

PRO PHARMACEUTICALS INC  
Form 10QSB  
May 14, 2003  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-QSB**

(Mark One)

**Quarterly report under Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended March 31, 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

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**PRO-PHARMACEUTICALS, INC.**

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

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Nevada  
(State or other jurisdiction of incorporation or organization)

04-3562325  
(I.R.S. Employer Identification No.)

189 Wells Avenue, Newton, Massachusetts 02459

(Address of principal executive offices)

(617) 559-0033

(Issuer's telephone number)

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**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 March 31, 2003 was 20,343,571.

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

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**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Financial Statements****PRO-PHARMACEUTICALS, INC.**

(A Development Stage Company)

**CONDENSED BALANCE SHEETS (Unaudited)**

	<b>March 31, 2003</b>	<b>December 31, 2002</b>
	<u>          </u>	<u>          </u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 2,150,617	\$ 1,921,233
Prepaid expenses and other current assets	97,945	72,733
	<u>          </u>	<u>          </u>
Total current assets	2,248,562	1,993,966
	<u>          </u>	<u>          </u>
PROPERTY AND EQUIPMENT, Net	189,788	177,160
INTANGIBLE ASSETS	100,586	85,090
DEPOSITS AND OTHER ASSETS	26,951	26,951
	<u>          </u>	<u>          </u>
Total assets	\$ 2,565,887	\$ 2,283,167
	<u>          </u>	<u>          </u>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 251,613	\$ 302,899
Accrued expenses	45,549	174,644
Offering costs payable		174,250
Convertible notes payable	15,000	15,000
	<u>          </u>	<u>          </u>
Total current liabilities	312,162	666,793
<b>STOCKHOLDERS EQUITY:</b>		
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 March 31, 2003 and December 31, 2002, respectively	20,343	19,034
Additional paid-in capital	11,043,757	9,635,531
Stock subscriptions receivable		(150,000)
Deferred compensation	(32,277)	(54,959)
Deficit accumulated during the development stage	(8,778,098)	(7,833,232)
	<u>          </u>	<u>          </u>
Total stockholders equity	2,253,725	1,616,374

TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	<u>\$ 2,565,887</u>	<u>\$ 2,283,167</u>
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See notes to condensed financial statements.

**Table of Contents****PRO-PHARMACEUTICALS, INC.****(A Development Stage Company)****CONDENSED STATEMENTS OF OPERATIONS (Unaudited)**

	<b>Three Months Ended March 31, 2003</b>	<b>March 31, 2002</b>	<b>Cumulative Period From Inception (July 10, 2000) To March 31, 2003</b>
	<u>          </u>	<u>          </u>	<u>          </u>
<b>OPERATING EXPENSES:</b>			
Research and development	\$ 393,879	\$ 309,082	\$ 2,870,613
General and administrative (a)	559,187	408,087	3,718,713
	<u>          </u>	<u>          </u>	<u>          </u>
Total operating expenses	(953,066)	(717,169)	(6,589,326)
INTEREST INCOME	11,590	5,671	61,026
INTEREST EXPENSE	(3,390)	(240,795)	(2,249,798)
	<u>          </u>	<u>          </u>	<u>          </u>
Net loss	\$ (944,866)	\$ (952,293)	\$ (8,778,098)
	<u>          </u>	<u>          </u>	<u>          </u>
<b>NET LOSS PER SHARE BASIC AND DILUTED</b>	<u>          </u>	<u>          </u>	<u>          </u>
	(0.05)	(0.06)	
	<u>          </u>	<u>          </u>	
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING</b>			
Basic and diluted	19,993,185	15,524,410	
	<u>          </u>	<u>          </u>	

(a) The following summarizes the allocation of the stock-based compensation charge:

General and administrative	\$ 46,961	\$ 16,072
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See notes to condensed financial statements

**Table of Contents****PRO-PHARMACEUTICALS, INC.****(A Development Stage Company)****CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)**

