PRO PHARMACEUTICALS INC
Form 10QSB
November 14, 2003
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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 September 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 September 30, 2003 was 22,723,100.

Transitional Small Business Disclosure Format (Check one): Yes ¨ No x

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Part 1 Financial Information

Item 1. Financial Statements

PRO-PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED BALANCE SHEETS (Unaudited)

	September 30, 2003	December 31, 2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,787,646	$ 1,921,233
Prepaid expenses and other current assets	46,910	72,733
Total current assets	4,834,556	1,993,966
PROPERTY AND EQUIPMENT, Net	162,644	177,160
INTANGIBLE ASSETS	128,113	85,090
DEPOSITS AND OTHER ASSETS	26,951	26,951
Total assets	$ 5,152,264	$ 2,283,167
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 341,614	$ 302,899
Accrued expenses	57,438	174,644
Offering costs payable	1,892	174,250
Convertible notes payable		15,000
Total current liabilities	400,944	666,793
STOCKHOLDERS EQUITY:		
Common stock, $0.001 par value; 100,000,000 shares authorized, 22,743,071 and 19,034,647 issued and outstanding at September 30, 2003 and December 31, 2002, respectively; 5,000,000 undesignated shares, $.01 par value, 0 issued and outstanding	22,743	19,034
Additional paid-in capital	15,913,559	9,635,531
Stock subscriptions receivable	0	(150,000)
Deferred compensation	(49,821)	(54,959)
Deficit accumulated during the development stage	(11,135,161)	(7,833,232)
Total stockholders equity	4,751,320	1,616,374
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 5,152,264	$ 2,283,167

See notes to condensed financial statements.

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PRO-PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative Period From Inception (July 10, 2000) To September 30,
	2003	2002	2003	2002	2003
OPERATING EXPENSES:					
Research and development	$ 454,358	$ 316,592	$ 1,256,181	$ 1,077,304	$ 3,732,915
General and administrative (a)	945,630	322,430	2,078,729	1,120,387	5,238,255
Total operating expenses	(1,399,988)	(639,022)	(3,334,910)	(2,197,691)	(8,971,170)
INTEREST INCOME	17,558	3,726	36,861	15,683	86,297
INTEREST EXPENSE	(25)	(28,264)	(3,880)	(376,255)	(2,250,288)
Net loss	$ (1,382,455)	$ (663,560)	$ (3,301,929)	$ (2,558,263)	$ (11,135,161)
NET LOSS PER SHARE BASIC AND DILUTED	$ (0.06)	$ (0.04)	$ (0.16)	$ (0.16)	
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING					
Basic and diluted	22,343,154	15,990,355	21,010,099	15,726,838	
(a) The following summarizes the allocation of the stock-based compensation charge:					
General and administrative	$ 162,504	$ 24,638	$ 246,564	$ 65,364	

See notes to condensed financial statements.

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PRO-PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended September 30,		Cumulative Period From Inception (July 10, 2000) To September 30,
	2003	2002	2003
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (3,301,929)	$ (2,558,263)	$ (11,135,161)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	58,948	29,691	114,787
Amortization of debt discount on convertible notes			1,258,012
Amortization of deferred extension costs through interest expense		139,447	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			10,274
Stock based compensation expense	246,564	65,364	499,210
Changes in current assets and liabilities:			
Prepaid and other expenses	25,823	70,290	(43,782)
Deposits and other assets			(26,951)
Accounts payable	38,715	(6,890)	332,586
Accrued interest related to convertible notes payable		(3,988)	
Accrued expenses	(2,058)	(27,900)	172,586
Net cash used in operating activities	(2,933,937)	(2,056,262)	(7,804,936)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(39,360)	(83,966)	(272,359)
Increase in patents costs and other assets	(48,095)	(20,777)	(133,185)
Net cash used in investing activities	(87,455)	(104,743)	(405,544)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net proceeds from issuance of common stock and warrants			2,229,750
Net proceeds from issuance of common stock	5,887,805	1,925,310	9,524,746
Return of placement fee		20,000	
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	5,887,805	1,945,310	12,998,126
NET INCREASE IN CASH AND CASH EQUIVALENTS	2,866,413	(215,695)	4,787,646
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	1,921,233	1,491,172	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 4,787,646	$ 1,275,477	$ 4,787,646

See notes to condensed financial statements.

