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

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2004

**Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 000-32877

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**PRO-PHARMACEUTICALS, INC.**

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Nevada  
(State or other jurisdiction  
of incorporation)

189 Wells Avenue, Newton, Massachusetts  
(Address of principal executive offices)

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

02459  
(Zip Code)

(617) 559-0033  
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). YES  NO

The number of shares outstanding of the registrant's common stock as of November 11, 2004 was 27,315,411.

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**PRO-PHARMACEUTICALS, INC.**  
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**FOR THE QUARTER ENDED SEPTEMBER 30, 2004**

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Our website address is [www.pro-pharmaceuticals.com](http://www.pro-pharmaceuticals.com).

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	September 30, 2004	December 31, 2003
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 12,454	\$ 7,608
Prepaid expenses and other current assets	68	88
<b>Total current assets</b>	<b>12,522</b>	<b>7,696</b>
PROPERTY AND EQUIPMENT - NET	93	144
INTANGIBLE ASSETS - NET	186	135
DEPOSITS AND OTHER ASSETS	27	27
<b>TOTAL ASSETS</b>	<b>\$ 12,828</b>	<b>\$ 8,002</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 340	\$ 144
Accounts payable - related party	—	22
Accrued expenses	267	212
<b>Total current liabilities</b>	<b>607</b>	<b>378</b>
CONTINGENCIES (Note 5)		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock, \$0.001 par value; 100,000,000 shares authorized, 27,315,411 and 24,079,300 shares of common stock issued and outstanding at September 30, 2004 and December 31, 2003, respectively; Undesignated shares, \$0.01 par value; 10,000,000 and 5,000,000 shares authorized at September 30, 2004 and December 31, 2003, respectively; none issued and outstanding	27	24
Additional paid-in capital	29,924	20,376
Deferred compensation	(2)	(70)
Deficit accumulated during the development stage	(17,728)	(12,706)
<b>Total stockholders' equity</b>	<b>12,221</b>	<b>7,624</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 12,828</b>	<b>\$ 8,002</b>

See notes to unaudited condensed consolidated financial statements.

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**PRO-PHARMACEUTICALS, INC.**  
**(A Development-Stage Company)**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**  
**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003, AND CUMULATIVE PERIOD**  
**FROM INCEPTION (JULY 10, 2000) TO SEPTEMBER 30, 2004**  
**(In thousands, except share and per share data)**

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative Period from Inception (July 10, 2000) to September 30, 2004
	2004	2003	2004	2003	
<b>OPERATING EXPENSES: (a)</b>					
Research and development	\$ 666	\$ 454	\$ 2,039	\$ 1,256	\$ 6,467
General and administrative	1,133	946	3,070	2,083	9,221
<b>Total operating expenses</b>	<b>(1,799)</b>	<b>(1,400)</b>	<b>(5,109)</b>	<b>(3,339)</b>	<b>(15,688)</b>
<b>INTEREST AND OTHER INCOME</b>	<b>36</b>	<b>18</b>	<b>87</b>	<b>37</b>	<b>206</b>
<b>INTEREST AND OTHER EXPENSES:</b>					
Amortization of debt discount on convertible notes	—	—	—	—	1,258
Debt conversion expense	—	—	—	—	503
Interest expense on convertible notes	—	—	—	—	485
<b>Total interest and other expenses</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>(2,246)</b>
<b>NET LOSS</b>	<b>\$ (1,763)</b>	<b>\$ (1,382)</b>	<b>\$ (5,022)</b>	<b>\$ (3,302)</b>	<b>\$ (17,728)</b>
<b>NET LOSS PER SHARE - BASIC AND DILUTED</b>	<b>\$ (0.07)</b>	<b>\$ (0.06)</b>	<b>\$ (0.20)</b>	<b>\$ (0.16)</b>	
<b>WEIGHTED AVERAGE COMMON SHARES</b>					
<b>OUTSTANDING - BASIC AND DILUTED</b>	<b>26,380,628</b>	<b>22,343,154</b>	<b>25,229,248</b>	<b>21,010,099</b>	

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

Research and development	\$ 1	\$ —	\$ 7	\$ —	\$ 142
General and administrative	—	163	117	247	853
<b>Total</b>	<b>\$ 1</b>	<b>\$ 163</b>	<b>\$ 124</b>	<b>\$ 247</b>	<b>\$ 995</b>

See notes to unaudited condensed consolidated financial statements.

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**PRO-PHARMACEUTICALS, INC.**  
**(A Development-Stage Company)**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**  
**NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003, AND CUMULATIVE PERIOD**  
**FROM INCEPTION (JULY 10, 2000) TO SEPTEMBER 30, 2004**  
**(In thousands)**

	Nine Months Ended September 30,		Cumulative Period from Inception (July 10, 2000) to September 30, 2004
	2004	2003	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (5,022)	\$ (3,302)	\$ (17,728)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	63	59	209
Stock-based compensation expense	124	247	995
Amortization of deferred extension costs through interest expense	—	—	168
Settlement of accrued interest through issuance of common stock	—	—	10
Amortization of debt discount on convertible notes	—	—	1,258
Writeoff of intangible assets	—	—	107
Debt conversion expense	—	—	503
Interest expense related to issuance of warrants to purchase common stock	—	—	236
Changes in current assets and liabilities:			
Prepaid expenses and other current assets	21	26	(64)
Deposits and other assets	—	—	(27)
Accounts payable and accrued expenses	228	36	724
	(4,586)	(2,934)	(13,609)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of property and equipment	—	(39)	(272)
Increase in patent costs and other assets	(64)	(48)	(215)
	(64)	(87)	(487)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Net proceeds from issuance of common stock and warrants	9,496	5,888	25,307
Net proceeds from issuance of convertible notes payable	—	—	1,320
Repayment of convertible notes payable	—	—	(86)
Proceeds from shareholder advances	—	—	9
	9,496	5,888	26,550
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>4,846</b>	<b>2,867</b>	<b>12,454</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>7,608</b>	<b>1,921</b>	<b>—</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 12,454</b>	<b>\$ 4,788</b>	<b>\$ 12,454</b>
<b>SUPPLEMENTAL DISCLOSURE – Cash paid for interest</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 19</b>
<b>NONCASH FINANCING ACTIVITIES</b>			
Issuance of warrants in connection with equity offerings	\$ 393	\$ —	\$ 2,999
Conversion of accrued expenses into common stock	—	303	303
Cashless exercise of employee stock options	—	—	74
Conversion of convertible notes and accrued interest into common stock	—	—	1,220
Conversion of extension costs related to convertible notes into common stock	—	—	171
Issuance of warrants to induce conversion of notes payable	—	—	503
Issuance of stock to acquire Pro-Pharmaceuticals-NV	—	—	107

See notes to unaudited condensed consolidated financial statements.

**PRO-PHARMACEUTICALS, INC.**  
**(A DEVELOPMENT-STAGE COMPANY)**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**

**1. BASIS OF PRESENTATION**

The consolidated financial statements as reported in Form 10-Q reflect all adjustments which are, in the opinion of management, necessary to present fairly the financial position of Pro-Pharmaceuticals, Inc. (the "Company") as of September 30, 2004 and the results of its operations and cash flows for the three and nine month periods ended September 30, 2004 and September 30, 2003. All adjustments made to the interim financial statements included all those of a normal and recurring nature. The results for interim periods are not necessarily indicative of results which may be expected for any other interim period or for the full year.

The unaudited condensed consolidated financial statements of Pro-Pharmaceuticals, Inc. should be read in conjunction with the Company's annual report on Form 10-K for the year ended December 31, 2003.

As shown in the consolidated financial statements, the Company incurred net losses of \$17,728 for the cumulative period from inception (July 10, 2000) through September 30, 2004. The Company's net losses have resulted principally from costs associated with research and development expenses, including clinical trial costs, and general and administrative activities. As a result of planned expenditures for future research, discovery, development and commercialization activities, the Company expects to incur additional losses and use additional cash in its operations for the foreseeable future. From inception (July 10, 2000) through September 30, 2004, the Company has raised \$26,627 in capital and used \$13,609 in its operations. The capital was raised through (i) the issuance of convertible notes; (ii) the sale of common stock through a public offering; and (iii) the sale of common stock and warrants through private placements. Based on the \$12,454 of cash and cash equivalents on hand at September 30, 2004, management believes the Company has sufficient cash to fund its operations through at least March 31, 2006.

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. Successful completion of the Company's development program, achieving a level of revenues adequate to support the Company's cost structure and, ultimately, the attainment of profitable operations is dependent upon future events, including obtaining adequate financing to fulfill its development and commercialization activities.

**2. STOCK-BASED COMPENSATION**

*Stock-Based Compensation* – The Company accounts for stock-based compensation to employees and non-employee directors under the intrinsic method in accordance with Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees", and the related interpretations. Under APB No. 25, no compensation expense is recognized for stock options and restricted stock awards granted at fair market value and with fixed terms. The Company uses the fair value method to account for stock-based compensation granted to all other non-employees.