	Three Months Ended March 31, 2003	2002	Cumulative Period From Inception (July 10, 2000) To March 31, 2003
	<u>          </u>	<u>          </u>	<u>          </u>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (944,866)	\$ (952,293)	\$ (8,778,098)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	16,846	8,471	72,685
Amortization of deferred compensation			
Amortization of debt discount on convertible notes			1,258,012
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
Interest expense related to convertible notes payable		4,808	10,274
Stock based compensation expense	46,961	16,072	467,104
Changes in current assets and liabilities:			
Prepaid and other expenses	(25,213)	(13,907)	(94,818)
Deposits and other assets			(26,951)
Accounts payable	(51,286)	(30,707)	242,585
Accrued expenses	(838)	99,697	173,806
	<u>          </u>	<u>          </u>	<u>          </u>
Net cash used in operating activities	(958,396)	(631,872)	(5,829,395)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of property and equipment	(29,474)	(31,302)	(262,473)
Increase in patents costs and other assets	(15,496)	(16,553)	(100,586)
	<u>          </u>	<u>          </u>	<u>          </u>
Net cash used in investing activities	(44,970)	(47,855)	(363,059)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Net proceeds from issuance of common stock and warrants			2,229,750
Net proceeds from sale of common stock	1,232,750	156,000	4,869,691
Net proceeds from issuance of convertible notes payable			1,320,602
Repayment of convertible notes payable			(86,000)
Proceeds from shareholder advances			9,028
	<u>          </u>	<u>          </u>	<u>          </u>
Net cash provided by financing activities	1,232,750	156,000	8,343,071
	<u>          </u>	<u>          </u>	<u>          </u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	229,384	(523,727)	2,150,617
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	1,921,233	1,491,172	
	<u>          </u>	<u>          </u>	<u>          </u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 2,150,617	\$ 967,445	\$ 2,150,617





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**PRO-PHARMACEUTICALS, INC.**

**(A Development Stage Company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)**

**March 31, 2003**

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**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 toxicity and improve the efficacy of currently existing chemotherapy drugs by combining the drugs with a number of specific carbohydrate compounds. The carbohydrate-based drug delivery system may also have applications for drugs now used to treat other diseases and chronic health conditions.

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 January 2003.

To date the Company has raised approximately \$8.3 million in capital principally through the issuance of convertible notes, the sale of common stock through public offering and the sale of common stock through private placements.

**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's financial statements have been presented on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is in the development stage, has incurred a net loss since inception of \$8,778,098

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and expects to incur additional losses in the near future. These factors raise substantial doubt about the Company's ability to continue as a going concern. Successful completion of the Company's development program and, ultimately, the attainment of profitable operations is dependent upon future events, including obtaining adequate financing to fulfill its development activities and achieving a level of revenues adequate to support the Company's cost structure. The Company will seek additional financing to fund future operations and future significant investments in the business. However, there can be no assurance that the Company will be able to obtain financing on acceptable terms, or at all.

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The condensed financial statements included herein have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in 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 (of a normal, recurring nature) 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.

## **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 1,894,026 and 2,078,091 shares at March 31, 2003 and 2002, respectively, issuable pursuant to the exercise of stock options and warrants and conversion of convertible debt would have been antidilutive.

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**3. STOCKHOLDERS EQUITY**

*2002 Private Placement* In September 2002, the Company began a private placement (the 2002 Private Placement ) of up to 10 million shares of common stock at \$1.00 per share, exempt from registration pursuant to Rule 506 of Regulation D under the Securities Act of 1933. As of December 31, 2002, the Company had sold 3,223,360 shares for proceeds of \$2,860,902, net of issuance costs of \$212,458 and stock subscription receivable of \$150,000, which related to shares purchased but for which payment had not been received as of December 31, 2002. In the three months ended March 31, 2003, the Company sold an additional 1,088,000 shares for additional gross proceeds of \$1,088,000. This offering closed on January 14, 2003.

The Company agreed to compensate a registered investment advisor with respect to shares purchased by its clients. As of December 31, 2002, the advisor was entitled to received 173,500 shares of common stock. The Company also agreed to compensate a finder registered under applicable law, and such finder s agents, for identifying qualified investors. As of December 31, 2002, one of the finder s agents was entitled to receive 750 shares of common stock. In the three months ended March 31, 2003, the Company agreed to issue the advisor an additional 2,500 shares and the finder and its other agent an aggregate of 9,750 additional shares and \$5,250 in cash in connection with the shares sold subsequent to December 31, 2002.

In March 2003, the Company issued 186,500 shares of common stock as compensation to these registered investment advisors, finder and finder s agent. Shares placed by such registered advisor, finder and finder s agent were accounted for as offering costs and valued at \$1.00 per share, consistent with the price paid for shares placed in the offering. Such offering costs were netted against the proceeds of the 2002 Private Placement.