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PRO-PHARMACEUTICALS, INC.

(A Development Stage Company)

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

September 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.

The Company raised gross proceeds of approximately $4,800,000 in capital, of which approximately $4,300,000 was raised in the quarter ended September 30, 2003, through a private placement of securities that began in May 2003 and concluded in July 2003.

The Company raised gross proceeds of approximately $4,600,000 through a private placement of securities to certain institutional investors that closed subsequent to the quarter ended September 30, 2003.

On September 10, 2003, following approval of a listing application, shares of the Company s common stock began trading on the American Stock Exchange under the symbol PRW .

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 available cash and cash equivalents of approximately $4,800,000 as of September 30, 2003 and the gross proceeds of approximately $4,600,000 raised subsequent to such date, the Company believes it will be able to proceed with its current plan of operation and meet its obligations through at least the first quarter of 2005. If actual expenses exceed the budget, however, the Company would 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 has the ability to control costs due to the outsourced nature of its business model.

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

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financial statements prepared in accordance with generally accepted 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 plan, 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 September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net loss, as reported	(1,382,455)	$ (663,560)	(3,301,929)	$ (2,558,263)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(2,113,938)		(2,238,698)	(9,883)
Pro forma net loss	$ (3,496,393)	$ (663,560)	$ (5,540,627)	$ (2,568,146)
Net loss per share:				
Basic and diluted as reported	$ (0.06)	$ (0.04)	$ (0.16)	$ (0.16)
Basic and diluted pro forma	$ (0.16)	$ (0.04)	$ (0.26)	$ (0.16)

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The Company estimated the fair value on the date of grant using the Black-Scholes option pricing model. Key assumptions used to apply this pricing model were based on deemed fair market values of the Company s common stock ranging from $2.89 to $4.05 per share on the grant date, an assumed volatility of 95%, risk-free interest rates ranging from 2.06% to 2.32%, a weighted average expected life of three to five years, and a dividend rate of 0.0%. In September 2003, the Company granted stock options under the Pro-Pharmaceuticals, Inc. 2001 Stock Incentive Plan to certain employees to purchase an aggregate of 1,415,000 shares of common stock. These options are scheduled to vest over a one-year period from the date of grant, expire ten years from the date of grant and are exercisable at $4.05 per share.

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 3,806,054 and 1,852,423 shares at September 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 anti-dilutive.

3. STOCKHOLDERS EQUITY

May 2003 Private Placement On July 15, 2003, the Company concluded the private placement it commenced in May 2003 in which it sought to raise up to $5,000,000 by means of a private placement of up to 2,500,000 shares of common stock at a per share price of $2.00. The private placement resulted in gross proceeds of $4,799,000 and the Company s issuance of 2,399,500 shares of its common stock. In consideration for services performed as part of the private placement, the Company 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). The Placement Group received $132,470 in cash and 109,613 warrants to purchase common stock at a price of $5.40 per share, expiring on July 15, 2006. The Company has valued these warrants at approximately $260,989 using the Black-Scholes option pricing model, based on a deemed fair value for the Company s common stock of $2.38 per share, and an assumed volatility of 95%, a risk-free interest rate of 1.96%, a weighted average expected life of three years and a dividend rate of 0.0%. The issuance costs have been offset against the proceeds from the private placement.

4. NON-EMPLOYEE STOCK OPTIONS

In March 2003, the Company entered into a contract with a board member and stockholder of the Company, pursuant to which such director would provide consulting services in connection with its business development and related financial services. As compensation for these services, the Company agreed to compensate the stockholder 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 $1.40 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%.

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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 with respect to 5,000 of those options vested on May 8, 2003. The exercise rights of the remaining 5,000 options vest as of May 8, 2005. The options were valued at approximately $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%.