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Had the Company used the fair-value method to measure all stock-based compensation awarded to employees and non-employee directors, the Company's net loss and basic and diluted loss per share would have been as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative Period from Inception (July 10, 2000) to September 30, 2004
	2004	2003	2004	2003	
Net loss—as reported	\$ (1,763)	\$ (1,382)	\$ (5,022)	\$ (3,302)	\$ (17,728)
Add stock-based compensation expense to employees and non-employee directors included in reported net loss	—	—	—	—	114
Deduct stock-based compensation to employees and non-employee directors determined under the fair value method	(227)	(2,114)	(684)	(2,239)	(3,977)
Net loss—pro forma	\$ (1,990)	\$ (3,496)	\$ (5,706)	\$ (5,541)	\$ (21,591)
Basic and diluted loss per share:					
As reported	\$ (0.07)	\$ (0.06)	\$ (0.20)	\$ (0.16)	
Pro forma	\$ (0.08)	\$ (0.16)	\$ (0.23)	\$ (0.26)	

### 3. ACCRUED EXPENSES

Accrued expenses consist of the following:

	September 30, 2004	December 31, 2003
Scientific and clinical fees	\$ 201	\$ 40
Unbilled legal and accounting fees	16	142
Accrued vacation	33	14
Other	17	16
Total	\$ 267	\$ 212

### 4. STOCKHOLDERS' EQUITY

On August 12, 2004, the Company closed a private offering, structured as a "PIPE" (Private Investment in Public Equity) and exempt from registration under Section 4(2) of the Securities Act of 1933, in which it sold to certain institutional investors 2,000,000 shares of common stock in tandem with 2,000,000 common stock warrants (exercisable at \$4.20 per share) at \$3.00 per share for proceeds of approximately \$5,512, net of cash issuance costs of approximately \$488. The placement agent also received 100,000 common stock warrants (exercisable at \$4.20 per share) in connection with this offering. The exercise price of the warrants is subject to adjustment solely as a result of stock splits, recapitalizations and similar events.

On April 7, 2004, the Company closed a private equity offering, structured as a "PIPE" and exempt from registration under Section 4(2) of the Securities Act of 1933, in which it sold to certain institutional investors 1,236,111 shares of common stock and 618,056 common stock warrants (exercisable at \$5.30 per share) at \$3.60 per share for proceeds of approximately \$3,984, net of cash issuance costs of approximately \$466. The placement agent also received 61,806 common stock warrants (exercisable at \$5.30 per share) in connection with this offering. The exercise price of the warrants is subject to adjustment pursuant to anti-dilution and other provisions.

Since the shares of common stock issued in the August 2004 PIPE were sold at a price below the exercise price of the warrants issued in the October 2003 and April 2004 PIPE transactions, the exercise price of the common stock warrants granted to the investors and placement agent in the Company's October 2003 and April 2004 PIPE transactions has been adjusted to reflect the subsequent issuance of dilutive securities as

provided for in the respective warrants. Accordingly, the exercise price of the warrants issued to the investors and placement agent in October 2003 has been adjusted from their original amounts of \$5.29 and \$6.86 per share to \$4.66 and \$6.05 per share, respectively. The exercise price of the warrants issued to the investors and placement agent in April 2004 has been adjusted from its original amount of \$5.30 per share to \$4.91 per share.

As previously disclosed in Forms 4 filed with the SEC, the Company on September 15, 2004, pursuant to the "2003 Pro-Pharmaceuticals, Inc. Non-Employee Director Stock Option Plan" adopted by the stockholders at the Company's 2004 annual meeting, granted options to purchase its common stock to each of its directors, ranging from 250 to 9,000 per director, in consideration of service on the Board of Directors during 2003. A total of 37,750 options were granted at an exercise price of \$3.86 per share.

## 5. CONTINGENCIES

In May 2003, a former employee commenced a lawsuit in Massachusetts Superior Court against the Company and filed a related complainant letter with the Occupational Safety and Health Administration of the U.S. Department of Labor. The plaintiff asserted claims for wrongful discharge in violation of public policy and of employee protection provided for under the Sarbanes-Oxley Act of 2002, and seeks monetary damages. In August 2003, the Department of Labor dismissed the complaint. The plaintiff objected and requested a hearing by an Administrative Law Judge at the Department. The hearing occurred in April 2004 and a decision is not expected until late 2004.

In October 2003, the Company received an informal inquiry from the Securities and Exchange Commission (the "SEC") requesting information related to the foregoing and timely responded prior to year-end. The Company also complied with a May 14, 2004 request from the SEC to provide copies of transcripts of testimony taken prior to and at the hearing, post-hearing briefs and other information. On November 8, 2004, the Company was notified that the SEC has converted the inquiry to a formal investigation, which investigation includes whether statements concerning the Company were false or misleading.

In February 2004, the Company received an order from the Commonwealth of Massachusetts to provide information concerning its offerings of securities. The Company timely responded, and has not received further communication from the state on this matter. The Company believes the Massachusetts investigation may be related to the matters disclosed in the preceding paragraphs.

Each of the foregoing matters is subject to various uncertainties, and it is possible one or more may be resolved unfavorably. Management believes that any liability that may ultimately result from the resolution of these matters will not have a material adverse effect on the financial position, results of operations or cash flows of the Company.

In January 2004, Dr. Platt, the Company's Chairman and Chief Executive Officer, filed a lawsuit in Massachusetts Superior Court against GlycoGenesys, Inc. for various claims including breach of contract. In its filing in February 2004, GlycoGenesys asserted counterclaims against the Company and Dr. Platt alleging tortious interference and misappropriation of proprietary rights. The counterclaims seek monetary damages and injunctive relief related to the Company's intellectual property. In March 2004, the Company and Dr. Platt answered the counterclaims and denied any liability. On June 15, 2004, the Court allowed, without opposition, a motion of GlycoGenesys for leave to file a supplemental counterclaim against the Company for defamation and unfair competition. The Company and Dr. Platt intend to contest these counterclaims vigorously and believe they will ultimately prevail. However, if the Company does not prevail, there could be a material adverse impact on the financial position, results of operations or cash flows of the Company.

Pursuant to Board approval, the Company has agreed to indemnify Dr. Platt for the expenses of his defense of the counterclaims, some of which may be recoverable under insurance. During the three and nine month periods ended September 30, 2004, the Company paid approximately \$67 and \$130 in legal and related costs in connection with the indemnification. No amount, if any, potentially recoverable from the insurance company has been recorded at September 30, 2004.

## 6. RELATED PARTY TRANSACTION

During the three and nine month periods ended September 30, 2004, the Company incurred \$360 and \$552, respectively, in legal and related costs in connection with an arbitration entitled *GlycoGenesys, Inc. and International Gene Group, Inc. and David Platt*, the defendant being the Company's Chairman and Chief Executive Officer. Dr. Platt owns U.S. patent application no. 08/024,487 (the "Patent Application"), which together with other patent applications owned by him are licensed to an affiliate of GlycoGenesys under a license agreement dated January 7, 1994 (the "1994 License"). The proceedings arbitrated rights to control the prosecution of the Patent Application and performance by GlycoGenesys of the 1994 License. As determined by the arbitrator on November 11, 2004, David Platt will control prosecution of the Patent Application and other patent applications subject to the arbitration, and the 1994 License remains in effect. The costs incurred by the Company are considered to be ordinary and necessary costs of the Company in connection with protection of its intellectual property in general and for purposes of defense of claims against its intellectual property alleged by GlycoGenesys in February 2004 in litigation described in Note 5 to these financial statements.



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On November 11, 2004, the Company executed an option agreement (the "Option Agreement") with Dr. Platt, effective as of September 15, 2004, pursuant to which the Company for \$5 purchased an option, exercisable until September 14, 2014 by the Company or a designated affiliate, to acquire an irrevocable, royalty-bearing, exclusive, worldwide license to make, use, sell, offer to sell or import any product covered by the Patent Application, or any patent issued therefrom, to the extent rights therein are retained or revert to Dr. Platt. The Option Agreement specifies certain terms of the optioned license agreement including payment of a royalty to Dr. Platt based on the 25 Per Cent Rule; i.e., the royalty is a percentage of sales revenue derived from 25% of the estimated operating profit (at the time of entering the license agreement) from sales of a product or services that embody the applicable intellectual property.

### **7. LOSS PER SHARE**

Basic loss per share is calculated using the weighted-average number of common shares outstanding during the period. Diluted loss per share is calculated using the weighted-average number of common shares and common share equivalents resulting from outstanding options and warrants, except where such items would be anti-dilutive.

Anti-dilutive shares were not included in the per-share calculations for all periods presented due to the reported net losses. Anti-dilutive shares which could exist pursuant to the exercise of outstanding stock options and warrants at September 30, 2004 and September 30, 2003 were 5,062,952 and 3,997,318, respectively.

### **8. RECLASSIFICATIONS**

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

\* \* \* \* \*

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations (in thousands, except share and per share data)**

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial information included in this Quarterly Report on Form 10-Q, the "Factors That May Affect Future Results" set forth on page 13 and our Annual Report on Form 10-K for the year ended December 31, 2003. The following discussion contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, and is subject to the safe-harbor created by such Act. Forward-looking statements express our expectations or predictions of future events or results. They are not guarantees and are subject to many risks and uncertainties. There are a number of factors – many beyond our control – that could cause actual events or results to be significantly different from those described in the forward-looking statement. Any or all of our forward-looking statements in this report or in any other public statements we make may turn out to be wrong. Forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts. They use words such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" or words of similar meaning. They may also use words such as "would," "should," "could" or "may". Our actual results could differ materially from the results contemplated by these forward-looking statements as a result of many factors, including those discussed below and elsewhere in this Quarterly Report on Form 10-Q.

### **Overview**

We are a development-stage company engaged in research and development of drug technologies to enable targeted delivery of chemotherapy drugs. We intend initially to "reformulate" existing widely-used chemotherapies with our proprietary carbohydrate compounds. We believe our technology may increase the body's tolerance to these toxic drugs by targeting the delivery directly to cancerous cells and increase the efficacy of the drugs, thereby creating a

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preferable treatment to existing first-line oncology regimens. Our goal is to develop and commercialize a new generation of reformulated drugs enabling targeted delivery. For additional information, please see “Item 1. Business — Business of Pro-Pharmaceuticals” included in our Annual Report on Form 10-K for the year ended December 31, 2003.

