The two patent-pending, drug delivery platforms, which we have identified and trademarked, are as follows:

DAVANAT™, a galactomannan derivative, is a formulation using oligomeric carbohydrates as the target vehicle for chemotherapeutic drugs.

UNIVERSAL CARBOHYDRATE LINKAGE TECHNOLOGY™, or UCLT™, enhances the delivery of chemotherapeutic drugs by utilizing carbohydrate specific receptors found on cancer cells.

DAVANAT™-1

DAVANAT™ combined with 5-Fluorouracil (5-FU), referred to as DAVANAT™ -1, is our first drug combination that has advanced to human clinical trials. DAVANAT™ was selected using animal models as the most promising combination for 5-FU. In 2002, DAVANAT™ -1 was submitted to the FDA and was approved as an investigational new drug (IND), which authorizes us to begin human clinical trials. On February 10, 2003 we began Phase I clinical trials in humans. See Phase I Clinical Trials below.

Toxicity Studies

Our initial toxicity studies in smaller animals, conducted in early 2001, were performed to test the potential reduction of toxicity of anticancer drugs in combination with certain of our polysaccharide compounds. The results of one study demonstrated that one of our polysaccharide compounds, DAVANAT™, might significantly decrease the toxicity of 5-FU. A second, similar study was performed to test a potential reduction of toxicity of Adriamycin® in combination with each of two selected polysaccharide compounds. The results indicated that DAVANAT™ might decrease the toxicity of Adriamycin®. The fact that two different cancer drugs, with chemically unrelated structures, showed a marked reduction of their toxicity in combination with DAVANAT™ indicates that there might be some fundamental underlying biological reasons related to this polysaccharide, rather than to the drugs, for the reduction in toxicity.

In subsequent pre-clinical experiments conducted in 2001 and 2002, we studied on larger animals the toxicity reduction of DAVANAT™-1, a DAVANAT™ combination with 5-FU, which had demonstrated toxicity reduction in the prior studies. These experiments were performed in accordance with FDA guidelines and recommendations on rats (acute and long-term toxicity study) and dogs (acute and long-term toxicity study) measuring the effect of the DAVANAT™/5-FU combination on body weight, feed consumption, blood structure and survival of these animals. Preliminary results indicate that the DAVANAT™/5-FU combination decreased toxicity, resulting in lower animal mortality and decreased loss of blood structure components in comparison to the results in animals that were administered 5-FU/leucovorin alone. These studies were presented to the FDA as part of our IND submission (detail below). We conducted additional toxicity studies on rats using escalating dosages of

Table of Contents

DAVANAT™ and submitted these results to the FDA in an amendment to our IND in support of our Phase I clinical trials. The results of these additional toxicity studies were such that the FDA approved our commencement of Phase I clinical trials.

Efficacy Studies

We undertook independent studies at Southern Research Institute and Charles River Laboratories to test a potential change in the therapeutic efficacy of the DAVANAT™/5-FU combination that had decreased toxicity of the drug in healthy animals. Results of the studies demonstrated that DAVANAT™ might also increase the efficacy of 5-FU when administered into cancer-carrying animals. The studies, conducted with two different human colon tumors implanted into the test animals, demonstrated a decrease in tumor size following administration of 5-FU/leucovorin alone, as well as a significant decrease with the administration of the DAVANAT™/5-FU combination.

Two of our efficacy studies were conducted to evaluate the compatibility of DAVANAT™ with leucovorin, which is commonly used in cancer treatment with 5-FU. The studies showed that DAVANAT™ and leucovorin do not interfere with each other when administered following standard procedure, and that the DAVANAT™/5-FU combination is superior, compared to 5-FU/leucovorin when both are administered in tumor-bearing animals. Leucovorin is a folinic acid derivative, which may enhance both the therapeutic and toxic effect of 5-FU in cancer therapy. In these studies, the growth of the tumor was decreased significantly by using a DAVANAT™/5-FU combination compared to a 5-FU/leucovorin combination.