On September 2, 2003, the Company granted two members of its Scientific Advisory Board non-qualified stock options enabling each to purchase 25,000 shares of common stock exercisable for five years at $4.05 per share. These stock options were fully vested as of September 2, 2003, the effective date of the grant. The options were valued at approximately $122,092, using the Black-Scholes option pricing model, based on a deemed fair value of the Company s common stock of $2.43 per share, an assumed volatility of 95%, a risk-free interest rate of 2.23%, a weighed average expected life of three years, and a dividend rate of 0.0%.

On September 18, 2003, the Company, subject to stockholder approval, adopted the 2003 Non-employee Director Stock Incentive Plan, which permits awards of non-qualified stock options and restricted stock to non-employee directors. As of September 30, 2003, 1,000,000 shares were reserved, and remain available, for issuance under such plan.

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 re-measured 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 approximately $246,564 and $65,364 for the nine months ended September 30, 2003 and 2002 respectively and approximately $162,504 and $24,638 for the three months ended September 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 the Company. On August 25, 2003, the Department of

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Labor reported that its investigator found the Plaintiff s allegations are without merit and dismissed the complaint. The Plaintiff timely objected to the findings and requested a hearing on the record by an Administrative Law Judge at the Department. Based on the foregoing and its own investigation, the Company believes the claims are without merit, and accordingly intends to defend the allegations vigorously. On October 31, 2003, the Company received an informal inquiry from the Securities and Exchange Commission requesting certain information related to the foregoing. The Company intends to voluntarily cooperate with the request.

6. SUBSEQUENT EVENTS

October 2003 Private Placement On October 2, 2003, the Company completed a private placement of securities in which it sold to institutional investors 1,314,571 shares of common stock at $3.50 per share and 657,293 five-year warrants to purchase common stock exercisable at $5.29 per share. Upon the completion of the private placement, the Company received gross proceeds of approximately $4,600,000. For services in connection with such private placement, the Company compensated its placement agent by paying approximately $470,000 in fees and issuing 65,729 three-year warrants to purchase common stock exercisable at $6.86 per share. Pursuant to contemporaneous registration rights agreements with the investors, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission on October 22, 2003 to register for resale such shares and the underlying shares issuable upon the exercise of such warrants.

In connection with the resignation of the Company s Chief Financial Officer on October 8, 2003, the Company accelerated the vesting of 50,000 stock options under his April 2003 grant agreement and 100,000 stock options under his September 2003 grant agreement. The Company anticipates recording a compensation charge of approximately $118,000 during the fourth quarter of 2003, representing the intrinsic value of such shares on the date of resignation.

Item 2. Plan of Operation

This quarterly report on Form 10-QSB contains, in addition to historical information, forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995. These statements can be identified by the use of forward-looking terminology such as may, will, could, expect, anticipate, estimate, continue or other similar words. 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 on Form S-3, filed with the Securities and Exchange Commission on October 22, 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 may 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 and recognition mechanism should reduce the toxicity and increase the efficacy of these drugs thereby creating a preferable treatment to existing first line oncology regimens. Additionally, we believe this drug development strategy will enable our company to gain patent protection on drugs we reformulate with our carbohydrate compounds.

In 2002, the U.S. Food and Drug Administration (the FDA) approved our first Investigational New Drug Application (IND) for Phase I human clinical trials relating to colorectal cancer.

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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 are traded on the American Stock Exchange under the symbol PRW .

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 recognizing and targeting specific receptors (lectins) found on cancer cells. Our studies indicate that a polysaccharide with a suitable chemical structure, in combination with a chemotherapy drug, would increase cellular membrane fluidity and permeability, thereby assisting delivery of the chemotherapy drug.