All of our drug candidates are currently in preclinical and clinical development. To commercialize our drug candidates, we will be required to successfully complete preclinical studies and clinical trials to obtain regulatory approvals. We do not expect to file with the FDA a New Drug Application (“NDA”) for a drug candidate before 2006 even if development of our drug candidates continues successfully. Any delay in obtaining or failure to obtain required approvals will materially adversely affect our ability to generate revenues from commercial sales or licenses relating to our drug candidates. We expect our sources of funding for the next several years to come from finance transactions.

We are devoting substantially all of our efforts toward product research and development, raising capital, and protection of our intellectual property. We have no source of revenue and have incurred significant losses to date. We have incurred net losses of \$17,728 for the cumulative period from inception (July 10, 2000) through September 30, 2004. Our losses have resulted principally from costs associated with research and development expenses, including clinical trial costs, and general and administrative activities. As a result of planned expenditures for future research, discovery, development and commercialization activities, we expect to incur additional operating losses for the foreseeable future.

From inception (July 10, 2000) through September 30, 2004, we have raised \$26,627 in capital and used \$13,609 in our operations. The capital was raised through (i) the issuance of convertible notes; (ii) the sale of common stock through a public offering; and (iii) the sale of common stock and warrants through private placements. Based on the \$12,454 of cash and cash equivalents on hand at September 30, 2004, we believe we have sufficient cash to fund our operations through at least March 31, 2006.

Because we lack revenue and must continue our research and development, we must continually identify new sources of capital and complete financing transactions in order to continue our business. We must also continually monitor the monthly “burn rate” of our capital resources.

### **Results of Operations**

#### ***Three Months Ended September 30, 2004 Compared to Three Months Ended September 30, 2003***

***Research and Development Expenses.*** Research and development expenses were \$666 during the three months ended September 30, 2004, or 47% higher than the \$454 incurred in the three months ended September 30, 2003. Research and development expenses primarily represent costs of clinical research organizations (CRO), clinical data management services, outsourcing chemical research laboratories, regulatory and medical consultants, drug manufacturing for clinical trials and salaries and other personnel-related expenses, including stock compensation. We began our Phase I clinical trial of DAVANAT<sup>®</sup> alone and in combination with the proven chemotherapeutic drug 5-FU (DAVANAT<sup>®</sup>-1) in February 2003 and announced the interim results on June 23, 2004. We are in the sixth and final cohort of Phase I. We initiated our Phase II clinical trial of DAVANAT<sup>®</sup>-1 for colon cancer patients in January 2004, and are currently finalizing our negotiations and contracts with the clinical sites. The increase in research and development costs in the three months ended September 30, 2004 primarily reflects pre-clinical, drug manufacturing and CRO costs for the Phase II clinical trials (\$188). We expect the Phase I and Phase II trials to be completed in calendar 2004 and 2006, respectively. We are continuing to develop our pipeline of additional drug candidates. Accordingly, we expect that our research and development costs will continue to increase in 2004 and thereafter and could comprise a higher percentage of our annual expenditures.

***General and Administrative Expenses.*** General and administrative expenses were \$1,133 during the three months ended September 30, 2004, or 20% higher than the \$946 during the three months ended September 30, 2003. General and administrative expenses primarily represent salaries and other personnel-related expenses, including stock compensation, legal and accounting fees, consultants, corporate governance, insurance, rent, depreciation and other office costs. The increase in costs in the three months ended September 30, 2004 was primarily due to higher legal fees (\$486) including \$360 related to the arbitration entitled *GlycoGenesys, Inc. and International Gene Group, Inc. and David Platt*, offset by lower stock-based compensation expenses (\$-163) and stock-listing fees (\$-77). The lower stock-based compensation expenses were primarily due to no compensatory option

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grants in the three months ended September 30, 2004. The higher stock-listing fees in the prior year period included the initial costs to join the American Stock Exchange in September 2003. We expect our general and administrative costs to decrease or to continue at current levels, depending primarily on the legal costs.

*Interest and Other Income.* Interest and other income for the three months ended September 30, 2004 was \$36 compared to \$18 for the three months ended September 30, 2003, and primarily consists of interest income on interest-bearing cash equivalents. The increase in interest income is due to higher average cash balances, partially offset by lower average interest rates in 2004. During the nine months ended September 30, 2004, we raised approximately \$9,496 of new financing versus \$5,888 in the comparable period in 2003. Average interest rates were approximately 1.30% per annum in the three months ended September 30, 2004 versus approximately 1.50% per annum in the comparable period in 2003.

### ***Nine Months Ended September 30, 2004 Compared to Nine Months Ended September 30, 2003***

*Research and Development Expenses.* Research and development expenses were \$2,039 during the nine months ended September 30, 2004, or 62% higher than the \$1,256 incurred during the nine months ended September 30, 2003. As described above, we began our Phase I clinical trial of DAVANAT<sup>®</sup> and DAVANAT<sup>®</sup>-1 in February 2003, which is in its sixth and final cohort, and we initiated our Phase II clinical trial of DAVANAT<sup>®</sup>-1 for colon cancer patients in January 2004, and are currently finalizing our negotiations and contracts with the clinical sites. The increase in research and development costs in the nine months ended September 30, 2004 primarily reflects the impact of a full nine months' research and project management costs for the Phase I clinical trial (\$405) and pre-clinical, drug manufacturing and CRO costs for the Phase II clinical trials (\$366). We expect the Phase I and Phase II trials to be completed in calendar 2004 and 2006, respectively. We are continuing to develop our pipeline of additional drug candidates. Accordingly, we expect that our research and development costs will continue to increase in 2004 and thereafter and could comprise a higher percentage of our annual expenditures.

*General and Administrative Expenses.* General and administrative expenses were \$3,070 during the nine months ended September 30, 2004, or 47% higher than the \$2,083 during the nine months ended September 30, 2003. The increase in costs in the nine months ended September 30, 2004 was primarily due to (a) higher legal fees (\$1,039), principally costs related to ongoing litigation and \$552 related to the arbitration referred to above, and (b) increased investor relations activities (\$96), offset by lower stock-based compensation expense (\$-130) as described above. We expect our general and administrative costs to decrease or to continue at current levels, depending primarily on the legal costs.

*Interest and Other Income.* Interest and other income for the nine months ended September 30, 2004 was \$87 compared to \$37 for the nine months ended September 30, 2003, and primarily consists of interest income on interest-bearing cash equivalents. As described above, the increase in interest income is due to higher average cash balances resulting from larger financings in 2004, partially offset by lower average interest rates. Average interest rates were approximately 1.30% per annum in the nine months ended September 30, 2004 versus approximately 1.60% per annum in the comparable period in 2003.

### **Liquidity and Capital Resources**

As described above in the Overview and elsewhere in this Quarterly Report on Form 10-Q, we are in the development stage and have not generated any revenues to date. Since our inception on July 10, 2000, we have financed our operations primarily through private placements of convertible debt, shares of common stock and warrants, and a public offering of shares of common stock. As of September 30, 2004, we have raised a total of \$26,627 from these offerings and had \$12,454 of available cash.

Net cash used in operations increased to \$4,586 for the nine months ended September 30, 2004 from \$2,934 for the nine months ended September 30, 2003, primarily due to (a) the impact of a full nine months' research and project management costs for the Phase I clinical trial (\$405), (b) pre-clinical, drug manufacturing and CRO costs for the Phase II clinical trial (\$366) and (c) higher legal costs (\$1,039).

Net cash used in investing activities decreased to \$64 for the nine months ended September 30, 2004 from \$87 for the nine months ended September 30, 2003 because we did not purchase property and equipment during such period in 2004. The lower fixed asset purchases is due to the timing of the expenditures, as we expect to spend approximately \$75 for leasehold improvements and other equipment over the next six months.

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Net cash provided by financing activities was \$9,496 for the nine months ended September 30, 2004 compared to \$5,888 for the comparable period in 2003. In April 2004, we raised \$3,984 (net of cash issuance costs of approximately \$466) from the sale of 1,236,111 shares of common stock and 618,056 common stock warrants (exercisable at an adjusted price of \$4.91 per share—see Note 4 to the financial statements) at \$3.60 per share to certain institutional investors in a private offering. On August 12, 2004, we raised an additional \$5,512 (net of cash issuance costs of approximately \$488) from the sale of 2,000,000 shares of common stock and 2,000,000 common stock warrants (exercisable at \$4.20 per share) at \$3.00 per share to certain institutional investors in a private equity offering.

Net cash provided by financing activities in the nine months ended September 30, 2003 includes \$1,233 (net of cash issuance costs of \$5) raised from the sale of 1,088,000 shares of common stock at \$1.00 per share and collection of a \$150 receivable in a private placement that concluded on January 14, 2003 and \$4,655 (net of cash issuance costs of \$132) received from the sale of 2,399,500 shares of common stock at \$2.00 per share in a private placement that concluded on July 15, 2003.

We believe that our cash on hand at September 30, 2004 of \$12,454 will be sufficient to enable us to meet our financial and operating obligations through at least March 31, 2006. We will require more cash to fund our operations over the long-term and believe that we will be able to obtain additional financing. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us.