We also conducted a study that involved injecting radiolabeled DAVANAT™ (with and without 5-FU) into tumor-free and tumor-bearing animals. The study provided experimental data with respect to DAVANAT™ distribution in organs and tissues (liver, kidney, lungs, plasma, and tumor) and the capacity of such organs and tissue to clear DAVANAT™ after various time periods. The study suggested that DAVANAT™ may protect the liver from the toxic effect of 5-FU yet increase the amount, and hence the therapeutic effect, of 5-FU in the tumor. In other words, we have indications that DAVANAT™ may decrease toxicity and increase efficacy of 5-FU.

In addition to the DAVANAT™/5-FU combination, we are also conducting pre-clinical studies for doxurubicin and paclitaxel, both in combination with DAVANAT™ and other polysaccharide compounds.

Although the foregoing studies are encouraging, the results achieved in preclinical studies with animals are often not duplicated in human patients. Please see Risk Factors Our product candidates will be based on novel technologies in our Annual Report Form 10-KSB for the year ended December 31, 2002 and Risk Factors We Have Only Recently Began Clinical Trials And Results Are Uncertain in our Registration Statement, as amended, filed on Form SB-2 on July 17, 2003.

Table of Contents

Phase I Clinical Trials

We submitted an IND to the FDA on May 26, 2002 based on the pre-clinical data obtained from our 5-FU studies. The FDA accepted the IND as of June 26, 2002, which authorized us to begin Phase I clinical trials with humans. We filed an amendment to the IND on November 27, 2002 in order to incorporate new toxicology data and to enable us to undertake dose escalation in our Phase I trials. In response to the amendment, the FDA approved the dose escalation schema which would allow assessment in clinical trials of DAVANAT™ doses anticipated to be in the range of those for which the pre-clinical studies suggested efficacy.

In Phase I we are evaluating the ability of cancer patients to tolerate increasing doses of DAVANAT™ while receiving a stable dose of 5-FU for treatment of a variety of solid tumors which have not responded to accepted therapies. The Phase I study has two primary objectives: (1) to determine the maximum dose of DAVANAT™ that can be tolerated when administered with a stable dose of 5-FU, and (2) to define the dose-limiting toxicities of DAVANAT™ in combination with 5-FU. We expect that up to 40 male and female patients suffering from advanced solid malignancies, who failed the accepted chemotherapeutic, radiation, and/or surgical treatments, will participate in the study.

We have identified four clinical sites and lead investigators in which to undertake our Phase I trials: The Ochsner Cancer Institute, located in New Orleans, Louisiana; Norris Cotton Cancer Center at Dartmouth-Hitchcock Medical Center, located in Lebanon, New Hampshire; Florida Oncology Associates, located in Jacksonville, Florida; and The University of Michigan Comprehensive Cancer Center, located in Ann Arbor, Michigan.

We have also engaged a professional consultant, Dr. Marilyn Pike, who is affiliated with Harvard Medical School and Massachusetts General Hospital, to serve as Medical Director of our clinical trials.

The pharmaceutical company with which we contracted to produce DAVANAT™, a certified GMP facility, has manufactured sufficient quantities for the doses that will be needed for the human clinical trials.

We have engaged PRA International Inc. to serve as our independent Contract Research Organization (CRO) to manage and implement the clinical trials on our behalf. Additionally, Medidata Solutions Inc. has constructed for us an on-line electronic data capture (EDC) method to collect and aggregate our clinical trial data. We expect that EDC will better enable us to manage clinical trial data and increase the speed at which such data is reported and compiled. We believe this may accelerate our commencement of Phase II clinical trials.

Other Carbohydrate-Cancer Drug Formulations

We have chemically synthesized four novel products that are carbohydrate derivatives of Adriamycin®, and have conducted preclinical studies in mice of both toxicity (effects on healthy animals) and efficacy (on cancer-carrying animals). Preliminary results of these experiments indicate that all four of the synthesized carbohydrate-Adriamycin® compounds, and particularly one, named Galactomycin™, are significantly less toxic compared with the original Adriamycin®, and demonstrate

13

Table of Contents

therapeutic efficacy as well. In the case of Galactomycin™, the preliminary results indicated a therapeutic index improvement over the parent Adriamycin®. These studies were conducted at the Academy of Medical Sciences, Moscow, Russia. We have started the scale-up manufacturing for Galactomycin™ and are currently conducting pre-clinical efficacy studies in tumor-bearing animals.