The first group of drugs selected to go through our upgrade programs are 5-fluorouracil, doxorubicin (Adriamycin®), paclitaxel (Taxol®), cyclophosphamide (Cytoxan®), irinotecan (Camptosar®) and cisplatin (Platinol®). Our lead drug and our first drug delivery platform are, respectively, as follows:

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

- UNIVERSAL CARBOHYDRATE LINKER TECHNOLOGY™ (UCLT™), which enhances the delivery of chemotherapeutic drugs by covalently binding one of our carbohydrate compounds to a chemotherapy drug and 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 authorized 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 anti-cancer 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 study was performed to test a potential reduction of toxicity of doxorubicin in combination with each of two selected polysaccharide compounds. The results indicated that DAVANAT™ might

decrease the toxicity of doxorubicin. The fact that two different cancer drugs, with chemically unrelated structures, showed a marked reduction of their

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toxicity in combination with DAVANAT™ indicates 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, 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. Results of this study indicated 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 which were administered 5-FU/leucovorin alone. As discussed below under Efficacy Studies, leucovorin is commonly administered with 5-FU. These studies were presented to the FDA as part of our IND submission. We conducted additional toxicity studies on rats using escalating dosages of 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 for all solid tumors.

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 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. Results of 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 further decreased by using a DAVANAT™/5-FU combination compared to a 5-FU/leucovorin combination.

We also conducted a study that involved injecting radio-labeled 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 doxorubicin, irinotecan and paclitaxel, both in combination with DAVANAT™ and other polysaccharide compounds.

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

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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.

We have contracted with Sigma Aldrich, a certified GMP facility, to produce DAVANAT™ in 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. Medidata Solutions Inc. has developed, on our behalf, an on-line electronic data capture (EDC) system to collect and aggregate our clinical trial data. We expect this EDC system will better enable us to manage clinical data and increase the speed at which such data is reported and compiled. We believe this EDC system may accelerate our commencement of Phase II clinical trials.

Other Carbohydrate-Cancer Drug Formulations

We have chemically synthesized carbohydrate derivatives of doxorubicin and have conducted pre-clinical studies in mice of both toxicity (effects on healthy animals) and efficacy (on cancer-carrying animals). Preliminary results of these experiments indicate that all of our synthesized carbohydrate-doxorubicin compounds, and particularly one, named Galactomycin™, are significantly less toxic compared with the original doxorubicin and demonstrate therapeutic efficacy as well. In the case of Galactomycin™, the preliminary results indicated a therapeutic index improvement over the parent doxorubicin. These studies were conducted at the Academy of Medical Sciences, located in 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. Moreover, we have not yet completed our Phase I clinical trials and therefore do not have reportable data from such trials. Please see Risk Factors Our product candidates

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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 and Risk Factors We have only recently begun clinical trials and results are uncertain in our Registration Statement on Form S-3, filed on October 22, 2003.

Patents and Proprietary Rights

Prior to September 30, 2003, we had received a Notice of Allowance from the U.S. Patent and Trademark Office for two United States patent applications relating to the use of a polysaccharide composition in the treatment of cancer. Subsequently, the U.S. Patent and Trademark office issued the following two patents based on such applications: (i) No. 6,645,946 Delivery of a Therapeutic Agent in a Formulation for Reduced Toxicity and (ii) No. 6,642,205 Methods and Compositions for Reducing Side Effects in Chemotherapeutic Treatments. In addition, we have other United States patent applications and a foreign patent application pending with respect to our technology.

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

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.

In May 2003, we commenced a private placement that concluded in July 2003, which resulted in gross proceeds of $4,799,000 and the issuance of 2,399,500 shares of common stock.

As of September 30, 2003, we had approximately $4,788,000 in cash and working capital of approximately $4,434,000. Our budgeted expenditures for the next twelve months total approximately $5,400,000, including research and development expenditures of approximately $3,000,000 and general and administrative expenditures of approximately $2,400,000.

On October 2, 2003, we completed a private placement in which we sold to institutional investors 1,314,571 shares of common stock at $3.50 per share and 657,293 five-year warrants to purchase common stock exercisable at $5.29 per share. We received gross proceeds of approximately $4,600,000. Pursuant to contemporaneous registration rights agreements with the investors, on October 22, 2003 we filed a registration statement on Form S-3 with the Securities and Exchange Commission to register for resale such shares and the underlying shares issuable upon exercise of such warrants.

We intend to dedicate all proceeds 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 to general and administrative expenses.