### **Payments Due Under Contractual Obligations**

The following table summarizes the payments due under our contractual obligations at September 30, 2004, and the effect such obligations are expected to have on liquidity and cash flow in future periods:

<u>Contractual Obligations</u>	Payments due by period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Clinical trial and related scientific contracts	\$ 1,597	\$ 1,406	\$ 191	\$ —	\$ —
Operating leases	181	108	73	—	—
<b>Total Payments Due Under Contractual Obligations</b>	<b>\$ 1,778</b>	<b>\$ 1,514</b>	<b>\$ 264</b>	<b>\$ —</b>	<b>\$ —</b>

Approximately \$78 and \$1,519 of the clinical trial and related scientific obligations relate to the Phase I and Phase II clinical trials, respectively, and primarily represent project management, drug manufacturing and contract research expenses.

In connection with the operating lease for our office space in Newton, Massachusetts included in the table above, a commercial bank has issued a letter of credit collateralized by cash we have on deposit with that bank. As of September 30, 2004, we held \$22 of restricted cash. The letter of credit expires on May 31, 2005, and we expect to renew the letter of credit for an additional 12 months prior to its expiration.

### **Off-Balance Sheet Arrangements**

We have not created, and are not party to, any special-purpose or off-balance sheet entities for the purpose of raising capital, incurring debt or operating parts of our business that are not consolidated into our financial statements. We do not have any arrangements or relationships with entities that are not consolidated into our financial statements that are reasonably likely to materially affect our liquidity or the availability of capital resources.

### **Application of Critical Accounting Policies and Estimates**

The preparation of consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to intangible assets, income taxes, accrued expenses, stock-based compensation, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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Critical accounting policies are those policies that affect our more significant judgments and estimates used in preparation of our consolidated financial statements. We believe our critical accounting policies include our policies regarding stock-based compensation, accrued expenses and income taxes. For a more detailed discussion of our critical accounting policies, please refer to our annual report on Form 10-K for the fiscal year ended December 31, 2003.

### **FACTORS THAT MAY AFFECT FUTURE RESULTS**

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information before deciding to invest in our common stock. The risks described below are not the only ones facing our company. Additional risks not presently known to us, or that we currently consider immaterial, may also adversely affect our business. We have attempted to identify below the major factors that could cause differences between actual and planned or expected results, but we cannot assure you that we have identified all of those factors.

If any of the following risks actually happen, our business, financial condition and operating results could be materially adversely affected. In this case, the trading price of our common stock could decline, and you could lose part or all of your investment.

#### **Risks Related to Pro-Pharmaceuticals**

***We Are At An Early Stage Of Development With Limited Operating History.*** We are a development-stage company with a limited operating history, and we have not generated any revenues to date. We have no therapeutic products available for sale, and none are expected to be commercially available for several years, if at all. We may never generate revenue or become profitable, even if we are able to commercialize any products.

***We Have Incurred Net Losses To Date And Depend On Outside Capital.*** Our accumulated deficit as of September 30, 2004 was \$17,728. We will need to continue to conduct significant research, development, testing and regulatory compliance activities that, together with projected general and administrative expenses, we expect will result in substantial operating losses for the next several years. Accordingly, we will not be generating sales or other revenue and will remain dependent on outside sources of financing during that time. If we are unable to raise funds from outside sources for our continuing operations, we may be adversely affected.

We may raise such capital through public or private equity financings, partnerships, debt financings, bank borrowings, or other sources. Additional funding may not be available on favorable terms or at all. If adequate funds are not otherwise available, we may curtail operations significantly. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, products and/or potential markets. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, our equity holders may experience dilution of their proportionate ownership of the company.

***Our Product Candidates Will Be Based On Novel Unproven Technologies.*** Our product candidates will be based upon novel unproven technologies using proprietary carbohydrate compounds in "reformulations" of drugs currently used in the treatment of cancer and other diseases. Carbohydrates are difficult to synthesize, and we may not be able to synthesize carbohydrates that would be usable as delivery vehicles for the anti-cancer drugs we plan to work with.

***We Have Only Recently Begun Clinical Trials And Results Are Uncertain.*** We have one product candidate in human clinical trials. Pre-clinical results in animal studies are not necessarily predictive of outcomes in human clinical trials. Clinical trials are expensive and time-consuming, and may not be successful. They involve the testing of potential therapeutic agents, or effective treatments, in humans, typically in three phases, to determine the safety and efficacy of the product candidates necessary for an approved drug. Many products in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our products progress successfully through initial human testing, they may fail in later stages of development. We will be dependent on others to conduct our clinical trials, including clinical research organizations and, possibly, government-sponsored agencies. These trials may not start or be completed as we forecast, or may be unsuccessful.

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***Our Product Candidates May Not Be Successfully Commercialized.*** Even if our product candidates are successful in clinical trials, they may not be successfully commercialized. Potential products may fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical to produce, fail to achieve market acceptance, or be precluded from commercialization by proprietary rights of third parties.

***Our Lack Of Operating Experience May Cause Us Difficulty In Managing Our Growth.*** We have no direct experience in manufacturing or procuring products in commercial quantities, conducting other later-stage phases of the regulatory approval process, selling pharmaceutical products or licensing our technology, or negotiating, establishing and maintaining strategic relationships. Any growth of our company will require us to expand our management and our operational and financial systems and controls. If we are unable to do so, our business and financial condition would be materially harmed. If rapid growth occurs, it may strain our operational, managerial and financial resources.

***We Will Depend On Third Parties To Manufacture And Market Our Products.*** We do not have, and do not now intend to develop, facilities for the manufacture of any of our products for clinical or commercial production. Accordingly, we will need to develop relationships with manufacturers and enter into collaborative arrangements with licensees or have others manufacture our products on a contract basis. We expect to depend on such collaborators to supply us with products manufactured in compliance with standards imposed by the FDA and foreign regulators.

In addition, we have no direct experience in marketing, sales or distribution, and we do not intend to develop a sales and marketing infrastructure to commercialize our pharmaceutical products. If we develop commercial products, we will need to rely on licensees, collaborators, joint venture partners or independent distributors to market and sell those products.

***We Depend On Key Individuals To Develop Our Products And Pursue Collaborations.*** We are highly dependent on Dr. David Platt, President and Chief Executive Officer; Dr. Anatole Klyosov, our Chief Scientist (on a consulting basis) and member of our Scientific Advisory Board; and Dr. Eliezer Zomer, Vice President, Manufacturing and Product Development. The loss of any of these persons, or failure to attract or retain other key personnel, could prevent us from pursuing collaborations or developing our products and core technologies.

***We Have Been Named a Counterclaim Defendant in a Lawsuit Involving our Intellectual Property.*** Dr. Platt filed a lawsuit in Massachusetts in January 2004 against GlycoGenesys, Inc. for claims including breach of contract. In its answer GlycoGenesys names us as a counterclaim defendant alleging tortious interference and misappropriation of proprietary rights, and seeks monetary damages and injunctive relief related to our intellectual property. In March 2004, we answered the counterclaim and denied any liability. On June 15, 2004, the court allowed, without opposition, a motion of GlycoGenesys for leave to file a supplemental counterclaim for defamation and unfair competition against us. If we do not prevail there could be a material adverse impact on our financial position, results of operations or cash flows.

### **Risks Related to the Drug Development Industry**

***We Will Need Regulatory Approvals To Commercialize Our Products.*** We currently do not have products approved for sale in the U.S. or any foreign market. We are required to obtain approval from the U.S. Food and Drug Administration in order to sell our products in the U.S. and from foreign regulatory authorities in order to sell our products in other countries. The FDA's review and approval process is lengthy, expensive and uncertain. Extensive pre-clinical and clinical data and supporting information must be submitted to the FDA for each indication for each product candidate in order to secure FDA approval. The FDA could reject an application or require us to conduct additional clinical or other studies as part of the regulatory review process. Delays in obtaining or failure to obtain FDA approvals would prevent or delay the commercialization of our products, which would prevent, defer or decrease our receipt of revenues. If we receive initial regulatory approval, our product candidates will be subject to extensive and rigorous ongoing domestic and foreign government regulation.

***Our Competitive Position Depends On Protection Of Our Intellectual Property.*** Development and protection of our intellectual property are critical to our business. If we do not adequately protect our intellectual property, competitors may be able to practice our technologies. Our success depends in part on our ability to obtain patent protection for our products or processes in the United States and other countries, protect trade secrets, and prevent others from infringing on our proprietary rights.

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Since patent applications in the United States are maintained in secrecy for at least portions of their pendency periods (published on U.S. patent issuance or, if earlier, 18 months from earliest filing date for most applications) and since other publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we are the first to make the inventions to be covered by our patent applications. The patent position of biopharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents.

We cannot assure you that all of our patent applications will issue as patents or that the claims of any issued patents will afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Patent litigation is widespread in the biotechnology industry and could harm our business. Litigation might be necessary to protect our patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue such litigation or to protect our patent rights.

Although we require our scientific and technical employees and consultants to enter into broad assignment of inventions agreements, and all of our employees, consultants and corporate partners with access to proprietary information to enter into confidentiality agreements, these agreements may not be honored.

We have been named as a counterclaim defendant in a lawsuit instituted by Dr. Platt. See “Risks Related to Pro-Pharmaceuticals” above.

***Our Products Could Infringe The Intellectual Property Rights Of Others.*** We cannot assure that products based on our patents or intellectual property that we license from others will not be challenged by a third party claiming infringement of its proprietary rights. If we were not able to successfully defend our patents or licensed rights, we may have to pay substantial damages, possibly including treble damages, for past infringement.