Although the foregoing studies are encouraging, the results achieved in preclinical studies with animals are often not duplicated in human patients. Please see Risk Factors Our product candidates will be based on novel technologies in our Annual Report on Form 10-KSB for the year ended December 31, 2002 and Risk Factors Our product candidates will be based on novel unproven technologies in our Registration Statement, as amended, initially filed on Form SB-2 on July 17, 2003.

Patents and Proprietary Rights

We have one patent application that has received a Notice of Allowance from the U.S. Patent and Trademark Office. We also have four non-provisional utility patent applications, and two provisional patent applications, pending in the U.S. Patent Office. The patent applications cover methods and compositions for reducing side effects in chemotherapeutic formulations, and improving efficacy and reducing toxicity of chemotherapeutic agents. The patent that received the Notice of Allowance is entitled Methods and Compositions for Reducing Side Effects in Chemotherapeutic Treatments and covers improved targeting of Doxorubicin using Galactomycin. In addition, international patent applications corresponding to two of our U.S. applications have been filed under the Patent Cooperation Treaty and we have an application pending before the European Patent Office.

We filed with the U.S. Patent and Trademark Office applications to register several trademarks and service marks. For more detailed information on our trademarks/servicemarks, see our Annual Report on Form 10-KSB for the year ended December 31, 2002 and we have an application pending before the European Patent Office.

Plan of Operation

As discussed in our 2002 Annual Report on Form 10-KSB, we are a development-stage company and have not generated any revenues to date. We have raised funds primarily through private placements of convertible debt and shares of common stock, and a public offering of shares of common stock.

As of June 30, 2003, we had $1,791,058 in cash and working capital of $1,467,012. Our budgeted expenditures for the next twelve months total of approximately $3,700,000, including research and development expenditures of approximately $2,200,000 and general and administrative expenditures of approximately $1,500,000.

In May 2003, we began a private placement at $2.00 per share of up to 2,500,000 shares of common stock, exempt from registration pursuant to Rule 506 of Regulation D under the Securities Act 1933, which shares insofar as they were restricted securities were sold at a price approximately 25 percent below the market price of the shares of our common stock that were trading at the time the private placement began. We terminated this private placement on July 15, 2003. In connection with the private placement, we received gross proceeds of approximately $4,800,000, of which $491,000 was received as of June 30, 2003. Earlier this year, we raised a total of approximately $4,311,000 in a private placement of common stock begun in September 2002 and completed in January 2003. We are dedicating all proceeds of these private placements to research and development, including expenses of Phase I/II clinical trials of our drug candidate for which the FDA approved our

investigational new drug application, and general and administrative expenses.

Table of Contents

We plan to raise additional capital through private placements or public offerings of equity securities in order to cover our future budgets. Given our recent attempts to raise additional capital and our available cash and cash equivalents as of June 30, 2003, we believe we will be able to proceed with our current plan of operations and meet our obligations for all of 2003 and through at least the third quarter of 2004. If actual expenses exceed our budget, however, we will need to raise additional capital sooner in order to meet our cash needs. If we cannot raise the additional funds when needed, we would slow or halt our research and development expenditures until adequate funding became available. Our business structure is somewhat flexible because we outsource most of our research and development.

We have one product candidate in Phase I clinical trials. During the next twelve months, we anticipate that our research and development activities will include continuation of this Phase I clinical trial, as discussed above under Phase I Clinical Trials, as well as continuing pre-clinical animal experiments to study toxicity and efficacy of 5-FU and other cancer chemotherapies both in combination with our polysaccharide compounds and, in the case of Adriamycin®, as chemically modified with sugar residues via linkers of a certain chemical structure that are our proprietary technology.