During 2002, the Company also agreed to issue an employee 2,100 shares of common stock for finding investors in connection with the 2002 Private Placement. None of the shares had been issued as of December 31, 2002. Accordingly, the Company recorded the obligation to general and administrative expenses in the statement of operations in the amount of \$6,300. On January 14, 2003, the Company closed the 2002 Private Placement, at which point the Company agreed to issue such employee an additional 7,000 shares in connection with shares sold subsequent to December 31, 2002 and through the closing date. In March 2003, the Company issued 9,100 shares of common stock to this employee. The Company recorded a stock compensation charge of \$21,000 to general and administrative expenses in the statement of operations for the three month period ended March 31, 2003. In March 2003, the Company issued 9,100 shares of common stock to such employee.

**Table of Contents****4. STOCK OPTION PLANS**

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. At March 31, 2003, the Company had one stock incentive plan. 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:

	<b>Three Months Ended March 31,</b>	
	<b>2003</b>	<b>2002</b>
Net loss, as reported	\$ (944,866)	\$ (952,293)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(40,097)	
Pro forma net loss	<u>\$ (984,963)</u>	<u>\$ (952,293)</u>
Net loss per share:		
Basic and diluted as reported	(0.05)	(0.06)
Basic and diluted pro forma	(0.05)	(0.06)

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 \$2.91 to \$3.50 per share on the grant date, risk free interest rates ranging from 2.25% to 2.32%, an expected life 3 years, and a dividend rate of 0.0%.

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### **Item 2. Plan of Operation**

This quarterly report on Form 10-QSB contains, in addition to historical information, forward-looking statements within the meaning of the safe harbor provisions of 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, filed with the Securities and Exchange Commission. 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 widely used chemotherapy drugs. We intend initially to combine our proprietary carbohydrate compounds with existing generic chemotherapy drugs used to treat cancer. We believe our technology will increase the body's tolerance to these toxic drugs by targeting the delivery directly to cancerous cells. Our company's novel approach of improving existing chemotherapy drugs by adding a targeting mechanism should reduce the toxicity and increase the efficacy of these drugs thereby creating a preferable treatment to existing first line 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. We also believe our drug delivery system may have applications for drugs now used to treat other diseases and chronic health conditions.

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. We have begun clinical trials of our drug and are in the process of collecting results. Also, we are currently conducting preclinical 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.

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### **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 utilizing sugar-specific receptors 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 drug.

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

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

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

#### ***DAVANAT -I***

DAVANAT combined with 5-fluorouracil (5-FU), referred to as DAVANAT-1 is our first drug combination that is advancing 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 application (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<sup>®</sup> in combination with each of two selected polysaccharide compounds. The results indicated that DAVANAT might decrease the toxicity of Adriamycin<sup>®</sup>. 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





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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 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 which were administered 5-FU alone. 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.

### *Efficacy Studies*

We undertook independent studies at Southern Research Institute and Charles River Laboratories to test a potential change in the therapeutic efficacy of DAVANAT in a combination with 5-FU, which had decreased toxicity of the drug in healthy animals. Results of the studies demonstrated that DAVANAT, might also increase 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 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 DAVANAT-1, we are also conducting pre-clinical studies for doxorubicin and paclitaxel, both in combination with DAVANAT and other polysaccharide compounds.

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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.

### ***Phase I Clinical Trials***

We submitted an investigational new drug application (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 will evaluate 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 three clinical sites and lead investigators in which to undertake our Phase I trials. Two of the sites are in a position to recruit patients. On February 10, 2003 we dosed the first patients at a private oncology treatment center in Howell, New Jersey, at which Dr. Kenneth E. Nahum serves as our lead investigator.

We have also engaged a professional consultant, 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 undertake the clinical trials and undertake data management on our behalf, and Medidata Solutions Inc. to construct an on-site data electronic data capture (EDC) methodology. We expect that this will better enable us to manage clinical 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.

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### ***Other Carbohydrate-Cancer Drug Formulations***

We have chemically synthesized four novel products that are carbohydrate derivatives of Adriamycin<sup>®</sup>, and have conducted preclinical animal experiments, studying both toxicity (on healthy animals) and efficacy (on cancer-carrying animals). Preliminary results of these experiments indicate that all four of the synthesized carbohydrate-Adriamycin<sup>®</sup> compounds, and particularly one, named Galactomycin, are significantly less toxic compared with the original Adriamycin<sup>®</sup>, and demonstrate therapeutic efficacy as well. In the case of Galactomycin, the preliminary results indicated a therapeutic efficacy higher than that for the parent Adriamycin<sup>®</sup>. 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.