***We Face Intense Competition In The Biotechnology And Pharmaceutical Industries.*** The biotechnology and pharmaceutical industries are intensely competitive. We face direct competition from U.S. and foreign companies focusing on drug delivery technologies which are rapidly evolving. Our competitors include major, multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. Many of these competitors have greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations, than we do. In addition, academic and government institutions are increasingly likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to market commercial products based on technology developed at such institutions. Our competitors may succeed in developing or licensing technologies and products that are more effective or less costly than ours, or succeed in obtaining FDA or other regulatory approvals for product candidates before we do.

***Health Care Cost Containment Initiatives and The Growth Of Managed Care May Limit Our Returns.*** Our ability to commercialize our products successfully will be affected by the ongoing efforts of governmental and third-party payors to contain the cost of health care. These entities are challenging prices of health care products and services, denying or limiting coverage and reimbursement amounts for new therapeutic products, and for FDA-approved products considered experimental or investigational, or which are used for disease indications without FDA marketing approval.

Even if we succeed in bringing any products to the market, they may not be considered cost-effective and third-party reimbursement might not be available or sufficient. If adequate third-party coverage is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after any of our proposed products are approved for marketing.

***Our Insurance Coverage May Not Be Adequate In All Circumstances.*** In the future, we may, in the ordinary course of business, be subject to claims by, and liability to, persons alleging injury as a result of taking products we have under development. If we are successful in having products approved by the FDA, the sale of such products

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would expose us to additional potential product liability and other claims resulting from their use. This liability may result from claims made directly by consumers or by pharmaceutical companies or others selling such products. Although we currently have insurance coverage for both product liability and professional liability, it is possible that we will not be able to maintain such insurance on acceptable terms. Any inability to maintain insurance coverage on acceptable terms could prevent or limit the commercialization of any products we develop.

### **Risks Related to Our Stock**

***Stock Prices for Biopharmaceutical and Biotechnology Companies Are Volatile.*** The market price for securities of biopharmaceutical and biotechnology companies historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. Fluctuations in the trading price or liquidity of our common stock may adversely affect our ability to raise capital through future equity financings.

***Large Sales Could Reduce The Trading Price Of Our Common Stock.*** We listed our common stock on the American Stock Exchange in September 2003, prior to which our stock traded on the OTC Bulletin Board. Accordingly, there is a limited history of trading of our stock on a national exchange and, based on varying trading volume to date, our stock could be considered “thinly traded.” In the last six months of 2003 we undertook the registration on behalf of certain of our stockholders a total of 11,358,835 shares of our common stock and 832,635 shares of stock issuable upon exercise of immediately-exercisable warrants. In the nine months ended September 30, 2004, we registered an additional 3,286,111 shares of common stock and 2,779,862 shares of stock issuable upon exercise of warrants on behalf of certain of our stockholders. In general, shares of registered common stock may be re-sold into the public markets without volume or other restrictions. Large sales of our registered shares could place substantial downward pressure on the trading price of our common stock, particularly if the amount sold significantly exceeds the then-current trading volume of our stock.

***Downward Pressure on Our Stock Price Could Result if Certain Stockholders Become Short-term Investors.*** We sold shares of common stock and warrants to purchase common stock in so-called PIPE (Private Investment in Public Equity) transactions in October 2003, April 2004 and August 2004 to investors who, as an incentive to purchase our securities in private placements, required us promptly to register their shares (including shares issuable upon exercise of the warrants) for resale into the public markets. We may enter into similar financing transactions in the future with the same or different investors. Because such investors typically receive registered shares well in advance of the expiration of the holding periods under Rule 144 of the Securities Act, they may choose to sell their shares after a short period of holding our stock. If sufficient quantities of stock are sold during a brief interval of time, this could result in downward pressure on the market price for shares of our publicly-traded common stock.

***Four Principal Stockholders Own Enough Shares To Control The Company.*** As of September 30, 2004, four of our principal stockholders, David Platt, James Czirr, Offer Binder and Anatole Klyosov own or control approximately 43% of the outstanding shares of our common stock, and Dr. Platt and Mr. Czirr together own approximately 34%. Some or all of these stockholders, acting in concert, may be able to substantially influence the election of the Board of Directors and other corporate actions requiring stockholder approval, such as recapitalization or other fundamental corporate action, as well as the direction and policies of our company. Such concentration of ownership also could have the effect of delaying, deterring or preventing a change in control of the company that might otherwise be beneficial to stockholders.

***Changes In Laws, Regulations And Financial Accounting Standards May Affect Our Reported Results Of Operations.*** The Sarbanes-Oxley Act of 2002 and related regulations, including rule changes adopted by stock exchanges in connection with such legislation, may result in changes in accounting standards or accepted practices within our industry and could add significant new costs to being a public company. New laws, regulations and accounting standards, as well as potential changes to currently accepted accounting practices, including the expensing of stock options, could adversely affect our reported financial results and negatively affect our stock price. Additional unanticipated expenses incurred to comply with new requirements could also negatively impact our results of operations.



### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Market risk represents the risk of loss that may impact our financial position, operating results or cash flows due to changes in the U.S. interest rates. The primary objective of our investment activities is to preserve cash until it is required to fund operations. To minimize risk, we maintain our portfolio of cash and cash equivalents in operating bank accounts and money market funds. Since our investments are short-term in duration, we believe that we are not subject to any material market risk exposure. We do not have any interest-bearing debt, foreign currency or other derivative financial instruments.

### **Item 4. Controls and Procedures**

Our management, with the participation of the Chief Executive Officer and Acting Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in the SEC rules promulgated under the Securities Exchange Act of 1934, as amended) as of September 30, 2004. Based on this evaluation, our CEO and Acting CFO concluded that, as of September 30, 2004, our disclosure controls and procedures were (1) designed to ensure that material information relating to Pro-Pharmaceuticals, Inc., including its consolidated subsidiaries, is made known to our CEO and Acting CFO by others within Pro-Pharmaceuticals, Inc. particularly during the period in which this Report was being prepared, and (2) effective, in that they provide reasonable assurance that information that we are required to disclose in the reports we file under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

No change in our internal control over financial reporting (as defined in the SEC rules promulgated under the Securities Exchange Act of 1934, as amended) occurred during the quarter ended September 30, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II –OTHER INFORMATION**

### **Item 1. Legal Proceedings**

In May 2003, a former employee commenced a lawsuit in Massachusetts Superior Court against us and filed a related complainant letter with the Occupational Safety and Health Administration of the U.S. Department of Labor. The plaintiff asserted claims for wrongful discharge in violation of public policy and of employee protection provided for under the Sarbanes-Oxley Act of 2002, and seeks monetary damages. In August 2003, the Department of Labor dismissed the complaint. The plaintiff objected and requested a hearing by an Administrative Law Judge at the Department. The hearing occurred in April 2004 and a decision is not expected until late 2004.

In October 2003, we received an informal inquiry from the Securities and Exchange Commission (the "SEC") requesting information related to the foregoing and we timely responded prior to year-end. We also complied with a May 14, 2004 request from the SEC to provide copies of transcripts of testimony taken prior to and at the hearing, post-hearing briefs and other information. On November 8, 2004, we were notified that the SEC has converted the inquiry to a formal investigation, which investigation includes whether statements concerning our company were false or misleading.

In February 2004, we received an order from the Commonwealth of Massachusetts to provide information concerning our offerings of securities. We timely responded and have not received further communication from the state on this matter. We believe the Massachusetts investigation may be related to the matters disclosed in the preceding paragraphs.

Each of the foregoing matters is subject to various uncertainties, and it is possible one or more may be resolved unfavorably. Management believes that any liability that may ultimately result from the resolution of these matters will not have a material adverse effect on our financial position, results of operations or cash flows.

In January 2004, Dr. Platt, our Chairman and Chief Executive Officer, filed a lawsuit in Massachusetts Superior Court against GlycoGenesys, Inc. for various claims including breach of contract. In its filing in February 2004, GlycoGenesys asserted counterclaims against us and Dr. Platt alleging tortious interference and misappropriation of proprietary rights. The counterclaims seek monetary damages and injunctive relief related to our intellectual property. In March 2004, we and Dr. Platt answered the

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counterclaims and denied any liability. On June 15, 2004, the Court allowed, without opposition, a motion of GlycoGenesys for leave to file a supplemental counterclaim against us for defamation and unfair competition. We and Dr. Platt intend to contest these counterclaims vigorously and believe we will ultimately prevail. However, if we do not prevail, there could be a material adverse impact on our financial position, results of operations or cash flows.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

On August 12, 2004, we closed a private equity offering, structured as a "PIPE" (Private Investment in Public Equity) and in reliance on the exemption under Section 4(2) of the Securities Act of 1933, in which we sold to institutional investors 2,000,000 shares of our common stock and 2,000,000 five-year warrants (exercisable at \$4.20 per share) at \$3.00 per share. We received proceeds of approximately \$5,512,500 net of transaction expenses of approximately \$487,500 (inclusive of placement agent commissions). The placement agent also received 100,000 warrants (exercisable at \$4.20 per share). Pursuant to contemporaneous registration rights agreements, we registered the resale of the shares (including shares issuable upon exercise of the warrants) by the investors and the placement agent on Form S-3 (file no. 333-118907), which the Securities and Exchange Commission declared effective on September 20, 2004.

### **Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description of Document</b>
10.1	Form of Incentive Stock Option Agreement (under the 2001 Stock Incentive Plan)
10.2	Form of Non-Qualified Stock Option Agreement (under the 2001 Stock Incentive Plan)
10.3	Form of Non-Qualified Stock Option Agreement (under the 2003 Non-Employee Director Stock Incentive Plan)
10.4	Option Agreement dated November 11, 2004 between David Platt and Pro-Pharmaceuticals, Inc.
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

### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on November 19, 2004.