We do not anticipate building in-house research or development facilities, or hiring staff to conduct those activities. Consequently, we do not expect to make any purchases or sales of plant or significant equipment during the next twelve months. We currently have seven employees, all full-time. We do not expect a substantial increase to our employee headcount.

Item 3. Controls and Procedures

(a) Evaluation of disclosure controls and procedures. An evaluation was performed under the supervision and with the participation of the Corporation s management, including the principal executive officer and principal financial officer, of the effectiveness of the design and operation of the Corporation s disclosure controls and procedures pursuant to Rule 13a-15(e) of the Securities Exchange Act of 1934 (the Exchange Act) as of June 30, 2003. Based upon that evaluation, the Corporation s principal executive officer and principal financial officer concluded that the Corporation s disclosure controls and procedures are effective to ensure that information required to be disclosed by the Corporation in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

(b) Changes in internal controls. There has been no change in the Corporation s internal control over financial reporting during the quarterly period ended June 30, 2003, that has materially affected, or is reasonably likely to materially affect, the Corporation s internal control over financial reporting.

Table of Contents

PART II OTHER INFORMATION

Item 1. Legal Proceedings

On May 14, 2003 an action titled Sheila Jayaraj v. Pro-Pharmaceuticals, Inc. and David Platt (Commonwealth of Massachusetts, Middlesex Superior Court, Case No. 03-2102) was instituted against us. A related complainant letter dated May 14, 2003 was filed with the Occupational Safety and Health Administration of the U.S. Department of Labor. The plaintiff, who was Vice President of Investor Relations and Corporate Strategy for approximately five months, asserts against us claims for wrongful discharge in violation of public policy and of employee protection provided for under the Sarbanes-Oxley Act of 2002. The plaintiff seeks monetary damages and full reinstatement of her position at Pro-Pharmaceuticals, Inc. Based on a preliminary investigation we have conducted, we believe the claims are without merit, and accordingly we intend to defend the allegations vigorously.

Item 2. Changes in Securities

In May 2003, we began a private placement of securities at $2.00 per share of up to 2,500,000 shares of common stock, exempt from registration pursuant to Rule 506 of Regulation D under the Securities Act of 1933 in order to raise up to $5,000,000 to cover our expenditures. Such shares, insofar as they are restricted securities , were sold at a price approximately 25 percent below the market price of the shares of our common stock that were trading at the time the private placement began. Purchasers under the private placement must qualify as accredited investors as such term is defined in Regulation D. During the quarter ended June 30, 2003, we had sold approximately 245,500 shares under this offering for gross proceeds of approximately $491,000. We terminated this private placement on July 15, 2003 and as of August 4, 2003 had received gross proceeds of approximately $4,800,000.

Item 3. Defaults Upon Senior Securities

None

Item 4. Submission of Matters to a Vote of Security Holders

The following matters were submitted to a vote of stockholders at our Annual Meeting of Stockholders, held on May 28, 2003, with the vote tabulations as indicated below:

Stockholders who voted elected eight directors to one-year terms. The vote tabulation for individual directors was:

Director	Shares For	Shares Withheld

David Platt, Ph.D.	15,299,513	0
James Czirr	15,299,513	0

Table of Contents

Burton C. Firtel	15,299,513	0
Dale H. Conaway, D.V.M.	15,299,513	0
David H. Smith	15,299,513	0
Edgar Ben-Josef, M.D.	15,299,513	0
Mildred Christian, Ph.D.	15,299,513	0
Steven Prelack	15,299,513	0

Stockholders who voted also approved the ratification of the appointment of Deloitte & Touche LLP, as Pro-Pharmaceuticals independent public accountants for the fiscal year ending December 31, 2003, by a vote of 15,239,265 for and 60,348 against.

There were no abstentions or broker non-votes.