We may raise additional capital through private placements or public offerings of equity securities in order to cover our future budgets. Given our available cash and cash equivalents as of September 30, 2003 and additional capital raised subsequent to such date we believe we will be able to proceed with our current plan of operation and meet our obligations through at least the

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first quarter of 2005. 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, 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 doxorubicin, 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 facilities or significant equipment during the next twelve months. We currently have six full-time employees. We do not expect a substantial increase to our employee headcount.

Item 3. Controls and Procedures

An evaluation was performed under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the Exchange Act) as of September 30, 2003. Based upon that evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarterly period ended September 30, 2003, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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. On August 25, 2003, the Department of Labor reported that its investigator found the Plaintiff s allegations are without merit and dismissed the complaint. The Plaintiff timely objected to the findings and requested a hearing on the record by an Administrative Law Judge at the Department.

Item 2. Changes in Securities

May-July 2003 Private Placement On July 15, 2003, we concluded the private placement we began in May in which we sought to raise up to $5,000,000, in a transaction exempt from registration pursuant to Rule 506 of Regulation D under the Securities Act of 1933, through the sale to accredited investors of up to 2,500,000 shares of common stock at a price of $2.00 per share. In the private placement, we received gross proceeds of $4,799,000 and issued 2,399,500 shares of our common stock.

October 2003 Private Placement On October 2, 2003, we completed a private placement of securities exempt from registration pursuant to Section 4(2) of the Securities Act of 1933 in which we sold to institutional investors 1,314,571 shares of common stock at $3.50 per share and 657,293 five-year warrants to purchase common stock exercisable at $5.29 per share, and received gross proceeds of approximately $4,600,000. Pursuant to contemporaneous registration rights agreements with the investors, we filed a registration statement on Form S-3 with the Securities and Exchange Commission on October 22, 2003 to register for resale such shares and the underlying shares issuable upon exercise of such warrants.

Item 3. Defaults Upon Senior Securities

None

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

None.

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Item 5. Other Information

On September 10, 2003, following approval of a listing application, shares of our common stock began trading on the American Stock Exchange under the symbol PRW .

On September 18, 2003, our Board of Directors, subject to stockholder approval, adopted the 2003 Non-employee Director Stock Incentive Plan which permits awards of non-qualified stock options and restricted stock awards to non-employee directors on a non-discretionary basis.

On October 8, 2003, our Chief Financial Officer resigned for personal reasons and to pursue other opportunities. Our Chief Operating Officer, who has a background in financial management, has agreed to serve as our Acting Chief Financial Officer while we conduct an executive search.

On October 31, 2003, our Executive Vice President of Business Development resigned for personal reasons. He also resigned as a director.

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 filed Current Reports with the SEC on Form 8-K on September 9, 2003, September 26, 2003, October 10, 2003 and November 14, 2003, reporting matters under, respectively, Items 5 and 7, Item 5, Items 5 and 7, and Items 5 and 7.

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 November 14, 2003.

PRO-PHARMACEUTICALS, INC.

Registrant

By: /s/ David Platt

Name: David Platt

Title: President and Chief Executive Officer

(Principal Executive Officer)

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Exhibit Index

Exhibit Number	Description of Document
10.7	Securities Purchase Agreement, dated October 2, 2003, by and among Pro-Pharmaceuticals, Inc. and the Purchasers named therein*
10.8	Registration Rights Agreement, dated October 2, 2003, by and among Pro-Pharmaceuticals, Inc. and the Purchasers named therein*
10.9	Form of Common Stock Purchase Warrant to be issued to the Purchasers under the Securities Purchase Agreement*
10.10	Form of Common Stock Purchase Warrant to be issued to Rodman and Renshaw, Inc.*
10.11	Pro-Pharmaceuticals, Inc. 2003 Non-employee Director Stock Incentive Plan**
31.1	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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* Incorporated by reference to the Registrant s Current Report on Form 8-K/A as filed with the Commission on October 10, 2003 for the period October 2, 2003.

** Incorporated by reference to the Registrant s Registration Statement on Form S-8, as filed with the Commission on October 22, 2003.