PRO-PHARMACEUTICALS, INC.

By          /s/ David Platt

Name: David Platt, Ph.D.

Title: Chief Executive Officer and  
Acting Chief Financial Officer

**PRO-PHARMACEUTICALS, INC.**  
**INCENTIVE STOCK OPTION AGREEMENT**

**Under the 2001 Stock Incentive Plan**

Pro-Pharmaceuticals, Inc. (the "Company"), a Nevada corporation, hereby grants, effective as of \_\_\_\_\_, 20\_\_ (the "Effective Date"), to \_\_\_\_\_ (the "Optionee") the right and option (the "Option") to purchase up to \_\_\_\_\_ shares of its Common Stock, \$.001 par value, at a price of \$\_\_\_\_\_ per share (the "Exercise Price"), subject to the following terms and conditions.

**1. Relationship to Plan.** The Option is granted pursuant to the Company's 2001 Stock Incentive Plan (the "Plan"), and is in all respects subject to the terms and conditions of the Plan, a copy of which has been provided to the Optionee (the receipt of which the Optionee hereby acknowledges). Capitalized terms used and not otherwise defined in this Agreement are used as defined in the Plan. The Optionee hereby accepts the Option subject to all the terms and provisions of the Plan (including without limitation provisions relating to expiration and termination of the Option and adjustment of the number of shares subject to the Option and the exercise price therefor). The Optionee further agrees that all decisions under and interpretations of the Plan by the Company shall be final, binding, and conclusive upon the Optionee and his or her successors, permitted assigns, heirs, and legal representatives.

**2. Vesting.** The Option shall vest and become exercisable only as follows, *provided*, in each case, that the Optionee continues to be employed by the Company or a Subsidiary (as defined in the Plan) of the Company on each applicable vesting date:

<u>Date</u>	<u>Number (or Percentage) of Shares for which Option Exercisable</u>
_____	_____ %

**3. Termination of Option.**

(a) The Option shall terminate on the earlier of (x) 5:00 p.m. Eastern Time on the tenth anniversary of the Effective Date and (y) if the Optionee's employment with the Company or a Subsidiary terminates for any reason, the applicable date determined from the following table:

<u>Reason for Termination of Employment</u>	<u>Option Termination Date</u>
(i) death of employee	Twelve months thereafter
(ii) total and permanent disability of employee (as defined in Section 22(e)(3) of the Internal Revenue Code of 1986, as amended)	Twelve months thereafter
(iii) termination of employment for any other reason	Three months thereafter

Military or sick leave shall not be deemed a termination of employment provided that it does not exceed the longer of 90 days or the period during which the absent employee's reemployment rights are guaranteed by statute or by contract.

(b) If this Option has not earlier terminated pursuant to paragraph (a) of this §3, upon the termination of the Optionee's employment with the Company or a Subsidiary, (i) the Option, with respect to any shares of Common Stock issuable pursuant to the Option which have not become vested pursuant to §2 as of the date of such termination of employment, shall irrevocably expire and the Optionee shall not have any right to purchase such shares of Common Stock issuable pursuant to the Option, (ii) the Company shall have the right to terminate the Option with respect to any shares of Common Stock which have become vested pursuant to §2 but which have not been purchased by the Optionee by paying to the Optionee an amount equal to the Fair Market Value of such shares as of the date of the termination of employment minus the Exercise Price of such shares, and (iii) the Company shall have the right to purchase from the Optionee all of the shares of Common Stock previously issued pursuant to the Option at a price equal to the Fair Market Value as of the date of repurchase of such shares.

**4. "Lock-Up" Agreement.** The Optionee agrees that upon the Company's request at any time, whether before or after the exercise of the Option, the Optionee shall enter into an agreement pursuant to which, if the Company deems it necessary or desirable to make any public offering of shares of Common Stock, then without the prior written consent of the Company or the managing underwriter, if any, of any such offering, the Optionee shall not sell, make any short sale of, loan, grant any option for the purchase of, pledge, or otherwise encumber or otherwise dispose of any shares of Common Stock issued or issuable pursuant to the Option, during such period (not to exceed 365 days) commencing on the effective date of the registration statement relating to such offering as the Company may request.

## 5. Methods of Exercise.

In the event that the Optionee's employment with the Company or a Subsidiary has not been terminated and except as contained in this §5 or as may otherwise be agreed by the Optionee and the Company, the Option shall be exercisable only by a written notice in form and substance acceptable to the Company (the "Election Notice"), specifying the number of shares to be purchased and accompanied by payment in cash of the aggregate purchase price for the shares for which the Option is being exercised; provided, that the Optionee shall be entitled to pay the Exercise Price for the shares of Common Stock for which the Option is being exercised by surrendering a number of such shares having a Fair Market Value equal to the Exercise Price required to be paid. Thereupon, the Company shall issue to the Optionee such number of fully paid and nonassessable shares of Common Stock as is computed using the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where X = the number of shares of Common Stock to be issued to the Optionee pursuant to this §5;

Y = the number of shares of Common Stock currently being exercised under this Option;

A = the Fair Market Value for the Common Stock as of the date of the exercise; and

B = the Exercise Price in effect under this Option at the time the exercise is made pursuant to this §5.

**6. Characterization of Option for Tax Purposes.** Although the Option is intended to qualify as an "incentive stock option" under the Internal Revenue Code of 1986, as amended, the Company makes no representation or warranty as to the tax treatment to the Optionee upon receipt or exercise of the Option or sale or other disposition of the shares covered by the Option. In addition, options granted to the Optionee under the Plan and any and all other plans of the Company and its affiliates shall not be treated as incentive stock options for tax purposes to the extent that options covering in excess of \$100,000 of stock (based upon fair market value of the stock as of the respective dates of grant of such options) first become exercisable in any calendar year; and such options shall be subject to different tax treatment (including the possibility of income tax withholding in accordance with the Plan).

## 7. Withholding; Notice of Disposition of Stock Prior to Expiration of Specified Holding Period.

(a) At the request of the Company, the Optionee agrees to remit to the Company an amount sufficient to satisfy any federal, state, local or other withholding tax requirements (whether so required to secure for the Company an otherwise available tax deduction or otherwise) if and to the extent required by law prior to the delivery of any certificate or certificates representing shares of Common Stock to be issued upon exercise of the Option.

(b) With respect to shares of Common Stock issued upon exercise of the Option, the Optionee agrees to report to the Company any disposition thereof prior to the expiration of the holding periods specified by Section 422(a)(1) of the Code. If and to the extent that such disposition imposes upon the Company any federal, state, local or other withholding tax requirements, or any such withholding is required to secure for the Company an otherwise available tax deduction, the Optionee shall remit to the Company an amount sufficient to satisfy those requirements.

**8. Compliance with Laws.** The obligations of the Company to sell and deliver Shares upon exercise of the Option are subject to all applicable laws, rules, and regulations, including all applicable federal and state securities laws, and the obtaining of all such approvals by government agencies as may be deemed necessary or appropriate by the Board or the relevant committee of the Board. If so required by the Board or such committee, no shares shall be delivered upon the exercise of the Option until the Optionee has given the Company a satisfactory written statement that he is purchasing such shares for investment, and not with a view to the sale or distribution of any such shares, and with respect to such other matters as the Board may deem advisable in order to assure compliance with applicable securities laws. All shares issued upon exercise of the Option shall bear appropriate restrictive legends.

**9. General.** The Optionee may not transfer, assign, or encumber any of his or her rights under this Agreement without the prior written consent of the Company, and any attempt to do so shall be void. This Agreement shall be governed by and interpreted and construed in accordance with the internal laws of the Commonwealth of Massachusetts (without reference to principles of conflicts or choice of law). The captions of the sections of this Agreement are for reference only and shall not affect the interpretation or construction of this Agreement. This Agreement shall bind and inure to the benefit of the parties and their respective successors, permitted assigns, heirs, devisees, and legal representatives.

**IN WITNESS WHEREOF**, the Company and the Optionee have executed and delivered this Agreement, which may be in counterpart originals, intending it to be effective as an agreement under seal as of the Effective Date.

PRO-PHARMACEUTICALS, INC.

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

OPTIONEE

\_\_\_\_\_

\_\_\_\_\_

**PRO-PHARMACEUTICALS, INC.**  
**NON-QUALIFIED STOCK OPTION AGREEMENT**  
**Under the 2001 Stock Incentive Plan**

Pro-Pharmaceuticals, Inc. (the "Company"), a Nevada corporation, hereby grants, effective as of \_\_\_\_\_, 20\_\_ (the "Effective Date"), to \_\_\_\_\_ (the "Optionee") the right and option (the "Option") to purchase up to \_\_\_\_\_ shares of its Common Stock, \$.001 par value, at a price of \$ \_\_\_\_\_ per share (the "Exercise Price"), subject to the following terms and conditions.

**1. Relationship to Plan.** The Option is granted pursuant to the Plan, and is in all respects subject to the terms and conditions of the Plan, a copy of which has been provided to the Optionee (the receipt of which the Optionee hereby acknowledges). Capitalized terms used and not otherwise defined in this Agreement are used as defined in the Plan. The Optionee hereby accepts the Option subject to all the terms and provisions of the Plan (including without limitation provisions relating to expiration and termination of the Option and adjustment of the number of shares subject to the Option and the exercise price therefor). The Optionee further agrees that all decisions under and interpretations of the Plan by the Company shall be final, binding, and conclusive upon the Optionee and his or her successors, permitted assigns, heirs, and legal representatives.