### **Intellectual Property Protection**

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 one provisional patent application, pending in the 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.

We filed with the U.S. Patent and Trademark Office (PTO) applications to register the numerous trademarks/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.

### **Plan of Operation**

As discussed in our 2002 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. Most recently, 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 intend to dedicate the proceeds of that private placement 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.

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As of March 31, 2003, we had \$2,150,617 in cash and working capital of \$1,936,400. Our budgeted expenditures for the year ending December 31, 2003, total \$3,700,000, including research and development expenditures of \$2,200,000 and general and administrative expenditures of \$1,500,000.

We plan to raise additional capital through private placements or public offerings of equity securities in order to cover our budget. If we are limited to the capital we have raised to date, we may be unable to proceed with our current plan of operations and meet our obligations for the next twelve months. Given our current attempts to raise additional capital, we believe we will be able to proceed with our current plan of operations and meet our obligations for the next twelve months. If we do not raise the additional funds, we would slow or halt our research and development expenditures until adequate funding becomes available. Our business structure is somewhat flexible because we outsource most of our research and development.

Our financial statements have been presented on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We are in the development stage, have incurred a net loss since inception of \$8,778,098 and expect to incur additional losses in the near future. These factors raise substantial doubt about our ability to continue as a going concern. Successful completion of our development program and, ultimately, the attainment of profitable operations is dependent upon future events, including maintaining adequate financing to fulfill our development activities and achieving a level of sales adequate to support our cost structure. We are actively seeking additional financing to fund future operations, but cannot assure we will be successful.

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 first-in-man clinical trial, as discussed above under Phase I Clinical Trials, as well as continuing preclinical 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 six employees, all full-time. We have hired a Chief Financial Officer whose employment commenced as of April 1, 2003. We do not expect a substantial increase to our employee headcount.

### **Item 3. Controls and Procedures**

(a) *Evaluation of disclosure controls and procedures.* Based on their evaluation as of a date within 90 days prior to the filing date of this Quarterly Report on Form 10-QSB, our principal executive officer and our principal financial officer have concluded that

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our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934) are effective to ensure that information required to be disclosed by us 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.

(b) *Changes in internal controls.* There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

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**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

None

**Item 2. Changes in Securities**

In September 2002, the Company began a private placement of up to 10 million shares of common stock at \$1.00 per share, exempt from registration pursuant to Rule 506 of Regulation D under the Securities Act of 1933. As of December 31, 2002, the Company had sold 3,223,360 shares for proceeds of \$2,860,902, net of issuance costs of \$212,458 and stock subscription receivable of \$150,000, which related to shares purchased but for which payment had not been received as of December 31, 2002. This offering was closed on January 14, 2003 although subsequent to year end the Company sold an additional 1,088,000 shares for additional gross proceeds of \$1,088,000.

In March 2003, the Company issued 186,500 shares of common stock as compensation to registered investment advisors, finder and finders agents for services provided in association with the private placement that was completed in January 2003. In March 2003, the Company also issued 9,100 shares of common stock to an employee for finding investors in connection with the 2002 Private Placement.

**Item 3. Defaults Upon Senior Securities**

None

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

None

**Item 5. Other Information**

None

**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.

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*(b) Reports on Form 8-K*

We did not file any Current Reports on Form 8-K during the quarter ended March 31, 2003.



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**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 May 14, 2003.

PRO-PHARMACEUTICALS, INC.

Registrant

By: /s/ David Platt

Name: David Platt

Title: President, Chief Executive Officer and Secretary

(Principal Executive Officer)

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**CERTIFICATION**

I, David Platt, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of Pro-Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

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b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other

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factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: May 14, 2003

/s/ DAVID PLATT \_\_\_\_\_

Name: David Platt

Title: President, Chief Executive Officer and Secretary

(Principal Executive Officer)

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**CERTIFICATION**

I, David Christopher, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of Pro-Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

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b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other

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factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: May 14, 2003

/s/ DAVID CHRISTOPHER

Name: David Christopher

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

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**EXHIBIT INDEX**

<b>Exhibit</b>		
<b>Number</b>	<b>Description of Document</b>	
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	**
16	Letter from Scillia Dowling & Natarelli LLC to the Commission, dated February 25, 2002, concerning change in certifying accountant	***
21	Subsidiaries of the Registrant	None
99.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	
99.2	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 as filed with the Commission on February 25, 2002.		