Item 5. Other Information

During the quarter ended June 30, 2003, the Compensation Committee of the Board of Directors previously comprised of James Czirr, Burton Firtel and, until March 20, 2003, Peter Hauser, was replaced with a new group of directors to enhance the independence of this committee. As of June 2003, the Compensation Committee is comprised of Mildred Christian, Ph.D. and Edgar Ben-Josef, M.D. The Compensation Committee is responsible for reviewing matters pertaining to the compensation of employees of, and consultants to, Pro-Pharmaceuticals, fixing the cash compensation of officers of Pro-Pharmaceuticals and administering, and making grants and awards to directors, officers, employees, consultants and advisors under Pro-Pharmaceuticals 2001 Stock Incentive Plan.

The Audit Committee of the Board of Directors, comprised of Dale Conaway, Burton Firtel and, until March 20, 2003, Peter Hauser was modified. In March 2003, Peter Hauser resigned from the Board of Directors for personal reasons. In April 2003, Steven Prelack joined our Board of Directors and agreed to replace Mr. Firtel on the Audit Committee. Mr. Prelack qualifies as an Audit Committee financial expert under regulations recently adopted by the SEC in connection with future required disclosures, and he is independent of management, also as determined in accordance with the new regulations. The Audit Committee is responsible for oversight of the quality and integrity of the accounting, auditing and reporting practices of Pro-Pharmaceuticals.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

The Exhibits filed as part of this Form 10-QSB are listed on the Exhibit Index immediately preceding such Exhibits, which Exhibit Index is incorporated herein by reference.

(b) Reports on Form 8-K

We did not file any Current Reports on Form 8-K during the quarter ended June 30, 2003.

Table of Contents

SIGNATURE

In accordance with Section 13 or 15(d) of the Exchange Act, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on August 14, 2003.

PRO-PHARMACEUTICALS, INC.

Registrant

By: /s/ David Platt

Name: David Platt

Title: President, Chief Executive Officer and Secretary

(Principal Executive Officer)

Table of Contents

Exhibit Index

Exhibit Number	Description of Document	
3.1	Articles of Incorporation of the Registrant, dated January 26, 2001	*
3.2	Amended and Restated By-laws of the Registrant	**
10.1	Assignment and Assumption Agreement, dated April 23, 2001, by and between Developed Technology Resource, Inc. and DTR-Med Pharma Corp.	*
10.2	Stock Exchange Agreement, dated April 25, 2001, by and among Developed Technology Resource, Inc., DTR-Med Pharma Corp., Pro-Pharmaceuticals, Inc. (Massachusetts) and the Shareholders (as defined therein)	*
10.3	Pro-Pharmaceuticals, Inc. 2001 Stock Incentive Plan	**
10.4	Consulting Agreement, dated as of March 14, 2002, as amended November 14, 2002, by and between Pro-Pharmaceuticals, Inc. and Burton Firtel	****
10.5	Consulting Agreement, dated as of January 16, 2003, by and between Pro-Pharmaceuticals, Inc. and David H. Smith	****
10.6	Employment Agreement, dated effective as of April 1, 2003, by and between Pro-Pharmaceuticals, Inc. and David A. Christopher	
16.1	Letter from Scillia Dowling & Natarelli LLC to the Commission, dated February 25, 2002, concerning change in certifying accountant	***
16.2	Letter from Scillia Dowling & Natarelli LLC to the Commission, dated March 7, 2002, concerning change in certifying accountant	***
21	Subsidiaries of the Registrant	None
31.1	Certification of the Chief Executive Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934	
31.2	Certification of the Chief Financial Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934	
32.1	Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted	

Table of Contents

Exhibit Number	Description of Document
	Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Incorporated by reference to the Registrant s Registration Statement on Form 10-SB, as filed with the Commission on June 13, 2001.

** Incorporated by reference to the Registrant s Quarterly Report on Form 10-QSB for the period ended September 30, 2001, as filed with the Commission on November 14, 2001.

*** Incorporated by reference to the Registrant s Current Report on Form 8-K/A as filed with the Commission on March 8, 2002.

**** Incorporated by reference to the Registrant s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, as filed with the Commission on March 31, 2003.