**2. Vesting.** The Option shall be fully vested and exercisable only as follows, *provided*, in each case, that the Optionee continues to be employed, retained or otherwise engaged by the Company or a Subsidiary (as defined in the Plan) of the Company on each applicable vesting date:

Date	Number (or Percentage) of Shares for which Option is Exercisable
_____	_____ %

**3. Termination of Option.**

The Option shall terminate on \_\_\_\_\_, 20\_\_ unless the Optionee's death occurs prior to such date in which event the termination date shall be the first anniversary of the date of death.

**4. "Lock-Up" Agreement.** The Optionee agrees that upon the Company's request at any time, whether before or after the exercise of the Option, the Optionee shall enter into an agreement pursuant to which, if the Company deems it necessary or desirable to make any public offering of shares of Common Stock, then without the prior written consent of the Company or



the managing underwriter, if any, of any such offering, the Optionee shall not sell, make any short sale of, loan, grant any option for the purchase of, pledge, or otherwise encumber or otherwise dispose of any shares of Common Stock issued or issuable pursuant to the Option, during such period (not to exceed 210 days) commencing on the effective date of the registration statement relating to such offering as the Company may request.

**5. Methods of Exercise.** In the event that the Optionee's employment with the Company or a Subsidiary has not been terminated and except as contained in this §5 or as may otherwise be agreed by the Optionee and the Company, the Option shall be exercisable only by a written notice in form and substance acceptable to the Company (the "Election Notice"), specifying the number of shares to be purchased and accompanied by payment in cash of the aggregate purchase price for the shares for which the Option is being exercised; provided, that the Optionee shall be entitled to pay the Exercise Price for the shares of Common Stock for which the Option is being exercised by surrendering a number of such shares having a Fair Market Value equal to the Exercise Price required to be paid. Thereupon, the Company shall issue to the Optionee such number of fully paid and nonassessable shares of Common Stock as is computed using the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where X = the number of shares of Common Stock to be issued to the Optionee pursuant to this §5;

Y = the number of shares of Common Stock currently being exercised under this Option;

A = the Fair Market Value for the Common Stock as of the date of the exercise; and

B = the Exercise Price in effect under this Option at the time the exercise is made pursuant to this §5.

**6. Characterization of Option for Tax Purposes.** The Option is intended not to qualify as an "incentive stock option" under the Internal Revenue Code of 1986, as amended, and shall be subject to different tax treatment than that accorded incentive stock options (including the possibility of income tax withholding in accordance with the Plan).

**7. Withholding.** At the request of the Company, the Optionee agrees to remit to the Company an amount sufficient to satisfy any federal, state, local or other withholding tax requirements (whether so required to secure for the Company an otherwise available tax deduction or otherwise) if and to the extent required by law prior to the delivery of any certificate or certificates representing shares of Common Stock to be issued upon exercise of the Option.

**8. Compliance with Laws.** The obligations of the Company to sell and deliver Shares upon exercise of the Option are subject to all applicable laws, rules, and regulations, including all applicable federal and state securities laws, and the obtaining of all such approvals by

government agencies as may be deemed necessary or appropriate by the Board or the relevant committee of the Board. If so required by the Board or such committee, no shares shall be delivered upon the exercise of the Option until the Optionee has given the Company a satisfactory written statement that he is purchasing such shares for investment, and not with a view to the sale or distribution of any such shares, and with respect to such other matters as the Board may deem advisable in order to assure compliance with applicable securities laws. All shares issued upon exercise of the Option shall bear appropriate restrictive legends.

**9. General.** The Optionee may not transfer, assign, or encumber any of his or her rights under this Agreement without the prior written consent of the Company, and any attempt to do so shall be void. This Agreement shall be governed by and interpreted and construed in accordance with the internal laws of the Commonwealth of Massachusetts (without reference to principles of conflicts or choice of law). The captions of the sections of this Agreement are for reference only and shall not affect the interpretation or construction of this Agreement. This Agreement shall bind and inure to the benefit of the parties and their respective successors, permitted assigns, heirs, devisees, and legal representatives.

[Remainder of Page Intentionally Left Blank]

**IN WITNESS WHEREOF**, the Company and the Optionee have executed and delivered this Agreement, which may be in counterpart originals, intending it to be effective as an agreement under seal as of the Effective Date.

PRO-PHARMACEUTICALS, INC.

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Optionee: \_\_\_\_\_

\_\_\_\_\_

## PRO-PHARMACEUTICALS, INC.

## NON-QUALIFIED STOCK OPTION AGREEMENT

## Under the 2003 Non-Employee Director Stock Incentive Plan

Pro-Pharmaceuticals, Inc. (the "Company"), a Nevada corporation, hereby grants, effective as of \_\_\_\_\_, 20\_\_ (the "Effective Date"), to \_\_\_\_\_ (the "Optionee") the right and option (the "Option") to purchase up to \_\_\_\_\_ shares of its Common Stock, \$.001 par value, at a price of \$\_\_\_\_\_ per share (the "Exercise Price"), subject to the following terms and conditions. The Optionee is a member of the Board of Directors, and not an employee, of the Company.

**1. Relationship to Plan.** The Option is granted pursuant to the Company's 2003 Non-employee Director Stock Incentive Plan (the "Plan"), and is in all respects subject to the terms and conditions of the Plan, a copy of which has been provided to the Optionee (the receipt of which the Optionee hereby acknowledges). Capitalized terms used and not otherwise defined in this Agreement are used as defined in the Plan. The Optionee hereby accepts the Option subject to all the terms and provisions of the Plan (including without limitation provisions relating to expiration and termination of the Option and adjustment of the number of shares subject to the Option and the exercise price therefor). The Optionee further agrees that all decisions under and interpretations of the Plan by the Company shall be final, binding, and conclusive upon the Optionee and his or her successors, permitted assigns, heirs, and legal representatives.

**2. Vesting.** The Option shall vest and become exercisable as of the Exercise Date.

**3. Termination of Option.** Exercise rights with respect to the Option shall terminate on the \_\_\_\_\_ ( ) anniversary of the Effective Date unless the Option's death occurs prior to such anniversary date, in which case exercise rights shall terminate on the first anniversary of the date of death.

**4. "Lock-Up" Agreement.** The Optionee agrees that upon the Company's request at any time, whether before or after the exercise of the Option, the Optionee shall enter into an agreement pursuant to which, if the Company deems it necessary or desirable to make any public offering of shares of Common Stock, then without the prior written consent of the Company or the managing underwriter, if any, of any such offering, the Optionee shall not sell, make any short sale of, loan, grant any option for the purchase of, pledge, or otherwise encumber or otherwise dispose of any shares of Common Stock issued or issuable pursuant to the Option, during such period (not to exceed 365 days) commencing on the effective date of the registration statement relating to such offering as the Company may request.

## 5. Methods of Exercise.

In the event that the Optionee's service as a director of the Company or a Subsidiary has not been terminated and except as contained in this § 5 or as may otherwise be agreed by the Optionee and the Company, the Option shall be exercisable only by a written notice in form and substance acceptable to the Company (the "Election Notice"), specifying the number of shares to be purchased and accompanied by payment in cash of the aggregate purchase price for the shares for which the Option is being exercised. The foregoing notwithstanding, the Optionee shall be entitled to pay the Exercise Price (in a so-called "cashless" exercise) for the shares of Common Stock for which the Option is being exercised by surrendering a number of shares which the Optionee (a) has owned for at least 183 days (i.e., more than half a year) or (b) acquired under a broker-assisted exercise and sell agreement through a Company-approved broker having a Fair Market Value equal to the Exercise Price required to be paid. Thereupon, the Company shall issue to the Optionee such number of fully paid and nonassessable shares of Common Stock as is computed using the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where X = the number of shares of Common Stock to be issued to the Optionee pursuant to this § 5;

Y = the number of shares of Common Stock being exercised under this Option;

A = the Fair Market Value for the Common Stock as of the date of the exercise; and

B = the Exercise Price in effect under this Option at the time the exercise is made pursuant to this § 5.

**6. Characterization of Option for Tax Purposes.** The Option is intended not to qualify as an "incentive stock option" under the Internal Revenue Code of 1986, as amended, and shall be subject to different tax treatment than that accorded incentive stock options.

**7. Withholding.** At the request of the Company, the Optionee agrees to remit to the Company an amount sufficient to satisfy any federal, state, local or other withholding tax requirements (whether so required to secure for the Company an otherwise available tax deduction or otherwise) if and to the extent required by law prior to the delivery of any certificate or certificates representing shares of Common Stock to be issued upon exercise of the Option.

**8. Compliance with Laws.** The obligations of the Company to sell and deliver Shares upon exercise of the Option are subject to all applicable laws, rules, and regulations, including all applicable federal and state securities laws, and the obtaining of all such approvals by government agencies as may be deemed necessary or appropriate by the Board or the relevant committee of the Board. If so required by the Board or such committee, no shares shall be delivered upon the exercise of the Option until the Optionee has given the Company a satisfactory written statement that he or she is purchasing such shares for investment, and not with a view to the sale or distribution of any such shares, and with respect to such other matters as the Board may deem advisable in order to assure compliance with applicable securities laws.

**9. General.** The Optionee may not transfer, assign, or encumber any of his or her rights under this Agreement without the prior written consent of the Company, and any attempt to do so shall be void. This Agreement shall be governed by and interpreted and construed in accordance with the internal laws of the Commonwealth of Massachusetts (without reference to principles of conflicts or choice of law). The captions of the sections of this Agreement are for reference only and shall not affect the interpretation or construction of this Agreement. This Agreement shall bind and inure to the benefit of the parties and their respective successors, permitted assigns, heirs, devisees, and legal representatives.

**IN WITNESS WHEREOF**, the Company and the Optionee have executed and delivered this Agreement as an agreement under seal as of the Effective Date.

PRO-PHARMACEUTICALS, INC.

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Optionee

\_\_\_\_\_  
\_\_\_\_\_

## OPTION AGREEMENT

**OPTION AGREEMENT** entered into November 11, 2004 (this “**Agreement**”) and effective as of September 15, 2004 (the “**Effective Date**”) by and between David Platt, an individual residing in Newton, Massachusetts (“**Optionor**”), and Pro-Pharmaceuticals, Inc., a Nevada corporation with a principal place of business in Newton, Massachusetts (“**Optionee**”).

**Recitals**

A. Optionor owns that certain U.S. patent application no. 08/024,487, including the invention described and claimed therein and resultant U.S. and foreign patents obtainable therefrom (the “**Patent Application**”), which is subject to that certain License Agreement dated January 7, 1994 (the “**1994 License**”) between Optionor and International Gene Group, Inc. (the “**Licensee**”) in which Optionor has a payment interest and retained or reversionary rights in and to the Patent Application in the event (i) the licensee under the 1994 Agreement abandons or takes other actions specified therein in connection with the Patent Application, or a patent based thereon, or (ii) the 1994 License is otherwise modified or terminated (collectively, the “**Optionor Rights**”) ; and

B. Optionee desires to procure an option to purchase an exclusive license (the “**Option**”) under (i) the Patent Application to the extent of Optionor’s right to grant such a license and (ii) any and all of the remaining Optionor Rights, and Optionor is willing to grant such a license to Optionee upon the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the agreements herein below set forth, the receipt and sufficiency of which are hereby acknowledged, the parties intending to be bound hereby, agree as follows:

**1. Grant of the Option.** Optionor hereby grants to Optionee, for a term ending the tenth (10th) anniversary of the Effective Date (the “**Term**”), the Option in consideration of \$5,000 which shall be paid not later than sixty (60) days after the Effective Date.

**2. Exercise and Related Matters.**

(a) Manner of Exercise. Optionee, in its sole discretion at any time during the Term, may exercise the Option by delivering to Optionor (i) a form of license agreement containing the terms set forth below (the “**License Agreement**”) with a request that Optionor execute and deliver the License Agreement to Optionor within sixty (60) days thereafter, and (ii) a written document stating the operating profit projections, including detail as to Optionor’s assumptions and calculations underlying such projections (the “**Profit Projections**”), that Optionor expects to receive from exploitation of the applicable Optionor Rights for a ten (10) year period, and the resultant royalty payable therefor under the License Agreement. Unless Optionor objects to the form of License

Agreement or the Profit Projections and arbitration in connection with such objection is initiated within such 60-day period (the “**Review Period**”), Optionee shall be deemed to have executed and delivered the License Agreement and Optionor shall be entitled to seek specific enforcement thereof.

(b) License Agreement. The License Agreement shall provide for an irrevocable royalty-bearing, exclusive, worldwide license to Optionee, or its designated affiliate, to make, use, sell, offer to sell or import any product covered by the Optionor Rights, and to sub-license such rights, and to succeed to Licensor’s payment interest, if any, within the meaning of Optionor Rights as defined above. The royalty rate under the License Agreement (other than for sublicense revenue described below) shall be based on the “25 Per Cent Rule,” i.e., the royalty is a percentage of sales revenue derived from 25% of estimated (at the time of entering into a license agreement) operating profit of a licensee from gross revenue of sales of a product or services that embody the applicable intellectual property. The License Agreement shall also provide that (i) any sub-licensing revenues received by Optionee shall be shared equally between Optionee and Optionor; (ii) any royalties payable thereunder shall be initially reduced dollar-for-dollar in respect of all amounts expended by Optionee (in its sole discretion) prior to and after the Effective Date to perfect its title to the Optionor Rights (including, without limitation, expenses incurred for preparation, filing, prosecutions, oppositions and interferences related thereto, and defense of the Optionor Rights under the License and for advancement of the Patent Application); (iii) Optionee shall acquire the prospective right to royalties and other payments due to Optionor under the 1994 License if then in effect; (iv) Optionor shall cooperate with Optionee’s efforts to perfect, enforce and exploit its rights in the acquired property, as reasonably requested by Optionee, subject to reimbursement of Optionor’s reasonable costs of compliance, and service compensation if Optionor is not then an employee or consultant of Optionee; and (v) other customary terms and conditions for an exclusive license of intellectual property with payments calculated using the income method.

(c) Arbitration. Optionor at any time within the 60-day Review Period may object to the form of License Agreement or Profit Projections set forth in the documents delivered pursuant to clause (a) above (which objection shall be in writing stating the reasons therefor), whereupon the parties shall attempt in good faith for up to sixty (60) days thereafter to reach agreement on the matters stated in such objection. If during such 60-day period the parties cannot reach agreement, Optionor in its discretion by written notice may (i) elect to defer or abandon its exercise of the Option, or (ii) proceed with the exercise of the Option, subject to arbitration. In either case, a party may refer the matter to arbitration administered by the American Arbitration Association (New England Region), such hearing to be held in Boston, Massachusetts, under the Patent Arbitration Rules of the AAA. Except as stated in subsection (c) below, each party shall pay its own costs. The determination of the arbitrator(s) as to the disputed matters shall be binding and enforceable between the parties in any court of competent jurisdiction.

(d) Cancellation of Exercise. In the event the arbitration decision determines that (i) the License Agreement was in material nonconformity with the provisions of



clause (b) above or otherwise does not reflect a good faith effort by Optionee, or (ii) the Profit Projections would result in royalty payments less than half of what such projections would result in if they had been based on profit projections stated in the arbitration decision, Optionee (x) may elect within thirty (30) days thereafter to withdraw its exercise, (y) go forward with the License Agreement based on the arbitration decision and (iii) shall in either event pay all of Optionor's costs of arbitration (including reasonable attorneys' and experts' fees and disbursements), in each such case without prejudice to Optionee's right to exercise the Option later during the Term.

**3. Representations, Warranties and Covenants.**

(a) Optionor represents and warrants that he has not granted any rights or other property interest in and to the Patent Application to any person or entity other than the licensee under the IGG-License, and has not granted rights or other property interest in or to the Optionor Rights, and covenants not make any such grant during the Term.

(b) Optionee represents and warrants that it is duly organized and validly existing in its state of incorporation and that its has full corporate power and authority to enter into this Agreement and carry out its provisions.

**4. Miscellaneous.**

(a) Notices. Any notice required to be given or made under this Agreement by one of the parties hereto to the other shall be in writing, by personal delivery, registered United States mail or overnight courier, addressed to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and shall be effective upon the date received.

If to Optionee: Pro-Pharmaceuticals, Inc.  
189 Wells Avenue  
Newton, MA 02459

If to Optionor: Dr. David Platt  
12 Appleton Circle  
Newton, MA 02459

(b) Entire Agreement. This Agreement and the attachments hereto contain the entire understanding between the parties with respect to the subject matter hereof. This Agreement may be amended subsequent to the Effective Date if mutually agreed upon in writing by the parties hereto. Any subsequent amendment shall not abrogate the Effective Date of this Agreement. All expressed or implied agreements and understandings, either oral or written, heretofore made are expressly merged in and made a part of this Agreement.

(c) Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, excluding its conflict of laws provision. Each party hereto shall comply with all applicable laws, rules, ordinances, guidelines, consent decrees and regulations of any federal, state or other governmental authority.

(d) Assignment. Neither party may without the written approval of the other assign this Agreement to any third party.

(e) Modification. This Agreement may only be modified by a writing signed by both parties hereto.

(f) Successors. The successors, heirs and assigns of the parties shall enjoy all rights and responsibilities of this agreement. This Agreement shall be binding upon the successors, heirs and assigns of the parties hereto.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date set forth above,

**OPTIONOR:**

**OPTIONEE:**

Pro-Pharmaceuticals, Inc.

/s/ David Platt  
David Platt

By: /s/ Maureen Foley  
Maureen Foley  
Chief Operating Officer

## Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934

I, David Platt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pro-Pharmaceuticals, Inc;
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 19, 2004

/s/ David Platt

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Name: David Platt, Ph.D.  
Title: President and Chief Executive Officer  
(Principal Executive Officer)

## Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934

I, David Platt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pro-Pharmaceuticals, Inc;
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 19, 2004

/s/ David Platt

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Name: David Platt, Ph.D.  
Title: Acting Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C SECTION 1350, AS ADOPTED PURSUANT TO SECTION  
906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Pro-Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2004 as filed with the Securities and Exchange Commission (the "Report"), I, David Platt, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 19, 2004

/s/ David Platt

\_\_\_\_\_  
Name: David Platt, Ph.D.  
Title: President and Chief Executive Officer  
(Principal Executive Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Pro-Pharmaceuticals, Inc. and will be retained by Pro-Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION PURSUANT TO 18 U.S.C SECTION 1350, AS ADOPTED PURSUANT TO SECTION  
906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Pro-Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2004 as filed with the Securities and Exchange Commission (the "Report"), I, David Platt, Acting Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 19, 2004

/s/ David Platt

\_\_\_\_\_  
Name: David Platt, Ph.D.  
Title: Acting Chief Financial Officer  
(Principal Financial Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Pro-Pharmaceuticals, Inc. and will be retained by Pro-Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.